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Part G. Non-Voluntary Uses

Part H. Other Intellectual Property Issues

Terms of Reference

INTELLECTUAL PROPERTY RIGHTS OVER GENETIC MATERIALS AND GENETIC AND RELATED TECHNOLOGIES

(1) I, DARYL WILLIAMS, Attorney-General of Australia, following consultation with the Commonwealth Biotechnology Ministerial Council, and having regard to:

- the objective of the protection of intellectual property rights to contribute to the promotion of technological innovation, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

- the rapid advances in human genome research and genetic and related technologies which potentially can aid in improving the quality of life of all Australians by contributing to Australia's economic development and by improving human health; and

- the economic, legal, technological, ethical, and access and equity issues relating to the intellectual property protection of genes and genetic and related technologies; and

- the need to utilise modern genetic technologies to further Australia's national interest, including such areas as agriculture and industry;

- the trade and investment issues relating to the intellectual property protection of genes and genetic and related technologies; and

- international practices and developments, including any existing or proposed international obligations;

REFER to the Australian Law Reform Commission for inquiry and report under the *Australian Law Reform Commission Act 1996* the following matters, with a particular focus on human health issues:

(a) the impact of current patenting laws and practices—including licensing—related to genes and genetic and related technologies on:

(i) the conduct of research and its subsequent application and commercialisation;

(ii) the Australian biotechnology sector; and

(iii) the cost-effective provision of healthcare in Australia;

(b) what changes, if any, may be required to address any problems identified in current laws and practices, with the aim of encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies; and

(c) any other relevant matter.

(2) In performing its functions in relation to this reference the Commission shall ensure widespread public consultation, and identify and consult with key stakeholders, including relevant government agencies, the research community, the health and medical sector, the biotechnology sector, and industry bodies.

(3) The Commission is to report to the Attorney-General by 30 June 2004.

Dated 17 December 2002

Daryl Williams
ATTORNEY-GENERAL

Participants

Australian Law Reform Commission

Division

The Division of the ALRC constituted under the *Australian Law Reform Commission Act 1996* (Cth) for the purposes of this Inquiry comprises the following:

Professor David Weisbrot (President)
Professor Anne Finlay (Commissioner in charge)
Mr Brian Opeskin (Commissioner in charge)
Mr Ian Davis (Commissioner)
Justice Susan Kenny (part-time Commissioner from May 2003)
Justice Susan Kiefel (part-time Commissioner from April 2003)

Senior Legal Officers

Bruce Alston
Miranda Biven
Lynne Thompson (until March 2003)

Legal Officers

Gabrielle Carney
Imogen Goold
George Spiteri (until August 2003)

Project Assistant

Tina O'Brien

Legal Interns

Sandy Cameron
Wendy Chang
Lisa Eckstein
Claire Gaston-Parry
Anthony Hoo
Melanie O'Brien
Christopher Pettigrew

Advisory Committee Members

Associate Professor Ian Anderson, Deputy Director, Centre for the Study of Health and Society, University of Melbourne

Justice Annabelle Bennett, Federal Court of Australia

Dr Kerry Breen, Chair, Australian Health Ethics Committee of the National Health & Medical Research Council

Professor Don Chalmers, Head, University of Tasmania Law School

Professor Andrew Christie, Intellectual Property Research Institute of Australia, University of Melbourne

Dr Trevor Davies, Partner, Allens Arthur Robinson

Dr Carina Dennis, Australasia Correspondent, *Nature*

Professor Paul Greenfield, Senior Deputy Vice-Chancellor, University of Queensland

Dr Eric Haan, Head, South Australian Clinical Genetics Service and Chair of the Human Genetics Society of Australasia

Dr Jane Hall, Director, Centre for Health Economics Research and Evaluation, University of Technology, Sydney

Ms Helen Hopkins, Executive Director, Consumers Health Forum

Professor John Mattick, Director, Institute of Molecular Bioscience, University of Queensland

Dr Dianne Nicol, University of Tasmania Law School

Professor Alan Pettigrew, CEO, National Health & Medical Research Council

Dr Bill Pickering, Partner, Blake Dawson Waldron

Dr Deborah Rathjen, CEO, Bionomics Ltd

Dr Vivien Santer, Principal, Griffith Hack

Professor Vicky Sara, CEO, Australian Research Council

Professor Sue Serjeanston, Executive Secretary, Australian Academy of Science

Professor Brad Sherman, Director, Centre for Intellectual Property Research, Griffith University

Mr John Stonier, Davies Collison Cave

Professor Ron Trent, Head, Department of Molecular & Clinical Genetics, Royal Prince Alfred Hospital and University of Sydney

Mr Guy Wilmington, Manager–Scientific & Technical Affairs, Medicines Australia (until October 2003)

Consultant

Dr Dianne Nicol, University of Tasmania Law School

List of Proposals and Questions

Chapter 5 Domestic Legal Framework

Question 5–1 Does the filing of divisional applications present problems in the context of patents over genetic materials and technologies? If so, would any of the following address these concerns:

(a) specifying a time period within which a divisional application must be filed;
(b) specifying a time period within which a divisional application must be accepted by IP Australia; or
(c) limiting the subject matter that may be claimed in a divisional application to inventions other than those claimed in the original application.

Proposal 5–1 IP Australia should regularly review the schedule of patent fees for standard patents and innovation patents to:

(a) assess the impact of the fees on the actual term of Australian patents; and
(b) ensure that fees are set at a level appropriate to discourage patent holders from maintaining patents that lack real commercial value.

Chapter 6 Patentability of Genetic Materials and Technologies

Proposal 6–1 IP Australia should assess patent applications relating to genetic materials and technologies according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.

Proposal 6–2 The responsible Minister should request the Advisory Council on Intellectual Property to review the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law.

Proposal 6–3 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to:

(a) include 'usefulness' as a requirement in the assessment of an application for a standard patent and in the certification of an innovation patent;
(b) require the Commissioner of Patents to be satisfied on the balance of probabilities that the criterion of usefulness is made out in order to accept an application for a standard patent or to certify an innovation patent; and

(c) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation.

Proposal 6–4 IP Australia should develop guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should require that the claimed 'usefulness' must be 'specific, substantial and credible' to a person skilled in the relevant art.

Question 6–1 Do the 'fair basis' and 'sufficiency' requirements in s 40 of the *Patents Act* adequately limit the scope of claims in gene patents? If not, what are the deficiencies in the way these requirements are applied, and what reforms are needed to address these concerns?

Chapter 7 Exclusions from Patentability

Proposal 7–1 The *Patents Act 1990* (Cth) (*Patents Act*) should not be amended specifically to exclude genetic materials or technologies from patentable subject matter.

Proposal 7–2 The *Patents Act* should not be amended specifically to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter.

Proposal 7–3 The *Patents Act* should not be amended to expand the circumstances in which social and ethical considerations may be taken into account in decisions about granting patents. Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of the patented invention.

Chapter 8 Patent Office Practices

Proposal 8–1 To ensure the on-going competence of Australian patent examiners in assessing patent applications, IP Australia should continue its efforts to provide examiners with continuing education in areas of technology relevant to their particular specialty. IP Australia should review and update its education programs regularly so that new developments can be incorporated as required.

Proposal 8–2 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to authorise IP Australia to establish panels of experts to advise patent examiners in assessing patent applications, as circumstances require.

Proposal 8–3 IP Australia should ensure that appointments to the panel of experts reflect a balance of independent scientific and legal expertise, and that they be made only after consultation with relevant industry organisations and other stakeholders. IP Australia should also develop procedures for the operation of the panel, including procedures in relation to confidentiality, conflict of interest, and decision making by the panel.

Proposal 8–4 IP Australia should develop examination guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

Proposal 8–5 The Commonwealth should amend the *Patents Act* to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination. (See also Proposal 6–3.)

Chapter 9 Challenging and Enforcing Patent Rights

Proposal 9–1 IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should be accessible to the public through IP Australia's website and should provide user-friendly access and search capabilities on a wide variety of bases. If a fee is charged for use of the database, it should be kept at a level that does not unreasonably limit access.

Chapter 10 Jurisdictional Issues

Proposal 10–1 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to provide that original jurisdiction in matters arising under the Act be conferred exclusively on federal courts. The original jurisdiction presently exercised by state and territory courts under the Act should be abolished. The Federal Court of Australia should continue to exercise appellate jurisdiction in matters arising under the Act, exclusive of all courts other than the High Court of Australia.

Proposal 10–2 Courts exercising jurisdiction under the *Patents Act* should continue to develop procedures and arrangements, in consultation with relevant stakeholders, to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.

Chapter 12 Publicly Funded Research and Intellectual Property

Question 12–1 Should the *National Principles for Intellectual Property Management for Publicly Funded Research* and the National Health and Medical Research Council's *Interim Guidelines: Intellectual Property Management for Health and Medical Research* be expanded to require research institutions to favour Australian industry when commercialising patented inventions created through the use of public funds? Should the *National Principles* or the *Interim Guidelines* include a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement involving patented inventions created through the use of public funds? If so, how should such requirements be implemented?

Proposal 12–1 The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review their principles and guidelines on intellectual property and research to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Proposal 12–2.)

Proposal 12–2 As part of the review proposed in Proposal 12–1, the ARC and NHMRC should include guidance on what is meant by 'public benefit' in their principles and guidelines on intellectual property and research.

Proposal 12–3 The principles and guidelines developed in accordance with Proposal 12–1 should enable conditions to be attached to the grant of funding for genetic research, to limit the commercialisation of publicly funded research in appropriate circumstances. Such conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.

Proposal 12–4 Universities and other publicly funded research organisations should ensure that their guidelines on intellectual property ownership cover research undertaken by visiting researchers and students, as well as staff—whether undertaken solely within the organisation or jointly with other bodies.

Chapter 13 Patents and Human Genetic Research

Proposal 13–1 The Australian Research Council and the National Health and Medical Research Council, as part of the review proposed in Proposal 12–1, should develop principles and guidelines for researchers to ensure that the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.

Chapter 14 Experimental and Research Use Defences

Proposal 14–1 The Commonwealth should amend the *Patents Act 1990* (Cth) to establish a new defence to a claim of patent infringement based on the use of a patented invention to study or experiment on the subject matter of the invention; for example, to investigate its properties or improve upon it. The legislation should make it clear that the existence of a commercial purpose or intention does not affect the availability of the defence.

Chapter 15 Research Culture, Patents and Commercialisation

Question 15–1 In assessing the research record of grant applicants, is sufficient weight given to the applicant's record in applying for and obtaining patents? Are there any other disincentives for researchers to seek patents over genetic research outcomes?

Question 15–2 Are any additional strategies or policies required by the National Health and Medical Research Council, the Australian Research Council, universities, or other publicly funded research institutions to encourage researchers to patent and commercialise the outcomes of genetic research?

Question 15–3 Do researchers in human genetics possess sufficient expertise to participate in the process of applying for and exploiting gene patents? If not, what measures might be taken to address any lack of expertise?

Proposal 15–1 Universities and other publicly-funded research institutions should continue to take steps to raise the awareness of researchers in the health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required.

Proposal 15–2 Universities should ensure that students undertaking degrees in the health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research

Proposal 15–3 The responsible Minister should request the Advisory Council on Intellectual Property to review the grace period provisions in the *Patents Regulations 1991* (Cth) (*Patents Regulations*) to ascertain whether these provisions are having an adverse impact on the commercialisation of Australian research in Australia or overseas.

Proposal 15–4 Universities and other publicly funded research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the *Patents Regulations*, particularly in relation to the effect of publication before filing a provisional patent application, and the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.

Chapter 16 Stem Cell Technologies

Proposal 16–1 IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cell technologies. The examination guidelines should address, among other things, the patentability of inventions involving:

(a) totipotent, pluripotent and multipotent cells; and
(b) processes involving stem cell technologies.

Question 16–1 Should specific mechanisms be established to regulate the exploitation of patented stem cell technologies? If so, would any of the following initiatives be desirable:

(a) establishing an Australian stem cell bank or collaborating with existing stem cell banks in other countries;
(b) conferring responsibility on a new or existing body to consider the potential exercise of any patent rights that might arise from research conducted by Australian entities using human stem cell lines; or
(c) developing guidelines and principles by the National Health and Medical Research Council and the Australian Research Council to ensure that the public interest in the commercial exploitation of inventions involving stem cell technologies is balanced with the public interest in dissemination of such technologies?

Chapter 18 Technology Transfer from Publicly Funded Research Institutions

Proposal 18–1 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should:

(a) continue to develop and implement programs to assist technology transfer offices in universities and publicly-funded research institutions in commercialising inventions involving genetic materials and technologies; and
(b) develop strategies to ensure widespread participation of technology transfer offices in these programs. (See also Proposals 19–1 and 23–1.)

Proposal 18–2 The Australian Research Council and the National Health and Medical Research Council should review their principles and guidelines on intellectual property and research to emphasise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research. (See also Proposals 12–1 to 12–3.)

Proposal 18–3 Universities and other publicly funded research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research. (See also Proposals 12–4 and 18–2.)

Question 18–1 Are there any other measures that could be implemented to improve technology transfer practice in relation to genetic research?

Proposal 18–4 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should develop model materials transfer agreements for use by universities and other publicly funded research institutions, along the lines of the models developed by the United States Association of University Technology Managers.

Chapter 19 Patents and the Biotechnology Industry

Proposal 19–1 Biotechnology Australia, in consultation with State and Territory governments and other relevant stakeholders, should:

(a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and
(b) develop strategies to ensure widespread participation of biotechnology companies in these programs. (See also Proposals 18–1 and 23–1.)

Chapter 20 Gene Patents and the Healthcare System

Proposal 20–1 The Australian Health Ministers' Advisory Council (AHMAC) should establish processes for:

(a) an economic evaluation of medical genetic testing and other new genetic medical technologies; and
(b) an examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

Proposal 20–2 AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

Proposal 20–3 Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should actively consider whether to: request re-examination of a patent; initiate proceedings to oppose a patent; apply for revocation of a patent; apply for the grant of a compulsory licence; or exploit or acquire a patent under the Crown use and acquisition provisions of the *Patents Act 1990* (Cth) (*Patents Act*).

Proposal 20–4 Commonwealth, state and territory health departments should establish specialist offices to monitor and manage intellectual property issues relating to genetic materials and technologies. The offices should be staffed by qualified individuals who are capable of giving specialist legal and policy advice about intellectual property, biotechnology and human health. Health departments should also establish mechanisms to enable them to draw on expertise in other government departments and agencies to advise and assist them in dealing with intellectual property issues arising from gene patents.

Proposal 20–5 The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. In conducting such monitoring, the HGCA should have the following functions:

(a) providing information to IP Australia during the examination of a patent about the proper scope of the patent, in appropriate cases;
(b) liaising with AHMAC, health departments, and other relevant stakeholders about the advisability of opposition, re-examination or revocation of a patent under the *Patents Act*, and about who might take such action and in what circumstances; and
(c) liaising with AHMAC, health departments, and other relevant stakeholders about whether access to patented genetic inventions should be obtained under the Crown use, Crown acquisition or compulsory licensing provisions of the *Patents Act*.

Proposal 20–6 Pending the establishment of the HGCA, AHMAC should establish a mechanism for monitoring the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases.

Chapter 22 Medical Treatment Defence

Question 22–1 In the absence of a general defence relating to medical treatment, should the *Patents Act 1990* (Cth) be amended to enact a new defence to claims of patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment?

Chapter 23 Licensing of Patent Rights

Proposal 23–1 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should continue to develop and implement education programs to assist research institutions and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies. (See also Proposals 18–1 and 19–1.)

Proposal 23–2 AusBiotech Ltd should develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. The model agreements should be developed in consultation with Biotechnology Australia, state and territory governments, and other relevant stakeholders as a non-binding model of desirable licensing practices. (See also Proposals 13–1 and 18–4.)

Proposal 23–3 AusBiotech Ltd should consider ways in which industry initiatives can facilitate the licensing of patent rights over genetic materials and technologies, for example through the establishment of patent pools or patent clearinghouses.

Chapter 24 Patents and Competition Law

Proposal 24–1 The Australian Competition and Consumer Commission (ACCC) should develop guidelines regarding the relationship between Part IV of the *Trade Practices Act 1974* (Cth) and intellectual property, with particular regard to patented genetic materials and technologies. The guidelines should extend to patent pools and cross-licensing involving patented genetic materials and technologies.

Proposal 24–2 The ACCC should review the conduct of firms dealing with patented genetic materials and technologies, as the need arises, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act.* The ACCC should liaise, on an ongoing basis, with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns in this field.

Chapter 25 Prices Surveillance

Proposal 25–1 The Australian Competition and Consumer Commission should conduct informal price monitoring of patented medical genetic tests and other genetic inventions involved in the provision of healthcare services if evidence emerges that such prices are having an adverse impact healthcare services.

Chapter 26 Crown Use and Acquisition

Proposal 26–1 The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the *Patents Act 1990* (Cth) (*Patents Act*) for the purposes of promoting human health. Similarly, the Commonwealth Department of Health and Ageing should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health.

Proposal 26–2 The Commonwealth should amend the *Patents Act* to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or the State' if the exploitation of the invention is for the provision of healthcare services or products to members of the public.

Proposal 26–3 The Commonwealth should amend the *Patents Act* to provide that when a patent is exploited or acquired under the Crown use or Crown acquisition provisions of the *Patents Act*, the Crown must pay such remuneration or compensation as is:

(a) agreed between the parties; or
(b) determined by a prescribed court to be just and reasonable having regard to the economic value of the patent.

Question 26–1 Should the Commonwealth amend the *Patents Act* to require a patent holder to transfer 'know-how' relating to the patented product or process to the Crown when the Crown uses or acquires a patent under the Act.

Chapter 27 Compulsory Licensing

Question 27–1 Should the Commonwealth amend the *Patents Act 1990* (Cth) to clarify the test for the grant of a compulsory licence? If so, should the Commonwealth

(a) clarify the circumstances in which the 'reasonable requirements of the public' will not have been satisfied; or
(b) specify that s 135 is not an exhaustive list of the circumstances in which a patented invention would fail to satisfy the 'reasonable requirements of the public'?

Proposal 27–1 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to insert the competition-based test that was recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence. The amendment should also provide for an independent review of the operation of the compulsory licensing provisions in addressing competition concerns arising in relation to patented inventions. This review should be conducted five years after the new test commences operation.

Question 27–2 Should the *Patents Act* be amended to allow a compulsory licence to be granted to a patent holder who cannot work his or her patent without using another patent for which authorised use cannot be obtained? If so, in what circumstances?

Question 27–3 Given the provision in the *Patents Act* for Crown use of patented inventions, should the Act also make provision for the grant of a compulsory licence over a patented invention in circumstances of 'a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use'? If so, should a compulsory licence be available whether or not the applicant has tried for a reasonable period to obtain a licence from the patent holder?

Question 27–4 Should the Commonwealth amend the *Patents Act* to authorise a prescribed court, when granting a compulsory licence, to require the transfer of 'know-how' relating to the patented product or process?

Chapter 28 A Statutory Licensing Scheme

Question 28–1 Should the Commonwealth amend the *Patents Act 1990* (Cth) to include a statutory licensing scheme for patented inventions? If so:

(a) should the scheme be available only to a limited class of patents or a limited class of users;
(b) should the scheme be voluntary or compulsory in nature; and
(c) how should a reasonable royalty for the scheme be determined and who should administer the scheme?

Chapter 29 Copyright, Trade Secrets and Designs

Proposal 29–1 The Commonwealth should amend the *Copyright Act 1968* (Cth) to clarify the extent to which 'fair dealing for the purpose of research or study' applies to commercial genetic research

Chapter 30 Protection of Genetic Databases

Question 30–1 Should the Commonwealth amend the *Copyright Act 1968* (Cth) to provide that, in relation to genetic databases protected by copyright, the operation of the provisions for fair dealing for the purpose of research or study must not be excluded or modified by contract or technological protection measures?

Question 30–2 Should the Commonwealth amend the *Copyright Act* to establish a statutory licensing scheme in relation to genetic databases protected by copyright?

Question 30–3 Does the new Celera subscription agreement cause any significant concerns for public research institutions or researchers engaging in publicly funded research? If so, what are these concerns?

Question 30–4 Should the National Health and Medical Research Council, or another Commonwealth body, have responsibility for monitoring the operation of agreements between genetic database owners and publicly funded research institutions within Australia?

PART A

Introduction

1. Introduction to the Inquiry

Contents

Background to the Inquiry

1.1 On 4 December 2002 the Australian Government announced that it would ask the Australian Law Reform Commission (ALRC) to conduct an Inquiry into intellectual property issues raised by genetic information.[1] Soon afterwards, the Government released the Terms of Reference for the Inquiry,[2] signalling the formal start of the Inquiry. The Government's media releases indicated that an examination of these issues was important because of the rapid advances in human genome research and genetic and related technologies.

1.2 The need for such an Inquiry had previously been identified by the ALRC and the Australian Health Ethics Committee (AHEC) during the course of their two-year Inquiry into the protection of human genetic information. That Inquiry, which was initiated in February 2001, had been asked to examine how best to protect privacy, prevent unfair discrimination, and maintain high ethical standards in relation to human genetic information.

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1 Attorney-General and Minister for Health and Ageing, 'Who Owns Your Genes?', *News Release*, 4 December 2002.

2 Attorney-General and Minister for Health and Ageing, 'Inquiry into Human Genetic Property Issues', *News Release*, 17 December 2002.

1.3 The earlier Inquiry acknowledged the importance of gene patenting issues but took the view that it was not possible to examine those issues in that investigation. This was because the considerations involved in gene patenting differed substantially from those at the core of the Inquiry into ethics, privacy and discrimination; and because additional time and resources would be necessary to do justice to the complex gene patenting issues.[3] Accordingly, in October 2001 the ALRC and AHEC wrote to the Attorney-General and the Minister for Health and Aged Care to suggest that the intellectual property issues raised by genetics become the subject of a fresh Inquiry with its own Terms of Reference. The present Inquiry is the outcome of that request.

1.4 The current Inquiry is being conducted independently of the earlier Inquiry into the protection of human genetic information, but the relationship between them is nevertheless important. The final Report of the joint Inquiry by the ALRC and AHEC, *Essentially Yours: The Protection of Human Genetic Information in Australia*, was tabled in Parliament on 29 May 2003.[4] It contained 144 recommendations, addressed to over 30 bodies, in relation to areas as diverse as medical research, health services, employment, insurance, immigration, sport, parentage and law enforcement. The Report made recommendations about how to close emerging gaps in the legal protection of human genetic information so that Australia may harness the benefits of human genetic science and technology, while avoiding the dangers, as we enter a new genetics era. The Report, and the consultation documents that preceded it, can be downloaded free of charge from the ALRC's website <www.alrc.gov.au>. The Report is referred to frequently in this Discussion Paper.

Defining the scope of the Inquiry

Terms of Reference

1.5 The Terms of Reference, which define the scope of this Inquiry, are reproduced at the beginning of this Discussion Paper. The 'operative part' of the Terms of Reference require the ALRC to examine the impact of patent laws and practices, as they relate to 'genes and genetic and related technologies'. This is to be done in three contexts:

- the conduct of research and its subsequent application and commercialisation;
- the Australian biotechnology sector; and
- the cost-effective provision of healthcare.

1.6 The ALRC is also asked to report on what changes may be required to address any problems that are identified in current laws and practices, 'with the aim of

3 Australian Law Reform Commission and Australian Health Ethics Committee, *Protection of Human Genetic Information*, IP 26 (2001), [1.77].

4 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003).

encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies'. Thus, although the focus of the Inquiry is on patent laws and practices, other intellectual property issues may be relevant to proposed reforms. And all this must be done 'with a particular focus on human health issues'.

1.7 In addition to the operative section, the Terms of Reference ask the ALRC to have regard to a number of considerations in making its Inquiry. These may be summarised as follows:

- the role of intellectual property rights in promoting technological innovation;
- the potential for human genetics to improve the quality of life of all Australians;
- the ethical, legal and social issues arising from intellectual property in genes and genetic technologies;
- the national interest in using genetic technologies in agriculture and industry;
- trade and investment issues affecting intellectual property; and
- international obligations and practices, both existing and proposed.

1.8 To recount these wide ranging considerations is to emphasise the complex nature of the Inquiry and the many contexts in which the patenting of genetic materials and technologies may be relevant. One dimension of the Inquiry is the effect of gene patents on human health; another is the effect of gene patents on industry and economic development. Spanning both areas are the constraints imposed by ethical and social considerations, and by Australia's obligations under international treaties. An analysis of these issues, and the degree to which the constraints affect practical options for reform, are canvassed in subsequent chapters.

Related matters not under investigation

1.9 There are several matters which, although associated with intellectual property and genetic information, nevertheless fall outside the scope of the present Inquiry. In July 2003, the ALRC released an Issues Paper, *Gene Patenting and Human Health* (IP 27), which discussed these matters in some detail.[5] In summary, the excluded areas are as follows:

- The Inquiry is confined to examining patent laws and practices as they relate to genes or genetic technologies in specified contexts, and reporting on what changes may be required to intellectual property laws to address any problems

5 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), [1.9]–[1.17].

identified. It is not a general review of Australian law in relation to patents or other intellectual property rights. However, some proposals for reform do have a wider application because of the difficulty of confining reform to gene patents.

- The Inquiry does not generally consider the impact of gene patents associated with plants and animals. However, where an animal's genetic material is used to develop a therapeutic product or process to be used in human medical treatment, the patent issues arising in this context may be relevant to human health and thus fall within the scope of the Inquiry.

- The Inquiry does not extend to genetic research on humans for purposes unrelated to human health. For example, patents over genetic tests used to determine biological kinship, or used in DNA profiling for law enforcement purposes, fall outside the scope of the Inquiry.

Process of reform

Advisory Committee

1.10 It is standard operating procedure for the ALRC to establish a broad-based, expert Advisory Committee to assist with the development of its inquiries. In this Inquiry, the Advisory Committee includes a number of judges, as well as leaders in the areas of genetic and molecular biological research, clinical genetics, community health, indigenous health, health economics, health education, intellectual property law and practice, commercialisation of biotechnology, and pharmaceuticals.[6] As always, attention has been paid to achieving a balance of interests and perspectives, while also giving consideration to matters of gender and geography.

1.11 The Advisory Committee met on 23 May 2003 and 27 November 2003, and will probably meet again during the course of the Inquiry to provide general advice and assistance to the ALRC. The Committee has particular value in helping the Inquiry to maintain a clear focus and arrange its priorities, as well as in providing quality assurance in the research and consultation effort, and commenting upon reform proposals. However, ultimate responsibility for the report and recommendations of the Inquiry remains with the Commissioners of the ALRC. The Advisory Committee does not determine the ALRC's policies on any issue addressed by the Inquiry.

Community consultation

1.12 Under the terms of its constituting Act, the ALRC 'may inform itself in any way it thinks fit' for the purposes of reviewing or considering anything that is the subject of

6 The members of the Advisory Committee are listed in the front of this Discussion Paper.

an Inquiry.[7] One of the most important features of ALRC inquiries is the commitment to widespread community consultation.[8]

1.13 The nature and extent of this engagement is normally determined by the subject matter of the reference. Areas that are seen to be narrow and technical tend to be of interest mainly to experts. Other ALRC references have involved a much greater level of interest and involvement from the general public and the media. The present Inquiry into gene patenting falls into the latter category. In releasing the Terms of Reference for the Inquiry, the Australian Government specifically asked the ALRC to 'undertake widespread public consultation and consult with key stakeholders'.[9] Thus, while it is essential that the ALRC familiarises itself with the latest developments in Australia and overseas, it is equally important that it consults widely and provides the community with an opportunity to have its say.

1.14 For this purpose, the Inquiry has arranged a large number of targeted meetings with key stakeholders, to gain expertise, perspectives and experiences, which are valuable in informing the Inquiry and helping to develop sound policies that will meet existing concerns and work effectively in practice. As of January 2004, 48 such meetings had taken place around Australia, involving several hundred individuals. These included meetings with:

- federal, state and territory departments responsible for health, industry and technology;
- advisory bodies to government in the areas of intellectual property, health, biotechnology and innovation;
- the government regulator in the field of competition policy;
- organisations concerned with health consumer education and advocacy;
- leading genetic research laboratories and genetic researchers;
- companies involved in the commercialisation of genetic research or in the delivery of medical genetic services;
- peak industry bodies in the areas of biotechnology and pharmaceuticals;
- professional and academic associations dealing with intellectual property; and

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7 *Australian Law Reform Commission Act 1996* (Cth) s 38.

8 See B Opeskin, 'Engaging the Public: Community Participation in the Genetic Information Inquiry' (2002) 80 *Reform* 53.

9 Attorney-General and Minister for Health and Ageing, 'Inquiry into Human Genetic Property Issues', *News Release,* 17 December 2002.

- academics in intellectual property, competition law and health economics.

Written submissions

1.15 The Inquiry has strongly encouraged interested persons and organisations to make written submissions to help advance the policy-making process. Nearly all submissions received to date have been in response to IP 27, addressing the issues and questions specifically raised in that paper.

1.16 As of January 2004, 65 written submissions had been received. The submissions vary substantially in size and style, ranging from short notes written by individuals providing personal views, to large, well-researched documents prepared by government departments and agencies, research centres, industry bodies, professional associations and individual researchers. From the outset, the Inquiry was aware that some of the information in submissions might have commercial sensitivity, and the ALRC left open the possibility of receiving submissions in confidence. Of the 65 submissions received to date, only two have been designated as confidential.

1.17 With the release of this Discussion Paper, the ALRC once again invites individuals and organisations to make submissions to the Inquiry, prior to the release of the final Report. There is no specified format for submissions. The Inquiry will gratefully accept anything from handwritten notes and emailed dot-points, to detailed commentary on gene patenting issues. Details about making a submission may be found at the front of this Discussion Paper.

Timeframe for the Inquiry

1.18 Under the Terms of Reference, the ALRC is required to report to the Attorney-General by 30 June 2004. The ALRC's usual operating procedure is to produce two community consultation papers—an Issues Paper and a Discussion Paper—prior to producing the final Report.

1.19 IP 27 was released in July 2003 and sought to identify the main issues relevant to the Inquiry, provide background information, and encourage informed public participation. This Discussion Paper (DP 68) was released in February 2004 and differs from the Issues Paper in that it contains a more detailed treatment of the subject matter, as well as specific proposals for reform. The Discussion Paper may be obtained free of charge in hard copy from the ALRC, and may be downloaded free of charge from the ALRC's website.

In order to be considered for use in the final Report, submissions addressing the proposals in this Discussion Paper must reach the ALRC no later than **Friday, 16 April 2004**. Details about how to make a submission are set out at the front of this publication.

1.20 As mentioned above, the Report, containing the final recommendations, is due to be presented to the Attorney-General by 30 June 2004. Once tabled in Parliament, the Report becomes a public document.[10] The final Report will not be a self-executing document—the Inquiry provides advice and recommendations about the best way to proceed, but implementation is a matter for others.[11]

1.21 In an earlier era, the centrepiece of any significant law reform effort was the recommendation of a major new piece of legislation. However, in a more complex environment in which authority is more diffused, modern law reform efforts are likely to involve a mix of strategies, including legislation and subordinate regulations; official standards and codes of practice; industry and professional guidelines; education and training programs; and so on. Although the final Report will be presented to the Attorney-General, it is likely that some of its recommendations will be directed to other government departments, independent agencies, and non-government groups.

The subject matter of gene patents

1.22 Genetic science and related technologies are important in medical research and in the development and provision of healthcare, and are likely to become increasingly significant as more becomes known about the biological function of genes and the proteins they produce. An introductory 'primer' on the relevant genetic science was included in Chapter 2 of IP 27.

1.23 Human genetic research aims to enhance understanding of how genes and environmental factors operate and interact to influence the health of individuals and populations—and in so doing, to generate knowledge with the potential to improve individual and community health.[12] Human genetic research may translate into the development and provision of new forms of healthcare involving, among other things, medical genetic testing, pharmacogenetics, gene therapy, and the use of therapeutic proteins or stem cells.

1.24 The Terms of Reference for this Inquiry require the ALRC to examine the impact of current patent laws and practices 'related to genes and genetic and related technologies'. This Discussion Paper uses 'gene patent' as the most convenient term to describe all patents or potential patents that fall within the ALRC's Terms of Reference—notwithstanding that some of these patents may not claim rights with respect to genes or other genetic material per se.

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10 The Attorney-General must table the Report within 15 sitting days of receiving it: *Australian Law Reform Commission Act 1996* (Cth) s 23.

11 However, the ALRC has a strong record of having its advice followed. About 60% of the Commission's previous reports have been fully or substantially implemented, about 20% of reports have been partially implemented, and the remaining 20% have not been implemented or are still under consideration.

12 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), Ch 16.

1.25 There are many ways in which the potential subject matter of gene patents might usefully be categorised, and various opinions have been expressed to the Inquiry on this issue. For the purposes of IP 27, the ALRC grouped the potential subject matter of gene patents into four broad categories. The categories did not have a precise scientific or legal meaning, nor were they mutually exclusive. However, they were convenient for the purpose of explaining the issues arising in the Inquiry, and submissions and consultations revealed broad acceptance of this nomenclature. The same approach is therefore adopted in this Discussion Paper. The four categories are listed below and described in greater detail in the sections that follow. For the sake of brevity, elsewhere in this paper the term 'genetic materials and technologies' is sometimes used to encompass all four categories.

- **Genetic technologies**—the methods and items used in genetic research and genetics-based healthcare, including those used in sequencing DNA, medical genetic testing, other diagnostic uses, and gene therapy.

- **Natural genetic materials**—forms of genetic material in their natural state, including DNA, RNA, genes and chromosomes.

- **Isolated genetic materials**—forms of genetic material isolated from nature, including genetic materials of whole genomes, single genes and gene fragments.

- **Genetic products**—items produced by the use of genetic materials, including proteins, nucleic acid probes, nucleic acid constructs such as vectors and plasmids, and anti-sense DNA.

Genetic technologies

1.26 The term 'genetic technologies' is used to cover a broad category of methods and items used in genetic research and healthcare services, including those used in:

- Sequencing DNA. Many different methods, products and technologies are used in amplifying DNA, such as polymerase chain reaction (PCR) methodology, or cloning DNA using a vector or host system, to enable sequencing to be conducted. In relation to amplification, DNA primers, Taq or other polymerases and temperature cycling apparatus are used. DNA sequencing itself uses instruments that rely on variations of fluorescence labelling, PCR and gel electrophoresis.[13]

- Medical genetic testing. As research establishes linkages between genetic variations and diseases, genetic tests are developed in parallel to screen individuals who show symptoms or are at risk because of family medical

13 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997), 19.

history.[14] Genetic testing for clinical (medical) purposes normally involves mutation analysis—the identification of variations in DNA sequences that are associated with disease or dysfunction.[15] Many genetic tests are patented by their developers, with medical testing conducted under licensing agreements.

- Gene therapy. Gene therapy involves the use of methods, products and technologies for the transfer of DNA or RNA into human cells to treat disease. Gene therapy uses various delivery methods to enable genes to be transferred and expressed, including improving membrane permeability to DNA, microinjection, and the use of viral vectors.[16]

- Recombinant technology. This involves the use of micro-organisms that have been transformed by exogenous genetic material to produce a desired protein. Examples include the production of insulin, growth hormone and recombinant antibodies.

1.27 Genetic technologies involve the use of many different combinations of methods, genetic materials and products, some of which may be patented or patentable. The patenting of new and improved genetic technologies is generally the least controversial area of gene patenting, since issues of 'invention', 'novelty', and 'usefulness' may be clearer than they are in the case of patents over genetic materials.

1.28 Genetic technologies also include forms of information technology. Genetic research is increasingly reliant on the use of genetic databases holding compilations of genetic sequences or biochemical pathways. As discussed in Chapter 30, the potential application of forms of intellectual property law other than patents (such as copyright or special database rights) are highly relevant to genetic information technology.

Natural genetic materials

1.29 The term 'natural genetic materials' is used in this Discussion Paper to refer to forms of genetic material in their natural state, including DNA, RNA, genes and chromosomes. In general, the Inquiry is concerned with human genetic materials. However, genetic material from other organisms, such as viruses, also may be important to medical research or healthcare provision.

1.30 As discussed in Chapter 6, patent law in Australia and most other jurisdictions distinguishes between a gene or gene fragment *in situ* (that is, in the human body or another organism) and a gene or gene fragment that has been extracted from the body by a process of isolation and purification. As the Human Genome Project's website states:

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14 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 2, 3, 10.

15 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997), 28.

16 Ibid, 155.

> In general, raw products of nature are not patentable. DNA products usually become patentable when they have been isolated, purified, or modified to produce a unique form not found in nature.[17]

1.31 Although isolated genetic materials may be patentable, genetic materials in their natural state usually are not. For example, the Australian Patent Office does not allow claims that encompass DNA as it exists in nature. Claims must be formulated so as to distinguish clearly what is claimed from the naturally occurring molecule.

1.32 'Natural genetic materials' include genetic material in living cells, such as stem cells. As discussed in Chapter 16, naturally occurring stem cells may be patentable when isolated and propagated to produce a cell line. Natural genetic materials also include living cells that have been modified by genetic manipulation, such as in gene therapy.

Isolated genetic materials

1.33 The term 'isolated genetic materials' is used to refer to genetic material that has been isolated from nature, for example, in the form of DNA copies known as complementary DNA (cDNA), and the genetic sequences in this material.[18] Isolated genetic material may relate to whole genomes, single genes, or gene fragments. When gene patents extend to isolated genetic materials, the genetic sequences of that material form part of the description of the patented invention.[19]

1.34 According to the Human Genome Project, over three million genome-related patent applications have been filed. While there is no single patent over the whole human genome, the whole genetic sequence of some non-human genomes have been patented. For example, the genome of the Hepatitis C virus has been patented by Chiron Corporation and has been used in the development of diagnostic agents and methods of blood supply screening for this infectious disease.[20] The virus has also been patented in Australia.

1.35 Most practical applications of genetic science and technology depend on the sequencing of DNA found in genetic material. DNA sequencing refers to the identification of individual nucleotide bases along a segment of DNA forming a genetic sequence.[21] As a practical matter, sequencing generally requires natural DNA

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17 Human Genome Project, *Patenting Genes, Gene Fragments, SNPs, Gene Tests, Proteins, and Stem Cells*, United States Department of Energy, <www.ornl.gov/TechResources/Human_Genome/elsi/patents.html#2> at 17 June 2003.

18 The literature often refers to the patenting of 'genetic sequences'. Where convenient, this usage is also adopted in this Discussion Paper, though it is more accurate to say that isolated genetic materials are the subject matter.

19 Human Genome Project, *Patenting Genes, Gene Fragments, SNPs, Gene Tests, Proteins, and Stem Cells*, United States Department of Energy, <www.ornl.gov/TechResources/Human_Genome/elsi/patents.html#2> at 17 June 2003.

20 US Pat No 5,350,671.

21 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997), 23.

to be isolated from its cellular or tissue source and cloned or amplified. Although other methods are available, the usual method of DNA amplification is by PCR to produce cDNA.[22] PCR technology was developed in 1985 (and then patented) by Dr Kary Mullis and others at Cetus Corporation in California.[23] It is now used routinely in all biochemical and molecular biology, research, clinical and forensic laboratories. The capacity and sophistication of PCR technology has expanded rapidly with the development of more automated processes, the use of different or multiple primers, the use of more powerful information technology, and the advent of chip technology (microarrays).

1.36 A gene contains all the information required to determine the expression of one or more proteins or a chain of amino acids. Isolated genetic material relating to whole genes (or the coding sequences of whole genes) may be used in the diagnosis of genetic conditions, the production of therapeutic proteins, gene therapy, and other uses. Examples of patented isolated genes include those associated with breast and ovarian cancer, familial adenomatous polyposis, and fragile X syndrome.

1.37 Gene fragments include a wide range of different types of isolated genetic materials, including single nucleotide polymorphisms (SNPs), expressed sequence tags (ESTs), and other gene fragments encoding important regions of proteins. The Human Genome Project has identified the value of SNPs for research relating to human health in the following terms:

> Variations in DNA sequence can have a major impact on how humans respond to disease; environmental insults such as bacteria, viruses, toxins, and chemicals; and drugs and other therapies. This makes SNPs of great value for biomedical research and for developing pharmaceutical products or medical diagnostics. Scientists believe SNP maps will help them identify the multiple genes associated with such complex diseases as cancer, diabetes, vascular disease, and some forms of mental illness. These associations are difficult to establish with conventional gene-hunting methods because a single altered gene may make only a small contribution to the disease.[24]

1.38 ESTs are DNA sequences of several hundred nucleotides, which form part of a gene. An EST is cDNA, derived from RNA. The RNA usually codes for a protein or protein fragment of unknown function. Among other things, ESTs may be used as a probe to identify genes that are active or expressed under certain conditions or in certain tissues.[25]

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22 Ibid, 19.

23 See K Mullis, 'The Unusual Origin of the Polymerase Chain Reaction' (1990) 262 *Scientific American* 56. Mullis was awarded the Nobel Prize for this work in 1993.

24 Human Genome Project, *Patenting Genes, Gene Fragments, SNPs, Gene Tests, Proteins, and Stem Cells*, United States Department of Energy, <www.ornl.gov/TechResources/Human_Genome/elsi/patents.html#2> at 17 June 2003.

25 C Feldbaum and C Ludlam, *Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine*, Biotechnology Industry Organization, <www.bio.org/genomics/primer.html> at 8 January 2003.

1.39 The patenting of gene fragments, in the absence of any disclosure of the function of the gene to which they relate, may be controversial. The Human Genome Project has noted that:

> Some say that patenting such discoveries is inappropriate because the effort to find any given EST is small compared with the work of isolating and characterizing a gene and gene product, finding out what it does, and developing a commercial product. They feel that allowing holders of such 'gatekeeper' patents to exercise undue control over the commercial fruits of genome research would be unfair. Similarly, allowing multiple patents on different parts of the same genome sequence—say on a gene fragment, the gene, and the protein—adds undue costs to the researcher who wants to examine the sequence. Not only does the researcher have to pay each patent holder via licensing for the opportunity to study the sequence, he also has to pay his own staff to research the different patents and determine which are applicable to the area of the genome he wants to study.[26]

1.40 Isolated genetic material may relate to coding or non-coding sequences, or both. Coding genetic sequences, such as in ESTs, code for particular proteins. The role of non-coding DNA is yet to be fully established, but it is thought that it may produce secondary signals that integrate and regulate the activity of genes and proteins.[27] An Australian company, Genetic Technologies Limited, holds several US patents covering the use of non-coding DNA for genetic analysis[28] and for gene mapping.[29] Patents have also been granted in Australia in relation to non-coding DNA.[30]

Genetic products

1.41 Genetic materials may be used to produce a range of items, which are referred to in this Discussion Paper as 'genetic products'. Patentable genetic products include:

- Proteins or important functional regions of proteins. As with genetic materials, proteins are naturally occurring but may be patentable when isolated or synthesised. Proteins may be used to produce new medicines or therapies. As the Human Genome Project has noted, proteins 'have unique shapes or structures. Understanding these structures and how potential pharmaceuticals will bind to them is a key element in drug design'.[31] Proteomics is widely seen

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26 M Howlett and A Christie, 'An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)' (2003) 34 *International Review of Industrial Property and Copyright Law* 581.

27 L Hood and D Galas, 'The Digital Code of DNA' (2003) 421 *Nature* 444. See also G O'Neill, 'Ghost in the Machine', *The Bulletin*, 11 March 2003, 55.

28 US Pat Nos 5,192,659; 5,612,179; 5,789,568. See Genetic Technologies Limited, *Slide Presentation May 2003*, <www.gtg.com.au/Presentation0503/index.html#btn> at 18 June 2003.

29 US Pat No 5,851,762. See Ibid.

30 See, eg, Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes AU67519; Genomic Mapping by Direct Haplotyping Using Intron Sequence Analysis AU647806; Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes AU654111.

31 Human Genome Project, *Patenting Genes, Gene Fragments, SNPs, Gene Tests, Proteins, and Stem Cells*, United States Department of Energy, <www.ornl.gov/TechResources/Human_Genome/elsi/patents.html#2> at 17 June 2003.

as the next phase in the development of genetic science, following on from the successful sequencing of the human genome.

- Nucleic acid 'probes'. These are fragments of DNA used to locate or identify particular parts of genetic sequences.

- Oligonucleotides. These are DNA molecules, usually composed of 25 or fewer nucleotides, which are used as a DNA synthesis primer.[32]

- Anti-sense DNA. This is DNA that has been synthesised to have the opposite sequence to a gene. Anti-sense DNA may be used to regulate gene expression, for example to block production of cancer cell proteins.

- DNA encoding interfering RNA. Australian biotechnology company Benitec has been awarded patents in the United States and the United Kingdom for its DNA-based technology, ddRNAi, which triggers RNA interference in human and other cells, and may be used to delay or repress the expression of a target gene.[33]

32 Human Genome Project, *Genome Glossary*, United States Department of Energy, <www.ornl.gov/TechResources/Human_Genome/glossary> at 5 June 2003.

33 M Moser Jones, *Benitec Gets First US Patent for ddRNAi, Plans to Enter US Market*, GenomeWeb Daily News, 6 June 2003, <www.genomeweb.com> at 17 June 2003.

2. The Patent System and the Nature of Reform

Contents

An outline of the patent system

Historical origins

2.1 Patents are the oldest form of intellectual property, but their historical origins are obscure.[1] In England, in the fifteenth century, the monarch began to grant monopoly rights as a means of attracting new industries from continental Europe, but these were more in the nature of royal licences to avoid the effects of guild regulations than a true grant of exclusive rights to carry on an activity.[2] It was only in the following century that patents began to be granted in respect of inventions, and the patent system was put on a statutory basis for the first time in the seventeenth century with the passage of the *Statute of Monopolies 1623*. Despite its age, this English statute continues to have relevance in Australian patent law today.[3]

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1 See, eg, A Gomme, *Patents of Invention: Origin and Growth of the Patent System in Britain* (1946); H Fox, *Monopolies and Patents* (1947).

2 S Ricketson, *The Law of Intellectual Property* (1984), 859–861.

3 The *Patents Act 1990* (Cth) s 18(1)(a) requires a patentable invention to be a 'manner of manufacture within the meaning of section 6 of the Statute of Monopolies'.

2.2 As it first developed, the English patent was a slow, costly and cumbersome procedure for encouraging and protecting inventions. The procedure was described in derisory terms by Charles Dickens in a short story published in 1850, 'A Poor Man's Tale of a Patent'.[4] Over the years there were many piecemeal reforms to the system, but it was the *Patents Act 1883* (UK) that provided the basis of modern patent law, though this Act too has since been amended and re-enacted many times.

2.3 Patent legislation in Australia has always been closely modelled on that of the United Kingdom. Prior to Federation, each of the Australian colonies had its own legislation based on the *Patents Act 1883* (UK). In 1901, the *Australian Constitution* gave the newly established Commonwealth Parliament power to make laws with respect to 'copyrights, patents of invention and designs, and trade marks'.[5] In 1903, this power was exercised with passage of the *Patents Act 1903* (Cth). As in the United Kingdom, there have been many amendments to Australian patent legislation in response to formal commissions of inquiry. The 1903 Act was re-enacted with substantial changes in 1952 and again in 1990. The *Patents Act 1990* (Cth) (*Patents Act*) provides the current legislative framework governing the grant and administration of patents in Australia.

Functions of patents

2.4 Patent law has been described as a 'stressful if fertile union' between certain contradictory principles: self-interest and the common good; monopoly rights and liberty; the ownership of ideas and public disclosure of knowledge.[6] This union results from the dual goals of patent law—to benefit society by encouraging the provision of new and useful goods, and to encourage and reward inventiveness.

2.5 These goals are achieved by providing incentives for innovation and knowledge-sharing by granting monopoly rights, for a limited period, to exploit a new product or process.[7] Monopoly rights encourage investment by providing an opportunity to recoup the financial outlays involved in developing an invention. They also reward the inventor by allowing a return to be made on the time and resources expended on research and development.[8]

2.6 The limited duration of the monopoly means, however, that the patented invention eventually will be available for free and unrestricted use when the patent term expires: the compromise is thus 'a way of securing future benefits for the common good'.[9] In addition, patents promote knowledge-sharing during the term of

4 C Dickens, 'A Poor Man's Tale of a Patent' (1850) II(70) *Household Words* 1.
5 *Australian Constitution* s 51(xviii).
6 L Kass, 'Patenting Life' (1981) 63 *Journal of the Patent Office Society* 570, 580.
7 *Patents Act 1990* (Cth) s 13(1), sch 1 defines 'exploit' to include make, hire, sell or otherwise dispose of the product, use or import it, or keep it for the purpose of doing any of those things.
8 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 136.
9 P Baird, 'Patenting and Human Genes' (1998) 41 *Perspectives in Biology and Medicine* 391, 391.

the patent by requiring the patent holder to place the details of the invention in the public domain, in return for exclusive rights. As one United States judge has stated:

> The purpose of the patent system is not only to provide a financial incentive to create new knowledge and bring it to public benefit through new products; it also serves to add to the body of published scientific/technological knowledge. The requirement of disclosure of the details of patented inventions facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance.[10]

Nature of patents

2.7 A patent is an intellectual property right granted by a government to the inventor of a new, inventive and useful product or process. A patent gives the inventor the right to stop others from exploiting the invention for a limited period.[11] However, a patent does not grant an absolute right to exploit an invention in any way the inventor may choose. A patent holder may have to satisfy regulatory requirements in order to exploit the patented product or process; for example, a patented pharmaceutical compound may need approval under the *Therapeutic Goods Act 1989* (Cth) before it can be marketed lawfully and sold as a treatment for a particular condition. Similarly, the use of a patented invention is subject to the general law; for example, the components required to manufacture a car may be the subject of many patents, but the car must still be used in accordance with motor traffic laws.

2.8 A patent holder is not obliged to exploit a patented invention, but the failure to do so may have implications for the patent holder's rights. For example, the patent could be subjected to compulsory licensing, or it could be used or acquired by the Crown under relevant provisions of the *Patents Act*. A patent holder may authorise others to exploit the patent by granting a licence on agreed terms. This may be on an exclusive, sole or a non-exclusive basis, and almost certainly will require the licensee to pay royalties or other fees to the patent holder.[12]

2.9 It is important to note that while patents are a form of intellectual property, they do not confer ownership in the physical material described in the claims for a patented product or process. Thus, a patent over a genetic sequence does not amount to ownership of the sequence itself.

Criteria for patentability

2.10 Although there is considerable variance in the detail from one jurisdiction to another, most countries apply similar tests for patentability: an invention must be novel (ie, new), must involve an inventive step, and must have a useful application. In addition, the description of an invention in a patent application must be sufficient to allow a skilled person to create the invention independently.

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10 *Integra Life Sciences v Merck KgaA* 307 F 3d 1351 (2002) (Newman J, dissenting).

11 In Australia, a standard patent has a term of 20 years; an innovation patent has a term of eight years.

12 Common terms in patent licences are described further in Ch 23.

2.11 Chapter 6 of this Discussion Paper provides a detailed discussion of the criteria for patentability under Australian law. Briefly, the *Patents Act* provides that an invention will be patentable if it:

- is a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*—that is, the invention is appropriate subject matter for patent protection;
- is novel;
- involves an inventive or innovative step;
- is useful; and
- has not been used secretly within Australia prior to filing the patent application.[13]

2.12 Certain inventions are expressly excluded from patentability. Australia has relatively few express exclusions from patentability, but they include inventions involving 'human beings, and the biological processes for their generation', as well as inventions the use of which would be contrary to law.[14] Other jurisdictions recognise a broader range of exceptions, including inventions involving diagnostic, therapeutic and surgical methods of treatment of humans and animals; and inventions whose commercial exploitation would be contrary to morality or public order.[15] Exclusions from patentability are discussed in Chapter 7.

Patents and genetic technologies

Accommodating new technologies

2.13 The patent system is over 400 years old. It has accommodated the arrival of many new technologies including: inventions associated with mechanics in the industrial revolution; electricity and electronics; industrial and chemical materials; food production and agriculture; scientific instruments and devices; transportation and energy; warfare; medical devices and pharmaceutical products; computing and information technology; and business methods. In the last 20 years, inventions in the field of biotechnology have become a new focus of the patent system, particularly in relation to genetic materials and technologies.

2.14 Each new field of technology has brought with it new challenges for the patent system, as those responsible for processing patent applications seek to assess the

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13 *Patents Act 1990* (Cth) s 18.

14 Ibid ss 18(2), 50(1)(a), 101B(2)(c), (d). See Ch 7.

15 See *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 27(2).

novelty, inventiveness and usefulness of each new claimed invention, in the light of what has gone before. These challenges have been felt in the area of gene patents, where the difficulty of the examiners' task has been compounded by the newness of the claims, the increasing pace of technological change, the global nature of scientific inquiry, the highly specialised nature of genetic science and technology, and the sheer volume of inventions. No doubt, once patent examiners have become familiar with genetics, they will be met with a new range of challenges from emerging disciplines such as bioinformatics, pharmacogenomics, proteomics and nanotechnology.

2.15 Thus the problems identified with gene patents in this Discussion Paper should be seen in historical perspective. The patent system has been durable because it has been highly adaptive. There have been many inquiries into the patent system, and many legislative changes to refine and improve the system inherited from the United Kingdom. Many of these changes have been incremental, whereas the principal concepts underlying the modern patent system have been in existence for a long time.

A chronology of genetic technologies and patents

2.16 This section gives a brief chronology of the patenting of genetic materials and technologies as background to the issues identified in this Discussion Paper.

2.17 In 1953, the foundation for modern genetics was laid when the scientific journal, *Nature*, published Watson and Crick's hypothesis about the double helix structure of DNA. Their article suggested a mechanism by which genetic material could be stored, transferred and copied.

2.18 Twenty years later, Cohen, Boyer and Chang developed a technique that allowed sections of DNA to be transferred from one life form into another, thereby producing the first 'recombinant organism'. This advance was significant because, for the first time, scientists could artificially introduce genetic traits into other species.

2.19 Commercialisation of genetic technology followed soon after when, in 1976, Boyer and Swanson established the first known biotechnology company, Genentech Inc, in Berkeley, California. In 1977, Genentech reported the production of the first human protein manufactured in a bacterium.[16] The technology demonstrated that molecules could be produced in large quantities in bacterial vectors and then administered to patients, raising hopes that recombinant technology could aid the treatment of human disease.

2.20 A second crucial breakthrough in genetic science occurred in 1977, when Sanger identified a method for reading DNA sequences.[17] Scientists could now read the genetic code, and so gain an understanding of genetic mutations that cause human

16 The protein produced was somatostatin, a human growth hormone-releasing inhibitory factor.

17 Gilbert and Maxam also created a sequencing method at this time, based upon the 'cleavage method'.

disease as well as the functional and evolutionary relationships between genes. The Sanger methodology remains the basis of modern gene sequencing.

2.21 A third major innovation in genetics was the development of the polymerase chain reaction (PCR). Developed in the 1980s by Mullis and others at Cetus Corporation, PCR provided a quick and easy method for selective amplification of DNA fragments, removing the need for cloning in micro-organisms.[18] Amplifications that previously took weeks could now be done in a matter of hours. After patenting the process, Cetus sold the patent to Hoffman-La Roche Inc (Roche). Roche now holds more than 130 patents in the United States related to the PCR process.[19] The process has become the foundation for almost all genetic laboratory work, making access to the patented technology crucial.

2.22 While genetic technology was progressing apace, legislatures, courts and regulators were also forced to address issues arising from the commercialisation of genetic inventions. The controversial decision in *Diamond v Chakrabarty*,[20] handed down by the United States Supreme Court in 1980, allowed a patent to be granted for a recombinant bacterium, thus determining that life forms are patentable subject matter under United States law. In the same year, the United States Congress passed the *Bayh-Dole Act*, providing that intellectual property rights arising from publicly funded research vest in the organisations that carry out the research.[21] The underlying policy of the legislation was to encourage innovation and exploitation by allowing universities to patent inventions flowing from their research.[22] In 1982, the US Food and Drug Administration (FDA) approved the first recombinant DNA drug for market,[23] demonstrating that government agencies had accepted some genetically manipulated products as safe for medical use.

2.23 The biotechnology industry expanded rapidly during the 1980s. In 1985, the FDA gave approval for the first drug to be both manufactured and marketed by a biotechnology company.[24] Sequencing methods improved with the introduction in 1986 of the automated DNA fluorescence sequencer developed by the Californian Institute of Technology and Applied Biosystems Inc. In 1988, the United States Patent and Trademark Office granted the first US patent over an entire animal, the 'Harvard Mouse'.[25] This move provoked widespread concern about the ethics of patenting

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18 The PCR process is described in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [10.2].

19 Roche Molecular Diagnostics, *PCR Information for Journalists*, <www.roche-diagnostics.com/ba_rmd/pcr_jounalists.html> at 9 December 2003.

20 *Diamond v Chakrabarty* 447 US 303 (1980).

21 Previously, the US government retained title to such intellectual property. This meant that universities and researchers had little incentive to commercialise their inventions.

22 See D Mowery and others, 'The Growth of Patenting and Licensing by US Universities: An Assessment of the Effects of the Bayh–Dole Act of 1980' (2001) 30 *Research Policy* 99, 103.

23 The drug was a recombinant human insulin, produced by Genentech and licensed to Eli Lilly & Co.

24 This was Genentech's protropin as a treatment for child growth hormone deficiency.

25 The 'Harvard Mouse' was genetically engineered to be highly susceptible to breast cancer.

higher life forms.[26] Genetically altered mice (and other animals) are valuable research tools for both industry and academic researchers, principally because they serve as animal models of human disease.[27]

2.24 The role of patent law in facilitating innovation in the field of genetics continued to excite controversy in the 1990s. One issue of contention was the level of usefulness or utility that needed to be demonstrated to support a claim over a genetic invention. In 1991, the US National Institutes of Health (NIH) filed patent applications on approximately 2,700 partial gene sequences, known as 'expressed sequence tags' (ESTs). The applications included not only claims over the ESTs, but also over their full-length gene sequences and derivative proteins.[28] These claims were controversial because the functions of these sequences were unknown at the time of filing. The NIH eventually abandoned the applications.

2.25 Another issue for patent law has been the breadth of claims made in applications for patents over genetic inventions. An example is the patent issued in 1993, to Australian scientist Dr Malcolm Simons, over 'the use of non-coding DNA for genetic analysis',[29] and the grant five years later of a further patent to cover the use of non-coding DNA for the purposes of gene mapping.[30]

2.26 The commencement of the Human Genome Project in 1990 was an indication of the thriving state of genetic research.[31] The international consortium led by Dr Francis Collins of the US National Human Genome Research Institute had the ambitious objective of determining the complete sequence of the three billion base pairs comprising the human genome. It is a tribute to the enormous biotechnological advances of the previous two decades that such a task could even have been contemplated.[32]

2.27 A new era of genomics was entered in February 2001, with the publication by the Human Genome Project and Celera Genomics Group (Celera) of the working draft of the human genome sequence.[33] Final sequencing of the human genome was completed in April 2003.[34] The sequence data produced by the Human Genome Project

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26 See, eg, Greenpeace, *Supreme Court of Canada Rejects Patent for Mouse, 5 December 2002*, <www.greenpeace.ca/e/campaign/gmo/depth/highlights> at 18 December 2003.

27 Mice and other animals may be genetically engineered by adding a foreign gene to its cells (a 'transgenic mouse'), or deleting or making inactive a specific gene in its cells (a 'knockout mouse').

28 M Holman and S Munzer, 'Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags' (2000) 85 *Iowa Law Review* 735, 750.

29 Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes: US Pat No 5,192,659. See also US Pat No 5,612,179 and 5,789,568.

30 Genomic Mapping Method by Direct Haplotyping Using Intron Sequence Analysis: US Pat No 5,851,762.

31 K Davies, *Cracking the Genome: Inside the Race to Unlock Human DNA* (2001), 3.

32 In 1998 geneticist Craig Venter entered the 'race' to sequence the human genome, claiming that Celera Genomics would single-handedly sequence the entire human genome in just three years: C Venter and others, 'Shotgun Sequencing of the Human Genome' (1998) 280 *Science* 1540.

33 The draft was published in special issues of *Science* (16 February 2001) and *Nature* (15 February 2001).

34 National Human Genome Research Institute, *Home Page*, <www.nhgri.nih.gov> at 9 December 2003.

have been deposited into public gene banks. In contrast, Celera sought patent protection over the sequences that it had identified. There is little doubt that the vast amount of information released during the course of the Project will be a spur to further research and innovation, and may bring with it a new array of problems for gene patenting.[35]

Concerns about gene patenting

2.28 As noted in Chapter 1, the ALRC has received 65 submissions to date in relation to gene patenting and has conducted nearly 50 targeted consultations with stakeholders, involving many hundreds of individuals. The submissions have come from individuals, organisations and government departments spanning a wide range of interests.

2.29 A number of submissions expressed the view that the patent system works reasonably well across all fields of technology, including human genetics. On this view, if there are real or perceived problems with gene patents, these are no more than the expected consequence of applying an established and generalised patent system to a new field of human endeavour. From this standpoint, the problems of today will be viewed by the next generation in the same way we now view the problems produced by technologies of the previous generation. The broad conclusion of these submissions is that the patent system is robust and adaptable, and should be left alone—or, at most, adapted at the margins to address the limited problems that have been shown to exist.

2.30 At the other end of the spectrum were those who considered the patent system to be fundamentally flawed in its application to *all* technologies, with a consequent degradation in the quality and economic value of patents throughout the industrialised world. The concerns identified in these submissions and consultations extended beyond the Terms of Reference of the current Inquiry. Their principal criticism was the 'functional redundancy' of patents, which was said to arise because many granted patents plagiarise earlier ones, or because the only innovation is the use of alternative linguistic expressions to describe a previously patented invention.[36] The problem was said to stem from the inadequacies of the examination process, combined with the incentive for patent offices to be overly generous in their grant of patents because their revenues depend on receipt of patent fees.

2.31 Between these extremes were the far more numerous submissions and consultations in which concerns were expressed about the patenting of genetic materials and technologies—ranging from mild dissatisfaction with particular arrangements, to strenuous objection to the way in which the patent system deals with genetic materials and technologies. These concerns are described and analysed in detail in later chapters of this Discussion Paper. For present purposes it is sufficient to

35 See F Collins and others, 'A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era' (2003) 422 *Nature* 835.

36 M.CAM Inc, *The Problem with Patents and the Impact on the Investing Public* (2001). The criticisms were directed principally to the United States Patent and Trademark Office.

distinguish between two classes of criticism: those relating to the law or practice of patenting genetic materials and technologies; and those relating to the manner in which gene patents are exploited in the marketplace.

2.32 Submissions that criticised the patenting of genetic materials and technologies identified a broad range of concerns, including the following:

- Patent legislation fails to take sufficient account of ethical considerations, such as whether human genetic sequences are a proper subject matter for a statutory monopoly.

- Human genetic sequences should not be patentable because they are discoveries, not inventions. Alternatively, the level of inventiveness required to isolate and purify human genetic material is insufficient to justify the grant of a patent.

- Patents granted over genetic materials and technologies are often too broad, and are granted without proper evidence that the invention is useful.

- Patents over genetic materials and technologies are too easily granted in Australia, in comparison with overseas patent offices; and patent examiners should be more highly skilled in assessing applications in the field of biotechnology.

2.33 Many submissions directed their attention not to the patentability of genetic materials and technologies but to the manner in which gene patents are exploited in the marketplace by a patent holder or its licensee. Again, many different views were expressed, including the following:

- Restrictive licensing practices limit access to medical genetic testing, and compromise the quality of such testing, to the detriment of public health.

- Exploitation of the monopoly rights conferred by gene patents drives up the cost of medical genetic testing beyond a fair and equitable level, to the detriment of public health.

- Licensing practices restrict access to genetic materials and technologies for research purposes. Negotiating licences for a large number of related or overlapping gene patents is problematic due to the high transaction costs and the lack of expertise of many researchers.

- The use of gene patents in research should be exempt from claims of patent infringement, so as to facilitate research, not hinder it.

Approach to reform

2.34 In later chapters of this Discussion Paper, the ALRC canvasses reforms that are designed to address possible problems with the patenting of genetic materials and technologies. This section explains the overall approach taken by the Inquiry in examining these problems and in proposing reforms.

Working with the patents system

2.35 The Inquiry's approach is predicated on acceptance of the fundamental objective of the patent system in seeking to encourage innovation by granting limited monopoly rights. As indicated in Chapter 1, the ALRC has not been asked to undertake a wholesale review of intellectual property laws or the patent system, but to examine ways in which the patent system can be changed to 'further the health and economic benefits of genetic research and genetic and related technologies'.[37]

2.36 In this context, there should be realistic expectations of the patent system and what it can achieve. For example, as discussed in Chapter 7, the patent system may be ill-suited to addressing all the social and ethical concerns that are raised by the use or exploitation of patented inventions. Those issues are better addressed by laws and practices that exist outside the patent system. Some of the needed reforms were considered by the ALRC and the Australian Health Ethics Committee in its 2003 report, *Essentially Yours: The Protection of Human Genetic Information in Australia*,[38] where recommendations were made, for example, to improve the ethical oversight of human genetic research.

2.37 An important feature of the patent system is its long-term perspective of the role of monopoly rights in fostering innovation and delivering public benefit. For example, some people may think that exclusive rights to exploit a particular genetic invention are not in the public interest because they prevent open access to a specific medical genetic test for a period of 20 years. Yet this consideration must be weighed against the role of patent rights in promoting the innovation and investment that led to the availability of the test in the first place. Research and development are not only costly, but time-consuming. Many therapeutic benefits are still to be realised from the genetics revolution that began in the 1970s, whose landmarks have been described above.

2.38 In developing its proposals, the ALRC has been mindful of the need for reforms that make the existing system work better, rather than conceiving an entirely new system. This approach recalls the much quoted conclusion of Professor Fritz Malchup in his seminal study of the economic benefits of the United States patent system:

> If one does not know whether a system 'as a whole' (in contrast to certain features of it) is good or bad, the safest 'policy conclusion' is to 'muddle through'—either with

37 See Terms of Reference, reproduced at the front of this Discussion Paper.

38 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003).

> it, if one has long lived with it, or without it, if one has lived without it. If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.[39]

2.39 As Machlup's conclusion implies, the patent system can be improved if particular features can be identified as good or bad. This Inquiry is directed to that task.

Evidence of the impact of gene patents

2.40 The previous section identified some of the concerns that have been raised about the patenting of genetic materials and technologies. One difficulty in assessing these concerns is that there have been very few empirical studies in Australia addressing gene patents and their impact on research, biotechnology or healthcare.[40] Overseas studies are also few in number, and their conclusions may not be capable of being generalised to Australian conditions.[41] Where studies have been conducted, the conclusions are often equivocal.

2.41 The ALRC received a broad range of comments and opinions about the actual or potential effects of gene patents, including anecdotal accounts about research or healthcare being hindered by gene patents, or by the commercial strategies of patent holders. There are limits to what may be learned from the experience of one patent or set of patents, or the exploitation of patent rights in a specific social and commercial situation. Just as an old common law saying is that 'hard cases make bad law', hard cases may also make for poor law reform proposals. Even if firm evidence can be found that the exploitation of a specific gene patent has led to problems for research or healthcare, it does not follow that this justifies a systemic response by which widespread change is sought to the entire patent system.

2.42 The ALRC believes that there is limited evidence to date that gene patents or licensing practices have had any significant adverse impact on the conduct of genetic research or on healthcare provision in Australia. Many of the concerns that have been expressed to the Inquiry relate to possible future problems and are based on assumptions that may or may not be borne out with time—for example, assumptions about the future development of the market in medical genetic testing, or the intentions of patent holders with regard to the exploitation and enforcement of gene patents.

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39 F Machlup, *An Economic Review of the Patent System* (1958), 80.

40 See D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6; M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003).

41 See J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285; Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002); M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

2.43 In view of the equivocal nature of evidence about adverse impacts on research and healthcare, the ALRC considers that it should adopt a cautious approach towards proposing radical changes in patent law and practice. Major changes should be proposed only in response to demonstrated problems. This is particularly so given that such changes have uncertain flow-on effects; for example, on future investment and innovation in genetic technologies, and on the development of the biotechnology industry. On the other hand, caution does not imply inaction, and the patent system must be flexible enough to deal with problems as they emerge.

Need for flexibility

2.44 While adverse effects of gene patents may not yet be manifest, the ALRC recognises that this may change in response to shifts in the commercial, scientific, medical and technological environments, or in the interactions among them.

2.45 For example, patent holders may become more active in enforcing certain patent rights, perhaps in response to the success of new business models. New medical, scientific and technological developments in the field of human genetics may provide new opportunities to exploit genetic inventions. Medical, scientific or technological change may also mean that some foreseen problems do not eventuate or are manifested in different ways to those anticipated. Thus, some genes (and hence gene patents) may come to have an importance that was unanticipated, while other much-heralded patents may end up as technological backwaters, rather than being at the forefront of developments.

2.46 The nature and extent of the potential problems—and whether existing legal mechanisms provide appropriate and effective remedies—are difficult to assess. The appropriate response to this challenge is to ensure that patent laws and practices are sufficiently flexible and robust to anticipate and respond to future problems. This approach has influenced the proposals made in this Discussion Paper, which are more often directed to influencing patent practices than to proposing substantive changes to patent law. The need for flexible regulation has been described by the ALRC elsewhere as one mechanism for ensuring that today's law reform is relevant to the scientific developments of tomorrow.[42]

Constraints on reform

Terms of Reference

2.47 There are other factors that constrain the extent to which it would be appropriate for the ALRC to propose sweeping changes to the patent system. One of these is the Inquiry's Terms of Reference, which instruct the ALRC to report on the impact of patenting laws and practices related to 'genes and genetic and related technologies'.

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42 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [4.18], [4.35]–[4.49].

2.48 In general, the ALRC does not believe that concerns about the patenting of inventions involving genetic materials and technologies should be addressed by provisions in the *Patents Act* dedicated only to these types of inventions. There are cogent reasons for maintaining, so far as possible, the technology-neutral nature of the *Patents Act*.[43] However, there is scope for technology-specific regulation through guidelines and principles issued by the Patent Office (that is, IP Australia) and other relevant institutions. The introduction of legislative provisions that are specific to inventions involving genetic materials and technologies may suggest that specific provisions also should be implemented for future technologies—an approach that would unnecessarily fragments and complicate Australian patent law in the long term.

2.49 Legislative reform that is specific to genetic materials and technologies would also represent a departure from attempts to harmonise the patent laws of various jurisdictions and lead to divergence between Australian patent law and that in major industrialised countries—with implications for investment in the Australian biotechnology sector.[44] Further, the adoption of specific laws for genetic materials and technologies may have implications for Australia's obligations under multilateral agreements dealing with patents and other intellectual property laws, and under bilateral free trade agreements with other states.[45]

2.50 Many reforms considered by the Inquiry do not lend themselves to being formulated in a manner that is specific to genetic materials and technologies. Some proposals, therefore, have been framed so as to apply to all patented inventions. These include, for example, proposals made in relation to an experimental use defence,[46] Crown use and acquisition,[47] and compulsory licensing.[48] In some cases, the decision to propose reforms applicable to all patentable inventions, and not just genetic materials and technologies, was bolstered by submissions that identified similar problems with respect to other patentable subject matter.[49] In other cases, the uncertain implications of reform on other patentable subject matter constituted one reason not to propose change.[50]

2.51 The Terms of Reference direct the ALRC to consider the impact of gene patents on: (a) research and its subsequent application and commercialisation; (b) the biotechnology sector; and (c) the cost-effective provision of healthcare. However, the interests of each of these sectors are different and sometimes conflict—at least on the surface—and must be balanced in recommending reform. For example, when making

43 See, eg, Ch 6 in relation to patentability requirements.
44 Chapter 4 discusses the recently concluded Free Trade Agreement between Australia and the United States, and the agreement that the parties work to reduce differences between them in intellectual property laws and practices, including in relation to patents.
45 See Ch 4.
46 See Ch 14.
47 See Ch 26.
48 See Ch 27.
49 See, eg, Ch 14 in relation to the proposed new experimental use defence.
50 See, eg, Ch 22 in relation to a medical treatment defence.

proposals directed primarily to promoting access to patented inventions for healthcare purposes, the ALRC has been mindful of the impact of reforms on the biotechnology sector and on the potential for commercialisation of research. Not surprisingly, perhaps, the views expressed in submissions from health departments often differed markedly from those expressed in submissions from departments responsible for industry and innovation.

International legal framework

2.52 As discussed in Chapter 4, elements of the international legal framework have an important influence on the reform of Australian patent law. In particular, reforms proposed by the ALRC may have implications for Australia's obligations under multilateral agreements dealing with patents and other intellectual property laws and under bilateral free trade agreements with other states. For example, the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement)[51] imposes constraints on the extent to which the national laws of Contracting States may discriminate by 'field of technology'.[52] As noted above, this provides an important reason why it may be appropriate to extend the application of some proposed reforms beyond gene patents to all patentable inventions.

2.53 Although it is possible to amend domestic laws so that they are inconsistent with Australia's international treaty obligations, Australia may be held responsible on the international plane for breaches of such obligations. The ALRC would need compelling reasons to recommend any reform of patent law or practice that would raise doubts about Australia's compliance with its existing international obligations.[53]

Summary of proposals

2.54 To date, the Inquiry has not identified fundamental flaws in patent law or practice as applied to genetic materials and technologies such that we feel the need to propose radical change. However, there are means by which patent law and practice could be fine-tuned to address existing problems and provide greater flexibility in addressing future problems as they arise. This Discussion Paper makes 49 proposals for reform. These proposals are directed to:

- improving patent law and practice concerning the *patenting* of genetic materials and technologies, including through proposed amendments to the *Patents Act* and changes in the practices and procedures of IP Australia, patent examiners and the courts;

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51 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

52 Ibid, art 27.1.

53 This is especially important in light of the legislative requirement that the ALRC, in performing its functions, 'must have regard to all of Australia's international obligations that are relevant to the matter': *Australian Law Reform Commission Act 1996* (Cth) s 24(2).

- improving patent law and practice concerning the *exploitation* of gene patents, including in relation to new defences to claims of patent infringement, Crown use and the compulsory licensing of gene patents;

- ensuring that publicly funded research, where commercialised, results in appropriate public benefit, including through the adoption of appropriate patent practices;

- encouraging universities and other publicly funded research institutions to raise the awareness of researchers about patenting issues and the commercialisation of research;

- ensuring that Australian research institutions and biotechnology companies are adequately skilled to deal with issues concerning commercialisation and the licensing of patented inventions;

- establishing mechanisms for monitoring the implications of gene patents for research and healthcare so that governments have the ability to intervene where gene patents are considered to have an adverse impact, either in specific cases or systemically; and

- applying competition law to business practices involving patented genetic inventions.

2.55 The mechanisms for implementing these proposals vary. A number of proposals are directed to legislative change, generally involving amendment of the *Patents Act* or the *Patents Regulations 1991* (Cth). A small number of these proposals would make substantive changes to patent law; for example, through the enactment of a new requirement that the Patent Office be satisfied during examination that the criterion of 'usefulness' is satisfied;[54] a new defence relating to the use of a patented invention to study or experiment on the subject matter of the patented invention;[55] and a new competition-based test as an additional ground for the grant of a compulsory licence.[56] Other proposals for legislative reform are of a more minor nature, or are directed to clarifying existing law. These include proposals to elucidate the ambit of the Crown use provisions[57] and the extent to which the 'fair dealing' provisions of the *Copyright Act 1968* (Cth) apply to commercial genetic research.[58]

2.56 However, most proposals do not require legislative change but involve the development of new or revised guidelines, or other action by government and non-government bodies involved with various aspects of the patent system or its impact on

54 See Ch 6.
55 See Ch 14.
56 See Ch 27.
57 See Ch 26.
58 See Ch 29.

research, biotechnology or healthcare. These bodies include: IP Australia; the Australian Competition and Consumer Commission (ACCC); the Australian Research Council (ARC); the National Health and Medical Research Council (NHMRC); Biotechnology Australia; AusBiotech Ltd; and the Australian Health Ministers' Advisory Council (AHMAC).

2.57 Some of these non-legislative proposals are intended to improve the operation of the patent system and the practices and procedures of IP Australia, patent examiners and the courts. For example, the ALRC proposes that IP Australia develop examination guidelines to assist patent examiners in applying the 'usefulness' requirement of patentability,[59] and to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.[60] The ALRC also proposes that courts should continue to develop procedures to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving gene patents. This is a matter of particular importance to the Federal Court, which hears and determines most patent litigation in Australia.[61]

2.58 Other non-legislative proposals are directed to the relationship between the patent system and the three sectors to which the ALRC is required to have regard—namely, research, biotechnology and healthcare. For example, the ALRC proposes that the ARC and the NHMRC review their principles and guidelines to ensure that publicly funded research, where commercialised, results in appropriate public benefit,[62] and that universities continue to take steps to raise the awareness of researchers about intellectual property issues and the commercialisation of research.[63] It is also proposed that Biotechnology Australia take steps to assist universities and biotechnology companies in commercialising inventions involving genetic materials and technologies.[64] Commonwealth, state and territory health departments are encouraged to consider actively whether to intervene in patent proceedings where particular gene patents are thought to have an adverse impact on healthcare provision.[65]

2.59 Another category of proposals comprises those directed to monitoring the ongoing impact of gene patents. These reforms are intended to ensure that problems are identified at an early stage; for example, through monitoring of anti-competitive conduct and informal prices surveillance by the ACCC.[66] The ALRC also proposes processes for examining the economic and financial impact of gene patents on healthcare services and the monitoring of gene patents by specialist offices within Commonwealth, state and territory health departments.[67]

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59 See Ch 6.
60 See Ch 8.
61 See Ch 10.
62 See Ch 12.
63 See Ch 15.
64 See Ch 18–19, 23.
65 See Ch 20.
66 See Ch 24–25.
67 See Ch 20.

2.60 It should be apparent that this raft of proposals adopts a nuanced approach to reform, which seeks to recognise both the generality and longevity of the patents system, on the one hand, and the new challenges generated by human genetic science and technology, on the other. There are many different points at which the patent system may be reformed to address the actual and anticipated problems posed by the patenting of genetic materials and technologies. This does not mean that reform should be sought at every point, but rather that intervention—where needed—should be directed to those places where it will be most effective. This Discussion Paper seeks to describe the complexities of the Australian patent system and to explain the ALRC's views about the desirability of reform in dealing with the problems generated by the 'new genetics'.

3. Economic, Social and Ethical Dimensions

Contents

Introduction

3.1 When patents over isolated human genetic materials were initially granted, ethical concerns centred on the appropriateness of granting such patents. As gene patenting became more widespread, concerns about the exploitation of gene patents came more to the forefront of the debate. This chapter discusses the early ethical objections to granting patents on human genetic materials and more recent concerns about the economic, social and ethical implications of gene patents. The concerns include those about the effects of gene patents on research and innovation; resource use and knowledge sharing; access to healthcare; benefit sharing; and issues of consent to, and control of, research that leads to the development of patentable inventions.

3.2 The economic, social and ethical dimensions of gene patents are relevant to potential reform of the patent system because the fundamental rationale for patents is to promote the social good. It is important, therefore, that any negative consequences of gene patents do not outweigh the benefits.

Economic dimensions

3.3 The grant and exploitation of gene patents have a range of possible economic impacts. The Organisation for Economic Co-operation and Development (OECD) has noted that the 'genomics revolution' has reopened debate about intellectual property rights, and the challenge of balancing:

> the need to keep information and access to genetic data open in order to encourage the diffusion of research results with the commercial need to protect inventions in order to create revenue from investments in research and development.[1]

3.4 This section considers some of the issues that arise from this challenge, including those relating to:

- promotion of innovation;
- investment and economic growth implications of patenting; and
- resource use and knowledge sharing.

Promoting innovation

3.5 Innovation benefits the community by creating new and improved goods and services that meet social needs. For example, innovations in medical research may produce new genetic tests and treatments, which may improve community health.

3.6 As discussed in Chapter 2, patents promote innovation through the grant of limited monopolies over the exploitation of new products and processes. These limited monopolies encourage investment in developing and manufacturing new inventions by affording the investor extra opportunity to recoup financial outlays. For example, in relation to healthcare, the Walter and Eliza Hall Institute of Medical Research stated:

> Not granting patents, coupled with disclosure, would make the IP unattractive to a company since it would have to invest heavily in further research and especially clinical development with no protection from competitors using the invention and underselling them because they do not have to recover extensive R&D costs. The result could be no further development of the potential health care product by anyone.[2]

3.7 Without the incentive provided by patents, private investors may be reluctant to invest, resulting in greater calls on government funding or a failure to develop and exploit new technology.

3.8 Patents promote innovation by rewarding inventors for the time, effort and ingenuity invested in creating new products and processes.[3] The potential for financial returns adds an incentive to the traditional rewards of scientific innovation, such as academic recognition and promotion within research institutions.

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1 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 7.

2 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

3 Cancer Council of New South Wales, *Submission P1*, 5 June 2003; D Isaacs, *Submission P6*, 12 September 2003.

3.9 The role of patents as an incentive for innovation, investment in research and as a means to recoup the costs of research was widely acknowledged in submissions.[4] For example, the Children's Cancer Institute Australia for Medical Research recognised:

> the importance of the patent system as a cornerstone in driving innovation in medical research by enabling researchers to have protection of their intellectual property and the possibility of capitalizing on their inventions. The involvement of industry in this process is also well-established and important … Intellectual property protection has been, and will continue to be, an essential component of the innovation process that drives medical research.[5]

3.10 Patents also benefit Australian companies by providing a system for trading knowledge internationally through licence agreements. The grant of licences to international companies to exploit locally developed inventions provides returns to inventors and access to foreign markets. The grant of licences to Australian companies to manufacture inventions developed overseas can improve the skill and know-how available within the Australian community.

3.11 However, patents do not always reward innovation and research investment equitably. In most jurisdictions, including Australia, where two researchers independently create the same invention, only the first to apply for patent protection will be awarded a patent over the invention.[6] This may discourage some researchers from embarking on a course of research that is already being pursued elsewhere, despite the possibility that they may do better or more efficient work.

Investment and economic growth

3.12 Possessing a patent may help a company to grow by capitalising on the market potential of its inventions. Small companies may use patents to attract financial backing and in negotiations for funding and support from venture capitalists and manufacturers.[7]

3.13 In addition, patents may stimulate the growth of national industry because local companies that hold patents can attract overseas investment and develop products for

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4 Cancer Council of New South Wales, *Submission P1*, 5 June 2003; R Edson, *Submission P9*, 23 September 2003; Children's Cancer Institute Australia for Medical Research, *Submission P13*, 30 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; D Isaacs, *Submission P6*, 12 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; *Confidential Submission P54 CON*, 3 November 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

5 Children's Cancer Institute Australia for Medical Research, *Submission P13*, 30 September 2003.

6 United States patents are granted to the first inventor regardless of who is the first to file a patent application.

7 See Ch 17.

export.[8] Profits generated by patent exploitation can be invested in further research and development, which may stimulate commercial and industrial growth.

3.14 However, patents may also have undesirable commercial and economic effects. The limited monopoly awarded by a patent might enable the patent holder to charge a higher price than would apply if others were allowed to produce competing versions of the patented invention. Licence fees may drive up prices.[9]

3.15 There are transaction costs associated with seeking the grant of a patent and enforcing patent rights. Fees must be paid before a patent application will be examined or granted, and to maintain patent rights once granted.[10] Claims of infringement may need to be pursued through the courts: asserting patent rights or challenging those of a competitor may be costly and difficult, particularly for small and medium-sized enterprises.[11]

3.16 From a global perspective, patent systems may have adverse consequences for countries, like Australia, that are net importers of intellectual property. That is, expenditure on licence fees or royalties for the use of patents owned by foreign entities may exceed the income earned from the use by foreign entities of inventions patented by local entities. Most Australian biotechnology patents are owned by foreign entities and Australian researchers generally pay licence fees to overseas companies to utilise these patented inventions in research.[12] Chapters 17 and 19 discuss the Australian biotechnology industry and international patent ownership.

Resource use and knowledge sharing

3.17 Patents promote knowledge sharing by requiring the details of the patented invention to be placed in the public domain in return for the exclusive right to exploit the invention. In the absence of this exchange, inventors might protect the details of new inventions through secrecy. The disclosure requirements of the patent system are based on the idea that 'scientific and technical openness benefits the progress of society more than do confidentiality and secrecy'.[13]

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8 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441, 445.

9 D Nicol, 'Gene Patents and Access to Genetic Tests' (2003) 11 *Australian Health Law Bulletin* 73, 75. Concern about this issue was also expressed in submissions eg, D McAndrew, *Submission P14*, 30 September 2003; Australian Huntington's Disease Association (NSW) Inc, *Submission P27*, 1 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003. The implications for medical genetic testing and other healthcare services are discussed in more detail in Ch 20–21.

10 A patent holder is required to pay an annual fee to maintain a patent: see Ch 5.

11 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 13. See also L Andrews, 'Genes and Patent Policy: Rethinking Intellectual Property Rights' (2002) 3 *Nature Reviews Genetics* 803, 806. Processes for challenging and enforcing patent rights are discussed in Ch 9.

12 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 362–363.

13 J Goldstein and E Golod, 'Human Gene Patents' (2002) 77 *Academic Medicine* 1315, 1315.

3.18 By encouraging knowledge sharing, through the requirement of full disclosure, patents reduce the duplication of research effort and encourage researchers to build on existing inventions. Researchers may study a patented product and find ways to improve upon it. Access to patented inventions may also facilitate research that would not otherwise be possible. For example, access to a patented research tool may enable vital research into the causes of a genetic disorder and lead to the creation of a genetic test or treatment. This research may not have occurred if the tool had remained secret. Due to the cumulative nature of much genetic research, knowledge sharing may be particularly important in this context.[14]

3.19 However, patents may also inhibit research by discouraging knowledge sharing prior to filing for patent protection. The results of new research may be withheld until an inventor is in a position to apply for a patent and the invention is sufficiently well-developed to ensure that the patent will be granted.[15] Chapter 15 considers issues relating to secrecy, publication and gene patenting.

3.20 The patent system is premised, in part, on the idea that, if a resource is held in common, it may not be put to its optimal use. This has been called the 'tragedy of the commons'. On this view, a resource will be used more efficiently if it is privately owned. In the context of patents, this suggests that the potential of inventions may be wasted if they are publicised without the right to prevent others from exploiting them.[16]

3.21 In contrast, Professors Michael Heller and Rebecca Eisenberg have suggested that the grant of numerous patents for biomedical inventions may produce a 'tragedy of the anti-commons'—the under-use of a scarce resource where multiple owners exclude others and no one has an effective privilege to use the resource.[17] In the context of gene patents, this may occur when multiple blocking patents are granted over pre-market or upstream research products, such as isolated genetic materials. The cost and inconvenience involved in obtaining multiple licences to use upstream products in marketable or downstream research may stifle research and innovation.[18] Chapter 19 discusses this issue further.

3.22 Gene patents also raise issues about access to, and ownership of, research results. Granting patents to private organisations or individuals is said to stimulate research as researchers race to be the first to patent a new technology. However, private control of new technology may have unwanted ethical and social implications for healthcare provisions if private organisations limit access to tests, therapies or

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14 D Eliades, *Submission P24*, 30 September 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003.

15 D Dickson, 'UK Clinical Geneticists Ask for Ban on the Patenting of Human Genes' (1993) 366 *Nature* 391, 391. The disclosure of an invention may render patent protection unavailable: see Ch 5 and 6.

16 J Goldstein and E Golod, 'Human Gene Patents' (2002) 77 *Academic Medicine* 1315, 1323.

17 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 698.

18 See D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 358–360.

drugs, because of pricing or monopoly control. Access for research purposes may also be restricted.[19]

3.23 It has been suggested that government agencies should hold patents over research results that have significant social and ethical implications. Alternatively, it may sometimes be appropriate to preclude patenting of research results by making them available without charge. This could avoid some of the drawbacks of private control of research results by allowing researchers to use and build on the work of others without having to deal with the cost and difficulty of obtaining licences.[20] Chapters 12 and 13 discuss these issues further.

Social dimensions

3.24 The social dimensions of gene patents include the impact of gene patents on the conduct of research and the provision of healthcare. Some aspects of these concerns are discussed below.

The conduct of research

3.25 Gene patents may promote genetic research by providing an incentive for investment in research and development. The exclusive rights associated with the grant of a patent may provide sufficient security to attract research and development funding. As patented inventions may be commercialised more effectively, this provides an additional incentive for researchers to obtain patent protection for their research outcomes.

3.26 At the same time, it has been argued that gene patents may have a 'chilling effect' on research and innovation, rather than promoting them. For example, research may be hindered by researchers' concerns about infringing patents or if there are difficulties in obtaining licences to use patented inventions on appropriate terms. Researchers may be reluctant to put information about research outcomes into the public domain because of concerns that this might undermine the potential to commercialise their own research.

3.27 In research areas where commercial incentives are less important, patents may be seen as creating more problems than benefits. For example, much medical research is not conducted solely to reap the commercial rewards of patenting and marketing new treatments. Rather, it is undertaken because governments, researchers and clinicians seek to improve community health. In this context, patents may drive up the cost of new products that would have been developed regardless of patent protection. In such cases, the public benefit may be promoted if inventions are not patented, or are widely

19 See Ch 13.

20 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 698.

licensed. This concern may be relevant, for example, to gene patents and research into medical genetic testing.

3.28 The economic rewards of patenting may channel investment into more profitable areas and away from other important goods and services, such as medical treatments for rare diseases.[21] Concerns have been raised that an increasing emphasis on the commercialisation of public sector research may skew basic research priorities.[22]

3.29 Chapter 13 discusses the general impact of gene patents on research and describes the specific subject matter and claims of gene patents that are most likely to hinder research.

Access to healthcare

3.30 Gene patents may encourage the development of new products and processes with important healthcare applications. The prospect of obtaining a patent over a new or improved diagnostic test or therapeutic product provides incentives to invest the time and resources necessary to develop the new invention.

3.31 However, it is also possible that gene patenting may have an adverse impact on the cost and quality of healthcare services. Because patents award monopoly rights over the patented product or process, this may enable the patent holder to set a higher price than would otherwise apply. Where a patent holder adopts restrictive licensing practices, this may limit access to a particular test, therapy or drug.

3.32 Some submissions expressed concerns about the potential for gene patents to adversely affect access and equity in the delivery of genetic healthcare services.[23] The Royal College of Pathologists of Australasia (RCPA) emphasised the need to promote equitable access to affordable genetic testing and therapies:

> The challenge is to balance public access to genetic health services with appropriate commercial returns for socially beneficial research. A major concern regarding gene patents is the potential for commercial patent holders to create genetic monopolies. The potential for abuse of monopoly power will increase if a handful of large biotechnology companies emerges from existing small and medium sized biotechnology firms. Commercial monopolies are the anti-thesis of public health

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21 See also Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 137.

22 Similar concerns have been raised in relation to patents on genetically modified organisms in the House of Representatives Standing Committee on Industry, Science and Technology. The Committee rejected suggestions that patenting would distort research priorities: House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), [7.91]–[7.96].

23 For example, National Health and Medical Research Council, *Submission P52*, 31 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Support Council WA (Inc), *Submission P59*, 7 November 2003; Queensland Government, *Submission P57*, 5 January 2004.

> because they serve the commercial interests of shareholders rather than the public ... Holders of gene patents and licenses need to recognise that they have ethical and social responsibilities and be responsive to government, health care provider and community concerns as well as their shareholders' interests.[24]

3.33 Chapter 20 discusses the current and potential uses of patented genetic materials and technologies within the Australian healthcare system, and the cost implications of such patented inventions. It contains several proposals for reform to address these cost concerns. Chapter 21 discusses the impact of gene patenting on medical genetic testing and access to healthcare services.

Ethical dimensions

3.34 Ethical concerns about gene patenting can be divided into two broad categories—ethical objections to granting patents on genes and genetic material, and ethical concerns about the exploitation of gene patents.

3.35 When gene patents were a relatively new phenomenon, ethical concerns focused mainly on whether it was acceptable to patent human genetic materials—although the distinction between natural and isolated genetic materials was seldom appreciated. Concerns about whether it is ethical to patent genetic materials are no longer as prominent as they once were. In part, this may be because existing gene patents are unlikely to be revoked. Many such patents have been issued in numerous countries, including Australia, and the practice of patenting isolated human genetic materials appears to be more widely accepted. The New South Wales Cancer Council noted that, while the ethical objections to gene patents cannot be discounted, the genetics 'horse' has bolted.[25]

3.36 Ethical concerns now tend to focus more on the exploitation of gene patents. Such concerns include those about sharing the benefits of genetic research; consent to the use of genetic material in research that leads to commercial outcomes; and indigenous issues.[26]

What is ethics?

3.37 Ethical analysis is the rational and impartial application of principles and values to a given fact situation to inform and justify decisions and actions.[27] In the report

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24 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

25 Cancer Council of New South Wales, *Submission P1*, 5 June 2003. Also: South Australian Government, *Submission P51*, 30 October 2003. Some submissions disputed community acceptance of gene patenting: eg, G Suthers, *Submission P30*, 2 October 2003. The Human Genetics Society of Australasia suggested instead that '[t]he apparent acceptance of patenting in this area results not from a systematic consideration of the potentially new or unique issues presented by genetic technologies, but by isolated decisions made in various patent offices': Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

26 The capacity of the patenting system to deal with ethical considerations is discussed in Ch 7.

27 Australian Law Reform Commission and Australian Health Ethics Committee, *Protection of Human Genetic Information*, DP 66 (2002), [9.13].

Essentially Yours: The Protection of Human Genetic Information in Australia (*Essentially Yours*), the ALRC and the Australian Health Ethics Committee (AHEC) noted that 'ethics searches for reasons for acting or refraining from acting; for approving or not approving conduct; for believing or denying something about virtuous or vicious conduct or good or evil rules'.[28] It also noted that 'ethics expresses the fundamental considerations that inform any societal decisions'.[29]

3.38 Ethics contains normative statements about what ought or ought not to be done, It also gives justifications for why things ought or ought not be done. These justifications can be based on one of the many approaches to ethics. For example, 'principlist ethics' seeks to establish a set of principles that must be respected when determining how to act. According to principlist ethics, the goodness or badness of an action is determined by whether or not it accords with accepted principles. This approach is characterised by:

> an assumption that scientific progress is essential for the good of humanity, coupled with a concern to protect individual and group rights that may be endangered in the course of scientific research.[30]

3.39 The principlist school of ethics has dominated health research ethics since the 1960s. Its principles include: respect for autonomy, beneficence, non-maleficence and justice.[31] The statement that 'gene patenting is wrong because it restricts an individual's right to direct what is done with his or her genes' is an example of an ethical objection based on the principle of respect for autonomy.[32]

3.40 This section outlines a range of ethical concerns that have been expressed about granting gene patents and the potential consequences of exploiting these patents. Objections to gene patenting voiced by the community are rarely articulated in terms of ethical theory, but simply reflect the moral values and beliefs of individuals and groups. However, these objections often rest implicitly on an acceptance of some ethical principles and values, and for this reason these concerns may be characterised as 'ethical concerns'.

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28 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [6.3].

29 Ibid, [6.9].

30 Ibid, [6.25].

31 A principlist approach to research ethics was formally articulated in the Belmont Report in the late 1970s and in the principles set out in the 'Georgetown mantra', formulated by James Childress and Thomas Beauchamp in 1979: Ibid, [6.25]. See also T Beauchamp and J Childress, *Principles of Biomedical Ethics* (5th ed, 1999).

32 Other approaches to ethical considerations include consequentialist ethics; professional ethics; critical ethics; civic ethics; and narrative ethics. See further Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 7. In relation to duty ethics and gene patenting, see also Danish Council of Ethics, *Patenting Human Genes* (1994), 27–34.

3.41 Some of these values and principles might include:

- *Respect for persons*: a commitment to treating people as autonomous agents, and to protecting those with diminished capacity for autonomy. This principle encompasses concepts of respect for the inherent dignity of persons, human rights and the promotion of informed decision-making.[33]

- *Justice*: a commitment to ensure fair distribution of benefits and burdens and to avoid oppression of vulnerable groups.[34]

- *Beneficence*: an obligation to maximise possible benefits and minimise possible harms (non-maleficence).[35]

3.42 The ALRC has not subscribed to a particular approach to ethical inquiry in considering concerns about gene patenting and responses to them. However, the discussion in this section does take account of the principles and values that may inform ethical concerns about gene patenting raised in submissions and more generally.

Ethics and the patenting of human genetic materials

3.43 A variety of ethical objections have been made to granting patents on human genes and genetic materials. Although the 'genetics horse' may have bolted, there remain those in the community who are not persuaded that the patent system adequately takes account of ethical concerns.[36] Many submissions to the Inquiry raised ethical objections to granting gene patents. This section canvasses a number of these objections and some of the responses that have been made to them.

3.44 Critics of gene patents often assert that these patents are morally wrong because they are incompatible with:

- the view that the human genome is the common heritage of humanity;

- respect for human dignity;

- self-determination and self-ownership; or

- certain religious beliefs.

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33 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), 4. See also Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 7.

34 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), 4. See also Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 7.

35 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), 4.

36 National Health and Medical Research Council, *Submission P52*, 31 October 2003.

Common heritage of humanity

3.45 The human genome is often described as the common heritage of humanity, a view that has been supported by the Human Genome Organisation's (HUGO) Ethics Committee and by the United Nations Educational, Scientific and Cultural Organization (UNESCO).[37] Patents on human genetic materials are sometimes criticised because they are thought to grant exclusive rights over this common heritage to a limited number of entities.[38] This objection rests in part on concern for fair distribution of the benefits of genetic research.

3.46 This view of the genome was expressed in a number of submissions.[39] For example, the New South Wales Health Department commented that the human genome:

> [is] the common inheritance of all people and that information obtained about the genetic constructs of humanity should be shared freely as fundamental knowledge for the benefit of humankind. The human genome and the information it contains should not be regarded as a commodity to be carved up, granted exclusive rights, and sold off for profit making purposes, for either the individual from whom it came or an organisation.[40]

Respect for human dignity

3.47 Another objection to patents on genetic materials is that they may engender a lack of respect for human life and dignity.[41] On this view, to grant a proprietary right on something suggests that it is a fit subject for such rights. Consequently, patents on genetic materials are thought to commodify parts of human beings by treating them as objects, or as something to be placed in the stream of commerce for financial gain.[42] Others suggest that genetic materials have a unique significance, which requires them to be treated with special respect. For example, it has been suggested that '[b]ody parts,

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37 HUGO Ethics Committee, *Statement on the Principled Conduct of Genetics Research* (1996); *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, UNESCO, art 12(a). See also *Recommendation No 1425: Biotechnology and Intellectual Property*, Council of Europe Parliamentary Assembly, (entered into force on 23 September 1999), rec 10; *Recommendation No 1468: Biotechnologies*, Council of Europe Parliamentary Assembly, (entered into force on 29 June 2000), rec 10.

38 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 22–23.

39 G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003; S Karpeles, *Submission P44*, 20 October; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; New South Wales Health Department, *Submission P37*, 17 October 2003.

40 New South Wales Health Department, *Submission P37*, 17 October 2003.

41 See D Resnik, 'The Morality of Human Gene Patents' (1997) 7 *Kennedy Institute of Ethics Journal* 43, 55–57.

42 The House of Representatives Standing Committee on Industry, Science and Technology noted similar objections but concluded that allowing ownership or patenting of animals would not degrade life: House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), [7.37]–[7.42].

including genes, are not like other materials to be owned and traded in the market place as common commodities'.[43]

3.48 These objections rest on the principle of respect for persons and promotion of individual autonomy. Commodification of parts of human beings is ethically problematic because it might affect how we value people.[44] It is said to be incompatible with respect for human dignity because it reduces human beings to things to which no respect is owed,[45] and is ethically unacceptable because it precludes respect for individual autonomy.

3.49 Concern about the potential commodification of the human genome was expressed in many submissions.[46] For example, Adam Johnston argued that current patent office practice underlined the commodification of life and called for structures to be put in place to address this.[47] Similarly, Del Weston stated that:

> the patenting of genes is immoral in the ontological sense and against the broad interests (including health) of humanity. Patenting of life engenders many questions of the morality of conceptualizing living organisms, including humans, and their components as commodities.[48]

3.50 Dr Warwick Neville emphasised the importance of ensuring that patent law recognises and protects 'the human dignity of the human person':

> It is insufficient that the unspoken but accepted utilitarian philosophical/ jurisprudential tradition undergirding patent law and practice remains unchallenged … there must be formal recognition and protection of the inherent and inviolable dignity of the human person. The commodification of human life is inimical to the recognition and protection of human dignity.[49]

3.51 Others emphasised the special dignity of the human genome and the need for it to be treated with particular respect. For example, Dr Graeme Suthers stated that 'our genetic code is our heritage. It deserves this degree of respect. It is not merely a commercial resource'.[50]

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43 Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 June 1996, 2332 (Natasha Stott Despoja), 2333. See also *Howard Florey/Relaxin* [1995] EPOR 541, [6.4].

44 N Holtug, 'Creating and Patenting New Life Forms' in P Singer and H Kuhse (eds), *A Companion to Bioethics* (1998), 206, 213.

45 T Claes, 'Cultural Background of the Ethical and Social Debate about Biotechnology' in S Sterckx (ed) *Biotechnology, Patents and Morality* (2nd ed, 2000), 179, 182. See also T Schrecker and others, *Ethical Issues Associated with the Patenting of Higher Life Forms* (1997), x.

46 G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003; D McFetridge, *Submission P23*, 30 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003.

47 A Johnston, *Submission P15*, 30 September 2003.

48 D Weston, *Submission P62*, 12 November 2003.

49 W Neville, *Submission P50*, 29 October 2003.

50 G Suthers, *Submission P30*, 2 October 2003. Also W Neville, *Submission P50*, 29 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003.

3.52 Commodification arguments have been criticised on the basis that treating parts of humans (such as natural genetic materials) as objects does not necessarily equate with treating whole persons as objects or commodifying individuals.[51] Critics further suggest that it is not apparent that the widespread grant of patents on human genetic materials has led to a change in how human beings are perceived and treated.

Promoting self-determination

3.53 It has also been argued that patents over genetic materials are incompatible with respect for an individual's self-determination because they grant ownership rights over genetic material and, consequently over parts of human beings, to someone other than the person from whom the genetic material was taken.[52] On this view, self-determination—the right to make one's own choices about how to live—is fundamentally linked to self-ownership—the right to choose how one's body is used.

3.54 A number of submissions objected to gene patenting on the ground that it shifted ownership of genetic material away from the person from whom it was obtained, and expressed support for self-ownership of genetic material.[53] The RCPA stated that:

> All individuals have natural ownership of their genetic material, which they share with their genetic relatives and ultimately with all life. According to the principles of patent law, because genomic DNA is a naturally occurring substance, it is not patentable. Yet, tens of thousands of patents have been granted on DNA sequences that are identical to their natural form. These patents effectively confer ownership rights because they allow these sequences to be used, sold, traded, licensed and can be used to prevent others from doing so. The effect is that gene patents rob individuals of their natural ownership of their genetic material.[54]

3.55 Critics suggest that these arguments confuse intangible intellectual property rights with physical property rights. Stephen Crespi points out that 'intellectual property provides a quite different type of ownership and lack of clarity about this can easily skew the whole debate' about gene patents.[55] Patents grant intangible property rights over isolated genetic material and inventions for analysing, sequencing, manipulating or manufacturing genetic sequences. Patents do not grant physical property rights in or over parts of a person's body, and so do not enable one person to exert control over how another individual uses his or her own body. In its submission, AusBiotech Ltd concurred with this view, stating that concerns about self-

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51 D Resnik, 'DNA Patents and Human Dignity' (2001) 29 *Journal of Law, Medicine & Ethics* 152, 155–159.

52 N Hildyard and S Sexton, 'No Patents on Life' (2000) 15 *Forum For Applied Research and Public Policy* 69.

53 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; A Johnston, *Submission P15*, 30 September 2003; D McFetridge, *Submission P23*, 30 September 2003.

54 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

55 R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71. Professor Jill McKeough has stated that 'ownership of life' and 'commodification' objections about gene patenting 'misconceive the function and use of the patent system': J McKeough, 'Patenting Genetic Material: What are People Concerned about?' (1997) 30 *Intellectual Property Forum* 12, 15.

determination and gene patenting arise in part 'from a misunderstanding of the nature of and rights conferred by a patent'.[56]

3.56 The ALRC and AHEC canvassed some of the issues surrounding self-ownership of genetic material and arguments for allowing people to exercise proprietary rights over their genes in their previous report, *Essentially Yours*. That report concluded that granting individuals new property rights in their own genetic material would not be the most effective means by which to regulate the collection and use of such material.[57]

Religious objections

3.57 Patents on genetic materials are sometimes criticised on religious grounds.[58] Some religions maintain that human worth—including the genetic basis for life—derives from the divine aspect of creation. Religious critics argue that patents on genetic materials attribute ownership of the basis of life to someone other than God, suggesting that human worth derives from something other than divine creation.[59]

3.58 The ALRC received few submissions expressing religious concerns about gene patenting. The Caroline Chisholm Centre for Health Ethics stated that genes and gene sequences, as parts of nature, are:

> freely given to all, to humanity as a whole, by the Creator – it is a given of the human condition. We do not believe it would be ethical to patent natural sequences of DNA.[60]

3.59 In 1998, Bruce Lehman, then United States Patent Commissioner, responded to religious objections to patents by stating: '[w]e are not patenting life. God, I suppose, has a patent on life. We are patenting technology'.[61]

Ethics and the exploitation of gene patents

3.60 IP 27 noted that an ethical issue raised by the commercialisation of research, and the granting of gene patents, is whether people whose tissue samples are used to develop patented genetic inventions should have any rights, entitlements or expectations to exercise control over, or benefit from, the research results.[62] IP 27 also

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56 AusBiotech Ltd, *Submission P58*, 7 November 2003.

57 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 20.

58 For example, in 1995 a group of religious leaders in the United States released a public statement against human gene patenting. The statement asserted that 'humans … are creations of God, not humans, and as such should not be patented as human inventions': quoted in S Goldberg, 'Gene Patents and the Death of Dualism' (1996) 5 *Southern California Interdisciplinary Law Journal* 25, 27.

59 Danish Council of Ethics, *Patenting Human Genes* (1994), 32.

60 Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003.

61 D Slater, 'HuMouse', *Legal Affairs*, Nov-Dec 2002, 21, 26.

62 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), [4.34]. The ALRC and AHEC examined issues relating to consent and control of genetic samples and information in the context of human genetic research in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 15, 16, 18, 19.

noted that research involving Indigenous peoples may raise particular ethical issues in relation to benefit sharing and control.

Benefit sharing and control

3.61 It has been suggested that individuals or groups who provide tissue samples for use in genetic research have an ethical right to control the use of those samples, or to control or share in the ownership of any patented genetic inventions resulting from the research. It has also been suggested that tissue donors have an ethical right to share in the benefits of research and development using their genetic material.[63] This view may to be based on the ethical principles of respect for the person, justice and beneficence.

3.62 The HUGO Ethics Committee has recommended that all humanity should share in, and have access to, the benefits of genetic research. It also recommended that, at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation; and that profit-making entities should dedicate a percentage (for example, 1–3%) of their annual net profit to healthcare infrastructure or to humanitarian efforts.[64]

3.63 There are several barriers to a research participant asserting a legal right to control or share in the benefits of genetic research in Australia. These include:

- The law is uncertain about the nature of property rights in human tissue.[65]
- The *Human Tissue Acts* generally prohibit the sale of human tissue[66] and it is therefore arguable that it is unlawful to provide financial benefits in exchange for tissue donation.
- The *Patents Act 1990* (Cth) provides that a patent may be granted only to a limited category of persons,[67] which does not specifically include research participants.

3.64 It is possible, however, for research participants to enter into contractual arrangements with researchers that provide some form of control or benefit, in exchange for participation in a research program.

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63 Benefit sharing could take many forms, including a financial benefit (such as an upfront payment, or a share in any profits or royalties made from the patent), or access to free medical care, treatment or therapy.

64 HUGO Ethics Committee, *Statement on Benefit Sharing* (2000).

65 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003).

66 *Human Tissue Act 1983* (NSW) s 32(1), (5) and cognate state and territory legislation.

67 Patents may be granted to a person who is the inventor; would be entitled to have the patent assigned to him or her; derives title to the invention from the inventor or an assignee; or is the legal representative of a deceased person who falls within these categories: *Patents Act 1990* (Cth) s 15(1).

3.65 IP 27 noted that, in the United States, gene patenting has led to significant concerns about research participants' rights to control and share in the benefits of research results. For example, in *Moore v Regents of the University of California*,[68] Moore sued the University after it patented a cell line from tissue obtained from him in the course of treatment. The Supreme Court of California held that Moore did not have a property interest in his tissue, but did have a right to be informed about both the intent to develop a cell line and the potential commercial interests of the physicians with whom he dealt.[69]

3.66 In *Greenberg v Miami Children's Hospital Research Institute*, the Greenberg family commenced legal proceedings against the hospital and scientist who identified and patented the gene associated with Canavan disease. The Greenberg family had two children afflicted with the disease. They had asked the scientist to conduct research into the genetic basis of the disease, and had assisted him with money and tissue samples from their own children and others. The scientist identified the gene and developed a diagnostic genetic test for it. The hospital at which he was working patented the gene, and began charging a fee for the test. The plaintiffs sought a permanent injunction restraining the hospital and scientist from enforcing the patent rights. This case has recently been settled.[70]

3.67 In contrast, in at least one case, research participants have successfully asserted control and ownership over the results of genetic research. In the United States, the parents of two children afflicted with a rare genetic disease, PXE,[71] established a foundation, found 2,000 people with the disease to donate tissue for research, set up a repository to store the tissue samples, and raised money for research. They required researchers to enter into a contract that provided that the foundation would be named in any patent applications arising from the work, any profits or revenue from the discoveries would be shared with the foundation, and any genetic test must be made readily available to the foundation.[72]

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68 *Moore v Regents of the University of California* (1990) 51 Cal 3d 120.

69 Ibid. See also J Merz and others, 'Protecting Subjects' Interests in Genetics Research' (2002) 70 *American Journal of Human Genetics* 965; A Nichols Hill, 'One Man's Trash is Another Man's Treasure, Bioprospecting: Protecting the Rights and Interests of Human Donors of Genetic Material' (2002) 5 *Journal of Health Care Law and Policy* 259, 264–265.

70 A Nichols Hill, 'One Man's Trash is Another Man's Treasure, Bioprospecting: Protecting the Rights and Interests of Human Donors of Genetic Material' (2002) 5 *Journal of Health Care Law and Policy* 259. The plaintiffs asserted the following causes of action: lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion and misappropriation of trade secrets. In May 2003, the Court granted a motion to dismiss each of these counts except unjust enrichment: *Greenberg v Miami Children's Hospital Research Institute* (Unreported, District Court for the Southern District of Florida, Moreno J, 29 May 2003). The plaintiffs filed a motion for reconsideration of the order in relation to the count based on the lack of informed consent. The case was later settled: Canavan Foundation, *Canavan in the News, 29 September 2003*, <www.canavanfoundation.org/news.php> at 2 February 2004.

71 PXE—Pseudoxanthoma elasticum, which causes mineralisation of elastic tissue.

72 G Kolata, 'Sharing of Profits Is Debated as the Value of Tissue Rises', *New York Times* (New York), 15 May 2000.

3.68 IP 27 asked whether there was any need to make special provision for individuals or groups whose genetic samples are used to make a patented invention to benefit from any profits from the patent.[73]

3.69 Several submissions suggested that the patent system is not the appropriate vehicle to address issues of benefit sharing and control.[74] For example, the NHMRC submitted that there are mechanisms other than the patent system to ensure that the rights of tissue donors from which genetic material might be isolated for use in research are paramount.[75]

3.70 The Queensland Government submitted that, while individuals' claims to share in the benefits of the patented invention are understandable, it is necessary to recognise that the invention resulted from the researchers' expertise, skill, time and expense. It noted that:

> Universities and ethicists are generally of the view that no special provisions are required to ensure that individuals or groups, whose genetic samples are used to make patented inventions, benefit from any profits derived from that patent, apart from the requirement of ensuring that prior informed consent is obtained. However, where the groups or individuals have been instrumental in both the research and funding … then an arrangement should be reached between the parties (namely industry and the individuals or groups) in relation to the commercialisation and the use of the patented material/invention.[76]

3.71 Most submissions supported some form of benefit sharing for research participants, but considered that such arrangements should be negotiated between the researcher and participant directly.[77] For example, the RCPA submitted that:

> There are ethical, moral, practical and economic concerns with a general claim that subject should share in the financial rewards of research: subjects often stand to benefit indirectly as consumers, it may be unmanageable to provide individuals with any share in potential profits, the burden of such royalties might impede downstream research, and the contribution of individual subjects may be quite minimal given that they bear little of the risk. Furthermore, financial reward may establish a legal precedent to permit the sale of body tissues, eg kidneys for transplantation.
>
> Entities involved in commercial aspects of research should be expected, as a matter of public policy and research ethics practice, to openly negotiate with individuals, foundations, disease associated advocacy groups to resolve issues of ownership, downstream control, limits on financial profit sharing and other acknowledgements of all contributions before the research is done. These processes should be incorporated

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73 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 4–3.

74 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003.

75 National Health and Medical Research Council, *Submission P52*, 31 October 2003.

76 Queensland Government, *Submission P57*, 5 January 2004.

77 For example, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

> into national guidelines (eg those of the National Health and Medical Research Council on the ethical practice of research).[78]

3.72 The Department of Industry, Tourism and Resources noted that there are moves underway at the international level to enable individuals and communities providing genetic samples to share in any benefits obtained.

> The framework of such benefit sharing arrangements will likely involve agreeing (signing of a contract) at the time of sample collection to return royalties to the source of samples. Such agreements will be subject to successful research leading to new products or techniques.[79]

Indigenous peoples

3.73 IP 27 noted that Indigenous peoples have expressed concerns about the practice that has become known as 'bioprospecting'—that is, the collection, screening, and use for commercial purposes of indigenous knowledge, and of genetic and biological products taken from Indigenous peoples and from their land.[80]

3.74 In Australia, an existing mechanism for ethical review of research involving Indigenous communities—including genetic research—involves the use of Indigenous subcommittees working in conjunction with Human Research Ethics Committees (HRECs).[81] These subcommittees review proposed research projects and ensure that the subject group has given informed consent to the proposed project. At least one Indigenous subcommittee has a right of veto over HREC approval of research projects.[82]

3.75 In 2003, the NHMRC released a new set of guidelines for ethical conduct in indigenous health research.[83] The NHMRC has stated that, in addition to the *National Statement on Ethical Conduct in Research Involving Humans*, these guidelines are the authoritative statement on health research involving Aboriginal and Torres Strait Islander people. The guidelines assist researchers in the conception, design and

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78 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

79 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

80 See generally, M Davis, *Indigenous Peoples and Intellectual Property Rights* (1996-7), 4. In the early 1990s, the Human Genome Diversity Project (HGDP) was established to collect, preserve and analyse blood, skin and hair samples from people around the world, including Indigenous groups, and to establish databases of genetic information from this material for use in further research. The HGDP has been widely criticised by Indigenous peoples: M Dodson, 'Human Genetics: Control of Research and Sharing of Benefits' (2000) 1 *Australian Aboriginal Studies* 56, 56. For example, the *Mataatua Declaration on Cultural and Intellectual Property Rights* (1993) called for the HGDP to be put on hold until Indigenous peoples have been fully briefed on the project's implications: see T Janke, *Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights* (1998), 29.

81 M Dodson, 'Human Genetics: Control of Research and Sharing of Benefits' (2000) 1 *Australian Aboriginal Studies* 56, 61.

82 See J Condon and L Stubbs, *Top End Human Research Ethics Committee: Policy and Procedures Manual* (2000), 9.

83 National Health and Medical Research Council, *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* (2003).

conduct of research. The guidelines are based on six values: spirit and integrity; reciprocity; respect; equality; survival and protection; and responsibility.[84]

3.76 IP 27 asked whether any separate or special considerations apply in relation to benefit sharing for genetic research involving Indigenous people.[85] Several submissions commented that whenever Indigenous Australians are involved in genetic research, their cultural values and wishes must be taken into account.[86] The Aboriginal and Torres Strait Islander Services (ATSIS) stated:

> Indigenous people have a unique attachment to their genetic resources since they are a vital part of their spiritual and cultural existence (cosmology). Misuse of their resources by others can cause Indigenous people to suffer deep psychological trauma, leading to sickness and even death ... even though their genetic material is a unique resource, and the vital 'raw material' without which no patent or intellectual property right can exist, Indigenous people remain unprotected under the current intellectual property regime ... ATSIS believes that *sui generis* (specific or stand alone) legislation is required to protect Indigenous peoples' rights.[87]

3.77 ATSIS suggested two fundamental principles in relation to Indigenous participation in genetic research:

- Indigenous people whose resources are used must be properly consulted, and their genetic material may only be used with their informed consent.

- Indigenous people should have a legal right to own, control the use of, and benefit fairly from, their genetic resources (including DNA extracted from skeletal remains). Any person seeking to use their resources in any way must enter into a benefit sharing agreement to do so. Serious civil and criminal penalties should apply.[88]

3.78 The South Australian Government submitted that:

> any human research conducted on Indigenous communities be assessed by at least a Human Research Ethics Committee (HREC) and preferably also by an Indigenous sub-committee. It is recommended that there be a mandatory requirement that research conducted on Indigenous people not proceed without ethics assessment by either a separate Indigenous Research Ethics Committee or an Indigenous sub-committee of the appropriate HREC. South Australia is apparently the only state currently to have a separate Indigenous Research Ethics Committee.[89]

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84 See Ibid, 8–20.
85 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 4–3.
86 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Aboriginal and Torres Strait Islander Services, *Submission P55*, 4 November 2003.
87 Aboriginal and Torres Strait Islander Services, *Submission P55*, 4 November 2003.
88 Ibid.
89 South Australian Government, *Submission P51*, 30 October 2003.

3.79 The Queensland Government suggested that one option would be for Australia to support the efforts being undertaken in the World Intellectual Property Organization Working Group on Genetic Resources, Traditional Knowledge and Folklore to determine whether a form of intellectual property could be developed to protect traditional knowledge.[90]

3.80 The ALRC recognises that individuals and organisations who participate in genetic research may consider they have an ethical right to control or own the results of that research, or share in the benefits of the research in some way. Approaches to allowing for such control, ownership and benefit sharing could take several forms, including legal recognition as joint inventors of the patented invention, social recognition of their contribution to research and development, or some form of financial or other benefit in exchange for participation.

3.81 The ALRC notes that the NHMRC has recently released its new guidelines on ethical matters in Aboriginal and Torres Strait Islander research. The ALRC has formed a preliminary view that issues of control and benefit sharing are better addressed outside the patent system, for example through the established system of ethical review of medical research, and through contractual arrangements between researchers and research participants.

90 Queensland Government, *Submission P57*, 5 January 2004.

PART B

Patent Laws and Practices

4. International Legal Framework

Contents

Introduction

4.1 This chapter provides an overview of the international legal framework within which Australian patent law and practice operates, with reference to a number of international conventions that seek to harmonise procedural and substantive aspects of patent law. The Terms of Reference specifically require the ALRC to have regard to Australia's existing or proposed international obligations in relation to patent law and practice. In addition, the ALRC has a general legislative obligation to have regard to Australia's international obligations in performing its functions.[1]

4.2 Elements of the international legal framework have an important influence on the reform of Australian patent law. While domestic laws can be amended so that they are inconsistent with Australia's international treaty obligations, Australia may be held responsible on the international plane for breaches of such obligations. For example, there may be international repercussions such as a requirement to pay compensation or exposure to trade retaliation. The ALRC would therefore need compelling reasons to recommend any reform of patent law or practice which would raise doubts about Australia's compliance with its existing international obligations.

4.3 In particular, reforms proposed by the ALRC may have implications for Australia's obligations under multilateral agreements dealing with patents and other intellectual property laws and under bilateral free trade agreements with other states, including that recently concluded with the United States.

1 *Australian Law Reform Commission Act 1996* (Cth) s 24(2).

International legal instruments

4.4 Australia is a party to a number of international legal instruments relating to intellectual property. The major international instruments that affect patent laws and practices in Australia are:

- *Paris Convention for the Protection of Industrial Property 1883* (Paris Convention);[2]
- *Patent Cooperation Treaty 1970* (PCT);[3]
- *The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977* (Budapest Treaty);[4] and
- *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[5]

4.5 Significant provisions of each of these instruments are outlined below and have been given effect in Australian domestic law.

Paris Convention for the Protection of Industrial Property

4.6 The Paris Convention is the principal international agreement in the field of 'industrial property', including patents, trademarks, utility models and industrial designs.[6] In relation to patents, the Paris Convention addresses three issues. First, it requires a contracting State to provide the same rights to the nationals of other contracting States as are provided to its own nationals.[7] Second, it establishes the right of priority, which provides that an applicant who files for intellectual property protection in one contracting State and then in a number of other States within a set period of time—12 months in the case of patents—may have all applications treated as if they were filed on the date of the first application.[8] Third, the Paris Convention

2 *Paris Convention for the Protection of Industrial Property 1883*, [1972] ATS 12, (entered into force on 27 September 1975). The Paris Convention has been revised a number of times, most recently in Stockholm in 1967. Australia has been a party to the Stockholm revisions since 27 September 1975.
3 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978).
4 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, [1987] ATS 9, (entered into force on 19 August 1980).
5 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).
6 *Paris Convention for the Protection of Industrial Property 1883*, [1972] ATS 12, (entered into force on 27 September 1975) art 1(2).
7 Ibid art 2(1).
8 Ibid art 4.

provides that eligibility for patent protection is independently assessed by each contracting State.[9]

Patent Cooperation Treaty

4.7 The PCT establishes administrative procedures to facilitate the simultaneous filing of patent applications on a single invention in multiple jurisdictions.[10] Under the PCT, an inventor may seek patent protection in any number of PCT member countries by filing a single international application in one country—called the 'Receiving Office'—and designating other jurisdictions in which he or she may wish to obtain a patent.[11]

4.8 A PCT application may substantially reduce an inventor's initial costs in filing for patent protection in multiple jurisdictions. It also allows an inventor time to determine whether to pursue patent protection in a particular jurisdiction while maintaining the priority date given to the original PCT application.[12]

4.9 The grant or refusal of a patent based on a PCT application is, however, determined by each of the national or regional patent offices with which the PCT application is filed.[13]

Budapest Treaty

4.10 The Budapest Treaty provides an international system for the deposit of micro-organisms as a means of satisfying the disclosure requirement for the grant of a patent by a national or regional patent office.[14] The Budapest Treaty establishes that the deposit of a micro-organism with a designated 'international depositary authority' will satisfy the patent procedure requirements of national or regional patent offices that have recognised the effects of the Treaty.[15]

4.11 Sections 6, 41 and 42 of the *Patents Act 1990* (Cth) (*Patents Act*) address requirements for the deposit of a micro-organism and implement the provisions of the Budapest Treaty. IP Australia regards 'hosts containing materials such as vectors, cell organelles, plasmids, DNA, RNA, genes and chromosomes' as being within the scope of the term micro-organism.[16]

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9 Ibid art 4bis.

10 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978). The PCT was incorporated into Australian law by the *Patents Amendment (Patent Cooperation Treaty) Act 1979* (Cth).

11 Ibid arts 3, 4, 11.

12 See IP Australia, *International Patent Application Kit*, <www.ipaustralia.gov.au/pdfs/patents/internationalpatentapplicationkit.pdf> at 1 May 2003.

13 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978) art 27.

14 An invention is usually disclosed by means of a written description. However, in the case of an invention involving a micro-organism or the use of a micro-organism, disclosure of the invention in writing may not be possible. The disclosure requirements for patentability are discussed further in Ch 6.

15 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, [1987] ATS 9, (entered into force on 19 August 1980).

16 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [6.1.5].

Agreement on Trade-Related Aspects of Intellectual Property Rights

4.12 The TRIPS Agreement establishes the minimum standard of patent (and other intellectual property) protection that each member of the World Trade Organization, including Australia, must provide under its national laws.[17] More extensive patent protection may be provided under Australian law so long as it would not affect the operation of other provisions of the TRIPS Agreement.

4.13 This section discusses significant provisions of the TRIPS Agreement relating to patents, including the following:

- a requirement that member States make patent protection available for any inventions, whether products or processes, in all fields of technology;[18]
- optional exclusions from patentability that may be adopted by contracting States;[19]
- a right for member States to provide limited exceptions to patent rights (including public policy exceptions) so long as such exceptions do not unreasonably conflict with exploitation of a patent, nor unreasonably prejudice a patent holder's rights;[20]
- limitations on compulsory licensing and government use of patents, including a requirement that adequate compensation be given for such use;[21] and
- a minimum patent term of 20 years.[22]

4.14 Amendments to the *Patents Act* were necessary to bring Australian law into conformity with the TRIPS Agreement, and were enacted in the *Patents (World Trade Organization Amendments) Act 1994* (Cth). The amendments included extension of the standard patent term from 16 to 20 years and changes to compulsory licensing and Crown use provisions.

4.15 The implications of the TRIPS Agreement for patent reform are discussed below in general terms, and are given further consideration in the context of specific reform options and proposals considered elsewhere in this Discussion Paper.[23]

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17 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).
18 Ibid art 27(1).
19 Ibid art 27(2), 27(3).
20 Ibid art 30.
21 Ibid art 31.
22 Ibid art 33.
23 See, eg, Ch 7, 14, 22, 26 to 28.

4.16 Disputes between members of the World Trade Organization (WTO) including disputes in relation to the TRIPS Agreement, are subject to a binding dispute resolution process under the WTO Dispute Settlement Understanding. Like the TRIPS Agreement, the Dispute Settlement Understanding is an integral part of the WTO framework. A Dispute Settlement Body establishes panels to hear disputes, adopts panel and Appellate Body reports, supervises the implementation of recommendations and rulings, and authorises sanctions for failure to comply. The Appellate Body reviews rulings made by panels, which are normally composed of three members.

4.17 Panel and Appellate Body reports of WTO dispute panels provide assistance in clarifying relevant provisions of the TRIPS Agreement. Panel Reports and Appellate Body reports are binding on the parties to a dispute in respect of the matters at issue in the dispute, once the Dispute Settlement Body adopts them. These reports are not legally binding precedents in relation to subsequent cases but they are looked to for guidance, both by WTO members and by subsequent dispute settlement panels.

4.18 There has been only one WTO case that provides guidance on relevant provisions of the TRIPS Agreement.[24] The WTO panel report in the *Canada–Patent Protection* case[25] involved a complaint by the European Communities (EC) and their member states against Canada. It provides significant commentary on the application of TRIPS provisions relating to discrimination by field of technology and permissible exceptions to patent protection.

Discrimination as to field of technology

4.19 The TRIPS Agreement provides that patents shall be available for any inventions and patent rights shall be enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.[26] It has been suggested that the main aim of the proponents of the non-discrimination clause was to 'restrain the use of compulsory licences for lack of local exploitation'.[27]

4.20 The *Canada–Patent Protection* case sets out some of the parameters for assessing prohibited discrimination by field of technology. The WTO panel drew a distinction between 'differentiation' and 'discrimination' and clarified that the latter, and not the former, is the conduct prohibited by art 27.1. The panel stated that the ordinary meaning of the word 'discriminate':

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24 Department of Foreign Affairs & Trade, *Submission P29*, 2 October 2003.

25 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R.

26 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 27.1.

27 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 15.

> certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment. Discrimination may arise from explicitly different treatment, sometimes called '*de jure* discrimination', but it may also arise from ostensibly identical treatment which, due to differences in circumstances, produces differentially disadvantageous effects, sometimes called 'de facto discrimination'. The standards by which the justification for differential treatment is measured are a subject of infinite complexity.[28]

4.21 The non-discrimination provision may place constraints on the extent to which gene patents may be singled out for special treatment—for example, through new exclusions from patentability or defences to claims of infringement, although the nature of these constraints is not clear.

Exclusions from patentability

4.22 The TRIPS Agreement provides that member states may exclude inventions from patentability if prevention of the commercial exploitation of an invention is necessary to protect '*ordre public* or morality' including 'to protect human, animal or plant life or health or to avoid serious prejudice to the environment'.[29]

4.23 Non-patentability may be established only if the commercial exploitation of the invention needs to be prevented to protect the interests set out in art 27.2. One interpretation of this provision states that:

> This excludes the possibility of applying such exceptions when, for instance, it would be in the interest of public health to promote the diffusion of an invention (eg a medicinal product), since a Member cannot refuse a patent on *ordre public* or morality grounds and, at the same time, permit the commercialisation of the invention.[30]

4.24 The TRIPS Agreement also provides that Members may exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' and 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals'.[31] The exclusions from patentability permitted under the TRIPS Agreement are discussed further in Chapters 7 and 16.

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28 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 171.

29 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 27.2.

30 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 37.

31 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 28.3.

Exceptions to patent rights

4.25 The TRIPS Agreement provides that a patent shall confer on its owner exclusive rights to make, use, offer for sale, sell or import the patented product or process.[32] However, the agreement allows contracting states to provide exceptions to this level of patent protection. Article 30 sets out the criteria that must be met in order for a exception to patent rights to be permissible. Article 30 states:

> Members may provide limited exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.[33]

4.26 Article 30 establishes three conditions for a permissible exception. The exception must be 'limited', must not 'unreasonably conflict with the normal exploitation of the patent' and must not 'unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties'. These conditions are cumulative, that is, failure to comply with any one of the three may result in the exception being found to be inconsistent with the TRIPS Agreement.[34]

4.27 At the time of the negotiation and adoption of the TRIPS agreement, national laws adopted various exceptions to patent rights. It has been observed that while these existing exceptions limited the rights of patent holders, the purpose and scope of the exempted acts varied considerably.[35] Therefore

> [t]he TRIPS Agreement has not attempted to constrain the freedom of Members to determine the *grounds* of the possible exceptions, but has established the substantive *conditions* for their admissibility.[36]

4.28 In relation to the first condition, it has been suggested that an exception may be regarded as 'limited' when it is:

> subject to certain boundaries, for instance, with regard to the *acts* involved (e.g., importation, exportation, evaluation), the *purpose* of the use (eg for private purposes of education), the *outcome* of the invention's use (eg preparation of individual medicinal prescriptions), the *persons* that may invoke the exception, or its *duration*. An exception may be limited in relation to a *field of technology* as well (eg food or pharmaceuticals).[37]

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32 Ibid art 28.1.
33 Ibid.
34 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 152.
35 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 95.
36 Ibid, 95.
37 Ibid, 97.

4.29 The relationship between art 30 and art 27.1, which prohibits 'discrimination' as to field of technology, has been the subject of some debate.[38] In the *Canada–Patent Protection* case the panel found that art 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.

4.30 Australia's third party arguments, submitted in the *Canada-Patent Protection* case, stated that enjoyment of patent rights without discrimination as to field of technology did not require that identical rules should apply to patents in all technological fields. The Australian submission suggested that:

> Patent administration could require differential treatment according to technological subject-matter. The key to non-discrimination was for the overall balance of rights and obligations to be maintained. Where legislatures or courts sought to sustain this balance by taking account of technology-specific factors (such as specific regulatory regimes for pharmaceuticals), this was legitimately characterized as seeking to ameliorate discrimination rather than as creating it.[39]

4.31 The *Canada-Patent Protection* case confirmed that art 27 of the TRIPS Agreement does not 'prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.[40] In the ALRC's view it is therefore possible to craft defences to claims of infringement of patent rights, or other exceptions to patent rights, that are specific to a defined subset of gene patents. Such a law would differentiate between certain product areas but would not 'discriminate' by field of technology within the meaning of the TRIPS Agreement. Nevertheless, there would need to be strong arguments to justify differentiating gene patents, or a category of gene patents, from patents in other fields of technology.

4.32 The extent of permissible exceptions to patent protection under the TRIPS Agreement, including through new defences to claims of infringement, are discussed in more detail in Chapters 14, 22 and Chapters 26 to 28.

Compulsory licensing and Crown use

4.33 The TRIPS Agreement contains detailed provisions dealing with the use of patented inventions 'without the authorization of the right holder, including use by the government or third parties authorized by the government'.[41] In the context of Australian patent law and practice, these provisions apply to compulsory licensing and Crown use of patented inventions.

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38 See, eg, *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 170–171; compare M Matsushita, T Schoenbaum and P Mavroidis, *The World Trade Organization: Law, Practice, and Policy* (2002), 428.

39 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 95.

40 Ibid, 170–171.

41 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31.

4.34 Under the TRIPS Agreement, the basic obligation of member states is to ensure that any use permitted without the authorisation of the patent holder is considered on its individual merits.[42] Use may only be permitted if the proposed user has made unsuccessful efforts to obtain authorisation from the patent holder on reasonable commercial terms, except in cases of national emergency or other extreme urgency, or for public non-commercial use.[43] There are detailed provisions in relation to the permissible duration and scope of authorised use, remuneration of the patent holder, and judicial or other independent review of compulsory licensing or Crown use decisions.[44]

4.35 The compulsory licensing provisions of TRIPS were the subject of the November 2001 Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).[45] The Doha Declaration provided a mandate for negotiations between WTO members on a range of subjects, including issues concerning the implementation of the TRIPS Agreement.

4.36 In the Doha Declaration, the Ministerial Conference of the WTO stressed that the TRIPS Agreement does not and should not prevent action being taken to address public health problems afflicting developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. In particular, the Declaration stated that members have the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted, and what constitutes a national emergency or other circumstances of extreme urgency.

4.37 An outstanding issue from the Ministerial Conference at Doha was the application of art 31(f) of the TRIPS Agreement, which requires that production under compulsory licensing must be primarily for the supply of the domestic market. In August 2003, the WTO Council for TRIPS reached a decision to permit WTO Members with insufficient or no pharmaceutical manufacturing capacity to import compulsorily licensed pharmaceuticals needed to address public health problems.[46]

4.38 The provisions of the TRIPS Agreement dealing with compulsory licensing and Crown use are discussed further in Chapters 26 and 27.

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42 Ibid art 31(a).

43 Ibid art 31(b).

44 Ibid art 31(c)–(l).

45 *Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, World Trade Organization 4th Ministerial Conference, WT/MIN (01)/DEC/2.

46 *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 30 August 2003, World Trade Organization Council for TRIPS, WT/L/540.

Patent term

4.39 The TRIPS Agreement provides that the term of protection shall not end before the expiration of a period of 20 years.[47] Therefore, any system for standard patents that does not provide protection to the patent holder for 20 years would not be consistent with the TRIPS Agreement.

4.40 In relation to possible reform of patent term, the Department of Foreign Affairs and Trade submitted that:

> The impact of intellectual property rights on broader social policies has been at the forefront of negotiations and discussions in key international fora over the past few years. There has been no sustained nor substantive suggestions in these discussions that amending the period of a patent is a constructive or practical way to address these broader policy concerns.[48]

4.41 As discussed in Chapter 5, Australian patent law recognises a 'second tier' of protection called an innovation patent. These patents have a term of eight years, provide protection for inventions that represent a lesser inventive level over the prior art, and are subject to less scrutiny by the Patent Office prior to grant. In Australia, the TRIPS Agreement has been interpreted as permitting a shorter term of protection for inventions that do not qualify for standard patent protection.

Other international legal instruments

4.42 Activity in the international community to further the global harmonisation of patent laws may affect Australian patent laws and practices in the future. For example, the *Patent Law Treaty 2000*[49]—which primarily addresses administrative issues relating to the patent system—opened for signature on 1 June 2000 at a Diplomatic Conference of the World Intellectual Property Organization (WIPO).[50] The Treaty, which is not yet in force, enters into force three months after ratification or accession by ten States.[51]

4.43 In addition, WIPO member states are currently drafting a Substantive Patent Law Treaty, which aims to achieve greater convergence among national patent laws in relation to the examination and grant of patents.[52] As of its ninth session in May 2003, WIPO's Standing Committee on the Law of Patents had agreed in principle on a number of issues, such as the scope of the Substantive Patent Law Treaty, the right to a

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47 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 33.

48 Department of Foreign Affairs & Trade, *Submission P29*, 2 October 2003.

49 *Patent Law Treaty* (1 June 2000).

50 See World Intellectual Property Organization, *Intellectual Property Protection Treaties*, <www.wipo.int/treaties/ip/index.html> at 5 June 2003.

51 Ibid art 21(1).

52 World Intellectual Property Organization, *Draft Substantive Patent Law Treaty* (2003); World Intellectual Property Organization, 'Member States Review Provisions on Patent Law Harmonization', *Update No194/2003*, 22 May 2003, <www.wipo.int/pressroom/en/index.jsp>.

patent, novelty, inventive step and the requirement of sufficient disclosure. However, other provisions, such as those relating to patentable subject matter and exceptions to patentability, had not been resolved.[53]

4.44 In addition, other international legal instruments that are not primarily concerned with patent law or practice may nevertheless have an impact on Australian patent laws and practices, such as the *Convention on Biological Diversity*.[54]

Patent reform and bilateral free trade agreements

4.45 The TRIPS Agreement is the most comprehensive multilateral agreement on intellectual property. In addition, Australia may enter into international obligations with respect to intellectual property protection as part of bilateral free trade agreements with other countries. Such obligations may also place constraints on reform of Australian patent law and practice in so far as reforms may be inconsistent with them.

4.46 Most importantly, given the dominant position of the United States in biotechnology, Australia and the United States have recently concluded negotiations for an Australia–United States Free Trade Agreement (AUSFTA). On 8 February 2004, the Australian Trade Minister, the Hon Mark Vaile concluded an agreed text for the AUSFTA with the United States Trade Representative, Robert Zoellick.

4.47 The outcome of past free trade agreements involving the United States has included 'TRIPS-plus' patent protection obligations. For example, the US–Singapore Free Trade Agreement includes compulsory licensing provisions that go beyond the patent protection obligations contained in the TRIPS Agreement.[55] The ALRC understands that the AUSFTA text does not contain any specific agreements on TRIPS-plus patent protection, but the parties have agreed to work to reduce differences between them in intellectual property laws and practices, including in relation to patents.[56]

4.48 Australia also has comprehensive free trade agreements with Singapore, Thailand and New Zealand. Australia signed an Australia–Japan Trade and Economic Framework in July 2003, committing the two countries to work towards trade and

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53 World Intellectual Property Organization, *Substantive Patent Law Harmonization*, <www.wipo.int/patent/law/en/harmonization.htm> at 21 October 2003.

54 *Convention on Biological Diversity*, [1993] ATS 32, (entered into force on 29 December 1993). The *Convention on Biological Diversity* was implemented by the United Nations for the purpose of conserving biological diversity, and ensuring sustainable use of its components, as well as the fair and equitable sharing of the benefits from the use of genetic resources: see *Convention on Biological Diversity*, (entered into force on 5 June 1992).

55 United States and Singapore, *United States-Singapore Free Trade Agreement*, 6 May 2003 art 16.7. For example, other than in the case of public non-commercial use, national emergency or other extreme urgency, compulsory licensing may only be invoked 'to remedy a practice determined after judicial or administrative process to be anti-competitive under the competition laws of the party': art 16.7.6.

56 Department of Foreign Affairs & Trade, *Australia–United States Free Trade Agreement: Intellectual Property*, <www.dfat.gov.au/trade/negotiations/us_fta/outcomes/08_intellectual_property.html> at 9 February 2004.

investment liberalisation on a comprehensive basis. The Australian Government is developing a Closer Economic Partnership between the Association of South-East Asian Nations (ASEAN) and Australia and New Zealand. Australia and China have also recently committed to undertake a study into the feasibility of concluding a free trade agreement.[57]

57 Department of Foreign Affairs & Trade, *Australia–United States Free Trade Agreement: Frequently Asked Questions*, <www.dfat.gov.au/trade/negotiations/us_fta/faqs.html> at 8 December 2003.

5. Domestic Legal Framework

Contents

Introduction

5.1 This chapter provides an overview of the domestic legal framework within which the Australian patent system operates. It outlines the relevant legislation and institutions that comprise the Australian patent system and focuses primarily on procedural aspects of Australian patent law and practice. The chapter considers the different types of patent protection available under Australian law, the process for obtaining a patent, and the duration of patent rights.

5.2 Other chapters in this Discussion Paper address substantive aspects of Australian patent law and the application of these principles to inventions involving genetic materials and technologies. The requirements that must be satisfied to obtain a patent, and the limitations on the availability of patent protection for certain types of inventions, are considered in Chapters 6 and 7. Chapters 9, 10 and 23 outline the provisions in Australian patent law relating to challenges to, and the enforcement and licensing of, patent rights, respectively. Later chapters also examine other

Commonwealth legislation that may affect patent practices in Australia, in particular the *Trade Practices Act 1974* (Cth).

Domestic legal framework

5.3 Australian patent law operates within an international legal framework, which shapes certain procedural and substantive aspects of the patent system. The principal international conventions relevant to patent law were discussed in Chapter 4.

5.4 Australia has enacted legislation, in accordance with its international obligations, which regulates patenting practices within the Australian 'patent area'[1] with respect to inventions involving any type of technology. The procedures for obtaining a gene patent in Australia are, broadly speaking, the same as those that apply to patents claiming any other type of technology. The majority of the discussion of Australian patent law and practice in this chapter is therefore cast in general terms.

Legislation

5.5 Section 51(xviii) of the *Australian Constitution* grants the Commonwealth Parliament power to make laws with respect to 'copyrights, patents of inventions and designs, and trade marks'. Pursuant to this power, the Parliament has enacted the *Patents Act 1990* (Cth) (*Patents Act*) and the *Patents Regulations 1991* (Cth) (*Patents Regulations*), which regulate the patent system in Australia.

5.6 Patent legislation has been in force in Australia since before Federation. Most Australian colonies had a *Patents Act* based on United Kingdom patent statutes. These colonial Acts continued in force until the Commonwealth Parliament enacted the *Patents Act 1903* (Cth).

5.7 The 1903 Act was reviewed in 1935 and again in 1952.[2] Recommendations made in those reports, and the reforms introduced in the United Kingdom as a result of the *Patents Act 1949* (UK), influenced the provisions of the *Patents Act 1952* (Cth).[3] The 1952 Act was subject to a number of important amendments, including the introduction of the petty patent system in 1979.

5.8 A review of the 1952 Act by the Industrial Property Advisory Committee (IPAC) in 1984 recommended reform of the Australian patent system.[4] Based on the recommendations in the IPAC report, the government introduced the Patents Bill 1989

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1 'Patent area' is defined in the *Patents Act 1990* (Cth) to include Australia, the Australian continental shelf, the waters above the Australian continental shelf, and the airspace above Australia and the Australian continental shelf: *Patents Act 1990* (Cth) sch 1.

2 The committees undertaking the reviews were known as the Knowles Committee and the Dean Committee, respectively: J McKeough, K Bowrey and P Griffith, *Intellectual Property: Commentary and Materials* (2002), 241.

3 Ibid, 241.

4 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984).

(Cth), and after some amendments, the Patents Bill 1990 (Cth). The *Patents Act 1990* (Cth) came into force on 30 April 1991.

5.9 Patent protection in most countries is available for inventions that are new, involve an inventive step, and have a useful application. In Australia, the *Patents Act* provides that an invention is patentable if it:

- is a manner of manufacture—that is, the invention is appropriate subject matter for patent protection;
- is novel;
- involves an inventive or innovative step;
- is useful; and
- has not been used secretly within Australia prior to filing the patent application.[5]

5.10 The application of these requirements to inventions involving genetic materials and technologies is discussed in Chapters 6 and 7.

Administration

5.11 The Australian patent system is administered by the Patent Office of IP Australia.[6] IP Australia is a division of the Department of Industry, Tourism and Resources, but operates independently and reports directly to the Minister.[7]

5.12 Under the *Patents Act*, the Commissioner of Patents has power to grant a patent upon an application being filed with and examined by the Patent Office. IP Australia has developed the *Patent Manual of Practice and Procedure* (the *Manual*) to assist Australian patent examiners in applying the *Patents Act* and *Patents Regulations*.[8] IP Australia's examination practices are discussed later in this chapter and in Chapter 8.

5.13 State and federal courts and the Administrative Appeals Tribunal (AAT) also have a role in administering the Australian patent system. Decisions of the Commissioner of Patents may be subject to review by the AAT or the Federal Court.[9]

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5 *Patents Act 1990* (Cth) s 18.

6 IP Australia also administers trademark and design rights in Australia. See <www.ipaustralia.gov.au>.

7 IP Australia, *What is IP Australia?*, <www.ipaustralia.gov.au/about/whatis.html> at 16 December 2003.

8 IP Australia, *Patent Manual Practice and Procedure Volume 1: International* (2003); IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002); IP Australia, *Patent Manual of Practice and Procedure Volume 3: Oppositions, Courts, Extensions & Disputes* (2002).

9 A limited set of decisions by the Commissioner (primarily those made under the *Patents Regulations*) are not generally subject to review by either the AAT or the Federal Court. See further: Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General, Report 43* (1998).

The AAT may undertake merits review of the Commissioner's decisions with respect to certain procedural matters prescribed by the *Patents Act*.[10] A direct approach may be made to the Federal Court for judicial review in relation to other decisions of the Commissioner, essentially those related to the grant of patents or matters closely allied to the grant (for example, amendments to patent specifications and revocations).[11]

5.14 The Federal Court and state and territory Supreme Courts share original jurisdiction over matters related to the exploitation and enforcement of patent rights, including challenges to patent rights, infringement proceedings and compulsory licences.[12] The AAT has no jurisdiction in relation to such issues. Jurisdictional matters are considered further in Chapter 10.

Types of patents

5.15 Australian patent law recognises two principal types of patents: standard patents and innovation patents. An applicant for an Australian patent may elect to obtain protection for an invention under either the standard patent or innovation patent system.

5.16 Figure 5–1 outlines the key features of standard and innovation patents and indicates the difference in the scope of protection conferred by each type of patent.

Standard patents

5.17 A standard patent is the basic form of patent protection for inventions under Australian law and is consistent with the minimum requirements for patent protection provided under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[13] Unless otherwise indicated in this Discussion Paper, references to an Australian patent and discussions of patent rights relate to the standard patent system.

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10 *Patents Act 1990* (Cth) s 224; *Patents Regulations 1991* (Cth) r 22.26. Decisions of the AAT on matters of law may be appealed to the Federal Court: *Administrative Appeals Tribunal Act 1975* (Cth) s 44.

11 *Patents Act 1990* (Cth) s 154. The Federal Court also has jurisdiction to review decisions of the Commissioner under the *Administrative Review (Judicial Decisions) Act 1977* (Cth) and under s 39B of the *Judiciary Act 1903* (Cth) on the basis of legal or procedural error. In addition, judicial review is available by the High Court unders 75(v) of the *Australian Constitution*.

12 Ibid s 155. A 'prescribed court' is defined to mean the Federal Court, the Supreme Court of a State and the Supreme Court of each of the Australian Capital Territory, the Northern Territory and Norfolk Island: *Patents Act 1990* (Cth) sch 1.

13 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995). See further Ch 4.

Figure 5–1 Features of standard patents and innovation patents

Features	Standard patent	Innovation patent
Term	20 years (s 67) Extension of up to 5 years available for certain pharmaceutical patents under limited circumstances (ss 70–79A)[I]	8 years (s 68)
Number of claims	No statutory limits	Maximum of 5 claims (s 40(2)(c))
Inventions excluded from patentability, or excludable at the discretion of the Commissioner of Patents[II]	Human beings and the biological processes for their generation (s 18(2)) Inventions the use of which would be contrary to law (s 50(1)(a)) Inventions capable of application as a food or medicine that are a mere mixture of known ingredients (s 50(1)(b))	Same as for a standard patent,[III] and Plants and animals and the biological processes for the generation of plants and animals (other than microbiological processes, or the products of such processes) (ss 18(3), 18(4))
Level of invention required[IV]	'Inventive step' over the prior art (ss 7(2)–(3), sch 1)	'Innovative step' over the prior art (ss 7(4)–(6), sch 1)
Review by Patent Office prior to grant[V]	Substantive review for compliance with the requirements for patentability (ss 44–49)	Formalities check only; no substantive review unless requested (ss 52, 120(1A))

Notes

I This extension is available upon application to the Commissioner of Patents for patents relating to 'pharmaceutical substances' for which marketing approval is obtained from the Therapeutic Goods Administration. Limitations on the rights of a patent holder during the extended term of such pharmaceutical patents are discussed in Chapters 9 and 14.

II See Chapters 6 and 7 for discussion of the exceptions to patentable subject matter under Australian law.

III Sections 18(2), 101(b)(2)(d) and 101B(4) of the Patents Act are the equivalent provisions specifying inventions for which protection may not be available under the innovation patent system; these constitute grounds upon which the Commissioner may revoke an innovation patent.

IV See Chapter 6 for a discussion of the requirements for patentability under Australian law, including the 'inventive step' and 'innovative step' requirements. Except as noted in Figure 5–1, the statutory requirements for patentability of an innovation patent are the same as those which apply to a standard patent.

V See discussion of the procedures for examination of a patent in the following sections.

Innovation patents

5.18 The innovation patent system is a 'second tier' of protection, which was introduced in 2001 to replace the petty patent system.[14] Innovation patents are intended to provide protection for 'lower level' inventions for which standard patent protection is not available and which are not covered by the designs legislation.[15] Desmond Ryan has commented that:

> The sort of things that the innovation patent would be designed to protect were small innovative steps essentially of a practical nature necessary to achieve functional and commercial acceptance of a product or process.[16]

5.19 The innovation patent system has been criticised on a number of grounds. These include:

- the absence of formal examination of an innovation patent prior to grant may lead to uncertainty about the validity of such patents, as well as innovation patents being granted for inventions that should not receive any patent protection;[17]
- the quicker and more affordable nature of an innovation patent may result in patent protection being granted for too many undeserving inventions, which might 'slow down procedures and confuse the public';[18]
- the definition of 'innovative step' in s 7(4) of the *Patents Act* is unclear;[19] and
- the exclusion of plants and animals and the biological processes for their generation from the types of inventions that may be protected by an innovation

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14 Following a review of the petty patent system in 1995, the Advisory Council on Industrial Property (ACIP) recommended the introduction of innovation patents to replace petty patents as a 'second tier' of patent protection in Australia: Advisory Council on Industrial Property, *Review of the Petty Patent System* (1995). A further report strongly supported ACIP's recommendation: Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 157. Other jurisdictions also provide a 'second tier' of patent protection, including Germany, Japan, Ireland and Spain: Advisory Council on Industrial Property, *Review of the Petty Patent System* (1995), ch 3; D Ryan, 'Innovation Patents: What is their Likely Impact?' (2002) 48 *Intellectual Property Forum* 30, 31.

15 G McGowan, 'The New Innovation Patent System: Will It Work?' (2002) 76 *Law Institute Journal* 64; Advisory Council on Industrial Property, *Review of the Petty Patent System* (1995), rec 2.

16 D Ryan, 'Innovation Patents: What is their Likely Impact?' (2002) 48 *Intellectual Property Forum* 30, 31.

17 For example, a Melbourne patent attorney applied for an innovation patent on a wheel to highlight the inadequacies of the innovation patent system as implemented: G McGowan, 'The New Innovation Patent System: Will It Work?' (2002) 76 *Law Institute Journal* 64, 66.

18 Ibid, 66.

19 D Ryan, 'Innovation Patents: What is their Likely Impact?' (2002) 48 *Intellectual Property Forum* 30, 33; G McGowan, 'The New Innovation Patent System: Will It Work?' (2002) 76 *Law Institute Journal* 64, 65, 66

patent is undesirable given the high quality of Australia's research in biological and medical sciences.[20]

5.20 To date, the innovation patent system has been considered in only one decision of the Federal Court.[21] However, the innovation patent at issue in the case was not contested, so the Court was not required to interpret and apply the statutory requirements for an innovation patent.[22]

Patents of addition

5.21 The *Patents Act* also provides for the grant of a 'patent of addition' for an improvement in, or modification to, an invention claimed in a standard patent that has already been granted.[23] A patent of addition may be obtained only by the owner of the earlier patent, or a person authorised by the owner.[24] The term of a patent of addition expires at the same time as that of the patent on the main invention.[25]

Procedure for grant of a patent

5.22 Patent rights do not arise automatically. A patent can be obtained only by following the procedures set out in the *Patents Act* and *Patents Regulations*. An understanding of the procedure for obtaining a patent is important to understanding Australian patent law generally.

5.23 The steps in obtaining an Australian patent are described below. A flow chart describing the stages in the patent application process is also included in s 4 of the *Patents Act* and is reprinted below.

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20 D Ryan, 'Innovation Patents: What is their Likely Impact?' (2002) 48 *Intellectual Property Forum* 30, 33–34.

21 *Datadot Technology Ltd v Alpha Microtech Pty Ltd* [2003] FCA 962. The case involved Datadot Technology Ltd's (Datadot) innovation patent entitled 'Identifier Label Application System'—a mechanism that sprays thousands of identity labels, known as microdots, on to an article for the purposes of identification. The Federal Court held that Alpha Microtech Pty Ltd (Alpha) had infringed Datadot's patent and restrained Alpha from distributing or selling its infringing product.

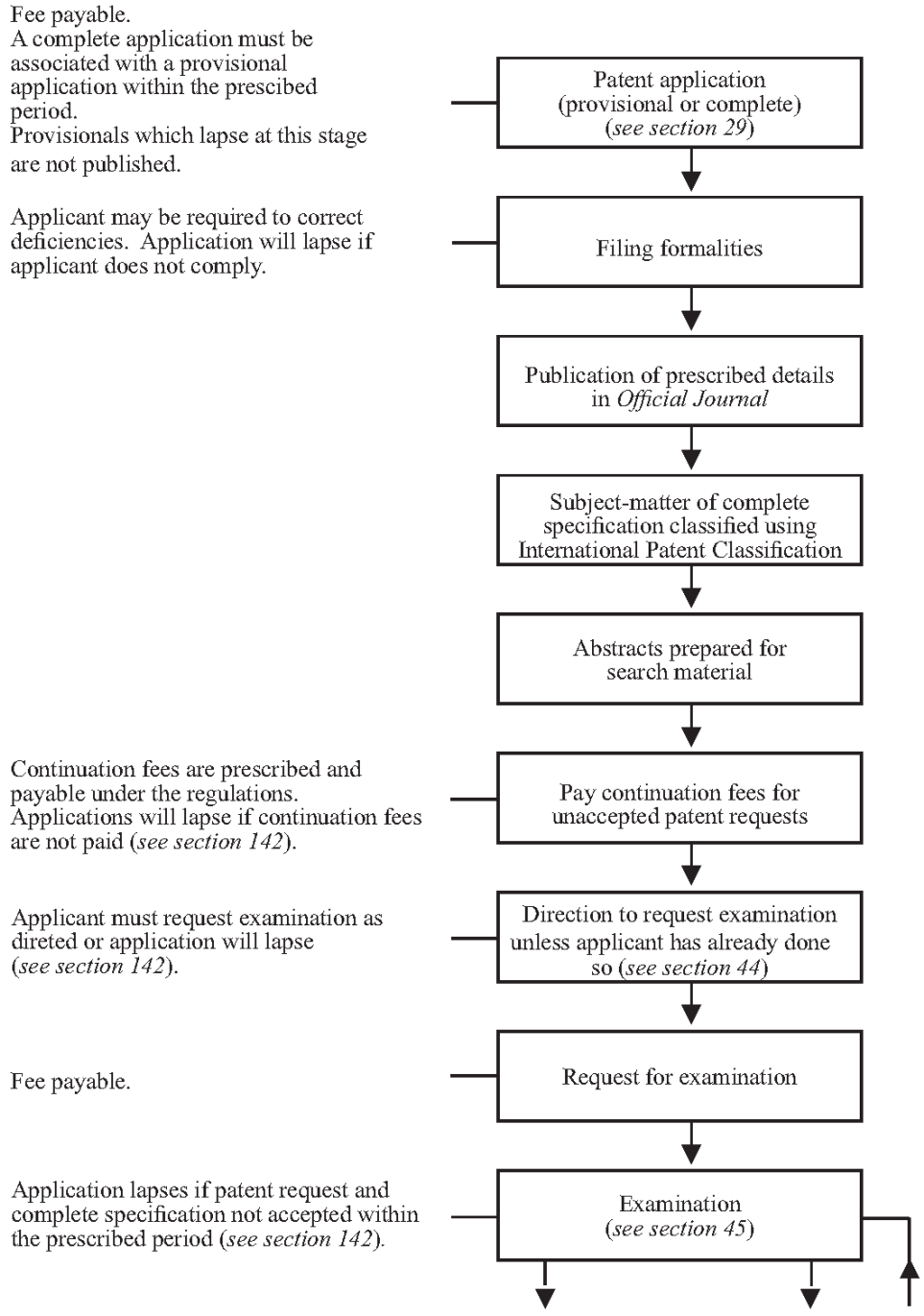
22 Although Alpha filed a cross-claim for revocation of Datadot's innovation patent, Alpha failed to appear at the hearing, or to adduce evidence in support of its cross-claim. The cross-claim was, therefore, dismissed without any substantive consideration.

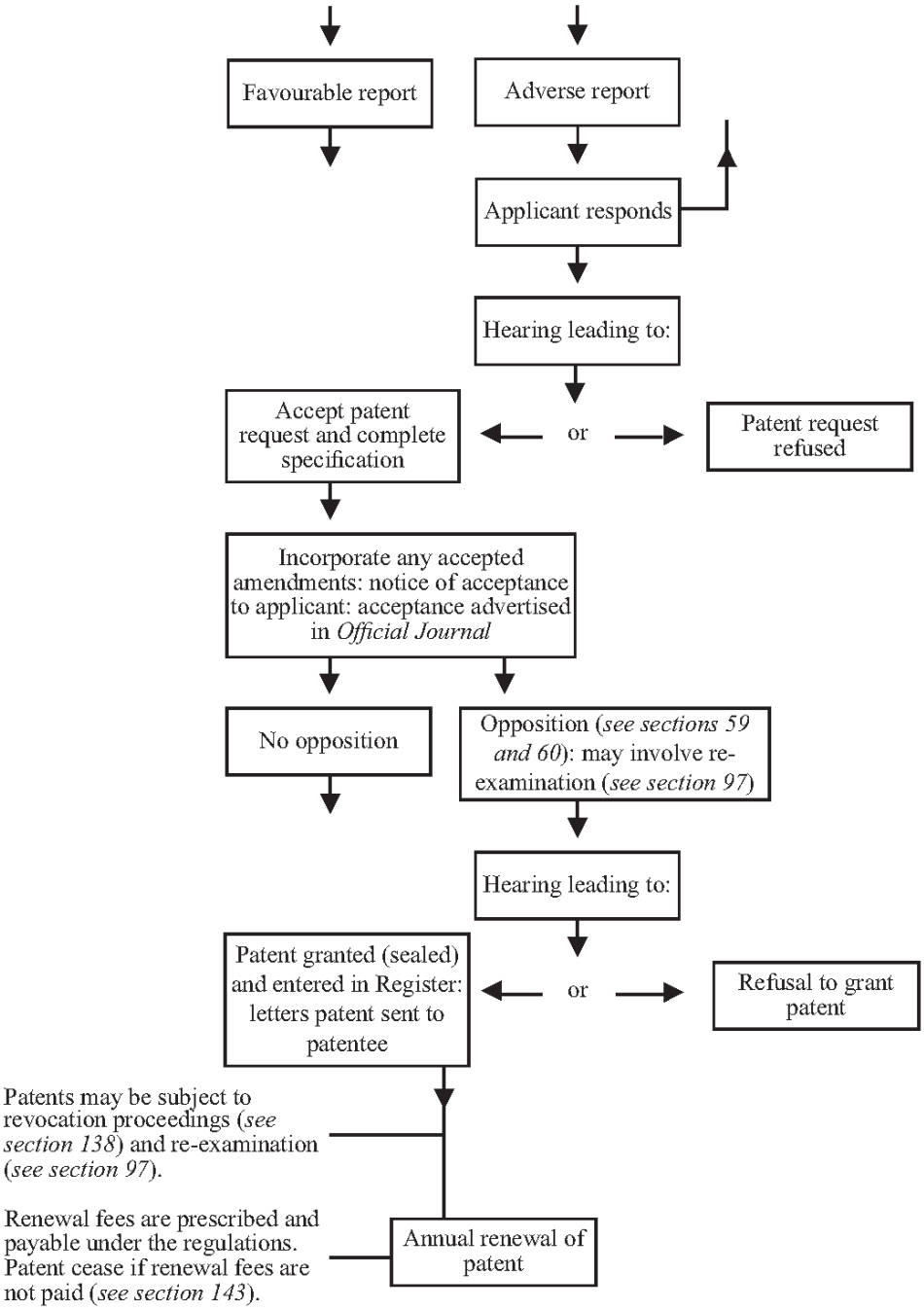
23 *Patents Act 1990* (Cth) s 81. A patent of addition is not available in relation to an innovation patent: *Patents Act 1990* (Cth) s 80.

24 *Patents Act 1990* (Cth) s 81(1)(b).

25 Ibid s 83.

Figure 5–2 Getting and maintaining a standard patent





Note: This diagram is reproduced from s 4 of the *Patents Act 1990* (Cth)

Filing an application

5.24 For a patent to be granted in Australia, an eligible person must file an application in the form prescribed by the Patent Office.[26] A patent application must include a specification of the invention, which contains instructions adequate to enable a skilled person in the relevant area of technology to produce or perform the invention. The specification must also indicate the 'claims' that define the invention; that is, the scope of protection that the applicant is seeking.

5.25 Typically, patent applications are prepared on behalf of an inventor by a qualified patent attorney. Professional assistance in drafting a patent application and communicating with the Patent Office about such application is not, however, required.[27]

Types of patent applications

5.26 Australian patent law recognises two types of patent applications—provisional and complete.[28] Provisional and complete applications may be filed to obtain either a standard patent or an innovation patent. The majority of complete standard applications are filed by way of the *Patent Cooperation Treaty* (PCT).[29]

5.27 A provisional application need only contain a description of the invention.[30] Often, an inventor files a provisional application before all the details of an invention are known. The applicant then has 12 months from the date of filing a provisional application to file a complete application.

5.28 A complete application must contain a full description of the invention, together with claims, and an abstract summarising the invention being disclosed.[31] A complete application may be based on one or more provisional applications, and only those claims that are 'fairly based'[32] on the relevant provisional application will be entitled to the priority date of the provisional application.

5.29 The 'priority date' of a patent claim is important in determining whether the requirements for patentability of an invention have been met. As discussed further in Chapter 6, the requirements of novelty and inventive (or innovative) step are assessed

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26 Eligible persons are the inventor of the invention claimed in the application, or a person to whom the inventor has assigned his or her rights in the invention. If an inventor or his or her assignee is deceased, that person's legal representative may file for patent protection: Ibid s 15, sch 1.

27 The *Manual* contains specific instructions to examiners as to how to deal with 'personal' applicants: IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [1.12], [12.5.7]–[12.5.8], [12.8.4]–[12.8.7]. The *Patents Act* does, however, prevent any person other than a qualified patent attorney from preparing a patent application for gain: *Patents Act 1990* (Cth) ss 200(1), 201(7).

28 *Patents Act 1990* (Cth) s 29.

29 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978); *Patents Act 1990* (Cth) s 88.

30 *Patents Act 1990* (Cth) s 40(1).

31 *Patents Regulations 1991* (Cth) rr 3.1, 3.2A, 3.3.

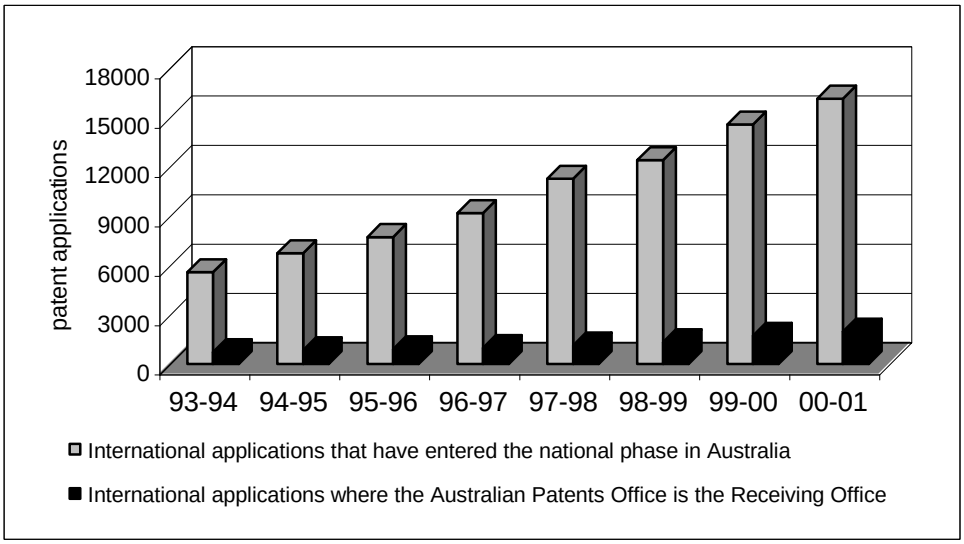
32 The 'fair basis' requirement under Australian patent law is discussed in Ch 6.

against the prior art as it existed before the priority date.[33] For Australian patent applications, the priority date is typically the date on which a provisional application is filed, or the date on which an application is filed in another participating jurisdiction.[34]

5.30 An applicant may also elect to file a PCT application with the Patent Office.[35] As discussed in Chapter 4, a PCT application designates all the jurisdictions that are parties to the PCT (including Australia), and secures an international priority date.

5.31 PCT applications that have entered the national phase (and will be processed as a complete application) are the main type of applications received by IP Australia.[36] IP Australia also acts as a Receiving Office under the PCT for the purposes of receiving and processing PCT applications. Figure 5–3 shows the growth in the number of PCT applications from 1993–94 to 2000–01. 'International applications where Australian Patent Office is the Receiving Office' represents the number of PCT applications that IP Australia received during this period. 'International applications that have entered the national phase in Australia' represents PCT applications filed in any jurisdiction (including Australia) during this period, which designated Australia as one of the jurisdictions in which the inventor wishes to obtain patent protection and for which the Australian filing fee was paid to IP Australia.[37]

Figure 5–3 Patent applications under the Patent Cooperation Treaty (PCT)



Source: IP Australia, *Industrial Property Statistics*, various years, Table 3.

33 *Patents Act 1990* (Cth) s 18(1)(b) (standard patent); s 18(1A)(b) (innovation patent).
34 Ibid s 43; *Patents Regulations 1991* (Cth) rr 3.12–3.14.
35 *Patents Act 1990* (Cth) Ch 8 Pt 1.
36 IP Australia, *Annual Report* (2003).
37 IP Australia may not, however, have undertaken substantive examination of the applications in this category: IP Australia, *Submission P56*, 4 November 2003.

Divisional applications

5.32 Each patent application may claim protection only for a single invention.[38] If, following assessment of a patent application, a patent examiner finds that an applicant has claimed more than one invention in the application, the applicant may elect to file a 'divisional application'—that is, a new application divided from the original or parent application. A divisional application allows an applicant to continue to benefit from the priority date of his or her original application.

5.33 Divisional applications may be filed only in connection with a complete patent application that has not lapsed, been refused or withdrawn at the time the divisional application is filed.[39] Divisional applications may claim subject matter not contained in the original application so long as all the features of at least one of the claims were disclosed in the original application. There are no statutory limits on the number of divisional applications that may arise from a single complete application.

5.34 The time period within which any divisional application must be filed, and the subject matter that may be claimed, are limited under the *Patents Act* as follows:[40]

- if a divisional application is filed before the date of grant of the original patent, the claims of the divisional application may be directed to subject matter falling within the scope of the claims of the original application when accepted;[41] or

- if, as is more commonly the case, a divisional application is filed within three months of advertisement of acceptance of an original application in the *Official Journal of Patents* (the *Official Journal*), the claims of a divisional application may be directed to an invention not falling within the scope of the claims of the original standard application when accepted.[42]

5.35 Once a divisional application has been filed, it is subject to the same procedural requirements, including examination, as any other complete patent application.

5.36 Divisional applications might allow for strategic patent filing by an applicant. For example, Professor James Lahore has commented that divisional applications have

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38 *Patents Act 1990* (Cth) s 40(4).

39 Ibid s 79B(1). A divisional application may also be filed in connection with an innovation patent: *Patents Act 1990* (Cth) s 79C; *Patents Regulations 1991* (Cth) r 6A.2. The *Patents Act* does not provide for a divisional application based on a provisional application: *Patents Act 1990* (Cth) s 79B; IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [9.8].

40 The requirements and timing for filing divisional applications based on an innovation patent are separately set out in the *Patents Act* and *Patents Regulations*: see *Patents Act 1990* (Cth) s 79C; *Patents Regulations 1991* (Cth) r 6A.2; IP Australia, *Divisional Applications*, <www.ipaustralia.gov.au/pdfs/patents/specific/div.pdf> at 16 December 2003.

41 *Patents Act 1990* (Cth) s 79B(1)(a); *Patents Regulations 1991* (Cth) r 3.11(2).

42 *Patents Act 1990* (Cth) s 79B(1)(b); *Patents Regulations 1991* (Cth) r 6A.1. Equivalent provisions exist with respect to the permitted subject matter of any divisional application based on an innovation patent and the time for filing such a divisional application: *Patents Act 1990* (Cth) s 79C; *Patents Regulations 1991* (Cth) r 6A.2.

been used to refile the claims of the original application when the acceptance period for an application is about to expire and the original application has not been accepted.[43] Divisional applications have also been filed during an opposition of the original application so that the opposed original application can be abandoned.[44]

5.37 In its submission to the Inquiry, IP Australia indicated that divisional applications are currently 'open to abuse'.

> Some applicants file a divisional application with the objective of lengthening the time to a decision, and to increase the chance of procuring broader claims for the same invention. This behaviour considerably increases uncertainty in the market.[45]

5.38 The concern raised by IP Australia does not appear to be limited to gene patent applications, although minimising uncertainty and ensuring that the claims in gene patents are appropriately limited is relevant to the ALRC's Inquiry.

5.39 No other submissions or consultations addressed this issue. The ALRC is, however, interested in the extent to which divisional applications may raise issues in the context of patents over genetic materials and technologies, and invites comments and further information on this matter.

Question 5–1 Does the filing of divisional applications present problems in the context of patents over genetic materials and technologies? If so, would any of the following address these concerns:

(a) specifying a time period within which a divisional application must be filed;

(b) specifying a time period within which a divisional application must be accepted by IP Australia; or

(c) limiting the subject matter that may be claimed in a divisional application to inventions other than those claimed in the original application.

Time for filing a patent application

5.40 The patent system only protects inventions that have not been previously disclosed to the public. This is expressed in the requirement that an invention must be 'novel' when compared to the prior art.[46] Until recently, public disclosure or use of an

43 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8025]. Acceptance of patent applications is discussed in the following sections.

44 Ibid, [8025]. Opposition proceedings are discussed in Ch 9.

45 IP Australia, *Submission P56*, 4 November 2003.

46 *Patents Act 1990* (Cth) s 18(1)(b)(i) (standard patent), s 18(1A)(b)(i) (innovation patent). See further Ch 6.

invention prior to filing a patent application was permitted in only very limited circumstances, including disclosure of the invention at a recognised exhibition or to a learned society.[47]

5.41 Recent amendments to the *Patents Regulations* mean that any publication or use of an invention by or with the consent of a patent applicant within a period of 12 months prior to filing a complete patent application no longer invalidates a patent application filed with the Patent Office within the prescribed period. This is often referred to as a 'grace period'.[48] These more lenient requirements apply only to disclosures made on or after 1 April 2002.[49] While these provisions may save eligible patent applications filed in Australia, prior disclosure of an invention may still prevent the grant of a patent in some other countries or regions which do not recognise a grace period, or which have different grace period requirements.[50] These issues are discussed further in Chapter 15.

Examination

5.42 Once an application has been filed with the Patent Office, a number of additional steps must be followed before a patent may be issued. An applicant must file a request that the Patent Office examine the application.[51] Examination is not automatic and a request for examination must generally be filed within five years of the date of filing a complete specification.[52]

5.43 The Commissioner of Patents may also direct an applicant to file a request for examination within a shorter period[53] and the applicant must comply with any such request within six months or the application will lapse.[54] IP Australia's standard practice is to direct applicants to file a request for examination if no request has been received within approximately 32 months of the priority date.[55] An abbreviated examination may be requested if the Australian patent application is related to a patent that has already been granted by the patent office in a prescribed foreign jurisdiction.[56]

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47 Ibid s 24; *Patents Regulations 1991* (Cth) rr 2.2, 2.3.

48 On the effects of the amendment, see A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475; W Condon and R Hoad, 'Amazing Grace: New Grace Period for Patents in Australia' (2002) 15 *Australian Intellectual Property Law Bulletin* 73. See also Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 159–161.

49 *Patents Regulations 1991* (Cth) rr 2.2(1A), 2.3(1A).

50 For example, Europe adopts an 'absolute novelty' requirement. See further, A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475.

51 *Patents Act 1990* (Cth) s 44(1).

52 *Patents Regulations 1991* (Cth) r 3.15.

53 *Patents Act 1990* (Cth) s 44(2)–(4); *Patents Regulations 1991* (Cth) r 3.16(1).

54 *Patents Act 1990* (Cth) s 142(2)(a); *Patents Regulations 1991* (Cth) r 3.16(2).

55 IP Australia, *Submission P56*, 4 November 2003. According to IP Australia, examination of Australian patents typically occurs about two and a half years after the date of filing.

56 *Patents Act 1990* (Cth) s 47; *Patents Regulations 1991* (Cth) rr 3.20. The prescribed jurisdictions under the *Patents Regulations* are: signatory countries to the *Convention on the Grant of European Patents*; Canada; New Zealand; and the United States: *Patents Regulations 1991* (Cth) r 3.21.

5.44 The purpose of examination is to determine whether the invention meets the statutory requirements for patentability set out in the *Patents Act*.[57] The Patent Office carries out searches of previously published documents—including scientific and patent literature (the 'prior art base')—to determine the prior art material relevant to the claimed invention.[58] In addition, an applicant must disclose to the Patent Office the results of searches carried out by or on behalf of foreign patent offices in respect of the invention claimed in an Australian application, or in a corresponding patent application filed overseas.[59] An examiner with expertise in the relevant area of technology then examines the application taking into account the information contained in the results of these searches and any other prior art information.[60]

5.45 Examination of a patent application typically involves an exchange between the examiner and the applicant about the appropriate scope of the specification and the claims in the patent application in light of the relevant prior art. This process is known as 'prosecution' of a patent application.

5.46 Following receipt of a request for examination, an examiner will make an initial assessment of an application for a standard patent and either accept the application as filed, or issue a 'first report' detailing the procedural and substantive grounds for objecting to the application.[61] An applicant then has a period of 21 months to address the objections raised by the examiner. The examiner may issue further reports for each response by the applicant that does not address the objections raised. An application for a standard patent will generally lapse if it is not in order for acceptance within 21 months after the date of the first report.[62]

5.47 No substantive examination is required in connection with an application for an innovation patent. The Patent Office is required to determine only that the application is complete and passes a 'formalities check'.[63] The formalities check primarily ensures that an applicant has fulfilled the procedural requirements for filing an innovation

57 Currently, a patent examiner is not required to consider all criteria for patentability in s 18, in particular, whether the invention is 'useful': *Patents Act 1990* (Cth) s 45; *Patents Regulations 1991* (Cth) r 3.18. See Ch 6.

58 'Prior art base' is defined in the *Patents Act 1990* (Cth) s 7, sch 1. See further Ch 6.

59 Ibid s 45(3); *Patents Regulations 1991* (Cth) r 3.17A. Equivalent disclosure requirements exist with respect to documentary searches relating to an innovation patent application: *Patents Act 1990* (Cth) s 101D; *Patents Regulations 1991* (Cth) r 9A.2A.

60 'Prior art information' is defined in the *Patents Act 1990* (Cth) sch 1. The qualifications of Australian patent examiners and the capacity of IP Australia to conduct adequate prior art searches are discussed in Ch 8.

61 Ibid s 45(1); *Patents Regulations 1991* (Cth) r 3.18.

62 *Patents Act 1990* (Cth) s 142(2)(e); *Patents Regulations 1991* (Cth) r 13.4.

63 *Patents Act 1990* (Cth) s 52; *Patents Regulations 1991* (Cth) r 3.2B.

patent.[64] However, substantive examination of an innovation patent is required before it can be enforced.[65]

Acceptance, publication and sealing

5.48 The Commissioner of Patents must notify an applicant of the decision to accept or refuse a patent application, and must publish notice of the decision in the *Official Journal*.[66] Formal refusal of an application is rare.[67] IP Australia indicated that there have been only four or five such refusals since *Patents Act 1990* (Cth) came into force.[68] More commonly, applications for standard patents lapse for failure to obtain acceptance within the prescribed 21 month period following a first report, as discussed above. The *Official Journal* also publishes notices of lapsed applications.[69]

5.49 Publication of a notice of acceptance in the *Official Journal* should be distinguished from the publication of a complete specification for a standard patent. This typically occurs 18 months after the earliest priority date for the application in question,[70] and is also advertised in the *Official Journal*.[71] Prior to publication of the complete specification, an application is confidential and only bibliographic details, such as the applicant's name and title of the invention, are made available by the Patent Office.[72]

5.50 A patent is granted when the Commissioner causes the patent to be sealed with the seal of the Patent Office. For a standard patent, this generally occurs within six months of the date of publication of the notice of acceptance of the application in the *Official Journal*, unless the application is opposed.[73] An innovation patent will be sealed provided that there is no order in place preventing publication of information about the claimed invention.[74]

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64 *Patents Regulations 1991* (Cth) r 3.2B. An applicant for an innovation patent generally has two months in which to correct any deficiencies in the application following a formalities check, or the application will lapse: *Patents Regulations 1991* (Cth) r 3.2B(3), (5)–(7).

65 *Patents Act 1990* (Cth) s 120(1A). Procedures relating to the examination of an innovation patent are set out in *Patents Act 1990* (Cth) Ch 9A, Pt 1.

66 *Patents Act 1990* (Cth) s 49(5), 49(7) (standard patents) and s 62(2) (innovation patents).

67 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8180].

68 IP Australia, *Submission P56*, 4 November 2003.

69 *Patents Regulations 1991* (Cth) r 13.5 (standard patent); r 3.2B(7) (innovation patent).

70 *Patents Act 1990* (Cth) ss 54, 55; *Patents Regulations 1991* (Cth) r 4.2.

71 *Patents Act 1990* (Cth) s 54(1) (standard patents) and s 62(2) (innovation patents). Certain information may be prohibited from being disclosed to the public under the *Patents Act*, even after examination and acceptance of an application of a standard patent or the grant of an innovation patent: *Patents Act 1990* (Cth) ss 152, 173.

72 *Patents Act 1990* (Cth) s 53; *Patents Regulations 1991* (Cth) r 4.1. See also IP Australia, *Submission P56*, 4 November 2003.

73 *Patents Act 1990* (Cth) s 61; *Patents Regulations 1991* (Cth) r 6.2. IP Australia indicated that a standard patent is typically sealed approximately four months after acceptance of the application has been advertised in the *Official Journal*: IP Australia, *Submission P56*, 4 November 2003. Opposition proceedings and other challenges to patent rights are discussed in Ch 9.

74 *Patents Act 1990* (Cth) s 62(1).

Duration of patent protection

5.51 As noted in Figure 5–1, a standard patent generally has a term of 20 years, commencing on the date of the patent, and an innovation patent has a term of 8 years.[75] A patent holder must pay the prescribed maintenance fees to keep a patent in force.[76]

International obligations

5.52 As discussed in Chapter 4, art 33 of the TRIPS Agreement requires Contracting States to provide protection for a term of not less than twenty years from the filing date of a patent.[77] Article 27(1) of the TRIPS Agreement requires Contracting States to make patent protection available for all inventions, without discrimination as to the field of technology to which an invention relates.[78] The *Patents Act* was amended in 1994 to extend the term of protection for a standard patent from 16 years to 20 years in order to bring Australian patent law into conformity with the requirements of the TRIPS Agreement.[79]

5.53 While the TRIPS Agreement provides some flexibility to Contracting States in developing their own patent laws—for example, permitting optional exclusions from patentability for certain types of inventions[80]—the minimum term of patent protection is not subject to any exceptions or qualifications.[81]

5.54 The TRIPS Agreement does, however, permit Contracting States to require compliance with reasonable procedures and formalities as a condition to the acquisition or maintenance of intellectual property rights.[82] Such procedures and formalities

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75 Ibid ss 67–68. The 'date of the patent' is the date on which the complete specification was filed or, if applicable, a different date determined by the *Patents Regulations*: *Patents Act 1990* (Cth) s 65; *Patents Regulations 1991* (Cth) r 6.3. As noted in Figure 5–1, an extension of the term of a standard patent relating to 'pharmaceutical substances' is available in certain circumstances: *Patents Act 1990* (Cth) ss 70–79A. The Department of Industry, Tourism and Resources is currently reviewing the operation of pharmaceutical patent term extension provisions in the *Patents Act*. The Department's final report is not yet publicly available: Department of Industry Tourism and Resources, *Discussion Paper on Patent Extensions and Springboarding, and the Effect on Generic Pharmaceuticals Manufacturers in Australia* (2002).

76 Maintenance fees are discussed later in this chapter.

77 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995), art 33.

78 Ibid, art 27(1).

79 *Patents (World Trade Organisation Amendments) Act 1994* (Cth). The 20-year patent term applies to all standard patents granted after 1 July 1995, or granted prior to that date for a 16-year term that had not expired as of that date: *Patents (World Trade Organisation Amendments) Act 1994* (Cth) s 7.

80 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995), art 27(2), 27(3).

81 See further Ch 4.

82 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995), art 62(1).

include the payment of fees for the filing and processing of a patent application, and for maintaining existing patent rights.

Maintaining patent rights

5.55 Under Australian law, maintenance fees must be paid to keep a standard or innovation patent in force.[83] Such fees are due annually, commencing on the fifth anniversary of the filing of the complete application for a standard patent, and from the second anniversary for an innovation patent.[84]

5.56 For a standard patent, maintenance fees increase incrementally from $180 (payable on the fifth anniversary) to $1,000 (payable on the nineteenth anniversary).[85] Maintenance fees for an innovation patent increase incrementally from $100 (payable on the second anniversary) to $235 (payable on the seventh anniversary).[86] A standard patent or innovation patent will cease if the prescribed fees are not paid.[87]

5.57 The report of the Intellectual Property and Competition Review Committee (the IPCRC Report) suggested that use of more steeply rising renewal fees might reduce the effective length of the patent term under Australian law. The IPCRC Report recommended that 'the scope for, and impact of, implementing more steeply rising renewal fees should be considered by IP Australia'.[88] IP Australia acted on this recommendation and increased the amount of annual maintenance fees in 2002.[89]

5.58 The actual (or effective) term of a patent is the period, after sealing, during which a patent remains in force. According to IP Australia, the average actual term of standard biotechnology patents in Australia is approximately 12 years.[90] This is higher than the average actual term for standard patents generally, which is approximately eight and a half years.[91] In its submission to the Inquiry, IP Australia commented that standard biotechnology patents may have a higher average actual term because:

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83 *Patents Act 1990* (Cth) ss 142–143A, 227. Renewal fees are not payable for patents of addition, unless such patent becomes an independent patent: *Patents Act 1990* (Cth) ss 86–87.

84 *Patents Regulations 1991* (Cth) sch 7 Pt 2. Fees are subject to amendment by the Commissioner of Patents from time to time.

85 Ibid sch 7 Pt 2. Also: IP Australia, *Patent Fees*, <www.ipaustralia.gov.au/patents> at 3 December 2003; IP Australia, *Submission P56*, 4 November 2003. Annual maintenance fees for pharmaceutical patents during any extended term are $1,200 each year.

86 *Patents Regulations 1991* (Cth) sch 7 pt 2. Also: IP Australia, *Patent Fees*, <www.ipaustralia.gov.au/patents> at 3 December 2003.

87 *Patents Act 1990* (Cth) s 143(a) (standard patent); s 143A(d) (innovation patent). Fees may be paid up to six months late, subject to a penalty of $100 for each month, or part of a month, following the due date during which payment is not made: *Patents Regulations 1991* (Cth) sch 7, pt 2.

88 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 144, 157.

89 Under the previous fee structure, which had been in effect since 1993, maintenance fees for a standard patent increased from an initial amount of $165 (payable on the fifth anniversary) to $790 (payable on the nineteenth anniversary and each anniversary thereafter in the case pharmaceutical patents).

90 IP Australia, *Submission P56*, 4 November 2003.

91 Ibid.

> biotechnology products take longer to develop and acquire regulatory approval for use than most other technologies, and so take longer to repay the investment.[92]

5.59 Even if Australian patents claiming biotechnological or genetic inventions persist for a longer average actual term, IP Australia informed the ALRC that:

> IP Australia is not aware of evidence that the maintenance of gene patents for above average periods has a detrimental effect. In their early stage, other technologies have also experienced rapid advancement, and broad claims have been maintained for up to twenty years.[93]

Options for reform

5.60 IP 27 asked whether the term for protection of gene patents should be limited to a period of less than 20 years and, if so, whether limiting the term for protection of gene patents would conflict with Australia's obligations under the TRIPS Agreement. The issue was raised as a potential solution to concerns about the existence of monopoly rights over genetic materials and technologies and the impact that such rights might have on the Australian healthcare system, as well as on competition within the Australian biotechnology industry.

5.61 If the term of protection for gene patents were limited to a period of less than 20 years, there are a number of possible reform options. These include:

- specifying a different term of protection for gene patents in the *Patents Act*;[94]
- amending the *Patents Act* to provide that inventions involving genetic materials and technologies may be protected only under the innovation patent system; or
- increasing maintenance fees payable in connection with patents to encourage holders of gene patents to keep only commercially useful patents in force.

Submissions and consultations

International obligations

5.62 Many submissions indicated that limiting the term of protection for gene patents would be 'likely' to be inconsistent with Australia's obligations under the TRIPS

92 Ibid.
93 Ibid.
94 Other jurisdictions have proposed limited terms for patents on certain types of technology. For example, Mexico recently considered limiting the term of pharmaceutical patents to ten years, with the right to renew protection for a further ten years; and under Indian patent law, patents claiming foods, medicines and drugs have terms of less than 20 years: L Schmidt, 'Threat to Mexican Patent Holders', *Legal Media Group News*, 16 March 2003, <www.legalmediagroup.com>; *Patents Act 1970* (India) s 53. Compliance with the TRIPS Agreement may, however, be an issue: A McBratney and others, *Submission P47*, 22 October 2003.

Agreement.[95] Some submissions were more definitive and commented that such a restriction would 'clearly' conflict with the TRIPS Agreement. For example, the Department of Foreign Affairs and Trade (DFAT) submitted that:

> any system for standard patents that did not provide protection to the patentee for 20 years, would not be consistent with the TRIPS Agreement.[96]

5.63 Two submissions commented on other aspects of Australia's international relations in support of the view that limiting the term of gene patents to a period less than 20 years would be undesirable. DFAT commented that there was no general support in the international arena for 'amending the period of a patent' as a 'constructive or practical way to address broader policy concerns'.[97] Dr Amanda McBratney and others commented that limiting the term of protection for gene patents may 'adversely impact on the current negotiations for a Free Trade Agreement between Australia and the United States'.[98]

Suitability of the innovation patent system

5.64 A number of submissions suggested that it would be preferable for an invention involving genetic materials and technologies to be protected only by an innovation patent. These submissions were critical of the proposition that genetic sequences are treated as inventions for the purposes of patent law and they therefore considered that the shorter term of patent protection provided by an innovation patent would be more appropriate.[99] Associate Professor Agnes Bankier, for example, commented:

> Discovery of a gene sequence is not an invention. The intellectual effort would be better regarded as an innovation with a shorter term of eight years for the patent.[100]

5.65 The South Australian Government suggested that protection of genetic inventions under the innovation patent system would be 'more advantageous for the healthcare sector'.[101] The Department of Health Western Australia agreed with this view, but commented that 'a tightening of the requirements for an innovation patent'

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95 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

96 Department of Foreign Affairs & Trade, *Submission P29*, 2 October 2003. See also GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

97 Department of Foreign Affairs & Trade, *Submission P29*, 2 October 2003.

98 A McBratney and others, *Submission P47*, 22 October 2003. See Ch 4 for discussion of the Free Trade Agreement between Australia and the United States.

99 A Bankier, *Submission P19*, 30 September 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

100 A Bankier, *Submission P19*, 30 September 2003.

101 South Australian Government, *Submission P51*, 30 October 2003.

might be required to guard against patent holders exercising their patent rights more aggressively.[102]

5.66 Other submissions, however, commented that the innovation patent system is unsuitable to provide patent protection for inventions involving genetic materials and technologies.[103] Some submissions based this claim on the fact that innovation patents are not subject to substantive examination by IP Australia prior to grant.[104]

5.67 The Australian Centre for Intellectual Property in Agriculture also considered that the ability to obtain innovation patents quickly and easily would exacerbate problems that biotechnology patents are already said to create.[105] The Commonwealth Department of Health and Ageing supported this view:

> If standard gene patents were excluded leaving only innovation patents on genes, the underlying issues of patent breadth coupled with the uniqueness of human genes would not be addressed. This may even exacerbate the proliferation of overly broad patents, given the lower level of justification needed by patent applicants as well as patent office scrutiny of their claims required before innovation patents would be awarded.[106]

5.68 In its submission, IP Australia indicated that, because of the limitations on the scope of protection available under an innovation patent:

> Innovation patents are little used for genetic inventions, except where immediate protection is desired while the assessment of a corresponding standard application is in progress.[107]

Existing mechanisms for limiting patent term

5.69 Some submissions commented that the Australian patent system already contains mechanisms that may effectively limit the term of patent protection. For example, IP Australia submitted:

> The patent maintenance fee structure set out in the Patents legislation is designed to encourage patent holders in all technologies to relinquish patents for which a commercial advantage is no longer gained.[108]

5.70 DFAT expressed a similar view and noted that such mechanisms are consistent with Australia's obligations under the TRIPS Agreement.[109]

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102 Department of Health Western Australia, *Submission P53*, 3 November 2003.
103 Queensland Government, *Submission P57*, 5 January 2004; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
104 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
105 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
106 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.
107 IP Australia, *Submission P56*, 4 November 2003.
108 Ibid.

5.71 In addition, two submissions commented that the effective term of a gene patent is much shorter than 20 years because the development cycle of genetic products leaves a relatively limited period of time for commercial exploitation. The Walter and Eliza Hall Institute of Medical Research submitted:

> The average time from gene patent to commercial returns can often be 10–15 years as a result of several years of research. Shorter terms would only discourage long-term developments of therapeutics and diagnostics and not be in the interests of translating research for healthcare benefits.[110]

ALRC's views

5.72 The ALRC's preliminary view is that the term of protection for gene patents should not be more limited than the term of patent protection available for any other type of technology. There is no firm evidence that providing patent protection to genetic inventions for a period of 20 years is particularly problematic. As noted in some submissions, the development and commercialisation of genetic products may not be complete until many years after patent protection is first granted, leaving a patent holder only a limited period in which to benefit from the monopoly rights conferred by a gene patent.

5.73 Submissions and consultations that supported a shorter term of protection for gene patents did not suggest an alternative period for protection of gene patents, other than the eight-year term available for innovation patents. The innovation patent system appears to provide useful and desirable patent protection for lower level inventions. However, in the ALRC's view, the features of the innovation patent system—in particular, the lack of substantive pre-grant examination of applications—make it unsuitable as the only form of patent protection available to genetic materials and technologies under Australian law.

5.74 In addition, a general restriction on the term of patent protection available to genetic materials and technologies might be inconsistent with Australia's obligations under the TRIPS Agreement.

5.75 The ALRC considers that inventions involving genetic materials and technologies should be eligible for protection by a standard patent, or by an innovation patent, at an applicant's election, subject to satisfying the substantive requirements for patentability set out in the *Patents Act*.

5.76 However, the ALRC does consider that, to the extent possible, the Register of Patents should contain only those patents that are in use by a patent holder. The IPCRC Report and some submissions to the Inquiry suggested that if patent fees are set at an

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109 Department of Foreign Affairs & Trade, *Submission P29*, 2 October 2003. See also *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995), art 62(1).

110 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003. See also A McBratney and others, *Submission P47*, 22 October 2003.

appropriate level, a patent holder will be more inclined to evaluate whether the investment he or she makes to maintain patent protection over a particular invention is worthwhile. The ALRC agrees with this view but invites further comment on this matter.

Proposal 5–1 IP Australia should regularly review the schedule of patent fees for standard patents and innovation patents to:

(a) assess the impact of the fees on the actual term of Australian patents; and

(b) ensure that fees are set at a level appropriate to discourage patent holders from maintaining patents that lack real commercial value.

6. Patentability of Genetic Materials and Technologies

Contents

Introduction

6.1 Concerns about gene patents may be divided into two broad categories. The first involves objections to gene patents on the basis that inventions involving genetic materials and technologies do not satisfy the requirements for patentability under Australian law. The second relates to concerns about the way in which gene patents are exploited, and the way in which inventions covered by such patents are commercialised.

6.2 This chapter and Chapter 7 address issues in the first category. This chapter considers the requirements for patentability under Australian law, and the application of each requirement to inventions involving genetic materials and technologies. Chapter 7 considers whether existing exclusions from patentable subject matter are applicable to any types of inventions involving genetic materials and technologies and whether the *Patents Act 1990* (Cth) (*Patents Act*) should be amended to include additional exclusions from patentability. Later chapters of this Discussion Paper address concerns about the exploitation of gene patents.[1]

6.3 To provide a context for the discussion in this chapter, it is instructive to understand the types of inventions claimed in gene patents. The following is a selected list of inventions involving genetic materials and technologies for which IP Australia has granted patent protection:

- synthetic genetic or DNA sequences;
- mutant forms and fragments of genetic sequences (including polymorphisms);
- isolated or recombinant DNA coding for a sequence of a gene;
- proteins expressed by a gene;
- vectors containing a gene;
- probes for a gene;
- methods of transformation using a gene;
- host cells, higher plants or animals carrying a gene; and

1 See Ch 12, 14, 15, 18, 20, 21, 24, 26 and 27.

- recombinant DNA methods—such as polymerase chain reaction (PCR) and novel expression systems.[2]

Requirements for patentability

6.4 For an invention to be protected by an Australian patent, it must satisfy the requirements for a 'patentable invention' in s 18 of the *Patents Act*.[3] Section 18 provides that a patentable invention is one which:

- is a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies 1623* (UK) (*Statute of Monopolies*);
- is novel when compared to the prior art;
- involves an inventive (or innovative) step when compared to the prior art;
- is useful; and
- has not been secretly used in Australia before the priority date by or with the authority of the patent holder.[4]

6.5 The *Patents Act* expressly excludes certain categories of subject matter from patentability, and grants the Commissioner of Patents discretion to refuse a patent application for other types of inventions.[5] Chapter 7 discusses these exclusions.

6.6 For reasons outlined later in this chapter, the ALRC does not consider that inventions involving genetic materials and technologies raise issues that warrant major changes to the patentability requirements under Australian law. Moreover, as a general proposition, the ALRC does not consider that the patentability requirements should be applied to genetic inventions differently to the way in which they are applied to inventions involving any other type of technology. Inventions involving gene patents do, however, highlight issues about the way in which the usefulness of an invention is assessed under Australian law. The ALRC has, therefore, proposed specific reforms to the current approach to this requirement in order to clarify the application of the usefulness requirement for all types of inventions.

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2 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 31 March 2003.

3 *Patents Act 1990* (Cth) s 18(1) (standard patents); s 18(1A) (innovation patents). 'Invention' and 'patentable invention' are defined in sch 1 to the Act.

4 The application of this requirement (commonly referred to as 'secret use') in the context of gene patents is not materially different to any other type of technology and thus will not be considered in any detail in this chapter. For judicial consideration, see *Azuko Pty Ltd v Old Digger Pty Ltd* (2001) 52 IPR 75.

5 *Patents Act 1990* (Cth) ss 18(2), 50 (standard patents); ss 18(2), 18(3), 101B(2)(d), 101B(4) (innovation patents).

Overview of submissions

6.7 Submissions and consultations expressed a range of concerns about the patentability of genetic materials and technologies, including:

- general ethical objections;
- the identification of a gene or other genetic material (such as a protein) is a 'discovery' not an 'invention';
- genetic sequences and other genetic materials are not novel and should not be patentable;
- the identification of a genetic sequence or other genetic material does not involve an inventive step;
- gene patents may be granted over inventions even if the use of the invention is not yet known; and
- gene patents contain broad claims and the disclosure in such patents does not justify the scope of the claims.

6.8 Chapters 3 and 7 discusses the objections to gene patents on the basis of ethical or social considerations. The other objections outlined above are considered in this chapter, in the context of the relevant requirement for patentability.

6.9 Many submissions to the Inquiry criticised the way in which the requirements for patentability have been applied to inventions involving genetic materials and technologies. In some cases, criticisms were directed to the patentability requirements generally and it was not evident which particular requirements were a cause of concern. In other cases, comments in submissions were addressed to a specific question asked in IP 27, but responses raised issues that were relevant to other patentability requirements or to additional issues addressed by the ALRC in this chapter. In these cases, the ALRC has cited submissions in the context of the patentability requirement or issue to which they appear most related.

6.10 A number of submissions also expressed opinions about the specific types of inventions involving genetic materials and technologies that should be patentable, and those for which patent protection should not be available; for example, it was said that genetic sequences and proteins should not be patentable, but combinations of genes, recombinant proteins and processes for identifying such materials should be. These comments appear to be based on assumptions about the type of inventions that will *prima facie* fail to satisfy the criteria for patentability. Such an approach is contrary to the basic notion of patent law, namely, that each patent application (and the invention claimed in it) should be assessed independently to determine whether it satisfies the

requirements for patentability. However, to the extent possible, the ALRC has considered these comments in relation to particular patentability requirements.

Should gene patents be treated differently?

6.11 The requirements that must be satisfied in order to obtain a gene patent are the same as those that apply to patents over inventions involving any other type of technology. An initial question arises as to whether the concerns that have been expressed about gene patents differ significantly from objections to patents over other types of technologies and whether those differences, if any, justify implementing specific requirements in the *Patents Act* that would apply only to patents over genetic materials and technologies.

Submissions and consultations

6.12 The weight of submissions did not favour creating requirements for patentability that would apply only to the grant of gene patents. Submissions generally considered that the establishment of special rules for gene patents was neither necessary nor desirable.[6] Submissions suggested that implementing specific requirements for gene patents may add complexity to the Australian patent system, both in relation to inventions involving genetic materials and technologies and for other new technologies that may arise in the future.[7]

6.13 IP Australia indicated that specific provisions applicable only to genetic materials and technologies should not be adopted.

> IP Australia strongly recommends against introducing technology-specific laws and procedures. Such measures invariably lead to uncertainty over the bounds of the subject matter, involved debate in individual cases, and increased cost and uncertainty for users of the system. Such measures may eventually prove at least partially ineffective, as it may be possible to draft claims to avoid the intent of [any] exclusion. Defining the bounds of a technology is a non-trivial issue.[8]

6.14 Similarly, Dr Graeme Suthers commented:

> Either there is a consistent approach to patentability by the patent office and the courts (and no need to alter the existing patent regulations), or there will continue to be a mess of confusion, disputes, and uncertainty expense.[9]

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6 For example, Medicines Australia, *Submission P21*, 30 September 2003; L Palombi, *Submission P28*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; IP Australia, *Submission P56*, 4 November 2003.

7 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

8 IP Australia, *Submission P56*, 4 November 2003.

9 G Suthers, *Submission P30*, 2 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

6.15 Dr Amanda McBratney and others suggested that proposals for the special treatment of a new technology often arise when the technology has implications for 'human health or subsistence'—as is the case for inventions involving genetic materials and technologies. McBratney and others suggested that the problematic aspects of such technologies more commonly relate to the way in which patented inventions are exploited, rather than the existence of patent rights.

> [This] problem is not addressed by adjusting patent legislation to address each perceived jump in technology, or for inventions that have 'special' features or raise 'special' issues. The result would be a complex and unwieldy system that would neither serve the patentee nor the public … [W]e have established legal principles that have served our society well. These can be implemented in a reasoned manner to decide on the patentability of a new technology that might be perceived as 'special' or of a 'different nature' to the more traditional notion of a patentable invention.[10]

6.16 Other submissions said that imposing particular requirements for gene patents would lead to inconsistency between the way in which genetic materials and technologies are treated under Australian patent law and the patent laws of other jurisdictions. Submissions suggested that such a divergence would create unnecessary difficulties for Australian entities seeking to obtain patent protection in foreign jurisdictions[11] and might have adverse implications for the place of the Australian biotechnology sector in the global economy.[12]

6.17 Some submissions suggested that the introduction of specific requirements relating to the patentability of genetic materials and technologies may conflict with the provisions of the *Agreement on the Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement).[13]

6.18 However, some submissions commented that there have been difficulties in applying existing requirements for patentability to inventions involving gene patents and that such difficulties did not always reflect inadequacies in the requirements for patentability.[14] Rather, they may result from difficulties encountered by patent offices, including IP Australia, in applying these requirements to genetic materials and technologies. As a result, these submissions supported more stringent application of existing requirements for patentability in the future. Chapter 8 considers procedures to assist Australian patent examiners in assessing gene patent applications.

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10 A McBratney and others, *Submission P47*, 22 October 2003.

11 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

12 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

13 For example, GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Queensland Government, *Submission P57*, 5 January 2004.

14 For example, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

6.19 Some submissions identified particular characteristics of genetic materials and technologies that may justify the application of specific rules to these types of inventions.[15] For example, the Department of Health and Ageing submitted:

> It is generally accepted that, in practice, a pure monopoly is unlikely to arise through the application of patent law. This is due to the availability of alternative or substitute products and processes and the scope for imitation. However, the uniqueness of human genes provides wide scope for inappropriate monopoly behaviour. A patent on a particular gene or gene sequence has the practical effect of monopolising the knowledge and exploitation of the gene. In effect, it patents the particular condition or characteristic. In doing so it prevents work on alternative ways of dealing with the condition or characteristic and may limit the capacity to invent around the patent.[16]

6.20 IP Australia also acknowledged that such views have been expressed:

> It is perhaps arguable the gene patents are different from most other technologies on the issue of whether they can be 'invented around'. It may be that no other genetic material has a function similar to that of a patented material, and so alternatives cannot be developed.[17]

6.21 As noted above, however, IP Australia did not consider that this characteristic warranted the application of special requirements for patentability.

ALRC's views

6.22 In the ALRC's view, concerns about the patenting of inventions involving genetic materials and technologies should not be addressed by the introduction of legislative requirements that would relate only to these types of inventions.

6.23 The ALRC agrees with those submissions that suggested such an approach may set an undesirable precedent in relation to how the patent system should accommodate new technologies in the future. The current requirements for patentability set out the *Patents Act* are technology-neutral and are generally able to adapt to new technologies as they arise. Introducing specific rules for inventions involving genetic materials and technologies may suggest that special requirements for patentability should be implemented for future technologies that raise a different set of issues. Such an approach would unnecessarily complicate Australian patent law.

6.24 To introduce requirements that would apply only to genetic materials and technologies is also undesirable from an international perspective. Rules applicable only to genetic materials and technologies would represent a departure from attempts to harmonise the patent laws of various jurisdictions.[18] Further, it would result in a

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15 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

16 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004. See also G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; E Milward and others, *Submission P46*, 20 October 2003.

17 IP Australia, *Submission P56*, 4 November 2003. See also Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

18 See further Ch 4.

marked divergence from approaches to inventions involving genetic materials and technologies adopted by other major economies, such as the United States, Europe and Japan. Such an approach is likely to have significant implications for the willingness of foreign entities to participate in the Australian biotechnology sector, and for the ability of Australian entities to commercialise genetic inventions in other jurisdictions. As discussed in Chapter 4, the adoption of specific requirements for genetic materials and technologies may be inconsistent with the provisions of the TRIPS Agreement.

Proposal 6–1 IP Australia should assess patent applications relating to genetic materials and technologies according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.

Patentable subject matter

'Manner of manufacture' test

6.25 Currently, genetic materials and technologies are treated as 'inventions' for which patent protection is available under Australian law, provided the requirements set out in the *Patents Act* are satisfied.[19] 'Invention' is defined in the *Patents Act* as:

> Any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention.[20]

6.26 The *Statute of Monopolies* was enacted in the United Kingdom in 1623, but is not reproduced in the *Patents Act*. Section 6 of the Statute provides as follows:

> Provided also and be it declared and enacted that any declaration before mentioned shall not extend to any letters patent and grants of privilege, for the term of 14 years or under hereafter to be made of the sole working or making of any *manner of new manufacture* within this realm to the true and first inventor and inventors of such manufactures which others, at the time of making such letters or grant, shall not use, so as also they be not contrary to law nor mischievous to the state by raising prices of commodities at home or hurt trade or generally inconvenient.[21]

6.27 The concept of 'invention' under Australian law has not, to date, been limited to the literal meaning of the term 'manner of new manufacture' in the *Statute of Monopolies*.[22] In the leading Australian decision on the concept of 'invention',

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19 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 31 March 2003.

20 *Patents Act 1990* (Cth) sch 1.

21 21 Jac 1 c 1 (1623) (emphasis added).

22 J Pila, 'Inherent Patentability in Anglo-Australian Law: A History' (2003) 14 *Australian Intellectual Property Journal* 109, 110.

National Research Development Corporation v Commissioner of Patents (*NRDC*),[23] the High Court indicated that a policy-oriented approach should be adopted to the meaning of the term:

> The word 'manufacture' finds a place in the present Act, not as a word intended to reduce the question of patentability to a question of verbal interpretation, but simply as the general title found in the Statute of Monopolies for the whole category under which all grants of patents which may be made in accordance with the developed principles of patent law are to be subsumed.[24]

6.28 The High Court held that the following approach should be adopted in determining whether the invention claimed in a particular patent application constituted patentable subject matter under Australian law:

> The right question is: 'Is this a proper subject of the letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?'[25]

6.29 For an invention to be a 'manner of manufacture', as interpreted in *NRDC*, it must belong to the useful arts rather than the fine arts, it must provide a material advantage and its value to the country must be in the field of economic endeavour.[26]

6.30 The categories of inventions that may satisfy the 'manner of manufacture' test have gradually expanded over time. A report of the Intellectual Property Competition Review Committee (the IPCRC Report) in 2000 outlined the expansion of the categories of patentable subject matter from a method for extracting lead from humans, to agricultural processes, new plant varieties, micro-organisms, methods of cosmetic and therapeutic treatment of humans, and mathematical applications (in computer programs).[27] This expansion mirrors developments in other jurisdictions.[28]

6.31 Judicial interpretation of the 'manner of manufacture' test has also recognised a number of categories of subject matter that will fail to satisfy the test. These include mere discoveries, ideas, scientific theories and laws of nature.[29]

6.32 The 'manner of manufacture' test is expressed in terms that appear obscure in a modern context.[30] However, reviews of Australian patent law have recommended that

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23 *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252. The patent at issue claimed a novel treatment for killing weeds in crops. The question before the High Court was whether agricultural and horticultural inventions were patentable under Australian law.

24 Ibid, 269.

25 Ibid, 269.

26 Ibid, 275.

27 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 147.

28 See, eg, W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 21–25. However, the Supreme Court of Canada has recently held that patent protection is not available for higher life forms—in that case a genetically modified mouse pre-disposed to cancer: *Harvard College v Canada (Commissioner of Patents)* [2002] SCC 76.

29 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.5]–[8.2.6].

the requirement be preserved as the threshold test for patentability. A 1984 report of the Industrial Property Advisory Committee (the IPAC Report) considered that the concept 'operates quite satisfactorily' and 'has, in the past, exhibited a capacity to respond to new developments'.[31] The IPAC Report recommended:

> that the present threshold test for patentability by reference to section 6 of the Statute of Monopolies and to the expression 'manner of new manufacture' be retained, without specific legislative inclusions or exclusions.[32]

6.33 The Australian Government accepted this recommendation when drafting the Patents Bill 1990 (Cth) (Patents Bill). The Explanatory Memorandum stated:

> The requirement in s 18(1)(a) that an invention, in order to be patentable, must be a 'manner of manufacture' invokes a long line of UK and Australian court decisions … The Government accepted the Industrial Property Advisory Committee's recommendation that this flexible threshold test of patentability be retained in preference to adopting a more inflexible codified definition.[33]

6.34 Similarly, the IPCRC Report considered that the 'open-textured standard' represented by the 'manner of manufacture' test should be retained. It concluded that:

> Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the 'manner of manufacture' test.[34]

6.35 In reaching the conclusion that the 'manner of manufacture' test should be retained, both the IPAC Report and the IPCRC Report considered that codification of a concept of 'invention' in the *Patents Act* would be likely to result in greater uncertainty (with the attendant costs) than the 'manner of manufacture' test.[35]

Patentable subject matter in other jurisdictions

6.36 Other jurisdictions frame the test for patentable subject matter differently. United States patent law provides that to be patentable subject matter 'the claimed invention must be a process, machine, manufacture, or composition of matter that has a practical utility'.[36] Patent legislation in the United Kingdom defines patentable subject matter by exclusion: an invention is patentable if it satisfies the other requirements for

30 See, eg, New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), [22]–[31].
31 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 41.
32 Ibid, rec 12.
33 Explanatory Memorandum, Patents Bill 1990 (Cth), [31].
34 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 149.
35 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 41; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 148–149.
36 35 USC §101.

patentability and is not, among other things, a 'discovery, scientific theory or mathematical method' or 'a scheme rule or method for performing a mental act'.[37]

6.37 Associate Professor Ann Monotti and Professor Sam Ricketson have commented that the choice of (often seemingly outdated) statutory language relating to the test for patentable subject matter in patent statutes in Australia, the United Kingdom and the United States:

> seems to reflect a general understanding, by both courts and legislatures, that it is impossible to find a form of language that will adequately cover, at any one time, the multifarious and diverse forms in which human inventiveness may manifest itself.[38]

6.38 Monotti and Ricketson also suggested that the issue of what is an 'invention' for the purposes of patent law may only become contentious at the margins, as new developments in science and technology occur. Historically, courts have been able to address patentable subject matter by 'a process of progressive interpretation'.[39] Even where legislatures have expressly stated exceptions to patentable subject matter, these provisions 'have generally been limited in their effect'.[40]

6.39 A 2003 review of New Zealand patent law by the Ministry of Economic Development (the NZ Report) recommended that the definition of patentable invention in the *Patents Act 1953* (NZ) be amended to mirror the definition adopted in Australian law, including that the invention must be a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*.[41] The Report commented that such an approach would allow current judicial exclusions from patentable subject matter to be retained and continue to allow 'the courts the flexibility to develop the definition on a case by case basis'.[42]

Application to genetic materials and technologies

6.40 There has been limited consideration in Australia of the application of the 'manner of manufacture' test to genetic materials and technologies, except by

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37 *Patents Act 1977* (UK) s 1(1), (2). Until 1977, United Kingdom patent law also relied on the 'manner of manufacture' requirement as the test for patentable subject matter.

38 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [3.21].

39 Ibid, [3.22]. See also R Eisenberg, 'Re-examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 *Emory Law Journal* 783, 791–792.

40 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [3.22].

41 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), pt 1, rec 2(i). The current legislative definition of 'invention' includes 'any new method or process of testing applicable to the improvement or control of manufacture', in addition to 'a manner of new manufacture': *Patents Act 1953* (NZ) s 2.

42 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), pt 1, [33].

IP Australia.[43] The requirement does not appear to have limited the types of inventions involving genetic materials and technologies that will be patentable.[44] Dr Dianne Nicol has suggested that inventions involving genetic materials and technologies appear to satisfy the *NRDC* requirements because genetic research and treatments are commercial in nature and have value in an economic sense, both directly through the activities of the Australian biotechnology industry and indirectly through the ability of such technology to alleviate disease.[45]

Discoveries

6.41 Traditionally, 'discoveries' have been regarded as outside the scope of patentable subject matter because no knowledge or ingenuity has been applied to produce a new and useful thing.[46] However, distinguishing between discoveries and inventions for the purposes of patent law is difficult. The High Court in *NRDC* suggested that drawing such a distinction may be misleading and often only true in a formal sense.[47] IP Australia's *Patent Manual of Practice and Procedure* (the *Manual*) also notes that 'no general definition can be given as to what constitutes a discovery as opposed to an invention'.[48]

6.42 Consideration of the distinction between a discovery and an invention in the context of biotechnology patents first arose in relation to patent claims over micro-organisms. In Australia and in other jurisdictions, 'man-made' micro-organisms have been accepted as constituting patentable subject matter;[49] 'isolated and purified' cultures of micro-organisms may also be patentable. However, micro-organisms in their naturally occurring state are regarded as discoveries and, as a consequence, patent protection will not be available.

6.43 The difference between a discovery and an invention has also arisen for consideration in relation to patent applications claiming genetic sequences. The decisions that have addressed this issue in Australia and overseas have drawn a distinction between genetic materials in their natural state and those that have been 'isolated and purified'.

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43 See, eg, IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 31 March 2003.

44 See the list of patented inventions at the beginning of this chapter.

45 D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 237. See also K Ludlow, 'Genetically Modified Organisms and their Products as Patentable Subject Matter' (1999) 21 *European Intellectual Property Review* 298.

46 *Lane Fox v Kensington and Knightsbridge Electric Lighting Co* (1892) 9 RPC 413, 416, cited with approval in *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252, 263. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 22–24.

47 *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252, 264.

48 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.5.2].

49 See, eg, *Ranks Hovis McDougall's Application* [1976] 46 AOJP 3915 (Australia); *Diamond v Chakrabarty* 447 US 303 (1980) (United States).

Australia

6.44 *Kiren-Amgen Inc v Board of Regents of the University of Washington* involved an opposition to a patent application for the purified or isolated DNA sequence encoding the human protein erythropoietin (which plays a major role in the formation of red blood cells).[50] The Deputy Commissioner of Patents stated:

> In my view, a claim directed to *naturally occurring* DNA characterised by specifying the DNA coding for a portion of that molecule would likely be claiming no more than a discovery per se and not be a manner of manufacture.[51]

6.45 The Deputy Commissioner found, however, that the principle did not apply to the patent application at issue because the claims were directed to 'purified and isolated' DNA sequences that were 'an artificially created state of affairs'.[52]

6.46 Applying this principle more generally, IP Australia has indicated that the following subject matter will not be deemed to be a discovery under Australian patent law:

> The building blocks of living matter, such as DNA and genes (including human DNA and genes) which have for the first time been identified and copied from their natural source and then manufactured synthetically as unique materials with a definite industrial use.[53]

6.47 In addition, IP Australia's *Manual* provides specific guidance on the difference between a discovery and an invention in the context of gene patents:

> [T]he discovery of a micro-organism, protein, enantiomer or antibiotic in nature can be claimed in its isolated form or as substantially free of (perhaps, specified) impurities. Also, a gene can be claimed as the gene *per se* (as long as the claim does not include within its scope the native chromosome of which the gene forms part) or as the recombinant or isolated or purified gene.[54]

Other jurisdictions

6.48 In 1988, the European Patent Office (EPO), United States Patent Office (USPTO) and Japanese Patent Office (JPO) issued a joint statement explaining the distinction between natural and man-made substances for the purposes of patent law in those jurisdictions:

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50 'Manner of new manufacture' was not a ground of opposition in the case but arose in relation to the Deputy Commissioner's consideration of whether the claimed invention was a mere discovery: *Kiren-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557.

51 Ibid, 569 (emphasis added).

52 Ibid, 569. The decision was appealed to the Federal Court on other grounds: *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106.

53 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 31 March 2003.

54 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.5.3].

> Purified natural products are not regarded as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.[55]

6.49 Article 52(2) of the European Patent Convention (EPC) provides that, among other subject matter, 'discoveries, scientific theories and mathematical methods' shall not be regarded as inventions for the purposes of the European patent law.[56] The EPO was required to consider the application of this provision in the case of *Howard Florey/Relaxin*.[57] The case involved an opposition to a patent for a DNA fragment coding for a human H2-preprorelaxin—a synthetic genetic sequence that had the same operative function as natural H2-relaxin, but lacked certain introns found in the naturally occurring sequence. The Opposition Division of the EPO held that:

> a substance freely occurring in nature is a mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if this substance can properly be characterised by its structure and it is new in the absolute sense of having no previously recognised existence, then the substance *per se* may be patentable.[58]

6.50 Following the implementation of the Directive of the European Parliament and *Council on the Legal Protection of Biotechnology Inventions* (the EU Biotechnology Directive) in 1998, the patentability of isolated genetic sequences is now expressly recognised under European law.[59] Article 5 of the EU Biotechnology Directive provides that, while the human body and 'the simple discovery of one of its elements, including a sequence or partial sequence of a gene' is not patentable,

> [a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.[60]

6.51 In the United States, biological material was first recognised as patentable subject matter by the United States Supreme Court in *Diamond v Chakrabarty*.[61] The issue before the Supreme Court was whether a genetically engineered bacterium

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55 'Trilateral Co-operation of the US, European and Japanese Patent Offices' (1988) 7 *Biotechnology Law Review* 159, 163 cited in R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71.

56 *European Patent Convention*, (entered into force on 7 October 1977).

57 *Howard Florey/Relaxin* [1995] EPOR 541. Upheld on appeal: *Relaxin/Howard Florey Institute* (Unreported, Boards of Appeal, European Patent Office, T0272/95, 23 October 2002).

58 *Howard Florey/Relaxin* [1995] EPOR 541, 548.

59 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998).

60 Ibid art 5(2). Certain provisions of the EU Biotechnology Directive were adopted by the EPO as supplementary interpretation of the EPC: see Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001). Rule 23(e) of the implementing regulations of the EPC contains a provision equivalent to art 5 of EU Biotechnology Directive.

61 *Diamond v Chakrabarty* 447 US 303 (1980).

capable of breaking down crude oil constituted patentable subject matter under United States law. Upholding the patent at issue, the Supreme Court held:

> [T]he patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter.[62]

6.52 The Supreme Court indicated that the concept of patentable subject matter under United States law included 'anything under the sun that is made by man'.[63] Dr Dianne Nicol and Jane Nielsen have commented that this decision 'laid the foundation for a growing body of case law and patent office decisions' in the United States supporting the patentability of a range of biological material, including whole organisms, gene, proteins, and cell lines.[64]

Criticisms of the discovery/invention distinction

6.53 Various criticisms have been made of the distinction between naturally occurring genetic materials and those that have been purified and isolated including the following:

- Isolated and purified genetic materials are structurally similar or identical to the form that exists in nature.
- Even if genetic material is isolated and purified, the characteristics of such materials—which are the 'useful' properties or information—are naturally occurring, not created by the person who isolates and purifies the material.
- Isolation and purification of genetic materials may not, in fact, occur because genetic materials (particularly genetic sequences) may be identified by computational techniques.[65]

Submissions and consultations

Manner of manufacture test

6.54 IP 27 did not specifically request submissions on the application of the 'manner of manufacture' test to inventions involving genetic materials and technologies. A few submissions did, however, comment on this issue.

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62 Ibid, 309–310.

63 Ibid, 308. The Supreme Court noted that there were limitations on patenting 'laws of nature, physical phenomena and abstract ideas': *Diamond v Chakrabarty* 447 US 303 (1980), 308.

64 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 23. See, eg, *Ex parte Allen* (1998) 2 USPQ 2d 1425 aff'd on appeal 846 F 2d 77 (1998) (polypoid oyster); *Moore v Regents of the University of California* (1990) 51 Cal 3d 120 (human cell line); *Amgen Inc v Chugai Pharmaceutical Co Ltd* (1991) 927 F 2d 1200 (genetic sequence).

65 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 27–28; D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 76.

6.55 The Australian Centre for Intellectual Property in Agriculture (ACIPA) considered that:

> the scope of patentable subject matter under the definition of 'manner of manufacture' in s 18(1) of the *Patents Act* [should] remain broad and flexible to deal with a range of different technologies.[66]

6.56 Similarly, Davies Collison Cave, proposed that the:

> adaptiveness and flexibility recognised in the ['manner of manufacture'] test should be retained so as to allow the concept of patentable subject matter to develop with future advances in technology.[67]

6.57 However, one submission suggested that there may be scope for making the test more transparent.[68] In addition, a small number of submissions suggested that the 'manner of manufacture' test does not seem to have placed any limits on patents claiming genetic materials to date.[69]

Discoveries

6.58 Many submissions asserted that genetic materials, and in particular genetic sequences, are discoveries and should not be patentable.[70] Most submissions that expressed such concerns came from participants in the research and healthcare sectors. Some submissions considered that genetic materials should not be patentable subject matter because an 'improved' version of naturally occurring genetic material cannot be developed (except, perhaps, by natural selection).[71] For example, Dr Graeme Suthers submitted:

> If a patent is granted on a process … a better process can conceivably be patented in the future. A patented process may be the only means of achieving some task today, but it need not be the exclusive means in the future. Conversely, a patent on a naturally occurring item or concept represents a very different sort of right. A naturally occurring entity cannot be improved, and there is no prospect of another person patenting a better version in the future.
>
> A law of nature or a physical attribute (such as $E=mc^2$ or the charge of an electron) cannot be patented because it exists independently of the inventor and there is no

66 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
67 Davies Collison Cave, *Submission P48*, 24 October 2003.
68 D Jackson, *Submission P43*, 20 October 2003.
69 Cancer Council Australia, *Submission P25*, 30 September 2003; L Palombi, *Submission P28*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.
70 For example, A Morley, *Submission P18*, 30 September 2003; A Bankier, *Submission P19*, 30 September 2003; Medicines Australia, *Submission P21*, 30 September 2003; D McFetridge, *Submission P23*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003.
71 New South Wales Health Department, *Submission P37*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

> conceivable way that it could be made redundant by a new patent. The same rationale must apply to a naturally occurring chemical such as a human DNA sequence.[72]

6.59 Similarly, the Australian Association of Pathology Practices Inc commented:

> Since an invention is normally taken to be the creation of something, which previously did not exist, it is difficult to see how a gene sequence can truly be considered an invention.[73]

6.60 A few submissions suggested that further consideration needs to be given to the distinction between a discovery and an invention in addressing whether genetic materials and technologies constitute patentable subject matter.[74] For example, Dr Michela Betta indicated that the distinction between natural and isolated genetic materials has not been adequately justified.[75] Luigi Palombi suggested that the concept of 'isolated and purified' genetic material (and other naturally occurring materials such as viruses) is a 'legal and scientific fiction': regardless of the process of isolation and purification, the fundamental characteristics of isolated genetic material remain the same as those found in nature.[76] Mr Palombi suggested that the comparison between inventions involving genetic materials and those involving chemical compounds is 'not helpful and is misleading' in determining whether genetic materials should constitute patentable subject matter and that the useful and commercially valuable characteristic of a genetic sequence is information—namely, instructions that code for a protein. He submitted that a chemical molecule that has medicinal properties merely acts as a catalyst for treatment in the body, and does not carry a 'biological formula' for the production of a protein, as does a gene.[77]

6.61 Some submissions that objected to the patenting of genetic sequences on the basis that such material is a discovery nonetheless considered that the acceptance of genetic sequences as patentable inventions may not be able to be revisited at this point in time.[78] Two submissions proposed that the practice of patenting human genetic materials should be acknowledged as 'regrettable and probably in error', but did not address the consequences of this for existing gene patents.[79]

6.62 Other submissions considered that the fundamental approach to the patenting of genetic materials required reform, despite the difficulties that this may present for

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72 G Suthers, *Submission P30*, 2 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

73 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003. See also D McAndrew, *Submission P14*, 30 September 2003; A Bankier, *Submission P19*, 30 September 2003.

74 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

75 M Betta, *Submission P20*, 30 September 2003.

76 L Palombi, *Submission P28*, 1 October 2003. See also E Milward and others, *Submission P46*, 20 October 2003.

77 L Palombi, *Submission P28*, 1 October 2003.

78 For example, A Morley, *Submission P18*, 30 September 2003.

79 Cancer Voices NSW Inc, *Submission P7*, 16 September 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003.

already granted gene patents.[80] These submissions suggested that many of the problematic aspects of gene patents stemmed from the failure to treat genetic materials as non-patentable discoveries.

> The messy confusing issues in gene patenting have arisen because the fundamental distinction between a discovery and an invention has not been addressed by the patent offices.[81]

6.63 Some submissions considered that, while an isolated genetic sequence should not be patentable subject matter, patent protection should be available for a 'significantly modified' genetic sequence or other genetic material.[82] For example, the Human Genetics Society of Australasia (HGSA) suggested that while gene fragments, spliced gene transcripts and proteins derived from human genes should not, in principle, be patentable, a combination of genes—for example, a human gene in a viral vector—or a recombinant protein could be.[83] The National Health and Medical Research Council (NHMRC) proposed different categories of inventions that should not be patentable, namely 'isolated genetic sequences *per se*' and 'inferred possible functions for a genetic sequence without the development of a new use'.[84]

6.64 However, a range of other submissions regarded the patentability of isolated and purified forms of naturally occurring material, including genetic material, as a well-established principle.[85] The Royal College of Pathologists of Australasia (RCPA) commented on the competing assumptions that affected whether genetic materials are regarded as discoveries or inventions:

> One view maintains that a novel isolated sequence cannot be regarded as an invention because nothing that did not exist before has been created … The other view, in essence, argues that a novel isolated substance is an invention because it has been rendered useful….Overall, this [latter] approach is socially preferable.[86]

6.65 IP Australia suggested that, if some genetic materials were considered to be non-patentable discoveries, there may be difficulties in determining which genetic inventions should be treated as discoveries.[87]

> Treating isolated genetic materials and genetic products as 'discoveries', and therefore excluding them from patentability, would not be a straightforward task.

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80 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

81 G Suthers, *Submission P30*, 2 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

82 Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003.

83 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003. See also G Suthers, *Submission P30*, 2 October 2003.

84 National Health and Medical Research Council, *Submission P52*, 31 October 2003.

85 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003.

86 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

87 IP Australia, *Submission P56*, 4 November 2003.

> Many genetic products and materials are semi-synthetic, and again there are questions regarding the scope and meaning of 'genetic materials' and 'genetic products'. For example, it would need to be determined whether such terms included:
>
> - proteins and peptides encoded by polynucleotides;
> - microarrays of genetic material;
> - processes and test kits using such entities;
> - methods of using information derived from genetic materials;
> - protein computer modelling and products thereof;
> - stem cells;
> - genetically modified organisms; and
> - gene therapy techniques.

6.66 Davies Collison Cave commented that claims that genetic materials are non-patentable discoveries may be based on a misunderstanding of the nature of patents.

> It is a common … misconception that a claim to such an 'isolated' material product somehow seeks to claim the material or product that exists in nature; such misconceptions reflect a general misunderstanding of the nature of patents and particularly of the role of the claims of a granted patent in defining the rights of the patent holder under the patent.[88]

6.67 Other submissions suggested that the argument that inventions involving genetic materials are discoveries does not adequately take into account the requirements that are relevant to an assessment of patentability.[89] For example, the procedures required to isolate and purify particular genetic materials are relevant to an assessment of the inventive step requirement. Further, mere isolation and purification of genetic material without the identification of some corresponding commercial application is an aspect of the assessment of 'usefulness', which in Australia is relevant to the manner of manufacture test and the disclosure requirements. These requirements are considered further in the following sections.

6.68 Other submissions stated that inventions involving genetic materials and technologies should continue to be patentable to ensure: the continued prosperity of the Australian biotechnology industry, the ability to attract foreign investment to fund biotechnology research, and the delivery of new products.[90]

ALRC's views

6.69 It is clear that the processes for identifying, isolating and purifying naturally occurring materials, including biological material such as genetic sequences, should be

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88 Davies Collison Cave, *Submission P48*, 24 October 2003.

89 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

90 R Barnard, *Submission P32*, 7 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.

patentable when those processes satisfy the other requirements of patentability, namely, when they are novel, inventive, useful and fully disclosed. However, legitimate concerns have been raised about the patenting of biological materials that occur in nature, but have been isolated and purified by 'man'. Isolated biological materials may, in some cases, replicate exactly the composition and characteristics of the material that occurs in nature. There are attractive arguments for the view that such materials should not have been treated as patentable subject matter. This view does not deny the legitimacy of patenting the processes for isolating and purifying naturally occurring materials, nor the legitimacy of patenting new chemical substances that are the product of human ingenuity.

6.70 However, the time for taking this approach to the patenting of products and materials has long since passed. Naturally occurring chemicals have, for decades, been regarded as patentable subject matter by patent offices in many jurisdictions—including Australia. This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are 'merely' complex organic compounds. This development was certainly not foreseen when the modern patent system was established, and a different approach might have been available when the issue first arose for consideration.

6.71 Nonetheless, the ALRC considers that a new approach to the patentability of genetic materials is not warranted at this stage in the development of the patent system for the following reasons:

- It would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions, and may adversely affect investment in the Australian biotechnology industry.

- It may fail to deliver the anticipated benefits because many pure and isolated genetic sequences do not exist in the exact same form in nature—for example, patented sequences may not contain the introns that are found in the naturally occurring material.

- Claims to genetic materials in their natural form (that is, in situ) do not constitute patentable subject matter in Australia or other jurisdictions.

- Arguments that genetic materials are not patentable inventions do not always adequately take into account the fact that the issue of 'patentable subject matter' is only one of a number of requirements that must be satisfied for patent protection to be obtained. In particular, patent protection cannot be conferred over genetic materials unless a use for such materials has been identified and adequately disclosed.

- It would be difficult to confine a reform to genetic materials and technologies on any rational basis, yet the extension of the reform to other fields—where the patenting of pure and isolated chemicals that occur in nature is uncontroversial—may have unknown consequences.

6.72 Nevertheless, the ALRC considers that the test for patentable subject matter under Australian law is problematic and may warrant reform. The 'manner of manufacture' test was considered in 1984 by the IPAC Report and in 2000 by the IPCRC Report, and was endorsed on both occasions. However, it has become apparent during the course of this Inquiry that there are problems with the test.

6.73 The ALRC is a law reform body whose statutory functions are to bring the law into line with current conditions, remove defects in the law, simplify the law, adopt more effective methods for administering the law, and provide improved access to justice.[91] From this perspective, it is indeed odd that the key concept of 'manner of manufacture' depends on a provision in a 380 year old English statute that has long since been repealed in the jurisdiction in which it was enacted; and that the relevant section of the statute is not reproduced in Australian patent legislation.

6.74 Moreover, when one looks at the terms of s 6 of the *Statute of Monopolies 1623* (reproduced earlier in this Chapter), it is apparent that they are beset with ambiguity and obscurity. For example, the grant of letters patent under s 6 does not extend to any manner of new manufacture that is 'generally inconvenient'. As discussed in Chapter 7, this requirement has been largely disregarded by Australian courts and IP Australia, to date. In addition, the discussion of the 'usefulness' requirement later in this chapter indicates that, while the usefulness of an invention is an aspect of the 'manner of manufacture' test and relevant to the disclosure requirement, the way in which the requirements interact in practice is unclear.

6.75 In the light of the ALRC's Terms of Reference, any general reform of the way in which Australian patent law should approach the concept of patentable subject matter is beyond the scope of the current Inquiry. It would involve in-depth analysis of the way in which the manner of manufacture test has been applied to a broad range of inventions—not merely those involving genetic materials and technologies—and require consultations with a more diverse group of stakeholders.

6.76 The ALRC considers that the Advisory Council on Intellectual Property (ACIP) would be an appropriate body to undertake such a broad ranging review. The ALRC envisages, however, that any reform of the 'manner of manufacture' test should take into account the final recommendations arising from this Inquiry, including those relating to the 'usefulness' of an invention claimed in a patent application.

91 *Australian Law Reform Commission Act 1996* (Cth) s 21.

Proposal 6–2. The responsible Minister should request the Advisory Council on Intellectual Property to review the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law.

Novelty

Novelty requirement under Australian law

6.77 An Australian patent will only be granted for an invention that is 'novel'. In other words, the invention must be new.[92] The novelty of each claim in a patent application is assessed against the 'prior art base' that comprises publicly available 'prior art information' as it existed at the 'priority date' of the relevant patent claim.[93]

6.78 The 'prior art base' includes information that is made publicly available in a document or a related series of documents, or through doing an act or a related series of acts, as well as information contained in a published patent application that has an earlier priority date than the application under examination.[94] Separate disclosures of an invention in more than one document, or by more than one act, will only be considered together if the relationship between the documents or the acts is such that a person skilled in the relevant art would treat them as a single source of information.[95]

6.79 The *Patents Act* provides that a limited range of disclosures will not preclude an invention satisfying the novelty requirement. As discussed further in Chapter 15, a 'grace period' was introduced into Australian law by recent amendments to the *Patents Regulations 1991* (Cth) (*Patent Regulations*). Consequently, any publication or use of an invention on or after 1 April 2002 made by, or with the consent of, an inventor is irrelevant to an assessment of novelty, provided a complete application for the invention is filed within 12 months of such publication or use.[96] For disclosures made prior to 1 April 2002, a more limited range of publications is excluded from an assessment of novelty.[97]

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92 *Patents Act 1990* (Cth) s 18(1)(b)(i) (standard patents); s 18(1A)(b)(i) (innovation patents).

93 Ibid s 18(1)(b)(i) (standard patents); s 18(1A)(b)(i) (innovation patents); sch 1. The significance of the 'priority date' is discussed in Ch 5.

94 Ibid s 7(1), sch 1. As a result of the *Patents Amendment Act 2001* (Cth), the definition of 'prior art base' has been extended to include both documentary publications worldwide and oral disclosures and acts done anywhere in the world. For existing patents, and patent applications filed prior to 1 April 2002, only acts occurring within the patent area (ie Australia) are relevant to an assessment of novelty.

95 *Patents Act 1990* (Cth) s 7(1). Seeking to connect disclosures made in more than one document (or act) to support a claim that an invention is not novel—often referred to as 'making a mosaic'—is not permitted under Australian law: see *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1989) 91 ALR 513; *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 292–293.

96 *Patents Regulations 1991* (Cth) rr 2.2, 2.3.

97 For example, publication of an invention at a 'recognised exhibition' or before a 'learned society': *Patents Act 1990* (Cth) s 24; *Patents Regulations 1991* (Cth) rr 2.2, 2.3.

6.80 The test applied to determine whether an invention is novel is known as the 'reverse infringement' test.[98] The prior art information must disclose all of the features of an invention—or all of the essential features—in clear, unequivocal and unmistakable terms in order for the invention at issue to lack novelty.

6.81 Whether or not a disclosure relating to an invention is 'publicly available' has been the subject of much judicial consideration. Public availability may exist even if the disclosure was limited to a small number of people,[99] was contained in a foreign language document that could be understood only by an expert in the field,[100] or if a limited number of embodiments of the invention were distributed to members of the public on a non-confidential basis.[101]

6.82 IP Australia has indicated that the novelty requirement will be satisfied in relation to inventions covering biological materials—including genes, genetic sequences and DNA—if the claimed invention is 'new in the sense of not being previously publicly available'.[102]

6.83 Patent laws in other jurisdictions express the novelty requirement in similar terms to the *Patents Act*.[103] The assessment of the novelty of inventions involving genetic materials and technologies in other jurisdictions does not appear to have raised issues that are materially different from those that arise under Australian patent law.

Submissions and consultations

6.84 IP 27 sought comments on the way in which the novelty requirement should apply to inventions involving genetic materials and technologies and whether any special considerations were relevant in assessing the novelty of genetic inventions.

6.85 The ALRC has received a range of submissions from participants in the research and healthcare sectors suggested that isolated genetic materials, and genetic sequences in particular, are not novel.[104] For example, the RCPA submitted:

> Natural materials are only novel in the sense that they have not previously been discovered by humans. Natural DNA sequences are the result of over a billion years of evolution and exist independent of inventors.[105]

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98 *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228; IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [3.2.1].

99 *Sunbeam Corp v Morphy-Richards (Aust) Pty Ltd* (1961) 180 CLR 98.

100 *Dennison Manufacturing Co v Monarch Marking Systems Inc* (1983) 66 ALR 265.

101 *Fomento Industrial SA v Mentmore Manufacturing Co Ltd* [1956] RPC 87.

102 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 31 March 2003.

103 See, eg, 35 USC s 102; *Patents Act 1977* (UK) s 2.

104 For example, Medicines Australia, *Submission P21*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003.

6.86 Some submissions also indicated that the application of the novelty requirement to gene patents would not be contentious if genetic sequences were regarded as naturally occurring material that is not patentable.[106]

6.87 However, other submissions considered that isolated genetic materials are capable of satisfying the novelty requirement for patentability under Australian law, in the same manner as other naturally occurring products that have been isolated and purified.[107] These submissions noted that genetic materials do not exist in nature in an isolated or purified form; and human intervention is required to achieve this. For example, GlaxoSmithKline submitted that:

> Genetic material, or DNA, is simply a chemical compound. To the extent that it can be regarded as a natural product, obtained by isolating it from nature, there is ample precedent for patenting natural products … Furthermore, DNA which is the subject of patent claims is frequently claimed as cDNA (complementary DNA) which is a copy of the genomic DNA but lacking the interspersed intron sequences. cDNA does not occur naturally (except in rare cases where a gene is not interrupted by introns) and is novel for that reason alone.[108]

6.88 Genetic Technologies Limited (GTG) commented that:

> The substantial body of granted global patents accepts that the isolation and purification of a newly discovered gene is sufficiently novel. The fact that it exists in every human body does not mean that it was identifiable or separable in any way and in this regard its identification, isolation and purification is rightly treated like any other naturally occurring organic compound.[109]

6.89 Similarly, IP Australia submitted that:

> newly isolated genetic materials are considered to satisfy the novelty requirement by all major patent offices, including IP Australia, because the isolated material has not existed before. In order to be acceptable, patent claims must not include within their scope anything which occurs already, either artificially or naturally. As a consequence, patents are not granted for genetic materials which already exist in the body of any living thing. The same principle applies to all chemical compounds which have been newly isolated from nature. In fact, it could be argued that most new materials or devices merely comprise naturally occurring components that have been arranged into a new state through human intervention. There appear to be no special considerations relevant in assessing the novelty of isolated genetic materials.[110]

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105 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

106 G Suthers, *Submission P30*, 2 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

107 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

108 GlaxoSmithKline, *Submission P33*, 10 October 2003. However, at least one submission took issue with the distinction patent offices worldwide have drawn between cDNA and genomic DNA: see Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003.

109 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

110 IP Australia, *Submission P56*, 4 November 2003.

6.90 IP Australia also emphasised that the date at which the novelty of an invention claimed in a patent application is assessed—the priority date—may be some time before a patented invention becomes known to the public.

> Concerns are sometimes raised over the validity of a particular patent because it is seen as merely being for a common, everyday practice … It is usually several years between the priority date and when a controversial patent comes to the attention of the general public. Such a period can be critical in rapidly developing technologies such as genetics.[111]

6.91 Some submissions commented on the application of the novelty requirement to inventions involving genetic materials and technologies. Dr Amanda McBratney and others submitted that, as a result of the amendments, in 2002, to the definition of 'prior art information' in the *Patents Act*,

> Australia's novelty requirements are … some of the most strict in the world; no further upward adjustment to accommodate gene-related inventions is necessary.[112]

6.92 Further, Dr McBratney and others submitted that changes to IP Australia's current approach in assessing the novelty of genetic materials and technologies are undesirable because they would represent a 'departure from the internationally accepted approach'.[113]

6.93 The Department of Industry, Tourism and Resources also considered that the test for novelty did not require reform:

> The particular sequence of nucleic acids that defines a gene lends itself for comparison with previously described genes that form the prior art base, allowing clear judgements on its novelty.[114]

6.94 Some other submissions agreed that the application of the novelty requirement to inventions involving genetic materials and technologies did not raise any particular issues that might not be raised by inventions over other types of technologies.[115]

ALRC's views

6.95 Inventions involving genetic materials and technologies do not appear to raise any special issues regarding the application of the novelty requirement. Many submissions suggested that genetic materials in a pure and isolated form are not 'new'

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111 Ibid.

112 A McBratney and others, *Submission P47*, 22 October 2003. See also Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

113 A McBratney and others, *Submission P47*, 22 October 2003.

114 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003. See also A McBratney and others, *Submission P47*, 22 October 2003.

115 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

because they are 'discoveries' of pre-existing material. For reasons considered earlier in this chapter, the ALRC is not persuaded that this approach should be adopted. The fact that genetic materials exist in nature in combination with other biological material does not mean that genetic materials are 'previously available', and therefore not novel, for the purposes of patent law.[116]

6.96 However, if an invention involving genetic material has been previously disclosed or described in prior art information—for example through one of the available databases of gene sequence information—then the novelty requirement might not be satisfied. The novelty of genetic inventions can only be determined for each patent application on a case by case basis in light of the prior art and should not be based on *a priori* assumptions relating to the field of technology.

Inventive or innovative step

6.97 Reports published in Australia and overseas have suggested that inventions involving certain types of genetic materials and technologies, particularly genetic sequences, may not satisfy the requirement that claims in a gene patent must involve an inventive step.

6.98 In 1992, a report of the House of Representatives Standing Committee on Industry, Science and Technology suggested that it was 'unlikely … that [genetic sequence] patents would pass the test of "non-obviousness"'.[117]

6.99 Similarly, a 2002 report of the United Kingdom's Nuffield Council on Bioethics (the Nuffield Council) considered that the technological advances in DNA sequencing may mean that isolating a genetic sequence can no longer be regarded as inventive, as it is a routine and industrialised process.[118] In its view, once a gene associated with a disease is identified, the use of the genetic sequence in gene therapy is obvious—particularly when such use is claimed on a purely speculative basis—and should seldom be protected by gene patents.[119]

6.100 A 2003 report produced by Professor William Cornish, Dr Margaret Llewelyn and Dr Michael Adcock for the United Kingdom Department of Health (the UK Report) also commented on the significance of the inventive step requirement in the context of inventions involving genetic materials and technologies:

> Patent Offices now lay emphasis on the standard requirement of inventive step (non-obviousness) as the requirement which will do most to retain genetic patenting within acceptable bounds … With the growth of bioinformatics techniques to achieve

116 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 29.
117 House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), 240–241.
118 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 29.
119 Ibid, 62.

> automated comparison of gene functions between different species, it becomes increasingly difficult to characterise the work as anything other than routine.[120]

6.101 Some academic consideration of the 'inventive step' requirement under Australian law has expressed similar views to those of the Nuffield Council. Dr Charles Lawson has argued that the cloning and sequencing of a gene is unlikely to amount to an inventive step because once information about an amino acid sequence is known, the cloning of a gene is the obvious next step to a person skilled in the art of molecular biology, armed with the common general knowledge in the field.[121] Similarly, David Keays has suggested that 'once a sequence for a specific gene has been isolated in one species, then to a person skilled in the art, it is the next obvious step to develop probes and identify the analogous protein in different species'.[122]

Inventiveness requirement under Australian law

6.102 Patent protection will only be granted in Australia for novel inventions that involve an 'inventive step' (in the case of an application for a standard patent) or an 'innovative step' (in the case of an application for an innovation patent).[123]

Inventive step

6.103 Inventive step is defined in s 7 of the *Patents Act* and requires a determination of whether an invention would have been obvious to a person skilled in the relevant art. This assessment is made in light of the common general knowledge as it existed in Australia before the priority date of the claim. It may also take into consideration prior art information before the priority date, that a person skilled in the art could reasonably be expected to have ascertained, understood and regarded as relevant.[124]

6.104 The High Court recently considered the inventive step requirement in *Aktiebolaget Hässel v Alphapharm Pty Ltd* (*Alphapharm*).[125] The Court held that, in assessing whether or not the inventive step requirement has been satisfied, the issue is whether a notional research group in the field 'would have been led directly as a matter of course to pursue one avenue in the expectation that it might well produce the [claimed compound]'.[126] The Court found that the results of a 'routine literature search' that have not entered into the common general knowledge are not relevant to an assessment of inventiveness.[127] Further, the Court stated that:

> The tracing of a course of action which was complex and detailed, as well as laborious, with a good deal of trial and error, with dead ends and the retracing of steps

120 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 32.
121 C Lawson, 'Patenting Genetic Materials: Old Rules May be Restricting the Exploitation of New Technology' (1999) 6 *Journal of Law and Medicine* 373, 379.
122 D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 79.
123 *Patents Act 1990* (Cth) s 18(1)(b)(ii) (standard patents); s 18(1A)(b)(ii) (innovation patents).
124 Ibid s 7(2), (3).
125 *Aktiebolaget Hassel v Alphapharm Pty Ltd* (2002) 194 ALR 485.
126 Ibid, 499.
127 Ibid, 500.

> is not the taking of routine steps to which a hypothetical formulator was taken as a matter of course.[128]

6.105 The *Patents Amendment Act 2001* (Cth) introduced changes to the assessment of the inventive step requirement by allowing 'mosaicing' of prior art information during patent examination.[129] 'Mosaicing' allows a patent examiner to assess the inventive step in light of two or more pieces of prior art information in combination, provided that a person skilled in the relevant art could reasonably have been expected to combine such information.[130] Prior to the amendment, patent examiners were only permitted to assess the inventive step in light of a single piece of prior art information, alone or combined with common general knowledge in the relevant art in Australia.

Innovative step

6.106 As discussed in Chapter 5, the innovation patent system is a 'second tier' of patent protection, which is intended to provide protection for 'lower level' inventions for which standard patent protection is not available.[131] To obtain an innovation patent, an applicant need only show that its invention involves an 'innovative step', rather than the 'inventive step' required to obtain a standard patent.

6.107 'Innovative step' is defined in s 7(4) of the *Patents Act*. An invention is taken to have involved an 'innovative step' if it makes 'a substantial contribution to the working of the invention' compared to the prior art, as understood by a person skilled in the relevant art in light of the common general knowledge as it existed in Australia at the priority date of the relevant claim.[132]

6.108 The term 'innovative step', and the difference between it and an 'inventive step' applicable to standard patents, have not yet been the subject of judicial consideration.[133] However, the Revised Explanatory Memorandum to a recent amendment to the *Patents Act* states that 'the test for *innovative step* will require an inventive contribution lower than that required to meet the *inventive step* threshold set for standard patents'.[134] The Revised Explanatory Memorandum further suggests that to satisfy the 'innovative step' requirement, an invention must differ from what is already known 'in a way that it not merely superficial or peripheral to the invention'.[135]

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128 Ibid, 501.

129 *Patents Amendment Act 2001* (Cth). The amendments apply to complete patent applications filed on or after 1 April 2002 (s 13).

130 *Patents Act 1990* (Cth) s 7(3). See also IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [4.1.4.2].

131 G McGowan, 'The New Innovation Patent System: Will It Work?' (2002) 76 *Law Institute Journal* 64; Advisory Council on Industrial Property, *Review of the Petty Patent System* (1995), rec 2.

132 *Patents Act 1990* (Cth) ss 7(4)–(6); IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [30.4.5.4].

133 The Federal Court has made only one decision in relation to innovation patents, but the case did not require consideration of the substantive requirements for an innovation patent: *Datadot Technology Ltd v Alpha Microtech Pty Ltd* [2003] FCA 962.

134 Revised Explanatory Memorandum to Patents Amendment (Innovation Patents) Bill 2000 (Cth), [6].

135 Ibid, [6].

Application to genetic materials and technologies

6.109 To date, consideration of how the inventive step requirement will apply to gene patent applications has primarily occurred at the Patent Office level and little guidance on this issue has been provided by the courts.[136]

6.110 The *Manual* indicates that patent examiners should adopt a 'problem-solution' approach to the requirement of inventive step.[137] The *Manual* instructs patent examiners to consider whether a claimed invention would fail to satisfy the test because 'the solution would have been obvious to any person of ordinary skill in the art who set out to solve the problem'.[138] Professor Andrew Christie and Melanie Howlett have explained the approach of IP Australia thus: a patent claim will not be regarded as involving an inventive step if,

> although the essential features of a claim have not been previously disclosed, the claimed features would be obvious to a person skilled in the particular art who set out to solve the problem and those features could be achieved as a matter of routine.[139]

6.111 A study by Christie and Howlett comparing the approaches of the Trilateral Patent Offices[140] and IP Australia in assessing patent applications claiming partial DNA sequences, such as expressed sequence tags (ESTs), concluded that IP Australia's approach to 'inventive step' exhibited similarities with the approaches of the EPO and JPO.[141] Christie and Howlett concluded that Australian patent examiners do not, as a general matter, consider that the 'application of standard techniques and practice in the art to isolate and sequence a gene from the tissue of interest' constitutes an inventive step, unless 'the isolated sequence possesses an unexpected property that provides an advantageous effect'.[142]

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136 For a discussion of relevant opposition proceedings, see C Lawson and C Pickering, 'Patenting Genetic Material: Failing to Reflect the Value of Variation in DNA, RNA and Amino Acids' (2000) 11 *Australian Intellectual Property Journal* 69.

137 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [4.1.6].

138 Ibid, [4.1.6.1], citing *HPM Industries Pty Ltd v Gerard Industries Ltd* (1957) 98 CLR 424, 437.

139 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 13.

140 The Trilateral Project (also referred to as the Trilateral Offices) is a cooperative venture of the USPTO, the EPO and the JPO. It has been in operation since 1983, primarily to facilitate the exchange of information regarding patent examination practices: United States Patent and Trademark Office, European Patent Office and Japanese Patent Office, *About Trilateral Cooperation*, <http://www.jpo.go.jp/saikine/tws/gen.htm> at 6 February 2004.

141 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 16.

142 Ibid, 15–16.

Inventiveness requirement in other jurisdictions

6.112 Under European patent law, the inventiveness requirement will not be satisfied by an invention involving isolated genetic sequences that have a structure closely related to existing sequences with a known function.[143] The EPO has stated:

> sequences as well as all other chemical compounds should solve a technical problem in a non-obvious manner to be recognised as inventive.[144]

6.113 For example, opposition to a patent granted to Myriad Genetics Inc on the BRCA1 gene[145] has been filed with the EPO on the basis that, among other things, the claim lacks an inventive step 'because it was possible to isolate the gene with the elements already known at the date of filing of the patent'.[146]

6.114 In the United States, the requirement of inventive step (known there as 'non-obviousness') has been applied to inventions involving genetic sequences in a different manner. Under United States law, a claimed genetic sequence may not be obvious even if the prior art discloses the structure of the protein for which the gene codes and the general methods for isolating a gene encoding a known protein.[147]

6.115 In adopting this approach, the United States Court of Appeals has stated that 'the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein'.[148] The Court considered that, in the absence of prior art information suggesting a particular DNA sequence encoded the relevant protein, a person skilled in the relevant art could not know the structure of that sequence without conducting appropriate experiments.[149] Further, the Court indicated that the existence of a general method of isolating genetic sequences is 'essentially irrelevant'.[150]

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143 European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Trilateral Project B3b: Mutual Understanding in Search and Examination: Report on Comparative Study on Biotechnology Patent Practices* (2001), Annex 2, 43. The Nuffield Council has agreed with this approach: Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 30, 50.

144 European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Trilateral Project B3b: Mutual Understanding in Search and Examination: Report on Comparative Study on Biotechnology Patent Practices* (2001), Annex 2, 43.

145 EP 705 902.

146 Institut Curie and Assistance Publique Hopitaux de Paris and Institut Gustav-Roussy, *Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer Associated with the BRCA1 Gene* (2002).

147 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 365. See also D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 83; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 30.

148 *Re Dueul* (1995) 51 F 3d 1552, 1558. Also: *Re Bell* (1993) 991 F 2d 781, 784. See generally, P Ducor, 'In re Deuel: Biotechnology Industry v Patent Law?' (1996) 18 *European Intellectual Property Review* 35.

149 *Re Dueul* (1995) 51 F 3d 1552, 1558–1559; *Re Bell* (1993) 991 F 2d 781, 784–785.

150 *Re Dueul* (1995) 51 F 3d 1552, 1559, citing *Re Bell* (1993) 991 F 2d 781.

6.116 This approach means that the 'non-obviousness' requirement under United States law may be easier to satisfy for inventions involving genetic sequences than in Europe. The Nuffield Council has criticised the United States approach as setting the threshold for 'inventiveness' too low. The Nuffield Council has argued that by applying the United States approach:

> the outcome of any complex procedure which could not have been predicted in advance, however familiar the procedure, will be judged inventive. While there is a sense in which such a result is 'non-obvious', that is not the sense relevant to questions as to whether a patent should be granted.[151]

Submissions and consultations

6.117 A number of submissions from healthcare and research sector organisations argued that the identification of genetic sequences or the linking of identified genetic sequences to a particular disease do not involve an inventive step.[152] For example, the Australian Association of Pathology Practices submitted:

> It can be argued that prior and public knowledge of the structure of DNA, how it codes for proteins, and the technique of sequencing, will allow someone expert in the field of genomics or proteomics to arrive at the derivation of specific gene sequences by diligent application rather than by ingenious invention … Similarly the application of gene sequencing and linkage disequilibrium analysis and subsequent mapping to link gene with disease is neither an invention nor is it novel, but is a discovery combined with the application of medical and scientific knowledge.[153]

6.118 Other submissions suggested that, although identification of genetic sequences may have had the required 'inventiveness' in the past, this is no longer true. The RCPA submitted:

> The invention of methods for sequencing DNA was one of the most significant and revolutionary advances in biological science. The sequencing of genes in the late 1970s and 1980s was a heroic task. Today, all reagents and equipment required for sequencing known and unknown DNA sequences are commercially available and it can be performed on an enormous scale … The process of identifying unknown DNA sequences is now commonplace and can easily be performed by someone skilled in the art, even if the sequence is novel and non-obvious.[154]

6.119 However, other submissions emphasised that whether a genetic invention represents an inventive (or innovative) step over the prior art can only be determined

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151 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 30.

152 G Suthers, *Submission P30*, 2 October 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

153 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003.

154 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. See also South Australian Government, *Submission P51*, 30 October 2003.

on a case-by-case basis. These submissions commented that determinations as to inventiveness should not be based on assumptions about the current state of the art in the field of technology to which the invention relates. For example, GlaxoSmithKline submitted:

> The assessment of inventive/innovative step takes place against the background of the state of the art at the relevant time. Certainly, the issue of whether identification or isolation of genetic material today is inventive/innovative will be affected by advances in sequencing technology and may perhaps mean that it is more difficult to meet the relevant test. However, each case must be assessed on its merits and while the way in which an invention was made is a relevant consideration for the assessment of inventive step, it is not the only or the determinative one: what is important is what the patent contributes over the prior art, not how the invention was made.[155]

6.120 A number of submissions were critical of the way IP Australia appears to apply the inventive step requirement to inventions involving genetic materials and technologies and, in particular, genetic sequences. The RCPA submitted:

> The test for inventiveness … now rests entirely on whether the sequence of a particular gene was not obvious. The test will apply in most instances because the sequence of bases of an unknown gene cannot be known before it was isolated.[156]

6.121 However, Dr McBratney and others stated:

> [I]n light of High Court authority [in *Alphapharm*], it is not valid to judge the obviousness of an invention by the fact that the avenue of research was obvious to try. *A fortiori*, whether those methods were complicated or required little work will be irrelevant; it is the invention as claimed that matters. The ease with which sequences are generated with today's technology should therefore not be seen as *ipso facto* depriving a new molecule of patentability.[157]

6.122 IP Australia indicated that few gene patents are associated with processes for isolating genetic material and identifying genetic sequences, and that only a small number of gene patents are now granted on the basis that the means of identifying and isolating genetic material was inventive.[158] IP Australia submitted:

> the inventive or innovative step of most granted patents is now associated with what can be achieved by using the isolated and identified genetic material. There continues to be innovation in the purpose for which a given polynucleotide can be put. The employment of a standard process of isolating genetic material does not automatically render unpatentable an application directed to a use of the genetic material. Similarly, isolating and identifying any type of chemical compound through standard techniques

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155 GlaxoSmithKline, *Submission P33*, 10 October 2003. See also Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71.

156 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; L Palombi, *Submission P28*, 1 October 2003; A Hughes, *Submission P42*, 20 October 2003; E Milward and others, *Submission P46*, 20 October 2003.

157 A McBratney and others, *Submission P47*, 22 October 2003.

158 IP Australia, *Submission P56*, 4 November 2003.

> does necessarily render unpatentable an application directed to the use of the compound. Hence, patents continue to be granted by IP Australia and the major IP offices for genes and parts thereof, on the basis that the applicant has inventively or innovatively determined a useful property associated with the gene or part thereof.[159]

ALRC's views

6.123 Some submissions to the Inquiry revealed a concern that the inventive step requirement under Australian law is not sufficiently stringent, at least with respect to genetic materials and technologies.[160] However, on the basis of information currently available to it, the ALRC is not inclined to propose any changes to the inventive step or innovative step requirement in the *Patents Act*, nor to how those requirements are applied by IP Australia to inventions involving genetic materials and technologies.

6.124 The ALRC agrees with those submissions that emphasised the importance of an 'inventive step' analysis being conducted on a case by case basis, and of not relying on *a priori* assumptions about inventiveness based on the field of technology to which the claimed invention relates.

6.125 It appears that IP Australia will typically require more than the identification and isolation of a genetic sequence to grant a gene patent, in line with the current state of the art in the genetics field. Recent changes to the definition of 'prior art information' in the *Patents Act* will also allow patent examiners greater access to prior art material in assessing the inventiveness of a particular genetic invention claimed in a patent application. The evolution of searching and cross-referencing systems in electronic databases is likely to result in links between documents being more readily established and may, therefore, lead to a more expansive interpretation of the information that is relevant in assessing the inventiveness of a patent application.[161]

6.126 In Chapter 8, the ALRC proposes procedures to assist patent examiners in their assessment of gene patent applications, including assistance in understanding the extent to which a particular invention may involve advances over the current state of the art. These proposals call for the establishment of an expert panel to provide advice to examiners on issues that may be raised by a particular gene patent application or a class of applications. The development of examination guidelines relating specifically to biotechnological inventions is also proposed.[162]

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159 Ibid.

160 See, eg, K O'Connell and J Cooke, 'Australia: A Patentee's Paradise' (2003) 25 *European Intellectual Property Review* 481.

161 T Moore, 'IP Australia's Experience with Biotech Inventions' (Paper presented at Legal Protection of Australian Biotechnology, Sydney, 30 May 2002). See also D Nicol, 'Gene Patents and Access to Genetic Tests' (2003) 11 *Australian Health Law Bulletin* 73, 76–77.

162 See Proposals 8–1 to 8–4.

Usefulness

6.127 There has been considerable debate about whether isolated genetic materials of various types fulfil the requirement that an invention be 'useful'. For example, the Nuffield Council has noted that:

> Since the development of large-scale DNA sequencing techniques over the past ten years, more DNA sequences have become available without a concomitant understanding of their function. As a result, many patent applications have been filed on genes or parts of genes without the demonstration of a 'credible utility'.[163]

6.128 In particular, concerns have been expressed that inventions involving ESTs and single nucleotide polymorphisms (SNPs)[164] may not display the requisite usefulness for patentability.[165] ESTs and SNPs may be used to identify previously unknown genetic sequences or as templates for expressing and characterising proteins for the purposes of further research. Questions have been raised about whether such uses should be sufficient to satisfy the concept of usefulness.[166]

6.129 Gene patents have also been criticised on the basis that they capture for a patent holder 'any number of possible applications even though those uses may be unattainable and unproven'.[167] In relation to this requirement under United States law, it has been proposed that:

> claim scope should be limited to uses that are disclosed in the patent application and that allowing claims to DNA itself would enable the inventor to assert claims to 'speculative' uses of the DNA that were not foreseen at the time the patent application was filed.[168]

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163 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 31.

164 See Ch 13 for a discussion of ESTs and SNPs.

165 C Baldock and others, 'Report Q 150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes' (2000) 22 *European Intellectual Property Review* 39; M Howlett and A Christie, 'An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)' (2003) 34 *International Review of Industrial Property and Copyright Law* 581; S Chambers, 'Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *American Intellectual Property Law Association Quarterly Journal* 53; R Eisenberg and R Merges, 'Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *American Intellectual Property Law Association Quarterly Journal* 1; R Eisenberg and R Merges, 'Reply to Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *American Intellectual Property Law Association Quarterly Journal* 61; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 32–34.

166 For example, the United States National Institutes of Health (NIH) filed patent applications claiming ESTs in the early 1990s, which were rejected by the USPTO for lack of utility. The applications were later abandoned: see P Ginsburg, 'Patentability and Technology Transfer Issues Relating to the NIH Patent Applications' (1994) 382 *Practising Law Institute Patents, Copyrights, Trademarks and Literary Property Course Handbook Series* 441.

167 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092, [1095].

168 Ibid, [1095].

Usefulness requirement in Australia

6.130 Australian patent law requires that an invention be 'useful', both as an express requirement in s 18 of the *Patents Act* and as an implicit requirement that an invention be a 'manner of manufacture'.

6.131 As interpreted by Australian courts, the express requirement of 'usefulness' in s 18 has a limited meaning. It requires only that the patent must produce the results that are promised upon a fair reading of the specification, and that the end in itself is useful.[169] Nicol and Nielsen have commented that the 'usefulness' criterion does not require that an invention be useful in the sense that it is worthwhile or commercially practical; only that if a particular result is claimed, it must be achievable.[170]

6.132 The 'manner of manufacture' requirement in s 18 has also been interpreted to include an assessment of the usefulness of an invention. In *NRDC*, the High Court indicated that to constitute a 'manner of manufacture' an invention 'must be one that offers some advantage which is material' and 'its value to the country is in the field of economic endeavour'.[171]

6.133 IP Australia's *Manual* indicates that an invention claimed in a patent application may not satisfy the 'manner of manufacture' test if it fails to indicate a specific use or practical application.

> Since an application must be in respect of a manner of manufacture, it is essential that the specification indicates an area of usefulness for the invention claimed, where such use is not self-evident. Where no such use is described (implicitly or explicitly), the claims might be directed to a mere scientific curiosity, discovery or idea.[172]

6.134 In the context of genetic sequences, the *Manual* notes:

> if a claim defines a DNA sequence, it would be insufficient to describe the sequence as being broadly useful as a 'probe'. The specification must disclose a specific gene which can be probed by the DNA sequence or a specific use.[173]

6.135 The usefulness of an invention may also be considered indirectly pursuant to the requirement in s 40 of the *Patents Act* that a complete specification adequately describe the use of the invention and how it can be achieved. If the invention cannot be

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169 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 277. See also *Martin Engineering Co v Trison Holdings Pty Ltd* (1989) 14 IPR 330.

170 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 32. See also *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 81 ALR 79, 96–98; *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205.

171 *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252, 275.

172 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.4.1].

173 Ibid, [8.4.2].

achieved on the basis of the description in the specification, it might fail to satisfy this sufficiency requirement.[174]

6.136 Currently, the usefulness of an invention is not an express requirement for examination of an Australian patent application. Usefulness is addressed only at the examination stage as an aspect of the 'manner of manufacture' and through the disclosure requirements. The Commissioner of Patents does not have to be satisfied that an invention is 'useful' under s 18(1)(c) before accepting a patent application.[175] 'Lack of utility' (as the objection is phrased) can be raised as an express objection only in revocation proceedings.[176] It is not a separate basis upon which a patent may be opposed or re-examined.[177] There may, however, be scope to raise the usefulness of an invention claimed in an accepted application in opposition proceedings on the basis of failure to satisfy the 'manner of manufacture' or disclosure requirements.[178]

Approach to usefulness in other jurisdictions

6.137 In other jurisdictions, the requirement that an invention be useful is more clearly expressed and is relevant in the examination of a patent application.

United States

6.138 Under United States law, the requirement is known as 'utility'.[179] United States courts have held that in order to satisfy the utility requirement, a patent application must disclose an invention that is 'practically useful'. The United States Supreme Court has explained the requirement in the following terms:

> Unless and until a process is refined and developed to the point of a substantial utility—where a specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.[180]

6.139 The Supreme Court also stated that an invention which 'either has no known use or is useful only in the sense that it may be an object of scientific research' is not patentable.[181]

6.140 In 2001, the USPTO issued revised examination guidelines setting out the way in which the utility requirement should be applied by United States patent examiners (the US Revised Utility Guidelines).[182] The Guidelines require a patent applicant to

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174 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 18.
175 *Patents Act 1990* (Cth) s 49(1) (standard patents); s 101B(2) (innovation patents).
176 Ibid s 138(3)(b).
177 Opposition, re-examination and revocation proceedings are discussed in Ch 9.
178 A McBratney and others, *Submission P47*, 22 October 2003; IP Australia, *Submission P56*, 4 November 2003.
179 35 USC s 101.
180 *Brenner v Mason* (1966) 383 US 519, 534–535.
181 Ibid, 535.
182 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092.

demonstrate a utility for an invention that is 'specific, substantial and credible'.[183] A patent applicant will demonstrate a 'specific and substantial' utility where 'any particular practical purpose' for the claimed invention is stated in the application, so long as such purpose is not 'throw-away', 'insubstantial' or 'non-specific'.[184] The Training Materials for Patent Examiners, released by the USPTO in conjunction with the US Revised Utility Guidelines, further explain that a 'substantial' utility is one that defines a 'real world' use; that is, no further research is required to identify an immediate benefit.[185] The requirement that the utility claimed for an invention is 'credible' will be satisfied if it is believable to a person of ordinary skill in the art, based on the totality of evidence and reasoning provided.[186]

6.141 The USPTO's comments on the US Revised Utility Guidelines indicate that a patent application claiming a purified and isolated genetic sequence may satisfy the utility requirement if 'it can be used to produce a useful protein or it hybridises near and serves as a marker for a disease gene'.[187]

European Union

6.142 Under European law, the criterion of usefulness takes the form of a requirement that an invention must be 'capable of industrial application'.[188] The EPC further provides that an invention shall be considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.[189]

6.143 Additional requirements apply with respect to the industrial applicability of inventions relating to the sequence or partial sequence of a gene, following the implementation of the EU Biotechnology Directive.[190] Article 5(3) of the Directive requires a patent applicant to disclose the industrial application of a sequence or partial sequence of a gene.[191] The UK Report commented that this provision appears to result in a two-fold disclosure requirement for inventions involving genetic sequences:

183 Ibid, 1098.

184 Ibid cl B(2)(a). The Guidelines state that use of a complex invention as landfill is an example of a purpose that will not be regarded as specific and substantial.

185 United States Patent and Trademark Office, *Revised Interim Utility Guidelines Training Materials*, <www.uspto.gov/web/offices/pac/utility/utilityguide.pdf> at 4 February 2004, 6.

186 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092 cl B(2)(a)(2). United States Patent and Trademark Office, *Revised Interim Utility Guidelines Training Materials*, <www.uspto.gov/web/offices/pac/utility/utilityguide.pdf> at 4 February 2004, 6.

187 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092, 1094.

188 *European Patent Convention*, (entered into force on 7 October 1977) art 52(1).

189 Ibid art 57.

190 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998).

191 The implementing regulations of the EPC were amended in 1999 to ensure consistency between the EPC and the EU Biotechnology Directive: Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001). Rule 23e of the implementing regulations of the EPC contains provisions equivalent to art 5 of the Directive.

> the applicant must disclose both the industrial application of the sequence or partial sequence within which the invention resides *and* the industrial application of the gene from which the sequence comes.[192]

6.144 Revised examination guidelines were issued by the EPO in December 2003. The guidelines address the 'industrial applicability' requirement in the context of inventions involving genetic sequences. They provide:

> A mere nucleic acid sequence without an indication of a function is not a patentable invention … In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could eg be that the sequence exhibits a certain transcription promoter activity.[193]

United Kingdom

6.145 Under United Kingdom law, an invention must also be capable of 'industrial application'.[194] The *Patents Act 1977* (UK) (the UK Patents Act), which implements the provisions of the EPC and EU Biotechnology Directive, provides that, subject to limited exceptions relating to methods of treatment for humans and animals, 'an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture'.[195] Further, patent applications claiming a genetic sequence must disclose the industrial application of that sequence.[196]

6.146 The United Kingdom Patent Office appears to have adopted a standard similar to the USPTO in assessing the 'industrial application' of biotechnological inventions. Referring to the US Revised Utility Guidelines, recent guidelines issued by the United Kingdom Patent Office relating specifically to biotechnological inventions (UK Biotechnology Examination Guidelines) indicate that:

> a 'specific, substantial, and credible' utility, is arguably the sort of disclosure, relating to industrial application that we would expect to appear in a UK application.[197]

6.147 The UK Biotechnology Examination Guidelines note that this approach has not yet been considered by courts in the United Kingdom, or by the EPO, and may not be

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192 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 62.
193 European Patent Office, *Guidelines for Examination in the European Patent Office* (2003) pt C, IV.4.5.
194 *Patents Act 1977* (UK) s 1(1)(c).
195 Ibid s 4.
196 Ibid sch A2, [6].
197 United Kingdom Patent Office, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office (November 2003)*, <www.patent.gov.uk/patent/reference/index>, [35].

upheld if challenged by a patent applicant.[198] Nonetheless, the Guidelines suggest that the approach has been followed in the EPO to date.[199]

New Zealand

6.148 Changes to the 'usefulness' requirement have also been recommended under New Zealand patent law. The NZ Report endorsed the approach set out in the US Revised Utility Guidelines and recommended that the *Patents Act 1953* (NZ) be amended to:

> require that usefulness should be a specific criterion that must be satisfied before a patent is granted, and that the usefulness must be credible, specific, and substantial.[200]

6.149 The NZ Report commented that such an amendment would make New Zealand patent law consistent with international practice.[201] Further, the Report suggested that including usefulness as a basis upon which a patent application may be rejected would reduce the frequency of revocation proceedings.[202] The NZ Report did not consider how this recommendation would fit with its recommendation that the 'manner of manufacture' test be retained as the test for patentable subject matter.

Analysis of approaches to utility in other jurisdictions

6.150 As discussed above, several jurisdictions have endorsed the approach adopted by the US Revised Utility Guidelines and interpret the requirement of utility (or industrial application) as requiring an applicant to disclose a 'specific, substantial, and credible' use for a claimed invention.

6.151 However, some criticisms have been levelled at the standard adopted in the US Revised Utility Guidelines. The Nuffield Council considered that the standard of utility established by the Guidelines is 'too low',[203] and suggested that a 'credible' utility merely required an applicant to claim a 'theoretically possible' purpose.[204] Given the state of genetic science and the ability to hypothesise the function of genetic material on the basis of homology with other species, the Nuffield Council considered that a theoretical purpose should not be a sufficient basis on which to award a patent.[205]

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198 Ibid, [35].

199 Ibid, [36]. The December 2003 version of the EPO's Examination Guidelines do not, however, refer expressly to the requirement of 'industrial applicability' being satisfied if the disclosed use of an invention is 'specific, substantial and credible': see European Patent Office, *Guidelines for Examination in the European Patent Office* (2003) Pt C, ch IV.

200 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003) Pt 2, [50].

201 Ibid Pt 2, [38].

202 Ibid Pt 2, [37].

203 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 31.

204 Similar comments were made in W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 31.

205 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 31.

6.152 The US Revised Utility Guidelines have also been criticised for not addressing adequately whether a patent should be awarded on the basis that only a single useful function for a particular gene has been disclosed. The commentary on the Guidelines state that to obtain a patent, an applicant is 'only required disclose one utility, that is teach others how to use the patent in at least one way';[206] the applicant is not required to disclose all possible uses. The result seems to be that other uses disclosed in the patent claims are not required to satisfy the standard of a 'specific, substantial and credible' utility. The UK Report stated that the UK Biotechnology Examination Guidelines appear to adopt a similar approach.[207]

Reform of the usefulness requirement under Australian law

6.153 In 2000, the IPCRC Report stated that the 'manner of manufacture' and 'utility' criteria 'have taken on greater importance in some new areas of technology, particularly biotechnology, where the dividing line between mere discovery and invention has become more difficult to define'.[208]

6.154 The IPCRC Report concluded that references to 'use' or 'utility' in current Australian law may conflict. The Report considered that 'it has not always been clear how this requirement [to demonstrate a defined use for an invention] has been imposed'.[209] The Report commented that the extent to which s 40 requires a patent application to contain a 'clear statement' of use or utility is not currently evident.[210]

6.155 Seeking to address these concerns, the IPCRC Report endorsed the approach adopted by the USPTO in the US Revised Utility Guidelines and recommended that IP Australia should ensure that 'the use described in the specification is specific, substantial and credible to a person skilled in the art'.[211] The IPCRC Report did not, however, recommend specific changes to the *Patents Act* or the *Patents Regulations.*

6.156 In response to the IPCRC's recommendations, the Australian Government indicated that it would ask IP Australia to ensure that examinations of patent applications address all aspects of the use of an invention being specific, substantial and credible.[212] However, the Government noted that the 'specific, substantial and credible' test is already broadly included within current examination practice under the 'manner of manufacture' and 'fair basis' requirements.[213] As noted above, IP Australia's *Manual* does not explain how the standard of 'specific, substantial and

206 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092, 1095, 1097.
207 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 31, 62.
208 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 152.
209 Ibid, 152.
210 Ibid, 152.
211 Ibid, 154.
212 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003.
213 Ibid.

credible' use is incorporated into the requirements for patentability under Australian law. IP Australia has stated that it is in the process of amending the *Manual* to address this issue.[214]

6.157 Dr Dianne Nicol and Jane Nielsen have suggested that a 'specific, substantial and credible requirement marks a radical change from the previous interpretations of the usefulness criterion by the Federal Court'.[215] Nicol and Nielsen stated that amendments to the *Patents Act* and *Patents Regulations* may be required to implement the recommendation in the IPCRC Report effectively.[216] They also suggested that s 45 of the *Patents Act* may need to be amended to allow patent examiners to consider the usefulness of an invention in examining an application.[217] Alternatively, they proposed that s 18(1)(a) of the *Patents Act* be amended to add the words 'as prescribed', and that utility requirements be provided in the *Patents Regulations*.[218]

Submissions and consultations

Reform of the usefulness requirement

6.158 Many submissions to the Inquiry supported reform of the 'usefulness' requirement, but the weight of opinion was that any change should apply to inventions involving all types of technology, not only genetic materials and technologies.[219]

6.159 A number of submissions expressed concern about the grant of patents over genetic inventions, where the use of such inventions is unknown or speculative.[220] For example, the Walter and Eliza Hall Institute of Medical Research (WEHI) submitted that although inventions involving genetic materials and technologies are not 'unique', gene patent applications render concerns about the utility requirement more evident

214 IP Australia, *Submission P56*, 4 November 2003.

215 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 367.

216 Ibid, 367; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 234–235.

217 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 367.

218 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 234.

219 For example, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A Hughes, *Submission P42*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

220 Cancer Council of New South Wales, *Submission P1*, 5 June 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

because 'genetic technologies have almost infinite *potential* uses'.[221] Similarly, the RCPA stated that:

> One of the major problems relating to the utility of genes is that we do not know the varied roles of most genes and claims about their actual or potential utility are largely grounded in ignorance.[222]

6.160 The South Australian Government suggested that changes to the 'usefulness' requirement may 'curb the practice by inventors of making theoretical claims of utility without any substantiated basis'.[223]

6.161 Luigi Palombi commented on the fact that gene patents often claim uses for an invention that are 'speculative and premature', [224] but did not believe that reforming the usefulness requirement would address this concern. Rather, he considered that the issue should be addressed by excluding patent claims to 'isolated or purified polyproteins and nucleotides' from the category of patentable subject matter.[225] Dr Graeme Suthers and the HGSA expressed a similar view and considered that only 'genetic processes' not 'genetic materials' should be patentable.[226]

6.162 Other submissions focused on the desired result of a strengthened usefulness requirement, rather than offering a view on how the requirement should be formulated. The Cancer Council of Australia submitted that there should be a 'clear and obvious purpose' stated in gene patent applications.[227] The NHMRC submitted that patent applications claiming genetic materials should 'disclose an invention that is of a practical use'.[228] The New South Wales Department of Health considered that patent applications should be required to indicate 'specific, proven uses' of the claimed invention, 'rather than merely establish that [an invention] had a commercial value'.[229]

6.163 Some submissions expressed the view that a reformed usefulness requirement could address concerns about the scope of gene patent claims.[230] WEHI submitted that

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221 Other submissions agreed that gene patents do not raise new issues with respect to the utility requirement: G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

222 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. Also: G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

223 South Australian Government, *Submission P51*, 30 October 2003.

224 L Palombi, *Submission P28*, 1 October 2003.

225 Ibid.

226 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

227 Cancer Council Australia, *Submission P25*, 30 September 2003. See also Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

228 National Health and Medical Research Council, *Submission P52*, 31 October 2003. Also: Queensland Government, *Submission P57*, 5 January 2004.

229 New South Wales Health Department, *Submission P37*, 17 October 2003.

230 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Caroline Chisholm Centre for Health

the criteria for patentability should 'restrict the claims of the patent to *demonstrated industrial* uses'.[231] The Queensland Government suggested that patent applicants should be required to demonstrate 'specific use(s)' and 'a monopoly granted only in relation to the demonstrated use(s)'.[232] Associate Professor Ross Barnard submitted that 'applicants should not be allowed to claim all possible (including unknown) future uses of a particular nucleic acid (or derived protein) sequence'.[233] Similarly, ACIPA proposed that:

> The *Patents Act 1990* (Cth) be amended to ensure that the standard of utility requires demonstrable, rather than theoretical, uses.[234]

6.164 Some submissions opposed such a reform and stated that gene patent claims should not be limited to the disclosed uses of a claimed genetic invention. GlaxoSmithKline submitted:

> The contribution of a novel gene sequence comprises both the gene sequence and the use, and also all the inherent (but unappreciated) properties of the sequence, which provide a springboard for further invention. Use-restricted protection thus provides no reward at all for the contribution of the novel gene sequence and its inherent properties.[235]

6.165 GlaxoSmithKline also suggested that, since the majority of human genetic sequences are already in the public domain:

> unrestricted protection is no longer possible for new inventions. New uses of known gene sequences can only be protected by use restricted protection anyway.[236]

6.166 Similarly, IP Australia stated that:

> It is common for patents to be granted for new chemical compounds, materials and devices per se, and for which all possible uses are not yet known. This does not provide the owner of the patent with the exclusive rights to all such uses. In all technologies, those who invent a new use for a patented product may be able to obtain a patent for this use, however it may be necessary to obtain a cross licence from the owner of the patent on the product.

Basis for examination of a patent application

6.167 A number of submissions supported including usefulness as a separate ground upon which a patent application should be examined.[237] However, few considered in

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Ethics Inc, *Submission P38*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

231 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

232 Queensland Government, *Submission P57*, 5 January 2004. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003. See also G Suthers, *Submission P30*, 2 October 2003.

233 R Barnard, *Submission P32*, 7 October 2003.

234 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

235 GlaxoSmithKline, *Submission P33*, 10 October 2003.

236 Ibid.

any detail how Australian patent law should be revised to allow the requirement of usefulness to be addressed in the examination of patent applications.

6.168 Some submissions endorsed the proposition that patent applications should be able to demonstrate a utility for the claimed invention that is 'specific, substantial and credible'—relying on the standard established by the US Revised Utility Guidelines—but did not address the changes that may be required to the *Patents Act* to produce this result.[238]

6.169 The Queensland Government and the NHMRC considered that changes to the way in which usefulness is treated under Australian law could be achieved either by changes to the legislation or by developing 'operational guidelines and procedures' for use by patent examiners.[239] GTG submitted that:

> The time may have come for there to be some codified requirement for a demonstration of the function and potential usefulness of … a sequence. In practice most gene patents already include this additional material.[240]

6.170 Other submissions considered that the 'usefulness' of a claimed invention was already adequately addressed by patent law. AusBiotech Ltd considered that the requirement of 'usefulness' was encompassed by the requirements of 'manner of manufacture' and 'sufficiency of disclosure'.[241] The Department of Industry, Tourism and Resources commented that:

> [the] statutory treatment relating to utility of genetic inventions has evolved since the early 1990s and that Australia has already adopted a requirement that the utility of an invention claimed in a patent applications must be 'specific, substantial and credible'.[242]

6.171 IP Australia explained how the usefulness of an invention is currently assessed in the examination of a patent application:

> Manner of manufacture—s 18(1)(a) … For an application to be in respect of a manner of manufacture, it is essential that the specification indicates an economic use for the invention claimed, where such use is not self evident. However, the use of the

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237 For example, Cancer Council Australia, *Submission P25*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Queensland Government, *Submission P57*, 5 January 2004.

238 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

239 National Health and Medical Research Council, *Submission P52*, 31 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

240 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

241 AusBiotech Ltd, *Submission P58*, 7 November 2003.

242 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

> invention does not necessarily have to be explicitly defined in the claims. Patent law in all major jurisdictions allows patents for products *per se*.
>
> Sufficiency—s 40(2)(a)—To be sufficient, an application must adequately describe the use of the invention and how it can be achieved.
>
> Fair basis—s 40(3)—To be fairly based, any use defined in the claims of an application must be reasonably supported by the description.[243]

6.172 IP Australia also addressed the extent to which a standard of 'specific, substantial and credible' use is already incorporated into the requirements for patentability, although it indicated that it was in the process of revising the *Manual* to make this more evident.

> *Specific use*: Currently, both Australian and US patent systems require an invention to have a specific use. The useful purpose of many inventions is self-evident, or may be implied in the specification (eg a motor vehicle). In such circumstances, no formal statement of use is necessary in Australia. However, a statement of use that is so broad that it merely indicates that an invention has been made, without disclosing what that invention is, is not sufficient …
>
> *Substantial use*: Certain aspects of substantial utility are covered by current Australian manner of manufacture and sufficiency requirements. To be a manner of manufacture, an invention must have a practical, real world function. To be sufficient, the person skilled in the art performing the invention must not have to resort to unreasonable experimentation to make it work …
>
> *Credible use*: Under Australian law, whether an invention actually works is assessed to some extent under the criterion of sufficiency. An invention that is obviously not believable, such as being contrary to the laws of nature, may be objected to on the grounds of insufficiency under s 40.[244]

6.173 The Department of Health Western Australia acknowledged that 'specific, substantial and credible' usefulness may already be incorporated into the assessment of the manner of manufacture and fair basis requirements. Nonetheless, the Department considered that amendments to the *Patents Act* were required 'so that a more stringent review of the usefulness of an invention becomes a criterion in the application process'.[245]

6.174 Without specifically supporting any reform to the usefulness requirement, IP Australia suggested ways in which a higher threshold of use could be achieved in Australian patent law, if such a reform was considered desirable.

- The new threshold may be incorporated into the manner of manufacture test, under which use is currently assessed during examination.

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243 IP Australia, *Submission P56*, 4 November 2003.
244 Ibid.
245 Department of Health Western Australia, *Submission P53*, 3 November 2003.

- An entirely new criterion of utility may be introduced, similar to that in the US and assessed during the examination process. Such a test may replace the existing usefulness test under s 18(1)(c), with its current focus on the meeting of promised results.[246]

6.175 As to the merits of such reforms, IP Australia commented that:

> the IPCRC report recommended retaining the manner of manufacture test in its current form, as Australia has on the whole benefited from its flexibility … some confusion may result if use were to continue to be assessed under manner of manufacture according to a lower threshold [and also under s 18(1)(c)].[247]

6.176 IP Australia considered that 'a more subtle assessment of whether an invention works is more difficult to do at the examination stage as it requires evidence' and sufficient expertise on the part of those assessing such evidence. It suggested that the costs of examination may increase if patent examiners needed to maintain this type of expertise or contract the analysis out to experts in the field.[248] GTG suggested that it would also increase the costs involved in development of an invention and delay publication.[249]

6.177 The development of guidelines relating to the application of the 'usefulness' requirement was supported in a number of submissions.[250] The South Australian Government supported the 'specific, substantial and credible utility' test now adopted under United States law, but indicated that guidelines should 'be developed to clarify what these terms mean'.[251]

6.178 Similarly, McBratney and others commented that, although in their view no amendments to the *Patents Act* were required with respect to the requirement of usefulness:

> given utility is such an important factor in keeping the register clear of questionable inventions, … further guidance on the issue would be desirable. A set of technology neutral and concisely drafted guidelines would clarify the lingering uncertainty surrounding the requirement.[252]

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246 IP Australia, *Submission P56*, 4 November 2003.
247 Ibid.
248 Ibid.
249 Genetic Technologies Limited, *Submission P45*, 20 October 2003.
250 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.
251 GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003.
252 A McBratney and others, *Submission P47*, 22 October 2003.

Grounds for challenge

6.179 A number of submissions considered that 'usefulness' should be a separate basis upon which patent rights may be opposed and re-examined.[253] GlaxoSmithKline stated that it would

> support a proposal to include utility as a ground of opposition or re-examination in order that all patents which are granted have been subjected to an appropriately stringent application of the patentability criteria.[254]

6.180 IP Australia considered that 'usefulness' should, at most, be a ground upon which a patent may be opposed:

> Assessment of use may be conducted as part of the opposition process without any obvious difficulty, as the process is designed to deal with higher evidentiary burdens. [However,] re-examination is similar to the examination process, in that it is conducted *ex parte* and is not designed to consider evidence to the extent that would be required for a thorough assessment of use.[255]

6.181 However, other submissions suggested that adding 'usefulness' as a basis upon which a patent may be opposed or re-examined may have limited effect. The South Australian Government commented that, as most genetic material was already protected by patents, amendments to the grounds for opposition of a patent may not have a significant impact.[256] The RCPA noted that it was unlikely that a challenge would be initiated against a patent that was not useful.[257]

6.182 AusBiotech Ltd did not support making 'lack of utility' a basis upon which patent rights may be opposed or re-examined. It stated that 'lack of utility' is only an assertion that an invention does not work for its stated purposes and does not 'impose a requirement to demonstrate a function for the genetic material'.[258]

6.183 Finally, one submission commented that 'usefulness' did not need to be added as a specific ground upon which a patent may be opposed because such an objection may already be raised as part of the manner of manufacture test.[259]

ALRC's views

6.184 The ALRC considers that the current way in which the usefulness of an invention is addressed in the requirements for patentability requires reform.

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253 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; A Hughes, *Submission P42*, 20 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Queensland Government, *Submission P57*, 5 January 2004.

254 GlaxoSmithKline, *Submission P33*, 10 October 2003.

255 IP Australia, *Submission P56*, 4 November 2003.

256 South Australian Government, *Submission P51*, 30 October 2003.

257 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

258 AusBiotech Ltd, *Submission P58*, 7 November 2003.

259 A McBratney and others, *Submission P47*, 22 October 2003.

6.185 Based on submissions and consultations to date, it is evident that there is considerable confusion about the application of the 'usefulness' requirement. These misunderstandings relate to: the extent to which an invention claimed in a patent application must be 'useful'; how such a requirement is imposed; the standard for satisfying this requirement; and the extent to which 'usefulness' can or should limit the scope of patent claims.

6.186 While usefulness is an important consideration in awarding patent protection for inventions involving all types of technologies, the ALRC endorses the opinion expressed in the IPCRC Report that:

> The criteria of 'manner of manufacture' and 'utility' have taken on a greater importance in some new areas of technology, particularly biotechnology, where the dividing line between mere discovery and invention has become difficult to define.[260]

6.187 Reform of the usefulness requirement would clarify IP Australia's assessment of the function and application (that is, the use) of genetic material claimed in a patent application. However, for the reasons discussed earlier in this chapter, adopting specific provisions in relation to genetic materials and technologies is generally undesirable. The present approach of the *Patents Act* is essentially 'technology-neutral' and is capable of accommodating inventions in new technological fields as they arise. Implementing specific patent requirements for genetic materials and technologies would diverge from the approach adopted in most other jurisdictions and may conflict with Australia's obligations under the TRIPS Agreement. The ALRC's proposals in relation to the usefulness requirement are not, therefore, limited to inventions involving genetic materials and technologies.

6.188 The ALRC considers that Australian patent examiners should assess, and report on, the usefulness of an invention claimed in a patent application as a separate requirement, and not merely as one of a number of considerations in determining whether an invention satisfies the 'manner of manufacture' and disclosure requirements in ss 18 and 40 of the *Patents Act*. The standard of usefulness demonstrated in an application should satisfy the 'specific, substantial and credible' test endorsed by the IPCRC Report. Such reforms would make Australian law consistent with approaches to usefulness adopted in other major jurisdictions. In addition, such a standard would preclude a patent being granted over a genetic invention when further research or investigation is required to understand its practical application.

6.189 In Chapter 8, the ALRC proposed that a single standard of proof should apply to all requirements for patentability assessed by patent examiners.[261] As discussed in that chapter, requiring different standards of proof for the various requirements for

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260 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 152.

261 See Proposal 8–5.

patentability—as currently provided in s 49 of the *Patents Act*—adds unnecessary complexity to the assessment of patent applications. The ALRC considers, therefore, that the balance of probabilities standard should also apply to the requirement of usefulness. This reform may go some way to addressing concerns that the claimed 'use' of a genetic invention may be speculative.

6.190 The ALRC also proposes that challenges to patent rights on the basis of lack of usefulness of an invention should not be confined to post-grant proceedings by way of revocation. As discussed in Chapter 9, opposition proceedings may be initiated before a patent is sealed and may result in the narrowing or withdrawal of patent claims, or a determination not to allow an accepted application to be sealed. The ALRC proposes that the grounds for opposition set out in the *Patents Act* should be amended to include lack of 'usefulness'. This would allow third parties to adduce evidence that may not have been available to the examiner during examination. On the other hand, the ALRC does not believe that usefulness should be included as a new basis upon which a patent or patent application may be re-examined. Re-examination proceedings are conducted *ex parte*, based largely on documentary evidence, and are not significantly different in form to the examination of patent applications.

6.191 The ALRC proposes that IP Australia should also develop guidelines to assist patent examiners in applying the proposed usefulness requirement. This could be done by means of IP Australia's *Manual*, which applies the requirements of patentability to inventions involving all types of technology. However, the examination guidelines relating to biotechnological inventions—proposed in Chapter 8—should address the application of the usefulness requirement specifically to biotechnological inventions.[262] In formulating these examination guidelines, the training materials developed by the USPTO in conjunction with the US Revised Utility Guidelines could provide a useful model.

Proposal 6–3 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to:

(a) include 'usefulness' as a requirement in the assessment of an application for a standard patent and in the certification of an innovation patent;

(b) require the Commissioner of Patents to be satisfied on the balance of probabilities that the criterion of usefulness is made out in order to accept an application for a standard patent or to certify an innovation patent; and

262 See Proposal 8–4.

(c) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation.

Proposal 6–4 IP Australia should develop guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should require that the claimed 'usefulness' must be 'specific, substantial and credible' to a person skilled in the relevant art.

Disclosure of an invention

6.192 Patent law in Australia and in other jurisdictions requires a patent specification to disclose an invention in such a manner as to allow a person skilled in the relevant art to make or carry out the invention.[263] This requirement is intended to ensure that the scope of protection afforded by a patent is commensurate with the technical contribution made by the claimed invention.

Disclosure requirements under Australian law

6.193 Section 40 of the *Patents* Act sets out the requirement that a patent specification must fully disclose an invention. Section 40(2)(a) provides that a complete specification must 'describe the invention fully, including the best method known to the applicant for performing the invention'. This is known as the 'sufficiency' requirement. Section 40(3) requires the patent claims to be 'clear and succinct and fairly based on the matter described in the specification'. This is commonly referred to as the 'fair basis' requirement.

6.194 The Federal Court considered the application of s 40 to biotechnology inventions in *Genetics Institute v Kirin-Amgen Inc (No 3)*.[264] In that case, the principal claim at issue was for an isolated and purified polypeptide having the primary structural conformation, and one or more of the biological characteristics, of naturally occurring erythropoietin. Heerey J held that the claim was permissibly wide because it disclosed the coding sequence for erythropoietin, which is a 'principle capable of

263 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 22.

264 *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30 (Heerey J). This decision was an appeal from the decision of the Deputy Commissioner of Patents in *Kiren-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557 discussed above. An appeal to the Full Federal Court was dismissed: *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106.

general application'.[265] Heerey J held that a claim in correspondingly general terms was therefore acceptable.[266]

6.195 It has been suggested, however, that broad claims of the type accepted by Heerey J in *Kirin Amgen* may no longer satisfy the disclosure requirement given the developments that have occurred in the field of genetics since that case was decided.[267] There is, however, little other specific guidance in Australian case law to assist patent examiners in determining how the disclosure requirements should apply to gene patents.

6.196 IP Australia's *Manual* sets out its approach to one particular issue in the application of the disclosure requirements to inventions in the biotechnology field, namely the question of 'reach through claims'.[268] A 'reach through' claim is one that seeks to claim right to a future invention on the basis of a currently disclosed invention.[269] In such cases, the *Manual* explains that:

> The specification generally discloses a new peptide or nucleic acid sequence, or a newly discovered link between a peptide or a nucleic acid and a specific disease or medical condition, and then claims compounds that interact with the peptide or nucleic acid and downstream uses of those compounds.[270]

6.197 The *Manual* states that 'reach through' claims that seek to cover compounds that interact with a specific peptide or nucleic acid sequence may fail to satisfy the 'fair basis' requirement because they are not claims to the product of the invention, but are merely directed to compounds inherently capable of interaction with the invention.[271] In addition, such claims may fail to satisfy the 'sufficiency' requirement because they provide insufficient information to enable the production of the full range of compounds that potentially fall within the scope of the claims.[272] The *Manual* suggests, however, that reach through patent claims to *methods* of using candidate compounds may not raise the same issues.[273]

Disclosure requirements in the United States

6.198 In the United States, the disclosure requirements are expressed in terms of 'enablement' and 'written description'.[274] Enablement requires a determination of whether a person skilled in the art can make and use the claimed invention without

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265 *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30, 46.
266 Ibid, 46.
267 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 33.
268 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10].
269 S Kunnin and others, 'Reach-through Claims in the Age of Biotechnology' (2002) 51 *American University Law Review* 609, 618–619.
270 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10.1].
271 Ibid, [10.10.3].
272 Ibid, [10.10.4]. 'Reach through' compound claims may also fail to satisfy the novelty requirement: IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10.2].
273 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10.5].
274 35 USC § 112.

undue experimentation.[275] The 'written description' requirement is satisfied if a patent specification describes the claimed invention in detail sufficient that a person skilled in the art can reasonably conclude that the inventor 'had possession' of the claimed invention.[276] Satisfaction of the enablement and written description requirements are closely linked to the utility requirement because the application of an invention claimed in a patent must be described such that a person skilled in the art could make and use the invention themselves on the basis of the patent claims.

6.199 Recent decisions of the Court of Appeals for the Federal Circuit, interpreting the 'written description' and 'enablement' requirements, have begun to elucidate disclosure requirements for particular types of inventions.[277] In addition, in 2001, the USPTO introduced new guidelines for the application of the written description requirement by United States patent examiners.[278]

Submissions and consultations

6.200 A range of submissions expressed concern about the scope of gene patent claims.[279] Concerns about the breadth of claims in gene patents were primarily directed to the potential adverse impact such claims may have on further research and the development of new procedures and products involving genetic materials and technologies.

6.201 Some submissions commented that broad claims are characteristic of patents relating to all types of new technologies, not only gene patents. IP Australia submitted:

> the scope of patent claims in any emerging technology tend to be of a broad nature in the early years of development. This had been the case for areas such as genetics, electronics, e-commerce and polymer chemistry. This recurring phenomenon has been likened to that of a 'gold rush', where claims to new areas are staked out before their full potential have been determined. It is not clear whether gene patent experience this phenomenon to an unusual or detrimental degree.[280]

6.202 Similarly, the Department of Industry, Tourism and Resources commented:

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275 *Re Wands* (1988) 858 F 2d 731.

276 United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099.

277 See, eg, *Regents of the University of California v Eli Lilly & Co* (1997) 119 F 3d 1559; *Enzo Biochem Inc v Gen-Probe Inc* (2002) 285 F 3d 1013. See also A Cantor, 'Using the Written Description and Enablement Requirements to Limit Biotechnology Patents' (2000) 14 *Harvard Journal of Law & Technology* 267.

278 United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099.

279 For example, Cancer Council Australia, *Submission P25*, 30 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; South Australian Government, *Submission P51*, 30 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

280 IP Australia, *Submission P56*, 4 November 2003.

> The interdependence of inventions and the speed at which they are occurring, poses challenges for patent authorities to strike the appropriate balance between the contribution made by the patent and the reward to which the patent is entitled. Such challenges are, however, not unique to biotechnology or genetic technologies.[281]

6.203 In addition, Davies Collison Cave suggested that:

> In many instances, the claims of a patent which is a pioneer in its field, both claims which involve genetic materials or technologies and claims in other fields of technology, are subjected to inappropriate criticism as being 'too broad' or the like, without consideration being given to the appropriate scope of the claim at the relevant date, that is at the priority date (and not at some later date, perhaps years after the priority date, when the criticism is expressed).[282]

6.204 While a number of submissions commented that the scope of gene patent claims appears to have narrowed in recent times,[283] a few submissions considered that broad gene patent claims are still an issue. For example, ACIPA stated that:[284]

> The evidence would suggest that patent attorneys are still drafting broad claims in respect of genes and gene sequences, and such claims are being accepted by the Patent Office in large part.[285]

6.205 The Department of Health and Ageing submitted that:

> While there is some evidence that patent offices worldwide have become alert to the practical anomalies of this area and that patents are becoming narrower, we may not be able to rely on this trend to overcome the potential problems. We would therefore support moves to impose reasonable limits on the breadth of gene patents.[286]

6.206 However, GlaxoSmithKline submitted that the debate about broad patent claims and the adequacy of disclosure:

> has centred around the misguided notion that published patent claims represent the eventual scope of valid and enforceable patent claims (which of they of course do not) and isolated anecdotal examples of perceived problem patents …
>
> It is our experience that there are relatively few human gene patents that have been granted and often those that have been granted (mostly in the US) have claims that are significantly limited compared with the claims as filed with the original application.[287]

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281 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

282 Davies Collison Cave, *Submission P48*, 24 October 2003.

283 National Health and Medical Research Council, *Submission P52*, 31 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

284 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

285 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003. See also R Barnard, *Submission P32*, 7 October 2003.

286 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004. See also South Australian Government, *Submission P51*, 30 October 2003.

287 GlaxoSmithKline, *Submission P33*, 10 October 2003. On the failure of some patent holders to take out gene patents in Australia, see D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical*

6.207 Another submission addressed the question of whether product per se claims are appropriate for inventions involving genetic sequences. The Department of Health and Ageing commented:

> If it is only subsequent research that reveals a useful function for the sequence, then it is arguable that the DNA sequence as an invented product (as distinct from its application to achieve the new useful function) … [should] not be patented.[288]

6.208 There was a divergence of opinion in submissions on whether the ability to patent novel and inventive applications of a patented product adequately addresses the potential adverse consequences of product per se claims in gene patents. IP Australia submitted:

> Claims for products per se are commonly granted in all fields of technology, such as a newly isolated chemical or a new manufactured material or device. Such claims do not actually give the patent holder exclusive rights to all uses of the product, whether known or unknown, during the patent term. Patents may be awarded for new uses of a patented product.

6.209 However, IP Australia also acknowledged that a patent covering the new use of a previously patented product can only be exploited if a licence to the original product patent is obtained and that, except in limited circumstances, a patent holder is not required to grant a licence to such a patent.

6.210 On the other hand, the Australian Health Ministers' Advisory Council submitted:

> Human gene patents, as commonly issued in Australia to date, cover all functions of the gene that are specifically explained in the patent, as well as any future developments that are based on use of the genetic information covered by the patent specifications. This allows the patent holder to restrict access to any research and development uses, which may subsequently be discovered in relation to their patented gene including, for example, diagnostic, therapeutic and/or pharmaceutical uses … Even where the inventor is able to negotiate a licence the patent holder could, in effect, be generously rewarded for a later innovation that may be only obliquely related to the original inventive step protected by their patent.[289]

6.211 Some submissions suggested that the fair basis and sufficiency requirements should be strictly applied 'to ensure that the claims in gene patents are narrowly defined'.[290] The Queensland Government considered that these requirements should be

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Analysis of Issues Facing the Australian Industry (2003) Centre for Law and Genetics Occasional Paper No 6, 40–49.

288 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

289 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003. See also L Palombi, *Submission P28*, 1 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

290 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003. See also R Barnard, *Submission P32*, 7 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003. GlaxoSmithKline also supported application of the disclosure

applied to ensure that a gene patent 'does not extend to every subsequent use of the patent that is beyond the scope of the patent'.[291] These submissions are discussed above in connection with the 'usefulness' requirement.

6.212 ACIPA questioned the way in which the disclosure requirements have been applied by IP Australia:

> It is submitted that genetic materials are presently being patented in a way that fails to recognise the potential additional inventiveness … by granting broad claims which include the additional potential of the sequence and other biological processes associated with that sequence.[292]

6.213 AusBiotech Ltd proposed amendments to the examination guidelines to address a particular issue relating to the application of the disclosure requirements to genetic materials. It suggested:

> At present some specifications rely on predictions made on the basis of sequence homologies or motifs for their 'disclosure' of function. Since these predictions are speculative, they do not constitute a true disclosure of invention … The patent examination guidelines should be amended, for example via a Practice Note, to require that the specification must disclose an actual *experimental* demonstration of at least one biological function of the nucleic acid or corresponding protein.[293]

6.214 Another submission indicated that difficulties in the application of the fair basis and sufficiency requirements may have resulted from a lack of available guidance—either in the form of guidelines or case law—to assist patent examiners in applying these criteria.[294]

6.215 A few submissions suggested that the disclosure requirements under Australian law were in need of reform. McBratney and others considered that the 'fair basis' requirement under Australian patent law is 'long overdue for review and reform', but that the difficulties raised by the requirement are not restricted to inventions involving genetic materials and technologies:

> [T]here is great ambiguity as to what experimentation and disclosure is necessary to sufficiently enable Australian and US patents, especially as relating to 'gene patents' and more so with potential drug targets and 'method of treating disease' patents. The same problem may also be encountered with 'composition of matter' patents which claim broad classes of analogue compounds for inhibiting certain targets or proteins. The question is where to draw the line.[295]

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requirements so that the scope of the patent 'matches, as best it can, the contribution of the invention to the art': GlaxoSmithKline, *Submission P33*, 10 October 2003.

291 Queensland Government, *Submission P57*, 5 January 2004.

292 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003

293 AusBiotech Ltd, *Submission P58*, 7 November 2003.

294 GlaxoSmithKline, *Submission P33*, 10 October 2003.

295 A McBratney and others, *Submission P47*, 22 October 2003.

6.216 McBratney and others proposed, however, that this issue may be addressed by the development of 'clear and adequate guidelines on "sufficiency" and "fair basis", similar to the US Patent and Trademark Office's Written Description Guidelines'.[296]

6.217 AusBiotech Ltd considered that patent claims over genetic materials should be treated similarly to patents claiming chemical and pharmaceutical compounds:

> It is very common for a pharmaceutical case to claim a novel compound in terms of a generic formula which may cover hundreds of millions of compounds, whereas the specification provides specific details of structure, synthesis and activity for only a very small minority of these compounds … Once a given nucleic acid sequence is identified and its function demonstrated, the making and testing of variations on this sequence is a matter of mere routine.[297]

6.218 The Australian Health Ministers' Advisory Council suggested that the approach under European patent law should be implemented; that is 'experimental evidence of biological function [should be] disclosed in the patent specification'.[298] In a similar vein, the Department of Health Western Australia considered that a patent applicant should be required to support the claims in a patent with 'at the bare minimum, "proof of concept" data'.[299]

6.219 Subject to the comments considered above, views expressed in submissions and consultations did not address how the sufficiency and fair basis requirements apply to inventions involving genetic materials and technologies, nor the specific difficulties with the way in which those requirements are applied by IP Australia to gene patent applications. Nonetheless, many submissions commented that special rules for the fair basis and sufficiency requirements should not apply to patent applications claiming genetic materials and technologies.[300]

ALRC's views

6.220 The ALRC recognises concerns that granting patent protection that may encompass all subsequent uses of an isolated and purified genetic sequence may be disproportionate to the inventive activity involved in identifying a genetic sequence and determining (at least) one of its functions. The value that such inventions contribute to the state of the art appears to reside primarily in identifying the purpose or function of an isolated and purified genetic sequence. On this view, limiting gene

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296 Ibid.

297 AusBiotech Ltd, *Submission P58*, 7 November 2003.

298 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

299 Department of Health Western Australia, *Submission P53*, 3 November 2003.

300 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

patent claims to the particular use or uses that the applicant claims and can demonstrate may be justifiable.

6.221 However, where a gene patent claims an isolated genetic sequence or other genetic material per se, the patent holder does not necessarily have the exclusive rights to all uses of the sequence or material. Later patents might be granted to another party for novel and inventive applications of the isolated genetic sequence or other material. In practice, the later patent holder may require a licence from the holder of the patent on the genetic product in order to exploit its invention. Conversely, the holder of the patent on the genetic product may require a licence in order to exploit the patent on the new application. A question remains as to whether these initial (broad) patent claims prevent access to third parties to develop new applications.

6.222 These concerns are addressed in later chapters of this Discussion Paper. The ALRC proposes reforms to facilitate access by others to patented genetic materials and technologies. These reforms include: changes to the Crown use and compulsory licensing provisions of the *Patents Act*; the introduction of an experimental use defence; and the development of guidelines by the Australian Competition and Consumer Commission regarding the relationship between competition law and intellectual property law.

6.223 In addition, the ALRC considers that some concerns about the effect of broad gene patent claims may be addressed to some extent by modifications of the examination practices of IP Australia and existing procedures for access to patented technology. In Chapter 8, the ALRC makes proposals to assist Australian patent examiners in examining gene patent applications and assessing inventions in new fields of technology.[301] The ALRC also proposes that each requirement for patentability should be subject to the same standard of proof—namely, the balance of probabilities. This would raise the threshold from a 'benefit of the doubt' standard, which currently applies to the examination of the fair basis and sufficiency requirements.[302]

6.224 An issue remains as to whether reform is also required to the way in which fair basis and sufficiency are applied to patent applications claiming genetic materials and technologies. The purpose of such reform would be to ensure that patent claims over genetic materials and technologies are commensurate with the contribution to the art made by a claimed invention. Submissions received by the ALRC to date have not addressed this issue in any detail. The ALRC therefore seeks further comments and information as to whether such reform is desirable and, if so, how it might be achieved.

301 See Ch 8.
302 See Proposal 8–5.

Question 6–1 Do the fair basis and sufficiency requirements in s 40 of the *Patents Act* adequately limit the scope of claims in gene patents? If not, what are the deficiencies in the way these requirements are applied, and what reforms are needed to address these concerns?

7. Exclusions from Patentability

Contents

Introduction

7.1 A 'patentable invention' under Australian law is one that satisfies the requirements set out in s 18 of the *Patents Act 1990* (Cth) (*Patents Act*)[1]—namely that the invention is novel and inventive (or innovative) when compared to the prior art, is useful, and has not been secretly used in Australia before the priority date.

1 *Patents Act 1990* (Cth) s 18(1) (standard patents); s 18(1A) (innovation patents). 'Invention' and 'patentable invention' are defined in the *Patents Act 1990* (Cth) sch 1.

7.2 As discussed in Chapter 6, the *Patents Act* also requires that the invention fall within the concept of patentable subject matter under Australian law. Subject to certain exclusions expressly provided in the *Patents Act*, this requirement is primarily expressed in terms of the 'manner of manufacture' test.

7.3 Chapter 6 examined arguments that certain types of inventions involving genetic materials and technologies are not, or should not be, patentable on the grounds that such inventions do not satisfy patentability requirements—including on the basis that the subject matter constitutes a 'discovery' rather than an invention.

7.4 It has also been suggested that certain types of inventions involving genetic materials and technologies should not be patentable—even assuming that the inventions meet the requirements of patentability—on the ground that the inventions are not, or should not be, patentable subject matter. This amounts to a claim that certain genetic materials and technologies should fall within an exclusion from patentability.

7.5 This chapter begins by examining the existing exclusions from patentability contained in the *Patents Act* and their possible application to genetic materials and technologies. The chapter then outlines grounds on which some genetic materials or technologies might be excluded from patentability. These would involve new exclusions from patentability:

- for genes and genetic sequences specifically;
- for methods of medical treatment; or
- on social or ethical grounds.

Existing exclusions from patentability

7.6 The *Patents Act* excludes certain categories of subject matter from patentability and grants the Commissioner of Patents the discretion to refuse a patent application for other types of inventions.

7.7 As discussed below, 'human beings, and the biological processes for their generation' are excluded from patentability, as are 'plants and animals and the biological processes for the generation of plants and animals', although in the latter case only with respect to innovation patents.[2]

7.8 The Commissioner of Patents also has discretion to refuse a patent application where the use of the invention would be 'contrary to law' or where the invention is a food or medicine produced by admixture.[3] As these exclusions are discretionary, it is

2 *Patents Act 1990* (Cth) s 18(2) (standard patents); s 18(2), (3) (innovation patents).
3 Ibid s 50 (standard patents); s 101B(2)(d), (4) (innovation patents).

possible, in theory, for the Commissioner to accept applications for such patents notwithstanding that the patent falls within a class of excludable subject matter.

7.9 The existing grounds of excluded and excludable subject matter are limited and have been interpreted narrowly by IP Australia.

Human beings and the biological processes for their generation

7.10 'Human beings, and the biological processes for their generation' are excluded from patentability under s 18(2) of the *Patents Act*. To date, the scope of this provision has not been considered judicially, and its precise scope remains unclear. IP Australia's *Manual of Practice and Procedure* (the *Manual*) states that inventions that are 'clearly encompassed' by the provision include:

- human beings, foetuses, embryos or fertilised ova;
- methods of *in vitro* fertilisation or cloning methods that generate human beings; and
- processes—beginning with fertilisation and ending with birth—that are wholly biological and result in a human being.[4]

7.11 It seems unlikely that s 18(2) excludes many inventions involving genetic materials and technologies from patentability. In particular, the *Manual* states that 'human genes, tissues and cell lines' are outside the scope of s 18(2) and will be patentable, if the other requirements set out in the *Patents Act* are satisfied.[5]

7.12 The application of s 18(2) of the *Patents Act* to inventions involving human stem cells and stem cell technologies has been a matter of some debate.[6] This issue is discussed in Chapter 16.

Contrary to law

7.13 Section 50(1)(a) of the *Patents Act* provides that the Commissioner of Patents has the discretion to refuse an application for a standard patent on the grounds that its use would be 'contrary to law'.[7]

7.14 The *Manual* states that the discretionary power conferred on the Commissioner of Patents under s 50(1)(a) should only be invoked 'in the clearest of circumstances'.[8]

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4 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1]–[8.5.2].

5 Ibid, [8.5.1]. See also D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 241.

6 See Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [8.70]–[8.75]; M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448.

7 The Commissioner may revoke an innovation patent on equivalent grounds: *Patents Act 1990* (Cth) s 101B(2)(d). See Ch 8.

The *Manual* also states that the provision should only be relied on to exclude an invention if an unlawful use, and no alternative or additional lawful use, has been described in the application.[9]

7.15 Section 50(1)(a) will have limited application to inventions involving genetic materials and technologies because, in general, a patent applicant will be able to identify a lawful use for such an invention.

Food or medicine produced by mixture

7.16 The Commissioner of Patents may also refuse to accept an application for a standard patent that claims an invention capable of being used as a food or medicine for humans or animals and that is merely a mixture of known ingredients, or is a process to produce such substance by mere admixture.[10] It is unlikely that this exclusion would apply to genetic materials and technologies or other biotechnology inventions.[11]

Plants and animals

7.17 Finally, with respect to innovation patents only, plants and animals and the biological processes for the generation of plants and animals are not patentable inventions.[12] This provision is currently under review by the Advisory Council on Intellectual Property (ACIP). ACIP released an Issues Paper in 2002 and is conducting further consultations.[13]

Possible new exclusions from patentability

7.18 The existing exclusions from patentability do not place any significant constraints on the patenting of genetic materials or technologies. It has been suggested that some types of inventions involving genetic materials and technologies should not be patentable subject matter. The following section discusses possible new exclusions from patentability relevant to genetic materials and technologies.

Genetic materials and technologies

7.19 One way to exclude genetic materials and technologies, or some subset of them, from patentability would be through an exclusion directed specifically to genetic inventions.

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8 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.6.1].

9 Ibid, [8.6.3]–[8.6.4].

10 *Patents Act 1990* (Cth) s 50(1)(b). The Commissioner may revoke an innovation patent on equivalent grounds: *Patents Act 1990* (Cth) s 101B(4). See also IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.7].

11 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 39.

12 *Patents Act 1990* (Cth) s 18(3). This exclusion does not apply if the invention is a microbiological process or a product of such a process: *Patents Act 1990* (Cth) s 18(4).

13 Advisory Council on Intellectual Property, *Innovation Patent: Exclusion of Plant and Animal Subject Matter* (2002).

7.20 An exclusion from patentability applicable to inventions involving genetic materials was proposed in 1990 by Senator John Coulter (Australian Democrats) during consideration of the Patents Bill 1990 (Cth). The amendments, which were rejected by the Senate Standing Committee on Industry, Science and Technology (Senate Standing Committee), would have presumptively excluded genes, genetic material and genetically modified organisms from patentability.[14] The proposed amendment stated:

> (2) A patentable invention shall not include the following:
>
> (a) a gene or genes, whether derived from cells or chemically synthesised;
>
> (b) a genome either complete or one which has had genetic material added or deleted;
>
> (c) the altered organism (human, plant, animal or micro-organism) produced by having its genome manipulated; and
>
> (d) the progeny of the genetically engineered organism which also carry the altered genome.
>
> (3) Sub-section (2) does not limit the patenting of technologies, techniques and processes involved in the carrying out of genetic engineering.[15]

7.21 In 1996, Senator Natasha Stott Despoja proposed a similar amendment to the *Patents Act*.[16] The proposal provided that naturally occurring genes, gene sequences, or descriptions of the base sequence of a naturally occurring gene or gene sequence would not be regarded as either novel or inventive for the purposes of s 18 of the *Patents Act*.[17] Senator Stott Despoja put forward the proposal again in 2001[18] and the proposed amendments were re-tabled in 2002. There has been no further parliamentary consideration of them.[19]

Reform proposals in other jurisdictions

7.22 There have been suggestions in other countries that some genetic materials should not be patentable. In 2001, the Canadian House of Commons Standing

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14 Senate Standing Committee on Industry Science and Technology, *Report on the Consideration of the Patents Bill 1990* (1990), 2; Commonwealth of Australia, *Parliamentary Debates*, Senate, 20 September 1990, 2653 (J Coulter). The Senate Standing Committee adopted an alternate provision proposed by Senator Brian Harradine which is now embodied in s 18(2) of the *Patents Act*. See further Ch 16.

15 Senate Standing Committee on Industry Science and Technology, *Report on the Consideration of the Patents Bill 1990* (1990), 2–3.

16 Patents Amendment Bill 1996 (Cth); Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 June 1996, 2332 (Natasha Stott Despoja).

17 The terms 'genes', 'gene sequences' and 'descriptions of the base sequence of naturally occurring gene or a naturally occurring gene sequence' were not defined, but it appears that the amendment was intended to apply to both human and non-human genetic material.

18 As a proposed amendment to the Patents Amendment Bill 2001 (Cth): Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 September 2001, 28195 (N Stott Despoja).

19 Parliament of Australia, *Senate Daily Bills Update*, <www.aph.gov.au/parlinfo/billsnet/billsupd.pdf> at 19 January 2004.

Committee on Health (the Canadian Standing Committee) expressed concern that the *Patent Act 1985* (Can) did not specifically disallow patenting with respect to human genes, DNA sequences and cell lines. The Canadian Standing Committee recommended that the patenting of 'human materials' should be prohibited.[20]

7.23 However, in general, such a sweeping approach to reform has been rejected. For example, the Ontario government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (the Ontario Report) rejected the Canadian Standing Committee's call for a complete ban on gene patents and instead suggested a range of proposals to achieve an 'appropriate balance between the public interest in accessing the health benefits offered by genetic technologies and maintaining the economic and commercial incentives that fuel this research'.[21]

7.24 There have also been a number of international statements suggesting that genes and genetic sequences should be excluded from patentability. The United Nations Educational, Scientific and Cultural Organisation (UNESCO) *Universal Declaration on the Human Genome and Human Rights* states that 'the human genome in its natural state shall not give rise to financial gains'.[22] Similarly, the International Bioethics Committee of UNESCO has stated 'there are strong ethical grounds for excluding the human genome from patentability'.[23]

7.25 In March 2000, the European Parliament called on the European Patent Office (EPO) to ensure that patent applications in Europe do not violate the principle of non-patentability of human genes or cells 'in their natural environment'.[24] This resolution, originally made in the context of concerns about human cloning, was subsequently reiterated in connection with the patenting of the BRCA1 and BRCA2 genes associated with pre-disposition to breast and ovarian cancer.[25] However, as discussed in Chapter 6, genetic materials are generally considered to be patentable if they have been isolated from nature.

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20 House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families* (2001), rec 34.

21 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), iii, 31–32.

22 *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, UNESCO, art 4.

23 International Bioethics Committee of UNESCO, *Advice of the IBC on the Patentability of the Human Genome* (2001).

24 European Parliament, *Bulletin EU 3-2000 Human Rights (5/11): Parliament Resolution on the Decision by the European Patent Office (EPO) with Regard to Patent No EP 695 351 Granted on 8 December 1999*, <http://europa.eu.int/abc/doc/off/bull/en/200003/p102005.htm> at 19 January 2004.

25 European Parliament, *Bulletin EU 10-2001 Human Rights (3/9): Parliament Resolution on the Patenting of BRCA1 and BRCA2 Genes*, <http://europa.eu.int/abc/doc/off/bull/en/200110/p102003.htm> at 19 January 2004.

Submissions and consultations

7.26 Some submissions supported a specific amendment to the *Patents Act* to exclude genetic materials from the scope of patentable subject matter.[26] In general, however, submissions focused more on the application of the existing patentability requirements to genetic materials and technologies—and on whether the subject matter of some gene patents constitutes a 'discovery' or an invention—rather than on whether gene materials or technologies should be excluded altogether from patentable subject matter.[27]

7.27 Some submissions considered that the introduction of an exclusion from patentability was not necessary to address ethical and social concerns raised by patents on genetic materials,[28] or were concerned about the negative impact of such an exclusion. For example, the Cancer Council of Victoria noted that, while gene patents could have a negative impact on access to genetic testing 'there are risks in unilateral modification of existing laws, particularly retrospective changes'.[29]

7.28 Other submissions commented that, as a general matter, technology-specific provisions might not be effective. IP Australia submitted:

> Where it can be avoided, IP Australia strongly recommends against introducing technology-specific laws and procedures. Such measures invariably lead to uncertainty over the bounds of the subject matter, involved debate over individual cases, and increased cost and uncertainty for users of the system. Such measures may eventually prove at least partially ineffective, as it may be possible to draft claims to avoid the intent of the exclusion. Defining the bounds of a technology is a non-trivial issue.[30]

7.29 Similarly, it was suggested that the introduction of specific exclusions from patentability might increase the complexity of and costs involved in obtaining patent protection.[31] Dr Amanda McBratney and others suggested that to adjust patent legislation each time a new technology was perceived to raise special issues would produce an unwieldy patent system.[32]

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26 D McAndrew, *Submission P14*, 30 September 2003; G De Ruyter, *Submission P3*, 14 August 2003; J Graham, *Submission P5*, 26 August 2003; L Palombi, *Submission P28*, 1 October 2003. Luigi Palombi submitted that isolated genetic material should be excluded as patentable subject matter under the *Patents Act*, and that a new *sui generis* intellectual property right should be created (to be known as a 'genetic sequence right').

27 These submissions are discussed in Ch 6.

28 For example, National Health and Medical Research Council, *Submission P52*, 31 October 2003.

29 Cancer Council Victoria, *Submission P16*, 30 September 2003. See also G Suthers, *Submission P30*, 2 October 2003.

30 IP Australia, *Submission P56*, 4 November 2003. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

31 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

32 A McBratney and others, *Submission P47*, 22 October 2003.

7.30 Submissions generally supported amendments to, and interpretation of, patent laws in a technology-neutral manner. It was said that this would maintain the ability of patent law to adapt flexibly to new technologies as they arise.[33] For example, Davies Collison Cave submitted:

> In our view, it is not appropriate to propose amendments to the patent legislation which are specific to an area of technology. Even if such changes appear sensible and reasonable at their time of instigation, this type of approach has the potential to reduce the flexibility of the system and create difficulties in responding to demands of future technological development.[34]

7.31 The Royal College of Pathologists of Australasia (RCPA) noted that genes could be excluded from patent protection under Australian law on the basis that such patents represent a 'hazard to society'. However, the RCPA commented that such an exclusion would amount to 'a major deviation from the spirit and the letter of current patent law in Australia and the TRIPS Agreement'.[35] Other submissions referred to the potential for detrimental effects on the biotechnology industry and the development of new genetic products and technologies, if genetic materials were not patentable.[36]

ALRC's views

7.32 In the ALRC's view, there are significant impediments to amending the *Patents Act* to exclude genetic materials from patentability. In Canada, it has been observed in respect to such an exclusion that:

> The momentum of the biotech industry, the long history of patentability of gene sequences and the impact and complexity of existing international trade agreements make this, at present, an impractical and unrealistic option.[37]

7.33 Similar considerations apply in the Australian context. Importantly, excluding genetic materials from patentability could have detrimental effects on the Australian biotechnology industry. Dr Dianne Nicol has commented that jurisdictions that have substantial biotechnology research and commercialisation programs appear to agree that patents on inventions involving gene sequences should generally be permitted.[38] While the fact that other jurisdictions generally accept patents on genetic sequences is not conclusive of the approach that should be adopted in Australia, it is reason to question whether amending the *Patents Act* to implement such an exclusion from patentability is desirable.

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33 Ibid; Davies Collison Cave, *Submission P48*, 24 October 2003.

34 Davies Collison Cave, *Submission P48*, 24 October 2003.

35 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

36 R Barnard, *Submission P32*, 7 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003.

37 T Caulfield and others, 'Genetic Technologies, Health Care Policy and the Patent Bargain' (2003) 63 *Clinical Genetics* 15, 16.

38 D Nicol, 'Gene Patents: The Ultimate Snatch' (Paper presented at Hatching, Matching, Snatching and Dispatching, AIHLE 7th Annual Conference, Newcastle, 27–30 June 2002), 9; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 232.

7.34 Submissions encouraged the ALRC to consider the global nature of the biotechnology industry and patent rights.[39] The Australian biotechnology industry relies on foreign investment and partnerships with overseas entities to commercialise the results of research involving genetic materials and technologies. Australia's adoption of a position that diverges from the general international consensus would likely have adverse implications for Australia's participation in the global biotechnology market and the extent to which foreign entities participate in, and provide capital investment for, research and commercialisation of genetic materials and technologies in Australia.

7.35 Further, excluding genetic materials from patentability may conflict with Australia's international obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[40] As discussed in Chapter 4, the TRIPS Agreement provides that patents shall be available for any inventions, and that patent rights shall be enjoyable without discrimination as to 'the field of technology'.[41] Excluding genetic materials from patentability may be inconsistent with this provision.

7.36 Even assuming that the express exclusion of genetic materials from patentability is consistent with Australia's obligations under the TRIPS Agreement, it may be argued that such an exclusion would not provide a complete, or even a satisfactory, solution to the problems said to be associated with the recognition of some gene patents.[42] There would be considerable difficulty involved in defining the scope of any exclusion relating to genetic materials—for example, would proteins produced by genetic materials be covered? Dr Dianne Nicol and Jane Nielsen have suggested that excluding inventions involving gene sequences from patentability is likely only to 'invite patent attorneys to engage in creative drafting'.

> This is precisely what has happened with the *ordre public*/morality exclusion, the methods of medical treatment exclusion and the plant and animal variety exclusions in Europe, none of which impose any significant limitations on the types of patents being granted in Europe.[43]

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39 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; S Karpeles, *Submission P44*, 20 October; A McBratney and others, *Submission P47*, 22 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003; D Weston, *Submission P62*, 12 November 2003.

40 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

41 Ibid, art 27.1.

42 D Nicol, 'Gene Patents: The Ultimate Snatch' (Paper presented at Hatching, Matching, Snatching and Dispatching, AIHLE 7th Annual Conference, Newcastle, 27–30 June 2002), 9; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 161.

43 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 232.

7.37 Similar observations with respect to the interpretation of exclusions from patentability in the patent laws of other jurisdictions were made by IP Australia in its submission.[44]

7.38 The ALRC does not consider that the *Patents Act* should be amended to exclude genetic materials or technologies from patentability. Such a reform would pose a significant risk to the biotechnology industry, raise problems in terms of Australia's compliance with its obligations under the TRIPS Agreement and be difficult to implement effectively.

Proposal 7–1 The *Patents Act 1990* (Cth) (*Patents Act*) should not be amended specifically to exclude genetic materials or technologies from patentable subject matter.

Methods of medical treatment

Australian law

7.39 The *Patents Act* does not expressly exclude methods of medical treatment from patentability. However, before 1972, Australian law recognised non-medical procedures (including cosmetic treatment), as well as surgical or medical treatment of the human body as an exclusion from patentability.[45] The reason for the exception was that such treatment was thought of as being 'essentially non-economic' and 'generally inconvenient' within terms of s 6 of the *Statute of Monopolies*.[46]

7.40 Based on case law,[47] IP Australia considers that it is now 'firmly established that methods of medical treatment are patentable subject matter'.[48] IP Australia's practice is that no objection to a patent application may be made to 'methods or processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the human body is involved'.[49]

7.41 In *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (*Rescare*),[50] a Full Court of the Federal Court considered whether methods of medical treatment could constitute a

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44 IP Australia, *Submission P56*, 4 November 2003. For example, while the European Patent Convention provides that methods of treating humans are not patentable subject matter, new medical uses for known substances may be patented using the 'Swiss' form of claim.

45 *Joos v Commissioner of Patents* (1972) 126 CLR 611, 619 where Barwick CJ decided that a process for the cosmetic treatment of hair and nails could be patentable, but distinguished this from medical treatment of disease, malfunction or incapacity.

46 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.13.1].

47 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439.

48 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.13.3].

49 Ibid, [8.2.13.1].

50 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1. The case concerned the patentability of a method and device for the prevention of sleep apnoea.

'manner of manufacture' and, if so, whether such methods should nevertheless be excluded as 'generally inconvenient' in terms of s 6 of the *Statute of Monopolies*. Lockhart J stated that there was no reason in principle why a method of medical treatment should not be considered to be a manner of manufacture and thus patentable.[51]

> On both humanitarian and economic grounds the search for medical advance is to be encouraged. The award of limited monopolies is a standard way of helping to compensate for the expense of research. Ultimately the resolution of this question is a balancing exercise. There is on the one hand a need to encourage research in connection with methods of medical treatment and on the other hand the need not unduly to restrict the activities of those who engage in the therapy of humans.[52]

7.42 Wilcox J agreed that methods of medical treatment should be patentable, noting that the Parliament had an opportunity to include an exception in the *Patents Act* when it was re-enacted in 1990, and had chosen not to. Courts should, therefore, be hesitant to introduce the exclusion by reference to 'the very general principles' contained in s 6 of the *Statute of Monopolies*.[53]

7.43 The approach to the patentability of methods of medical treatment taken by Lockhart and Wilcox JJ in *Rescare* was affirmed by a Full Court of the Federal Court in *Bristol-Myers Squibb Company v FH Faulding & Co Ltd*.[54] Black CJ and Lehane J commented on:

> the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a *product* for treating the human body, but deny patentability for a *method* of treatment.[55]

Other jurisdictions

7.44 In the United Kingdom, methods of medical treatment of the human body are expressly excluded from patentability.[56] Section 4(2) of the *Patents Act 1977* (UK) provides that:

> An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

7.45 In other jurisdictions, including Canada and New Zealand, methods of medical treatment are excluded by reference to more general provisions of their respective patents legislation.

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51 Ibid, 19.
52 Ibid, 16.
53 Ibid, 42–43.
54 *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439. The case concerned the validity of a patent for the method of administering a drug used to treat cancer.
55 Ibid, 444.
56 See *Patents Act 1977* (UK) s 4(2).

7.46 The Canadian Patent Office states that subject matter 'related to a process of surgery or therapy on living humans' is not considered to be within the scope of 'invention' as defined by s 2 of the *Patent Act 1985* (Can).[57] Methods of medical treatment are not patentable inventions because they are generally considered not to meet the Canadian utility criteria.[58]

7.47 The *Patents Act 1953* (NZ) does not currently contain an express exclusion from patentability for methods of medical treatment, but case law has held that methods of medical treatment are not patentable on the basis that they do not constitute a 'manner of manufacture'.[59] Recently, however, the New Zealand Court of Appeal appears to have departed from this view in concluding that 'it can no longer be said that a method of treating humans cannot be an invention'.[60] To address potential uncertainty as to the patentability of methods of medical treatment under New Zealand law, the New Zealand Ministry of Economic Development has recommended that the *Patents Act 1953* (NZ) be amended to provide a specific exclusion from patentability for 'inventions concerning diagnostic, therapeutic and surgical methods of treatment of humans'.[61]

7.48 The medical treatment exclusion from patentability, as applied in the United Kingdom and other overseas jurisdictions, relates only to treatment or diagnosis on the human body—and not to procedures carried out *in vitro*, or exclusively outside the body.[62] In particular, methods of diagnosis performed on tissues or fluids that have been permanently removed from the body are not excluded.[63]

7.49 Article 27(3)(a) of the TRIPS Agreement permits members to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability. This exclusion has not been definitively interpreted but its scope may not be as broad as may appear at first glance.

7.50 It is not clear whether the TRIPS Agreement permits exceptions for *in vitro* procedures. While the language may be broad enough on its face to encompass *in vitro* procedures (for example, as a 'diagnostic method') these words may need to be interpreted in the light of the national laws existing at the time the treaty was

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57 Canadian Patent Office, *Manual of Patent Office Practice* (1998), [16.04(b)].

58 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 31.

59 See *Wellcome Foundation Ltd v Commissioner of Patents* [1983] 2 NZLR 385.

60 *Pharmaceutical Management Agency Limited v Commissioner of Patents* [2000] 2 NZLR 529, [29]. The Intellectual Property Office of New Zealand has continued to refuse patent claims to methods of medical treatment on the basis that a change in policy relating to the patenting of methods of medical treatment of humans is a matter for the legislature.

61 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 1, rec 2(ii).

62 Canada: Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 51. United Kingdom: United Kingdom Patent Office, *Manual of Patent Practice* (5th ed, 2003).

63 United Kingdom Patent Office, *Manual of Patent Practice* (5th ed, 2003).

negotiated.[64] The medical treatment exclusion from patentability, as applied in the United Kingdom and other overseas jurisdictions, relates only to treatment or diagnosis on the human body.

7.51 This limitation is significant when considering the possible application of a new exclusion for methods of medical treatment in the context of gene patents. Gene patents most often relate to products and processes for use outside the human body, notably in connection with genetic sequencing and diagnostic genetic testing. Even in the case of gene therapy, patents are likely to relate to processes carried out *in vitro*—such as inserting genes into a gene carrier (or 'vector') and using the vector to carry the genes into somatic cells. Procedures for introducing vectors, modified cells or stem cells into the human body (for example, by injection) could be excluded as methods of medical treatment. However, such an exclusion may have limited practical benefit if related *in vitro* processes remained patentable.

Submissions and consultations

7.52 A number of submissions supported the introduction of an exclusion from patentability for methods of medical treatment. The Department of Health Western Australia suggested that:

> Australia consider making provision for Article 27(3)(a) of the TRIPS Agreement, where 'diagnostic, therapeutic and surgical methods for the treatment of human or animals' may be excluded from patentability. This may preclude the patentability of materials required for diagnostic and predictive genetic testing.[65]

7.53 The Breast Cancer Network of Australia suggested that the ALRC should consider exclusions from patentability 'for specific public health purposes'.[66]

7.54 However, some submissions indicated that excluding inventions involving methods of diagnostic, therapeutic or surgical treatment from patentability might not be as effective as it first appears. Submissions cited patent practice in Europe with respect to methods of treatment as evidence that such an exclusion might have limited application.[67] IP Australia commented:

> The European Patent Office applies a narrow, technical interpretation of the exclusion for methods of treatment of the human body. 'Diagnosis' outside the body is considered to be patentable. The medical use of novel substances can be protected, as long as the patent claim is to the substance per se, rather than a method. New medical uses for known substances may in effect be patented using the 'Swiss' form of claim.

64 The general rules of treaty interpretation set out in the *Vienna Convention on the Law of Treaties* permit recourse to supplementary means of interpretation, including the preparatory work of the treaty (travaux préparatoires) and the circumstances of its conclusion: *Vienna Convention on the Law of Treaties*, [1974] ATS 2, (entered into force on 27 January 1980) art 31–32.

65 Department of Health Western Australia, *Submission P53*, 3 November 2003.

66 Breast Cancer Network Australia, *Submission P22*, 30 September 2003.

67 A McBratney and others, *Submission P47*, 22 October 2003.

7.55 Submissions also suggested that precluding methods of medical treatment from patentability might have an adverse effect on innovation in the healthcare field.[68] Genetic Technologies Limited and GlaxoSmithKline proposed that methods of treatment and diagnosis should continue to be patentable to provide incentives to invest in research and development in such methods.[69] The Walter and Eliza Hall Institute for Medical Research (WEHI) commented that removing patent protection for such inventions would 'simply prevent development or else encourage commercial secrecy'.[70]

7.56 Some submissions supported patent protection for methods of diagnostic, therapeutic, or surgical treatment involving genetic materials and technologies only on a conditional basis. For example, certain submissions indicated that patents on methods of medical treatment should be acceptable provided that patent protection was not available for genetic materials *per se*.[71]

7.57 The Human Genetics Society of Australasia (HGSA) proposed that naturally-occurring chemicals (including genes and gene sequences) should not be patentable, but medical methods and processes should continue to have patent protection. The HGSA considered that:

> Provided there is the potential for competition, for new and better processes to be invented and patented, then there is no justification for restricting patenting.[72]

7.58 If diagnostic, therapeutic and surgical methods of treatment were to be excluded from patentability, some submissions suggested that the exclusion should not be limited to methods involving genetic materials and technologies but should be technology neutral.[73]

7.59 Other submissions considered that, if protection continued to be available for these types of inventions, an appropriately crafted defence should be enacted to address the potential adverse consequences of patents on methods of medical treatment.[74] For example, the Australian Centre for Intellectual Property in Agriculture (ACIPA) submitted that:

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68 Genetic Technologies Limited, *Submission P45*, 20 October 2003; IP Australia, *Submission P56*, 4 November 2003.

69 GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.

70 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

71 South Australian Government, *Submission P51*, 30 October 2003.

72 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003. See also G Suthers, *Submission P30*, 2 October 2003.

73 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

74 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. Medical treatment defences are discussed in Ch 22.

> If methods of human treatment remain patentable, Australia should follow the lead of the United States, and introduce a limited liability defence for surgeons and medical practitioners in respect of patent infringement.[75]

ALRC's views

7.60 For the reasons set out in Chapter 22, the ALRC has concluded that if reform in relation to gene patents and medical treatment is justified, the introduction of a new defence—as opposed to an exclusion from patentability—would be the preferable approach because such a defence could apply to both *in vivo* and *in vitro* procedures and be more targeted in its application.[76]

7.61 Accordingly, the ALRC does not propose that a new exclusion from patentability for methods of medical treatment be introduced in Australia. In particular, the ALRC is concerned that such an exclusion would have adverse effects on investment in biotechnology, medical research and innovation in healthcare and may not be consistent with Australia's obligations under the TRIPS Agreement.

Proposal 7–2 The *Patents Act* should not be amended specifically to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter.

Exclusions from patentability on social or ethical grounds

7.62 Chapter 3 discussed the social and ethical dimensions of gene patents. These include concerns about ensuring equitable access to healthcare; recognising the human genome as the common heritage of humanity; respecting human dignity, self-determination and self-ownership; conflict between the premises of gene patenting and certain religious beliefs; and ensuring fair benefit-sharing of, and control over, research outcomes.

7.63 It has been suggested that the patent system should provide avenues for addressing these concerns, such as by making social and ethical considerations relevant in the assessment of gene patent applications.

7.64 The following material examines the extent to which social and ethical considerations may be taken into account under existing Australian patent law and the law of other countries, and then discusses whether the patent system is an appropriate mechanism through which to address these concerns and, if so, how.

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75 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

76 Such a defence is examined, and rejected, by the ALRC: see Ch 22.

Australian law

7.65 The *Patents Act* does not contain an explicit mechanism to allow social and ethical considerations to be taken into account by patent examiners in assessing the patentability of a particular invention. The Act may, however, include an indirect means for this to occur.

7.66 As discussed in Chapter 6, s 18 of the *Patents Act* states that a patent may be granted for a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies 1623*.[77] Section 6 provides that an invention should 'be not contrary to the law, nor mischievous to the state, by raising prices of commodities, or hurt of trade, or generally inconvenient'.

7.67 It is arguable that the term 'generally inconvenient' includes social and ethical considerations within its scope.[78] Decisions of the High Court and the Federal Court contain *obiter dicta* suggesting that the 'generally inconvenient' exception incorporates public policy considerations and may provide a basis upon which the grant of a patent could be refused.[79]

7.68 To date, however, Australian courts have declined to rely solely upon matters of public policy or ethics under the 'generally inconvenient' exception in considering whether an invention is inappropriate subject matter for the grant of a patent. The courts have suggested that such issues are for Parliament to determine, not judges.[80]

7.69 Further, as a matter of practice, it appears unlikely that ethical considerations are considered by Australian patent examiners in their assessment of whether an invention constitutes a 'manner of manufacture'. The *Manual of Practice and Procedure* specifically notes that ethical and policy considerations are not grounds upon which a patent examiner may reject a patent application. The *Manual* states:

> Arguments based solely on matters of ethics or social policy are not relevant in deciding whether particular subject matter is patentable. … it is for Parliament, not the courts or the Patent Office, to decide whether matters of ethics or social policy are to have any impact on what is patentable.[81]

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77 *Patents Act 1990* (Cth) s 18(1)(a) (standard patents); s 18(1A)(a) (innovation patents).

78 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441, 441. See also D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 241–242; M Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *Australian Intellectual Property Journal* 202, 215–218.

79 *Joos v Commissioner of Patents* (1972) 126 CLR 611, 623 (Barwick CJ); *Advanced Building Systems Pty Ltd v Ramset Fastners (Aust) Pty Ltd* (1998) 194 CLR 171, 190; *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 41 (Sheppard J); *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (1998) 41 IRP 467, 479–481 (Heerey J), on appeal to the Full Federal Court; *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439, 444–445 (Black CJ and Lehane J).

80 See, eg, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45 (Wilcox J).

81 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.1.2]

Other jurisdictions

7.70 In contrast to the Australian position, a number of overseas jurisdictions expressly permit an invention to be excluded from patentability on social or ethical grounds. Article 27(2) of the TRIPS Agreement provides that member States may exclude inventions from patentability if prevention of the commercial exploitation of an invention is necessary to protect '*ordre public* or morality' including 'to protect human, animal or plant life or health or to avoid serious prejudice to the environment'.

European Union

7.71 The European Patent Convention (EPC) includes an exception from patentability in similar terms to the TRIPS Agreement.[82] Article 53(a) of the EPC provides:

> European patents shall not be granted in respect of:
>
> (a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

7.72 Article 53(a) of the EPC is replicated in the European Parliament's Directive on the Legal Protection of Biological Inventions (EU Biotechnology Directive).[83] In addition, the EU Biotechnology Directive sets out certain inventions that presumptively fall within the ambit of the exclusion from patentability on the grounds of *ordre public* or morality.[84] Those inventions are: processes for cloning human beings or for modifying the germ line identity of human beings; uses of embryos for industrial or commercial purposes; and processes for modifying the germ line identity of animals which are likely to cause them suffering without substantial medical benefit to humans or animals, as well as any animals resulting from such processes.[85] This list of inventions is not, however, intended to be exhaustive.[86]

7.73 The terms '*ordre public*' and 'morality' are not defined in either the EPC or the EU Biotechnology Directive. In drafting art 53(a) of the EPC, the EPC Working Party

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82 *European Patent Convention*, (entered into force on 7 October 1977) art 53(a); *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998) art 6(1).

83 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998) art 6(1).

84 In 1999, the implementing regulations of the EPC were amended following introduction of the EU Biotechnology Directive to ensure consistency between the EPC and the Directive in relation to these provisions: see Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001) r 23(b)–23(e).

85 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998) art 6(2).

86 *Relaxin/Howard Florey Institute* (Unreported, Boards of Appeal, European Patent Office, T0272/95, 23 October 2002), [7].

concluded that European institutions from time to time should determine the interpretation of these concepts.[87]

7.74 The EPO has interpreted both terms. In *Plant Genetic Systems NV*,[88] the Boards of Appeal of the European Patent Office (EPO Boards of Appeal) upheld the validity of a patent claiming certain herbicide-resistant plants, which was challenged on the basis that it was contrary to *ordre public* or morality, among other grounds. In reaching this decision, the EPO Boards of Appeal stated that the concept of *ordre public* covers

> the protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment.[89]

7.75 The EPO Boards of Appeal also explained that the concept of 'morality'

> is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation.[90]

7.76 Despite the seemingly broad scope given to the concepts of *ordre public* and morality under European patent law, the exception has been narrowly applied.[91] The Examination Guidelines for the EPO (EPO Examination Guidelines) indicate that the application of art 53(a) is extremely limited:

> The purpose of this [provision] is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour … obvious examples of subject-matter which should be excluded under this provision are letter-bombs and anti-personnel mines. In general, this provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.[92]

7.77 In *Howard Florey/Relaxin*,[93] the Opposition Division of the EPO specifically rejected the relevance of the exception to a patent claiming a genetic sequence

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87 *Plant Genetic Systems/Glutamine Synthetase Inhibitors* (Unreported, Boards of Appeal, European Patent Office, T0356/93, 21 February 1995), [4].

88 Ibid.

89 Ibid, [5].

90 Ibid, [6].

91 See *Lubrizol/Hybrid Plants* [1990] EPOR 173; *Harvard/Oncomouse* [1990] EPOR 501; *Howard Florey/Relaxin* [1995] EPOR 541; *Plant Genetic Systems/Glutamine Synthetase Inhibitors* (Unreported, Boards of Appeal, European Patent Office, T0356/93, 21 February 1995).

92 European Patent Office, *Guidelines for Examination in the European Patent Office* (2003), Pt C–IV, [3.1]

93 *Howard Florey/Relaxin* [1995] EPOR 541. The patent at issue was opposed on the grounds that the invention involved the patenting of human life, an abuse of women, a return to slavery and the piecemeal sale of women to industry. The Opposition Division rejected these arguments as being unfounded in principle and in the circumstances of the case. The opponents also asserted that patent on human genes in general were immoral. The Opposition Division concluded that, in 1994, there was no general consensus that patenting human genes was immoral and that art 53(a) of the EPC did not, therefore, apply.

encoding human H2-preprorelaxin.[94] The decision was affirmed on appeal to the EPO Boards of Appeal. The EPO Boards of Appeal held that materials isolated from the human body were outside the scope of the *ordre public*/morality provision as a matter of statutory interpretation because r 23(e)(2) of the EPC—which provides that 'an element isolated from the human body' may be a patentable invention—qualifies the *ordre public*/morality exclusion in art 53(a) of the EPC.[95]

7.78 In *Harvard/Oncomouse*, a patent claiming a method for producing a mouse genetically predisposed to cancer was opposed, relevantly, on the basis that it was contrary to *ordre public* or morality pursuant to art 53(a) of the EPC.[96] The EPO Boards of Appeal held that to determine whether art 53(a) constituted a bar to patentability would require

> a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other.[97]

7.79 It appears that such a balancing of competing interests will rarely result in a patent challenged on *ordre public* or morality grounds being rejected. A recent report on the impact and management of intellectual property rights in the United Kingdom healthcare sector noted that:

> Patent practice to date is to apply a utilitarian (benefit/detriment) approach to determining whether the commercial exploitation of an invention would be contrary to morality or not. Provided some benefit can be shown to result, or be likely to result, from the exploitation of the invention, then the exclusion is unlikely to be invoked.[98]

7.80 Indeed, the *ordre public*/morality exception has been raised successfully in only two known cases—one involving a hairless mouse used to test hair growth products and the other an invention involving the cloning of a fused human and pig cell.[99]

7.81 Patent statutes in jurisdictions outside Europe also contain provisions permitting the exclusion of inventions from patent protection on ethical or social policy grounds.[100] To date, these ethical exceptions have rarely been invoked with any degree of success. However, recent reviews of patents legislation in other jurisdictions have suggested that adopting an exclusion from patentability on ethical grounds or expanding the scope of an existing provision might be desirable.

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94 The genetic sequence coded for human relaxin, a hormone of reproduction that appears to affect parturition, uterine accommodation, and sperm motility.

95 *Relaxin/Howard Florey Institute* (Unreported, Boards of Appeal, European Patent Office, T0272/95, 23 October 2002), [4], [6]–[7].

96 *Harvard/Oncomouse* [1990] EPOR 501.

97 Ibid, 513.

98 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 82.

99 See Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 39 fn 35.

100 *Patents Act 1953* (NZ) s 17(1); *Patent Law* (Law No 121 of 1959) (Japan) s 32.

New Zealand

7.82 Amendments to New Zealand patent law have been proposed to expand the scope of the exclusion from patentability on moral grounds. Currently, s 17 of the *Patent Act 1953* (NZ) grants the New Zealand Commissioner of Patents discretion to refuse an application if the use of the claimed invention would be 'contrary to morality'. The provision has rarely, if ever, been invoked to date.[101]

7.83 A recent review on the *Patents Act 1953* (NZ) by the Ministry for Economic Development (the NZ Report) recommended that the Act be amended to include a provision in similar terms to the European *ordre public*/morality exception.[102] The NZ Report indicated, however, that a patent is likely to be refused or revoked pursuant to this provision only if 'exploitation of the invention would be offensive to a substantial section of society'.[103]

Canada

7.84 The Ontario Report recommended that the Canadian Government consider amending the *Patent Act 1985* (Can) to include an *ordre public*/morality clause.[104] The Ontario Report contemplated that the bases upon which a patent might be challenged for contravention of the clause would be set out in the legislation.[105] The Ontario Report suggested that:

> Such a mechanism appropriately modified from the European experience would grant the Commissioner of Patents the ability to reject patents on processes, products and techniques which are deemed to violate Canadian morals and ethics.[106]

United States

7.85 As in Australia, United States patent law does not contain an express provision permitting patent applications to be refused or challenged on ethical grounds. United States courts have, however, interpreted the 'utility' requirement as preventing the patenting of inventions that are 'injurious to the well-being, good policy, or sound morals of society'.[107]

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101 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002), 17.

102 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003) Pt 2, rec 2(i).

103 Ibid, Pt 2, [28].

104 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(f).

105 Ibid, 50.

106 Ibid, xx. The modifications to the European model proposed by the Ontario report are discussed further below.

107 *Lowell v Lewis*, (1817) 15 Fed Cas 1018 (Story J) quoted in *Tol-O-Matic Inc v Promo Produkt-und Marketing Gesellschaft MbH* (1991) 945 F 2d 1546, 1553. See also United States Patent and Trademark Office, 'Facts on Patenting Life Forms Having a Relationship to Humans', *Media Advisory*, 1 April 1998, <www.uspto.gov/web/offices/com/speeches>.

Ethics and the patent system

7.86 There are widely differing views about the relevance of social and ethical considerations in the assessment of patents. One view is that patents form part of an economic system for encouraging investment in research and that the patent system should be concerned primarily with assessing the inventiveness and utility of new inventions.[108] Social and ethical concerns are separate issues to be dealt with by other means.[109]

7.87 Further, it is said that the patent system is an ineffective mechanism for dealing with the social and ethical considerations because it was not designed to address such issues.[110] The Organisation for Economic Co-operation and Development Working Party on Biotechnology Report (OECD Report) stated:

> Workshop participants generally agreed that in cases where fundamental ethical decisions are at stake, the debate needs to take place in society at large rather than in the patent offices, which have no special authority in moral matters … the patent law itself is most probably not a suitable medium for the raising of philosophical objections to the patenting of living organisms and genetic inventions. In such cases, legislative or regulatory action should be envisioned. Although some observers would encourage legislators to adopt a broader vision of patent law as an ethico-legal instrument of public policy, it was generally agreed that IP law is fashioned primarily to promote inventiveness and the disclosure of advances in technology and cannot be easily reformed to include such a vision.[111]

7.88 These views have been challenged on the basis that any system that affects the interests of individuals or groups—as the patent system does—cannot be socially or ethically neutral.[112] A number of general arguments have been made for dealing with social and ethical concerns through patent laws, which may be applicable in the context of gene patents. These include the following:

- Decisions made by patent examiners are affected by the values and social interests of the community of which they are a part. Therefore, social and ethical

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108 R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71.

109 C Ho, 'Building a Better Mousetrap: Patenting Biotechnology in the European Community' (1992) 3 *Duke Journal of Comparative and International Law* 173, 195 cited in B Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement' (1994) 26 *Law and Policy in International Business* 231, 121.

110 C Baldock and others, 'Report Q 150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes' (2000) 22 *European Intellectual Property Review* 39, 40.

111 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 75.

112 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441, 441. See also Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 36.

considerations are implicitly and unavoidably part of the patent granting process.[113]

- The patent system exists to serve the public interest: considerations of public purpose should be fundamental to the patent granting process.[114]

- Patents create incentives for research and investment, and the availability of a patent may affect the types of products and processes that are developed. Patent systems should bear some responsibility for ensuring that the research they encourage is consistent with the public interest.[115]

- The incentives that patents create may provide a useful mechanism for dealing with any social and ethical problems raised by the use of patented inventions. Thus, it may be effective to regulate the adverse consequences of patents through the laws that create these incentives, rather than by creating a separate set of rules.[116]

7.89 If the patent system is to address social and ethical considerations, there is a variety of ways in which this might be achieved. Some mechanisms may be more suitable than others, depending upon the nature of the social or ethical concerns at issue and, in particular, whether they relate to the grant of a patent covering a genetic invention or to the way in which such patents are exploited.

7.90 The *Patents Act* contains mechanisms that might be used indirectly to address social or ethical concerns about the manner in which patent rights are exploited. For example, the compulsory licensing provisions may be invoked where the reasonable requirements of the public with respect to a patented invention are not being satisfied.[117] This might include circumstances in which access to a patented medical genetic technology is not being provided equitably.

7.91 However, the material below focuses on reforms intended to allow social and ethical considerations to be assessed as part of the process for *granting* patents—that is, to allow certain subject matter to be excluded from patentability on social or ethical grounds. Suggestions that the patent system should deal with social or ethical concerns raises questions about how such decisions should be made, and by whom.

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113 B Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement' (1994) 26 *Law and Policy in International Business* 231, 121.

114 M Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *Australian Intellectual Property Journal* 202, 209.

115 Ibid, 211.

116 Ibid, 211.

117 *Patents Act 1990* (Cth) s 133. See Ch 26.

A role for patent examiners?

7.92 One option would be for patent examiners to consider whether a patent application should be rejected on social or ethical grounds, as part of the examination process.

7.93 However, it has been suggested that patent examiners lack the training and expertise to make decisions of this kind.[118] For example, one European patent attorney has stated that patent examiners are 'wholly incapable' of carrying out 'sophisticated balancing of subjective moral values as part of the examination procedure' and asked:

> Are EPO examiners to have courses in moral philosophy or theology? And if so, of what variety?[119]

7.94 The Ontario Report also commented that one of the difficulties with the European morality clause is that:

> the clause is applied, in the first instance, by patenting examiners who do not necessarily have expertise in ethical matters, and are therefore uncomfortable in applying the clause.[120]

7.95 The OECD Report concluded:

> In the absence of commonly agreed criteria for making moral judgments as to the application of new technology, therefore, it is difficult to apply morality provisions … In addition, the patent system is meant primarily to regulate competition, and patent examiners are not in a position to define or even interpret the basic values of society.[121]

7.96 Patent examiners could be assisted in assessing the social and ethical considerations involved in patent applications by guidelines drawn up by some authoritative body. An analogous set of ethics guidelines is the *National Statement on Ethical Conduct in Research Involving Humans*[122] (National Statement), developed by the Australian Health Ethics Committee of the National Health and Medical Research Council (NHMRC). Research proposals involving human participants must be reviewed and approved by a Human Research Ethics Committee (HREC). The

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118 See, eg, Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 40; R Ford, 'The Morality of Biotech Patents: Differing Legal Obligations in Europe?' (1997) 19 *European Intellectual Property Review* 315, 317; D Slater, 'HuMouse', *Legal Affairs*, Nov-Dec 2002, 21, 24; P Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (3rd ed, 1999), 258.

119 P Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (3rd ed, 1999), 258.

120 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 50.

121 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 45.

122 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999).

National Statement provides ethical guidance to members of HRECs in conducting this ethics review. The National Statement reflects international development of standards about the ethical conduct of human research, culminating in the Declaration of Helsinki,[123] which has become an international benchmark in this area.

7.97 There are no similar international precedents for the development of guidelines by which to assess the social and ethical implications of gene patents, or patents generally. Overseas jurisdictions that expressly permit an invention to be excluded from patentability on social or ethical grounds have not developed comprehensive guidelines. This may indicate that, given the breadth of potential social and ethical considerations of relevance to inventions in different technological fields, drafting guidelines in this area may be impracticable.

An ethics advisory body?

7.98 Another option would be to refer patent applications that raise social or ethical considerations to a specialised body that could provide guidelines or advice on these issues, or make determinations itself.[124] The establishment of such a body has been considered previously in Australia and overseas.

Australia

7.99 Review of certain types of patent applications by a committee, prior to any decision by the Commissioner of Patents, was proposed by Senator Coulter as part of the amendments to the Patents Bill 1990 (Cth). The proposal included provision for a committee (to be established by the regulations) to review patent applications that may have fallen within the scope of the proposed exclusion for genes, genetic material and genetically modified organisms, upon reference from the Commissioner of Patents.[125] The proposal for an additional layer of review of patent applications was criticised by some Senators on the basis that it would increase uncertainty[126] and further complicate the operation of the patent system.[127]

7.100 There are some Australian precedents for the establishment of ethics advisory bodies. For example, as mentioned above, the regulatory framework for the ethical conduct of research is centred on the review of research proposals by HRECs.[128]

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123 World Medical Association, *Ethical Principles for Medical Research Involving Human Subjects*, June 1964.

124 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), [2.10]; Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 40.

125 Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, 2478 (J Coulter).

126 See, eg, Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, 2481 (R Collins).

127 See, eg, Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, 2482 (B Archer).

128 The membership and role of HRECs is discussed in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 17.

Another precedent is the Gene Technology Ethics Committee (GTEC) established under the *Gene Technology Act 2000* (Cth), which introduced a national scheme for the regulation of genetically modified organisms in Australia. The Act established the position of the Gene Technology Regulator (the Regulator)[129] and three advisory bodies, including GTEC.[130]

7.101 GTEC provides advice to the Regulator and the Gene Technology Ministerial Council[131] on ethical issues associated with gene technology.[132] At present, GTEC comprises 12 members with expertise in matters such as ethics and the environment, health ethics, applied ethics, law, religious practices, and animal health and welfare; and two expert advisors with expertise in bioethics.[133] GTEC does not provide advice in respect of specific decisions of the Regulator.

Other jurisdictions

7.102 The introduction of an advisory body to assist patent examiners in assessing ethical issues has been considered in other jurisdictions. The NZ Report recommended that the Commissioner of Patents must 'seek advice from appropriate authorities outside the Intellectual Property Office' when determining whether to refuse to grant a patent on 'morality/*ordre public*' grounds.[134] The NZ Report indicated that such authorities might include the Maori Consultative Group and the Bioethics Council.[135] The NZ Report did not, however, consider the mechanisms by which appropriate authorities might provide advice to the Intellectual Property Office of New Zealand.

7.103 Similarly, the Ontario Report, which recommended that the Canadian Government consider the introduction of a morality clause into the *Patent Act 1985* (Can), also recommended that a specialised body separate from the Canadian Patent Office might undertake review of patents for compliance with particular moral standards.[136] The Ontario Report considered that a specialised review body, comprising experts in science, ethics and competition law, would 'overcome the reluctance faced by European patent examiners to make pronouncements based on ethical or moral

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129 See *Gene Technology Act 2000* (Cth) s 26–27.

130 Ibid s 111. The other subsidiary advisory bodies established under the Act are Gene Technology Technical Advisory Committee and the Gene Technology Community Consultative Committee: *Gene Technology Act 2000* (Cth) ss 100, 106.

131 The Gene Technology Ministerial Council comprises one representative from the Commonwealth and each of the States and Territories and was established by the intergovernmental *Gene Technology Agreement* (2001).

132 *Gene Technology Act 2000* (Cth) s 112.

133 Office of the Gene Technology Regulator, *The Gene Technology Ethics Committee*, <www.ogtr.gov.au/committee/gtec.htm> at 27 January 2004.

134 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 2, rec 2(ii).

135 Ibid, Pt 2, [29].

136 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 50. See also R Gold and T Caulfield, 'The Moral Tollbooth: A Method that Makes Use of the Patent System to Address Ethical Concerns in Biotechnology' (2002) 359 *The Lancet* 2268.

criteria'.[137] The Ontario Report also contemplated that such an ethics review body would have the power to suspend the operation of a patent deemed to be in contravention of the morality clause and to lift the suspension if and when the 'offending aspects' of the patent were remedied.[138]

7.104 As discussed above, in Europe, determinations about whether particular patent applications claim inventions that are contrary to *ordre public* or morality are made by patent examiners and are also open to challenge by third parties on such grounds. However, the European Group on Ethics in Science and Technologies (European Group on Ethics) is responsible for evaluating all ethical aspects of biotechnology[139] and may be consulted where biotechnology is to be evaluated at the 'level of basic ethical principles'.[140] In its 2002 report on the ethical aspects of patenting inventions involving human stem cells, the European Group on Ethics also proposed that ethics review of patent applications by an independent advisory body should be incorporated into the patent examination process.[141]

Submissions and consultations

Social and ethical considerations and the patent system

7.105 Many submissions suggested that social and ethical considerations should be taken into account in assessing gene patent applications.[142] For example, the Cancer Council of Australia recommended amendments to the *Patents Act* to introduce 'public interest and social impact criteria into the assessment criteria for patent applications'.[143] ACIPA referred to the 'insular attitude of patent administrations to matters of public policy'[144] and recommended that 'ethical and social concerns about patents on genetic materials and technologies should be addressed in part through the patent system'.[145] The South Australian Government suggested that the patent system cannot be ethically or socially neutral and that it would benefit from explicit direction on ethical issues.[146]

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137 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 50.

138 Ibid, 50.

139 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998) art 7.

140 Ibid recital 44.

141 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), [2.10].

142 See, eg, Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Breast Cancer Network Australia, *Submission P22*, 30 September 2003; D McFetridge, *Submission P23*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Foundation of Western Australia Inc, *Submission P34*, 10 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; D Jackson, *Submission P43*, 20 October 2003.

143 Cancer Council Australia, *Submission P25*, 30 September 2003.

144 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

145 Ibid.

146 South Australian Government, *Submission P51*, 30 October 2003.

7.106 Other submissions opposed any use of the patent system as a mechanism for assessing social or ethical considerations. Davies Collison Cave considered that:

> The patent system is not the appropriate forum for making assessments regarding ethical and moral issues. In this context it is pointed out that the grant of a patent does not provide the patentee with an endorsement or authority to exploit the invention concerned ... In our view, consideration of moral or ethical issues is incompatible with the commercial priorities and realities of the patent system.[147]

7.107 WEHI noted that the grant of gene patent rights and the use of genetic inventions were distinct issues and should be separately regulated. WEHI stated that:

> one should not confuse the granting of patent rights with practising the invention. Practice of the invention may fall under several different laws and codes of practice within each jurisdiction.[148]

7.108 Some submissions noted that if there are concerns about the type of research activities that lead to the development of genetic inventions, these concerns should be addressed directly, through regulating genetic research. The Department of Industry, Tourism and Resources submitted:

> The patent system is not the appropriate instrument to deal with perceived ethical concerns about research activity in the area of human genetics including 'gene manipulation' and commercialisation of technologies resulting from such research. Patentable inventions generally result from intensive R&D activity. Controls on patenting will not be effective as a means of regulating genetic research or technologies since such activities can still be carried out and results exploited. In addition, the community would lose some of the economic benefits arising from the new technology … ethical concerns regarding genetic research should be addressed at a much earlier stage of the research process, before the activity proceeds to the patenting stage.[149]

7.109 In a similar vein, GlaxoSmithKline commented:

> much of the debate about the ethics of patenting is actually about the ethics of particular areas of research … If a particular type of research is considered to be ethically objectionable, then the denial of patent protection for inventions arising from such work will not result in its cessation … Direct legislative controls (such as prohibition or strict regulation) on the conduct of certain types of research and/or on the sale of certain types of products are the appropriate means to ensure that any public policy objectives based on ethical concerns are achieved.[150]

147 Davies Collison Cave, *Submission P48*, 24 October 2003.
148 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.
149 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
150 GlaxoSmithKline, *Submission P33*, 10 October 2003.

Reform options

7.110 Submissions recognised that if social and ethical considerations are to be taken into account in assessing patent applications, Australian patent law and practice will need to be amended to facilitate this. The Cancer Council of Australia submitted:

> Public interest objectives should be included within patent law with an emphasis on defining a benefit to society before a patent is granted. A key consideration is whether such objectives should be made more explicit in the Patents Act.[151]

7.111 ACIPA stated that:

> Ethical considerations are and should be relevant in assessing applications for gene patents. The current manner of manufacture test is not sufficient to accommodate such considerations.[152]

7.112 The possibility of amending the Patents Act to include an *ordre public* or morality exception to patentability—similar to exceptions under European laws—was raised in some submissions.[153] The difficulties involved in incorporating social or ethical considerations into an exclusion from patentability were recognised. For example, IP Australia commented that:

> ethical exceptions to patentability in European patent law has increased uncertainty over patent rights, and is considered by many to be generally ineffectual.[154]

7.113 Several submissions advocated the development of statutory guidelines to assist in the assessment of social and ethical issues,[155] although they were not explicit about how these guidelines should be developed, applied or given legal effect as part of the patent examination process.

7.114 The appropriateness of the Patent Office making social or ethical determinations was questioned. Genetic Technologies Limited asserted that such matters were not properly within the province of the Patent Office.

> It is not the place of the patent office to consider ethical concerns—there are many other vehicles for this, many of which perform extremely well … Ethical control of the use of new technology sits appropriately with our legislators. It has never been

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151 Cancer Council Australia, *Submission P25*, 30 September 2003.

152 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003, 68.

153 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; D McFetridge, *Submission P23*, 30 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003.

154 IP Australia, *Submission P56*, 4 November 2003.

155 G Suthers, *Submission P30*, 2 October 2003, 9; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003, 25; Cancer Council Australia, *Submission P25*, 30 September 2003, 5; Cancer Council Tasmania, *Submission P40*, 29 September 2003, 5; Cancer Council South Australia, *Submission P41*, 9 October 2003, 5; D Jackson, *Submission P43*, 20 October 2003; South Australian Government, *Submission P51*, 30 October 2003, 25.

> and there is no reason in the future for it to be the role of the patent office to be making ethical judgments.[156]

7.115 Submissions noted the practical difficulties inherent in requiring patent examiners—who are specialists in scientific and technical fields—to assess social or ethical considerations. GlaxoSmithKline submitted that patent examiners are not equipped to determine such issues.[157] The Queensland Government considered that IP Australia may not be equipped to address ethical and moral issues if the patent system were amended to include these matters as relevant considerations.[158]

7.116 A number of submissions considered that a body other than IP Australia—for example, the proposed Human Genetics Commission of Australia (HGCA)[159]—could play a role in developing and implementing appropriate mechanisms to help ensure that the exploitation of gene patent rights does not conflict with other public policy goals.[160]

7.117 ACIPA proposed that an independent body comprising specialists in ethics, research and economics be established to assess the ethical implications of patent applications.[161] Other submissions supported the establishment of a such a body.[162] The Department of Health Western Australia recommended that:

> an ethical review panel, apart from the Patent Office, be involved in assessing applications for gene patents, with the power to suspend the exercise of patent rights. It is recommended that such an ethical review panel operate under the auspices of the proposed HGCA. Ethical considerations should be taken into account in assessing patent applications over genetic materials. Such an ethics body could also be employed to oversee and recommend the kinds of genetic tests that are available to the public.[163]

7.118 Some submissions suggested that it may be preferable to focus on addressing any social and ethical concerns that arise after gene patents have been granted, rather than in the examination process. IP Australia submitted:

> It may be more suitable for any such assessment [of ethical issues by IP Australia] to be conducted post-grant, and only for those patents which are identified to be of concern. In any case, close collaboration with other agencies may be required for any

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156 Genetic Technologies Limited, *Submission P45*, 20 October 2003.
157 GlaxoSmithKline, *Submission P33*, 10 October 2003.
158 Queensland Government, *Submission P57*, 5 January 2004.
159 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1.
160 G Suthers, *Submission P30*, 2 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.
161 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003, 68–69.
162 S Karpeles, *Submission P44*, 20 October, 6–7; D Jackson, *Submission P43*, 20 October 2003.
163 Department of Health Western Australia, *Submission P53*, 3 November 2003.

> such assessment to be sufficiently robust, as the patent system has relatively shallow experience in this area.[164]

7.119 The RCPA submitted:

> It is probably wiser to protect society from the occasional misuse or abuse of monopoly power by imposing conditions or restrictions on the use of gene patents and by enhancement of defences, exemptions and 'downstream' regulations rather than alter the patent system itself.[165]

ALRC's views

7.120 It is arguable that the 'generally inconvenient' proviso included in the 'manner of manufacture' requirement in s 18 of the *Patents Act* already provides some limited basis upon which social and ethical considerations may be relevant to the patentability of a genetic invention under Australian law.[166] However, the ALRC does not believe that the *Patents Act* should be amended to expand the circumstances in which such considerations are taken into account in decisions about granting patents.

7.121 In the ALRC's view, there is no compelling case for amending the *Patents Act* to allow expressly for the exclusion of particular subject matter from patentability on social or ethical grounds. If such a provision were to be included in the Act, an obvious model would be an exclusion from patentability on the grounds of *ordre public* or morality, as found in European law and as permitted by the TRIPS Agreement. Yet, adopting such a provision in Australia would not address the particular concerns expressed to the Inquiry about the patentability of genetic materials or technologies. In Europe, the difficulties in applying the exclusion have led to a very narrow interpretation of the provision, and it has had no discernible impact on the granting of gene patents in those jurisdictions.

7.122 Patent offices and examiners have no special authority in philosophical or moral matters. Examiners are chosen for their expertise in particular scientific and technical fields. For example, examiners who assess patent applications for genetic materials and technologies must have qualifications in the field of biochemistry.[167] It may be possible to provide examiners with training in social and ethical matters but they will not necessarily be the individuals best suited to making assessments on such grounds. Further, given the breadth of potential social and ethical considerations of relevance to inventions in different technological fields, it may not be possible to provide them with the training or guidelines necessary to assess the social and ethical implications of all new inventions.

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164 IP Australia, *Submission P56*, 4 November 2003.

165 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

166 *Patents Act 1990* (Cth) s 18. See also Proposal 6–1, which recommends review of the 'manner of manufacture' test in the *Patents Act* by the Advisory Council on Intellectual Property.

167 See Ch 8.

7.123 Where the use or exploitation of new inventions gives rise to social or ethical concerns, it may be argued that debate and decisions about new regulation should be taken by society as a whole—through community action and the political system—rather than by individuals whose training and experience is primarily scientific and technical in nature.

7.124 The establishment of a new ethics advisory body would be a more appropriate mechanism for assessing social and ethical considerations than leaving such an assessment to individual patent examiners. The membership of an ethics advisory body could be based on expertise in social and ethical issues and permit various ethical perspectives and standpoints to be represented. However, such a mechanism would inevitably add to the cost and complexity of the patent system. Any determination about the possible social and ethical implications of a particular invention is likely to be contested and new review or appeal mechanisms may be needed. Given that IP Australia examines more than 16,000 patent applications each year,[168] and that only a small proportion of these applications can be expected to have contentious social or ethical implications, ethics assessment of all patent applications seems unlikely to be the most efficient or effective form of regulation. Reform to permit inventions to be excluded from patentability based on the advice or determinations of patent examiners or some new ethics advisory body would thus have uncertain consequences for the efficiency of the patent system.

7.125 The ALRC's present view is that social and ethical concerns can be addressed most effectively through direct regulation of the use and exploitation of patented inventions (or through regulation of research activities that lead to the development of inventions), rather than through excluding particular subject matter from patentability. In this context, arguments about the relevance of social and ethical considerations tend to be directed towards two quite different outcomes: either that particular subject matter should not be patentable because the invention is objectionable and its use should be curtailed or prohibited; or that particular subject matter should not be patentable because the invention is beneficial and its use should be promoted.

7.126 In the ALRC's view, it is better in the former case to regulate use of the invention directly than to address the ethical or social concerns by excluding the subject matter from patentability. To exclude such an invention from patentability does not prevent the inventor from using the 'objectionable' technology, although it might have the incidental effect of encouraging secret use and limiting the dissemination of the technology. Thus, intervening at the point of patentability does not address the mischief that is said to arise from the invention. An example is human embryonic stem cells—these can generally be patented but their derivation and use in research is carefully controlled by federal, state and territory legislation, as well as guidelines and standards issued by the NHMRC.[169]

168 See Ch 5.
169 See Ch 16.

7.127 In the latter case—where an invention is seen as beneficial and access is to be encouraged—somewhat different considerations apply, but the ALRC here too has come to the view it is generally better to regulate use of the patented invention than to exclude the subject matter from patentability. Those who argue for an exclusion from patentability in order to promote broad access to the invention generally do so because the granting of a patent over the invention, with its concomitant monopoly rights, enables the patent holder to limit use of the invention through restrictive licensing practices or charging excessive prices. But this is to take a short term view. In the longer term, the inability to patent a particular type of technology (for example, diagnostic genetic tests) may have negative implications for research and development in that field. The net outcome might be to reduce access to that technology in the longer term.

7.128 Social and ethical considerations relating to access can be better addressed by specific measures to facilitate the use of particular patented inventions, both through the patent system and by other means. For example, research on a patented invention can be promoted by a new defence to claims of patent infringement (see Chapter 14); and exploitation of a patent can be promoted by better utilisation of the Crown use (Chapter 26) and compulsory licensing provisions (Chapter 27) of the *Patents Act*. Beyond the *Patents Act*, access on reasonable terms can also be facilitated by the vigilant application of competition law principles to the licensing of patent rights (Chapter 24). Solutions such as these allow for a targeted response to existing and emerging problems in the field of genetic materials and technologies, and this is unlikely to be achieved by the categorical exclusion of such inventions from patentability.

Proposal 7–3 The *Patents Act* should not be amended to expand the circumstances in which social and ethical considerations may be taken into account in decisions about granting patents. Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of the patented invention.

8. Patent Office Practices

Contents

Introduction

8.1 The Australian patent system is administered by the Patent Office of IP Australia.[1] This chapter provides an overview of certain aspects of IP Australia's practices and addresses concerns raised in some submissions and consultations about the manner in which IP Australia assesses applications for gene patents. It considers the resources available to IP Australia; the expertise of, and training provided to, Australian patent examiners; and the assistance available to patent examiners in applying Australian patent law to gene patent applications.

8.2 The issues raised in submissions and consultations about IP Australia's practices are not unique. Internationally, questions have been raised about the capacity of patent offices to assess applications for gene patents effectively and to process such applications efficiently.[2] It has been suggested that patent offices may lack the resources or expertise to deal with the volume and nature of patent applications being filed in this area. The reforms proposed in this chapter are intended to assist IP Australia in adapting its current practices to the challenges posed by applications claiming genetic materials and technologies, and to enhance mechanisms already adopted by IP Australia to address these issues.

Overview of IP Australia's examination practices

8.3 IP Australia receives patent applications from applicants within Australia and overseas. Patent applications may be filed in person at one of IP Australia's state offices, by mail, or electronically. The Patent Office is divided into various groups, which have responsibility for different aspects of processing a patent application, including groups responsible for patent administration and patent examination.

8.4 The patent administration branch initially processes patent applications. Applications are categorised and assigned to a particular examination section according to the International Patent Classification (IPC) system at the sub-class level.[3] The IPC system is a hierarchical classification system created by international convention and administered by the World Intellectual Property Organization (WIPO).[4] It comprises sections, classes, subclasses and groups (main groups and subgroups). All technological fields are categorised into one of the eight sections and then further classified. Relevantly, in the seventh edition of the IPC, there are 628 subclasses. No single category of the IPC encompasses all inventions involving genetic materials and technologies.

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1 IP Australia is the Commonwealth organisation that also administers trade mark and design rights. See website at <www.ipaustralia.gov.au>.

2 B Lehman, *Making the World Safe for Biotech Patents* (2002) International Intellectual Property Institute Discussion Paper, 26 June 2002; M Cooney, *Patent Reform Plans Win Approval: But Lawyers Call for Better Resourcing of Patent Office*, Computerworld, <www.computerworld.co.nz> at 1 September 2003.

3 IP Australia, *Submission P56*, 4 November 2003.

4 World Intellectual Property Organization, *General Information on the Seventh Edition of the International Patent Classification System (IPC)*, <www.wipo.org/classifications> at 16 December 2003.

8.5 The patent examination branch handles examination of patent applications and challenges to patent rights determined by the Commissioner of Patents.[5] Currently, the examination branch includes two Deputy Commissioners of Patents and eleven examination sections. Each examination section comprises one supervising examiner, three to four senior examiners and approximately 16 patent examiners. A third Deputy Commissioner is responsible for dealing with challenges to patent rights. This section comprises one supervising examiner, one senior examiner and two clerical staff.

8.6 Examination of a patent application is generally undertaken by a single patent examiner, although a team of three examiners may be needed when prior art searches are conducted. The work within each examination section, and of each patent examiner, is prioritised to ensure that statutory time limits are met and IP Australia's targets and standards are also fulfilled to the extent possible.

8.7 Each examination section includes a supervising examiner and senior examiners who perform a variety of functions, including training and evaluation of newly recruited examiners, managing any issues referred by examiners assigned to a particular application, and review of examiners' work for quality control purposes.

General concerns about examination practices

Issues and problems

8.8 Some submissions and consultations articulated a general concern about IP Australia's capacity to scrutinise gene patent applications,[6] but did not always identify areas in which IP Australia's practices were regarded as problematic. Some submissions and consultations encouraged the ALRC to examine the resources available to IP Australia, and its expertise in relation to genetic materials and technologies.[7]

8.9 A number of submissions commented that IP Australia should ensure that the requirements for patentability under current Australian law are stringently applied to gene patent applications.[8] Others suggested that more rigorous examination of gene patent applications was required.[9] It was also suggested that Australian patent

5 Challenges to patent rights are discussed further in Ch 9.

6 South Australian Department of Human Services, *Consultation*, Adelaide, 15 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003

7 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003.

8 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003.

9 R Barnard, *Submission P32*, 7 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

examiners might not have correctly applied particular requirements for patentability to gene patent applications—for example, the 'utility' criterion.[10]

8.10 A small number of comments were directed to IP Australia's examination of particular gene patents, and cited the grant of certain patents as evidence of a more general failure on the part of the Patent Office to examine gene patent applications adequately.[11]

8.11 However, other submissions and consultations did not perceive current problems with IP Australia's practices or its capacity to assess gene patent applications. The Department of Industry, Tourism and Resources (DITR), of which IP Australia is a division, and the Queensland Government commented that IP Australia currently scrutinises gene patent applications effectively.[12] Similarly, views expressed in some consultations suggested that, while IP Australia may have experienced difficulties in examining gene patent applications in the past, its practices had now improved.[13]

8.12 Some submissions and consultations suggested that patent examiners in Australia are more lenient than patent examiners in other jurisdictions,[14] or accept gene patent applications with overly broad claims.[15] The ALRC was informed that patent examiners in the United States seemed to subject gene patent applications to more rigorous assessment.[16] In addition, a few submissions and consultations expressed concern that Australian patent examiners may not rigorously assess Australian patent applications related to a patent that has already been granted in another jurisdiction.[17]

8.13 Similar views were expressed to Dr Dianne Nicol and Jane Nielsen as part of an empirical study that they conducted regarding medical biotechnology patenting and technology transfer in Australia.[18] Nicol and Nielsen found that one of the problems

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10 R Barnard, *Submission P32*, 7 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003; G Suthers, *Submission P30*, 2 October 2003.

11 L Palombi, *Submission P28*, 1 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.

12 Queensland Government, *Submission P57*, 5 January 2004; Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003.

13 Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003; AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003. See also BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

14 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003; Consumers' Health Forum of Australia, *Consultation*, Canberra, 23 September 2003.

15 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.

16 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003; Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

17 See, eg, South Australian Department of Human Services, *Consultation*, Adelaide, 15 September 2003.

18 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6.

consistently identified by respondents was the breadth of biotechnology patents granted by Australian patent examiners.[19]

8.14 However, in its submission to the Inquiry, IP Australia suggested that these concerns are misplaced.[20] IP Australia commented that patent applicants sometimes assume that the more objections raised by a patent office the higher the quality of the examination, but this assumption is incorrect.[21] In addition, IP Australia noted that even where patent claims granted by different patent offices appear to be of different scope, they may be similarly interpreted under the laws of the relevant jurisdictions.[22] IP Australia indicated that comparison with the United Kingdom Patent Office has suggested that similar patentability outcomes were reached by the two patent offices when examining the same patent applications.[23]

8.15 IP Australia's submission on this issue is supported by the results of a recent study comparing the approaches adopted by the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO), the Japanese Patent Office (JPO) and IP Australia to certain gene patents.[24] Professor Andrew Christie and Melanie Howlett compared the approach of each of these patent offices in examining a series of hypothetical claims for partial DNA sequences (or expressed sequence tags).[25] Christie and Howlett found that while each patent office adopted its own approach to interpreting and applying the requirements for patentability, the end result of the examination of such claims was the same for all the offices.[26]

8.16 DITR submitted that IP Australia's procedures are comparable with international best practice.[27] DITR supported IP Australia's comments that it has implemented procedures to monitor international patent activity and 'to adopt appropriate legally based examination procedures'.[28] In addition, DITR indicated in consultations that IP Australia was highly regarded and distributed results of prior art searches to patent offices in other jurisdictions.[29] IP Australia, in conjunction with the JPO, has been nominated to coordinate a project sponsored by WIPO to modernise patent offices in the Asia-Pacific region.[30]

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19 Ibid, 56.
20 IP Australia, *Consultation*, Canberra, 24 September 2003.
21 Ibid. See also Gene CRC, *Consultation*, Melbourne, 3 September 2003.
22 IP Australia, *Submission P56*, 4 November 2003.
23 Ibid.
24 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003).
25 The hypothetical claims were taken from a similar comparative study conducted by the Trilateral Offices—that is, the USPTO, EPO and JPO.
26 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 25–28.
27 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
28 Ibid.
29 Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003.
30 Ibid.

ALRC's views

8.17 The ALRC acknowledges the general concerns expressed in submissions and consultations about the capacity of IP Australia to assess gene patent applications. However, these concerns do not warrant fundamental changes to the functions or structure of IP Australia. Rather, the ALRC considers that concerns about IP Australia's practices may be addressed by specific proposals set out in this chapter with respect to the training of patent examiners, access to the advice of legal and scientific experts, and provision of additional guidance to patent examiners in applying general principles of patent law to inventions involving genetic materials and technologies.

Resources

8.18 The capacity of IP Australia to examine gene patent applications efficiently and effectively depends, in part, on the financial and human resources available to the organisation.

Funding for IP Australia

8.19 IP Australia operates on a full cost-recovery basis and funds its activities from revenue raised through charges for its intellectual property services.[31] Unlike some other government agencies, therefore, IP Australia is not dependent on appropriations from the Parliament to carry out its normal activities.[32] According to IP Australia's audited financial statements for the fiscal year ending 30 June 2003, IP Australia's annual revenue from its ordinary activities amounted to approximately $85.5 million. Of that amount, $50.6 million represented amounts collected in patent fees.[33]

Australian patent examiners

8.20 IP Australia currently has approximately 200 patent examiners.[34] This is a relatively small number compared with the USPTO, which has approximately 3,500 examiners.[35] As Figure 8–1 indicates, the number of patent examiners employed by IP Australia has increased in the last three years after a period of steady decline from 1996–97 to 1999–2000. Figure 8–1 also shows that, following a steady increase in the number of patents examined annually per examiner in the 1990s, that number has declined in the last two years. The total number of patent applications filed each year with IP Australia has risen steadily since 1990–91.[36] If this trend continues, the number of applications that Australian patent examiners will have to assess each year will also

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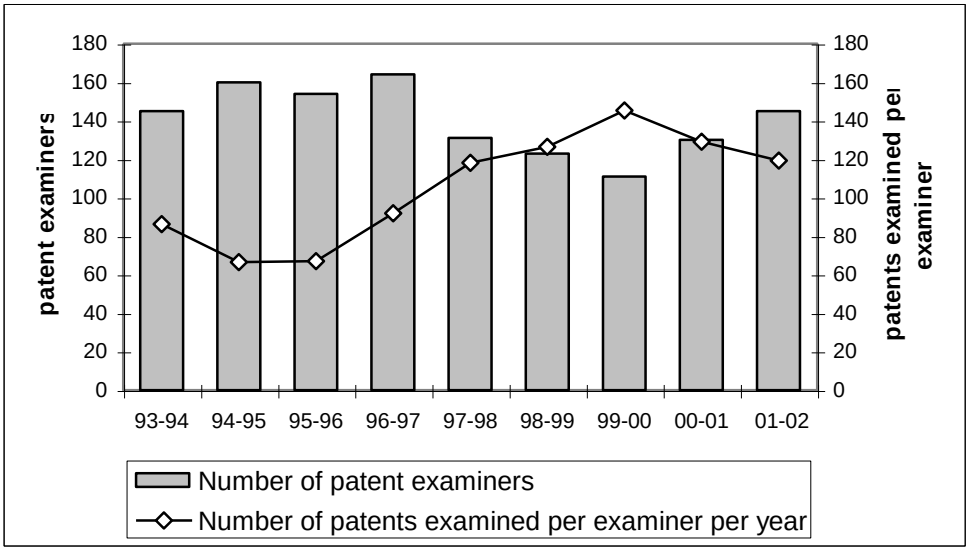
31 Department of Industry Tourism and Resources, *Annual Report* (2003).
32 Ibid.
33 The balance of IP Australia's annual revenue from its ordinary activities comprises trademark and design fees, revenue gained from sale of assets and from services provided by the Australian Government free of charge, as well as accrued interest: Ibid.
34 This figure includes supervising examiners and senior examiners.
35 IP Australia, *Submission P56*, 4 November 2003.
36 IP Australia, *Industrial Property Statistics*, Tables 1 and 2, various years.

continue to increase, unless there is a corresponding increase in the number of examiners.

Figure 8–1 Patent examiners and their workload



Sources: IP Australia, *Industrial Property Statistics*, Table 2, various years; Department of Industry Tourism and Resources, *Annual Report*, various years.[37]

United States Patent and Trademark Office

8.21 Concerns have also been expressed about the examination of patent applications by the USPTO.[38] It has been estimated that the USPTO currently has a backlog of 300,000 patent applications,[39] including 40,000 applications relating to biotechnology.[40] In response to concerns about the capacity of the USPTO to process pending patent applications efficiently and accurately, the USPTO introduced its *21st Century Strategic Plan*.[41] Changes to the USPTO proposed in the Plan included: hiring new examiners; increasing patent examination fees; reducing the level of 'fee diversion' to other government programs (that is, allowing the USPTO to retain and

37 The number of patents examined is based on data for the 'first reports issued' on patent applications filed with IP Australia.

38 United States Patent and Trademark Office, *Performance and Accountability Report for Fiscal Year 2002* (2002), 22.

39 J Kurlantzick, *Losing the Race: Is the Patent Office's Slowness Putting US Innovation at Risk?*, Entrepreneur, May 2003, <www.entrepreneur.com> at 13 May 2003.

40 T Zwillich, *Biotech Firms Want to Sway Patent Office Revamp*, Reuters Health, <www.reuters.com> at 2 May 2003.

41 See United States Patent and Trademark Office, *21st Century Strategic Plan*, <www.uspto.gov/web/offices/com/strat21/index.htm> at 2 June 2003. See also B Lehman, *Making the World Safe for Biotech Patents* (2002) International Intellectual Property Institute Discussion Paper, 26 June 2002, 5–6.

use more of the funds that it raises in patent fees for its own purposes);[42] and implementing an electronic filing and processing system for patent applications.

Submissions and consultations

Funding

8.22 While the Inquiry has received comments on the need to ensure that IP Australia has sufficient resources, only the Australian Centre for Intellectual Property in Agriculture (ACIPA) made a specific submission on this matter. ACIPA was critical of the current funding arrangements for IP Australia, which are based on a 'cost-recovery model'.[43] ACIPA considered that IP Australia should receive independent public funding, rather than being reliant upon application and maintenance fees to fund its activities. In its view, the fact that IP Australia's funding (like the USPTO's) is dependent upon patent fees may lead it to adopt a more service-oriented approach to the patent application process and provide incentives to IP Australia to issue patents in order to maintain funding levels.

Patent examiners

8.23 Concerns were expressed about whether IP Australia has access to a sufficient number of experienced examiners to assess applications for gene patents in an adequate and timely manner. For example, the Walter and Eliza Hall Institute of Medical Research suggested that 'the rapidly increasing volume of gene patents raises questions of access to sufficiently experienced examiners'.[44]

8.24 GlaxoSmithKline and ACIPA supported additional examiners being made available to IP Australia in all areas of technology.[45] GlaxoSmithKline suggested that 'the efficiency and quality of examination by IP Australia has noticeably improved' since the employment of significant numbers of new examiners in recent years.[46] GlaxoSmithKline contrasted current practices of IP Australia with the general decrease in the number of Australian patent examiners in the late 1990s which, combined with an increase in patent filing activity, adversely affected the timeliness and quality of examinations. ACIPA also submitted that:

> there is a need for the organisation to retain its cadre of patent examiners—so that its expertise is not lost to the patent attorneys and private law firms. Accordingly, the terms and conditions for patent examiners should be markedly improved.[47]

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42 The United States Federal Trade Commission has also recommended that the USPTO should receive greater funding from the United States Congress to ensure quality patent review: United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), rec 4.

43 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

44 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; UniQuest, *Consultation*, Brisbane, 3 October 2003.

45 GlaxoSmithKline, *Submission P33*, 10 October 2003.

46 Ibid. See also BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

47 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

ALRC's views

8.25 The ALRC acknowledges the concerns expressed in submissions and consultations relating to the number of Australian patent examiners and the resources available to IP Australia. The services provided by IP Australia, like any other governmental body, could no doubt be improved with additional funding. However, no evidence was presented to the Inquiry demonstrating that lack of funding is currently hampering IP Australia's examination of gene patent applications, or applications claiming any other type of technology. On the contrary, some submissions suggested that there have been significant improvements in IP Australia's examination practices in recent years. Furthermore, concerns about Australian patent examiners did not focus on the number of patent examiners per se but on the experience of examiners. This issue is addressed below.

Qualifications and training

8.26 A report on the Australian biotechnology industry published in 2001 noted that biotechnology inventions are assessed by examiners with particular expertise and training in the biotechnology field, in accordance with the practices of patent offices in other jurisdictions.[48] IP Australia has provided the ALRC with further information about qualification requirements and training programs for Australian patent examiners.[49]

8.27 To be eligible for a position as a patent examiner, an applicant must hold a university degree in science or engineering. Examiners who assess applications for genetic materials and technologies must have qualifications in the field of biochemistry. Experience in a relevant industrial field is preferable, but not mandatory. IP Australia informed the ALRC that the level of industrial experience of newly recruited examiners varies from year to year.[50]

8.28 IP Australia trains new recruits to allow them to perform the various functions required of a patent examiner. Supervising and senior examiners conduct this training, which covers Australian patent law and patent practice. It includes a formal assessment regime, as well as practical training and supervision. The purpose of this training is to enable new examiners to reach the required competency standard to exercise the 'acceptance delegation'.[51] 'Acceptance delegation' refers to the Commissioner of Patents' ability under the *Patents Act* to delegate his or her power to examine and, if appropriate, accept patent applications to examiners who meet IP Australia's standards for such a position.[52] Examiners must demonstrate an 'appropriate level and quality of

48 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001).
49 IP Australia, *Submission P56*, 4 November 2003.
50 Ibid.
51 Ibid.
52 Subject to certain formalities, the Commissioner may delegate any or all powers and functions conferred upon him or her under the *Patents Act* or any other Act: *Patents Act 1990* (Cth) s 209. Other powers of

work output and have the experience, knowledge and judgement to be able to reliably exercise the delegation'. [53] Typically, examiners reach this level of competence after approximately 30 months of service with IP Australia.

8.29 IP Australia also has a continuing professional development program for patent examiners. The program aims to develop examiners' skills in patent law, examination and searching practices, and examiners' knowledge in relevant technological fields. It includes both internal and external training programs, attendance at conferences, visits to relevant industries and placements in patent attorney firms.

8.30 IP Australia has a number of examination sections, each of which specialises in different areas of technology.[54] IP Australia commented that:

> While there is a degree of specialisation within each field, IP Australia examiners are expected to assess a greater range of technologies than may be the case in the larger offices such as the USPTO and EPO.[55]

Submissions and consultations

8.31 Concerns were raised in a number of submissions and consultations about patent examiners' expertise and the need for continuing training to allow patent examiners to keep abreast of technological developments in their relevant fields. Some of the submissions that addressed this issue indicated that the expertise of patent examiners is not currently a concern, but is a matter that warrants further review.[56]

8.32 Other submissions considered that the expertise of patent examiners in any rapidly developing area of science may be an issue, because the quality of patent examination is limited by the level of technical skill of a patent examiner.[57] The South Australian Government commented that this may be a particular issue in relation to genetic materials and technologies because the assessment of patent applications claiming such inventions might require a greater understanding of science than of law.[58] BresaGen commented that the issue might also arise for patent applications relating to stem cell technologies, where patent examiners may not have an adequate understanding of the relevant scientific background.[59]

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the Commissioner of Patents may also be delegated to more senior examiners, for example, the power to hear and determine opposition and re-examination proceedings.

53 IP Australia, *Submission P56*, 4 November 2003.

54 Ibid.

55 Ibid.

56 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003. See also New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003.

57 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; A McBratney and others, *Submission P47*, 22 October 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003.

58 South Australian Government, *Submission P51*, 30 October 2003.

59 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

8.33 In consultations, the National Stem Cell Centre commented that patent applications were typically allocated to a patent examiner with a background that is related to the technology involved in the invention.[60] Variations in the level of skills of Australian patent examiners were, however, noted.[61] The Department of Health Western Australia commented that, while Australian patent examiners may have a general science degree, the level of specialisation of patent examiners was not as great as within the USPTO.[62] BresaGen suggested that this might be the result of both a lack of resources within IP Australia and a lack of training of Australian patent examiners.[63]

8.34 Dr Amanda McBratney and others suggested that concerns about the expertise of patent examiners could be addressed by imposing 'a requirement for auditing and updating of examiner skills'.[64]

> Examiners should be involved in a process of ongoing education so that they are as up to date in the relevant technological areas as possible. Continuing education should be mandatory—not only course work, but attendance at conferences (as this is where the most up to date information is discussed).[65]

ALRC's views

8.35 In view of the number of examiners employed by IP Australia and the variety of patent applications, Australian patent examiners may be required to assess patent applications involving a diverse range of technologies. It is important that patent examiners have access to training and professional education to allow them to continue to develop knowledge and skills in the areas of technology in which they may be required to assess applications. IP Australia currently operates such programs, and submissions and consultations did not identify particular inadequacies in the training that Australian patent examiners currently receive. The ALRC considers that IP Australia should, however, ensure that it reviews the subject matter and structure of its education programs regularly to ensure that examiners remain up to date with new developments. The ALRC does not regard this issue as unique to inventions involving genetic materials and technologies.[66] It will also be an important issue in connection with new technologies that arise in the future.

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60 National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003.

61 Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003; National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003.

62 Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003; Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

63 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

64 A McBratney and others, *Submission P47*, 22 October 2003.

65 Ibid.

66 Similar concerns have been raised in connection with applications for patents relating to other technologies: see, eg, Institute of Patent and Trade Mark Attorneys of Australia, *Submission to Advisory Council on Intellectual Property's Inquiry into the Patenting of Business Systems*, Advisory Council on Intellectual Property, <www.acip.gov.au/bus_submissions/bus_submissions.htm> at 4 June 2003.

Proposal 8–1 To ensure the on-going competence of Australian patent examiners in assessing patent applications, IP Australia should continue its efforts to provide examiners with continuing education in areas of technology relevant to their particular specialty. IP Australia should review and update its education programs regularly so that new developments can be incorporated as required.

Expert assistance

8.36 A recent report of the Royal Society expressed concern that patent examiners in the United Kingdom may lack sufficient skills and experience in newer areas of science.[67] The Royal Society recommended that examiners should consult experts to ensure that their understanding of relevant areas of science is extremely high,[68] so that examiners are able to apply the same demanding standards in both developing and established areas of science.[69] In the Royal Society's view, scientific experts might provide a valuable resource because:

> [m]any scientists, especially in academia, have detailed and up-to-date knowledge (often including access to prior art not otherwise easily traceable) and experience in assessing experimental data and the significance of new scientific developments.[70]

8.37 To date, there is limited precedent in other jurisdictions for providing patent examiners with the type of access to scientific or technical expertise proposed by the Royal Society.[71] The USPTO has announced that it will expand its practice of 'second-pair-of-eyes' review to cover fields such as biotechnology, semiconductors and software.[72] A recent report by the United States Federal Trade Commission endorsed these initiatives:[73]

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67 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), [3.27].

68 Ibid, [3.28].

69 Ibid.

70 Ibid, [3.28].

71 For example, in Singapore the *Patents Act 1995* (Singapore), legislation grants the Registrar of Patents the discretion to appoint a scientific adviser from a panel of advisers established under the Act to assist the court and the Registrar of Patents: *Patents Act 1995* Chapter 221 (Singapore) s 90. The European Group on Ethics in Science and New Technologies has recommended that patent applications claiming human stem cells should be subject to ethical review by an independent advisory body as part of the examination process: European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), [2.10]. Creation of an independent ethical advisory body as part of the Australian patent system is considered further in Ch 7.

72 United States Patent and Trademark Office, *21st Century Strategic Plan*, <www.uspto.gov/web/offices/com/strat21/index.htm> at 2 June 2003; United States Patent and Trademark Office, *Patent Quality Improvement: Expansion of the Second-Pair-of-Eyes Review*, <www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm> at 1 December 2003.

73 United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), rec 5(c).

> In emerging areas such as biotechnology, second-pair-of-eyes review can significantly help improve the quality of patent application review, since in emerging areas, examiners necessarily lack experience in reviewing the new industry's patent applications, and the body of prior art is slim.[74]

8.38 Currently, Australian patent examiners may refer any issues to senior or supervising examiners within their section. IP Australia's *Patent Manual of Practice and Procedure* (the *Manual*) indicates that an examiner should raise any concerns he or she may have about mastering the technical and legal aspects of an application with a senior examiner.[75] In addition, IP Australia has adopted policies that require patent applications for certain types of technologies to be referred to a supervising examiner automatically, for example patent applications that may claim human beings or the biological processes for their generation.[76]

Submissions and consultations

8.39 A number of submissions proposed that expert advice should be available to patent examiners in assessing patent applications, whether involving genetic materials and technologies or new technologies generally. Dr Amanda McBratney and others submitted that:

> Engagement of experts within a particular field should be sought where broad patents are to be granted for a new area.[77]

8.40 Some submissions considered that a panel of expert advisers should be established to assist patent examiners. The Commonwealth Department of Health and Ageing suggested that there was a need for 'appropriate advice to assist patent examiners' in their assessment of patenting human genes and related technologies for health purposes.[78] The Department proposed that an expert committee should be set up to advise patent examiners on 'policy and scientific issues' surrounding gene patents.

8.41 Other submissions and consultations suggested that such an expert panel should have more of an oversight role. The Department of Health Western Australia suggested that IP Australia should consider 'the development of a secondary body of experts to oversee the granting of … highly specialised, significant and controversial patents'.[79] In consultations, the Consumers' Health Forum of Australia also indicated that expert oversight of decisions made by the Patent Office was desirable.[80]

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74 Ibid ch 6, 20.
75 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [12.1(f)].
76 Ibid, [8.5]. The exclusion from patentability of inventions claiming human beings or the biological processes for their generation is discussed in Ch 7 and 16.
77 A McBratney and others, *Submission P47*, 22 October 2003.
78 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.
79 Department of Health Western Australia, *Submission P53*, 3 November 2003.
80 Consumers' Health Forum of Australia, *Consultation*, Canberra, 23 September 2003.

8.42 One submission that supported the establishment of a panel of expert advisers considered that membership of the panel should include legal and scientific experts.[81] Others suggested that experts in social policy or ethics should also be included to assess the manner in which specific patents might impact on the healthcare system.[82] The Consumers' Health Forum of Australia proposed that the involvement of consumer representatives might also be desirable.[83]

8.43 In consultations, IP Australia indicated that use of expert panels in examining patent applications could be considered if this would improve the assessment of patent applications.[84] However, the organisation also noted that appointing a panel of experts to advise on applications on a case-by-case basis might raise conflict of interest issues, and potentially delay the examination and grant of a patent. In addition, the South Australian Government submitted that increasing the level of scrutiny to which gene patent applications are subjected might delay the grant of such patents.[85]

Expert advisory committees in other regulatory schemes

8.44 In examining the potential for advisory experts in patent examination, it is instructive to consider their use in other regulatory regimes in Australia. Expert advisory committees form part of the regulatory regime for genetically modified organisms in Australia. The *Gene Technology Act 2000* (Cth) created the position of the Gene Technology Regulator (the Regulator),[86] as well as certain subsidiary advisory committees to assist the Regulator in performing his or her functions set out in the Act.

8.45 One of the advisory committees created by the *Gene Technology Act* is the Gene Technology Technical Advisory Committee (GTTAC).[87] The GTTAC comprises mainly experts in relevant scientific disciplines[88] who provide scientific and technical advice to the Regulator and the Gene Technology Ministerial Council (the Ministerial

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81 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

82 Ibid; Department of Health Western Australia, *Submission P53*, 3 November 2003. Submissions and consultations that proposed the establishment of a separate advisory panel of expert ethicists to review patent applications claiming genetic materials and technologies are considered in Ch 7.

83 Consumers' Health Forum of Australia, *Consultation*, Canberra, 23 September 2003.

84 IP Australia, *Consultation*, Canberra, 24 September 2003.

85 South Australian Government, *Submission P51*, 30 October 2003.

86 *Gene Technology Act 2000* (Cth) s 26. The functions of the Regulator are prescribed in s 27 of the *Gene Technology Act* and include: administration of the Act and related legislation; assessment of any risks posed by genetically modified organisms; providing information and advice to other regulatory agencies about genetically modified organisms and products; and promoting harmonised risk assessment for such organisms and products by all regulatory agencies.

87 Ibid s 100(1). The other subsidiary advisory bodies established under the *Gene Technology Act* are the Gene Technology Ethics Committee and the Gene Technology Community Consultative Committee: *Gene Technology Act 2000* (Cth) ss 111, 106.

88 GTTAC comprises 18 members with expertise in matters such as biology, ecology, genetics, public health, botany, toxicology and risk assessment, as well as one layperson: *Gene Technology Act 2000* (Cth) ss 100(2), 100(5), 100(6). An expert adviser who provides further expertise in weed and pesticide resistance management also participates in determinations made by the GTTAC: *Gene Technology Act 2000* (Cth) s 102; Department of Health and Ageing, *Gene Technology Committees: The Gene Technology Advisory Committee*, <www.ogtr.gov.au/committee/gttac.htm> at 25 November 2003.

Council).[89] Members of the GTTAC are appointed by the Minister of Health, following consultations with the States and Territories, the Regulator, stakeholder groups and such other Ministers as may be appropriate.[90]

8.46 The GTTAC provides advice upon request by the Regulator or the Ministerial Council.[91] Such advice may relate to specific applications for licences to conduct 'dealings'[92] with genetically modified organisms under the Act.[93] The GTTAC may also provide general advice relating to genetically modified organisms and products, as well as the biosafety aspects of gene technology. In addition, the GTTAC may provide advice on the need for, and the content of, policies, codes of practices and guidelines in relation to genetically modified organisms and products.[94]

8.47 Members of the GTTAC are appointed on a part-time basis[95] and are subject to disclosure of interest requirements prescribed by regulation.[96] Prior to their appointment as a member of the GTTAC, nominated members must disclose to the Minister any direct or indirect interests (including pecuniary interests) in matters likely to be considered at a meeting of the GTTAC.[97] In addition, each member must disclose to the GTTAC any conflicts of interest (including pecuniary interests) that arise from time to time during the term of their appointment.[98] Any member who discloses a conflict of interest is not permitted to participate in deliberations relating to, or decisions on, the matter in connection with which a conflict exists.[99]

ALRC's views

8.48 As discussed in Chapter 6, novel and complex scientific and legal issues may be raised by patent applications claiming genetic materials and technologies. IP Australia already has some mechanisms in place to resolve difficult issues that may arise during the assessment of a particular patent application—for example, referral of particular matters to supervising or senior examiners. However, IP Australia employs a comparatively small number of Australian patent examiners, and these examiners assess patent applications in a broad range of technological fields.

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89 The Gene Technology Ministerial Council comprises one representative from the Commonwealth and each of the States and Territories and was established by the intergovernmental Gene Technology Agreement 2001: Commonwealth of Australia and others, *Gene Technology Agreement* (2001).

90 *Gene Technology Act 2000* (Cth) s 100(4). Consultation by the Minister does not appear to be required prior to the appointment of any expert advisers: *Gene Technology Act 2000* (Cth) s 102(1).

91 *Gene Technology Act 2000* (Cth) s 101.

92 'Dealings' is defined in the *Gene Technology Act* to include any of the following activities in relation to a 'genetically modified organism': conducting experiments; making, developing, producing or manufacturing; breeding; propagating; growing or culturing; and importing: Ibid s 10.

93 Ibid s 101(b). The GTTAC also provides comments on the Risk Assessment and Risk Management Plan prepared in connection with each such license application.

94 Ibid ss 101(a), (c), (d).

95 Ibid s 100(3); *Gene Technology Regulations 2001* (Cth) r 18.

96 *Gene Technology Act 2000* (Cth) s 104(1); *Gene Technology Regulations 2001* (Cth) rr 20, 22.

97 *Gene Technology Regulations 2001* (Cth) rr 20(1), 23(1).

98 Ibid rr 20(2), 23(2).

99 Ibid r 20(4). The same restriction does not appear to apply to expert advisers appointed by the Minister: *Gene Technology Regulations 2001* (Cth) r 22.

8.49 New developments in human genetics require an increasingly detailed grasp of the scientific context and background to distinguish potentially novel developments from what has come before. In the ALRC's view, the establishment of a panel of experts within IP Australia would assist Australian patent examiners in addressing issues raised during the examination of particular gene patent applications. The panel could also provide general advice about how to approach a specific legal or scientific issue that is raised by a class of genetic inventions. Similar panels of experts might also be established by IP Australia in relation to other novel areas of technology in the future.

8.50 Few submissions commented on the composition of such a panel of experts. However, the ALRC considers that a balance of independent legal and scientific experts (drawn from within Australia or internationally, as the circumstances require) should be appointed to the panel by the Commissioner of Patents, following appropriate consultation with industry groups and other relevant stakeholders. The ALRC is currently of the view that experts in bioethics, public health or social policy should not specifically be included on the panel. The panel of experts is not intended to be a broad policy-making body but to provide advice on specific patent applications or on particular legal or scientific issues raised by a class of inventions. The ALRC has made proposals elsewhere in this Discussion Paper to address the wider public policy and healthcare concerns raised by gene patents, and to establish mechanisms to ensure on-going review of these matters.[100]

8.51 The expert advisory committees established within the Office of the Gene Technology Regulator provide a model for developing procedures for the proposed panel of experts, particularly in relation to conflict of interest issues. In addition, IP Australia should establish appropriate procedures to maintain the confidentiality of any patent applications considered by the panel prior to publication of the application.

8.52 The establishment of a panel of experts has the potential to increase the level of scrutiny of patent applications, and thereby delay the grant of certain patents. However, assistance from the panel will be appropriate only in a relatively limited number of cases, and should be given only upon a request from the Commissioner of Patents. IP Australia should develop procedures to ensure that consideration by the panel of experts takes place as expeditiously as the circumstances allow; for example, by enabling the entire panel, or individuals members of it, to be called upon as the need arises. In the ALRC's view, an appropriate choice of procedures should enable panels of experts to be established and utilised with minimal additional cost.

8.53 Responsibility for determinations about a particular gene patent application should remain with the individual examiner to whom a patent application is assigned. In the ALRC's view, the Commissioner of Patents should not delegate any examination powers to the panel of experts, as the Commissioner does in the case of

100 See Ch 20.

patent examiners. A patent examiner who seeks the opinion of the panel of experts on a particular matter should, however, indicate that advice was sought from the panel in any resulting examination report.

Proposal 8–2 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to authorise IP Australia to establish panels of experts to advise patent examiners in assessing patent applications, as circumstances require.

Proposal 8–3 IP Australia should ensure that appointments to the panel of experts reflect a balance of independent scientific and legal expertise, and that they be made only after consultation with relevant industry organisations and other stakeholders. IP Australia should also develop procedures for the operation of the panel, including procedures in relation to confidentiality, conflict of interest, and decision making by the panel.

Examination guidelines for biotechnology patents

Australia

8.54 As discussed in Chapter 17, the Australian biotechnology industry is still in the early stages of development. One consequence of this is that there has been limited judicial consideration of how patent law principles apply to biotechnological inventions.[101] Little specific guidance is, therefore, available to patent examiners in assessing whether a particular biotechnological or genetic invention satisfies the requirements for patentability. Dr Dianne Nicol and Jane Nielsen have suggested that 'the absence of judicial guidance in this area is problematic'.[102]

8.55 IP Australia has developed the *Manual* to assist Australian patent examiners in applying the *Patents Act* and *Patents Regulations 1991* (Cth) (*Patents Regulation)*.[103] The *Manual* is intended as a reference guide for examiners on all aspects of patent practice including, for example, search and examination procedures, interpretation and application of the requirements of patentability under Australia law and relevant procedural provisions of the *Patents Act*, and practice and procedures in connection with patent applications filed under the *Patent Cooperation Treaty* (PCT).[104] The *Manual* does not, however, contain a section that specifically considers issues that may

101 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 20.

102 Ibid, 20.

103 IP Australia, *Patent Manual Practice and Procedure Volume 1: International* (2003); IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002); IP Australia, *Patent Manual of Practice and Procedure Volume 3: Oppositions, Courts, Extensions & Disputes* (2002). The *Manual* is available on IP Australia's website and in hard copy from IP Australia's state offices.

104 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978).

arise in applying each of the requirements of patentability to inventions involving genetic materials and technologies.[105]

8.56 IP Australia has developed a number of user guides relating to specific issues, including *Australian Patents for: Microoganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; and Genetically Manipulated Organisms.*[106] As discussed in Chapter 6, this user guide sets out the types of biological inventions for which IP Australia will currently grant patent protection if the statutory criteria for patentability are met. The user guide also briefly explains relevant considerations in relation to each of the requirements for patentability and provides more detailed information as to the way in which the disclosure requirements under Australia law might be satisfied in relation to biological inventions.[107]

Other jurisdictions

8.57 Other jurisdictions, particularly the United States and Europe, have more highly-developed case law on patents over biotechnological inventions generally, and inventions involving genetic materials and technologies specifically. In addition, patent offices in some jurisdictions have released specific guidelines outlining the way in which patent law might apply to biotechnological or genetic inventions.

United Kingdom

8.58 In September 2002, the United Kingdom Patent Office released its *Examination Guidelines for Patent Applications Relating to Biotechnology Inventions in the UK Patent Office* (UK Biotech Examination Guidelines).[108] These set out relevant considerations in applying each requirement for patentability under United Kingdom patent law to biotechnological inventions, and supplement the *Manual of Patent Practice* developed by the United Kingdom Patent Office for general use by patent examiners.

8.59 The introduction to the UK Biotech Examination Guidelines comments that applying the basic patentability requirements to biotechnological inventions can 'place considerable demands on the judgment of the examiner'.[109] To assist United Kingdom patent examiners in assessing such applications, the Guidelines set out relevant case

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105 There are isolated references to genetic materials in the *Manual* as well as a chapter setting out the principles and procedures relevant to the deposit of micro-organisms and other life forms: IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.4.2], ch 6.

106 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 31 March 2003.

107 The fair basis and sufficiency requirements for patentability under Australian law are discussed in Ch 6. The *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977* is discussed in Ch 4.

108 United Kingdom Patent Office, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office (November 2003)*, <www.patent.gov.uk/patent/reference/index>.

109 Ibid, [6].

law in this area, and also indicate how patentability requirements 'should be applied' to biotechnological inventions, subject to further guidance from the courts and the Boards of Appeal of the European Patent Office.[110] The UK Biotech Examination Guidelines also provide guidance to patent examiners about how to construe claims commonly used in applications for biotechnology inventions.[111]

8.60 A recent report on the impact and management of intellectual property rights in the United Kingdom healthcare sector, *Intellectual Property Rights (IPRs) and Genetics*,[112] outlined, and commented favourably on, the approach of the United Kingdom Patent Office in the UK Biotech Examination Guidelines. The report stated that:

> It is relevant to note that as these Guidelines are intended simply to outline the *practice* of the Patent Office they are not intended to act as a forum for discussion over the appropriateness of the principles being applied. However, the Guidelines do make a number of key statements on policy and these are to be applauded as they indicate a clear desire to ensure that patent law is applied in an appropriate and effective manner which is consistent with the public interest objectives that underpin the system.[113]

Japan

8.61 The JPO has also issued specific examination guidelines relating to biotechnological inventions. In 1997, the JPO published implementing guidelines for inventions in specific fields, including genetic engineering.[114] Subsequently, the JPO published model assessments of gene patent applications, which set out it's analysis of a range of hypothetical genetic inventions, including applications claiming DNA fragments (or expressed sequence tags) and single nucleotide polymorphisms.[115]

United States

8.62 The United States has not issued specific guidelines for examiners about the application of United States patent law to biotechnological or genetic inventions. United States case law in this area is, however, considerably more developed than in other jurisdictions.[116] In addition, the USPTO has provided guidance about its approach to gene patent applications in connection with its implementation of new

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110 Ibid, [6].
111 Ibid, [7], Annex A.
112 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003).
113 Ibid, app 6.
114 Japan Patent Office, *Implementing Guidelines for Inventions in Specific Fields: Biological Inventions*, <www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/txt/bio-e-m.txt> at 18 November 2003.
115 Japan Patent Office, *Examples of Examinations on the Inventions Related to Genes (DNA Fragments, Full-length cDNAs, and Single Nucleotide Polymorphisms) (Abridged Translation)*, <www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/dnas.htm> at 18 November 2003.
116 See, *Enzo Biochem Inc v Gen-Probe Inc* (2002) 285 F 3d 1013; *Regents of the University of California v Eli Lilly & Co* (1997) 119 F 3d 1559; *Re Dueul* (1995) 51 F 3d 1552; *Re Bell* (1993) 991 F 2d 781.

guidelines for examination of patent applications under the utility and written description requirements for patentability in United States law.[117]

8.63 Before final guidelines on the written description and utility requirements were adopted, the USPTO published interim guidelines for public comment.[118] The introduction to the interim guidelines indicated that, while the guidelines reflected the current understanding of the USPTO of the 'written description' requirement and applied to all relevant technologies, revisions to the guidelines were particularly intended for use by examiners in review of 'biological patent applications'.[119] Many of the comments received by the USPTO during the process of public comment thus addressed the application of the proposed guidelines to inventions involving genetic materials and technologies. The USPTO published responses to the comments it received, and in doing so set out the USPTO's understanding of the current United States law, as well as its practices, in relation to the issues raised.

Canada

8.64 Recent reports in Canada have also proposed that the Canadian Intellectual Property Office (CIPO) provide more assistance to patent examiners in assessing gene patent applications.[120] The report of the Ontario Government, *Genetics, Testing and Gene Patenting: Chartering New Territory in Healthcare* (the Ontario Report), recommended that new patent office guidelines, procedures and training manuals relating to gene patents should be developed. The Ontario Report indicated that:

> clear guidelines must be spelled out providing direction regarding novelty, non-obviousness and utility as they pertain to the issuing of genetic patents.[121]

8.65 A similar recommendation was made by the Canadian Biotechnology Advisory Committee (CBAC) in its 2002 report.[122] CBAC suggested that interpretive guidelines

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117 United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099; United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092.

118 United States Patent and Trademark Office, 'Request for Comments on Interim Examination Guidelines for Examination of Patent Applications under the 35 USC 112 para 1 "Written Description" Requirement' (1998) 63 *FR* 32639; United States Patent and Trademark Office, 'Revised Interim Guidelines for Examination of Patent Applications under the 35 USC 112 para 1 "Written Description" Requirement: Request for Comments' (1999) 64 *FR* 71427; United States Patent and Trademark Office, 'Revised Utility Examination Guidelines: Request for Comments' (1999) 64 *FR* 71440. Public comment on the USPTO's examination guidelines is not required under United States law: 5 USC §553(b)(A).

119 United States Patent and Trademark Office, 'Request for Comments on Interim Examination Guidelines for Examination of Patent Applications under the 35 USC 112 para 1 "Written Description" Requirement' (1998) 63 *FR* 32639. As a result of certain comments that the USPTO received on the interim written description guidelines, the agency determined that review of the utility examination guidelines was also required: United States Patent and Trademark Office, 'Revised Utility Examination Guidelines: Request for Comments' (1999) 64 *FR* 71440.

120 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 47.

121 Ibid, rec 13(b).

122 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), rec 10.

concerning biological inventions could be developed with the assistance of an expert advisory panel.[123] CBAC encouraged the CIPO to indicate its position on particular issues—such as the patentability of higher life forms.[124] CBAC considered that guidelines on how the requirements for patentability are applied by the CIPO to particular types of inventions would also be useful for smaller biotechnology companies who are inexperienced in the patent process.[125]

8.66 The CIPO is currently reviewing its *Manual of Patent Office Practice*[126] and expects to complete a full update of the Manual by September 2004.[127] It is unclear whether CIPO will adopt the recommendations made by the Ontario Government and CBAC as part of this process.

Submissions and consultations

8.67 A number of submissions proposed that IP Australia develop guidelines and procedures in relation to inventions involving genetic materials and technologies.[128] ACIPA commented that:

> The expansion of the patent system has involved drawing analogies between mechanical inventions and new technologies—such as chemical substances, pharmaceutical drugs, and biotechnological inventions. This process of adaptation has produced mixed results—sometimes there is a need for special administrative guidelines and legislative rules to accommodate new technologies.[129]

8.68 Other submissions commented that patent examination practices and procedures develop over time in new technological areas, and this gives the system a degree of flexibility.[130] Davies Collison Cave and GlaxoSmithKline considered that biotechnology patents do not present issues that are fundamentally different from other new technologies—such as organic chemistry, information technology, software or business methods.

8.69 Dr Amanda McBratney and others submitted that IP Australia should publish an information kit about its practices in processing and examining genetic inventions to improve public awareness and confidence on these issues.

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123 Ibid, 21.

124 Ibid, 21. Note that the issue of the patentability of higher life forms has now been considered by the Canadian Supreme Court and rejected: *Harvard College v Canada (Commissioner of Patents)* [2002] SCC 76.

125 *Harvard College v Canada (Commissioner of Patents)* [2002] SCC 76, 21.

126 Canadian Patent Office, *Manual of Patent Office Practice* (1998).

127 Canadian Intellectual Property Office, *Information about the Manual of Patent Office Practice*, <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop/mopop-e.html> at 28 November 2003.

128 Department of Health Western Australia, *Submission P53*, 3 November 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003.

129 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003, 39.

130 Davies Collison Cave, *Submission P48*, 24 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003.

> In order to address the public's concerns about gene patenting, it is submitted that a comprehensive information brochure or kit could be produced by IP Australia, giving the public accurate information about the Australian Patent Office's practices and some level of certainty or reassurance on the issue. It is not anticipated that such a brochure would be legally binding but may prove a useful educational exercise.[131]

8.70 In its submission, IP Australia indicated that it seeks to provide applicants with 'as much information and assistance as possible' and referred to the *Manual* and its various user guides as evidence of this policy.[132] IP Australia did, however, comment that:

> Although it can be difficult to provide definitive information in such a complex and case-specific matter, IP Australia recognises that further improvements to the clarity and user-friendliness of such information can always be made.[133]

8.71 Not all submissions favoured the implementation of new examination guidelines for biotechnological inventions. DITR noted that IP Australia already has a procedures manual, which provides detailed guidelines on the examination of gene patent applications.[134] The South Australian Government considered that IP Australia's resources would be better directed to increasing the number and skill level of patent examiners than developing specific patent guidelines.[135] The South Australian Government considered the creation of guidelines for the assessment of patent applications claiming human genes. It suggested, however, that the proposed Human Genetics Commission of Australia[136] might be an appropriate agency for coordinating the development of such guidelines, with input from researchers, clinicians, community representatives, as well as IP Australia, and subject to approval by the Australian Health Ministers' Conference and the Standing Committee of Attorneys-General.

ALRC's views

8.72 While IP Australia has published both general guidelines to assist patent examiners in applying Australian patent law to particular applications and a user guide on patent applications for biological material, the ALRC considers that additional guidelines to assist patent examiners in assessing patent applications claiming genetic materials and technologies are desirable. Currently, Australian patent examiners have little relevant case law to assist them in determining how the general requirements for patentability in s 18 of the *Patents Act* apply to a specific genetic invention.

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131 A McBratney and others, *Submission P47*, 22 October 2003.
132 IP Australia, *Submission P56*, 4 November 2003.
133 Ibid.
134 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
135 South Australian Government, *Submission P51*, 30 October 2003.
136 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1 to 5–9.

8.73 The ALRC considers that guidelines relating specifically to the examination of biotechnological inventions would assist patent examiners in applying patent law principles to biotechnological inventions.[137] The guidelines should outline IP Australia's general approach to such inventions, and the considerations it regards as relevant in applying each of the requirements for patentability to gene patent applications, particularly where analogies must be drawn with other technologies on the basis of established case law. The guidelines should be in a form that is comprehensible to both patent examiners and patent applicants. The UK Biotech Examination Guidelines are a worthwhile model in this regard.

8.74 Examination guidelines relating to patent applications claiming biotechnological inventions will make IP Australia's assessment of such applications more transparent. It will also assist applicants and their legal advisers in assessing the likely availability of patent protection for a particular genetic invention, and in drafting patent claims appropriately.

8.75 Any such guidelines must be consistent with the *Patents Act*, the *Patents Regulations* and existing case law. While it is recognised that the final interpretation of the Act and the Regulations lies with the courts—which may ultimately reject an interpretation of patent law that has been adopted by IP Australia—the ALRC considers that a clear explanation of IP Australia's approach in assessing gene patent applications would be useful.

8.76 IP Australia is clearly the most appropriate body to formulate specific guidelines relating to the assessment of patent applications for biotechnological inventions. IP Australia should, however, engage relevant stakeholders and other interested parties in consultations before adopting any guidelines in final form. IP Australia should also obtain assistance and advice from the panel of experts described in Proposal 8–2.

Proposal 8–4 IP Australia should develop examination guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

Prior art searches

8.77 A recent report of the Royal Society expressed concern that, at least in the United Kingdom, patent examiners may not have complete access to the relevant prior

137 Nicol and Nielsen have also proposed biotechnology-specific guidelines for assessing the 'description criteria' (this is, the sufficiency and fair basis requirements for patentability): D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 258.

art to enable patent applications to be examined effectively.[138] The Royal Society recommended that searches of the prior art by patent examiners should be as broad as possible, including journals and trade literature, patents and patent applications.[139] In addition, as discussed above, the Royal Society considered that patent examiners should be allowed to consult experts who 'have detailed and up-to-date knowledge (often including prior art not otherwise easily traceable)'.[140]

IP Australia

8.78 A report on the Australian biotechnology industry in 2001 indicated that IP Australia has adapted its processes to accommodate particular features of biotechnology inventions.[141] The report cited specific procedures that IP Australia has adopted to facilitate the processing of applications for gene patents, including acceptance of genetic and protein sequences on computer disks or CD for searching purposes.[142]

8.79 The *Manual* sets out general considerations that Australian patent examiners should take into account in determining the correct strategy for prior art searches and in assessing patent applications in light of prior art search results.[143] The *Manual* notes that examiners should rely on previous search results to the extent possible, including search results conducted by or on behalf of foreign patent offices in respect of an invention claimed in an Australia patent application or in a corresponding patent application filed overseas and disclosed by an applicant under s 45(3) of the *Patents Act*.[144] The *Manual* states that:

> Examiners should not conduct further searches unless, in the light of their knowledge of the art, it is likely that better art would be found that would invalidate the claimed subject matter not anticipated by the search results on file.[145]

8.80 The report of the Intellectual Property and Competition Review Committee (the IPCRC Report) commented on IP Australia's practice of relying on overseas search results, particularly for PCT applications:

> Searching prior art can be a time-consuming and costly and can require considerable expertise, judgement and skill on the part of patent examiners. In a small office such as IP Australia … resources can be stretched in some areas of technology.[146]

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138 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), [3.27].

139 Ibid, [3.27].

140 Ibid, [3.28].

141 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 31.

142 Ibid; *Patents Regulations 1991* (Cth) sch 3, cl 12.

143 IP Australia, *Patent Manual Practice and Procedure Volume 1: International* (2003), ch 1.2; IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [0.2.7]–[0.2.8], [1.4], ch 12

144 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [12.5.9]. Equivalent disclosure requirements exist with respect to documentary searches relating to an innovation patent: *Patents Act 1990* (Cth) s 101D. See also Ch 5.

145 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [0.2.7.1]

8.81 The IPCRC Report also noted that on-line journals and other information technology can reduce the disadvantages that smaller patent offices, like IP Australia, may face. The report, therefore, recommended:

> IP Australia devote additional resources to improving the quality of examination, particularly to prior art processes including through enhanced use of technology.[147]

8.82 IP Australia provided information to the ALRC about the resources available to Australian patent examiners in conducting prior art searches. IP Australia indicated that it has access to internationally recognised on-line databases for searches of complete and partial gene sequences, as well as corresponding polypeptide sequences.[148] IP Australia accesses a number of these databases via facilities at the Australian National Genomic Information Service. IP Australia also has access to Dgene—the international patent gene sequence database—and the World Patents Index.[149]

8.83 IP Australia assigns teams of three people to develop search strategies for all original prior art searches.[150] In addition, IP Australia has a Search Technical Team consisting of 12 patent examiners who conduct reviews of available search tools, examine new on-line search facilities and manage search training for all Australian patent examiners.[151]

8.84 IP Australia also conducts prior art searches for patent offices in other jurisdictions. As one of the 12 International Searching Authorities under the PCT, IP Australia prepares an International Search Report for each PCT application it receives in its capacity as an International Searching Authority.[152] An International Search Report cites any prior art relevant to the novelty or inventiveness of an invention claimed in a PCT application and is available to the patent offices in each jurisdiction in which a PCT application enters the national phase.[153] IP Australia also conducts prior art searches upon request for patent offices in certain countries in the Asia-Pacific region as part of IP Australia's bilateral arrangements with such offices.[154]

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146 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 168.

147 Ibid, 168.

148 IP Australia, *Submission P56*, 4 November 2003. The on-line databases IP Australia may access include Genebank, EMBL, Swiss-prot and PIR which cover gene data published in literature, including some patent literature.

149 Ibid.

150 Ibid.

151 Ibid.

152 See Ch 4 and 5 for further discussion of the *PCT* and IP Australia's responsibility in processing applications filed under it.

153 See further Ch 4; IP Australia, *International Patent Application Kit*, <www.ipaustralia.gov.au/pdfs/patents/internationalpatentapplicationkit.pdf> at 1 May 2003.

154 IP Australia, *Annual Report* (2003); Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 168.

Submissions and consultations

8.85 A few submissions questioned the capacity of IP Australia to conduct adequate prior art searches and to identify all relevant prior art against which the novelty and inventiveness (or innovation) of a claimed invention is tested.[155]

8.86 In consultations, some patent attorneys suggested that prior art searches performed by IP Australia were sometimes inadequate. In particular, it was suggested that IP Australia rarely raised any new prior art in considering applications filed under the PCT. Such comments appear to relate to PCT applications that enter the national phase in Australia, rather than those applications received by IP Australia in its capacity as an International Searching Authority.

8.87 A small number of submissions suggested that IP Australia might have failed to identify relevant prior art in assessing particular gene patents.[156] Suggestions were made that IP Australia should consider outsourcing some of its prior art searches to private entities, similar to the approach adopted by the USPTO.[157]

8.88 IP Australia noted that it had cooperated with the USPTO to compare search results on the same patent applications (including some gene patent applications), and with the United Kingdom Patent Office to compare searching and examination strategies. IP Australia submitted that:

> The exercise showed that, despite some variation in the tools used, IP Australia's searching results are at least equivalent to those obtained in the US and UK.[158]

ALRC's views

8.89 Conflicting views were expressed in submissions and consultations about IP Australia's capacity to conduct adequate prior art searches. Some submissions and consultations expressed concerns about their adequacy while others noted that IP Australia's searching practices are comparable to other major patent offices and subject to on-going internal review.

8.90 To the extent that concerns about IP Australia's searching practices focused on patent examiners' decisions to rely on the results of prior art searches conducted by patent offices in other jurisdictions, the ALRC notes that this practice can be appropriate to reduce duplication of effort and to allow Australian patent applications to be processed expeditiously. Further, although separate searches conducted by IP Australia might identify additional prior art not included in a search conducted by

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155 R Barnard, *Submission P32*, 7 October 2003; Benitec Ltd, *Consultation*, Brisbane, 3 October 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.

156 Department of Health Western Australia, *Submission P53*, 3 November 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.

157 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.

158 IP Australia, *Submission P56*, 4 November 2003. See also IP Australia, *Consultation*, Canberra, 24 September 2003.

another patent office, such information will not always be relevant. The cooperative activities conducted by IP Australia with the USPTO and United Kingdom Patent Office suggest the searching practices of all three offices are comparable.

8.91 As discussed above and in Chapter 5, the disclosure obligations imposed on patent applicants and the definition of 'prior art' in the *Patents Act* have recently been amended.[159] The impact of these changes is yet to be seen,[160] but such provisions may well result in a wider range of prior art information being made available to IP Australia. In the absence of further specific information about IP Australia's capacity to conduct prior art searches, the ALRC does not propose any reforms to the practices of IP Australia in conducting prior art searches at this stage.

Standard of proof

Australia

8.92 Section 49 of the *Patents Act* requires the Commissioner of Patents to accept an application for a standard patent if the Commissioner is 'satisfied' that the requirements of novelty and inventive step have been met and the Commissioner 'considers' that there is no lawful ground of objection to the patent.[161]

8.93 The satisfaction test was introduced into the *Patents Act* in 2001 by the *Patents Amendment Act 2001* (Cth) following recommendations in the 1999 report of the Advisory Council on Industrial Property (the ACIP Report) and in the IPCRC Report in 2000.[162]

8.94 Prior to the 2001 amendment, it was sufficient if the Commissioner 'considered' that there was no lawful ground of objection to a patent.[163] The IPCRC Report noted that, as interpreted by the courts, the earlier position gave the benefit of the doubt to a patent applicant and

> the Commissioner [could] only refuse to grant a patent where it [was] clear that a valid patent [could not] be granted.[164]

159 See [8.79] and Ch 6.

160 See D Nicol, 'Gene Patents and Access to Genetic Tests' (2003) 11 *Australian Health Law Bulletin* 73.

161 *Patents Act 1990* (Cth) s 49(1) (standard patents). Equivalent provisions exist in relation to the examination of innovation patents: *Patents Act 1990* (Cth) s 101E. Other grounds for objection to an application for a standard patent or to an innovation patent are discussed in Ch 9.

162 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 15; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 167. See Explanatory Memorandum, Patents Amendment Bill 2001 (Cth).

163 *Patents Act 1990* (Cth) s 49 (as in force at 30 September 2001).

164 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 167. See, eg, *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232.

8.95 Both the ACIP Report and the IPCRC Report recommended increasing the threshold for acceptance of patent applications 'so that granted patents would be more likely to be valid'. The ACIP Report specifically recommended that 'the rule giving the benefit of the doubt to the applicant should be abrogated in so far as it relates to novelty and obviousness'.[165] The IPCRC endorsed the views expressed in the ACIP Report, but cast its recommendation in more general terms:

> The Committee recommends changing the Patents Act to require a 'balance of probabilities' approach to be used during examination, rather than conferring the 'benefit of the doubt' to the applicant as at present.[166]

8.96 As now amended, s 49 of the *Patents Act* requires a patent examiner to apply two different standards of proof in assessing the requirements for patentability relevant to examination of a patent application.[167] The requirement that the Commissioner be 'satisfied' that an invention is novel and involves an inventive (or innovative) step is a 'balance of probabilities' standard. With respect to other requirements for patentability relevant at the examination stage, the Commissioner need only 'consider' that such grounds are met. As noted above, this has been interpreted as imposing a 'benefit of the doubt' standard.[168]

8.97 The *Manual* explains the considerations relevant in assessing whether each of the standards of proof has been met:

> [The 'balance of probabilities'] test requires an examiner to weigh up all the material before them and decide, on balance, whether a claimed invention is 'more likely than not' to be novel and inventive (or innovative).[169]
>
> In the case of objections other than novelty, inventive step, and innovative step, the benefit of the doubt is given to the applicant, and objections are maintained if there is little uncertainty as to whether the objection still applies (having regard to the response from the applicant).[170]

Other jurisdictions

8.98 Other jurisdictions formulate the standard of proof for acceptance of a patent application in a number of different ways. In general, however, the standard of proof is a 'balance of probabilities' standard, or equivalent. A 'balance of probabilities'

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165 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 2.

166 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 167.

167 The situation is the same for the equivalent provisions relating to examination of an innovation patent: *Patents Act 1990* (Cth) s 101E.

168 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [0.2.4], [12.5.2.1] (standard patent); [30.4.3.3] (innovation patent). See also Explanatory Memorandum, Patents Amendment Bill 2001 (Cth), [18], [23].

169 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [12.5.2.2].

170 Ibid, [12.5.2.3].

standard is applied, for example, by the United Kingdom Patent Office.[171] The USPTO applies a 'preponderance of the evidence' test, which is the civil standard of proof under United States law and, broadly speaking, equates with the 'balance of probabilities' standard applied in other jurisdictions.[172] In addition, unlike Australia, patent offices in other jurisdictions appear to apply a single standard of proof to all the elements for patentability relevant on examination.

New Zealand

8.99 A recent report of the New Zealand Ministry for Economic Development (the NZ Report) has recommended changes to the standard of proof applicable to the acceptance of New Zealand patent applications.[173]

8.100 Currently, a New Zealand patent examiner may reject a patent application only if he or she is 'practically certain' that any patent granted would be invalid. The NZ Report cited the amendments to the standard of proof for acceptance of Australian patent applications with approval. The report recommended that the *Patents Act 1953* (NZ) be amended to 'provide that patents can only be granted if, on the balance of probabilities, the requirements for patentability are met'.[174] As a result of other recommendations in the NZ Report, it appears that the New Zealand Ministry for Economic Development intended the 'balance of probabilities' standard to be met for each of the requirements for patentability, namely that an invention must be a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies 1623*, and must be novel, involve an inventive step, and be useful.[175]

Options for reform

8.101 IP 27 asked whether the standard of proof for acceptance of a gene patent should be raised and if so what the appropriate standard of proof should be. If the standard of proof were to be amended, there are two different standards of proof that could plausibly be applied during examination of an application.[176] These would involve:

- giving the 'benefit of the doubt' to the applicant; or

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171 United Kingdom Patent Office, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office (November 2003)*, <www.patent.gov.uk/patent/reference/index>. See also New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 1, [55].

172 United States Patent and Trademark Office, *Manual of Patent Examining Procedure* (2003), [706]. 'Preponderance of evidence' requires that the greater weight of evidence, or evidence which is more credible and convincing, is in favour of a particular conclusion: H Black, *Black's Law Dictionary* (4th ed, 1968); B Garner, *A Dictionary of Modern Legal Usage* (2nd ed, 1995).

173 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 1.

174 Ibid, Pt 1, rec 2(iii).

175 Ibid, Pt 1, rec 2(i).

176 See Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 166.

- requiring the criteria for patentability be demonstrated by the applicant on the 'balance of probabilities'.

8.102 The criminal standard of proof—'beyond a reasonable doubt'—is clearly inappropriate to a civil or administrative proceeding such as a patent application.

8.103 In determining the appropriate standard of proof for acceptance of a patent application, a number of considerations are relevant. First, the prosecution process is analogous to an *ex parte* procedure in that patent examiners do not generally have the benefit of arguments and supporting evidence on both sides of any issue. Second, the goal of maximising the certainty and validity of patents granted by a patent office must be balanced against the resources available to a patent office, and against other mechanisms in the patent system that allow the validity of patents to be tested. If most or many patents granted are never licensed or enforced, focusing extensive resources at the patent granting stage may not be efficient.[177]

Submissions and consultations

8.104 Some submissions considered that there was no reason to raise the standard of proof for acceptance of a gene patent application, or of applications claiming any other type of technology.[178] GlaxoSmithKline suggested that raising the standard of proof for acceptance of gene patent applications alone, and not other types of patent application, would conflict with art 27(1) of the TRIPS Agreement, which requires that patent rights shall be available without discrimination as to the field of technology.[179] Other submissions also rejected the suggestion that a different standard of proof should apply to the acceptance of gene patent applications, but did not refer specifically to the TRIPS Agreement.[180]

8.105 Genetic Technologies Limited and AusBiotech Ltd cautioned that raising the standard of proof for acceptance of gene patents may have adverse consequences for perceptions of Australian patent law and for Australian companies in the global biotechnology market and that these factors should be carefully considered before any amendments were proposed.[181]

8.106 IP Australia commented on the fact that there are two different standards of proof for acceptance of a patent application, depending upon the particular issue under examination. IP Australia indicated that this approach may be unprecedented and submitted:

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177 See further, M Lemley, 'Rational Ignorance at the Patent Office' (2001) 95 *Northwestern University Law Review* 1.

178 GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

179 GlaxoSmithKline, *Submission P33*, 10 October 2003.

180 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

181 Genetic Technologies Limited, *Submission P45*, 20 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

> IP Australia is not aware of any particular difficulty in extending the 'balance of probabilities' standard to all criteria of patentability, other than recommending that any such changes apply to all fields of technology.[182]

8.107 IP Australia rejected the proposition that an even higher standard of proof ought to be satisfied before a patent application was accepted, for example, increasing the standard of proof to 'beyond all reasonable doubt'.[183] IP Australia suggested that such a standard did not 'appear to be appropriate for any criteria of patentability, as this is the standard for criminal law'. IP Australia also commented:

> The IPCRC report noted that although the aim of the examination process is to issue patents with a high presumption of validity, in some respects it is a coarse sieve. It is questionable how much onus should be placed on the applicant at this stage.[184]

8.108 In contrast, the Royal College of Pathologists of Australasia considered that the current standards of proof for acceptance of a patent application appear to be 'too lenient'. The College stated:

> More stringent criteria, based on objective evidence, clearly need to be developed and implemented. If a patent application is judged to be novel or inventive, then the examiner must be *certain*, not satisfied, that this is indeed not the case.[185]

8.109 In addition, views expressed in a number of submissions and consultations suggested that a greater burden should be placed on patent applicants to prove that a patent should be granted, and supported reforms that would increase the presumption that a granted patent is valid.[186] In general, comments did not address precisely how this might be achieved, but seemed to indicate that the standard of proof for acceptance of patent applications should be more stringent than it is under current Australian patent law.

8.110 A number of submissions and consultations suggested that the standard of proof for deciding whether an invention is useful and whether the claims in an application are of an appropriate scope might need to be more stringent.[187] These views raise broader questions about the substantive requirements for patentability and the grounds upon which gene patent applications are currently examined. These matters are addressed in Chapter 6.

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182 IP Australia, *Submission P56*, 4 November 2003.

183 Ibid.

184 Ibid. See also Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 143–144, 166–167.

185 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

186 Ibid; *Confidential Submission P54 CON*, 3 November 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

187 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

ALRC's views

8.111 Submissions to the Inquiry did not support the adoption of a standard of proof that would apply only to gene patent applications. The ALRC agrees with this view and considers that gene patent applications should be subject to the same standard of proof as applications for patents over any other type of technology. Determining which patents should be subject to genetic-specific provisions is likely to be somewhat arbitrary and difficult to apply. Any such provision is likely to increase uncertainty in the application of patent law to inventions involving genetic materials and technologies. In addition, requirements that would apply only to gene patents may be inconsistent with Australia's obligations under the TRIPS Agreement to provide patent protection to all inventions without discrimination as to field of technology.

8.112 However, the ALRC considers that *Patents Act* should be amended to provide a single standard of proof for all patent applications examined by IP Australia and that the applicable standard of proof should be 'on the balance of probabilities'.

8.113 The rationale for maintaining two different standards of proof is unclear, given that each of the elements of patentability is a prerequisite for the grant of a patent. Applying different standards of proof to the various requirements for patentability adds unnecessary complexity to the examination of patent applications and might generate confusion on the part of patent applicants and patent examiners. Further, there are practical difficulties for examiners in applying different levels of proof to different criteria for patentability, and the practical effect of this might be that examiners apply a single standard of proof.

8.114 The ALRC agrees with the views expressed by ACIP and the IPCRC that requiring a 'balance of probabilities' standard to be met before a patent application is accepted will increase the chance that a granted patent is likely to be held to be valid. This is particularly important in relation to patents over genetic materials and technologies. The ALRC considers that this standard should be applied to all of the issues that an Australian patent examiner is required to assess in examining a patent application. This should include examination as to whether an invention claimed in a patent application is 'useful' (see Chapter 6). It would not, however, change the standard of proof applicable to the requirements of novelty and inventive (or innovative) step because a 'balance of probabilities' standard already applies to these requirements under the current law.

Proposal 8–5 The Commonwealth should amend the *Patents Act* to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination. (See also Proposal 6–3.)

9. Challenging and Enforcing Patent Rights

Contents

Introduction

9.1 This chapter addresses issues relating to the law and practice of challenging and enforcing gene patents in Australia. Procedures for challenging Australian gene patents are available both prior to the grant of a patent and after a patent has been sealed. These procedures are outlined and the potential for greater government participation in challenging gene patents is considered. The chapter then addresses the variety of ways in which gene patents may be enforced, from commercial negotiations to license a patent, to litigation proceedings. The chapter also discusses the factors that affect patent holders' decisions as to which enforcement strategy they will pursue. One important issue is the ability of Australian patent holders to detect infringing activities. The chapter therefore addresses mechanisms for monitoring compliance with patent rights, including through information made available by IP Australia. The chapter concludes with a discussion of insurance policies that provide coverage for the costs of patent litigation.

Rights of a patent holder

9.2 The *Patents Act 1990* (Cth) (*Patents Act*) provides that the grant of a patent confers upon a patent holder the exclusive right to exploit an invention, or to authorise another person to exploit an invention, during the patent term.[1] 'Exploit' is defined in the Act to include:

> (a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire, or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
>
> (b) where the invention is a method or process—use the method or process or do any act mentioned in (a) in respect of a product resulting from such use.[2]

9.3 A patent holder may assign or license his or her patent rights to a third party. An assignment of a patent results in the transfer of all of the rights owned by the patent holder to a third party (the assignee).[3] A licence of a patent does not transfer ownership of any patent rights; rather it establishes terms upon which a third party (the licensee) may exercise certain patent rights without such use constituting infringement.[4]

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1 *Patents Act 1990* (Cth) s 13(1). Note that the right to exploit an invention is subject to earlier patents not owned by the patent holder, as well as any necessary government approvals.

2 Ibid sch 1.

3 The assignment of a patent is subject to certain formalities, namely that it must be in writing and signed by both the assignor and the assignee: Ibid s 14(1). Partial assignment of a patent is also contemplated under the *Patents Act*, although whether such a transaction is properly characterised as a licence or results in co-ownership of a patent is an open question: J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [22,008].

4 The grant of an exclusive licence may carry with it some of the indicia of ownership; for example, an exclusive licensee has the right to enforce the licensed patent rights and a patent holder must seek a licensee's consent to amend a patent specification (unless this requirement is waived by the Commissioner of Patents): see *Patents Act 1990* (Cth) ss 120(1), 187, 103.

Licensing practices in Australia with respect to genetic and biotechnological inventions are discussed in Chapter 23.

9.4 If a patent is owned by more than one person, each is entitled to exercise the exclusive rights granted by the patent for his or her own benefit, without accounting to the other patent holders.[5] However, any licence or assignment of a co-owned patent requires the consent of all of the patent holders.[6]

9.5 Subject to a number of safeguards, including the compulsory licensing provisions in the *Patents Act*,[7] a patent holder is not obliged to exploit an invention claimed in a patent at any time during the patent term, or to license or assign the patent rights. Patent protection may be obtained purely for blocking purposes, that is, to prevent another person or company from using a patented invention in the development of other products.[8]

9.6 However, patents rights remain subject to challenge even after a patent application has been accepted by the Commissioner of Patents and after the patent is sealed. Section 20 of the *Patents Act* expressly states that nothing in the Act or in the *Patent Cooperation Treaty* (PCT)[9] guarantees that a patent is valid.

Challenges to patent rights

9.7 Opportunities to object to the grant of patent rights exist at each stage of the patenting process—prior to acceptance of a standard patent application, after the Commissioner of Patents has accepted an application, and after a patent has been sealed. The mechanisms for challenging patent rights at each stage are discussed in turn below.

Intervention in the examination process

9.8 Under s 27 of the *Patents Act* there is an opportunity for any person to intervene in the examination of a standard patent application.[10] The section permits any person to file a notice (commonly referred to as a 's 27 notice') with the Patent Office asserting

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5 Ibid s 16(1)(b).

6 Ibid s 16(1)(c). For example, recent difficulties have arisen in connection with the licensing of patents on siRNA (co-owned by the Whitehead Institute, Massachusetts Institute of Technology, the Max Planck Institute and the University of Massachusetts Medical School) because the patent holders cannot agree on the terms on which the patents should be licensed: M Moser Jones, *RNAi Roundup: Waltham Conference Participants Focus on Selection, Delivery and IP Issues*, GenomeWeb Daily News, 9 May 2003, <www.genomeweb.com> at 9 May 2003.

7 *Patents Act 1990* (Cth) s 133–140. Compulsory licensing is discussed in Ch 27. In addition, relevant provisions of the *Trade Practices Act 1974* (Cth) and the Crown use provisions of the *Patents Act 1990* (Cth) may provide a remedy if a patent holder fails to exploit its patent rights: see Ch 24 and 26.

8 See Ch 19 for a discussion of blocking patents and possible solutions to address them.

9 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978).

10 An equivalent provision relating to innovation patents provides for a similar notice to be filed after the grant of an innovation patent but prior to its certification: *Patents Act 1990* (Cth) s 28; *Patents Regulations 1991* (Cth) r 2.6.

that the invention claimed in the patent application is not novel or does not involve an inventive step.[11] The notice may be filed any time after publication, but before acceptance, of a complete application.[12] It must contain reasons for the assertion that the claimed invention is not patentable and attach any documentary evidence on which the assertion is based.[13]

9.9 Upon receipt of any such notice, the Commissioner of Patents must notify the applicant and provide copies of documents provided in support of the notice.[14] In practice, documents provided to the Patent Office pursuant to a s 27 notice are included in the prior art information relied on by the examiner assessing the application, and they are also open to public inspection.[15]

9.10 A patent examiner is not, however, required to raise an objection to an application based on information provided pursuant to a s 27 notice. Once the s 27 notice has been filed, the notifier does not take any further part in the prosecution of the patent application and cannot be aware of the impact of the notice until after acceptance of the patent application at issue.[16] Professor James Lahore has commented that a s 27 notice:

> has the advantage of cheapness and potential anonymity, and best suits circumstances of clear prior publication. There is the disadvantage of telegraphed intentions without an opportunity to stay involved.[17]

Opposition

9.11 The three primary mechanisms for challenging patents after acceptance of the patent application are opposition, re-examination and revocation.

9.12 Any person may initiate proceedings to oppose the grant of a standard patent within three months of publication of a notice of its acceptance by the Commissioner of Patents.[18] Opposition to a standard patent therefore occurs before the patent is sealed.[19]

9.13 Currently, the grounds upon which an application for a standard patent may be opposed are limited to the following:

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11 *Patents Act 1990* (Cth) s 27(1).
12 *Patents Regulations 1991* (Cth) r 2.5.
13 *Patents Act 1990* (Cth) s 27(1); *Patents Regulations 1991* (Cth) r 2.7.
14 *Patents Act 1990* (Cth) s 27(2).
15 Ibid s 27(3).
16 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8225].
17 Ibid, [8225].
18 *Patents Act 1990* (Cth) s 59; *Patents Regulations 1991* (Cth) r 5.3(1).
19 An innovation patent may be opposed any time after it has been certified: *Patents Act 1990* (Cth) s 101M; *Patents Regulations 1991* (Cth) r 5.3AA. See Ch 5 for a chart (reproduced from s 4 of the *Patents Act*) showing the stage at which an opposition may be filed.

- the applicant is not entitled to the grant of a patent, or is only entitled in conjunction with some other person;

- the invention is not a manner of manufacture, is not novel or does not involve an inventive step when compared to the prior art;

- the patent specification does not comply with the requirements of s 40(2) or s 40(3) of the *Patents Act*;[20] or

- the invention relates to human beings or to biological processes for their generation.[21]

9.14 An objection raised by an opponent and the prior art cited in support of such objections may be similar or in addition to that already overcome by an applicant during examination of the patent application by the Patent Office.[22] Opposition hearings are the responsibility of the Commissioner of Patents and are typically heard and determined by senior examination staff within the Patent Office.[23]

9.15 There are several possible outcomes of opposition proceedings. The Commissioner may dismiss an opposition on procedural grounds, either in whole or in part;[24] the proceedings may result in the amendment of one or more of the patent claims in order to rectify deficiencies in the opposed application; or the opposition may be successful, in which case the Commissioner may refuse to grant a patent.[25] The most common outcome of opposition proceedings is that the scope of the opposed patent claims is restricted. Decisions of the Commissioner may be appealed to the Federal Court by either the patent holder or the opponent.[26]

9.16 In practice, only a very small proportion of accepted applications—approximately 1.5%—are opposed.[27] Statistics on the number of oppositions filed in

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20 Sections 40(2) and (3) of the *Patents Act* require that the patent specification describes the invention fully including the best method known to the applicant to make the invention; that it ends with claims defining the invention; and that the claims are clear and succinct and fairly based on the subject matter described in the specification. See further Ch 6.

21 *Patents Act 1990* (Cth) s 59. Parallel provisions exist setting out the grounds on which an innovation patent may be opposed: see *Patents Act 1990* (Cth) s 101M.

22 Examination of patent applications and IP Australia's practices are discussed in Ch 5 and 8, respectively.

23 In other jurisdictions, such as the United States and Europe, which have larger case loads, the opposition procedure is independent and involves different personnel to the patent examiners responsible for the initial examination of patent applications: Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 173.

24 *Patents Regulations 1991* (Cth) r 5.5.

25 *Patents Act 1990* (Cth) s 60 (standard patents). The Commissioner may revoke an innovation patent where a ground for opposition is made out: *Patents Act 1990* (Cth) s 101N.

26 *Patents Act 1990* (Cth) s 60(4) (standard patents), s 101N(7) (innovation patents). See Ch 10 for a discussion of the jurisdiction of the Federal Court in patent matters.

27 IP Australia, *Submission P56*, 4 November 2003.

relation to gene patents are not readily available,[28] but data for the broader category of biotechnology patents suggest that the number of oppositions is also very small. According to data provided to the ALRC by IP Australia, in the five years from 1997–98 to 2001–02, there were only 14 substantive decisions made on biotechnology oppositions (an average of less than three per year), although 86% of these were successful.[29]

Review of the opposition process in Australia

9.17 Two reports have recently reviewed the system for opposing patents under Australian law—a 1999 report of the Advisory Council on Industrial Property (now the Advisory Council on Intellectual Property—ACIP)[30] and a 2000 report of the Intellectual Property and Competition Review Committee (the IPCRC Report).[31] The reports addressed two principal concerns about the current opposition process: whether oppositions should be available prior to the grant of a patent (as is currently the case) or only post-grant; and who should have responsibility for hearing opposition proceedings.

9.18 ACIP considered perceived deficiencies in the current system of pre-grant opposition,[32] and commented on the fact that opposition proceedings may be used by third parties to delay the grant of a patent. However, consultations conducted by ACIP indicated that industry did not generally support replacing pre-grant opposition with post-grant opposition.[33] Further, the IPCRC Report indicated that there may be concerns in adopting a post-grant opposition procedure because such a review might be regarded as an unconstitutional exercise of judicial power by a non-judicial body (that is, by IP Australia).[34]

9.19 However, both reports suggested that there was scope to improve the procedures for pre-grant opposition. The ACIP Report did not make a specific recommendation on

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28 Opposition proceedings in relation to patent applications covering genetic sequences have, however, been filed: see C Lawson and C Pickering, 'Patenting Genetic Material: Failing to Reflect the Value of Variation in DNA, RNA and Amino Acids' (2000) 11 *Australian Intellectual Property Journal* 69. Recently, Benitec Ltd announced that opposition proceedings filed by the Commonwealth Scientific and Industrial Research Organization (CSIRO) and the Queensland Department of Primary Industries regarding Benitec Ltd's DNA-directed RNA interference technology (ddRNAi) had been settled: GenomeWeb, *Benitec Settles ddRNAi Dispute with Australia's CSIRO and DPI*, GenomeWeb Daily News, 9 December 2003, <www.genomeweb.com> at 10 December 2003; Benitec Ltd, *Milestone Strategic Agreement to Commercialise Australian Biotech Invention*, <www.benitec.com/news/index.htm> at 15 December 2003.

29 In this context, 'successful' means that the Patent Office decided in favour of the opponent on at least some grounds. It does not mean that the opposed application was refused in all cases, because the applicant may have been given an opportunity to amend the specification to remove any deficiencies.

30 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999).

31 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000).

32 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 24–25.

33 Ibid, 24.

34 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 172.

this issue but encouraged IP Australia and the Institute of Patent and Trade Mark Attorneys of Australia to review the current procedures.[35] The IPCRC Report indicated that hearings officers in opposition matters should continue to comprise senior examination officers at the Patent Office. While a specialist hearing section (comparable to those in the United States Patent & Trademark Office (USPTO) and the Europe Patent Office (EPO)) did not need to be established,[36] the IPCRC Report recommended that:

> IP Australia take further measures to improve perceptions of the hearings process [for oppositions] being independent of, and more generally fair and equitable to, all parties.[37]

9.20 In its response to the IPCRC Report, the Australian Government indicated that it would ask IP Australia to appoint a senior officer who is to be directly responsible to the Commissioner of Patents for opposition hearings, and to take further steps to improve the transparency of the hearings process for oppositions.[38] IP Australia has now formed the Opposition Hearings and Legislation section to address the issues raised in the IPCRC Report.[39]

Re-examination

9.21 Re-examination provides another mechanism by which the validity of a patent (or, in limited circumstances, an accepted application for a standard patent) may be challenged.[40]

9.22 The only issues relevant in re-examination proceedings are whether the invention claimed in the patent or patent application is novel or involves an inventive (or innovative) step.[41] Re-examination may be conducted at the discretion of the Commissioner, upon the request of a patent holder or any other person, or at the direction of a prescribed court in connection with proceedings disputing the validity of a patent.[42]

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35 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 24.

36 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 175.

37 Ibid, 175.

38 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003.

39 The division of responsibility for patent matters among the various sections within IP Australia are outlined in Ch 8.

40 *Patents Act 1990* (Cth) s 97 (standard patents), s 101G (innovation patents). Re-examination was introduced as a result of the recommendations of the Industrial Property Advisory Committee: Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), rec 31. Re-examination is only available for patent applications filed after 30 April 1991: *Patents Act 1990* (Cth) ss 233(3), 234(4).

41 *Patents Act 1990* (Cth) s 98(1) (standard patents), s 101(G)(3) (innovation patents).

42 Ibid s 97 (standard patents), s 101G(1) (innovation patents).

9.23 Re-examination proceedings are conducted *ex parte*—that is, in the presence of one party, but not the other—and are typically undertaken by senior examination staff within the Patent Office, who also have responsibility for opposition matters.[43]

9.24 As a result of re-examination, one or more claims in a patent may be amended as directed by the Commissioner.[44] The Commissioner also has the power to refuse to grant a patent application, or to revoke an issued patent (either in whole or in part), that has been the subject of an adverse re-examination report.[45]

9.25 A patent holder may appeal decisions of the Commissioner on re-examination to the Federal Court.[46] Third parties, however, have no right of appeal against decisions of the Commissioner on re-examination. If, following re-examination, the Commissioner finds that a patent (or an application for a standard patent) is valid and a third party still wishes to challenge the enforceability of the patent, the only course of action available is an application for revocation under s 138 of the *Patents Act*.[47]

9.26 To date, the re-examination provisions of the *Patents Act* have been invoked only on a limited number of occasions.[48] Mr Philip Spann, a supervising examiner of patents at IP Australia, has suggested that the relatively small number of re-examinations may indicate that other mechanisms for challenging patents are more attractive.[49]

Revocation

9.27 After a patent has been granted, it remains subject to a claim for revocation. Typically, an application for revocation of a patent is filed as a counter-claim to a claim of infringement.[50] However, revocation of a patent may be sought by any person independently of infringement proceedings.[51]

9.28 The grounds upon which an application for revocation may be made are broader than the grounds upon which opposition or re-examination are available. An application for revocation of a patent may be made on the basis that:

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43 P Spann, 'Re-examination in Australia: 10 Years on' (2002) 13 *Australian Intellectual Property Journal* 97, 98.

44 *Patents Act 1990* (Cth) ss 100A(2)(b), 101(2)(b) (standard patents), s 101J(3)(c) (innovation patents).

45 Ibid ss 100A(1), 101(1) (standard patents), s 101J(1) (innovation patents).

46 Ibid ss 100A(3), 101(4) (standard patents), s 101J(5) (innovation patents).

47 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [21.9.4].

48 P Spann, 'Re-examination in Australia: 10 Years on' (2002) 13 *Australian Intellectual Property Journal* 97, 98.

49 For example, opposition to a patent involves a hearing *inter partes* and provides broader grounds on which an accepted application may be challenged. Alternatively, litigation may be a more appropriate forum in which to examine complex issues of validity with a high degree of commercial significance: Ibid, 98–99.

50 *Patents Act 1990* (Cth) s 121. The grounds for revocation of a patent in a counter-claim to infringement are set out in s 138(3).

51 Ibid s 138(1). An innovation patent must be certified before an application for revocation under s 138 may be filed: *Patents Act 1990* (Cth) s 138(1A).

- the patent holder is not entitled to the patent;
- the invention is not a 'patentable invention' as defined in s 18 of the *Patents Act*;
- the patent holder has contravened a condition in the patent;
- the patent (or an amendment to the patent request or complete specification) was obtained by fraud, false suggestion or misrepresentation; or
- the patent specification does not comply with s 40(2) or s 40(3) of the *Patents Act*.[52]

9.29 The *Patents Act* provides other circumstances in which a patent may be revoked. These include: pursuant to an order of a prescribed court following the expiration of a compulsory licence on the basis that a patent is no longer being worked and the reasonable requirements of the public have not been met;[53] by the Commissioner in response to a patent holder's offer to surrender his or her patent rights;[54] and, in the case of innovation patents, following an adverse report upon re-examination.[55]

Other jurisdictions

9.30 Other jurisdictions have recently considered improvements to the mechanisms for challenging patent rights with a view to promoting mechanisms that are cheaper and less complicated than court proceedings.[56]

9.31 In Canada, both a report of the Canadian Biotechnology Advisory Committee (the CBAC Report)[57] and a report of the Ontario Government (the Ontario Report)[58] recommended the introduction of an opposition procedure to allow challenges within a limited period following the grant of a patent.[59] If implemented, the opposition process

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52 *Patents Act 1990* (Cth) s 138(3). Additional grounds for revocation of an innovation patent exist as part of the examination procedure for an innovation patent: *Patents Act 1990* (Cth) s 101B(2), (4), (5)–(7). In essence, the grounds for revocation of an 'uncertified' innovation patent are equivalent to the bases upon which the Commissioner may refuse an application for a standard patent.

53 *Patents Act 1990* (Cth) s 134. The factors relevant to an assessment as to whether the 'reasonable requirements of the public' have been met are stipulated in *Patents Act 1990* (Cth) s 135. See also Ch 27.

54 *Patents Act 1990* (Cth) s 137(3).

55 Ibid s 101J. See further the discussion of re-examination above.

56 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 51.

57 Canadian Biotechnology Advisory Committee, *Higher Life Forms and The Patent Act* (2003).

58 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002).

59 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), rec 13; Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(g). The two reports had different views as to the time period within which an opposition should be filed. The CBAC Report set the time limit at six months, whereas the Ontario Report considered a nine-month period should be allowed.

would provide an additional mechanism for challenging gene patents under Canadian law. Currently, other than in litigation, a Canadian patent may be challenged only by 're-examination' proceedings, which are similar to the re-examination procedures under Australian law outlined above.

9.32 In the United States, a November 2003 report of the Federal Trade Commission (FTC) on the intersection between patent and competition law and policy (the FTC Innovation Report) recommended the creation of a 'new administrative procedure to allow post-grant review of and opposition to patents'.[60] Currently, the principal ways in which a United States patent may be challenged outside infringement litigation is by *ex parte* or *inter partes* re-examination.[61] Both types of proceedings permit any person to file a request for re-examination at any time following the grant of a patent. Re-examination will be commenced by the USPTO if the request raises a substantial new question of patentability. In the case of *inter partes* re-examination only, the third party requestor has access to relevant documents filed in the proceedings and may provide written comments to any response by the patent holder to an action on the merits.[62] Between its introduction in 1999 and July 2003, *inter partes* re-examination had been used only four times.[63]

9.33 The FTC recommended a new procedure for post-grant review, which would allow challenges to the patentability of an invention, at least with respect to novelty, non-obviousness, written description, enablement and utility.[64] Proceedings would include the ability to cross-examine witnesses and appropriate (but circumscribed) discovery.[65] The FTC made further recommendations to ensure that such review proceedings would be conducted expeditiously by an independent administrative judge.[66]

Submissions and consultations

9.34 IP 27 asked whether existing mechanisms for challenging gene patents were adequate, or whether additional or alternative mechanisms might be required. Submissions and consultations did not support the implementation of mechanisms to

60 United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), rec 1.

61 35 USC §§302–304 (*ex parte* re-examination); 35 USC §§311–313 (*inter partes* re-examination). United States patent law does not allow challenges to patent rights in the form of opposition proceedings, as in Australia and Europe.

62 35 USC §314. The right of third parties to appeal an adverse decision in federal court was only introduced in 2002. A third party requestor is also estopped from raising certain issues in any subsequent litigation involving a re-examined patent: 35 USC §§315(b), 315(c).

63 United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), ch 5, 16.

64 Ibid, ch 5, 23–24.

65 Ibid, ch 5, 24.

66 Ibid, ch 5, 24.

permit challenges specifically to gene patent applications or granted gene patents.[67] However, a number of submissions suggested that current avenues for challenging patent rights are inadequate.[68] Submissions indicated that, while the mechanisms for challenging patent rights might be effective if invoked, the financial cost of a patent challenge is often prohibitive.[69] The Royal College of Pathologists of Australasia (RCPA), for example, submitted:

> The process can be expensive and time consuming. Smaller organisations and companies are much more likely to make a pragmatic commercial decision to cease the alleged infringement activity or pay the requested licences and royalties even though they may believe the patent to be invalid or illegitimate … The public sector has additional difficulties with these provisions [because] … they have neither the resources to mount a challenge nor the support of government.[70]

9.35 In consultations, the Institute of Patent and Trade Mark Attorneys of Australia indicated that the decision to oppose or initiate another type of challenge to a patent may be based on strategic considerations, as well as financial ones.[71] Members of the Institute suggested that, in resolving opposition proceedings, IP Australia often seeks to modify the claims of an opposed application, rather than dismissing the application in its entirety. Consequently, a potential opposer must take into account the possibility that opposition proceedings might help an applicant get a better patent (even if one of more limited scope), rather than result in the application being rejected.

9.36 Two submissions proposed specific reforms to the current mechanisms for challenging patent rights under Australian law. The Australian Centre for Intellectual Property in Agriculture (ACIPA) suggested that third party participation in patent challenges should be facilitated:

> There needs to be greater participation of third parties in the initial interviews about a patent application, greater scope for opposition proceedings, greater scope to ask for re-examination, and the chance for third parties to appeal patent office re-examination decisions.[72]

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67 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003.

68 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

69 Cancer Council Australia, *Submission P25*, 30 September 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

70 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

71 Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.

72 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

9.37 The Department of Health Western Australia agreed that improvements to the re-examination process are desirable.[73] The Department did not make a specific proposals in this regard, but did consider that the time during which opposition proceedings may be initiated should be extended from the current three-month period to nine months, to allow interested parties sufficient time to respond to accepted patent applications.[74]

9.38 On the other hand, a number of submissions considered that the current mechanisms for challenging patents are satisfactory.[75] Dr Amanda McBratney and others considered that current mechanisms strike the right balance between giving third parties an opportunity to test the validity of a patent or patent application and not unduly delaying the grant of patent rights.[76] The Australian biotechnology industry organisation, AusBiotech Ltd, indicated that although opinions varied, its members generally considered that the procedures for challenging patents under Australian law were better than in other jurisdictions, such as Europe or the United States.[77]

ALRC's views

9.39 The ALRC's preliminary view is that no changes are currently required to the specific procedures for challenging gene patent applications and granted gene patents. The ALRC agrees with submissions that suggested that genetic materials and technologies do not give rise to any special needs in this regard.

9.40 No evidence was provided to the Inquiry that the opposition, re-examination or revocation procedures set out in the *Patents Act* are not adequate avenues for challenging patent rights. Third parties may intervene in each stage of the patent process and, in the ALRC's view, no additional avenues for intervention are required at this stage. However, in Chapter 6 the ALRC has proposed that 'usefulness' should be considered by Australian patent examiners in assessing patent applications and, consequently, should be a ground upon which an accepted patent application may be opposed (see Proposal 6–3).

9.41 Many submissions and consultations expressed concern about the cost involved in challenging patent rights. The large investment of time and resources required to challenge a gene patent might result in patents of questionable validity not being challenged. In the ALRC's view, this is not a failure of the mechanisms currently available to challenge patents, but it does raise questions as to who might initiate such challenges and for what purposes. This matter is discussed below.

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73 Department of Health Western Australia, *Submission P53*, 3 November 2003. See also South Australian Government, *Submission P51*, 30 October 2003.

74 Department of Health Western Australia, *Submission P53*, 3 November 2003.

75 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

76 A McBratney and others, *Submission P47*, 22 October 2003.

77 AusBiotech Ltd, *Submission P58*, 7 November 2003.

Government participation in patent challenges

9.42 One issue raised by the Inquiry is whether increased participation by relevant government departments or other organisations would assist in addressing some of the practical impediments that Australian companies and research organisation face in challenging gene patents. Reports about the patent system in Australia and in other jurisdictions are instructive on this issue.

Australia

9.43 As part of its review of Australian patent and competition law, the IPCRC Report recommended that IP Australia should assume responsibility for initiating test cases 'where substantial areas of uncertainty exist in application of the patent law'.[78] The IPCRC Report considered that problems raised by gene patents may continue for a number of years 'if it is left entirely to private litigation to correct areas of uncertainty'.[79]

9.44 The Australian Government accepted this recommendation.[80] However, Dr Dianne Nicol and Jane Nielsen have commented that 'it seems incongruous for the same body that grants patents to take responsibility for challenging their validity'.[81] On one view, IP Australia's expertise makes it particularly well qualified to identify areas of patent law that require clarification.

9.45 On the other hand, public confidence in the patent system might be undermined if IP Australia is required to initiate challenges to its own decisions to grant a patent. Further, IP Australia is not well-placed to know which patents may, in the future, present significant issues for competitors of a patent holder, or for the general public, such as to warrant a challenge being mounted. Nicol and Nielsen thus proposed that 'a public interest body with financial support from the Federal Government' might initiate challenges to patent validity, if required.[82]

United Kingdom

9.46 In 2003, the United Kingdom Department of Health commissioned a report by Professor William Cornish, Dr Margaret Llewelyn and Dr Michael Adcock (the UK Report)[83] on the impact and management of intellectual property rights in the healthcare sector, and in particular in genetic materials and technologies. The report recommended that the Department of Health should 'take an active role in monitoring

78 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 154.
79 Ibid, 154.
80 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003.
81 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 369.
82 Ibid, 369.
83 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003).

developments in relevant areas of intellectual property law (most notably patent law)'.[84]

9.47 The UK Report also recommended that the Department of Health establish mechanisms for intervening in the patent process, where appropriate. The UK Report considered that such intervention might include: providing information to the United Kingdom or European patent offices in connection with the examination of a gene patent application; challenging the validity of a gene patent either in United Kingdom Patent Office, in court, or (for a European patent) in the EPO; or challenging abuses of patent rights under the competition laws of the United Kingdom or the European Union.[85] The recommendations of the UK Report are discussed further in Chapter 20.

United States

9.48 The FTC Innovation Report canvassed whether the FTC should assume a more active role in the patent law area. The report made a series of recommendations designed to improve the quality of patents granted by the USPTO.[86] The report also indicated that the FTC intended to implement measures to address patent law issues that may have a significant impact on competition, including:

- To increase its competition advocacy role by filing *amicus curiae* briefs in appropriate circumstances;[87] and

- To ask the Director of the USPTO to re-examine questionable patents that raise competitive concerns.[88]

9.49 Public organisations in the United States have also begun to promote greater participation in the patent system. A non-profit organisation called the Public Patent Foundation[89] was recently established in New York to combat the effects of so-called 'illegitimate patents'[90]—that is, patents that have the potential, for example, to restrict the availability of medicines to the public, or that provide barriers to market entry for small businesses. The Foundation intends to rely on legal action and proceedings in the USPTO, advocacy and public awareness programs to challenge such patents, and to encourage others to do so.[91]

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84 Ibid, rec 1.

85 Ibid, rec 4. The UK Report also made recommendations in relation to 'licensing in' and 'licensing out' genetic materials and technologies: W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), Recs 2, 6–8.

86 United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), recs 1–5, 7.

87 Ibid, ch 6, 21–22.

88 Ibid, ch 6, 22.

89 See Public Patent Foundation, *The Public Patent Foundation*, <www.pubpat.org> at 11 December 2003.

90 Public Patent Foundation, *Public Patent Foundation Receives Seed Funding, Begins Operations*, <www.pubpat.org> at 8 December 2004.

91 Public Patent Foundation, *The Public Patent Foundation*, <www.pubpat.org> at 11 December 2003.

Submissions and consultations

9.50 IP 27 did not ask specific questions about the participation of government departments or other organisations in challenging gene patents. However, a number of submissions supported greater government involvement in patent challenges, given the financial and practical impediments faced by Australian companies and individuals in this regard.

9.51 The Cancer Council Australia commented that responsibility for challenging patent rights lies with the Australian Government.

> Given that patent law operates in the Federal jurisdiction and is subject to International Agreements, such responsibility [to initiate legal challenges to patents] should fall to the Australian Government.[92]

9.52 The RCPA suggested that, although governments might be reluctant to challenge patent rights, they are the only entities with the resources to do so.

> Governments are understandably wary of opposing patents as it suggests that their patent laws and processes are flawed, yet they alone have the resources to mount a public challenge that takes years and millions of dollars to resolve.[93]

9.53 The Walter and Eliza Hall Institute of Medical Research (WEHI) indicated gene patent were not being challenged because of the costs involved and proposed that:

> It might be desirable in some instance for potential infringers to pool together to challenge a questionable patent or, where it is in the public interest, for the Government to mount a challenge against broad, questionable patents.[94]

9.54 Submissions that addressed this issue canvassed a range of options by which government entities might coordinate participation in the patent system. The Cancer Council Australia considered that the Australian Health Ministers' Advisory Council might be an appropriate body.[95] ACIPA proposed 'the creation of a public advocate or ombudsman', or alternatively that the Australian Competition and Consumer Commission (ACCC) be given power to participate in the patent examination process.[96]

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92 Cancer Council Australia, *Submission P25*, 30 September 2003. See also Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

93 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

94 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

95 Cancer Council Australia, *Submission P25*, 30 September 2003. Also: A Morley, *Submission P18*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

96 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

9.55 A number of submissions also considered a role for the proposed Human Genetics Commission of Australia[97] in monitoring and evaluating the impact of gene patents.[98] Chapter 20 discusses these submissions in more detail.

ALRC's views

9.56 As discussed in other chapters of this Discussion Paper, questionable gene patents may adversely affect research and development in the Australian biotechnology industry by deterring innovation in that field or by increasing the cost of innovation and commercial development if the patent is licensed.[99] In turn, questionable gene patents may affect the provision and cost of healthcare in Australia.[100] A significant aspect of this Inquiry is to examine whether adequate procedures exist to ensure that applications for gene patents are properly examined and that gene patents, if granted, may be effectively challenged.

9.57 Chapter 8 contains proposals to assist IP Australia in examining gene patents to improve the quality of the patents being issued. However, as noted in that chapter, there are limitations to the examination process. Patent examiners depend primarily on information provided by only one party (the applicant) in making determinations about the patentability of a particular invention. Further, such determinations are necessarily made before the full impact of granting a patent can be known. Nicol and Nielsen have commented that allowing a patent to be challenged by third parties at later stages in the patent process balances inherent deficiencies of patent examination[101] It is important that such procedures are invoked when appropriate to ensure that the exclusive rights conferred on the holder of a gene patent are exercised only when warranted.

9.58 The ALRC considers that challenges to patents might be facilitated if Commonwealth, state and territory governments were to play a greater role in the patent system. Government resources are generally more extensive than those available to private companies and publicly-funded research organisations, although the ALRC recognises that such resources may already be committed to a wide range of projects.

9.59 The motivations of governments and private entities in challenging patent rights may differ significantly. Private entities will typically initiate challenges only for strategic business purposes, or in response to an allegation of infringement. At times, the cost involved in such a challenge may render such action prohibitively expensive. Governments, however, have greater incentives to challenge a patent if it is in the

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97 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1 to 5–9.

98 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

99 See Ch 11, 12, 13, 18, 19 and 23.

100 See Ch 20 and 21.

101 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 81–82.

public interest to do so; for example, if a patent has detrimental effects for the healthcare system or for competition generally, or if it highlights a particularly controversial patent law issue. Government action might also benefit a larger number of organisations than a challenge initiated by a private entity.

9.60 The ALRC does not regard IP Australia as being well-suited to coordinate patent challenges on behalf of the government, but on the other hand, nor is the creation of a new government office (such an ombudsman of patents) required to represent the public interest in patent matters. Rather, the ALRC considers that a more active role should be taken by government departments or agencies in connection with specific patents, as well as general patent law issues, within their portfolios.

9.61 In light of this, Chapter 20 contains proposals for health departments to take a more active role in monitoring patent laws and practices, and intervening in patent processes in appropriate circumstances. Chapter 24 discusses further proposals relating to an increased role for the ACCC in connection with competition law issues raised by gene patents.

Enforcement of patent rights

9.62 Patent protection is generally sought in order to secure and preserve the competitive and commercial advantage that may result from an invention, as well as to recoup the cost incurred in development of an invention. However, patent rights are of limited value unless they are enforced to deter potential infringers and to provide a remedy for a person or entity whose rights have been infringed. Nonetheless, a patent holder is typically required to make strategic decisions about the best use of resources in enforcing his or her rights.

Factors affecting the decision to enforce a patent

9.63 There is a range of factors that might affect Australian patent holders' decisions as to whether to enforce their patent rights. Enforcement of a patent is dependent on a patent holder identifying individuals or entities that are infringing his or her patent rights. In the case of gene patents, infringement may be difficult to detect.[102] A 2002 report of the Organisation for Economic Co-operation and Development (the OECD Report) noted that the use of 'research tools' occurs behind laboratory doors, making infringement particularly difficult to monitor.[103] A recent empirical study of medical biotechnology patenting and technology transfer in Australia conducted by Nicol and Nielsen (Nicol-Nielsen Study) reached a similar conclusion.[104] Further, many biotechnology companies may not yet have commercial products that could lead a patent holder to suspect that such products have been developed using patented

102 Ibid, 215.

103 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 47.

104 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 147–148, 257.

research tools.[105] The procedures for monitoring use of Australian patents, and the difficulties Australian gene patent holders may face in discovering infringement, are discussed later in this chapter.

9.64 Apart from the difficulties of detection, actions for infringement of gene patents, although warranted, may not be being instigated. Patent protection for an invention is frequently obtained in more than one jurisdiction and an Australian patent holder may choose to enforce his or her rights in the jurisdictions that represent the largest markets for a patented product. Even if the market for a patented product is significant, a patent holder may decide that pursuing certain infringers is not financially viable, or could attract too much adverse publicity.[106]

9.65 Alternatively, a patent holder may select certain defendants for tactical reasons.[107] For example, a patent holder might pursue alleged infringers with limited financial resources, who are therefore unlikely to challenge the patent holder's rights, before seeking to enforce the patent against better-resourced entities.

9.66 Infringement proceedings also expose the validity of a patent to attack. As discussed earlier in the chapter, a defendant may file a counter-claim for revocation[108] so that a patent holder seeking to enforce his or her rights may be required to prove both that the rights are valid and that they have been infringed. There has been relatively limited consideration of the application of Australian patent law to genetic materials and technologies to date. In the absence of judicial decisions delineating the scope of rights conferred by a gene patent, infringement proceedings may be thought to entail too great a risk.[109]

9.67 Finally, patent litigation is generally a complex, time-consuming and costly process. In Australia, it has been estimated that the cost to a patent holder of litigating a patent infringement action at first instance may be $750,000 or more.[110] This figure may be conservative. In light of the fact that the Australian biotechnology sector is

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105 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 48.

106 The respondents to the Nicol-Nielsen Study suggested that such factors may be particularly relevant where academic institutions are potentially infringing gene patent rights: D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 220.

107 J Berkowitz, *United States: Trends in Enforcing and Licensing Patents*, Mondaq, <www.mondaq.com> at 23 May 2003.

108 *Patents Act 1990* (Cth) s 121. The grounds upon which revocation may be sought are set out in s 138(3).

109 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 257.

110 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 152. The cost of patent infringement actions in Australia appears to be relatively low compared with the United States, where it has been estimated that the average cost of patent infringement litigation (including appeals) is US$1.5 million: Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 152. Higher amounts have also been suggested; for example, the FTC Innovation Report noted that litigation costs in biotechnology matters have ranged from US$5 million to US$7 million: United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), ch 3, 22.

dominated by small and medium sized enterprises (SMEs) and publicly-funded organisations,[111] such amounts are significant.

Commercial responses to infringement

9.68 If a patent holder decides to enforce its patent, it may employ a variety of means to do so, including commercial actions and legal proceedings. A patent holder may notify a potential infringer of the existence of a patent and indicate that its activities involving the use of the invention claimed in the patent should be terminated—often referred to as a 'cease and desist letter'. Alternatively, a patent holder may notify a potential infringer of the existence of a patent and that activities covered by the patent claims should be conducted only pursuant to a licence—commonly termed an 'offer to license'. If such approaches are not successful, a patent holder may need to consider initiating civil proceedings to enforce the patent.

Legal responses to patent infringement

9.69 A patent holder (or his or her exclusive licensee) may take legal action to prevent the infringement of the exclusive rights granted pursuant to a patent.[112] Patent infringement may be either direct or contributory. The infringement is direct if a person, without authorisation, exercises any of the exclusive rights conferred on the patent holder.[113] Contributory infringement exists if a person who is not the patent holder or a licensee supplies a product the use of which would constitute an infringement of the patent.[114]

9.70 A patent will be infringed if all of the essential features (or 'integers') of the patent holder's claim have been taken by a defendant.[115] That is, a court must determine whether or not the substantial idea of an invention disclosed in a patent specification (and subject to a definite claim) has been taken and embodied in an item alleged to infringe the patent. Australian courts have found that omitting an inessential part of a patent claim or replacing it with an equivalent will not necessarily prevent a

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111 See further Ch 17; D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347.

112 An exclusive licensee who initiates infringement proceedings must join the patent holder as a party to the suit, and the licensee's interest in the patent must be entered on the register of patents maintained by IP Australia: *Patents Act 1990* (Cth) ss 120(2), 187; *Patents Regulations 1991* (Cth) r 19.1. In infringement proceedings initiated by an exclusive licensee, the licensee stands in the shoes of the patent holder, subject to any additional terms relating to enforcement of patent rights in the licence agreement (for example, allocation of any damages awards, liability for the costs of any infringement proceedings, or the right to control proceedings).

113 Direct infringement of a patent is not defined in the *Patents Act 1990* (Cth). However, it can be inferred from s 13 that direct infringement will occur if a person engages in any activity in relation to which a patent holder is granted exclusive rights: see R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 318.

114 *Patents Act 1990* (Cth) s 117. Section 117(2) specifies that the use of a product falls within the scope of the provision if: (a) it is the only use of which the product is reasonably capable; (b) the supplier had reason to believe the customer would put the product to an infringing use and the product is not a 'staple commercial product'; or (c) the infringing use is in accordance with any instructions or inducement to use the product emanating from the supplier.

115 *Populin v HB Nominees Pty Ltd* (1982) 41 ALR 471, 475.

finding of infringement.[116] What constitutes an 'essential integer' of a patent is a matter of construction of the patent specification. In general, it is said that such construction must be purposive rather than purely literal.[117]

9.71 Infringement may occur any time after the date of publication of the complete specification, although proceedings may not be commenced until the patent has been granted—or, in the case of an innovation patent, certified.[118]

Remedies

9.72 If a patent holder successfully proves that its patent has been infringed, remedies are available to prevent continuation of the activities constituting the infringement and to compensate the patent holder for any loss incurred. These remedies include an injunction and compensation in the form of damages, or an account of profits, at the patent holder's option.[119] A court may also make orders for the inspection[120] and delivery up of infringing materials.[121]

9.73 Provisional relief is available to a patent holder to prevent an alleged infringement from occurring and to prevent infringing goods from entering the channels of trade pending the resolution of litigation. Provisional relief may also be available to preserve relevant evidence relating to an alleged infringement.[122]

Defences to patent infringement

Defences available under the Patents Act

9.74 The *Patents Act* establishes a limited number of defences, which may be asserted against a claim of patent infringement. General defences to a claim of patent infringement include:

- use of a patented invention on board a foreign vessel, aircraft or vehicle that only comes within the patent area of Australia temporarily or accidentally;[123]

116 *Fisher & Paykel Healthcare Pty Ltd v Avion Engineering Pty Ltd* (1991) 103 ALR 239.
117 *Populin v HB Nominees Pty Ltd* (1982) 41 ALR 471, 476. However, a recent decision has cautioned against broadening the scope of a claim by relying on a purposive construction: *Root Quality Pty Ltd v Root Control Technologies Pty Ltd* (2000) 177 ALR 231, 242–243.
118 *Patents Act 1990* (Cth) ss 57, 120(1A).
119 Ibid s 122(1).
120 Ibid s 122(2).
121 See, eg, *Roussel Uclaf v Pan Laboratories Pty Ltd* (1994) 51 FCR 316.
122 Interlocutory relief may also be available by means of an Anton Piller Order: *Anton Piller KG v Manufacturing Processes Ltd* [1976] Ch 55. See also R Meagher, D Heydon and M Leeming, *Meagher, Gummow and Lehane's Equity: Doctrine and Remedies* (4th ed, 2002), [21.495]–[21.500]; B Fitzmaurice, 'Protecting Intellectual Property with Anton Piller Orders' (2002) 15 *Australian Intellectual Property Law Bulletin* 103.
123 *Patents Act 1990* (Cth) s 118.

- prior use of an invention, so long as the alleged infringer had not obtained the subject matter of the invention from the patent holder (or their predecessor in title);[124]

- use of a patented invention that is subject to a contractual condition prohibited under s 144 of the *Patents Act* (such as a 'tie-in' arrangement);[125] and

- use of a patented invention pursuant to, and within the scope of the grant of a 'declaration of non-infringement' granted by a prescribed court.[126]

9.75 The *Patents Act* also provides a defence to the infringement of a patent covering a pharmaceutical substance for therapeutic purposes if the term of the patent has been extended under the Act.[127] This defence is limited to circumstances in which the pharmaceutical substance claimed in the patent was used: (a) after the extension of the patent term has been granted, for the purpose of registering a product on the Australian Register of Therapeutic Goods (or any foreign equivalent thereof); or (b) during the extended portion of the patent term, for a non-therapeutic purpose.

9.76 Even if a person is held to have infringed a patent, a court may decline to award damages or an account of profits if the infringement was 'innocent'; that is, if the infringer was not aware, and had no reason to believe, that a patent for the invention existed. 'Innocent infringement' does not, however, prevent the grant of an injunction to restrain future infringement.[128]

9.77 In addition to these defences, later chapters of this Discussion Paper examine whether the *Patents Act* should be amended to enact new defences based on experimental use of gene patents, or use of gene patents for the purposes of medical treatment.[129]

Defences available under general law

9.78 In addition to the defences specifically provided for by the *Patents Act*, it has been suggested that general equitable defences may be available against a claim of patent infringement.[130] The circumstances in which such defences may be able to be

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124 Ibid s 119.

125 See further Ch 24.

126 *Patents Act 1990* (Cth) ss 124–127. A declaration of non-infringement is a court order that use of an invention does not fall within the scope of the claims of a particular patent. It may be obtained only if a person or company has previously sought an admission from the patent holder that their proposed activities are not within the scope of the relevant patent claims and the patent holder has refused, or failed to provide, such an admission. A declaration of non-infringement is not a complete defence and may limit but not negate the award of damages: *Patents Act 1990* (Cth) ss 127(c), 127(d).

127 *Patents Act 1990* (Cth) s 78.

128 Ibid s 103.

129 See Ch 14 and 22.

130 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155.

invoked are outlined below, but there is little case law on this issue and the extent and effect of pleading such a defence is consequently unclear.

9.79 First, an alleged infringer may claim that the patent holder is estopped from enforcing its rights if, by its acts or words, the patent holder has led the infringer to believe that the patent rights would not be enforced and the alleged infringer has relied on that understanding to his or her detriment.[131]

9.80 Second, an alleged infringer may assert delay or acquiescence on the part of the patent holder in the enforcement of his or her rights.[132] Such a defence is unlikely to avoid an injunction restraining future infringement, but may substantially reduce the damages awarded if the patent holder successfully demonstrates that the patent has been infringed.[133]

Enforcement of gene patents in Australia

Submissions and consultations

9.81 In IP 27, the ALRC sought information about the level of enforcement of Australian gene patents, the factors affecting Australian entities' decisions to enforce gene patents, and the type of action such entities initiate in this regard.[134]

9.82 Submissions that addressed this issue adopted different views as to what amounted to 'enforcement' of a gene patent. A number of submissions used the term to refer only to infringement proceedings. Others adopted a broader view and regarded 'offers to license' a patent as also amounting to enforcement action. A few submissions considered that the term encompassed an even wider range of actions. For example, a multi-national pharmaceutical company, GlaxoSmithKline, commented that patents may be effective on a number of levels, including:

> (a) providing a deterrent against infringement, (b) giving rise to licensing or cross-licensing arrangements, (c) being the subject of letters of demand, and (d) being the subject of full scale patent infringement litigation.[135]

9.83 A number of submissions commented on the apparently low level of enforcement activity that is occurring in Australia with respect to gene patents. Two submissions indicated that they were not aware of any threats to enforce gene patents

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131 See, eg, *Woodbridge Foam Corp v AFCO Automotive Foam Components Pty Ltd* [2002] FCA 883.

132 See also Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155; J Bergmann and T Davies, 'Junk DNA or Junk Debate?', *Allens Arthur Robinson Biotech News*, 3 September 2003, <www.aar.com.au/pubs/bt>. The *Patents Act* provides that infringement proceedings must be commenced within three years from the day on which the patent at issue was granted, or six years from the day on which the infringing act was done, whichever period is longer: *Patents Act 1990* (Cth) s 120(4).

133 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155.

134 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 10–4.

135 GlaxoSmithKline, *Submission P33*, 10 October 2003. See also Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

in the genetic testing arena.[136] AusBiotech Ltd commented that 'so far there has been very little actual litigation'.[137] It noted however, that the low level of patent litigation does not take into account disputes that have settled, or that occur prior to a gene patent being granted (for example, opposition proceedings).[138] Other submissions agreed that the level of enforcement of gene patents is difficult to gauge,[139] particularly given that communications about such matters are generally confidential unless infringement proceedings are initiated.[140]

9.84 A few submissions identified specific examples of recent enforcement actions relating to gene patents, and expressed concern about such actions becoming more common.[141] Two submissions suggested that even if specific evidence about the enforcement of gene patents in Australia was not currently available, the ALRC should 'take a pro-active stance in looking for problems that have yet to arise'.[142]

9.85 The factors that may influence a patent holder's decision as to how to enforce a gene patent were addressed in a number of submissions. The Department of Industry, Tourism and Resources (DITR) suggested that the cost of gene patent litigation is 'a major factor influencing the capacity to enforce gene patents'.[143] Other submissions indicated that the costs of infringement litigation may act as a disincentive to pursue individuals or entities who are infringing Australian gene patents,[144] particularly in the case of academic institutions and research organisations.[145] A few submissions commented that the cost of infringement litigation is an issue in enforcing patents over any type of technology, not only gene patents.[146] Submissions also suggested that the cost of gene patent litigation encouraged patent holders and potential infringers to

136 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003.

137 AusBiotech Ltd, *Submission P58*, 7 November 2003.

138 Ibid.

139 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

140 AusBiotech Ltd, *Submission P58*, 7 November 2003.

141 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

142 G Suthers, *Submission P30*, 2 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

143 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003. See also Queensland Government, *Submission P57*, 5 January 2004

144 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

145 A McBratney and others, *Submission P47*, 22 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 220, 257.

146 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

license gene patent rights or reach some other commercial solution to potential infringement issues rather than face the cost of being involved in litigation.[147]

9.86 Other factors influencing a patent holder's decision to enforce its rights were also suggested in submissions. GlaxoSmithKline and Davies Collison Cave referred to the provisions in the *Patents Act* that provide for action to be taken against a patent holder who makes 'unjustified threats of infringement'.[148] These submissions indicated that such provisions meant that an Australian patent holder 'will generally not make threats of initiating legal proceedings unless they are prepared to actually proceed in this manner'. Other submissions commented that the potential for adverse publicity might also affect the decision to enforce patents against particular types of entities, for example academic institutions.[149]

Nicol-Nielsen Study

9.87 The Nicol-Nielsen Study received responses largely consistent with the views expressed in submissions in relation to IP 27. Nicol and Nielsen concluded that there has been little enforcement of gene patents in Australia to date.[150] Further, entities surveyed indicated that potential patent infringement issues are most often resolved by negotiating a licence to use the patented invention. Nicol and Nielsen noted, however, that there is a body of evidence in other jurisdictions suggesting that this situation may be changing and they indicated that enforcement actions may become more likely in Australia.[151] In particular, Nicol and Nielsen noted that Genetic Technologies Limited's (GTG) announcements of the steps being taken to license and enforce the company's non-coding DNA patents occurred after responses to the study had been received.[152]

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147 GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

148 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003 (referring to ss 128–132 of the *Patents Act*).

149 Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

150 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 38, 201–204, 217, 256–257.

151 Ibid, 61–63, 139–140, 199–203. Referring to studies conducted by Dr Mildred Cho and her colleagues: see, eg, M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3; J Merz and others, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577.

152 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 106, 139–140, 202, 256. GTG's licensing practices and its non-coding DNA patents are discussed in Ch 13.

Monitoring compliance with patent rights

By Australian patent holders

9.88 A patent holder's ability to enforce its rights depends on its ability to obtain information about third parties' activities that may infringe the claims of a patent. Such information may be obtained from a variety of sources, including in-house procedures established by a patent holder, patent offices, or private information services that monitor patent compliance. The mechanisms by which Australian patent holders may monitor and investigate potentially infringing activities are considered below.

9.89 Information and resources within a patent holder's organisation are two means by which potential patent infringers may be detected. Employees of a patent holder may be in the best position to identify potential infringement by third parties because of their familiarity with the relevant area of technology, the identity of competitors, and such entities' business activities.

9.90 'Patent watch' services may also be used. These services are frequently provided by law firms or patent attorneys. Patent watch services review notices in the Official Journals published by patent offices, as well as other computer databases covering patent and technical data, for information about inventions or patent filings that may infringe a patent holder's rights. Searches may be restricted by subject matter (for example, to a particular genetic sequence or technology), or by organisation name (for example, a key competitor or a researcher who is known to be active in the field). The available material is, however, limited because these sources of information do not reveal patent applications that have not yet been published.[153]

9.91 It is somewhat easier for patent holders to monitor the activities of third parties who have been authorised by them to use a patented genetic invention pursuant to a licence agreement. Mechanisms for monitoring a licensee's compliance with the terms of a licence are typically stipulated in the agreement. A patent licence may include a requirement that a licensee submit periodic reports detailing product sales or—if research and development is still required in connection with licensed gene patents—describing progress during the reporting period. In addition, a patent holder may have the right to audit a licensee's records relevant to activities covered by an agreement including, in some cases, laboratory workbooks. These mechanisms allow a patent holder to assess whether a licensee is using the patent rights in accordance with the licence, or for other purposes that may amount to an infringement.

By users of Australian gene patents

9.92 Individuals, academic institutions, research organisations and biotechnology companies may also conduct prior art searches before embarking on a particular line of

153 Most patent applications are published 18 months after the date on which the application was first filed: see Ch 8.

research, or commercialising any genetic material or technology, to ensure that their activities will not infringe existing patent rights.

9.93 Respondents to the Nicol-Nielsen Study indicated that conducting prior art searches is an onerous and expensive exercise, and is becoming increasingly more difficult as the gene patent landscape becomes more complex.[154] The study found that prior art searches are commonly conducted by Australian biotechnology companies to ensure that research does not infringe third party patent rights.[155] However, Australian research organisations and diagnostic facilities that were surveyed in the Nicol-Nielsen Study demonstrated less inclination to perform such searches.[156] To the extent prior art searches are conducted by such entities, it may only occur when a commercial application for the relevant research becomes apparent.[157] Nicol and Nielsen concluded that:

> There is some desirability for finding ways of reducing the onerous demands of patent searching and tracking infringement.[158]

Patent information available from IP Australia

9.94 IP Australia makes information about granted patents and published patent applications available in three forms:

- in the *Official Journal of Patents* (*Official Journal*);
- by way of searchable on-line databases on IP Australia's website; and
- on a subscription basis, by way of CD-ROM, containing copies of patent applications and specifications.

9.95 The information available in the *Official Journal* and via IP Australia's on-line databases are described further below.

9.96 Section 222 of the *Patents Act* provides for publication of the *Official Journal* by the Commissioner on a periodic basis. The *Official Journal* contains notices and other matters prescribed in the *Patents Act* and the *Patent Regulations*. The Journal reports all significant events and actions that occur in relation to each Australian patent, as well as general information and notices about amendments to Australian patent law or the PCT, or to IP Australia's practices. Currently, a supplement to the

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154 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 181–182.
155 Ibid, 178.
156 Ibid, 178–179.
157 Ibid, 180.
158 Ibid, 259. Note that Nicol and Nielsen considered mechanisms for regulating the use of biotechnology patents might provide a solution to this issue: see further Ch 23 and 28.

Official Journal is made available by IP Australia on its website,[159] but IP Australia intends to make the entire journal available electronically in the future.

9.97 IP Australia also provides on-line access to a number of databases that contain information about Australian patents and patent applications, including:

- Patents mainframe bibliographic databases—Patent Administration System (PatAdmin) and Patent Indexing System (PatIndex);
- AU Published Patent Data Searching (APPS);
- Patent specifications database; and
- New Patent Solution system (NPS).

9.98 PatAdmin and PatIndex provide bibliographic information about patent applications that have been filed up to 4 July 2002. The available information includes: patent and application numbers; patent title; inventor and applicant; the status of a patent or application; dates that are significant in processing the application and to maintain the patent in force; and whether any licences have been recorded against the patent.

9.99 APPS contains Australian patent abstracts, that is, the first page of a patent application at the time of its publication. Searches may be conducted by patent or application number, as well as by title or International Patent Classification mark.[160] For full copies of patent specifications, the user is transferred to the patents specification database.

9.100 The patent specifications database contains complete copies of published Australian patent applications. The database includes copies of applications prior to acceptance and after acceptance, as well as applications that have been republished following amendment after acceptance. Searches may be conducted by patent number or application number. The database does not contain information about the status of an Australian patent or application. A user may only obtain this information on-line from PatAdmin or the NPS system. In addition, a user is transferred to the EPO's on-line database 'esp@cenet' for copies of Australian patent applications filed under the PCT, which are published prior to acceptance.[161]

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159 The supplement to the *Official Journal* only contains information about patents included in the NPS system (see further below). A complete copy of the *Official Journal* containing information about all Australian patents is available from IP Australia's offices and is distributed on CD–ROM to libraries and other reference organisations throughout Australia.

160 The International Patent Classification marks are described in Ch 8.

161 Once transferred to the EPO's esp@cenet website, a user must conduct a new patent search using the World Patent Number, not the Australian Patent Number.

9.101 NPS is a new patent database developed by IP Australia. It contains bibliographic information on patent applications having a number format, which was recently implemented as a new patent numbering system by IP Australia. NPS contains bibliographic data for standard complete and provisional applications filed from July 2002, as well as all innovation patent data. Currently, the type of bibliographic data included in the NPS system is similar to that contained in PatAdmin and PatIndex. The NPS system is, however, still under development and both the search function and the content of the database are being upgraded. Full copies of the published Australian patent applications or granted patents are not included in this database, but will be incorporated into the patent specifications database by IP Australia. They are currently available on a subscription basis through IP Australia's CD–ROM products.

9.102 The databases on IP Australia's website contain overlapping information and each database has limitations in the information it contains. To conduct a patent search on IP Australia's website, at least two databases (and frequently more) must be used and the results of each search cross-referenced in order to cover all necessary information. The nature of a user's needs will determine which of IP Australia's databases must be accessed to obtain the relevant information. For example, if a user requires bibliographic information about a patent application, a search of both PatAdmin and the NPS system would be required to complete a search. However, if a user requires information on an invention claimed in a patent application, a search of APPS and certain of IP Australia's CD–ROM products would be appropriate.[162] This is a time-consuming task and may potentially produce misleading results, particularly for inexperienced users, or those with a limited understanding of the Australian patent system.

9.103 Online databases provided by patent offices in other jurisdictions, such as the USPTO and EPO, are more user-friendly. Search functionality is concentrated in one area of the websites of the USPTO and the EPO, and searches may be conducted using a wide range of fields.[163] Search results include both bibliographic information about the patent and a copy of the complete patent specification, or a patent application (if published).[164]

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162 IP Australia is in the process of ensuring that APPS contain abstracts from patent applications that are included in both the PatAdmin and NPS system so that a search of the APPS system alone would be sufficient in this case.

163 For example, the USPTO database allow searches using the following fields: patent number and application serial number; type of patent application; inventor name, applicant and assignee name or location; patent title; issue date; application date; claim and specification details; patent classification; registered interested (eg, security interests, exclusive licenses and US government interests); patent examiner who assessed the application; patent attorney of record.

164 Until relatively recently, United States patent applications were not published prior to a patent being granted so information about United States patent applications was limited unless based on a PCT application first filed in a jurisdiction outside the United States.

Submissions and consultations

9.104 The availability of information about gene patents and pending gene patent applications was identified as an issue in a number of submissions and consultations.[165] The South Australian Government submitted:

> The current methods of disseminating information about pending or granted patents are considered inadequate in relation to patents that may have a significant impact on healthcare. Clearly, information about the IP Australia database on patents should be promoted to parties and stakeholders in the community so that they are alert to and vigilant about patents that impact or are likely to impact on health care.[166]

9.105 GTG commented that the ability to search patent literature is generally poor and particularly so in Australia, making it difficult for patent holders to identify potential licensees.[167] GTG suggested that IP Australia might develop databases to facilitate searches of patent literature:

> There is an opportunity for leadership by IP Australia here to establish, for example, a database of all gene patents (indexed by gene) in force or under application in Australia. Also helpful would be a database of all genetic sequences that have been patented in Australia.[168]

9.106 The Department of Health Western Australia also supported increasing public awareness about gene patent applications.[169] The Department suggested that the *Official Journal of Patents* could be supplemented by an '*Official Journal of Patents for Genetic Technologies* or … *for Technologies Relating to Healthcare* to allow for more transparent review of gene patent applications'.[170] Alternatively, the Department considered that:

> The proposed HGCA could distribute information about human genetic patents, in the same manner that the Office of the Gene Technology Regulator distributes for comment all applications for release of GM crops.[171]

9.107 However, other submissions indicated that information is available to Australian patent holders, and the public generally, about activities that may lead a patent holder to believe that its patent is being infringed.[172] Some submissions commented that appropriate professional advice is required to obtain patent protection and that, within Australia, there are many intellectual property lawyers and patent attorneys from whom

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165 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

166 South Australian Government, *Submission P51*, 30 October 2003.

167 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

168 Ibid.

169 Department of Health Western Australia, *Submission P53*, 3 November 2003.

170 Ibid. See also: E Milward and others, *Submission P46*, 20 October 2003.

171 Department of Health Western Australia, *Submission P53*, 3 November 2003.

172 A McBratney and others, *Submission P47*, 22 October 2003.

such advice can be obtained.[173] Two submissions commented that patent holders are responsible for monitoring the use of their patent rights and detecting infringement, perhaps with the assistance of lawyers.[174]

9.108 In contrast, WEHI commented that, while sufficient information about gene patents may be available in Australia, such information is not always 'easily accessible or affordable'.[175]

ALRC's views

9.109 Notwithstanding the patents information already made available by IP Australia on its website, the ALRC considers that a comprehensive database of information about Australian patents should be developed by IP Australia.

9.110 Submissions and consultations, as well as respondents to the Nicol-Nielsen Study, indicated that information about Australian gene patents is not readily available or accessible and that this creates impediments to the licensing and enforcement of gene patents. The ALRC considers that a comprehensive database of patent information developed by IP Australia could assist inventors, biotechnology companies, research organisations and academic institutions in conducting preliminary searches of existing Australian patent and published patent applications, which are an important part of any prior art search. For individuals and entities with limited resources, such a database could assist in initial identification of whether a particular activity or area of research is problematic in relation to intellectual property issues, or to refine the scope of a comprehensive prior art search.

9.111 Currently, patent information is provided by IP Australia in a number of overlapping databases. The ALRC considers that, contrary to the suggestion in some submissions, developing a separate database containing information only about gene patents and applications would compound the difficulties that a user presently faces in obtaining information about Australian gene patents. Developing a comprehensive database relating to all Australian patents and published patent applications is preferable and would allow searches for patents and published patent applications claiming genetic materials and technologies, as well as all other types of inventions.

9.112 Much of the information that should be contained in any new patent database is already available to IP Australia, but would need to be compiled and centralised. This process is likely to involve considerable resources on the part of IP Australia, which the organisation might seek to recoup by charging an access fee for the use of the database. However, the ALRC is of the view that if IP Australia decides to charge a fee

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173 GlaxoSmithKline, *Submission P33*, 10 October 2003; Queensland Government, *Submission P57*, 5 January 2004; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

174 AusBiotech Ltd, *Submission P58*, 7 November 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

175 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

to some or all users seeking access to the database, the fee should be set at a level that does not impede access unreasonably.

9.113 In identifying the criteria by which such a database may be searched, search functionality similar to that contained in the databases offered on the USPTO and EPO websites are a worthwhile model. In the ALRC's view, the ability to conduct searches of the patents database based on any of the following information would be useful: patent number and application serial number; inventor name, applicant name and assignee name; patent title; issue date; application date; specification details; patent classification; and registered encumbrances (for example, security interests and exclusive licenses).

9.114 Some of the difficulties a user currently encounters in searching for patent information using IP Australia's on-line databases may be addressed when improvements to the NPS system are complete. For example, the NPS system currently allows searches to be conducted using the categories of information identified in the previous paragraph. However, in its current form, the NPS system does not appear to provide all of the information a user might require when conducting a patent search. For example, access to full copies of patent specifications (for the purpose of obtaining information about claimed inventions) is available only from a separate database with limited search capability.

9.115 The ALRC recognises that the role of IP Australia is not, and should not be, to provide legal advice to prospective patent applicants about their ability to obtain patent protection, or to users of patent rights about freedom to operate in a particular field. The ALRC agrees with submissions that identified the importance, in appropriate cases, of obtaining legal advice in connection with filing for patent protection, enforcing patent rights or defending against allegations of infringement. Patent watch services and commercial databases containing patent and other prior art information are also available to assist patent holders and others in monitoring compliance with patent rights.

9.116 The following proposal is not intended to implement suggestions made in some submissions that IP Australia could assist government health departments in identifying gene patents that may have implications for healthcare by providing such departments with information about granted gene patents and pending gene patent applications. The proposed database may well facilitate the assessment of such issues by government health departments by making information about Australian patents and published applications more accessible, but at this stage the ALRC does not envisage that IP Australia would have any specific responsibility in this regard. Use of patent information by federal and state health departments is addressed in later chapters of this Discussion Paper.[176]

176 See Ch 20.

Proposal 9–1 IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should be accessible to the public through IP Australia's website and should provide user-friendly access and search capabilities on a wide variety of bases. If a fee is charged for use of the database, it should be kept at a level that does not unreasonably limit access.

Patent litigation insurance

9.117 Patent litigation typically entails substantial costs and involves a degree of risk both to the patent holder, whose patent rights may be revoked, and to a defendant, who made be prevented from pursuing an aspect of his or her business if liability is found. In light of this, companies may consider investing in patent litigation insurance.[177]

Types of patent litigation insurance

9.118 There are several types of insurance policies covering contingencies related to patent litigation. The principal types of insurance and the characteristic elements of each policy are outlined below.[178]

9.119 *Patent enforcement litigation insurance* allows a patent holder to initiate legal proceedings to protect and enforce its patent rights.[179] This type of policy typically covers the legal costs involved in enforcing patent rights against an alleged infringer on a 'claims-made' basis.[180]

9.120 *Patent infringement liability insurance* provides coverage against allegations of patent infringement.[181] Such policies are often obtained by manufacturers, vendors and users of patent rights to cover the legal costs involved in defending a patent infringement claim and, in some cases, they may also cover damages awards if liability is found.

9.121 *Intellectual property litigation insurance* is a broad form of enforcement litigation insurance, which covers the enforcement of all intellectual property rights—for example, trademarks, copyrights and rights in computer software, as well as patents. Such policies may also cover legal costs incurred in defending a challenge to

177 As outlined in this chapter, a number of different types of insurance policies may cover the costs of patent litigation. The term 'patent litigation insurance' is used in the Discussion Paper to refer generally to all such policies.

178 See further: Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155–156.

179 This type of insurance may also be called, 'offensive patent insurance', 'patent pursuit insurance' or 'infringement abatement insurance'.

180 'Claims made' policies indemnify an insured against any liability that arises from an occurrence that happened during the relevant policy period.

181 This type of insurance may also be called, 'defensive patent insurance'.

the ownership, validity or title to covered intellectual property rights, or in enforcing the terms of intellectual property licences and non-disclosure agreements.

9.122 *Commercial general liability insurance* held by a company may also cover the cost of defending an intellectual property infringement claim.[182] However, the existence of such coverage depends on the scope and wording of the policy and many commercial general liability policies now contain express exclusions for intellectual property actions.[183]

Prevalence of patent litigation insurance

9.123 Patent litigation insurance is a relatively new development. The ALRC understands that currently no Australian insurers offer such policies,[184] although Australian companies may be able to obtain patent litigation insurance from overseas underwriters that cover patent infringement proceedings in foreign jurisdictions as well as Australia.[185]

9.124 Patent litigation insurance is more widely available in the United States and Europe. However, even in these jurisdictions the number of insurers offering patent litigation policies is relatively limited,[186] and the effectiveness of such policies is yet to be fully tested. A report on patent litigation insurance prepared for the European Commission in 2003 (the EC Insurance Report) concluded that, to date, litigation insurance had not been particularly successful in any jurisdiction.[187] While precise statistics were not available, the report estimated that approximately 750 patent litigation insurance policies had been issued in the European Union in the last 25 years—an extremely small number compared with the aggregate number of patents granted during the same period.[188]

Advantages of patent litigation insurance

9.125 Patent litigation insurance may provide a number of advantages, particularly for SMEs. Patent litigation insurance allows SMEs to enforce their patent portfolios

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182 Such coverage is based upon judicial interpretation of the scope of coverage for 'advertising injury' provided in commercial general liability policies: see M Simensky and E Osterberg, 'The Insurance and Management of Intellectual Property Risks' (1999) 17 *Cardozo Arts and Entertainment Law Journal* 321; J Cahill and T Fitzgibbon, 'Intellectual Property Assets Raise Insurance Issues', *National Law Journal*, 25 October 1999; IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association.

183 M Simensky and E Osterberg, 'The Insurance and Management of Intellectual Property Risks' (1999) 17 *Cardozo Arts and Entertainment Law Journal* 321, 325–329, 331–334.

184 Dexta Corporation Ltd, *Correspondence*, 10 December 2003. Until recently, patent litigation insurance was offered in Australia by Dexta Corporation.

185 J Walker, 'Patents Insurance Has Its Virtues', *Business Review Weekly*, 30 May 2002, 78.

186 For details of European and United States insurance companies offering patent litigation insurance, see: CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), app A; IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association, 14–18.

187 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), 1.

188 Ibid, [5.3].

against, or defend allegations of patent infringement by, larger companies without having to settle or license to avoid escalating costs. Further, it may strengthen a party's bargaining power in any negotiations to settle an infringement claim. In addition, it has been suggested that, for patent holders, 'publication of the existence of insurance in company literature and on websites acts as an effective deterrent to potential infringers'.[189]

9.126 In Australia, patent litigation insurance has recently received public attention in connection with the Melbourne-based biotechnology company, Genetic Technologies Limited,[190] which has patents in many jurisdictions.[191] The company has indicated that patent litigation insurance is an important part of its licensing and enforcement strategy, and has allowed the company to initiate proceedings against major biotechnology companies in the United States.[192] QPSX, a publicly-listed Australian broadband technology company, has expressed a similar view and is reportedly relying on a patent litigation insurance policy underwritten by Lloyd's of London to help finance patent infringement litigation in Germany against Siemens AG and Deutsche Telekom.[193]

9.127 In licensing negotiations, litigation insurance may strengthen a patent holder's ability to license its patents to corporate entities that want to commercialise aspects of the company's patented technology.[194] Potential licensees may indeed require a patent holder to obtain patent litigation insurance to ensure that the patent holder will be able to indemnify the licensee in the event that a patent infringement claim is made by a third party.[195]

9.128 Patent litigation insurance may also provide indirect benefits to a company.[196] A substantial portion of the value of many biotechnology companies is based on their intellectual property portfolio, making protection of such intellectual property rights paramount. Patent litigation insurance facilitates a company's protection of its intellectual property. This, in turn, may attract investors. An insurance company's assessment of the validity of a company's patent portfolio, which is a prerequisite to any patent litigation policy being issued, may add credibility to claims that the company's patents are both valid and valuable.[197] Finally, patent litigation obviates the

189 N Rawlingson Plant, 'Competitive Advantage of Patent Insurance' (2002) 15 *Australian Intellectual Property Law Bulletin* 27.

190 ABC Television, 'Patently a Problem', *Four Corners*, 11 August 2003, <www.abc.net.au/4corners/archive.htm>.

191 Genetic Technologies Limited, *Annual Report 2002* (2002).

192 J Walker, 'Patents Insurance Has Its Virtues', *Business Review Weekly*, 30 May 2002, 78, ABC Television, 'Patently a Problem', *Four Corners*, 11 August 2003, <www.abc.net.au/4corners/archive.htm>.

193 E Connors, 'New Insurance to Help SMEs Protect IP', *Financial Review*, 3 April 2002.

194 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 157.

195 N Rawlingson Plant, 'Competitive Advantage of Patent Insurance' (2002) 15 *Australian Intellectual Property Law Bulletin* 27, 28.

196 Ibid, 27–28; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 157.

197 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 156, 157.

need to 'self-insure', which involves a large capital commitment that may be beyond the capabilities of many SMEs.

Criticisms of patent litigation insurance

9.129 Patent litigation insurance does, however, have a number of limitations. The costs involved in obtaining and maintaining patent insurance are significant and, in some cases, prohibitive. For patent enforcement litigation insurance, annual premiums are approximately US$4,000 for US$500,000 in coverage—that is, less than 1% of the insured amount.[198] In addition, potential insureds are generally required to obtain patent validity opinions[199] or 'freedom to operate' opinions,[200] as applicable, at their own cost, before an insurance company will consider issuing a policy. Annual premiums for patent infringement liability insurance are generally between 1.5% to 4% of the insured amount.[201] Co-payment provisions of between 15% and 25% are also common in both types of policies.[202]

9.130 The EC Insurance Report concluded that, in the United States, Europe and Japan, 'high costs have meant that insurance has only been of interest to the few'.[203] Further, the EC Insurance Report commented that 'no insurance scheme [in Europe or the United States] has shown any capacity to provide adequate cover at premiums affordable to patentees in general'.[204]

9.131 The amount of coverage provided by a patent litigation insurance policy may be limited in a number of ways.[205] In addition to co-payment provisions, the quantum of legal costs that an insurer will cover is generally limited to a predetermined indemnity level. In the case of patent infringement liability litigation, predetermined indemnity levels also apply to damages awards—if such liability is covered by the policy at all—

198 IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association, 16; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 156. As no Australian insurer currently offers patent litigation insurance, information about insurance premiums is available only in United States dollars.

199 A 'validity opinion' is an opinion by a patent agent or attorney as to whether the claims of an issued patent would likely be held by a court in view of the available facts.

200 A 'freedom to operate opinion' (or 'non-infringement opinion') is an opinion provided by an attorney as to the likely holding of a court on whether a particular product or process would infringe any identified third party patents.

201 IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association, 15; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 156.

202 IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association, 15, 16; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 156. A co-payment, like an excess or deductible payment, is the amount that the insured must pay if a claim is made under a patent litigation insurance policy. Co-payments are typically calculated based on a percentage of a claim.

203 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), 1.

204 Ibid, 1.

205 J Bergmann and T Davies, 'Junk DNA or Junk Debate?', *Allens Arthur Robinson Biotech News*, 3 September 2003, <www.aar.com.au/pubs/bt>; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 157.

and certain types of damages may be excluded, such as punitive or exemplary damages and fines.

9.132 Territorial limitations may also apply, leaving the insured to pay all costs involved in patent litigation outside the designated countries covered by its policy.

9.133 For patent enforcement litigation insurance, coverage may be limited to specific patents or may only cover a company's patent portfolio at the date the policy was issued, with payments required to update the policy to cover any additional patents. In addition, certain types of claims may not be covered—for example, speculative claims—and coverage for appeals from adverse decisions may be at the insurance company's discretion.

9.134 Other conditions contained in patent litigation insurance policies may limit the insured's discretion in formulating a litigation strategy. Policies typically make coverage conditional on the insurer's approval of the patent holder's legal counsel and litigation budget.[206] In some cases, an insurer may also require control of the litigation.

Effect of litigation insurance on the patent system

9.135 Conflicting opinions have been expressed about the impact of patent litigation insurance on patent filing activity and enforcement of patent rights. Participants in workshops conducted in connection with the EC Insurance Report considered that wider use of patent litigation insurance in Europe could have a positive impact on the level of patent filing activity, enforcement and licensing of patent rights.[207] Participants in the workshop also suggested that an increase in the amount of patent litigation as a result of insurance would lead to greater effectiveness of the patent system.[208]

9.136 It has also been suggested that patent litigation could be disadvantageous to the operation of the patent system generally. The cushion of a patent insurance policy might encourage litigation in circumstances where negotiation and settlement may be more appropriate.[209] For this reason, the EC Insurance Report considered that a patent litigation insurance scheme in Europe should encourage out-of-court settlements.[210] In addition, it has been suggested that 'weak' patent rights might be successfully enforced simply because patent litigation insurance provides a patent holder with the resources necessary to take such action. However, in assessing this claim, it should be remembered that insurance companies generally obtain opinions about the strength of a patent prior to issuing a policy and that insurers may control, or advise on, the conduct of patent litigation covered by a policy.

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206 J Bergmann and T Davies, 'Junk DNA or Junk Debate?', *Allens Arthur Robinson Biotech News*, 3 September 2003, <www.aar.com.au/pubs/bt>.

207 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), ch 11.

208 Ibid, ch 11.

209 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 157.

210 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), 2.

Government consideration of patent insurance schemes

9.137 Currently, patent litigation insurance is available only from private sector insurers. However, reports in Australia and Europe have addressed the possibility of a patent insurance scheme being administered by the government as part of the patent system.[211]

9.138 In 1999, ACIP considered whether a levy should be imposed on all patent grants to fund insurance coverage for infringement litigation and validity challenges.[212] ACIP concluded, however, that such insurance should be left to the private sector and that involvement by government would be inconsistent with the government's policy that 'its primary role in the IP area is to ensure Australia has effective IP and legal systems'.[213] Nonetheless, ACIP suggested that industry associations, education institutions and IP Australia might wish to include intellectual property litigation insurance as a topic in future awareness programs.[214]

9.139 In Europe, the EC Insurance Report was commissioned to examine the feasibility of implementing a patent litigation insurance scheme for widespread use in the European Union. The report is based on a preliminary empirical and analytical study of the patent litigation insurance market in Europe, the United States and Japan. It concludes that the European Commission should continue its efforts to develop a patent litigation insurance scheme.[215] The EC Insurance Report also makes recommendations about the broad structure of any such scheme, including that it should be compulsory and that premiums should be collected annually through the patent system and might be varied according to the size of the patent portfolio.[216] The European Commission does not appear to have taken any action on the report to date.

Submissions and Consultations

9.140 While IP 27 did not ask specific questions about patent litigation insurance, some submissions commented on this issue. The Australian Health Minsters' Advisory Council (AHMAC) encouraged the ALRC to examine the extent of use and impact of patent litigation insurance. AHMAC and a number of other submissions suggested that

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211 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999); CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003).

212 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999).

213 Ibid, 27.

214 Ibid, 28. Biotechnology Australia included information about patent litigation insurance in its *Biotechnology Intellectual Property Manual*: Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155–157.

215 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), [15.1].

216 Ibid, [15.2], [15.15]–[15.16].

the existence of patent litigation insurance may reduce the number of challenges to patent rights.[217] AHMAC submitted:

> Patent insurance may possibly further discourage potential challengers to a patent, as they will be aware that those companies who hold patent insurance may not suffer any financial burden as a result of the litigation.[218]

9.141 Submissions also expressed concern that patent litigation insurance may make the cost of challenging and litigating patent rights prohibitively expensive. This view seems to assume that if a party to a patent suit is insured it will refuse to settle proceedings, or will engage in tactics requiring the other party to spend large amounts of time and resources to participate in the suit. The Cancer Council of Australia commented that:

> Since the mid 1990s, the development of patent insurance has also increased the level of legal protection available to patent holders against litigation and in the US insurance can be obtained for a little as $3000USD. This form of additional protection would therefore place legal challenges to patents outside of the financial capacity of most individuals and institutions other than Government itself.[219]

9.142 The RCPA suggested that patent litigation insurance may allow a patent holder to maintain their patent rights unjustifiably:

> A patent holder can take out patent insurance on the grounds that a hostile challenge from a large competitor could spell ruin. Patent insurance, however, can also be used to defend a weak patent, even one that should never have been issued in the first place. Once the patent holder takes out patent insurance the merit of the patent becomes immaterial—it merely becomes an issue of money.[220]

9.143 The limitations of patent litigation insurance were, however, noted by DITR:

> Patent insurance against infringement is available but is considered costly by many companies, and may not offer complete coverage.[221]

ALRC's views

9.144 The ALRC acknowledges the general concerns expressed in submissions and consultations about patent litigation insurance. However, in the ALRC's view, intervention either to encourage or further limit the availability of patent litigation insurance in Australia is not appropriate at this stage.

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217 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

218 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

219 Cancer Council Australia, *Submission P25*, 30 September 2003. See also Cancer Council South Australia, *Submission P41*, 9 October 2003.

220 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. See also G Suthers, *Submission P30*, 2 October 2003.

221 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

9.145 The decision to purchase patent litigation insurance is a commercial one to be made by an inventor, research organisation, biotechnology company or other entity having regard to its own commercial needs and business strategy. Those with limited resources may be willing to risk involvement in litigation without the cushion of insurance, and to invest the amount that would have been spent in insurance premiums in further research and development, or marketing efforts.

9.146 In relation to the operation of the patent system as a whole, the existence of patent litigation insurance may be beneficial. As outlined earlier in this chapter, the cost of challenging or enforcing patent rights and the complexity of such matters may be prohibitive for certain entities or individuals. Patent litigation insurance facilitates participation in such suits and could encourage challenges to accepted gene patent applications or granted gene patents that may be of questionable validity.

9.147 The ALRC agrees with ACIP that information about patent litigation insurance should be more readily available to Australian patent holders.[222] As a practical matter, the availability of patent litigation insurance to Australian inventors, research organisations and biotechnology companies is limited. However, such entities would benefit from having a greater understanding of the benefits and the limitations of patent litigation insurance. This would assist in determinations as to whether to invest in patent litigation insurance, as well as how to deal with a third party who has such insurance in licence negotiations or litigation. In Chapters 18, 19 and 23, the ALRC has proposed that Biotechnology Australia develop various programs to assist universities, technology transfer offices and Australian biotechnology companies.[223] Patent litigation insurance should be included as a topic in any such programs.[224]

222 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 28.
223 See Proposals 18–1, 19–1, 23–2.
224 See further Ch 18, 19 and 23.

10. Jurisdictional Issues

Contents

Introduction

10.1 This chapter addresses the jurisdiction of Australian courts and tribunals to make determinations about the validity and enforcement of patent rights. The chapter outlines the current allocation of jurisdiction with respect to matters arising under the *Patents Act 1990* (Cth) (*Patents Act*). It then considers various proposals for changing this allocation of jurisdiction in order to provide a more consistent approach to patent law in Australia and to facilitate enforcement of patent rights by small and medium-sized Australian enterprises. The chapter also discusses the relevance of these proposals to the enforcement of gene patents in Australia, and concludes with a discussion of the role of assessors in providing expert advice to judges in patent proceedings.

Judicial review and enforcement of patents

Existing allocation of jurisdiction

10.2 As outlined in Chapter 5, state and federal courts, as well as the Administrative Appeals Tribunal (AAT), have a role in the Australian patent system. Decisions of the Commissioner of Patents may be subject to various types of review by the AAT or the Federal Court of Australia (Federal Court).[1] The AAT may undertake merits review of

1 A limited set of decisions by the Commissioner of Patents (primarily those made under the *Patents Regulations 1991* (Cth)) are generally not subject to review by either the AAT or the Federal Court. See also Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General, Report 43* (1998).

the Commissioner's decisions with respect to certain procedural matters prescribed by the *Patents Act*.[2] Decisions of the AAT on matters of law may be appealed to the Federal Court.[3] A direct approach may be made to the Federal Court for judicial review in relation to other decisions of the Commissioner, essentially those related to the grant of patents or matters closely allied to the grant (for example, amendments to patent specifications and revocations).[4] The Federal Court also has jurisdiction to review decisions of the Commissioner under the *Administrative Review (Judicial Decisions) Act 1977* (Cth), and under s 39B of the *Judiciary Act 1903* (Cth), on the basis of legal or procedural error.[5]

10.3 The Federal Court and state and territory Supreme Courts share original jurisdiction over matters related to the exploitation and enforcement of patent rights,[6] including infringement proceedings, applications for relief against unjustified threats of infringement, the grant of declarations of non-infringement, and compulsory licences.

10.4 Appeals from decisions of a single judge of the Federal Court and from decisions of state and territory Supreme Courts may be heard by a Full Court of the Federal Court,[7] and then by the High Court, with special leave to appeal.[8]

Reform of jurisdiction in patent matters

10.5 Several reports in recent years have reviewed the allocation of jurisdiction over intellectual property matters (including patents) among various judicial or quasi-judicial bodies.[9] These reports have identified two competing concerns underpinning criticisms of the current enforcement system for intellectual property rights: on the one hand, a need for consistency in decision making; and on the other hand, a need to reduce the cost and complexity of the current system to facilitate the enforcement of intellectual property rights, particularly by small and medium-sized enterprises.

10.6 In the context of gene patents, both of the concerns underpinning arguments for reform of the existing system are evident. Gene patents raise a range of complex legal and scientific issues, which require a high level of expertise. In addition, there is a need

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2 *Patents Act 1990* (Cth) s 224; *Patents Regulations 1991* (Cth) r 22.26.
3 *Administrative Appeals Tribunal Act 1975* (Cth) s 44.
4 *Patents Act 1990* (Cth) s 154.
5 Judicial review is also available by the High Court under s 75(v) of the *Australian Constitution*.
6 *Patents Act 1990* (Cth) s 155, sch 1.
7 Ibid s 158. The Federal Court's leave is required to appeal a decision of a single Federal Court judge in relation to a decision or direction of the Commissioner: *Patents Act 1990* (Cth) s 158(2).
8 *Patents Act 1990* (Cth) s 158(3).
9 See: Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984); Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General, Report 43* (1998); Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), ch 7; Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), ch 20; Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999); Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000).

for consistency in decision making by the courts in this relatively new area. However, as discussed in Chapter 9, there are concerns about the cost of challenging patents, as well as participating in patent infringement suits, as a plaintiff or defendant. This concern is particularly significant in the context of gene patents because universities and non-profit organisations hold more than half of the gene patents granted in Australia to date[10] and these institutions have limited resources to undertake patent enforcement actions. Accessible and cost-effective enforcement mechanisms for gene patents are therefore desirable.

10.7 A range of options have been canvassed to address these issues, including: limiting or entirely removing the jurisdiction of state and territory Supreme Courts in patent matters; expanding the jurisdiction of the Federal Magistrates Court to include patent matters; and expanding the jurisdiction of the AAT to undertake merits review of all decisions of the Commissioner. These options are discussed below.

Concentration of jurisdiction in federal courts

10.8 The ALRC and the Advisory Council on Industrial Property (now the Advisory Council on Intellectual Property—ACIP) have each recommended that jurisdiction over intellectual property matters (including patents) be concentrated in federal courts, such as the Federal Court.[11] In *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation* (ALRC 92), the ALRC recommended that:

> Federal legislation should be amended to provide that original and appellate jurisdiction in matters arising under federal intellectual property laws be conferred exclusively on federal courts. The original jurisdiction presently exercised by state and territory courts in these matters should be abolished.[12]

10.9 In ACIP's report, *Review of Enforcement of Industrial Property Rights* (the ACIP Report), the recommendations on this issue were not as far-reaching. ACIP recommended only that the *Patents Act* be amended to 'remove the jurisdiction of state and territory supreme courts to revoke a patent'.[13] ACIP considered that state and territory Supreme Courts would retain jurisdiction over patent infringement suits.[14]

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10 See further Ch 17.

11 A 1984 review of the *Patents Act 1952* (Cth) by the Industrial Property Advisory Committee also recommended that the jurisdiction of state and territory Supreme Courts in patent matters be transferred exclusively to the Federal Court of Australia: Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), rec 35(i).

12 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), rec 20–1.

13 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 6.

14 Ibid, 20.

10.10 Both the ACIP Report and ALRC 92 noted that uniformity of decision making in intellectual property decisions is highly desirable.[15] In particular, the ACIP Report expressed concern about interpretations of Australian patent law that had produced 'inconsistencies with international trends'.[16] The ACIP Report considered that this could 'weaken our strong international IP position' and suggested that such problems could be reduced by 'the development of a core of specialist IP judges in Australia'.[17] ALRC 92 expressed a similar view and commented that the 'Federal Court has already developed substantial expertise and international standing in [the intellectual property] area'.[18]

10.11 The Federal Court currently has an intellectual property panel comprising selected judges based in Sydney and Melbourne. Judges from this panel sit on appeals in intellectual property matters on a national basis.[19] The ACIP Report noted and approved of this practice, but recommended that the Federal Court should be encouraged to promote further specialisation of intellectual property judges.[20]

Specialist intellectual property courts in other jurisdictions

10.12 The recommendations of the ALRC and ACIP relating to increased specialisation of intellectual property judges and concentration of jurisdiction with respect to patent matters reflects a trend in other jurisdictions in seeking greater consistency in patent decisions. For example, the United States Court of Appeals for the Federal Circuit was created in 1982 and has exclusive jurisdiction to hear appeals from decisions of United States District Courts relating to patent validity and infringement.[21] Similarly, in the United Kingdom, the Patents Court and Patents County Court have been established with jurisdiction to resolve disputes concerning patent matters.[22]

10.13 In July 2003, the creation of a specialist intellectual property court in Japan was also proposed as part of package of reforms intended to improve the protection of

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15 Ibid, 20; Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.23]–[20.32].

16 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 19.

17 Ibid, 19.

18 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.24], [20.26].

19 Ibid, [20.19].

20 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 7.

21 28 USC §§1295, 1338. See further: R Posner, *The Federal Courts: Challenge and Reform* (2nd ed, 1999), 252–253; United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), ch 6, 9–18. Note that concentration of jurisdiction over patent matters in the United States occurs at the appellate level, whereas the ALRC and ACIP recommended concentration of both original and appellate jurisdiction over Australia patent matters.

22 The Patents Court was established in 1981 and is part of the Chancery Division of the High Court: *Supreme Court Act 1981* (UK) s 6. The Patents County Court was created in 1990 pursuant to *Copyright, Design and Patents Act 1988* (UK) s 287. See also: D Drummond, 'Are the Courts Down Under Properly Handling Patent Disputes?' (2000) 42 *Intellectual Property Forum* 10, 20–21. Further expansion of the Patents County Court has recently been proposed by the United Kingdom Department of Trade and Industry: United Kingdom Department of Trade and Industry, *Innovation Report* (2003), [4.25].

intellectual property rights under Japanese law.[23] The reform package indicated that the creation of an Intellectual Property High Court could strengthen 'the competitiveness of intellectual property' and 'emphasize the intellectual property-oriented national policy both inside and outside of Japan'.[24] A Bill establishing such a court is scheduled to be submitted to the Japanese Diet for consideration in 2004.[25]

10.14 A report of the Organisation of Economic Co-operation and Development (OECD) in 2004 commented favourably on the concentration of jurisdiction over patent matters in a single court as one mechanism to improve the quality of granted patents. The OECD considered that:

> A centralised court system is necessary for ensuring higher level certainty of enforcement and the validity of rights.[26]

Criticisms of a specialist patent court

10.15 Concentration of jurisdiction with respect to patent matters in a single court has, however, been criticised. Justice Drummond of the Federal Court considered the merits of creating a specialist intellectual property court in Australia and identified a number of concerns with such an approach based on the operation of similar courts in the United States and the United Kingdom.[27]

10.16 The problems with a specialist intellectual property court identified by Justice Drummond included:

- A greater likelihood of 'pro-patentee' decisions;
- The tendency for a specialist court to be 'captured' by special interest groups, resulting in choices between competing policy considerations—such as patent versus competition issues—being masked as technical issues of patent law; and
- Insufficient evidence that a specialist intellectual property court would resolve patent suits more quickly or cheaply.[28]

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23 Japan Intellectual Property Policy Headquarters, *Strategic Program for the Creation, Protection and Exploitation of Intellectual Property*, Japan Government, <www.kantei.go.jp/foreign/policy/titeki/kettei/030708f_e.html> at 5 January 2004, [2.4.1].

24 Ibid, [2.4.1].

25 Ibid, [2.4.1]. See also R Cunningham, 'Specialist Court to Boost Profile of IP in Japan', *Legal Media Group News*, 1 June 2003, <www.legalmediagroup.com>; R Cunningham, 'New Court is Feature of Japanese IP Reforms', *Legal Media Group News*, 16 July 2003, <www.legalmediagroup.com/news>.

26 Organisation for Economic Co-operation and Development, *Patents and Innovation: Trends and Policy Challenges* (2004), 28.

27 D Drummond, 'Are the Courts Down Under Properly Handling Patent Disputes?' (2000) 42 *Intellectual Property Forum* 10.

28 Ibid, 17–21.

Role of the Federal Magistrates Court

10.17 As noted above, proposals have also been made to address concerns about the cost and complexity of enforcing intellectual property rights (including patent rights) in Australia. The need for a simpler, less expensive means of adjudicating patent rights was noted in the ACIP Report and in the report of the Intellectual Property and Competition Review Committee (the IPCRC Report).[29] Both reports considered that the Federal Magistrates Court (which is also called the Federal Magistrates Service) might have a role in this regard.[30] The IPCRC Report recommended that:

> the Federal Magistracy be used as a lower court for the patent system, particularly for matters involving the Innovation Patent.[31]

10.18 The Australian Government deferred its response to this recommendation of the IPCRC Report and asked ACIP to consider the issue in further detail.[32] ACIP's final report on this matter has not yet been released, but a discussion paper published in July 2002 noted that there is 'strong divergence of opinion as to whether the jurisdiction of the Federal Magistrates Service should be extended' to include, among other things, patent matters.[33]

Submissions and consultations

10.19 IP 27 asked whether the administration and enforcement of gene patents would benefit from concentrating jurisdiction for patent matters in a single court and, if so, how concerns about the cost and complexity of enforcing gene patents might be addressed.

10.20 Submissions did not support the establishment of a specialist court that would address only issues relating to gene patents.[34] Two submissions commented that the cost and complexity of litigation involving gene patents is not significantly different

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29 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 18–20; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 176–177.

30 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 20; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 177. See also Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.32].

31 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 178. At the time the ACIP Report was released in March 1999, the establishment of the Federal Magistrates Court was still under consideration by the Australian Government. As a result, ACIP made no formal recommendations on this issue.

32 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003.

33 Advisory Council on Intellectual Property, *Discussion Paper: Should the Jurisdiction of the Federal Magistrates Services be Extended to Include Patent, Trade Mark and Design Matters?* (2002), 1. The final report has been presented to the Australian Government but has not been made publicly available.

34 D Eliades, *Submission P24*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

from that of litigation involving patents in other fields of technology.[35] One submission suggested that the cost of establishing such a court would not be justified, particularly given it is unlikely to have a sufficient case load to be in continuous use.[36]

10.21 However, a number of submissions supported concentration of jurisdiction with respect to the administration and enforcement of all patent matters in a single court.[37] Submissions suggested this would increase consistency and certainty in judicial interpretation of the *Patents Act*[38] because judges would develop specialised skills, knowledge and experience in dealing with patent matters.[39]

10.22 A multi-national pharmaceutical company, GlaxoSmithKline, submitted that

> given the technical nature of … fields [such as genetics, chemistry and electronics] it is important that there are appropriately experienced judges who deal regularly with patent litigation. From these perspectives it is advisable that patent litigation should be dealt with in a single Court (which could conduct hearings wherever in Australia is most appropriate for the particular case).[40]

10.23 An Australian biotechnology company, Genetic Technologies Limited, considered that 'there is some merit in the idea of patent matters being dealt with by a "single court"'.[41] The company indicated that it is difficult for Australian courts 'to accumulate experience and build a consistent corpus of understanding and interpretation of the [*Patents Act*]' because of the low frequency of patent cases.[42] The South Australian Government commented that concentrating patent matters might also expedite proceedings.[43]

10.24 Two submissions considered the potential disadvantages of concentrating the administration and enforcement of patent matters in a single court. Dr Amanda McBratney and others noted the objections raised by Justice Drummond (discussed above), in particular that a specialist court may be too 'patent friendly'.[44] The

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35 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

36 South Australian Government, *Submission P51*, 30 October 2003.

37 GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

38 Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; South Australian Government, *Submission P51*, 30 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

39 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

40 GlaxoSmithKline, *Submission P33*, 10 October 2003.

41 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

42 Ibid.

43 South Australian Government, *Submission P51*, 30 October 2003. See also A McBratney and others, *Submission P47*, 22 October 2003.

44 A McBratney and others, *Submission P47*, 22 October 2003. This submission concluded, however, that despite such criticisms a specialised patent court could be beneficial.

Australian Centre for Intellectual Property in Agriculture (ACIPA) articulated a similar view and proposed that, although the Federal Court should continue to be the primary court to deal the administration and enforcement of patent matters, the state and territory Supreme Courts and the AAT could 'continue to play an important secondary role'.[45] Further, ACIPA suggested that the AAT's role in reviewing decisions of the Commissioner of Patents should be expanded.[46]

10.25 A small number of submissions commented that the current system for challenging and enforcing gene patents was effective, and no change to the current allocation of jurisdiction was required. The Queensland Government expressed concern about the removal of the original jurisdiction of the Supreme Court of Queensland in relation to intellectual property matters.[47] The Department of Industry, Tourism and Resources indicated that:

> the current arrangement provides easy and cost-effective access to the legal system by parties who wish to oppose or contest patents.[48]

10.26 Only two submissions considered mechanisms to address concerns about the cost and complexity of gene patent litigation. GlaxoSmithKline proposed that these issues could be addressed by measures such as: ensuring that any costs award adequately reflect the 'winner's' actual costs; penalising inefficient or oppressive litigation in costs awards; providing public funding for patent litigation; and encouraging alternative dispute resolution.[49] ACIPA submitted that, although conferring jurisdiction on the Federal Magistrates Court might provide a more cost-effective and expeditious avenue for enforcing Australian patents, it was not an appropriate forum to address 'the complex legal and scientific issues associated with gene patents'.[50]

ALRC's views

10.27 The ALRC considers that the *Patents Act* should be amended to confer original jurisdiction in matters arising under the Act exclusively on federal courts and that the original jurisdiction currently exercised by state and territory Supreme Courts under the Act should be abolished. The Federal Court should continue to exercise appellate jurisdiction in matters arising under the *Patents Act* and this jurisdiction should be exclusive of other courts, except the High Court. However, the ALRC agrees with the

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45 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

46 Ibid.

47 Queensland Government, *Submission P57*, 5 January 2004. The Queensland Government endorsed the submission of the Queensland Supreme Court to ALRC 92 which, among other matters, proposed that uniformity of decision making could be achieved if a state and federal court system was maintained and expressed concerns about narrowing of legal principles and agency capture if jurisdiction was concentrated solely in the Federal Court: see Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.15]–[20.18].

48 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

49 GlaxoSmithKline, *Submission P33*, 10 October 2003.

50 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

view that a specialist 'gene patent' court is neither necessary nor desirable, and has expressed Proposal 10–1 in general terms applicable to patents relating to all types of technology.

10.28 In the ALRC's view, it is important that a uniform body of patent law develops in Australia, particular in relation to new technological areas such as genetics, where the application of patent law principles might not be clear. Consistency in the interpretation of the *Patents Act* is fundamental to patent holders' and potential patent applicants' understanding of the scope of Australian patent rights. It is also significant for international perceptions of Australian patent law, and foreign entities' willingness to invest in research and development in Australia. A coherent and consistent interpretation of the *Patents Act* will be facilitated by concentration of judicial experience and expertise with respect to patent matters in a single court system.

10.29 Few submissions commented on which court was the appropriate one in which to concentrate jurisdiction with respect to patent matters. However, the ALRC considers that the federal court system is the most appropriate. Alleged infringements of patent rights—particularly gene patent rights—are often factually and legally complex. The Federal Court has already developed substantial expertise in determining such cases. It has an established panel of specialist intellectual property judges and continuing education programs to assist judges in keeping up to date with current patent law developments. In addition, available statistics suggest that the Federal Court is already the jurisdiction of choice in patent matters, and state courts are used only on an occasional basis.[51]

10.30 The ALRC recognises the concerns that have been expressed regarding judicial specialisation, including that the concentration of patent matters in a single court may lead to such a court being too 'patent friendly' and subject to the influence of particular interest groups. However, the Federal Court has jurisdiction over a very broad range of matters, including competition law issues. The ALRC considers that this breadth of jurisdiction will facilitate the Court's appreciation of the competing policy objectives that may be at issue in a particular patent matter.[52]

10.31 It has been suggested that there is already *de facto* specialisation in patent matters in Australia, and that there is value in preserving an alternative avenue for enforcement of patents in state and territory Supreme Courts. However, the choice of the forum in which a patent suit is filed is made by the plaintiff, and the proceeding may not be readily transferable to the Federal Court under cross-vesting legislation.

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51 D Drummond, 'Are the Courts Down Under Properly Handling Patent Disputes?' (2000) 42 *Intellectual Property Forum* 10, 22–29; Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.28].

52 The Federal Court's jurisdiction over matters arising under the *Trade Practices Act 1974* (Cth) was cited by the Industrial Property Advisory Committee as 'extremely relevant' to its recommendation that the jurisdiction of state and territory Supreme Courts over patent law matters be transferred exclusively to the Federal Court: Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 70.

This may create an element of injustice to a defendant if the litigation is brought in a state or territory court whose judges do not regularly deal with patent matters and thus lack relevant expertise.[53]

10.32 The ALRC's proposal that original jurisdiction in matters arising under the *Patents Act* should be conferred exclusively on federal courts intentionally leaves open the issue of which federal courts are the most appropriate. However, as discussed earlier in this chapter, ACIP is currently considering whether the Federal Magistrates Court might also be granted jurisdiction with respect to certain intellectual property matters, including matters arising under the *Patents Act*. Proposal 10–1 does not preclude the Federal Magistrates Court assuming such a role in appropriate patent matters, although it should be noted that the complexity and length of some patent matters may make the Federal Magistrates Court an inappropriate forum for trial. Further, this proposal is not intended to affect the jurisdiction presently conferred on the Commissioner of Patents and the AAT.

10.33 Chapter 9 outlined concerns expressed in submissions and consultations about the cost of litigating gene patent matters in Australia. As indicated in that chapter, the ALRC is not inclined to make any specific proposals to address the costs of gene patent litigation at this stage. However, Proposals 20–3 to 20–6 will assist in addressing these concerns because they envisage greater government participation, particularly by health departments, in monitoring the application of intellectual property laws to genetic materials and technologies, including by coordinating challenges to gene patents.

Proposal 10–1 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to provide that original jurisdiction in matters arising under the Act be conferred exclusively on federal courts. The original jurisdiction presently exercised by state and territory courts under the Act should be abolished. The Federal Court of Australia should continue to exercise appellate jurisdiction in matters arising under the Act, exclusive of all courts other than the High Court of Australia.

Role of assessors in patent cases

10.34 As discussed elsewhere in this Discussion Paper, gene patents raise complex scientific and legal issues whose resolution may require expert advice and assistance. In Chapter 8, the ALRC proposed that IP Australia have access to expert assistance in examining patent applications claiming genetic materials and technologies to assist

53 See also Ibid, 69.

Australian patent examiners in addressing such issues.[54] This section addresses the role of experts in providing advice to judges hearing gene patent matters.

Australia

10.35 Section 217 of the *Patents Act* provides for Australian judges to have access to expert assistance in patent proceedings in appropriate cases. The provision states:

> A prescribed court may, if it thinks fit, call in the aid of an assessor to assist it in the hearing and trial or determination of any proceedings under this Act.[55]

10.36 The term 'assessor' is not defined the *Patents Act*. The role of an assessor was, however, considered by the ALRC in its report *Managing Justice: A Review of the Federal Civil Justice System* (ALRC 89*)*.[56] The ALRC explained that an assessor is an expert available for a judge to consult if the judge requires assistance in understanding the effect or meaning of expert evidence.[57]

10.37 Justice Heerey considered the benefits provided by an assessor in *Genetic Institute Inc v Kirin-Amgen Inc (No 2)*.[58] That case involved complex and contested issues of molecular biology and, between them, the parties intended to call 15 scientific experts from various disciplines.[59] Heerey J held that, in such a case, a non-expert judge would likely be aided by expert assistance, such as that provided by an assessor, and perform the judicial task better.[60]

10.38 Concerns have, however, been expressed that assessors might be in a position to exercise too much influence over a judge, and about the procedural fairness of contact between judges and experts in chambers.[61] These matters may be appropriately addressed by a clear and detailed prescription of an assessor's functions.[62] Further, Heerey J explained that:

> There is no question of an assessor giving any judgment or making any order (even by consent) or otherwise exercising any judicial functions. An assessor is to assist the judge, both in hearing and trial and/or in determination of any proceeding. The

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54 See Proposals 8–2 and 8–3.

55 *Patents Act 1990* (Cth) s 217. A 'prescribed court' is defined to mean the Federal Court, the Supreme Court of a State and the Supreme Court of each of the Australian Capital Territory, the Northern Territory and Norfolk Island: *Patents Act 1990* (Cth) sch 1.

56 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000). See also P Heerey, 'Expert Evidence in Intellectual Property Cases' (1998) 9 *Australian Intellectual Property Journal* 92.

57 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), [7.150].

58 *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247.

59 Ibid, 251.

60 Ibid, 251–252.

61 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), [7.153]–[7.155].

62 *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247, 251; *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106, 117–118; *Beecham Group Ltd v Bristol-Myers Company* [1980] 1 NZLR 185, 190.

> judgment in the case, the exercise of the judicial power, remains that of the judge. In exercising judicial power, a judge is routinely assisted by persons who are not judges: counsel, solicitors, witnesses, the judge's associate and secretary and other court staff.[63]

10.39 The appointment of assessors in Australian patent cases is, however, rare. Although the power to appoint assessors had been included in Australian patents legislation since 1903,[64] it has been considered and invoked in a very limited number of cases to date.[65]

10.40 Amendments to the *Federal Court Rules 1979* (Cth) (*Federal Court Rules*) in 1999 have established a second regime for the appointment and use of an expert by the judges of the Federal Court in any type of proceedings.[66] Such 'expert assistants' may assist the Court on 'any issue of fact or opinion' identified by the Court or a judge (other than an issue involving a question of law).'[67]

10.41 However, the procedures for the appointment of an expert assistant, and role of such an expert in the proceedings, are more restricted than in the case of an assessor appointed pursuant to s 217 of the *Patents Act*. The appointment of an expert assistant under the *Federal Court Rules* requires the consent of both parties, and any assistance provided by the expert must be reduced to writing and made available to both parties.[68] In contrast, as discussed above, an assessor appointed under the *Patents Act* does not require the consent of the parties, and the manner in which the assessor assists a judge may be more flexibly adapted to the circumstances of a particular case.[69]

Other jurisdictions

10.42 Patent statutes in other jurisdictions also provide for assessors—or expert advisers[70]—to assist judges in hearing and determining patent cases in appropriate circumstances. In the United Kingdom, the Patents Court may, by its own motion, or

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63 *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247, 250.

64 *Patents Act 1903* (Cth) s 86(8). See also Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [7.149].

65 *Adhesives Pty Ltd v Aktieselskabet Dansk Gaerings-Industri* (1935) 55 CLR 523 (assessor appointed by consent); *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247 (assessor appointed by court order), upheld on appeal to the Full Federal Court, see *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106; *F Hoffman-La Roche AG v New England Biolabs Inc* (1999) 47 IPR 105 (appointment of assessor considered and deferred until later stage of proceedings). In addition, Branson J commented on the role of assessors in patent proceedings in a case arising under the *Evidence Act 1995* (Cth) concerning whether evidence given by an expert witness in response to questions was relevant in the proceeding: see *EI DuPont de Nemours & Co v Imperial Chemical Industries plc* (2002) 54 IPR 304.

66 *Federal Court Rules 1979* (Cth) O 34B. 'Expert' is defined in the rules as a 'person who has specialised knowledge based on the person's training, study or experience': *Federal Court Rules 1979* (Cth) O 34B r 2(3).

67 *Federal Court Rules 1979* (Cth) O 34B r 2(1).

68 Ibid O 34B r 3.

69 See also P Heerey, 'Expert Evidence: The Australian Experience' (Paper presented at World Intellectual Property Organization Aisa–Pacific Colloquium, New Delhi, 6 February 2002).

70 In some countries, such as the United Kingdom, New Zealand and Singapore, the term 'scientific adviser' is used instead of the term 'assessor'.

following the application of a party, appoint an independent scientific adviser to assist the court in patent proceedings.[71] In New Zealand, the *Patents Act 1953* (NZ) provides for the appointment of scientific advisers to assist the court in patent infringement proceedings, and other proceedings arising under the Act.[72] In Singapore, a judge hearing proceedings arising under the *Patents Act 1995* (Singapore) has discretion to appoint one or more scientific advisers, from a panel of advisers established under the Act, to assist the court and the Registrar of Patents.[73]

10.43 In the international arena, there are also initiatives to provide resources for the judges of national courts dealing with cases involving biotechnology and other novel scientific areas. The United Nations has recently agreed to fund the International Science and Technology Reference Forum, an advisory body of scientific and legal experts for national courts that are unable to resolve complex scientific cases.[74] Details of the composition of the Forum and its procedures are yet to be determined.[75] It is, however, anticipated that cases before national courts may be referred to the Forum for a non-binding verdict[76] that will be founded upon analysis of the science and technology involved, risk assessment, and the ethical and religious values that shape national legislation. In addition, private parties and administrative, regulatory and legislative bodies will be eligible for the Forum's assistance.[77]

ALRC's views

10.44 In ALRC 89, the ALRC noted that the use of assessors is relevant in patent cases before the Federal Court, given the novel and technical issues frequently raised.[78] The ALRC recommended that:

> The Federal Court should continue to develop appropriate procedures and arrangements, in consultation with legal and professional user groups, to allow judges to benefit from expert assistance in understanding the effect or meaning of expert evidence.[79]

10.45 In its response to the ALRC's recommendation, the Australian Government indicated that this was a matter for the Federal Court.[80] The Government noted that the

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71 *Supreme Court Act 1981* (UK) ss 54(9), 70(3), 70(4); *Civil Procedure Rules 1998* (UK), rr 35.15, 63.7.

72 *Patents Act 1953* (NZ) s 113(2). For consideration of the role of a scientific adviser in New Zealand patent proceedings: *Beecham Group Ltd v Bristol-Myers Company* [1980] 1 NZLR 185; *Beecham Group Ltd v Bristol-Myers Company (No 2)* [1980] 1 NZLR 192, 194–195.

73 *Patents Act 1995* Chapter 221 (Singapore) s 90.

74 N Nosengo, 'Biotechnology at the Bar' (2003) 425 *Nature* 116.

75 Ibid, 117. The Forum's provisional governing council is due to be elected in March 2004 and is likely to comprise a permanent team of judges, with scientific members acting as part-time consultants.

76 Ibid, 117. It is anticipated that national courts will be free to use or ignore the Forum's advisory verdict in resolving a dispute and that the Forum will not seek to enforce its decisions.

77 Ibid, 117.

78 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), [7.148].

79 Ibid, rec 85.

80 Australian Government, *Government Response to Recommendations of Australian Law Reform Commission Report Managing Justice: A Review of the Federal Civil Justice System* (2003), 39.

Federal Court Rules had been amended to provide for the appointment of a Court expert assistant, and that the Court had advised it would continue to consult with the legal profession and user groups on issues concerning expert evidence.[81] The Government's response did not make specific reference to the use of assessors pursuant to s 217 of the *Patents Act*.

10.46 In a paper delivered in 2002 about techniques used by the Federal Court to address issues posed by expert evidence, Justice Heerey commented that:

> Today the complexity of science expands at an exponential rate … Looking back to the 1960s, a decade when many of today's judges commenced their professional careers, there are many fields of science which were not merely less complicated than today; they simply did not exist … [Further,] scientific issues about which eminent scientists themselves have doubt, fall to be decided by judges who, in common law countries at any rate, usually do not have much in the way of formal scientific education.[82]

10.47 While some Australian judges may have specialist scientific training, or a familiarity with scientific matters as a result of their professional or personal interests, many judges could benefit, in appropriate cases, from the additional assistance that an assessor may provide in interpreting and understanding scientific evidence. As Justice Heerey observed, the pace of scientific change is rapid, and expert evidence may be complicated and voluminous. Even those judges who have specialist training in a relevant discipline are unlikely to have the detailed knowledge of an assessor or scientific adviser in the specific field to which the case relates.

10.48 The ALRC considers that the use of an assessor may be particularly beneficial in gene patent litigation, which may involve novel issues in the genetics field and complex scientific and technical evidence. The ALRC recognises the concerns that have been identified about the use of assessors, including issues relating to the appropriate role of an assessor in patent proceedings, the costs involved and potential conflicts of interest. However, the ALRC considers that such issues are capable of being addressed on a case-by-case basis with appropriate cooperation between the court and the parties to the proceedings.[83]

Proposal 10–2 Courts exercising jurisdiction under the *Patents Act* should continue to develop procedures and arrangements, in consultation with relevant stakeholders, to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.

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81 Ibid, 39.

82 P Heerey, 'Expert Evidence: The Australian Experience' (Paper presented at World Intellectual Property Organization Aisa–Pacific Colloquium, New Delhi, 6 February 2002).

83 See, for example, the orders made by Emmett J in a case relating to identification of an assessor at a time when a party was still in the process of retaining expert witnesses: *F Hoffman-La Roche AG v New England Biolabs Inc* (1999) 47 IPR 105, 107.

PART C

Patents and Genetic Research

11. Funding for Research and Development

Contents

Introduction

11.1 The Terms of Reference require the ALRC to consider the impact of patent laws and practices related to genes and related technologies on the conduct of research and its subsequent application and commercialisation.

11.2 This chapter outlines the structure of public research and development (R&D) funding in Australia, particularly in relation to medical research and human genetics. There are three broad categories of funding: support for basic research largely at public institutions; support for creating linkages between public sector research institutions and industry; and support for the commercialisation of that research by public sector spin-off companies and private sector biotechnology companies. The second and third

categories of funding are an element of the Commonwealth Government's policy of encouraging the commercial development of intellectual property generated through publicly funded research. The implications of this policy for the ownership of patents, and the question of whether there should be more direct public benefit derived from patents on research undertaken with public funds, are discussed in Chapter 12.

Value of investing in research and development

11.3 Public investment in research and development to promote innovation is widely recognised as a means of promoting economic growth.[1] For example, the Science and Innovation Mapping Taskforce recently commented:

> A strong science and innovation system can contribute to Australia's future through economic growth, environmental sustainability and social well-being. Science and innovation can provide the tools to manage risk, solve complex problems and adapt to change. They can underpin sustainable economic growth and the management of social and environmental challenges such as population ageing, land degradation and soil salinity.[2]

11.4 The 1999 National Health and Medical Research Strategic Review (the Wills Report)[3], which resulted from a major strategic review of health and medical research in Australia, cited Australia's growing $1 billion trade imbalance in pharmaceuticals, medical equipment and other health and medical industries as the basis for seeking to improve and enhance Australia's research performance. It stated that:

> Technology-based industries built on publicly funded research are the key to economic growth and prosperity. Academic research has shown that companies' stock performance in high technology industries is strongly related not only to the number of patents produced, but also to the strength of the linkage between these patents and basic science publications. Most linkages are to publicly funded research; 73% of the references to scientific publications listed as 'prior art' on the front pages of US patents are to publicly funded academic research. Patent references to basic public science have nearly tripled over the period from 1988 to 1994, highlighting the growing value of linkages between basic science and technological revolution …
>
> A vigorous industry sector in health and medical fields would bring additional benefits including:
>
> - A reduction in Australia's negative balance of trade in medical goods.
> - Better research workforce opportunities and salaries.[4]

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1 See, eg, Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 144; Commonwealth of Australia, *Backing Australia's Ability: Real Results, Real Jobs: The Government's Innovation Report 2001–02* (2002), 3–4; Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 45.

2 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 3.

3 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998).

4 Ibid, 125–126.

11.5 In its discussion of Australia's negative balance of trade in the medical and pharmaceutical sector, the Wills Report suggested that:

> [s]elling Australian developed intellectual property or licensing it for royalties is one way to help reduce this deficit although not in a significant manner. Even better would be the development of Australian intellectual property through local biotechnology companies combined with marketing and distribution throughout the region alone or in association with international pharmaceutical companies based in Australia.[5]

11.6 These views were reiterated in the 2003–04 Innovation Report on the *Backing Australia's Ability* initiative (the 2003–04 Innovation Report), which stated 'the important characteristic of R&D is that it can permanently lift the rate of economic growth'.[6]

11.7 Funding initiatives to support the overall process of innovative research leading to the development of healthcare products for the community can be divided into three broad categories of support:

- funding for scientific research, generally undertaken in publicly funded research institutions;
- funding and initiatives to promote transfer of technology to enable commercial development, which sometimes take the form of linkage programs; and
- initiatives to support commercial development of this research into products, such as tests and treatments.

Healthcare benefits

11.8 Public investment in biotechnology research and development specifically, has the additional benefit of providing healthcare benefits to the community in the form of new tests, treatments and therapies.

Funding scientific research

11.9 More than half of human health related biological research in Australia is funded by the Commonwealth Government and undertaken by publicly funded institutions alone, or with industry through links such as Cooperative Research Centres (CRCs).[7] The major funding schemes are outlined below. In 2001, approximately $300 million was spent on publicly funded research in biotechnology.[8]

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5 Ibid, 126.
6 Australian Government, *Backing Australia's Ability: The Australian Government's Innovation Report 2003–04* (2003), 24.
7 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), [1.2].
8 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 9.

Promoting commercialisation of research

11.10 Commonwealth Government policy encourages publicly funded researchers and research organisations to work with private industry to develop Australia's intellectual capital. This policy is discussed in Chapter 18.

11.11 Linkages between research, government and private industry have been described as a 'virtuous cycle' that provides:

> a structure of mutual support which [will] facilitate change and strengthen Australia's capacity to participate in the biotechnology revolution.[9]

11.12 The 1999 White Paper stated that:

> The culture of university research ... should become more entrepreneurial, seeking out opportunities in new and emerging fields of research that will provide social, cultural and economic benefit … An entrepreneurial approach is needed to harness the full cycle of benefits from their endeavours through commercialisation, where appropriate.[10]

11.13 There are two statutory organisations principally responsible for funding public sector biotechnology research and implementing research policies: the National Health and Medical Research Council (NHMRC) and the Australian Research Council (ARC). In addition, the Department of Education, Science and Training (DEST) funds and administers the CRC program. Biotechnology Australia[11] and the ARC jointly fund the Biotechnology Centre of Excellence, which is the National Stem Cell Centre. A number of programs are administered through AusIndustry,[12] to support R&D funding in industry and to assist with the commercialisation of research.

11.14 The *Australian Biotechnology Report 2001* states that the biotechnology industry is supported by 'effective public investment in R&D'[13] and that a substantial investment in fundamental research and research infrastructure occurs through universities, research institutes, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), CRCs and state funded research in biotechnology.[14]

11.15 Government policy to encourage research commercialisation has been stated in a number of discussion papers and reports including:

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9 Health and Medical Research Strategic Review Committee, *Enabling the Virtuous Cycle: Implementation Committee Report* (2000), 1.

10 Minister for Education Training and Youth Affairs, *Knowledge and Innovation: A Policy Statement on Research and Research Training* (1999), 5.

11 Biotechnology Australia is a agency of the Commonwealth Government which is responsible for co-ordinating non-regulatory biotechnology issues across departments.

12 AusIndustry is the Commonwealth Government's business agency within the Department of Industry, Tourism and Resources. It seeks to foster investment through a program of tax and duty concessions, grants, and access to venture capital.

13 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 8.

14 Ibid, 9.

- the Wills Report;[15]
- *Knowledge and Innovation: A Policy Statement on Research and Research Training* (the White Paper);[16]
- the Science Capability Review;[17]
- the Innovation Summit Implementation Committee's final report;[18] and
- *Backing Australia's Ability: An Innovation Action Plan for the Future* (the Innovation Statement).[19]

11.16 The Innovation Statement outlines the Australian government's current strategy for promoting research and commercialisation, *Backing Australia's Ability.*

Backing Australia's Ability

11.17 *Backing Australia's Ability* is a five-year strategy launched by the Australian Government in 2001 designed to promote research, development and innovation. The strategy was announced in the 2001 Innovation Statement, *Backing Australia's Ability: An Innovation Action Plan for the Future.*

11.18 Three broad themes were identified in the Statement: generating ideas through research; commercialisation of those ideas; and developing and retaining a highly skilled workforce.[20] Intellectual property protection was nominated as one of the strategies for accelerating the commercialisation of ideas:

> A strong Intellectual Property (IP) protection regime including easy access to information on IP protection is central to building a strong national innovation system in Australia. It promotes R&D through helping to better capture returns from commercialising Australian ideas and products. A strong IP system will also help create spin-off companies, especially from public sector research institutions and universities.[21]

11.19 As part of the strategy, the Australian Government announced a variety of measures to achieve its stated goals, including increased funding to the ARC; boosts to research infrastructure funding; expanding the CRC program with an additional $227 million; continuing the R&D Start program with funding of $535 million over five

15 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998).
16 Minister for Education Training and Youth Affairs, *Knowledge and Innovation: A Policy Statement on Research and Research Training* (1999).
17 Australian Science Capability Review, *The Chance to Change* (2000).
18 Innovation Summit Implementation Group, *Innovation: Unlocking the Future* (2000).
19 Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001).
20 Ibid.
21 Ibid.

years; and reforming the R&D tax concession to provide a premium rate of 175% for additional R&D activity and a tax rebate for small and medium enterprises (SMEs).[22] A recent evaluation of the CRC program has led to the program's objectives and selection criteria being further focused on 'industrial, commercial and economic growth'.[23]

Support for research

11.20 Two main bodies, the NHMRC and the ARC, provide funding support for early stage research in the sciences.

National Health and Medical Research Council

11.21 The NHMRC is an independent statutory body established under the *National Health and Medical Research Council Act 1992* (Cth) and falling within the portfolio of the Minster for Health and Ageing. It is the key national organisation for all aspects of health and medical research and brings together all major stakeholders in the medical sector. The NHMRC comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, environmental groups and the Aboriginal and Torres Strait Islander Commission.

11.22 The NHMRC funds research in areas ranging from biomedicine to clinical, health services and public health. It provides grants for research projects and more large-scale programs. The NHMRC also offers a variety of awards to individual researchers, including training awards, career development awards and research fellowships. Graduate, post-graduate and post-doctoral students are supported to undertake further training through scholarship and fellowship schemes.[24]

Australian Research Council

11.23 The ARC is an independent statutory body established under the *Australian Research Council Act 2001* (Cth) and reporting to the Minister for Education, Science and Training. It funds research in science, social science and the humanities on the basis of a peer review system. Four areas were identified as priority areas for ARC funding in 2003, with one third of all funding to be directed towards these areas.[25] One of these is 'genome/phenome research'.

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22 Ibid, 4–5.

23 Minister for Science, '2004 CRC Selection Round Announced', *Media Release*, 4 December 2003, <www.dest.gov.au/ministers/mcg/media.asp>.

24 National Health and Medical Research Council, *Description of Types of Research Grants for Funding Commencing in 2005* (2003), 4.

25 Australian Research Council, *Annual Report 2001–02* (2002), 60.

Public-private research linkages

11.24 As discussed above, it is government policy for public sector organisations to work with the private sector in carrying out or commercialising research. The importance of such linkages was affirmed recently by the Science and Innovation Mapping Taskforce, which noted that research–industry linkages were a key aspect of the Australian biotechnology sector.[26]

11.25 A key strategy in this policy has been the establishment of CRCs. Other initiatives include:

- the ARC's Centres and Networks, and Linkage programs;
- the NHMRC's Development Grants, Industry Fellowships and Health Research Partnerships;
- the Major National Research Facilities;[27] and
- linkages established by particular organisations.

11.26 In May 2003, the Minister for Education, Science and Training announced the creation of a new body to foster research–industry linkages. The Council for Business/Industry/University Collaboration will be chaired by a representative of a key business, industry, or employer group and its initial priorities will include:

- participation in the selection of business/industry/university projects for funding;
- development of strategies to encourage business/industry to invest more in the higher education sector;
- facilitation of involvement of small and medium enterprises in collaborative arrangements with universities;
- establishment of Awards for Business/University Collaborations; and
- advice to Government on initiatives to further facilitate the commercialisation of intellectual property.

11.27 The Council will receive seed funding of $200 million over its first two years.[28]

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26 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 312.

27 Department of Education Science and Training, 'Major National Research Facilities Programme', *Fact Sheet*, 15 December 2003, <www.dest.gov.au/MNRF>.

11.28 Some State governments have also established linkage programs, which are outlined briefly below.

Cooperative Research Centres

11.29 CRCs are collaborative centres for research between publicly funded researchers (universities, government laboratories or the CSIRO) and the private sector or public agencies. The Commonwealth Government established the CRC program in 1990. In December 2003, there were 71 CRCs, nine in the field of medical science and technology,[29] and one specifically in the human genome field. DEST funds and administers the CRC program. The Commonwealth Government contributes around $145 million annually in funding support for the CRC program. An extra $227 million in funding for CRCs will be supplied over three years from 2003/04–2005/06, as announced in the Innovation Statement.[30]

11.30 The average annual budget of a CRC is $7 million, with public funding of between $1.6 million and $3.14 million a year, averaging $2.45 million a year.[31] Successful CRC applicants are required to enter into a formal agreement of up to seven years duration with the Commonwealth. Under these agreements, the Commonwealth agrees to provide a specified level of annual funding to a CRC and participants agree to undertake certain activities, contribute specified personnel and certain levels of resources. As a condition of the funding, CRCs are required to have plans for the management of intellectual property.

11.31 The objectives of the CRC program are to enhance:

- the contribution of long-term scientific and technological research and innovation to Australia's sustainable economic and social development;
- the transfer of research outputs into commercial or other outcomes of economic, environmental or social benefit to Australia;
- the value to Australia of graduate researchers; and
- collaboration among researchers, between researchers and industry or other users, and to improve efficiency in the use of intellectual and other research resources.[32]

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28 Minister for Education Science and Training, 'Bringing Business and Universities Closer Together', *Media Release*, 13 May 2003, <www.dest.gov.au/ministers/nelson/media.asp>.

29 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 257.

30 Department of Education Science and Training, *CRC Compendium* (2002), vii.

31 Department of Education Science and Training, *Frequently Asked Questions about CRCs*, <www.crc.gov.au/faq.htm> at 14 April 2003.

32 Department of Education Science and Training, *CRC Compendium* (2002), vii.

11.32 CRCs focus strongly on commercialisation and technology transfer. In 2001–02, 116 patents were filed and 810 maintained, 107 intellectual property licences were established, 17 spin-off companies created and 31 technology agreements made, together valuing close to $13.5 million.[33] CRCs also aim to produce future researchers with entrepreneurial, as well as research skills by encompassing postgraduate training programs.[34]

11.33 As noted above, there is one CRC in the field of human genome research—the Discovery of Genes for Common Human Diseases CRC (the Gene CRC) based in Queensland and Victoria. Participants in the Gene CRC are the Institute for Molecular Bioscience at the University of Queensland, the Murdoch Children's Research Institute, the Queensland Institute of Medical Research, the Walter and Eliza Hall Institute of Medical Research, and the Menzies Centre for Population Health Research, with Cerylid Biosciences Ltd as industry partner. The Gene CRC was established in July 1997 for an initial period of seven years. The CRC funding for the total of the grant period is $13.1 million from a total of $45.6 million.[35]

11.34 The importance of CRCs has been recognised within the biotechnology industry. For example, the *Australian Biotechnology Report 2001* states that Australia's fundamental research base 'is now beginning to deliver products or services, that will provide financial returns for reinvestment in Australia. The CRC Program … spearheads this support'.[36] To date, CRCs have undertaken nearly 5,000 contracts for industry and other users, generating more than $350 million.[37]

ARC linkage programs

11.35 The ARC supports a variety of collaborative centres and networks, including:

- Research Networks;
- Centres of Excellence; and
- Special Research Centres and Key Centres for Teaching and Learning.

11.36 The Centres for Excellence program aims to 'promote research that will enhance Australia's future economic, social and cultural well being' and 'establish Centres of such repute in the wider community that they will serve as points of interaction among higher education institutions, Governments, industry and the private sector

33 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 260.
34 Department of Education Science and Training, *CRC Compendium* (2002), vii.
35 Ibid, 70.
36 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 9.
37 Australian Government, *Backing Australia's Ability: The Australian Government's Innovation Report 2003–04* (2003), viii.

generally'.[38] Interaction with industry is not mandatory for grant recipients, and is not expected within the short to medium term, however it is considered likely that the Centres will pursue research with the potential for commercial development.[39] The National Stem Cell Centre is one of the three Centres of Excellence that have been established to date.

11.37 The Research Networks program aims to encourage large-scale collaborative research across disciplines.[40] The Special Research Centres and Key Centres for Teaching and Learning were established under older programs, and focus on collaborative research arrangements and building the scale of research endeavours.[41] The Special Research Centres and Key Centres will eventually be replaced by Centres of Excellence.[42]

11.38 The ARC funds linkage programs to encourage collaboration between publicly funded research bodies and industry partners. Linkage program grants are designed to encourage links between public institutions and researchers and the private sector. In 2002, a total of $25.9 million was awarded in the form of 470 linkage program grants, involving 736 industry partners.[43] Of these, 98 were in the health and community sector, but it is not possible from the figures to determine those specifically awarded for work related to genetics.

NHMRC linkage schemes

11.39 The NHMRC administers a number of schemes to support research and commercialisation of research. Of particular relevance to the biotechnology industry are NHMRC Development Grants. These seek to boost the commercialisation of biomedical research where there are health and cost benefits for the Australian community and where the project has commercial potential and is close to marketing and commercialisation. Development Grants provide pre-seed funding for one year to enable the commercialisation of research at the proof of concept stage. The NHMRC states that the scheme:

> is pitched at the perceived funding gap between the end of a high quality basic research program and the developments required to make the project commercially attractive to potential investors.[44]

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38 Australian Research Council, *ARC Centres of Excellence*, <www.arc.gov.au/grant_programs/centre_excellence.htm> at 12 December 2003.

39 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 262.

40 Australian Research Council, *ARC Research Networks*, <www.arc.gov.au/grant_programs/centres_networks/research_networks.htm> at 12 December 2003.

41 Australian Research Council, *Centres & Networks*, <www.arc.gov.au/grant_programs/centres_networks/default.htm> at 12 December 2003.

42 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 263.

43 Australian Research Council, *Annual Report 2001–02* (2002), 36.

44 National Health and Medical Research Council, *Description of Types of Research Grants for Funding Commencing in 2004* (2003), 6.

11.40 The NHMRC also awards Health Research Partnership Grants to encourage collaborative research between the public and private sector. Private sector partners must contribute at least 50% of the cost of the research, with the NHMRC making up the balance.

11.41 The NHMRC Strategic Plan for 2000–2003 identified the commercial development of health and medical research as one of its key strategies in the 'translation of knowledge for the benefit of the Australian community'.[45] It indicated that the success of the effectiveness of this strategy will be measured by a number of factors, including:

> (ii) Numbers of patents applied for, awarded and licensed based on health and medical research;
>
> (iii) Amount of private sector money/numbers of seed projects attracted to institutions for proof of concept or other development work based on their IP;
>
> (iv) Numbers of Australian start-up companies based on local IP or health service/health care know-how; …
>
> (vii) Number and value of research agreements with public and private sector entities including spin-offs and joint ventures relative to the total NHRMC funding.[46]

State government linkage initiatives

11.42 State governments have established a variety of programs to encourage collaboration between the research industry sectors. Examples include the NSW Government's BioFirst program and the Queensland Government's Smart State agenda.

Support for commercialisation of research

11.43 The Industry Research and Development Board (the IR&D Board), an independent statutory body administered through AusIndustry, is responsible for a range of programs that seek to encourage commercialisation of research. The IR&D Board notes that 'support to a range of science fields remains an important objective of the Board'[47] and that it 'has continued to provide high levels of support for small and medium sized businesses'.[48] In 2001–2002, SMEs received about $422 million in assistance through the Board's programs.[49] Those programs most relevant to the human genetics sector are described below.

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45 National Health and Medical Research Council, *Strategic Plan 2000–03* (2000), 14.
46 Ibid, 21.
47 AusIndustry, *Industry Research and Development Board Annual Report 2001-02* (2003), 16.
48 Ibid, 17.
49 Ibid, 17.

Biotechnology Innovation Fund

11.44 The Biotechnology Innovation Fund (BIF) is a competitive grants program running from 2001–2004 to increase the rate and level of commercialisation of biotechnology developed in Australia and to assist with biotechnology developments in order to attract private sector investment. It provides financial assistance to companies seeking to move from the initial research stage of a biotechnology project to the early stage of its commercialisation. The BIF seeks to assist companies at the proof of concept stage of development. The fund provides grants of up to 50% of a project cost of $250,000.[50]

Innovation Investment Fund

11.45 The Innovation Investment Fund (IIF) seeks to promote the commercialisation of Australian R&D through the development of an Australian venture capital market for early-stage technology companies. It provides venture capital to small companies (those with an annual revenue of $4 million or less, averaged over the previous two years), in sectors including biotechnology. Eligible companies are those that are at the seed, start-up or early expansion stages. Funding is provided on a 2:1 government to private sector ratio and works through Commonwealth licensing of nine private sector fund managers. In 2001–2002, $34.5 million ($22.2 million from the Commonwealth) was provided to 31 companies, 14 of them in bioscience.[51] The Innovation Report 2003–04 suggested that the program has 'contributed to an increase in the number of early stage venture capital funds and the development of IIF fund managers'.[52]

R&D Start program

11.46 The R&D Start program is a competitive, merit-based grants and loans program providing assistance to firms to undertake research and development and its commercialisation. There is some support for biological and medical sciences projects but the majority of the funds go to the information technology, applied sciences and general engineering sectors. In 2002–03, 156 new applications were considered all from SMEs, of which 94 were successful and in total received $92 million in funding.[53]

Pooled Development Fund program

11.47 The Pooled Development Fund Program (PDF program) seeks to increase equity capital to SMEs. Established under the *Pooled Development Fund Act 1992* (Cth), pooled development funds (PDFs) are private companies that raise funds to take equity capital in Australian SMEs. The incentive to do so is a favourable tax rate of 15% for PDFs and their shareholders on the income generated through PDFs. There were 11 PDFs registered in 2002.

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50 AusIndustry, 'Biotechnology Innovation Fund', *Fact Sheet*, 26 March 2003, <www.ausindustry.gov.au>.

51 AusIndustry, *Industry Research and Development Board Annual Report 2001-02* (2003), 36.

52 Australian Government, *Backing Australia's Ability: The Australian Government's Innovation Report 2003–04* (2003), 66.

53 Ibid, 61.

11.48 Kelvin Hopper and Lyndal Thorburn suggest that 'the scheme is clearly only providing a very small amount of early stage funding for biotechnology firms'.[54] Ernst & Young have commented:

> Current PDF legislation provides no protection against the potential down side risk associated with such investments. While an investor whose investment increases in value gains access to tax free capital gains and concessionary taxed income, no mechanism exists for an investor who makes a loss on their investment to utilise that loss against another investment. Due to the level of business risk associated with the early stages of biotechnology ventures, such losses are common.

11.49 They recommend the introduction of 'legislation aimed specifically at the issues faced by investors in the start-up phase of biotechnology companies'.[55] Discussion of the merits of this suggestion is outside the terms of reference of the Inquiry.

R&D Tax Concession

11.50 Tax concessions are available for eligible R&D expenditure. The R&D Tax Concession program is the principal means by which the Commonwealth Government encourages R&D expenditure. Under the program, there is a 175% premium incremental tax concession for companies that increase their R&D expenditure above a three-year average. In addition, there are tax offsets for smaller companies and a 125% deduction for assets used in R&D.[56] At August 2003, 4,707 companies had registered for the concession for the 2001–02 financial year, and had reported $6.0 billion in R&D expenditure.

11.51 The Innovation Report 2003–04 stated that preliminary data on the tax concessions offered under *Backing Australia's Ability* suggested that these measures were encouraging business investment in R&D. Reported expenditure for firms with collaborative research and development arrangements with Registered Research Agencies and CRCs in 2002–03 increased by 28% and 21% respectively from expenditure in the previous year.[57] Preliminary results of a current independent review of the R&D Tax Concession program support the conclusion that the program is encouraging R&D expenditure by businesses.[58]

State government support

11.52 There is strong support at the state government level for the development of the biotechnology industry in Australia. Examples are found in schemes to attract researchers to universities within the various States; R&D funding to businesses

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54 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 40.

55 Ernst & Young, Committee for Melbourne and BioMelbourne Network, *Growing Our Knowledge Economy: Proposals for Further Reform* (2002), 6.

56 AusIndustry, *Industry Research and Development Board Annual Report 2001-02* (2003).

57 Australian Government, *Backing Australia's Ability: The Australian Government's Innovation Report 2003–04* (2003), 62.

58 Ibid, 62.

operating within the States; and grants to set up biotechnology incubator facilities.[59] Specific examples include BioFirst, a $68 million initiative of the NSW Government; the Queensland Government's $100 million sponsorship for the BioCapital venture fund and Victoria's $347 million Biotechnology Strategic Development Plan.[60]

Support for the pharmaceutical industry

11.53 Several schemes have operated within the pharmaceutical industry to promote investment in R&D. The 'Factor f' scheme operated for about a decade and, combined with 150% tax deductibility for R&D, led to some increase in investment. The purpose of the Factor f scheme was to compensate for low prices under the Pharmaceutical Benefits Scheme (PBS).

11.54 The Pharmaceuticals Industry Investment Program (PIIP) replaced the Factor f scheme in July 1999. PIIP is due to expire in 2004. Under the Factor f scheme, firms could raise prices on selected pharmaceuticals in return for undertaking R&D and manufacturing within Australia. Under PIIP, participating companies are subsidised 20% for production and R&D activity that exceeds a prescribed base level. The subsidy is only available to the extent that the price of PBS listed drugs is below those charged by the European Union.

11.55 In 2003, the Productivity Commission conducted an evaluation of PIIP and concluded that change was warranted, suggesting that 'the program is unlikely to generate net benefits'.[61] The Productivity Commission found that PIIP had had a positive effect on R&D in the pharmaceutical industry. It said that the amount of R&D generated by the program per dollar of subsidy was 'much higher than have been found for other R&D incentives in Australia and internationally'.[62] However, the Productivity Commission suggested that a revised program should be refocused towards subsidising only R&D and that eligibility be confined to those firms with products currently listed on the PBS. The Productivity Commission acknowledged that this would leave the domestic biotechnology industry 'outside the scope of the program' but stated it 'would still benefit through collaborations and other interactions with the pharmaceutical industry'.[63]

11.56 A new program was announced in the 2003 federal budget. The Pharmaceuticals Partnership Program (P3) will commence on 1 July 2004, replacing PIIP. The new scheme will provide $150 million over five years for a grants program to encourage new R&D by pharmaceutical companies.[64]

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59 See K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 56–59.

60 See Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 323.

61 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), XXII.

62 Ibid, XXIX.

63 Ibid, XXIII.

64 Treasurer of the Commonwealth of Australia and Minister for Finance and Administration, *2003–04 Budget Paper No 2: Budget Measures 2003–04* (2003).

Submissions and consultations

11.57 Comments on funding received in consultations largely agreed that there is a funding gap between the research stage and the development of saleable products that is not well covered by current funding programs.[65] In one consultation, this stage was referred to as a funding 'desert'.[66] However, Benitec Ltd suggested that government funding was problematic as there was too much nurturing of early stage companies.[67] The ARC commented that the Australian Government provides large amounts of funding to support research commercialisation.[68]

11.58 The South Australian Government commented that limited funding means that intellectual property developed in publicly funded research institutions cannot always be developed to the point where it is useful to the community. However, it considered it was a role for industry, rather than government, to fund this further development.[69] Another submission noted that limits on the resources of publicly funded research institutions may preclude them from filing patent applications on inventive research outputs in multiple jurisdictions.[70]

11.59 The Department of Health Western Australia made the point that:

> public funding supports the many scientific breakthroughs while patent holders are allowed to acquire monopolies that capitalise on the newly acquired knowledge. It is a concern that the commercialisation of publicly funded research is being embraced as de facto policy in Australia.[71]

11.60 Chapter 12 discusses issues relating to patenting of publicly funded research.

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65 UniQuest, *Consultation*, Brisbane, 3 October 2003; Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; Medical Researchers, *Consultation*, Adelaide, 15 September 2003; Australian Research Council, *Consultation*, Canberra, 22 September 2003.

66 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.

67 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.

68 Australian Research Council, *Consultation*, Canberra, 22 September 2003.

69 South Australian Government, *Submission P51*, 30 October 2003.

70 *Confidential Submission P54 CON*, 3 November 2003.

71 Department of Health Western Australia, *Submission P53*, 3 November 2003.

12. Publicly Funded Research and Intellectual Property

Contents

Introduction

12.1 The Terms of Reference direct the ALRC to examine the impact of current patenting laws and practices on the subsequent application and commercialisation of research into genes and genetic and related technologies. In doing so, the ALRC is to

consider reforms that may encourage the creation and use of intellectual property to further the health and economic benefits of genetic research.

12.2 This chapter examines the relationship between public funding of research and intellectual property ownership. The majority of human health related biotechnology research conducted in Australia is funded by the Australian government and occurs in public research institutions and universities. As a general rule, the government and its public funding agencies do not claim intellectual property rights over the results of the research they fund. This chapter considers the effectiveness of this approach in promoting research commercialisation to generate returns on government investment in research and in producing health care products and services for the Australian population. It examines a variety of approaches taken in other jurisdictions and a number of reform options.

Public funding of research

12.3 The Australian government provides public funding of medical and scientific research with the broad aim of promoting the national interest. Within this aim, there are a number of more defined objectives:

- promoting research;
- improving healthcare; and
- stimulating economic growth.[1]

12.4 This policy is also reflected in guidelines for intellectual property management released by the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC)[2]. For example, the NHMRC indicated a number of reasons why the protection and commercial exploitation of research provides important public benefits:

> The rapid development of science and technology, especially the emergence of modern biotechnology, provides Australia with an unprecedented opportunity to use its strong position in health and medical research to build knowledge-based industries that can compete in the global knowledge economy. Commercial exploitation of research findings benefits the economy through employment growth and national wealth generation, as well as being an essential step in the delivery of new drugs or health treatments to the community. It also presents new challenges for the research community to participate in the cultural change that is needed to position Australia to capture the benefits from the generation and diffusion of knowledge and technology.[3]

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1 See Ch 11.

2 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001); National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001).

3 National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), 1.

Promoting research

12.5 The Australian government provides funding for research through various agencies, principally the ARC and the NHMRC, with the objective of supporting research activities within universities and research institutions. Such funding enables researchers to purchase equipment and resources and may provide financial support for researchers to devote time to pursuing a particular project.

12.6 The outcome of this research may be placed directly in the public domain or may be the basis for the commercial development of new products. Promoting research is also a means of increasing the population of skilled researchers in Australia. It may contribute to the creation of a critical mass of researchers in a particular area, which may aid Australia in becoming well recognised in a field of research and consequently attract researchers from other countries.

Improving healthcare

12.7 Funding research into genetics and biotechnology allows researchers to investigate the causes of disease and promotes the development of new or improved treatments and tests. Such research may improve the options available to the medical profession for identifying and treating disease. For example, the development of a genetic test to establish a predisposition to an inherited condition may enable doctors to identify at-risk patients earlier. This may enable preventative measures to be taken earlier and to greater effect, or it may provide patients with greater knowledge about their condition and the choices available to them. Most publicly funded research is upstream research and further development may be needed to turn the outcomes of this research into downstream products. The public benefits from improved healthcare through reduced mortality and illness when new treatments and therapies are developed.

Stimulating economic growth

12.8 Public investment in research is a means by which the government can foster the development of a strong research base needed in a knowledge-based economy. It is recognised that developing such an economic structure is crucial for Australia's continuing economic growth. For example, it has been estimated that encouraging commercial development of research results has the potential to generate between 10,000 and 15,000 new jobs in Australia over five years.[4]

12.9 As noted above, it is government policy to promote the commercialisation of publicly funded research.[5] Encouraging effective commercial development of research

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4 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), xvii.

5 For example, the objective of the Cooperative Research Centres program is 'to enhance Australia's industrial, commercial and economic growth through the development of sustained, user-driven, cooperative public–private research centres that achieve high levels of outcomes in adoption and commercialisation.': Department of Education Science and Training, *Cooperative Research Centres Program: 2004 Selection Round Guidelines for Applicants* (2004), [1.2.1].

stimulates growth by creating products and product ideas. These might be manufactured and sold by Australian companies, creating employment and helping to develop the Australian manufacturing sector. If these products are marketed overseas, this may increase the export of Australian products. Alternatively, research results may be commercially developed to the stage where licensing agreements can be made with overseas companies to develop the product to market-ready stage. This generates income for Australian institutions holding intellectual property in the form of licensing fees and royalties. The financial returns from such agreements may be put back into research and development to support the Australian biotechnology research sector and industry further.

Public benefit from research funding

12.10 Few people would dispute that if public money is used to fund research, benefit from this research should flow back to the community in some form. IP 27 raised the issue of how best to ensure that the benefits of publicly funded research are realised.[6] One issue is the tension between freely sharing the results of publicly funded research and commercialisation of this research. There are arguments that the results of such research, because it has been supported with public funds, should also be publicly available. Exclusive control of new technology, such as through patent protection, may prevent others from freely using it.

12.11 However, the public benefits of such research may sometimes be realised more effectively through attracting investment for commercial development to take research through to the product stage. This chapter considers where the intellectual property rights should vest to ensure the public benefits from the research it helps to fund. This involves considering which organisation will most effectively realise these benefits.

Institutional benefit

12.12 Research institutions can benefit from holding intellectual property by exploiting it to generate financial returns that can be used for further research and to support the institution. They are able to do this by:

- establishing spin-off companies linked to the institution that develop and market products created from technology patented by the institution; and
- licensing patented technology to industry and other research institutions in return for licence and royalty payments or transfer agreements.

12.13 The Garvan Institute of Medical Research (Garvan Institute) in Sydney, is an example of an institution realising such benefits. The Garvan Institute is an autonomous, not-for-profit medical research institute with strengths in gene-based research. In 2002, the Garvan Institute's commercial relationships—which include licensing agreements, spin-off companies and research collaborations with

6 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003). Ch 5.

biotechnology companies—generated $2.5 million, which it used for its operations and growth.[7]

Intellectual property ownership

12.14 Where research is carried out in an organisation such as a university, hospital, or other government research organisation, normally the employer would be entitled to claim ownership of any intellectual property rights arising out of the research of its staff. This is a general principle of the common law and may also be found in relevant statutes, policies and employment agreements. However, where the research has been funded from outside the institution, such as by the NHMRC or the ARC, a question could arise as to whether such bodies should have rights to any resulting intellectual property.

Current law and practice

12.15 Publicly funded research institutions are entitled to apply for a patent over an invention created by researchers in the course of employment pursuant to s 15(1) of the *Patents Act 1990* (Cth) (*Patents Act*). Relevantly, the section provides that:

> a patent for an invention may only be granted to a person who:
>
> (a) is the inventor; or
>
> (b) would, on the grant of a patent for the invention, be entitled to have the patent assigned to the person; or
>
> (c) derives title to the invention from the inventor or a person mentioned in paragraph (b).[8]

12.16 Although the *Patents Act* does not explicitly address an employer's rights to inventions created by employees during employment, s 15(1)(b) is generally relied upon by an employer to claim proprietary rights over an invention by virtue of its employment of the inventor, or by virtue of the terms of an employment contract.[9]

12.17 The terms of the employment contract may include an explicit agreement to assign rights to an invention to the employer, allowing the employer to apply for a patent under s 15(1)(b).[10] Where there is no explicit agreement to assign, the court may imply such an agreement into a contract of employment. According to Professors Jill McKeough and Andrew Stewart:

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7 Garvan Institute of Medical Research, *Annual Report* (2002).

8 *Patents Act 1990* (Cth) s 15(1).

9 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8030]. See also J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed, 1997), [13.3]. It may also be that where no common law support can be found for assigning rights to the invention to the employer, and the inventor and the research institution have executed an agreement for intellectual property assignment, the institution may be entitled to apply for a patent under s 15 (1)(c).

10 J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed, 1997), [13.4].

> the courts have basically tended to favour employer ownership. Any invention will impliedly belong to the employer, so long as it is arrived at in the course of the duties the employee is engaged to perform.[11]

12.18 The nature of the employment and the duties it encompasses will therefore be determinative of whether an employer may assert rights to an invention created by the employee in the absence of an explicit assignment. Factors relevant to determining the nature of the employment include the business of the employer, the level of trust and responsibility of the employee and whether the resources, trade secrets, know-how or technology of the employer were used.[12]

12.19 Where the employer is a publicly funded research institution, and the employee is an academic staff member (in the case of a university) or an employed researcher (the researcher), the institution's claim to ownership of inventions created by the researcher will be determined by the nature and scope of the employment and the terms of the employment contract. The employer's rights may also be altered by institutional statutes and policies.[13]

12.20 According to a report released by the Department of Education, Science and Technology (DEST Report), universities may claim ownership of:

- inventions created using university resources;
- inventions created by academic staff in the course of their employment; and
- inventions created through publicly-funded research received as part of an agreement with a government funding agency.[14]

12.21 However, the institution's right to assignment of any resulting patent may be limited in two ways. First, where the express agreement in the employment contract is considered a restraint of trade, the agreement may be deemed unreasonable and unenforceable.[15] Second, in the absence of express agreement, or where the agreement is unenforceable, an agreement may not be implied if the researcher was not employed to invent in the specific field in which the invention falls, and the invention was not created during the hours of employment or using the institution's resources.[16]

12.22 In some instances, it may be difficult to determine which inventive activities fall within the scope of the researcher's employment. Associate Professor Anne Monotti and Professor Sam Ricketson note that:

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11 Ibid, [13.5]. See also *Sterling Engineering Co Ltd v Patchett* [1955] AC 534, 543–544, 547.
12 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 329.
13 These are discussed further below.
14 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), vii.
15 J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed, 1997), [16.5].
16 Ibid, [16.6].

> any right of a university employer to claim ownership of IP that its academic staff create during the term of employment is … dependent not only upon establishing the employment relationship but also upon the particular work being within the scope of the creator's duties of employment. As the scope of those duties is often unclear, resolution of this issue is equally so, particularly where creation occurs at home, at nights and weekend, and with or without use of university or third party resources.[17]

12.23 Monotti and Ricketson indicate that the situation is further complicated because:

- different research positions within institutions will have different duties attached to them, including teaching, curriculum development and leadership within research groups;
- a researcher will tend to move between institutions over the course of a career, and will enter each new position possessing knowledge and, in some cases, intellectual property from previous positions;
- a researcher may spend part of his or her time working in start-up companies, in collaborative research projects and centres, public teaching hospitals and other institutions; and
- a researcher may undertake research during leave or while on exchange to another institution.[18]

Students and visitors

12.24 A research institution's rights to inventions created by students and visitors are somewhat different to the general position.

12.25 As the relationship between a student and a research institution is not one of employment, the institution may not imply a right to ownership of inventions created by the student during the course of their education in the same manner as for academic staff. The relationship between the research institution and a student is in part based in contract,[19] but may also be a public law relationship if the research institution is established by statute.[20] While the student is bound by the institute's statutes, by-laws and regulations, he or she will not be automatically bound by non-legislative policies and resolutions.[21] A student may, however, agree to be bound and thereby agree to assign ownership of intellectual property to the institution.

12.26 Students funded through government scholarship schemes, such as the Australian Postgraduate Awards (APAs), may also be subject to conditions on the

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17 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.08].

18 Ibid, [4.09]–[4.20].

19 See *Bayley-Jones v University of Newcastle* (1990) 22 NSWLR 424.

20 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.21].

21 *Ex parte Foster; Re University of Sydney* [1964] NSWR 1000, 1007. See also A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.22].

award including that the institution administering the scholarship controls the grant and any research results arising from it. As the institution is required to adhere to its own intellectual property policy, which will generally direct that the research is exploited for the public benefit, the institution will exercise a degree of control over the intellectual property that results from the student's research.[22]

12.27 Visitors to research institutions include researchers on exchange from other institutions, and honorary or salaried appointees. The research institution's rights in relation to intellectual property created by a visitor will depend on the nature of the appointment.

12.28 A 1999 survey by the ARC of university research commercialisation in Australia (ARC Survey) found that all respondent universities had intellectual property policies in place for staff, and most also had policies for postgraduate students. However, fewer had policies covering undergraduate students and university visitors.[23]

Institutional intellectual property policies

12.29 As indicated above, publicly funded research institutes generally address intellectual property ownership issues through institutional statutes and policies. Institutions vary in their practices as to whether they will claim ownership of intellectual property generated by staff or within the university. Typically they will seek to claim ownership.

12.30 An example is the University of Adelaide, which released its intellectual property policy in December 1989. The policy states that:

> The University asserts common law ownership, either whole or partial, of all intellectual property arising from the work within its departments, institutes, centres or research groups. In most cases the University will agree to share the benefits derived from the commercial applications of intellectual property with the originator(s)/inventor(s), as defined in paragraph 8. However, it reserves its common law right of ownership as defined in paragraphs 4.3 to 4.9 inclusive and will assert this right in the event of dispute.[24]

12.31 In addition, the policy also states that the University encourages publication and the wide dissemination of research, however it asserts that:

> Where such creativity or research leads to invention the university seeks to encourage and facilitate commercial development for the benefit of the university, the inventor(s) and government, commercial or other partners. In such circumstances the

22 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.49].

23 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), 28.

24 University of Adelaide, *Commercial Development of the University's Intellectual Property Policy* (1989), [4.1].

> University may request and where appropriate require a delay of publication while the potential for patenting and commercial development is explored.[25]

12.32 In some Australian research institutions that retain intellectual property rights, where the institution does not wish to develop these to commercial stage, it may choose to assign these rights to the researcher. The researcher may then choose to develop the invention.

12.33 Alternatively, and more rarely, some institutions allow researchers to retain intellectual property rights in their research results. In these cases, the institution may foster commercialisation by supporting individual researchers through the commercialisation process. An example of this is the University of Melbourne, which allows academic staff who create intellectual property through research undertaken at the University to retain ownership of that intellectual property, instead of it being assigned automatically to the University.[26] University staff holding such intellectual property are required to disclose this to the University and must undertake to:

> use all reasonable endeavours to engage in any commercial exploitation in such a manner that any application of the intellectual property is for the benefit of Australia.[27]

12.34 The University supports researchers in exploiting these intellectual property rights through the Melbourne Research and Innovation Office of the University.

Collaborative research

12.35 A growing feature of biotechnology (and other) research in Australia is collaborative arrangements between institutions or between institutions and industry. These collaborations may take a broad range of forms, from informal sharing of knowledge to highly formalised collaborative arrangements. Collaboration may also involve staff, students or visitors from a number of institutions, funding bodies, government agencies and commercial entities in a variety of combinations. Such collaborations raise issues around intellectual property ownership.

12.36 In the absence of clear agreement on the terms of the collaboration, ownership of resulting intellectual property will be determined by legislation and common law

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25 Ibid, [1.4].

26 University of Melbourne, *Innovation 2000–01* (2001), 2. The University does, however, require that it be assigned ownership of intellectual property that arises directly from a researcher's involvement in a project that has been established through an agreement between the University and an external body: Melbourne Research and Innovation Office, *Academic Researcher Deed: Frequently Asked Questions*, University of Melbourne, <www.research.unimelb.edu.au/ridg/contracts/academic_resdeed_faq.html> at 19 January 2004.

27 University of Melbourne, *Statute 14.1: Intellectual Property* (1996), 14.1.3(3)(a), (h).

principles.[28] The *Patents Act* allows for co-ownership of patents. Section 16(1) provides that:

> subject to any agreement to the contrary, where there are 2 or more patentees:
>
> (a) each of them is entitled to an equal undivided share in the patent; and
>
> (b) each of them is entitled to exercise the exclusive rights given by the patent for his or her benefit without accounting to the others; and
>
> (c) none of them can grant a licence under the patent, or assign an interest in it, without the consent of the others.[29]

12.37 Some research institutions have included provisions to address collaborative research in their intellectual property policies and statutes. For example, James Cook University's policy for commercial research and consultancy services states that:

> Rights to intellectual property arising from collaborative research and development projects is negotiated on a case by case basis and depends on:
>
> - the equity contributions of the parties;
> - the existing intellectual property brought to the project by each party;
> - the capacity of the collaborator to commercialise project intellectual property and to otherwise utilise research outcomes.
>
> Joint ownership of intellectual property is a typical outcome, especially where the collaborator is another research institution. However joint ownership must always be subject to terms that clearly set out the capacity of the joint owners to use and commercially exploit project intellectual property. Without such terms the University may be disadvantaged by the rights accorded joint owners under legislation.[30]

12.38 However, regardless, of the policies of an institution, rights arising out of a particular collaboration will be determined by the contractual arrangements between the parties to the arrangement.

12.39 Much collaborative research in Australia also occurs within Cooperative Research Centres (CRCs). The model agreement for the establishment of a CRC provides that intellectual property generated through the research, training and commercialisation activities of the CRC shall be owned by the parties to the CRC agreement 'as tenants in common in proportion to their Participating Shares'.[31]

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28 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.59].

29 *Patents Act 1990* (Cth) s 16(1).

30 James Cook University, *Commercial Research and Consultancy Services: Policy and Procedures*, 6.2(a).

31 Cooperative Research Centres Programme, *Agreement for the Establishment and Operation of a Cooperative Research Centre*, cl 23.1.

Research institution policies may also provide that such agreements will override their own internal policies for intellectual property ownership.[32]

Jointly funded research

12.40 Questions of intellectual property ownership may also be complex where research is funded collaboratively by a number of bodies, as each body may have different policies regarding the ownership of research results.[33] This may be particularly problematic where research is funded partially from overseas bodies. For example, the *National Health and Medical Research Council Act 1992* (Cth) requires that intellectual property generated through NHMRC-funded research is vested in an Australian institution, however this may conflict with the requirements of other bodies that also provide funding.

Intellectual property and public funding

12.41 As indicated above, most health-related research in Australia is publicly funded. This raises issues about the role of the funding body in decisions about the commercialisation of any resulting research.

12.42 Management and exploitation of intellectual property resulting from publicly funded research is governed by guidelines and principles released by the ARC and the NHMRC. Each emphasises that institutions should seek to commercialise intellectual property for the public benefit where appropriate and addresses issues of identification and protection of intellectual property and issues of management.

12.43 In 2001, the then Minister for Education, Training and Youth Affairs and the Minister for Health released the *National Principles of Intellectual Property Management for Publicly Funded Research* (*National Principles*). The decision to create the principles came as a result of the Australian Government's policy to reinforce research investment and commercialisation.[34]

12.44 The Principles were developed by a working party comprising representatives from a number of key government organisations involved with, or with an interest in the outcomes from, publicly funded research.[35] The NHMRC also released its own intellectual property management guidelines in 2001, the *Interim Guidelines:*

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32 See, eg, Melbourne Research and Innovation Office, *Guide for Researchers and Research Administrators: An Overview of Research and Research-Related Policies and Procedures (2nd edn, September 2003)*, University of Melbourne, <www.research.unimelb.edu.au/guide/17.html> at 29 January 2004.

33 National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003.

34 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), 2.

35 The organisations were: the Australian Research Council, the Australian Tertiary Institutions Commercial Companies Association, the Australian Vice-Chancellors' Committee, the Department of Education, Training and Youth Affairs, the Department of Industry, Science and Resources, IP Australia and the National Health and Medical Research Council: Ibid, 2.

Intellectual Property Management for Health and Medical Research (*Interim Guidelines*), which largely mirror the content of the *National Principles.*[36]

12.45 The *National Principles* state that public funding bodies should have clear policies about whether they will claim ownership or associated rights for intellectual property generated from research supported by their funding. A requirement for compliance with the *National Principles* is often included in the ARC funding rules and agreements for particular grant programs. For example, the ARC funding rules for Discovery Projects require that:

> Applicants must agree to comply with the intellectual property regulations of the administering organisation and with the National Principles of Intellectual Property Management for Publicly Funded Research.[37]

12.46 Neither the ARC nor the NHMRC assert rights to the ownership of intellectual property arising out of their funding.[38] The *National Principles* state:

> The ARC and NHMRC do not wish to hold a stake in direct ownership of IP nor do they intend to benefit directly from commercial outcomes of the research they fund through their financial support.[39]

National Principles

12.47 The *National Principles* require institutions receiving funding to have procedures and policies to:

- support researchers in recognising discoveries that may have commercial value and provide for a review process to identify intellectual property that can be protected and exploited;[40]
- clarify staff responsibilities in relation to intellectual property, including the prevention of premature public disclosure of research results prior to obtaining intellectual property protection;[41]
- outline whether they will claim any ownership or associated rights to intellectual property from publicly funded research (including research conducted by postgraduate students);[42]

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36 National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001).

37 Australian Research Council, *Discovery Projects: Funding Rules for Applicants for Funding Commencing in 2004*, December 2003, [10.5]. The NHMRC takes a similar approach. For example, its Project Grant funding policy states that grant applicants must agree to comply with the *Interim Guidelines*: National Health and Medical Research Council, *Project Grant Funding Policy for Funding Commencing in 2005* (2004), [10.6].

38 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), 5.

39 Ibid, 2.

40 Ibid, Principle 2.

41 Ibid, Principle 3.

42 Ibid, Principle 4.

- guide researchers in assessing the existing intellectual property that may affect their freedom to operate in their field of research;[43]
- review intellectual property and associated commercial activities and outcomes;[44]
- recognise the rights and needs of all stakeholders involved in the research and define the way in which benefits from the development and exploitation of the intellectual property will be allocated;[45] and
- provide guidance in relation to potential conflicts of interest concerning ownership, management, protection and exploitation of intellectual property.[46]

12.48 The Principles also state that institutions and, where appropriate, individual researchers,[47] 'are expected to consider the most appropriate way of exploiting the IP generated from publicly funded research'.[48] The Principles indicate that the options range from exclusive and non-exclusive licences, research agreements or contracts, through to joint ventures or the establishment of spin-off companies.

12.49 Institutions are also required to be in a position to report on their intellectual property management.[49] However, the ARC does not currently take action to ensure that the results of ARC funded research are commercialised. It also does not require universities and research institutions receiving ARC funding to comply with any national interest policy.[50] However, it does track the research projects it funds and conducts surveys with the Commonwealth Scientific and Industrial Research Organisation and the NHMRC to see how many produce patents and commercial outcomes such as spin-off companies.[51]

12.50 The expert advisory committees of the ARC also do not take account of the commercialisation prospects of a project in granting funds; the criterion is excellence in research. However, grant applications must state the national benefit of the project. Patenting and commercialisation prospects are accepted as part of the national benefit assessment.[52] Some grants are self-selecting for commercialisation prospects, such as linkage grants, which require the applicant researcher to have an industry partner. Applications for such grants tend to be for research with an applied outcome, and the

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43 Ibid, Principle 5.
44 Ibid, Principle 6.
45 Ibid, Principle 7.
46 Ibid, Principle 9.
47 In some organisations, individual researchers can claim full or part ownership to rights arising from their research.
48 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), 6.
49 Ibid, Principle 7.
50 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 20.
51 Australian Research Council, *Consultation*, Canberra, 22 September 2003.
52 Ibid.

ARC will not fund them until there is a contract governing the intellectual property with an industry partner (in accordance with the *National Principles*).[53]

NHMRC Interim Guidelines

12.51 The requirements outlined in the NHMRC's *Interim Guidelines* are included within its grant application and approval process. The Guidelines note that 'commercial development, including patent registration will be considered along with other measures for grant report and review'.[54] The Guidelines state that, of various intellectual property rights:

> that which has the greatest potential for a positive economic outcome is patent, with some 'blockbuster' drugs and developments having multi-million sales. Specific tools, such as antibodies, probes, cell lines etc that are generated in the course of some research programs are an area of additional importance and potential value. Patents and 'materials transfer agreements' can be used to protect these 'tools'.[55]

12.52 The Guidelines also indicate the reasons for the promotion of commercialisation of intellectual property:

> IP *per se* is of little economic value unless it is protected and exploited; it is the rights that are attached to it that are valuable. In the case of patents this is the exclusive right to exploit the invention, or authorise others to exploit it; for a fixed term; in the case of copyright it is the exclusive right [among others] *'...to reproduce the work in a material form*', again for a fixed term. These temporary exclusive rights reward investment in research and innovation and can prevent others 'freeriding' on a creator's investment. Although there are established academic rights associated with the generation and ownership of IP in most institutions, it is the commercial exploitation of IP that has the major consequences for national, institutional and individual wealth creation.[56]

12.53 The Guidelines note that the NHMRC recognises its responsibility for 'setting an environment that assists the development of research findings to the national advantage, and in ensuring that NHMRC supported researchers are vigilant that they do not inadvertently, or through inaction, lose potentially valuable IP'.[57]

12.54 The provisions of the Guidelines largely mirror those of the *National Principles*. The Guidelines direct institutions to have policies for the identification, protection and exploitation of intellectual property.[58] As noted above, the Guidelines state that the NHMRC 'will not claim any ownership or associated rights for IP generated from its research support' however institutions are required to report intellectual property outcomes to the NHMRC, including information about:

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53 Ibid.
54 National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), 3.
55 Ibid, 2.
56 Ibid, 2.
57 Ibid, 3.
58 Ibid, Principles 2.1–2.8.

- newly generated intellectual property, and its status;
- the status of existing registered intellectual property; and
- commercialisation and income generation from the exploitation of intellectual property.[59]

12.55 However, the Guidelines do not stipulate how research results are to be commercialised nor what constitutes appropriate commercialisation:

> Individual researchers and their administering institutions are expected to consider the most appropriate way of exploiting their IP rights. It is acknowledged that there is no single 'best approach' to developing IP, and each instance has to be developed on a case by case basis. Options for consideration may range from exclusive and non-exclusive licenses, research agreements or contracts through to joint ventures or the establishment of spin-off companies.[60]

Issues and concerns

12.56 A range of issues arises from the current allocation of intellectual property rights in publicly funded research. These centre on whether this allocation promotes the major objectives of health and medical research funding, which is to generate health care and economic benefits for the Australian population.

12.57 In its 2003 report on patenting and licensing at public research organisations, the Organisation for Economic Co-operation and Development (OECD) noted that governments are increasingly recognising that 'placing the outputs of publicly funded research in the public domain is not sufficient to generate social and economic benefits from research'.[61] John Grace, former chief executive of Australian biotechnology company Amrad, has made a similar point, that if the benefits of research are to flow to the community, they must be patented to enable commercialisation.

> If a researcher is doing something really clever that might lead to a new drug, the only way that benefit will get to the community will be through the commercial activities of the company in developing it. And no company in the world will develop a drug without a patent. So … if you are a researcher that really wants to benefit mankind through a discovery, via some treatment, then a patent is not only essential, it is legitimate.[62]

12.58 However, a concern raised by some researchers is that if an institution exploits its intellectual property and makes a financial gain, public funding for that research will be reduced.[63] Others have suggested that shifting focus towards commercialisation

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59 Ibid, Principle 2.7.
60 Ibid, 7.
61 Organisation for Economic Co-operation and Development, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003), 9.
62 B Pheasant, 'The Value of a Pure Thought', *Australian Financial Review* (Sydney), 12–13 August 2000, 26.
63 Ibid.

of publicly funded research will direct research efforts away from some less lucrative fields. Some researchers are concerned they must favour work areas that will yield patentable discoveries that can be commercialised because they are expected to exploit intellectual property to fund further research.[64]

Exploitation of intellectual property in the public interest

12.59 There may be concerns that leaving the exploitation of research results to institutions will not ensure they are effectively translated into community benefits. This concern results in part from the absence of any requirement for institutions receiving public funding to exploit any resulting intellectual property in a way that benefits the national interest. As discussed above, for the most part, public funding bodies in Australia take a hands-off approach to the commercial development of research results and do not direct how those results should be exploited.

12.60 Allowing research institutions to hold intellectual property in the results of publicly funded research may limit access by other researchers and developers to these results. Given that these results have been generated using public money, there may be some need to ensure that in return benefits flow back to the public.

12.61 There may also be a tension between what might be perceived as institutional benefit and national benefit. In deciding how to develop its intellectual property, a university may be confronted with a choice between maximising its own financial returns and maximising the benefits that may flow to the Australian community in the form of jobs, wealth and health care.

12.62 An institution holding valuable intellectual property might maximise its own income through licensing agreements with larger companies, which will often be international firms. Depending on the terms of the licensing agreement and the level of royalties that flow back, this might bring initial financial returns, however the overseas company will reap the downstream profits of developing the research results into a marketable product. Conversely, the establishment of local spin-off companies to develop and market the technology locally, if successful, might better promote Australian interests. In the long term, this approach may also improve the institution's return on its initial investment.[65]

12.63 The ARC has suggested that this tension results from the lack of industry receptors in Australia, which causes institutions and other patent holders to license their technologies to larger, international companies with the capacity to develop the technology into a commercial product.[66]

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64 Ibid.

65 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), viii.

66 Ibid, viii.

Effective commercialisation

12.64 Another concern raised by allowing ownership of gene patents to vest in research institutions is whether they have the capacity to exploit patents on publicly funded research effectively. If patents are not properly exploited, the research may not be translated into public healthcare benefits.

12.65 This may occur for a number of reasons. The research institution may fail to transfer the technology to a commercial partner for development into a usable product, such as a test or therapy, if the institution does not prioritise commercialisation or lacks the skills needed for effective commercial negotiations. Alternatively, the institution may attempt to develop the technology through the creation of a spin-off company. If the attempt is unsuccessful, the patent may pass to another organisation, such as a private company. These concerns are discussed further in Chapter 18.

Lack of clear guidance on ownership

12.66 Genetic research undertaken by students or visitors may raise concerns about the ownership of resulting gene patents due to the complex relationship between the institution and students or visitors. Issues about clear ownership may arise in the absence of policies determining which party will own any resulting intellectual property.

12.67 Difficulties in determining ownership may also arise where research is conducted jointly by researchers at a number of institutions. Similarly, as discussed above, disputes about ownership may occur where research has been jointly funded and each funding body has differing policies about ownership. As noted in Chapter 18, joint ownership across institutions or other bodies may form a barrier to commercialisation, as industry partners are generally unwilling to invest in developing intellectual property where negotiation with multiple parties will be necessary.

Submissions and consultations

12.68 Comments received in a number of submissions suggested that realising public benefit from publicly funded genetic research was an important issue in patent law reform, with some submissions maintaining that such benefits should return to the community.[67] In particular, the NHMRC commented that:

> there is some expectation in the community of return to the 'public purse' from financial benefits acquired by private organisations from the commercialisation of NHMRC funded research. Similarly it has been suggested that public institutions that are able to realise financial benefits from the commercialisation of NHMRC funded

67 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; D Weston, *Submission P62*, 12 November 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Consumers' Health Forum of Australia, *Consultation*, Canberra, 23 September 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; South Australian Government, *Submission P51*, 30 October 2003.

> research should be required to use a certain percentage of the money for further health or medical research in their institution.[68]

12.69 The Human Genetics Society of Australasia (HGSA) suggested that:

> gene patents arising from publicly funded projects should have exemptions in regard to further research in human health. Such research should help provide cost effective health care in Australia.[69]

12.70 Del Weston commented:

> Genetic technology is the ultimate example of a sophisticated technology in health provision, which concentrates power in the hands of fewer expert elites. Patenting of the basis of this technology will further take it out of the realm of public direction and governance. This is, amongst other consequences, a community health issue.[70]

12.71 Dr Graeme Suthers raised the concern that 'if gene patents are awarded to public-sector institutions, then there is a potential conflict of interest between the public basis of funding used to identify the gene involved and the public interest in having the gene freely accessible to all'.[71]

12.72 Some submissions supported allowing researchers, rather than institutions, to hold rights to intellectual property in publicly funded genetic research, to provide greater incentives for commercialisation.[72]

12.73 To address some of the problems of inadequate commercialisation and ensuring the public benefits from research, some submissions advocated greater involvement of either funding bodies or government. For example, the Australian Centre for Intellectual Property in Agriculture (ACIPA) supported allowing public funding bodies to take a more active role in managing intellectual property for the public good:

> Arguably, though, there is need for greater government regulations on intellectual property management in respect of collaborations between the private sector and the public sector … Australian funding agencies should follow the lead of the National Institutes of Health, and the United Kingdom Department of Health, and play a much more active role in intellectual property management, policy, and litigation.
>
> It is recommended that Australian funding agencies—such as the Australian Research Council and the National Medical and Research Council—play an active role in intellectual property management, policy and litigation in the field of the life sciences.[73]

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68 National Health and Medical Research Council, *Submission P52*, 31 October 2003.
69 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
70 D Weston, *Submission P62*, 12 November 2003.
71 G Suthers, *Submission P30*, 2 October 2003.
72 Wondu Business & Technology Services Pty Ltd, *Submission P4*, 20 August 2003.
73 Australian Centre for Intellectual Property in Agriculture, *Consultation*, Brisbane, 3 October 2003.

12.74 Some suggested measures were the imposition of conditions for access to, and exploitation of, patented genetic technologies or prohibitions on exclusive licensing.[74] Support was also expressed for the introduction of guidelines similar to those introduced by the United States National Institutes of Health (NIH) to ensure wide dissemination of genetic research results.[75] The NHMRC suggested that:

> it may be appropriate for the NHMRC to review its current IP policy and to consider the need for any changes to the conditions included in deeds of agreement. Consideration could, at this time, be given to the advantages and disadvantages of providing for some return to the 'public purse' or enabling the Commonwealth to have some sort of first right of refusal on commercialisation opportunities arising from publicly funded research.[76]

Options for reform

12.75 Given that the public funding of research raises issues about the best ways to ensure public benefit, there are a range of possible options for reform. Some address the wide dissemination of research results; others consider issues around intellectual property identification, ownership and management as a means of ensuring effective commercialisation, in those circumstances where commercialisation is appropriate.

Ownership and access models

12.76 One approach could be to require all research results generated with public funding to be placed into the public domain, precluding anyone from claiming intellectual property rights in the results and excluding the ability to patent them. This approach has the advantage of making research results freely available for other researchers to use and build on.

12.77 A variation of this approach is taken internationally by the SNP Consortium (known as TSC). The TSC takes out patents over the single nucleotide polymorphisms (SNP) that the project identifies but subsequently releases the details of each into the public domain. The TSC does not plan to enforce the patents except to prevent others from patenting the same information.[77] The TSC's stated intellectual property objective is to ensure the SNP map it produces is 'free of third-party encumbrances such that the map can be used by all without financial or other IP obligations'.[78]

12.78 However, freely available information may not always be the most appropriate means of promoting the development of research results into health care products and services. Inventions that are not protected by a patent may not be further developed

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74 Cancer Council Australia, *Submission P25*, 30 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

75 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

76 National Health and Medical Research Council, *Submission P52*, 31 October 2003.

77 Human Genome Project, *Genetics and Patenting*, United States Department of Energy, <www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml> at 19 January 2004.

78 SNP Consortium Ltd, *The SNP Consortium: Full Genome Representative SNP Map Program Summary*, <http://snp.cshl.org/about/program.shtml> at 19 January 2004.

into health care products. Without the incentive of a limited monopoly to allow costs to be recouped, it is unlikely that a biotechnology company will make the significant investment in developing an invention to product stage.

12.79 For these reasons, various ownership approaches may be suitable depending on the nature of the technology and its uses. For example, free access may be more appropriate for foundational technology such as genetic sequence information, while patent protection may be necessary for downstream research results to promote investment in commercial development. As Professor Rebecca Eisenberg has argued:

> Neither the old-fashioned idea of leaving all new discoveries in the public domain nor the newer idea of assigning exclusive rights in such discoveries to private parties should be uniformly applied across the entire range of publicly-supported discoveries.[79]

12.80 Property rights could vest in one of a range of individuals and organisations involved in funding and producing research. Intellectual property rights to publicly funded research results could be vested in:

- the government;
- the body that provided funding for the research that led to the invention's creation;
- the researcher; or
- the institution, initially, but subsequently vested in the funding body or government if the commercial potential of the invention is not developed within a reasonable time period.

12.81 In its 2003 report, the OECD asserted that for governments, granting public research organisations rights to intellectual property generated with public funds

> can lead to better use of research results that might otherwise remain unexploited as well as to the creation of academic spin-offs or start-ups that create employment. For PROs [public research organisations] the benefits may include increased licensing and royalty revenues, more contract research and greater cross-fertilisation between entrepreneurial faculty and industry. Equally important, however, are the intangible benefits to an institution's reputation and to the quality of its research that closer interaction with the private sector can generate.[80]

12.82 The ARC has indicated that to date it has left commercial development to institutions and that intervention in commercialisation has not been its practice or that of the government.

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79 R Eisenberg, 'A Technology Policy Perspective on the NIH Gene Patenting Controversy' (1994) 55 *University of Pittsburgh Law Review* 633, 640.

80 Organisation for Economic Co-operation and Development, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003), 9.

> However, when there is real problem requiring a real solution then a top down approach may offer the most effective approach to bring about a significant change in the culture of Australia towards the commercialisation of university research.[81]

12.83 In a report in 2000, the ARC raised the issue of granting university researchers, rather than the institution, a licence to exploit the results of publicly funded research as a condition of the award of a grant. Such an approach would create financial incentives for researchers to identify and develop the commercial potential of their research.[82] This approach is sometimes known as the Cambridge model, as it is Cambridge University policy to assign rights to university researchers in this way.

12.84 The strength of the approach lies in its potential to stimulate a more entrepreneurial attitude to research among researchers, which may focus early research efforts on areas of study that may lead to commercially profitable products. However, placing the onus to exploit intellectual property onto researchers may be problematic where they lack the financial capacity to take their research results through to the commercialisation stage. University researchers also may not possess the business and legal expertise required for successful commercial negotiations.[83]

12.85 The ARC has suggested that these problems could be overcome if universities and research institutions provide appropriate support to researchers.[84] This support might extend only to an advisory service, or more hand-ons involvement in the commercialisation process.

12.86 The OECD Report supported ownership by institutions rather than vesting rights in individuals because it provides:

> greater legal certainty for firms interested in exploiting research results, lowers transaction costs for partners and encourages more formal and efficient channels for knowledge and technology transfer.[85]

12.87 The DEST Report also favoured institutional ownership[86] and suggested that the experience from Canada 'reveals many problems that may arise out of a laissez-faire approach to IP ownership'.[87] The Report argued against funding bodies retaining ownership and suggested 'the UK experience reveals problems that arise when research funders maintain too much control over IP generated from their funds' and

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81 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 20.

82 Ibid, 20.

83 Ibid, 21.

84 Ibid, 21.

85 Organisation for Economic Co-operation and Development, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003), 11.

86 The report does however suggest that research institutions should be able to assign patent rights "on a case-by-case basis where the institution believes such an assignment would lead to an optimal outcome with respect to commercialisation': Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), xii.

87 Ibid, x.

concludes that 'experiences therefore point to research bodies as the most desirable owners of IP'.[88]

Expanding the National Principles

12.88 The DEST Report argued that the right of institutions to own intellectual property 'should be coupled with the assumption of responsibility for the effective identification, protection, management and commercialisation of the invention'. The Report suggested this could be achieved through an expansion of the *National Principles* and the *Interim Guidelines*. In particular the Report suggested that the *National Principles* should be expanded to:

- require research institutions to notify funding bodies of any identified, valuable inventions created using public funds;
- emphasise that the ultimate responsibility for commercialising inventions rests with the research institution by adopting a time limit for applying for a patent;
- require research institutions to have intellectual property management infrastructure in place or that they allocate a certain proportion of granted funds towards exploitation;
- emphasise the need to ensure employees' work arrangements and responsibilities do not act as a disincentive to commercialise and to counter any existing disincentives; and
- direct research institutions to include knowledge transfer or commercialisation as an express component of their mission statement.[89]

12.89 The Report also noted of another possible reform, which it stressed would need further consideration if it were to be included in an expanded *National Principles*. It suggested that preserving funding body rights to intellectual property might be a means to ensure they are able to use and benefit from the research results generated with its investment. The Report commented, however, that:

> such a proposal should not be adopted without detailed evaluation of its potential to act as a disincentive to investment in commercialisation.[90]

'No Australian disadvantage'

12.90 The DEST Report also raised the possible inclusion in the *National Principles* and *Interim Guidelines* of a requirement that in commercialising intellectual property, research institutions should prioritise local industry to prevent Australian inventions being lost overseas. In particular, institutions should favour local businesses when licensing their intellectual property.[91] The Report noted, however, that 'an obligation to

88 Ibid, x.
89 Ibid, 79–83.
90 Ibid, 86.
91 Ibid, 84. The *Bayh–Dole Act* contains provisions of this kind: *Patents Act 1952* 35 USC (US), §204.

favour Australian commercialisation has several fairly complex indirect and dynamic effects.' It suggested that some of these effects include:

- an unclear net impact on employment;
- the possibility that if there are a limited number of Australian companies that have the expertise to undertake commercialisation, then commercialisation may not be as successful as it would have been were it undertaken by a foreign organisation;
- a reduction in researcher interaction with the 'best' companies, resulting in less opportunities for the 'best' knowledge spill-overs to further develop the idea; and
- potential growth of the local industry.[92]

12.91 The DEST report concluded that careful empirical and theoretical consideration and a full assessment of different policy options would be required to adequately assess these effects. It also noted that there may be other means of protecting and promoting local industry.[93]

12.92 This issue has also been considered by the Prime Minister's Science, Engineering and Innovation Council (PMSEIC), which suggested that 'government funding for biotechnology should be given on the understanding that recipients agree to a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement or for technology only to be licensed, not sold'.[94] PMSEIC suggested the inclusion of such provision in arrangements for publicly funded research would enable Australian companies the best opportunity to capitalise on Australian research results.

12.93 A requirement of this kind may aid the development of the Australian biotechnology industry, and further ensure that benefits from technologies developed in this country are not prevented from flowing back to the Australian community. For example, Australia may be disadvantaged if a patent were assigned overseas, and the patent holder subsequently does not license it in Australia or licences it exclusively in such a way as to disadvantage Australian health care or research. The ALRC is interested in receiving comments on whether there is need for the *National Principles* and the *Interim Guidelines* to include a requirement to favour Australian industry, or alternatively to avoid disadvantage to Australia.

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92 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 84–85.

93 Ibid, 85.

94 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 6.

Question 12–1 Should the *National Principles for Intellectual Property Management for Publicly Funded Research* and the National Health and Medical Research Council's *Interim Guidelines: Intellectual Property Management for Health and Medical Research* be expanded to require research institutions to favour Australian industry when commercialising patented inventions created through the use of public funds? Should the *National Principles* or the *Interim Guidelines* include a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement involving patented inventions created through the use of public funds? If so, how should such requirements be implemented?

ALRC's views

12.94 The ALRC considers that intellectual property rights in publicly funded research should vest in the individual or organisation that will best exploit them to promote national interest including the provision of health care in Australia.

12.95 In the ALRC's view, publicly funded research institutions are best placed to develop intellectual property in results of research and the ALRC has no evidence about a need to alter the current framework for ownership of publicly funded research carried out in these institutions. Although the capacity of some research institutions to commercialise technology may be limited by a lack commercial expertise or funding to develop products, it is unlikely that government funding agencies or researchers themselves will be more able to take on the task of commercialisation effectively. In the ALRC's view, commercialisation problems are better addressed through providing support to these institutions in the form of funding and advisory services. The options for providing support of this kind are discussed in Chapters 15, 18 and 23.

12.96 The ALRC is of the view that there may be merit in the ARC and the NHRMC implementing 'an expanded *National Principles* approach which would enlarge the content of responsibilities currently applied to research institutions'.[95] Although the ALRC has not made a specific proposal on this issue, it does consider that the ARC and NHMRC should draw on the reform suggestions made in the DEST Report listed above in any future review of the *National Principles* and the *Interim Guidelines*.

12.97 The ALRC considers there is no single model for achieving public benefit from genetic research. In some instances greater public benefit may result from making patented genetic materials or technologies freely accessible or widely licensed, in others, by allowing a patent to be exploited by a single company. The most appropriate approach to exploiting or using the results of genetic research can only be considered on a case-by-case basis.

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95 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), xii.

12.98 However, the ALRC is of the view that there is a need to ensure publicly funded genetic research is commercialised in a manner that benefits the Australian public. The ALRC regards the *National Principles* and the *Interim Guidelines* as the most appropriate forum in which to emphasise this need and proposes that the ARC and NHMRC should review their principles and guidelines on intellectual property and research to ensure that publicly funded research, where commercialised, results in appropriate public benefit.

12.99 There may be differing conceptions of the public benefit and, in some instances, there may be a variety of benefits that could be generated through exploiting patented research results in different ways. In the course of reviewing their guidelines and principles, the ARC and NHMRC should also develop guidance on what is meant by appropriate public benefit in the context of research, to address this issue.

12.100 The ALRC also considers that the ARC and NHMRC should be prepared to place conditions on grant funding to direct how any resulting technologies are exploited in those circumstances where it is considered that greater public benefit would result from the resulting research being placed in the public domain either with no patent being sought or, where a patent is sought, from being widely licensed. Provision for such conditions to be placed on the grant of public research funding should be incorporated into the *National Principles* and the *Interim Guidelines*.

12.101 One issue raised by the current framework of ownership of gene patents in publicly funded research is the need for guidance on the rights of institutions in research undertaken by students and visiting academics. In the ALRC's view, research institutions should ensure they have clear policies and effective practices in this area, although the ALRC does not seek to be prescriptive about the content of these policies or practices.

12.102 To avoid problems with determining ownership and rights to intellectual property in genetic research conducted jointly, either between research institutions or collaboratively with industry, institutions should also ensure their intellectual property policies include clear guidance on ownership of results of joint research.

Proposal 12–1 The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review their principles and guidelines on intellectual property and research to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Proposal 12–2.)

Proposal 12–2 As part of the review proposed in Proposal 12–1, the ARC and NHMRC should include guidance on what is meant by 'public benefit' in their principles and guidelines on intellectual property and research.

Proposal 12–3 The principles and guidelines developed in accordance with Proposal 12–1 should enable conditions to be attached to the grant of funding for genetic research, to limit the commercialisation of publicly funded research in appropriate circumstances. Such conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.

Proposal 12–4 Universities and other publicly funded research organisations should ensure that their guidelines on intellectual property ownership cover research undertaken by visiting researchers and students, as well as staff—whether undertaken solely within the organisation or jointly with other bodies.

March-in rights

12.103 The approach discussed above, and Proposals 12–2 and 12–3 in particular, are an alternative to a more restrictive approach under which the government maintains residual rights in any publicly funded research, known as 'march-in rights'.

12.104 Concerns about lack of commercially viable research emanating from the public sector led the United States Congress to enact a number of pieces of legislation in the 1980s which aimed at improving technology transfer from publicly funded research institutions to the private sector. In particular, the *Bayh–Dole Act 1980* (US) (*Bayh–Dole Act*) allowed recipients of government funding for the performance of experimental, developmental or research work to retain title to any invention made in the course of that work and accordingly to be able to patent that invention, subject to meeting patent requirements.

12.105 According to Eisenberg:

> Since 1980, the presumption has been that patenting discoveries made in the course of publicly funded research is the most effective way to promote tech transfer and product development in private sector (in US) because exclusive rights are needed as an incentive for commercialisation.'[96]

12.106 More than 60% of gene patents in the United States are based on publicly funded research.[97] One researcher has suggested that 'the close links between universities and industry are a principal reason why US firms now dominate the biotechnology market'.[98]

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96 R Eisenberg, 'A Technology Policy Perspective on the NIH Gene Patenting Controversy' (1994) 55 *University of Pittsburgh Law Review* 633, 635.

97 L Andrews, M Mehlman and M Rothstein, *Genetics: Ethics, Law and Policy* (2002).

98 See E Press and J Washburn, 'Secrecy and Science', *The Atlantic Online*, March 2000, <www.theatlantic.com/issues/2000/03/press2.htm>, citing the findings of Walter Powell.

12.107 However, unlike in Australia, under the *Bayh–Dole Act* the Federal agency that funds research retains certain residual rights to inventions developed from that research. These 'march-in' rights may be used to promote the utilisation of inventions arising from publicly funded research, including ensuring the commercial development and public availability of inventions. They allow the agency to take title to any inventions where practical application has been slow or not forthcoming or where action is needed to meet health or safety needs, or to meet the requirements for public use or where an exclusive licence has been granted. The agency may then assign title to another organisation more likely to pursue effective commercialisation.[99]

12.108 A example of the use of march-in rights in the United States concerns the broad patent held by the Wisconsin Alumni Research Foundation (WARF) over primate embryonic stem cells developed through publicly funded research. These patents affect a number of existing stem cell lines, including those held by WiCell Research Institute Inc, a non-profit subsidiary of WARF created to support human embryonic stem cell research at the University of Wisconsin–Madison. In September 2001, the NIH began negotiations with WARF over access to human embryonic stem cells. A subsequent agreement was reached providing access to the patented stem cells for federally funded researchers.[100]

Submissions and consultations

12.109 IP 27 asked whether there was any need in Australia for the government to retain a variety of rights to intellectual property developed from publicly funded research.[101] These rights included 'march-in' rights, the right to a government use license and the right to limit exclusive licences. The introduction of the concept of residual rights found some favour in submissions, albeit with reservation in a number of cases. For example, The Walter and Eliza Hall Institute of Medical Research (WEHI) commented that the use of 'march-in' rights in very exceptional instances could protect the public who had funded research, emphasising the need for clear and transparent guidelines to determine when such rights could be exercised. It cited a number of instances that might be appropriate, including the need to access intellectual property for the national good in wartime, for epidemics or for bio-defence purposes as examples of such instances. It noted, however, that:

> Overuse of these rights will erode the confidence of potential commercial users that such patents have real value and could prevent the development of effective treatments to the detriment of the public good. Overuse could also lead to greater reliance on reversion to proprietary protection rather than patents and then such provisions would be powerless.[102]

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99 *Patents Act 1952* 35 USC (US), §203.

100 WiCell Research Institute Inc and Public Health Service of the United States Department of Health and Human Services, *Memorandum of Understanding*, 5 September 2001.

101 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 5–3.

102 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

12.110 Professor John Mattick suggested that march-in rights could aid the government in addressing inappropriately wide use of gene patents,[103] while Dr Graeme Suthers suggested that if genes remained patentable, it might be necessary for the government to retain some residual rights to prevent exclusive control of genetic sequences.[104] The HGSA and the Royal College of Pathologists of Australasia (RCPA) took a similar view, with the HGSA arguing that the government could retain the right to use gene patents in the provision of public health services, either completely or at a reduced fee.[105]

12.111 The Genetic Support Council (WA) founded its support for introducing residual rights to the need to address equity of access issues in the public health system:

> The Public Health System continues to make substantial demands on financial resources of Government at both a State and Federal level. There would seem to be a very strong argument to support the proposition, that when public funding is involved, some controls be available to Government to protect individuals, reduce costs and maintain equity of access or pass on any benefits to individuals.[106]

12.112 The South Australian Government stated:

> Where research is publicly funded, agreements should be in place which ensure government ownership (or part ownership) of the IP, or which entitle government to a share of any financial returns, commensurate with the resources it contributes. The US arrangement where the government retains certain residual rights to IP developed from publicly funded research may be a strategy to ensure continued access by the public to the results of publicly funded research.[107]

12.113 Lack of incentive to commercialise was also raised as a reason to introduce residual rights. The RCPA argued that the introduction of residual rights could address the lack of incentives for researchers to commercialise their research. It commented that the Australian approach of allowing institutions to claim ownership of intellectual property arising from research conducted by employees provided 'minimal incentives for individual researchers to develop their basic research into a commercial product'. By contrast, it stated that the *Bayh–Dole Act* was as 'an excellent example of a social contract between government and inventors that has had highly beneficial effects'.[108]

12.114 Other submissions expressed a variety of reservations about the introduction of residual rights. Some stressed the Government's limited capacity to effectively commercialise patented genetic research. WEHI noted that:

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103 J Mattick, *Submission P35*, 13 October 2003. See also South Australian Government, *Submission P51*, 30 October 2003.

104 G Suthers, *Submission P30*, 2 October 2003.

105 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

106 Genetic Support Council WA (Inc), *Submission P59*, 7 November 2003.

107 South Australian Government, *Submission P51*, 30 October 2003.

108 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

> commercial parties in general do not like to deal with governments over IP (it is too slow and too complex) and governments in general do not have the capacity to actively seek commercial exploitation of the IP.[109]

12.115 The NHMRC stated that if a form of march-in rights were considered desirable, these could be exercised by the NHMRC through grant conditions.

> [I]f these outcomes (eg 'march-in' rights) are considered desirable there may be means for achieving these outcomes other than through the patents legislation. For example, through conditions of grant agreements that enable consideration of the merits of such powers on a case by case basis.[110]

12.116 The NHMRC commented that it is unclear how it, or the Government, would be able to commercially develop gene patents that arise from publicly funded research. It suggested it is also not clear whether it is necessary or desirable for it to do so.[111] Similarly, Wondu Business & Technology Services Pty Ltd stated that from experience 'in contract research, government administrators and their agents are often, though not always, very slow in acting on research, including in publication of research that is to be made available to the general public'.[112] Another submission commented:

> the government should not intervene in the commercialization process by retaining residual rights. The introduction of this type of initiative would only serve to complicate the process through increased bureaucracy and potential delays in the process. The Government does not have a good track record in 'picking winners' and should allow competitive market pressures to dictate outcomes, where there is no evidence of market failure.[113]

12.117 The Department of Industry, Tourism and Resources (DITR) agreed:

> Realising the value of IP requires successful commercialisation which is expensive and high risk. Effective government intervention in this area would require the establishment of the infrastructure necessary for commercialisation, risk calculation, financial and commercialisation skills. The public sector has no advantage over the private sector in the relevant areas of experience and expertise.[114]

12.118 Although supporting the introduction of residual rights, the RCPA also recognised this concern, noting that government agencies are not necessarily 'the most suitable vehicles for product development and commercialisation.'[115]

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109 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

110 National Health and Medical Research Council, *Submission P52*, 31 October 2003. March-in rights are discussed in more detail below.

111 Ibid.

112 Wondu Business & Technology Services Pty Ltd, *Submission P4*, 20 August 2003. See also Queensland Department of Innovation and Information Economy, *Consultation*, Brisbane, 2 October 2003.

113 A McBratney and others, *Submission P47*, 22 October 2003.

114 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

115 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

12.119 Others suggested that the introduction of residual or march-in rights would be ineffective in addressing the barriers to the commercialisation of genetic research in Australia. In part, this was attributed to the differences between the biotechnology industry in the United States and Australia, and the funding schemes for genetic research. For example, the Queensland Government made the point that the United States model may not be applicable in Australia for reasons of scale:

> The conditions attached to NIH funding have to be balanced against the sheer size of such agencies and the monetary amounts provided. Companies may view that the amount of funding and opportunities that agencies like NIH provide, may outweigh the onerous conditions imposed by those agencies and the retention of residual rights in relation to intellectual property. However, in the Australian context, such incentives and trade-offs may not exist as the Australian and State Governments operate on a much smaller scale.[116]

12.120 DITR was of the view that the introduction of residual rights was not a solution to the problems that face the Australian biotechnology sector in developing genetic research into marketable products, stating:

> The objective of march-in rights introduced under the Bayh-Dole Act in the US was to 'force' commercialisation of patented technology arising from publicly funded research where IP ownership was unclear. In Australia the institution undertaking research funded by the Australian Government owns the IP derived from that research. The failure to commercialise genetics and other medical inventions in Australia is usually attributed to the lack of venture capital and the relatively small and risk-averse nature of private sector investors. Therefore, it is not apparent that march-in rights similar to the US provisions would be an appropriate tool to address the difficulty in commercialising IP in Australia from research funded by the Australian Government.[117]

12.121 One submission argued that introducing residual rights would be a potential disincentive to industry collaboration in commercialising research. GlaxoSmithKline cited its experience in collaborating with United States universities operating under the *Bayh–Dole Act*, stating that:

> the prescriptive nature of the Act can limit flexibility in deal structure. For example, the university is unable to assign ownership of intellectual property to a sponsor unless the degree of federal funds applied to the research is truly zero. There are many situations where ownership of intellectual property is crucial to the sponsor. If this cannot be granted then the potential sponsor may withdraw from discussion and thus the Act works against collaboration … [introducing] an equivalent Bayh-Dole Act in Australia would almost certainly result in a decrease in collaborative research between universities and industry as our experience shows it has in the United States.[118]

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116 Queensland Government, *Submission P57*, 5 January 2004.
117 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
118 GlaxoSmithKline, *Submission P33*, 10 October 2003.

12.122 GlaxoSmithKline emphasised that maximum flexibility is necessary to encourage collaboration between publicly funded research institutions and industry, which would be limited by a restrictive approach. Instead, it argued that publicly funded research institutions should be free to manage their intellectual property without being subject to government control. It further warned against making technology-specific provisions on these issues because this may create disincentives to undertaking genetic research in Australia.[119]

12.123 The introduction of residual rights was not supported in some submissions on the basis that the Crown use, and compulsory and statutory licensing provisions of the *Patents Act* could be used to address issues that are dealt with through the *Bayh–Dole Act* in the United States.[120] For example, in one consultation it was suggested that compulsory licensing was preferable to the use of residual rights to address inadequate commercialisation where researchers and investors are unable to reach an agreement.[121]

12.124 The Queensland Government commented that 'there already exists the possibility of the government retaining certain residual rights to intellectual property under the provisions of the *Patents Act* relating to Crown use and compulsory licensing'.[122] Similarly, GlaxoSmithKline commented that:

> Government ownership or retention of rights in intellectual property resulting from government funding is not needed to manage potential abuses of the intellectual property, as compulsory licences, crown-use type provisions and similar safeguards are already built into the law.[123]

12.125 Others suggested that the government would require very good evidence of market failure before intervening in the licensing activity of a patent holder through Crown use.[124] DITR also pointed out that the Government does not wish to retain ownership of intellectual property in the research it funds, but instead expects grantees to undertake commercialisation. Under this policy, the government funds research, while commercialisation of any resulting intellectual property is left to the private sector. DITR noted that the private sector possesses greater expertise and experience in commercialisation than government.[125]

ALRC's views

12.126 March-in rights are aimed at allowing the government to step in and commercialise a patented invention where an institution has failed to do so. The

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119 Ibid.
120 AusBiotech Ltd, *Submission P58*, 7 November 2003; Queensland Government, *Submission P57*, 5 January 2004.
121 Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003.
122 Queensland Government, *Submission P57*, 5 January 2004.
123 GlaxoSmithKline, *Submission P33*, 10 October 2003. See also AusBiotech Ltd, *Submission P58*, 7 November 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003.
124 Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003.
125 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

government might also use these rights to take title to an invention and assign it to another organisation that is likely to commercialise it more effectively. For a variety of reasons, the ALRC does not consider it necessary to accord the Australian Government residual rights in intellectual property from publicly funded research. First, the ALRC concurs with the view expressed in a number of submissions that the government is not well placed to develop gene patents commercially. This is in part because the Government is neither structured to do so; nor do Government agencies generally have the commercial skills and experience to negotiate with industry to develop patented technology.

12.127 By contrast, publicly funded research institutions have been developing their capacity to undertake commercialisation over the past decade, through skill-building and the creation of infrastructure. This includes the establishment of dedicated technology transfer offices employing staff with commercial experience, and the provision of a range of educational and networking programs.

12.128 Further, in Australia, commercialisation of gene patents is promoted through a wide range of measures, including the *National Principles* and the *Interim Guidelines* and other funding requirements, government funding focused on industry linkages and technology transfer, state government programs supporting biotechnology industry development and research institutional benefit sharing schemes. Given the level of support already provided by these measures, it is unlikely that a lack of commercialisation activity in research institutions is generally attributable to reluctance to commercialise. Instead, as discussed in Chapter 18, commercialisation is better promoted through continuing financial and educational support programs to provide monetary support and raise commercialisation skills.

12.129 In addition, Proposal 12–3 is intended to allow funding bodies the option to place conditions on research grants where it is thought that public benefit will be maximised by not patenting the research results. The ALRC anticipates that this option would be utilised very sparingly but it does allow for one of the purposes of march-in rights to be achieved without the need for the government to retain residual rights.

12.130 Finally, the ALRC considers that there are already a number of mechanisms available for addressing some of the concerns at which march-in rights are directed, for example, restrictions on access to significant patented technology or a failure to exploit a patented invention appropriately. These include the compulsory licensing and Crown use provisions under the *Patents Act*.

12.131 However, the ALRC also recognises that these mechanisms may have been of limited use to date in some contexts and may not provide a complete solution to the issues raised in this chapter. For example, the Crown use provision under the *Patents Act* enables the Government to exploit a patented invention itself, or authorise another person to do so. To some extent, this provision gives the Government powers similar to those provided under the *Bayh–Dole Act*. However, Crown use is more limited than the march-in rights provided under the United States Act, as it only extends to use for the

services of the Commonwealth or a State.[126] These mechanisms, and proposed reforms for addressing some of these limitations, are discussed in Chapters 26 and 27.

Government contracted research

12.132 Although it is Australian Government policy for researchers or institutions whose research has been publicly funded to own any intellectual property generated by that research, this is not necessarily the case for research that is contracted by government. It is frequently a condition of a contract with a government department that the government retains any intellectual property rights.

12.133 For example, the Department of Health and Ageing indicated that it retains intellectual property rights in research that it has funded to ensure that relevant information can be widely disseminated. In these cases the Department grants non-exclusive licences to the intellectual property.[127]

12.134 IP 27 asked about the implications of the Government retaining ownership of intellectual property arising from contracted research.[128] A number of submissions objected to the Government retaining intellectual property in contracted research suggesting it was not best placed to commercialise patented genetic technology or ensure public benefits. AusBiotech Ltd stated:

> If the government retains intellectual property in research carried out pursuant to a contract, it may be that licensees will not be actively sought, and any inventions, which arise will not be developed for the benefit of the community. Further information on the outcome of government contracted research is needed. Once again, the global impacts, and Australia's ability to compete on international markets, also need to be considered in relation to this matter.[129]

12.135 Dr Amanda McBratney and others commented:

> IP is far better off being in the hands of the University commercialisation companies than with a government department. The government has limited ability to commercialise technology (i.e. resources, ideology, risk appetite). By retaining intellectual property rights, commercialisation is, at best delayed, and at worst stifled altogether. Retention of rights where the Government had a proven mechanism for exploiting the results would be another matter, but this is not the current situation. The

126 See further Ch 26. There are also a number of practical concerns about the efficacy of compulsory licensing as a solution in this context. No compulsory licences have been granted in Australia to date. In part, this may stem from costs involved in applying to a court for a compulsory order, or the difficulty in satisfying the legislative test for such an order. Compulsory licences may also be difficult to acquire because of pressure on governments from major trading partners. However, several commentators have suggested that the threat of compulsory licensing can encourage patent holders to negotiate a voluntary licence. See further Ch 27.

127 Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.

128 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 5–4.

129 AusBiotech Ltd, *Submission P58*, 7 November 2003.

likely outcome would be additional expense for government (patent expenses and additional staffing) and less community welfare outcome.[130]

ALRC's views

12.136 The ALRC has insufficient evidence about government contracted genetic research to make a specific proposal. It notes with approval the Department of Health and Ageing's response that it seeks to disseminate widely the results of contracted research. However, where public benefit would be maximised through commercialisation of research, then the government may not be best placed to do this. In such circumstances, the government may need to ensure policies are in place to promote appropriate commercialisation.

130 A McBratney and others, *Submission P47*, 22 October 2003. See also Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

13. Patents and Human Genetic Research

Contents

Introduction

13.1 The Terms of Reference direct the ALRC to consider the impact of current patent laws and practices related to genes and genetic and related technologies on the conduct of research. This chapter considers whether gene patents may have a 'chilling effect' on the conduct of research and, if so, in what situations this effect may be evident and what reform options may address this concern.

13.2 Research may be conducted at all stages of the continuum from basic research to research directed towards marketable end products. This chapter begins by briefly describing the research continuum, and the different interests of those involved in 'upstream' and 'downstream' research and inventions, and the different ways in which they may experience the impact of patent laws and practices.

13.3 The chapter discusses the general impact of gene patents on research, with reference to Australian and international empirical studies and the views expressed in submissions to this Inquiry and elsewhere.

13.4 The chapter then describes the specific subject matter and claims of gene patents that are most likely to hinder research—that is, broad patents on upstream or 'foundational' inventions. Patents on research tools are discussed in detail, with particular reference to the licensing of research tools, 'reach-through' licence agreements, and patents on isolated genetic materials.

13.5 The primary focus of this chapter is the impact of gene patents on basic or upstream research. Subsequent chapters examine the effects on downstream research environments and the commercialisation of patented inventions. For example, Chapter 15 describes the concept of the patent 'anti-commons' and examines the extent to which patent thickets and royalty stacking may hinder the commercialisation of research.

The research continuum

13.6 The terms 'upstream' and 'downstream' are commonly used to describe two ends of a continuum from basic research through to research directed toward marketable end products or processes.[1] Dr Dianne Nicol and Jane Nielsen have observed:

> The nature of biomedical research is that it is conducted on a cumulative basis: much basic research forms the foundation for later research and there are many steps between initial pioneering research and what consumers would consider to be end products.[2]

13.7 For example, in human genetic research, basic research may involve the identification of genetic sequences associated with particular biochemical functions. Downstream research may focus on the eventual use of these genetic sequences in the diagnosis of genetic disease or in novel therapies, such as gene therapy or the production of therapeutic proteins. Many steps may be involved before this end is reached:

> Different stakeholders conduct research at each stage of the research spectrum, developing products, methods or technologies that can be characterised as inputs into subsequent steps in the development of drugs, therapies, and diagnostic methods.[3]

13.8 Patents may be issued at different stages of the research continuum. Researchers developing downstream products will require access to patented inventions, including research tools. Access to many patented inventions may be required in order to develop a marketable product. While downstream researchers may view such inventions as essential research inputs to which open access is important, upstream patent holders may view research tools as valuable end products in themselves.[4]

13.9 It follows that the implications of patent reform may be quite different for different actors in the research and biotechnology sectors. For example, while small or

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1 See, eg, D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 15.

2 Ibid.

3 Ibid.

4 See R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 228–229; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 15.

start-up biotechnology firms may need patents on upstream discoveries in order to attract investors, for pharmaceutical companies, patents are needed not to raise capital but to ensure an effective commercial exploitation of their products.[5]

13.10 It has been suggested that patents have 'created an economic division in the research community' between those who benefit from and those who are hindered by such patents, particularly with regard to research tools. John Barton states:

> Those who benefit include universities and certain biotechnology firms. Now that universities and public institutions are encouraged to file for patents on their inventions, they often seek such patents on their fundamental innovations, and may seek to exercise these patents against those who might use the technologies in their research. Many biotechnology firms also support research-tool patents. These firms acquire such patents, either though their own research or by taking licences from universities … The opposing side, which includes many scientists and the pharmaceutical industry itself, is more doubtful about the wisdom of certain genomic and research-tool patents. This section of the industry would like to have complete freedom to use all the available research tools in order to be able to identify possible products.[6]

13.11 The changing nature of research institutions is another important background factor in considering the impact of patent law and practice on research. As discussed in more detail in Chapters 11 and 12, Australian Government policy is to promote the commercialisation of publicly funded research, including that conducted by universities. Traditionally, upstream research has been the province of the public sector, and the private sector has focused more on the downstream application of that research.[7]

13.12 In the United States, similar government policies have encouraged universities and other recipients of public research funding to patent the results of their research. As a consequence, there has been 'a dramatic increase in patent filings from institutions that, in an earlier era, were more likely to make their discoveries freely available'.[8] Professor Rebecca Eisenberg notes:

> Two dimensions of this change are particularly relevant to current problems surrounding the exchange of research tools. First, it has expanded and diversified the type of *institutions* claiming proprietary rights in their discoveries, as academic and nonprofit institutions have established technology exchange offices to patent faculty inventions and market them to commercial firms. Secondly is a corresponding expansion and diversification in the types of *discoveries* that are the subject of

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5 R Eisenberg, 'Patenting Research Tools and the Law' in National Research Council (ed) *Intellectual Property Rights and Research Tools in Molecular Biology, Summary of a Workshop Held at the National Academy of Sciences, February 15-16* (1996), <http://books.nap.edu/html/property>.

6 J Barton, 'Research Tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the World Health Organization* 121, 122.

7 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 15.

8 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 226–227.

> proprietary claims to include the early-stage discoveries, considerably removed from product development, that typically emerge from government-sponsored biomedical research.[9]

13.13 A 1998 study by the United States National Institutes of Health (NIH) Working Group on Research Tools found evidence that American universities are hindering the free exchange of basic research tools, such as genetic sequences and reagents, while making similar complaints about industry. The study found that universities impose conditions on the use of their research tools, such as insisting on vetting manuscripts before publication and claiming future discoveries derived from the use of their research tools.[10] Eisenberg has observed that, in the United States:

> Universities have embraced the patent system as patent owners and have been in the vanguard of claimants seeking patents on 'upstream' research discoveries that would have looked too far removed from the commercial marketplace to qualify for patent protection just a generation ago … Universities have barely begun to contemplate the patent system's implications for their interests as users of the patented technology of others.[11]

13.14 These changes, which also apply in Australia, mean that academic and non-profit research institutions increasingly have interests not only as potential users of patented inventions, but also as patent holders. Australian research institutions actively use the patent system in order to obtain protection for their inventions and routinely seek to license these rights to commercial organisations and enterprises.[12]

Impact of gene patents on research

13.15 The major debate in this area revolves around whether gene patents have a chilling effect on research and innovation, rather than promoting them. Two reasons are generally advanced for this possible effect. The first is that research may be hindered by researchers' concerns about infringing patents or about the difficulties of obtaining licences to use patented inventions on appropriate terms. The second reason, discussed in Chapter 15, is that researchers may be reluctant to put information about research outcomes into the public domain because of the potential to commercialise their own research.

13.16 Whether patent laws are the best means of encouraging research and innovation in knowledge-based areas, such as medical research, has been a matter of debate. The United Kingdom Commission on Intellectual Property Rights observed that, in contrast to the model for developing patented consumer products, which are most often the outcome of a 'linear research process':

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9 Ibid, 226–227.

10 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

11 R Eisenberg, 'Patent Swords and Shields' (2003) 299 *Science* 1018, 1019.

12 Davies Collison Cave, *Submission P48*, 24 October 2003.

> [in] many industries, and in particular those that are knowledge-based, the process of innovation may be cumulative, and iterative, drawing on a range of prior inventions invented independently, and feeding into further independent research processes by others. Knowledge evolves through the application of many minds, building often incrementally on the work of others … Moreover much research consists of the relatively routine development of existing technologies. For instance, gene sequencing, formerly a labour intensive manual technique, is now a fully automated process, involving little creativity.[13]

Empirical studies

13.17 Whether the proliferation of upstream intellectual property claims in rapidly advancing fields of technology such as genetics promotes or retards research and innovation has been described as 'an empirical question of considerable complexity'.[14] The Organisation for Economic Co-operation and Development (OECD) has referred to the 'conspicuous absence of rigorous economic studies' that explore the impact of gene patents on research.[15]

13.18 There have been some limited empirical studies about the impact of gene patents and licences on research. In general, their conclusions have been equivocal. For example, a study in the United States by John Walsh, Ashish Arora and Wesley Cohen (the Walsh study) noted that, while the patenting of upstream discoveries had increased, almost no-one reported that worthwhile projects had stopped because of restrictions on access to intellectual property rights for research tools.[16] Instead, the Walsh study found that most researchers, both in universities and industry, had adopted 'working solutions':

> These working solutions combine taking licenses (ie successful contracting), inventing around patents, going offshore, the development and use of public databases and research tools, court challenges and using the technology without a license (ie infringement), sometimes under an informal and typically self-proclaimed research exemption.[17]

13.19 In 2002, the OECD Working Party on Biotechnology Report (OECD Report) identified a number of issues concerning the possible adverse impact of gene patents on research, including blocking patents or overly broad patents; increases in secrecy and a slower pace of research; increased research and transaction costs; and increased

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13 Commission of Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (2002), 124.

14 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 223.

15 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 82.

16 J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285, 331.

17 Ibid, 331.

litigation involving public research organisations.[18] Despite documenting some specific concerns held by researchers,[19] the OECD Report did not substantiate fears that growth in the number and complexity of biotechnology patents is preventing access to inventions for research purposes.

13.20 In Australia, Dr Dianne Nicol and Jane Nielsen of the University of Tasmania have recently completed an empirical study of medical biotechnology patenting (the Nicol-Nielsen Study).[20] They analysed 49 written survey responses from respondents from private sector biotechnology and pharmaceutical companies, 23 from research institutions and 18 from diagnostic testing facilities, together with the results of 40 targeted interviews.[21]

13.21 While it is hard to draw firm conclusions from these empirical studies, their specific findings and conclusions are important in understanding how the impact of gene patents on research is perceived by researchers and others. These are discussed throughout this chapter.

Submissions and other views

13.22 The ALRC received a wide range of comments in submissions concerning the impact of gene patents and licensing on the conduct of research. Many submissions maintained that there is no current evidence that gene patents are inhibiting research in Australia.[22]

13.23 Some of these submissions focused on the benefits of patent protection for research. For example, AusBiotech Ltd submitted:

> There is no real evidence that gene patents or licences are inhibiting research in biotechnology in Australia. To the contrary, the flexibility of the Australian Patents Act, the availability of patents in this field and the resulting opportunity to obtain research funding from commercial sources has been an enormous boost to research in Australia in this field. This would not be possible if patent protection were not available.[23]

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18 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 12–15.

19 For example, about the impact of reach-through licensing agreements: Ibid, 79.

20 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6.

21 Ibid, 64–71.

22 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

23 AusBiotech Ltd, *Submission P58*, 7 November 2003.

13.24 Dr Amanda McBratney and others stated that in their experience the patent system allows further investment into areas of human health:

> Medical research cannot exist on government funding alone. In Australia, there is simply not a large enough tax base to provide the amount of funding required for wide-spread top level research. In many cases, the existence of gene and other biotechnology patents has attracted crucial financial support from the biotechnology and pharmaceutical industries (as well as private investors) and has allowed the continuation of medical research.[24]

13.25 The Walter and Eliza Hall Institute of Medical Research stated that patents have a major potential impact on the biotechnology industry, since they define the freedom to operate in certain areas. In relation to patents over isolated genetic materials the Institute observed:

> To date academic research in Australia has been largely unaffected and it is essential that this freedom continues.[25]

13.26 One reason for suggesting that research is not inhibited by gene patents is that 'researchers are often oblivious to the patent rights held by commercial entities'.[26] Dr McBratney and others stated:

> Moreover, even where research may infringe patent rights, the absence of infringement proceedings in Australia and the lack of enforcement of such rights by industry suggests that gene patenting is not in fact stifling innovation—at least in Australian universities.[27]

13.27 Other submissions were more equivocal. The South Australian Government suggested that, while gene patents do not appear to have an adverse effect on research to date

> this appears to be because patents are not being enforced rather than because they either encourage or inhibit biotechnology research. The successful enforcement of one patent could lead to a change in this situation which would result in a significant cost to research institutions and government.[28]

13.28 Dr Graeme Suthers suggested that while there may be no evidence that research is being hindered by gene patents 'the field is very new and there has been little time to observe such impact'.[29] The Royal College of Pathologists of Australasia (RCPA)

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24 A McBratney and others, *Submission P47*, 22 October 2003.
25 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.
26 A McBratney and others, *Submission P47*, 22 October 2003. Issues surrounding infringement by researchers and their reliance on legal and normative research exemptions are discussed in more detail in Ch 14.
27 Ibid.
28 South Australian Government, *Submission P51*, 30 October 2003.
29 G Suthers, *Submission P30*, 2 October 2003.

made the same observation and noted that it is not appropriate 'to stand back and wait for problems to occur'.[30]

> The ALRC must learn from the overseas experience and evaluate not only the previous or current problems but also the potential problems.[31]

13.29 The National Health and Medical Research Council (NHMRC) noted comments from members involved in the research sector that the complexities of the patent system may have a 'dampening' impact on research, particularly where organisations lack expertise in intellectual property management.[32]

13.30 Other submissions highlighted possible adverse impacts on research.[33] The Australian Health Ministers' Advisory Council referred to difficulties arising in 'negotiating commercially viable licences with patent holders in order to explore the development of alternative technologies in relation to an already patented gene'.[34] The RCPA stated that:

> Excessively broad patents, particularly on an upstream discovery, can block or place severe constraints on the ability of others to develop new tests or therapies that build on the patented discovery or invention. There is evidence that such practices have inhibited research in biotechnology.[35]

13.31 The Nicol-Nielsen Study provides other views on patents and research in biotechnology. Respondents from research institutions had predominantly positive views about the impact of patents on research and development.[36] Respondents in biotechnology companies also viewed the impact of patents on their research positively.[37] However, Nicol and Nielsen found that all sectors of the biotechnology industry had greater concern about the potential for gene patents to have a negative impact on research than for any other types of patents.[38]

13.32 Consistently with comments made in submissions to this Inquiry, warnings were sounded about the future. Nicol and Nielsen note that, as Australian companies and institutes gain an international presence, they may attract more attention from patent holders. While vigorous patent enforcement has not been typical:

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30 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
31 Ibid.
32 National Health and Medical Research Council, *Submission P52*, 31 October 2003
33 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.
34 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.
35 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
36 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 85.
37 Ibid, 84–85.
38 Ibid, 90.

> this is something that seems certain to change. Both overseas and Australian companies are starting to take a more aggressive approach to enforcement … The issue of restricted access to patents is therefore an important issue for the Australian industry. Even though a considerable amount of upstream research is conducted by the Australian industry, respondents in all of the sectors we investigated, frequently require access to upstream patents.[39]

13.33 Nicol and Nielsen conclude that there has been some evidence in Australia of exclusionary practices in relation to biotechnology patents. This is not surprising, as the right to exclude others from exploiting a patented invention is fundamental to patent protection. Nicol and Nielsen conclude:

> Our data demonstrates that there has been some evidence of restricted access to patents within the industry … However, it is probably fair to say that few of our respondents were concerned at the long-term effects of restricted access, and in most cases research was able to proceed albeit in a modified fashion.[40]

Broad patents

13.34 A specific category of concern in relation to research has been on what may be described as broad patents—patents that grant broad rights to the patent holder and which may be seen as covering applications invented later by someone else.

13.35 IP 27 noted that, unless widely licensed, broad patents could discourage further research and innovation either because researchers will be concerned about breaching existing patents or because downstream inventors will have to pay licence fees or royalties to those whose patents were granted first.[41] By contrast, a narrowly expressed patent may encourage others to 'work around' the patent, thereby having less impact on related research. Submissions confirmed a level of concern about the impact of broad patents on research.[42]

13.36 As discussed in Chapter 6, when gene patents are described as 'broad', the intended meaning may vary. Genetic discoveries often occur from the top down—that is, the discovery of the gene often precedes discovery of its constituent parts, proteins and functions.[43] As a consequence, patents covering an isolated genetic sequence are the most upstream category of gene patent.[44] Concern about the impact of broad gene

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39 Ibid, 140.

40 Ibid, 172.

41 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003) [11.13].

42 For example, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

43 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 42.

44 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 359.

patents on the conduct of research is most often expressed in relation to these kinds of gene patents.

13.37 Where gene patents contain 'product per se' or 'composition of matter' claims over isolated genetic materials (such as DNA sequences), the patents may be considered broad because all uses of the product may be covered by the patent:

> In analysing gene patents such as the BRCA patents, we have seen that claims are made to gene sequences, gene products, therapies, drugs and diagnostics. Patents that are cast in these terms effectively give the patent holder the exclusive right to control all downstream uses of the gene sequence, including commercial research and development of tests, therapies and drugs.[45]

13.38 Other gene patents do not claim isolated genetic materials but may nevertheless be considered broad because the claims—for example, over the diagnostic use of a DNA sequence—allow the patent holder, in effect, to assert rights over the DNA sequence itself because any other diagnostic test for the disease specified in the claim would infringe the patent.[46]

13.39 The Nicol-Nielsen Study examined the views of respondents on 'patent breadth and its impact on innovation'.[47] Seven of 23 research institution respondents, and similar proportions of other categories of respondent, said patent breadth had some negative impact on research.[48] Nicol and Nielsen observe that:

> There is clearly a theoretical link between patent breadth and limitations on research, and it is often impossible to provide adequate rewards to both basic inventors and follow-on inventors. Despite this, most respondents were fairly optimistic about their ability to continue research despite the presence of broad patents, and felt that the problem of broad patents was dissipating as patent offices tightened up their examination procedures.[49]

13.40 In the research context, patents may also be considered 'broad' because they cover a generally applicable research technique or resource. Such patents are better referred to as 'foundational' inventions because the subject matter is the basis for a wide range of further potential discoveries and inventions.[50] Foundational inventions are discussed below in the context of research tools.

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45 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 36.

46 See, eg, B Cain, *Legal Aspects of Gene Technology* (2003), 121–122; Ch 5.

47 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 86.

48 Ibid, 87.

49 Ibid, 89.

50 See, eg, Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 12.

Patents and research tools

13.41 The single most important concern has been about the effects on research of patents on genetic materials or technologies that are used as research tools. The literature in Australia and overseas expresses a range of concerns about the impact of patents on the use of research tools. The following material examines these concerns, some of which relate to research tools generally and some of which relate to those used in genetic research specifically—and in particular the use of isolated genetic materials.

13.42 IP 27 asked for comments on the impact of patent law and practice, including the terms of licensing agreements, on access to research tools, and in particular to expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs) and other isolated genetic materials. Comments from submissions to the Inquiry are also discussed.

13.43 In order to assess the significance of the concerns and possible means of addressing them, it is important to distinguish between the types of products and processes that may be referred to as research tools and the different meanings that may be given to this term.

What are research tools?

13.44 In IP 27, the ALRC defined research tools as the wide range of resources used by scientists in their laboratories, where those resources have no immediate therapeutic or diagnostic value. In biotechnology, research tools may include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools, methods, laboratory equipment and machines, databases and computer software.[51] In the context of genetic technologies, the OECD Report noted that the term research tool can be used to include genomics databases, DNA chips, recombinant DNA technology, polymerase chain reaction (PCR), combinatorial libraries, genes and receptors, and even transgenic mice.[52]

13.45 There are many different ways to categorise research tools used in genetic research. For example, three basic categories are:

- Research techniques. Some gene patents cover laboratory techniques that molecular biologists use in genetic research, such as the Cohen-Boyer techniques and the PCR methodology.

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51 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

52 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 50: 'A good proportion of the entire range of biotechnology can fall under this term'.

- Research consumables. Some gene patents cover particular enzymes or reagents that are used in the laboratory, such as Taq polymerase (used in PCR) and restriction enzymes (used in cloning and other applications).

- Research targets. Some gene patents cover genetic materials that are targeted in research, for example genes for receptor proteins used in designing new drugs or vaccines, such as the HIV-receptor CCR5.[53] This category also includes ESTs and SNPs, which can be targets of research or used to target other genetic materials.

Foundational research tools

13.46 In considering their impact on research, it is useful to distinguish foundational or upstream research tools from other research tools. The most important research tools are said to be

> fundamental research platforms that open up new and uncharted areas of investigation. These platforms can most fruitfully be developed by a variety of follow-on researchers. … a single patent holder is unlikely to see the myriad directions in which a broadly enabling research platform could be developed.[54]

13.47 Foundational inventions are of such importance that all or much that follows in the relevant field flows from them.[55] Examples include the Cohen-Boyer[56] and PCR[57] patents. The Cohen-Boyer technique has been described as a 'quintessential' research platform in that these recombinant DNA techniques were used in many different ways by many researchers.[58] Other research tools, including research consumables and some research targets, are not of this nature. For example, while genetic material used in diagnostic testing for a particular disease may be used in future research, it is unlikely to open up any significant new research field.[59]

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53 Receptor proteins are proteins that are found on the cell-surface. Upon binding a ligand, they set off a signal reaction inside the cell inducing a response. Many viruses gain entry to the cell by sticking to (or 'docking') a receptor protein. The CCR5 gene makes a receptor protein that the HIV virus uses as a docking receptor to gain access to an immune cell.

54 A Rai, 'Genome Patents: A Case Study in Patenting Research Tools' (2002) 77 *Academic Medicine* 1368, 1369.

55 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 12.

56 The Cohen-Boyer patents described a gene-splicing technique and were an important foundation of recombinant DNA technology. The patents expired in 1997.

57 The PCR technique enables a single piece of DNA to be copied exponentially and is used in most molecular biology laboratories.

58 'The clearest contemporary example of a research platform is probably human genetic stem cell lines': A Rai, 'Genome Patents: A Case Study in Patenting Research Tools' (2002) 77 *Academic Medicine* 1368, 1369.

59 Ibid, 1369.

13.48 A more recently developed genetic technology that might be characterised as foundational is RNA interference (RNAi).[60] Concerns about the impact of patents on foundational inventions were encapsulated by the following comments by the Medical Genetics Elective Group of the University of Newcastle:

> The area covered by these patents is at the cutting edge of research. The owners have the power to limit or extend the amount of research done. By their selectivity in granting licences, they may slow, or even halt, the discovery of further beneficial mechanisms of RNAi technology not only in mammals but also in plants and other organisms. A further means of selectivity of who performs research in this area is the cost of the licences. Small universities or hospital-based research laboratories may not be able to afford the privilege of conducting studies in this area, again limiting the progression of RNAi research.[61]

13.49 There is no bright line between foundational research tools and other tools. Further, the characterisation of a specific research tool may vary with time. As explained by Professor Arti Rai:

> Distinguishing broad research platforms from more downstream research is difficult … For example, it is not clear whether genes encoding receptors or enzymes that may be useful as drug targets should be considered research platforms … Once [the CCR5 gene] had clearly been identified as the HIV-receptor gene, the gene probably did not represent a broad research platform. When a gene has been fully characterized, it's difficult to say that the research in that area is really inchoate or uncharted. On the other hand, at the time that [the patent holder] isolated the gene, much less was known about it. At that point, the gene plausibly could have been thought of as a research platform. The arguments for thinking of targets as broad research platforms is bolstered by the fact that some targets may play roles in different disease pathways. Identifying a target's role in one disease pathway should not necessarily give the patent owner plenary rights over all uses of the target.[62]

13.50 The Walsh study suggests that if a research tool is foundational, the extent to which restricted access is likely to hinder progress in research will depend on whether the tool can be used in the development of a number of inventions that will eventually compete with one another. If a foundational invention is fundamental to competing downstream research applications, access is more likely to be restricted in some way, for example, through exclusive licensing. The problem then is that:

> exclusive exploitation of a foundational discovery is unlikely to realize the full potential for building on that discovery because no one firm can even conceive of all the different ways that the discovery might be exploited, let alone actually do so.[63]

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60 RNA-mediated interference is the inhibition of expression of specific genes by double stranded RNA (dsRNA): E Milward and others, *Submission P46*, 20 October 2003.

61 Ibid.

62 A Rai, 'Genome Patents: A Case Study in Patenting Research Tools' (2002) 77 *Academic Medicine* 1368, 1369.

63 J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285, 333. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 55.

13.51 Nicol and Nielsen state that 'more prolific patenting' of research tools sets up the main precondition for the concern that research may be impeded.[64]

> Two further preconditions may exacerbate the problem. First, broad interpretation of claims on upstream foundational discoveries may extend the reach of upstream patents and deter downstream innovators from researching in what they perceive to be a broad area of research. Second, reach-through rights to future inventions (for example, a right to a compound that acts on a patented target even though the compound itself is not described in the patent claims) could deter subsequent innovation.[65]

13.52 There are important differences between the Australian and United States research environments which are relevant to the impact of patents on foundational research tools. The Nicol-Nielsen Study investigated the patent status in Australia of a number of foundational biotechnology patents that have been mentioned in the literature as being problematic. The study found that, in many cases, the patents had not been filed or granted in Australia, meaning that certain avenues of research may not be as restricted in Australia as in the United States.[66]

Research tools and end products

13.53 One characteristic of genetic research is that patents are commonly held over genetic materials and technologies needed for further research, as well as over the ultimate products of research, like diagnostic tests and pharmaceuticals.

13.54 IP 27 noted that one institution's end product may be another institution's research tool. Further, some research tools have uses other than in research. For example, a patented DNA sequence may be used as part of a diagnostic test, as well as research to understand better the role of the relevant gene in disease. As Professor Eisenberg, who served as Chair of the NIH Working Group on Research Tools,[67] has noted:

> The term 'research tool' would seem to connote a user perspective, indicating something that is not yet an end product and has its primary value as an input into further research. Yet a user's research tool may be a provider's end product.[68]

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64 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 54.

65 Ibid, 54. In this context, reach-through rights are rights that derive from the patent claims themselves, as distinct from rights negotiated in reach-through licence agreements.

66 Ibid, 41–49.

67 See National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

68 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 228. See also National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

13.55 Some biotechnology enterprises focus on developing, manufacturing and supplying research tools to researchers. In relation to genetics, Clarissa Long has stated:

> The core business of an increasing number of new market entrants is information about the genetic codes of various organisms, not the sale of drugs or diagnostics.[69]

13.56 To these organisations, research tools are commercial end products. They have a strong commercial interest in full recognition of intellectual property rights over them. Further, institutions that obtain a competitive advantage from proprietary research tools will be unwilling to make them freely available and may seek to limit access, restrict use or delay disclosure of research results.[70] Eisenberg has observed:

> Institutions tend to be high-minded about the importance of unfettered access to the research tools they want to acquire from others, but no institution is willing to share freely the materials and discoveries from which they derive significant competitive advantage. Thus many of the people that spoke with the Working Group were eager to establish that the term 'research tool' means something other than their own institution's crown jewels.[71]

Use and licensing of research tools

13.57 Access to patented research tools is largely dependent on the availability and terms of licences granted by patent holders to researchers who wish to use them during the term of the patent. As discussed in Chapter 23, licensing is a means by which a person may use a patented product or process with the agreement of the patent holder, who would otherwise have exclusive rights to use the invention. It is also a means of transferring knowledge from an inventor to a researcher who wishes to make use of the invention, or to a party wishing to commercialise it.

13.58 There are many models for licensing research tools and other patented inventions. The following material highlights some aspects of licensing practice, as applied to the licensing of research tools in Australia and overseas. Other aspects of licensing are discussed in Chapter 23.

13.59 Licences may be exclusive or non-exclusive. For example, the Cohen-Boyer patents held by the University of California San Francisco and Stanford University were subject to the grant of multiple, non-exclusive licences in return for minimal

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69 C Long, 'Re-engineering Patent Law: The Challenge of New Technologies: Part II: Judicial Issues: Patents and Cumulative Innovation' (2000) 2 *Washington University Journal of Law and Policy* 229, 233.

70 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

71 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 229.

licence fees. This licensing strategy meant that potential infringers were inclined to obtain licences, which led to broad distribution of the technology.[72] One view is that:

> The dominance of these patents did not inhibit further development but instead spurred further innovation while providing profits to the patent owner.[73]

13.60 Alternative strategies for university based patent holders include granting an exclusive licence to a biotechnology company that can then develop and apply the technology, making it available by contract to other biotechnology enterprises. Firms with such business plans 'offer services such as the use of genomic array chips, procedures for producing a large variety of candidate drug compounds, and use of proprietary cell culture or identification techniques'.[74]

13.61 Licensing models may provide rights to use research tools with the purchase of products, rather than by a direct licence agreement. This is the model applied to PCR, where the Taq polymerase that is required for PCR is purchased from a biotechnology company licensed to manufacture and sell the enzyme. The purchase price includes limited non-transferable rights to use that product for research purposes only. Further, for PCR to be authorised it may have to be performed in thermal cyclers purchased from a licensed supplier.[75]

13.62 It is not uncommon for patent holders to distinguish between academic and commercial researchers in applying a licensing strategy. Licences granted for academic research may involve much lower fees than research licences granted to commercial entities or where the same patented invention is licensed for therapeutic or diagnostic use. For example, access to the Cohen-Boyer patents was free to academic researchers, yet involved a substantial fee for commercial researchers. F.Hoffmann-La Roche Limited, the PCR patent holder, has established different categories of licence, depending on the application and the users. Research and development licences do not include a right to perform or offer commercial services of any kind using PCR.[76]

13.63 Australian biotechnology companies have also distinguished between academic and commercial research in their patent licensing practices. In July 2003, Genetic Technologies Limited (GTG) granted a licence to the University of Sydney to use GTG's patents on methods of using non-coding DNA polymorphisms[77] (GTG's non-coding patents) in basic research for the remaining duration of the patents. GTG noted

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72 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 3.

73 Ibid, 3.

74 J Barton, 'Research Tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the World Health Organization* 121, 122.

75 Qbiogene, *Patent Information for PCR Products*, <www.qbiogene.com/products/pcr/patent.shtml> at 25 August 2003. Thermal cyclers are machines specifically designed to perform the PCR. They are capable of rapidly heating and cooling reaction tubes to specific temperatures. The PCR requires rapid cycling between approximately 50 and 95 degrees and so must be performed in a thermal cycler.

76 Ibid.

77 Sometimes also referred to as GTG's 'intron sequence patents'.

that the $1000 fee was 'several thousand-fold' less than the fee for similar licences granted to 'pure commercial entities'.[78]

Reach-through licence agreements

13.64 Licence agreements for the use of research tools may contain 'reach-through' provisions. Reach-through licence agreements may give the patent holder ownership, licence rights or royalties in relation to future discoveries made by licensed researchers.

> In effect, this approach calls for payment in future intellectual property rights or royalties on future products in lieu of cash. The primary motive for these reach-through provisions appears to be to obtain something of value for the firm in exchange for the contribution of a valuable asset. Recognizing that most academic users will not discover anything of commercial value, the owner of the tool seeks to recover a substantial profit in the rare case when a valuable discovery is made in order to cover the costs of all the other, unprofitable transfers.[79]

13.65 Reach-through licence agreements may offer advantages to both patent holders and researchers.

> They permit researchers with limited funds to use patented tools right away and defer payment until the research yields valuable results. Patent holders may also prefer a chance at larger payoffs from sales of downstream products rather than certain, but smaller, upfront fees.[80]

13.66 The NIH Working Group on Research Tools suggested that reach-through licence agreements are more often entered into where a research tool may be used directly to produce another product,[81] rather than in relation to 'more basic research tools that have a more remote relationship to commercial products'.[82]

13.67 Reach-through rights may be the best way for some patent holders to protect their investment. For example, where the patented invention is a molecule, its use provides significant competitive advantage in the search for therapeutic products and the ultimate therapeutic product is not covered by the patent:

> the firm will quickly lose its competitive advantage if the product is discovered elsewhere through use of the molecule as a research tool. A nonexclusive license to new uses may also be of little value in such a situation. Some firms will simply keep the proprietary molecule for their own exclusive use, or perhaps share it with commercial collaborators. If the firm makes the molecule available to a university

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78 Genetic Technologies Limited, 'Letter from GTG to Medical and Scientific Colleagues', *Press Release*, 21 July 2003, <www.gtg.com.au/Announcements.html>.

79 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

80 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

81 For example, a drug screening tool or a cell line that is used to produce an antibody.

82 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

> scientist, the only way to ensure that it is not undermining its own proprietary advantage may be to secure some form of reach-through rights to future discoveries.[83]

13.68 However, researchers may perceive reach-through rights as having the potential to benefit patent holders disproportionately, in the event that research outcomes may be commercialised. Further, the existence of reach-through rights may prejudice researchers' later technology transfer and commercialisation prospects. Potential commercial partners are likely to demand that intellectual property be unencumbered by competing interests.[84]

13.69 In the United States, Heller and Eisenberg provide examples of universities and other non-profit research institutions baulking at reach-through licence agreements for the use of research tools.[85] The DuPont Cre-lox gene-splicing tool is one such example.[86] This research tool was initially developed by Harvard University but licensed exclusively to DuPont Pharmaceutical Co, which required public sector researchers to sign agreements that limited their use of the technique and required pre-publication vetting of articles. DuPont also sought reach-through rights to future inventions that might result from experiments using the technique. These licence terms were said to give DuPont:

> the right to participate in future negotiations to develop commercial products that fall outside the scope of their patent claims. In effect, the license terms permit DuPont to leverage its proprietary position in upstream research tools into a broad veto right over downstream research and product development.[87]

13.70 Although some public sector institutions agreed to these terms, the NIH objected and the issue was resolved with a memorandum of understanding in 1998, which simplified access for public sector researchers in the United States.[88] One colourful criticism of this approach to reach-through rights stated that Cre-lox would be:

> no more an element of any eventual products or businesses that emerge … than a hammer is part of the eventual table it helps build … Some university licensing groups have come to call DuPont's approach the 'Steinway Piano Model'— 'If you sell me a piano, do you deserve royalties if I write a song on it?' asks one technology transfer official'.[89]

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83 Ibid.

84 See Ch 19.

85 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

86 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

87 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

88 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

89 N Freundlich, 'Cre-lox Controversy Divides Institutions, Prompts NIH Panel', *Signals Magazine*, 6 December 1998, <www.signalsmag.com>.

Infringing use of research tools

13.71 A range of commercial and practical factors are important in determining whether researchers seek to obtain licences from patent holders and, if not, whether patent holders enforce their rights against researchers. In practice, factors that influence whether researchers use patented research tools without obtaining a licence include 'the often secret nature of the experiments, the limited expectation of damages by a patentee, the significant cost of patent litigation, and the often limited impact on a patentee's commercial interests'.[90]

13.72 It can often be difficult to detect patent infringement. The use of research tools occurs behind laboratory doors, making infringement difficult to monitor.[91] For example, even in the case of Taq polymerase and the PCR patents, where a licence fee is incorporated into the purchase price of the product, some laboratories performing PCR or any other reaction reliant on enzymes may decide that it is cheaper to prepare their own enzyme. Such a process necessarily involves expression of a gene in a host cell before purifying the enzyme to make it ready for use in a biochemical reaction. This procedure is routine in molecular biology laboratories, even though it may infringe patent rights if the gene encoding the enzyme is the subject of a patent.

13.73 Researchers may be unaware of the legal implications of using patented research tools and, even if they are, the prospect of litigation may appear remote. As discussed in Chapter 14, researchers may assume that their use of research tools is exempt from claims of patent infringment. It has been suggested that, in practice:

> fear of litigation is low in the public sector, as research institutions usually generate no revenue through the use of the research tool and thus the patent owner has little incentive to sue. In short, many groups act as if an 'informal research exemption' exists for the use of patented research tools.[92]

13.74 Patent holders often tolerate academic research infringements. One recent study reported that some of the reasons patent holders may allow academic research to proceed unchallenged, include:

- the possibility that research would increase the value of the patent;
- the cost of a challenge;
- the risk that the patent itself would be narrowed or invalidated;
- the negative publicity from suing a university; and

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90 C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 16.

91 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 48.

92 Ibid, 48.

- a reluctance to upset norms of open access for fear of losing the goodwill of peers and associated access to materials and information.[93]

13.75 As discussed in Chapter 9, the remedies for patent infringement include injunctions and compensation in the form of damages, or an account of profits.[94] In the case of infringement by researchers, the most relevant remedy is likely to be an injunction to prevent further infringement. Damages or an account of profits will generally be relevant only where a product has been developed and sold. Most claims of infringement never reach the courts because the parties reach a settlement—possibly involving the payment of a licence fee.

Concerns about patents on research tools

Access to research tools

13.76 Concern has been expressed that patents on some research tools (particularly those referred to earlier as foundational research tools) can 'pre-empt large areas of medical research and lay down a legal barrier to the development of a broad category of products'.[95] It has been suggested that this result is highly likely in biotechnology because:

> there are so many broadly relevant patents; research builds on the use of so many prior discoveries; and solid and clear title to a product is so important to the pharmaceutical industry.[96]

13.77 The OECD Report referred to broad concern about the impact of research tool patents on collaboration and sharing of materials between researchers, stating that:

> the terms of licences or material transfer agreements—restricting publication and exchange of materials, demanding reach-through rights—can be such that they ultimately make collaboration and communication with other researchers more difficult.[97]

13.78 In Australia, the Nicol-Nielsen Study found that research tool patents were not considered to be particularly problematic by the majority of respondents.

> In our view this may be because industry participants in Australia may not yet have been faced with the aggressive enforcement practices of some research tool patent holders that have occurred in the United States, either because the relevant research

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93 J Walsh, A Arora and W Cohen, 'Working through the Patent Problem' (2003) 299 *Science* 1021. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 88–89: Some research institution respondents stated they were 'content to ignore relevant patents and challenge their validity if approached by the patent holder'.

94 *Patents Act 1990* (Cth) s 122(1).

95 J Barton, 'Research Tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the World Health Organization* 121, 122.

96 Ibid, 122.

97 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

> tools have not been patented in Australia or because attention has not yet been focused on the Australian industry.[98]

13.79 Their surveys found that refusals to license were not a pervasive issue within the industry.[99] However, researchers and companies stated that they avoided certain areas of research 'if patents were held by competitors, or if it looked like obtaining a licence might prove to be too problematic'.[100] In interviews, some respondents expressed frustration at difficulties in licensing-in enabling technologies, but they were greatly outnumbered by respondents who had not experienced any problems.[101]

13.80 In its submission to the Inquiry, the Queensland Government stated that Queensland universities are generally able to obtain fair and reasonable licences to use gene patents.[102] McBratney and others stated:

> We have no experience of research being hindered due to licensing or MTAs. Most researchers do not obtain licences for research purposes. They rely on a perceived exemption as a researcher and usually obtain the material through an MTA or produce it themselves.[103]

13.81 A common theme in consultations was that the marketplace is capable of solving most problems concerning access to patented research tools. A frequently cited example is PCR, where a number of different licensing models have been adopted by the patent holders as they responded to the reactions of potential licensees of the technology.[104]

Cost and delay

13.82 Patents on research tools may hinder research by requiring licence fees to be paid by researchers. From the perspective of researchers, the price demanded for use of a genetic invention may be too high.[105]

13.83 Researchers also face transaction costs in negotiating licences. Negotiations over access to technologies can be long and complicated, imposing delays and administrative burdens on research. Even if the total licence fees can be kept low, one

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98 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 92. Nicol and Nielsen caveat this conclusion with the observation that their data was collected before it became widely known that GTG was enforcing its non-coding patents, which may change views.

99 Ibid, 146.

100 Ibid, 147.

101 Ibid, 147.

102 Queensland Government, *Submission P57*, 5 January 2004.

103 A McBratney and others, *Submission P47*, 22 October 2003.

104 For example, Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003; M Simons, *Consultation*, Melbourne, 4 September 2003; Genetic Technologies Limited, *Consultation*, Melbourne, 5 September 2003.

105 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

'hold out' may be enough to cause a research project to be cancelled.[106] Researchers may choose not to pursue research using patented research tools where they have to navigate complex sets of patents held by a number of different patent holders.

13.84 In the United States, the NIH Working Group on Research Tools reported that 'many scientists and institutions involved in biomedical research are frustrated by growing difficulties and delays in negotiating the terms of access to research tools'.[107] The reasons for this included that the value of research tools is difficult to assess, and varies greatly from one tool to the next and from one use to the next—so providers and researchers are likely to differ in their assessments of the value of research tools. Users of research tools may also have limited resources for paying up-front fees and be reluctant to share profits from potential future discoveries (under the terms of licensing agreements) with institutions that do not share the risks and costs of product development.[108]

13.85 These complexities mean that case-by-case negotiation for permission to use research tools and materials may create significant administrative burdens, which delay research.[109] The NIH Working Group noted that efforts to standardise licence terms for research tools had experienced 'limited success' and that:

> Differences in the nature and value of research tools and differences in the missions and constraints of owners and users of research tools make it difficult and perhaps undesirable to standardize terms of access to research tools across the broad spectrum of biomedical research.[110]

13.86 Summarising information gathered from scientists, university technology transfer professionals, and private firms in the pharmaceutical and biotechnology industries, Eisenberg has stated:

> Within these communities, there seems to be a widely-shared perception that negotiations over the transfer of proprietary research tools present a considerable and growing obstacle to progress in biochemical research and product development. Scientists report having to wait months or even years to carry out experiments while their institutions attempt to renegotiate the terms of [Materials Transfer Agreements], database access agreements and patent license agreements.[111]

13.87 Eisenberg concludes that the exchange of research tools within the United States research community may cause delay in or abandonment of research.

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106 J Barton, 'Research Tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the World Health Organization* 121, 122.

107 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

108 Ibid.

109 Ibid.

110 Ibid.

111 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 225.

> Transaction costs have remained persistently high in this setting as the heterogenous institutions involved in the exchange of research tools have been unable to agree upon standardized contract language, or even to agree upon a universe of materials, information and techniques that are properly termed 'research tools'.[112]

13.88 In Australia, Nicol and Nielsen reported that a number of respondents had experienced difficulties in conducting negotiations, particularly in terms of delay:

> A respondent from an upstream company who had been involved in frequent deals estimated that it can take months to negotiate a licence, which can damage cash flow projections. In addition, some parties may be becoming increasingly difficult to deal with. About a third of our industry interview respondents commented that they were encountering difficulties dealing with universities, and that often the problem did not lie with the scientists who were often willing to provide unrestricted access to technology and materials, but with technology transfer or business management personnel. At the same time, a few respondents said that they felt the increased expertise within universities and in the industry generally was actually streamlining the negotiation process.[113]

Licence terms

13.89 Objections have been raised about the terms that may be proposed by patent holders in licensing agreements or Materials Transfer Agreements (MTAs).[114] These may include reach-through rights and restrictions on the publication of research results.

13.90 In the United States, reach-through rights are said to have led to some of the 'more intractable disagreements' about the terms of licensing agreements.[115] In Australia, the Walter and Eliza Hall Institute of Medical Research expressed concern about problems where materials suppliers 'seek inappropriate levels of control or commercial reach-through into the recipients' research activities'.[116]

13.91 Ultimately, it is up to patent holders and prospective licensees to reach mutually acceptable contractual terms. In some cases, patent holders have been unsuccessful in seeking to impose reach-through rights, for example in relation to the PCR patents, where reach-through rights were abandoned as a licensing model after strong resistance from downstream users.[117]

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112 Ibid, 248.

113 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 158.

114 MTAs are discussed in Ch 18.

115 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 230.

116 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

117 See M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

13.92 Nicol and Nielsen reported complaints from some respondents that patent holders over some research tools unreasonably demanded reach-through royalties.[118] They observed that a number of variables will determine whether or not reach-through rights to future inventions are likely to be included in a licensing arrangement:

- the nature of the technology or product being licensed;
- whether or not the licensed technology is core to the activities of the licensee; and
- the relative bargaining power of the negotiating parties.[119]

13.93 Heller and Eisenberg have suggested that while reach-through licence agreements may offer advantages in principle, in practice, reach-through licence agreements 'may lead to an anticommons as upstream owners stack overlapping and inconsistent claims on potential downstream products'.[120] Chapter 15 discusses issues relating to patents and the commercialisation of research by the biotechnology industry.

ESTs, SNPs and other types of tools

13.94 Particular concerns have been raised about patents over isolated genetic materials and the genetic sequences they contain. As discussed above, an important category of research tools comprises isolated genetic materials that are targeted in research or used to target other genetic materials. Such materials, and information about the genetic sequences they contain, are an important starting point for genetic research. The USPTO has noted:

> The characterization of nucleic acid sequence information is only the first step in the utilization of genetic information. Significant and intensive research efforts, however, are required to glean the information from the nucleic acid sequences for use in, *inter alia*, the development of pharmaceutical agents for disease treatment, and in elucidating basic biological processes.[121]

13.95 The USPTO summarised concerns about patents restricting access to the use of isolated genetic materials as research tools as follows:

> Many feel that by allowing genetic information to be patented, researchers will no longer have free access to the information and materials necessary to perform biological research. This issue of access to research tools relates to the ability of a patent holder to exclude others from using the material. Further, if a single patent

118 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 147.

119 Ibid, 166.

120 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

121 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 3.

> holder has a proprietary position on a large number of nucleic acids, they may be in a position to 'hold hostage' future research and development efforts.[122]

13.96 The United Kingdom's Nuffield Council on Bioethics has suggested a number of ways in which patents covering genetic sequences, whose primary function is as research tools, might inhibit innovation. These included increased costs of research; impediments to research if patents must be negotiated; possible issues about exclusive licensing or the withholding of licences to force up prices; and difficulty in negotiating a number of royalties ('royalty stacking').[123]

13.97 While the Nuffield Council stated that the granting of patents that assert rights over DNA sequences as research tools should be discouraged, it conceded that there was:

> insufficient evidence to judge the extent to which the granting of patents that assert a primary right over DNA sequences based on a primary use as research tools is producing the potentially deleterious effects.[124]

13.98 IP 27 noted two categories of isolated genetic material that raise particular concerns in the context of research use, namely, ESTs and SNPs.

Expressed sequence tags

13.99 EST patents are patents over gene fragments with unknown function.[125] Once an EST has been identified it can be used to locate a full-length gene or to infer the function of a gene. The use of ESTs has allowed the study of many genes whose function is not yet known. The patentability of ESTs is discussed in Chapter 6.

13.100 The Human Genome Organisation (HUGO) has suggested that although it is not particularly difficult to generate an EST, it is much more difficult to isolate a gene and to determine its function. HUGO says that it is this work with a gene, rather than the generation of the EST, that ought to receive the greater incentive.[126] The Nuffield Council recommended that 'when rights are asserted in terms intended to cover all sequences that contain an EST that is the subject of the original patent, no patent should be granted'.[127]

13.101 In Australia, Melanie Howlett and Professor Andrew Christie concluded from a study of the practices of the United States, European and Japanese Patent Offices that

> the fear of a flood of EST patent claims for probes without useful functions seems to be unjustified … not many ESTs will pass the stringent requirements for patentability.

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122 Ibid, 3.
123 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), [5.39].
124 Ibid, [5.40].
125 See Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), [2.60].
126 HUGO Ethics Committee, *Patenting of DNA Sequences* (1995).
127 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), [5.38].

> Accordingly, it seems that the fear of numerous EST patents inhibiting later research is also unfounded.[128]

13.102 It has been suggested that concerns about the impact of EST patents on research have turned out to be ill-founded because such patents have not been granted in any number. GlaxoSmithKline noted:

> We are not aware of any patents that have been granted on ESTs in Australia. None has been granted in Europe and only one has been granted in the USA (seemingly in error). As a result, it is difficult to see how research can be affected.[129]

13.103 The submission of the Department of Industry, Tourism and Resources stated that IP Australia's current examination practices substantially lessen the potential for patents to be granted over ESTs. The potential for multiple patents relating to parts of a single gene inhibiting research was thus considered unlikely.[130] In contrast, the Australian Centre for Intellectual Property in Agriculture (ACIPA) submitted that there remain 'real and serious' concerns about the patenting of ESTs.[131]

Single nucleotide polymorphisms

13.104 The patenting of SNPs raises similar concerns to those about ESTs. SNPs are valuable in determining the genetics of a disease or understanding the role of genetics in patients' responses to pharmaceuticals. However, as discussed below, much information about SNPs is in the public domain and therefore there are generally fewer problems about access for researchers. Submissions suggested that, as with ESTs, problems caused by the patenting of SNPs are unlikely to eventuate.[132]

Other types of research tools

13.105 Some concerns were expressed in submissions and consultations about the implications for research of GTG's non-coding patents. These patents are fundamental to many key applications in genetic analysis, molecular diagnostics and genomics.

13.106 While GTG has offered non-exclusive licences for basic research using GTG's non-coding patents for modest fees, much higher payments have been negotiated with commercial organisations.[133] In the United States, a major biotechnology company, Applera Corporation, is facing an infringement action for refusing to obtain a licence to

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128 M Howlett and A Christie, 'An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)' (2003) 34 *International Review of Industrial Property and Copyright Law* 581, 602.

129 GlaxoSmithKline, *Submission P33*, 10 October 2003.

130 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

131 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

132 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

133 For example, Sequenom ($US500,000): Z Moukheiber, 'Junkyard Dogs', *Forbes Magazine*, 29 September 2003.

use GTG's non-coding patents.[134] Other suits against United States biotechnology companies settled recently.[135]

13.107 Another specific set of concerns were expressed in relation to the effects on research of Chiron Corporation's patents relating to the Hepatitis C virus, which include claims to the composition of the virus itself and its use in diagnostic tests, vaccines and drug development.[136] It was suggested that the broad nature of the claims in these patents inhibit research on this virus.[137] In contrast, another submission maintained that the existence of Chiron's Hepatitis C patents was no deterrent to subsequent research.[138]

ALRC's views

13.108 The ALRC's preliminary view, based on submissions and its extensive consultation and research program, is that there is limited evidence to date that gene patents have had any significant adverse effect on the conduct of genetic research in Australia. International empirical studies suggest that patent holders and those in the research and biotechnology sectors are capable of developing 'a robust combination of working solutions' for dealing with problems that emerge.[139] While these solutions sometimes take time to work out, and may not be optimal, research generally moves forward.

13.109 The concerns that have been expressed to the Inquiry relate more to possible future problems for research. This is consistent with the conclusions of a literature review conducted for the United Kingdom Department of Health, which concluded that:

> There seems to be consensus that without an adequate exception, patents could adversely affect the ability of researchers to carry on R&D, but that to date there is only limited anecdotal evidence that such an adverse outcome is actually occurring. This seems to be an issue which commentators regard as requiring monitoring, not least to see whether a proliferation of patents directed at essentially the same genetic investigation creates an unduly monopolistic barrier to future research.[140]

13.110 In view of the equivocal nature of evidence about adverse impacts on research, the ALRC considers that it should adopt a cautious approach towards recommending major changes in patent law and practice in this area. As Nicol and Nielsen counsel:

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134 Ibid.

135 Genetic Technologies Limited, 'GTG Law Suits Against Nuvelo and Covance Now Settled', *Press Release*, 17 November 2003, <www.gtg.com.au/Announcements.html>.

136 L Palombi, *Submission P28*, 1 October 2003; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 48.

137 L Palombi, *Submission P28*, 1 October 2003.

138 AusBiotech Ltd, *Submission P58*, 7 November 2003.

139 J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285, 335.

140 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 43.

> a very delicate balance exists between the role played by patents in encouraging innovation and the potential for patents to impact negatively on research into, and the development of, new drugs, therapies and diagnostics. Whilst the existing system is not perfect, great care will need to be taken in modifying this system to ensure that the balance is not too greatly disturbed.[141]

13.111 The ALRC recognises that the current position may change, particularly if patent holders become more active in enforcing patent rights. As the Walsh study observed, it is not possible to rule out future problems, including those resulting from patents currently under review, court decisions, new technology, and assertions of patents on foundational discoveries.[142]

13.112 It is difficult to assess the nature and extent of the potential problems, and whether existing legal mechanisms to address them, such as those in patent and competition law, provide appropriate and effective remedies. More detailed consideration of reform options to address the impact of gene patents on research is justified.

13.113 In line with the cautious approach counselled above, the ALRC proposes a pattern of laws and practices that is flexible enough to anticipate and respond to future problems. This approach has influenced the proposals made elsewhere in this Discussion Paper, which are more often directed to influencing patent practices, rather than to proposing substantive changes to patent law. There are several existing mechanisms through which problems might be addressed, should they manifest. These include use of the compulsory licensing and Crown use and acquisition provisions of the *Patents Act*, competition law and prices surveillance.[143]

13.114 Elsewhere in this Discussion Paper, the ALRC proposes reforms intended to address the potential for future harm, including with respect to the conduct of genetic research. These include:

- changes to Patent Office practice relevant to some research tools, such as ESTs (see Chapter 8);
- the development of new Australian Research Council (ARC) and NHMRC principles and guidelines (see Chapter 12 and below);
- enacting a new experimental use defence (see Chapter 14);

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141 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 251.

142 J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285, 335.

143 See Ch 24 (competition law); Ch 25 (prices surveillance); Ch 26 (Crown use and acquisition); Ch 27 (compulsory licensing);

- encouraging health departments or other agencies to challenge questionable gene patents that may impact adversely on medical research (Chapter 20);

- establishing a role for the proposed Human Genetics Commission of Australia in monitoring the application of intellectual property laws to genetic materials and technologies, where these may have implications for human health (Chapter 20);

- model licensing agreements to encourage access to genetic inventions (see Chapter 23); and

- amendment and clarification of Crown use and compulsory licensing provisions (see Chapters 26 and 27).

New principles and guidelines on research tools

13.115 A particular focus of this chapter has been on genetic materials or technologies used as research tools. In addition to reforms proposed elsewhere in this Discussion Paper in relation to research, the ALRC proposes a specific initiative in relation to research tools, aimed at using the Australian Government's research funding leverage to reduce transaction costs and to encourage and maintain widespread access.

13.116 In Chapter 12, the ALRC proposed that the ARC and the NHMRC should review their principles and guidelines on intellectual property and research to ensure that publicly funded research, where commercialised, results in appropriate public benefit.[144]

13.117 One model for such an approach is found in the NIH's *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (the NIH principles and guidelines), which apply to recipients of NIH research grants and contracts.[145]

13.118 The NIH principles and guidelines derive from the report of the NIH Working Group on Research Tools,[146] which observed that 'the social value of research tools as a means of making future discoveries is greatest when they are widely distributed on a nonexclusive basis'. The NIH principles state that institutions should:

- Minimise administrative impediments to academic research. This principle states that recipients of NIH funds should streamline processes for transferring their own research tools to other academic institutions. Organisations that seek

144 Proposal 10–1.

145 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

146 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

to make a profit are required to minimise restrictions on not-for-profit bodies in relation to academic use of research tools.

- Ensure dissemination of research resources developed with NIH funds. This principle states that 'progress in science depends upon prompt access to the unique research resources that arise from biomedical research … ideally these resources should flow to others who advance science by conducting further research'.[147]

13.119 With specific reference to research tools, the NIH guidelines provide, among other things, that:

- exclusive licences for research tools should generally be avoided except in cases where the licensee undertakes to make the research tool widely available to researchers through unrestricted sale, or the licensor retains rights to make the research tool widely available;

- when an exclusive licence is necessary to promote investment in commercial applications of a subject invention that is also a research tool, the recipient should ordinarily limit the exclusive licence to the commercial field of use, retaining rights regarding use and distribution as a research tool;

- recipients are expected to avoid signing agreements to acquire research tools that are likely to restrict recipients' ability to promote broad dissemination of additional tools that may arise from the research;

- in determining the scope of licence or option rights that are granted in advance to a provider of materials, recipients should balance the relative value of the provider's contribution against the value of the rights granted, the cost of the research, and the importance of the research results; and

- recipients should reserve the right to negotiate licence terms that will ensure the continuing availability to the research community of any resulting new invention that is a unique research resource.[148]

13.120 Australia's principal research funding bodies, the ARC and the NHMRC, should take a similar approach to ensure that the public interest in encouraging commercial exploitation of inventions generated from publicly funded research is balanced with the wide dissemination of important research tools. Such an approach would be consistent with the conclusions of the OECD Report, which suggested that

147 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

148 Ibid.

governments should give attention to the development, in consultation with industry, of guidelines on acceptable licensing practice.[149]

Proposal 13–1 The Australian Research Council and the National Health and Medical Research Council, as part of the review proposed in Proposal 12–1, should develop principles and guidelines for researchers to ensure that the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.

149 See Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 82. As discussed in Ch 19, the OECD's Working Party on Biotechnology has established a steering group of experts to develop best practice guidelines for the licensing of genetic inventions: Organisation for Economic Co-operation and Development, *Brief Explanation of the Working Party on Biotechnology's Project on Best Practice Guidelines for the Licensing of Genetic Inventions*, <www.oecd.org/dataoecd/2/39/9230380.PDF> at 29 August 2003.

14. Experimental and Research Use Defences

Contents

Introduction

14.1 This chapter examines the existing law concerning experimental and research use of patented inventions in Australia and, in particular, the legal uncertainty about the existence and scope of an implied experimental use defence. The chapter also discusses the law in other jurisdictions, including New Zealand, the United States, Canada, the United Kingdom and other member states of the European Union.

14.2 The chapter examines a range of options for reform. Reform could be limited to better protecting experimental use relating to the subject matter of a patented invention—that is, research with a narrow focus on discovering more about the invention and its properties (an experimental use defence). An experimental use defence is recognised in many jurisdictions and applies to all patented subject matter, not just gene patents.

14.3 Other reform options concern the establishment of a defence to claims of infringement of gene patents, or some defined subset of gene patents, where the patented invention is used in research, extending to activities that would not

necessarily be considered 'experimental' (a research use defence). Such defences are not well established elsewhere, but have been proposed in a number of jurisdictions.

14.4 Finally, the implications of reform for Australia's compliance with its obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement) are also considered.[1]

Existing law

Australian law

14.5 The source of an experimental use defence in case law is said to be *Frearson v Loe*[2]—a nineteenth century English case—in which Jessel MR stated:

> no doubt if a man makes things merely by way of *bona fide* experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view to improving upon the invention the subject of the patent, or with the view to seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent.[3]

14.6 The *Patents Act 1990* (Cth) (*Patents Act*) does not expressly except experimental or research use of patented inventions from liability for infringement.[4] However, an implied experimental use defence may exist in Australian law, as it does in other common law jurisdictions.

14.7 Section 13 of the *Patents Act* provides that the grant of a patent confers upon a patent holder the exclusive right to exploit, or to authorise the exploitation of, an invention during the patent term. The definition of 'exploit' in Schedule 1 of the *Patents Act* sets out the activities that a patent holder has the exclusive right to conduct, including making, using, selling and importing a patented product, or a product resulting from use of a patented process. Arguably, it is implicit that these activities are commercial in nature. If so, activities that are not commercial—including those undertaken for scientific or research purposes if the results of the research will not be commercialised—may not amount to exploitation of a patent and may, therefore, be exempt from claims of infringement.

14.8 An experimental use defence might also be inferred from s 9 of the *Patents Act*, which excludes use 'for the purpose of reasonable trial or experiment' from the definition of 'secret use'.[5] This provision allows the patent holder to undertake trial and experimentation prior to filing a patent application. It could be argued that the patent

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1 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

2 *Frearson v Loe* (1876) 9 ChD 48.

3 Ibid, 66–67.

4 Nor was such a defence available under the *Patents Act 1952* (Cth).

5 *Patents Act 1990* (Cth) ss 9(a), 18(1)(d).

holder should not be able to later claim that trial and experimentation by others during the life of the patent amounts to infringement of the holder's exclusive rights.[6] However, such an argument is difficult to make because the purpose and the nature of the experiments that an alleged infringer might want to conduct will be different from those of a prospective patent holder. Further, while experimentation may be excluded from the definition of 'secret use', there is no provision in the Act expressly excluding experimentation from the patent holder's exclusive rights.[7]

14.9 While no Australian court has ruled on the matter,[8] the existence of an experimental use defence is widely assumed. For example, Australia's third party arguments in the *Canada–Patent Protection* case[9] stated that, in Australia, 'an experimental use exception did apply, but only to the extent that a court would find that specific experimental activities did not constitute infringing use'.

14.10 Others have argued that, as a matter of statutory interpretation, it is difficult to argue that the *Patents Act* implies an experimental use defence, especially given the breadth of the exclusive rights given to patent holders.[10]

14.11 Submissions to the Inquiry from legal commentators tended to cast doubt on the existence of an experimental use defence in Australian law. For example, Dr Amanda McBratney and others considered that arguments for its existence, based on interpretation of the term 'exploit' were 'strained'. They further submitted that:

> In any event … the interpretation would not be upheld by a court for the same kind of reasons that courts have generally been reluctant to rely on the 'generally inconvenient' exception. Patent rights exist in order to encourage and stimulate invention. Courts do not often feel it appropriate to derogate from a patentee's rights by reading down the patent legislation, or by expanding exceptions or defences not clearly set out in the legislation.[11]

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6 C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 15.

7 Ibid, 15.

8 Some consideration of experimental use has occurred in cases relating to patent validity, focusing on 'secret use' as an element of patentability under *Patents Act* s 18(1)(d). See, eg, *Longworth v Emerton* (1951) 83 CLR 539; *Re Application of Lake* (1992) 24 IPR 281. In *New York University v Nissin Molecular Biology Institute Inc* (1994) 29 IPR 173, the delegate of the Commissioner of Patents agreed that the words 'experimental purposes' in r 3.25(4) of the *Patents Regulations 1991* (Cth) should be 'construed analogously to those experimental uses that do not give rise to infringement of a patent'—suggesting the existence of an experimental use defence: 177–178.

9 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R. The Australian Government submission was prepared by the Department of Foreign Affairs and Trade, IP Australia, and the Department of Industry, Science and Resources: See C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, fn 1.

10 See C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14.

11 A McBratney and others, *Submission P47*, 22 October 2003.

14.12 The Advisory Council on Intellectual Property (ACIP) is currently undertaking a review of patents and experimental use. The terms of reference of the review are to examine whether some types of patents are inhibiting research and development in Australia and to determine whether Australian researchers and business would benefit from introducing an experimental use defence (or some other provision) into Australian patent legislation.[12] ACIP expects to release an Issues Paper in February 2004, with a request for written submissions by 30 April 2004. Given this timetable, it has not been possible for the ALRC to take ACIP's recommendations into account in formulating the proposals in this Discussion Paper.

Other jurisdictions

14.13 In some jurisdictions, including New Zealand, the United States and Canada, experimental use defences are recognised in case law—although there remains some dispute over their parameters. Other jurisdictions, including the United Kingdom and some other member states of the European Union, have express statutory provisions relating to the experimental use of patented inventions. The laws in these jurisdictions are briefly discussed below.

New Zealand

14.14 As in Australia, New Zealand patents legislation does not provide an express exception for experimental use of patented inventions. However, in at least two cases, the courts appear to have accepted that such a defence is available.[13]

14.15 The most recent of these is *Smith Kline & French Laboratories v Attorney General*[14] in which the Court of Appeal considered whether the importation of a patented pharmaceutical constituted an infringement of patent rights. The Court accepted the existence of an experimental use defence, referring to *Frearson v Loe*[15] and to the earlier New Zealand case of *Monsanto v Stauffer Chemical Company (NZ).*[16] In relation to the scope of the exception, Hardie Boys J commented:

> Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself, and does no more than further his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance him in the actual market place, then he infringes, for the marketplace is the sole preserve of the patentee.[17]

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12 Advisory Council on Intellectual Property, *Reviews*, <www.acip.gov.au/reviews.htm#expuse> at 24 November 2003.

13 *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515; *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560.

14 *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560.

15 *Frearson v Loe* (1876) 9 ChD 48.

16 *Monsanto Co v Stauffer Chemical Co (NZ)* [1984] FSR 559.

17 *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560, 566.

14.16 In *Monsanto v Stauffer Chemical Company (NZ)*[18] it was held to be an infringement to supply a patented herbicide to potential customers in order that they might conduct field trials with a view to obtaining regulatory approval for the use of the product once the patent had expired. This was found to be a use to obtain a commercial advantage by making potential customers aware of the existence and efficacy of the product.[19] This decision was cited with approval in Australia by the delegate of the Commissioner of Patents in *New York University v Nissin Molecular Biology Institute Inc*.[20]

14.17 Although the New Zealand courts have drawn distinctions between experimental and commercially directed research, the law is said to remain 'uncertain as to where the line actually falls between pure research and research for gaining a commercial advantage'.[21]

United States

14.18 United States case law recognises a limited experimental use defence. In *Roche Products Inc v Bolar Pharmaceutical Co*[22] the defence was found to be dependent on the experiments involved being 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry', and not for business reasons. The United States Court of Appeals for the Federal Circuit also stated that the experimental use defence cannot be construed 'so broadly as to allow a violation of the patent laws in the guise of "scientific inquiry", when that inquiry has definite, cognisable, and not insubstantial commercial purposes'.[23]

14.19 In *Embrex v Service Engineering Corp*[24] the Court of Appeals reaffirmed that the exception was to be interpreted narrowly and that a use is disqualified from the defence if it has even the 'slightest commercial implication'.[25]

14.20 A recent high profile decision dealing with the experimental use defence is *Madey v Duke University*[26] (*Madey*). The case involved the research use of patented free electron laser technology by Duke University. In *Madey*, the Court of Appeals stated that the *Roche* and *Embrex* cases emphasised that the defence is 'very narrow

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18 *Monsanto Co v Stauffer Chemical Co (NZ)* [1984] FSR 559.

19 Ibid; *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560, 565.

20 *New York University v Nissin Molecular Biology Institute Inc* (1994) 29 IPR 173. The springboarding provisions of the *Patents Act* (see below) were introduced in part because it was assumed that *Monsanto* would be followed and that clinical trials carried out in order to obtain regulatory approval would not be covered by an experimental use defence.

21 G Lynch and J Scarlett, *Experimental Defence to Patent Infringement*, Baldwin Shelston Waters, <www.bsw.com/articles/xfactor9.html> at 19 May 2003.

22 *Roche Products Inc v Bolar Pharmaceutical Co* (1984) 733 F 2d 858.

23 Ibid, 863.

24 *Embrex Inc v Service Engineering Corp* 216 F 3d 1343 (2000), 1349.

25 Ibid, 1353.

26 *Madey v Duke University* 307 F 3d 1351 (2002).

and strictly limited'. In particular, 'use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defence'.[27]

14.21 The Court held that the non-profit (or educational) status of the alleged infringer does not determine the availability of the experimental use defence.[28] Rather, the focus should be on whether the act was in furtherance of the alleged infringer's legitimate business.[29] In this context, the Court noted that:

> Major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.[30]

14.22 In June 2003, the Supreme Court of the United States denied a petition for review of the *Madey* decision. It has been argued that the *Madey* decision will render the experimental use defence unavailable to research institutions simply because their legitimate business is research.[31] The decision in *Madey* has major implications for the research community as a whole, and for United States universities in particular.[32] It has been claimed that researchers will have to redirect their attention from research to expensive and time-consuming patent searches and licensing activities. As a result, academic research could be diverted to foreign institutions in countries with broader experimental use exceptions, or no corresponding patent.

14.23 Proponents of the *Madey* decision have contended that universities should not be categorically exempted from patent infringement when university–industry collaborations are common and universities are actively commercialising their research.[33] Critics of the decision argue that the Court's decision will have a significant chilling effect on academic scientific research.[34] One view is that *Madey* fails to

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27 Ibid, 1362.

28 Ibid, 1362.

29 Ibid, 1362–1363.

30 Ibid, 1362. The Court was not required to determine whether the experimental use defence was made out on the facts. The Court ordered the case to be remanded to the District Court for such a determination.

31 Another view is that this approach is not compelled by the *Madey* decision when read as a whole. Research institutions are neither automatically entitled, nor automatically ineligible for the experimental use defence: see *Duke University v Madey* No 02–1007 (Supreme Court of the United States, 2003): Brief for the United States as Amicus Curiae (May 2003).

32 See, eg, Ibid: Brief for the Association of American Medical Colleges et al, as Amicus Curiae (January 2003); J Johnson, 'Experimental Use Exception Does Not Exempt University from Patent Infringement', *(2002) 10(1) Center for Advanced Study and Research on Intellectual Property Newsletter*, <www.law.washington.edu/casrip/newsletter/newsv10i1us1.PDF>; R Matthews, *United States: Experimental: Use Defense Does Not Automatically Shield Non-profit Universities*, Mondaq, <www.mondaq.com> at 4 August 2003.

33 J Johnson, 'Experimental Use Exception Does Not Exempt University from Patent Infringement', *(2002) 10(1) Center for Advanced Study and Research on Intellectual Property Newsletter*, <www.law.washington.edu/casrip/newsletter/newsv10i1us1.PDF>.

34 *Duke University v Madey* No 02–1007 (Supreme Court of the United States, 2003): Brief for the Association of American Medical Colleges et al, as Amicus Curiae (January 2003).

adequately recognise that the purposes of the patent system include facilitating research into the patented subject matter by persons other than the patent holder.[35]

Canada

14.24 As in New Zealand and the United States, case law in Canada establishes an experimental use defence. The defence dates from the 1971 decision of the Supreme Court of Canada in *Micro Chemicals Ltd v Smith Kline & French Inter-American Corporation*[36](*Micro Chemicals*). In that case, the Supreme Court focused on the fact that the experimentation involved was 'not for profit'. Hall J stated:

> The use Micro was making of the patented substance here was not for profit but to establish the fact that it could manufacture a quality product in accordance with the [patent] specifications … Micro's experiments … were not carried out for the purpose of improving the process but to enable Micro to produce it commercially as soon as the licence it had applied for could be obtained. I cannot see that this sort of experimentation and preparation is an infringement. It appears to me the logical result of the right to apply for a compulsory licence.[37]

14.25 The *Micro Chemicals* case has been said[38] to reflect the perspective expressed in *Frearson v Loe*, where Jessel MR said:

> Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purpose of experiment … ought not to be considered within the meaning of the prohibition, and if it were, it is certainly not the subject for an injunction.[39]

14.26 The *Micro Chemicals* decision was made in the context of research aimed at sustaining a compulsory licence under provisions of the Canadian Act that were subsequently repealed. In the light of this, the Canadian Biotechnology Advisory Committee (CBAC) concluded that the experimental use exception established by the *Micro Chemicals* case is 'vague' and later cases 'do little to amplify the meaning of the exception'.[40]

14.27 The existence of an experimental use defence is recognised in s 55.2(6) of the *Patent Act 1985* (Can). This provides that the Canadian 'springboarding' provisions,

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35 See T Sampson, 'Madey, Integra and the Wealth of Nations' (2004) 26 *European Intellectual Property Review* 1 and the dissenting judgment of Newman J in *Integra Life Sciences v Merck KgaA* 307 F 3d 1351 (2002).

36 *Micro Chemicals Ltd v Smith Kline & French Inter-American Corporation* (1971) 25 DLR (3d) 79.

37 Ibid, 89.

38 By the Ontario Court of Appeal in *Dableh v Ontario Hydro (CA)* [1996] 3 FC 751, 782.

39 *Frearson v Loe* (1876) 9 ChD 48, 67.

40 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 14.

which are intended to permit activities directed to obtaining regulatory approval,[41] do not affect:

> any exception to the exclusive property or privilege granted by a patent that exists at law … in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent.[42]

14.28 However, the enactment of this provision, while preserving the exception identified by the Supreme Court of Canada, does nothing to clarify either its nature or extent.[43] One view is that under Canadian law as it currently stands:

> it is unclear whether a researcher conducting research using a patented invention could successfully be sued where that research has *potential* in the longer term to result in a commercial product.[44]

United Kingdom

14.29 The United Kingdom enacted an experimental use defence in s 60(5) of the *Patents Act 1977* (UK). This provision states that:

> (5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if— …
>
> (b) it is done for experimental purposes relating to the subject-matter of the invention.[45]

14.30 Section 60(5) was enacted to ensure that United Kingdom law conformed with corresponding provisions of the Community Patent Convention (CPC).[46]

14.31 In *Monsanto Co v Stauffer Chemical Co*,[47] Falconer J in the High Court stated that s 60(5) was intended 'to continue in statutory form the prior United Kingdom law as to experimental use of a patented invention'.[48] He said it was reasonable to assume that Parliament intended to use the term 'experimental' in the sense in which it had previously been understood in case law.[49] Following an examination of this case law, the judge stated that an experiment is:

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41 *Patent Act 1985* RS c P-4 (Canada) s 55.2(1). Springboarding (regulatory review) provisions are discussed below.

42 Ibid s 55.2(6).

43 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 14.

44 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 49.

45 *Patents Act 1977* (UK) s 60(5).

46 Ibid s 130(7).

47 *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515.

48 Ibid, 523.

49 Ibid, 524.

- something done on a small scale having regard to the nature of the subject matter of the invention; and

- done for the purpose of finding out something about the invention (for example, whether it works or can be improved upon).[50]

14.32 While the decision in favour of Monsanto was largely upheld on appeal, the Court of Appeal differed on the relationship between the Act and prior case law. Dillon LJ stated that:

> Section 60 was … enacted to bring UK patent law into line with the corresponding provisions of the Community Patent Convention and I have no reason to suppose that the signatories of that convention were concerning themselves with the minutiae of earlier UK patent law. Beyond that, however, the word 'experiment' is an ordinary word in the English language and has never been a term of art in UK patent law.[51]

14.33 Dillon LJ held that use for 'experimental purposes' may have a commercial end in view.[52] However, the underlying purpose of the experiments must be technical—'to discover something unknown or to test a hypothesis' relating to the patented invention.[53] The *Monsanto* case involved field trials of a patented herbicide. The Court of Appeal held that the experimental use defence did not extend to any tests or trials designed to expand the commercial acceptance of the invention, or to increase marketability—including trials designed to obtain clearances or approvals from regulatory bodies.

14.34 The other element of s 60(5) is that the experimental purposes must relate to the subject matter of the invention. United Kingdom cases have held that this relationship is 'in the sense of having a real and direct connection with that subject matter'[54] and that, in determining what constitutes the subject matter of the patent, the court is to look at the entire patent document, including its aim.[55]

European Union

14.35 Article 27(b) of the CPC[56] provides that the rights conferred by a community patent shall not extend to 'acts done for experimental purposes relating to the subject-matter of the patented invention'—words virtually identical to those enacted in United Kingdom legislation. This provision has been widely incorporated into the national

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50 Ibid, 531.
51 Ibid, 537–538. See *Patents Act 1977* (UK) s 13(7).
52 *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515, 538.
53 Ibid, 542.
54 *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 513, 524.
55 *Auchinloss v Agricultural & Veterinary Supplies Ltd* [1999] RPC 397.
56 *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01. The Convention must be ratified by all European Union member states before it takes effect. Fewer than half of the member states have ratified it: European Union, *Patents*, <www.eurunion.org/legislat/iiprop/patents.htm> at 5 August 2003.

laws of other member states of the European Union,[57] in most cases without any significant variation in its English wording.[58]

14.36 Reviewing European case law on the interpretation of art 27 of the CPC, Professor William Cornish has concluded that the scope of permissible experimental use has expanded since art 27 began to be incorporated into national laws.[59] While the experimental use exception was previously confined, in at least some jurisdictions, to 'private and personal' experimental use:

> The changing nature of research among industrial competitors and in academic-industrial relationships has led to a step-wise expansion of the experimental use exception and this was apparently the intention of the governments which negotiated the CPC. No longer is any exception confined to the strictly non-commercial, because frequently scientific curiosity operates in conjunction with the desire to turn successful work to account. It has long been a major objective of the patent system that the latter should follow from the former.[60]

14.37 European case law establishes that experimentation to seek further knowledge about the patented invention[61] or to determine the adequacy of the disclosure in the patent application or other matters going to the validity of the patent are permissible.[62] A distinction is drawn between such experimentation and that which simply reiterates or publicises existing knowledge. Where the purpose of an experiment is not to obtain knowledge about an invention, but to demonstrate the effectiveness of a product to a third party, then the experiments will not fall within the experimental use exception.[63] Testing undertaken merely to satisfy regulatory requirements will also fall outside the exception.[64]

14.38 Cornish concludes that courts are likely to search for the primary motivation behind experimentation when deciding whether a defence is available:

> Even if the concern initiating the trial is a commercial organisation, the exception may apply if the immediate purpose is to discover more about the properties of the invention. The courts will no longer insist that that motivation must be 'solely' or 'exclusively' to gain more scientific knowledge.[65]

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57 C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 18.

58 W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 736.

59 Ibid, 752.

60 Ibid, 752.

61 Possibly including clinical tests of formulations of a patented active substance, as this will necessarily involve seeking new knowledge about clinical effectiveness, side-effects and so on: Ibid, 752, 753.

62 Ibid, 752, 738.

63 C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 19 referring to *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515; *Klinische Versuche I* [1994] RPC 623.

64 W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 753.

65 Ibid, 753.

14.39 European case law does not treat the collection of data for the purpose of regulatory approval as justified under the experimental use exception.[66] However, where scientific or technical improvement forms one genuine reason for the experimentation, a defence against infringement may be available, even if there are other motivations.

14.40 The high-water mark is the decisions of the German Supreme Court in *Klinische Versuche I*[67] and *Klinische Versuche II.*[68] In *Klinische Versuche I* the Court accepted that clinical trials aimed at finding further indications for a patented substance (interferon-gamma) were within the scope of the experimental use exception. The Court stressed that it made no difference that one motive for the clinical trial was to later obtain authority to market.[69]

14.41 In *Klinische Versuche II*,[70] the same conclusion was reached in relation to clinical trials of patented human erythropoietin, even though the tests were not in relation to new indications but to compare the effectiveness of the patented product with the defendant's own product and to present data to obtain regulatory approval.[71] Cornish concluded that these cases are 'strong statements' that:

> Art. 27(b) [of the CPC] should be interpreted so as to permit all clinical testing of a drug which genuinely seeks further information about its uses and about side-effects and other consequences of treatment … Accordingly, in my opinion they are likely to be followed in other European Union states.[72]

Summary of comparative law

14.42 The material above has highlighted significant variations in the nature and extent of the experimental use defence in different jurisdictions. Although the precise scope of the defence may vary, it is always necessary to differentiate between experimentation *on* a patented invention and experimentation *using* a patented invention for broader research purposes.

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66 Ibid, 739–740.

67 *Klinische Versuche I* [1994] RPC 623.

68 *Klinische Versuche II* [1998] RPC 423. See W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 747–751; C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 19.

69 W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 749.

70 *Klinische Versuche II* [1998] RPC 423. See W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 747–751; C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 19.

71 C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 19.

72 W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 750–751.

14.43 The patent laws of the United Kingdom and other member states of the European Union explicitly state that the experimental use defence applies only where the experimentation relates to the subject matter of the patented invention. The defence is limited to research that 'builds upon the knowledge provided by the patent, and aims to discover something unknown about the subject matter of the patent or to test a hypothesis about it'.[73]

14.44 This constraint is also evident in the case law of the other jurisdictions discussed. However, it has not been a major focus of the cases, perhaps because they have so clearly involved use for purposes primarily related to obtaining regulatory approval, rather than to find out more about the invention. In other cases, such as *Madey*, the commercial or business motives of the researchers were the determining factor, leaving no reason to focus on the relationship between the research and the subject matter of the patent.

14.45 An important difference between national laws concerns the extent to which experimental use of a patented invention may have a commercial motivation. In this respect, United States law, especially following the *Madey* decision, is significantly more restrictive than the law in the United Kingdom and other member states of the European Union. The position with regard to the significance of commercial motivations in New Zealand and Canada is unclear due to the paucity of case law. The law in these jurisdictions appears to be closer to that in Europe than the United States in that permissible experimentation may have some commercial objectives.

Reform proposals

14.46 Options for reform of experimental use defences have been under active consideration in several jurisdictions. Some of these proposals are discussed below. In assessing the relevance of these proposals it is important to bear in mind the starting point under the existing law of these jurisdictions, when compared with Australia.

United States

14.47 In the United States, there is a long history of reform proposals relating to experimental and research use defences. The decision in *Madey*,[74] limiting the ability of universities or non-profit organisations to rely on an experimental use defence, has been said to 'almost guarantee' that the United States Congress will reconsider earlier attempts to provide a statutory experimental or research use defence.[75] One reason is that a very narrow defence may provide incentives for certain industries to locate their research operations outside the United States.

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73 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 71.

74 *Madey v Duke University* 307 F 3d 1351 (2002).

75 S Maebius and H Wegner, *Ruling on Research Exemption Roils Universities: Finding of No Academic Privilege from Infringement May Lead to New Legislation*, Foley & Lardner, <www.foley.com/publications/pub_detail.aspx?pubid=1416> at 12 August 2003.

14.48 In 1990, a general exemption for the use of patented inventions 'for research or experimentation purposes' was proposed in Title IV of the Patent Competitiveness and Technological Innovation Bill 1990. The proposed defence did not apply to research tools except to allow study of an invention to create a second invention that falls outside the scope of the original patent. In other words, if an invention's primary use was as a research tool, and the use was not directed towards improving the tool, it did not fall under the exemption.[76]

14.49 More recently, a defence specific to infringement of gene patents was proposed in the Genomic Research and Diagnostic Accessibility Bill 2002.[77] The provision stated:

> It shall not be an act of infringement for any individual or entity to use any patent for or patented use of genetic sequence information for purposes of research. This paragraph shall not apply to any individual or entity that is directly engaged in the commercial manufacture, commercial sale, or commercial offer for sale of a drug, medical device, process, or other product using such patent for or patented use of genetic sequence information.[78]

14.50 This provision was a response to the fact that United States patent law does not ensure protection for 'scientists doing basic, fundamental, non-commercial research when they use patented tools, techniques and materials'. It would exempt from patent infringement the use of patented genetic sequence information for non-commercial research purposes.[79]

14.51 For these purposes, genetic sequence information was defined as 'any ordered listing of nucleotides comprising a portion of an organism's genetic code'. Research was defined to mean 'systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge'.[80] The co-sponsor of the Bill, the Hon Lynn Rivers, stated that creating a research use exemption would make genetic patent law comparable to copyright law, which has a 'fair use' defence that permits socially valuable uses without a licence.[81]

Canada

14.52 In Canada, recent inquiries have expressed concern about the effect that uncertainty regarding the status of the experimental use defence may be having on the Canadian biotechnology sector. In 2002, CBAC recommended that Canada should enact a 'research and experimental use exception' to provide that:

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76 See S Michel, 'The Experimental Use Exception to Infringement Applied to Federally Funded Inventions' (1992) 7 *Berkeley Technology Law Journal* 369, fn 106.

77 The Bill was referred to the House Subcommittee on the Courts, the Internet, and Intellectual Property on 5 May 2002, but lapsed at the end of the 107th Congress.

78 Genomic Research and Diagnostic Accessibility Bill 2002 (HR 3967) (US) s 2.

79 United States, *Congressional Debates, House of Representatives*, 14 March 2002, E353 (L Rivers), E354.

80 Genomic Research and Diagnostic Accessibility Bill 2002 (HR 3967) (US) s 2.

81 United States, *Congressional Debates, House of Representatives*, 14 March 2002, E353 (L Rivers), E354.

> It is not an infringement of a patent to use a patented process or product either:
>
> (a) privately and for non-commercial purposes; or
> (b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.[82]

14.53 The recommended reform is based on the wording of art 27 of the CPC, with certain modifications, and does not distinguish between research conducted for purely academic purposes and research with a commercial interest. The term 'study', which is broader than 'research' or 'experimental', was used to clarify that classroom use of an invention is excluded from patent infringement.[83] CBAC emphasised that only study related to the nature of the invention itself would be covered. Therefore, 'scientists who use patented inventions as mere tools to conduct further research will need to pay a licence fee'.[84]

14.54 CBAC's conclusions were supported in the Ontario government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (the Ontario Report), which concluded that Canadian law was not 'broad enough to assure that molecular biologists will not be sued for patent infringement respecting research that may ultimately have a commercial end'.[85] The Ontario Report recommended that the *Patent Act 1985* (Can) be reviewed with a view to clarifying the experimental use exception to indicate that 'general research use of patented material' is protected from infringement actions.[86]

United Kingdom

14.55 The Nuffield Council on Bioethics (Nuffield Council) has expressed particular concern about the experimental and research use of 'patented DNA sequences'.[87] The Nuffield Council stated that:

> We consider that the concept of the research exemption is very important, particularly in the area of research involving the use of genetic information. The knowledge embodied in patents claiming DNA sequences should, in our view, be freely available for all scientists to apply in the pursuit of non-commercial research.[88]

14.56 The Nuffield Council noted some of the constraints on, and legal uncertainties relating to, the 'research exemption' in United Kingdom, European and United States

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82 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 15.
83 Ibid, 16.
84 Ibid, 15.
85 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 49–50.
86 Ibid, 88.
87 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 60–61.
88 Ibid, 61.

law. The Council recommended that this exemption be 'given a statutory basis in the US and clarified in Europe by policy makers as a matter of urgency'.[89]

14.57 The Council referred to genetic research and development being hindered by the need for researchers to seek multiple licences for many DNA sequences and recommended that 'companies work together to extend the concept of the "research exemption" throughout industry for DNA sequences which appear in patents and which have a use in research'.[90] While the meaning of this recommendation is unclear, it suggests that the Council believes that the scope of existing defences should be extended to cover research that may have commercial purposes.

Related defences

14.58 Some jurisdictions, including Australia, recognise other defences that may protect some forms of experimental or research use of patented inventions. These defences are discussed below and relate to:

- the private and non-commercial use of a patented invention; and
- the use of a patented invention for regulatory review purposes (or 'springboarding').

Private and non-commercial use

14.59 Article 27(a) of the CPC[91] provides that the rights conferred by a community patent shall not extend to 'acts done privately and for non-commercial purposes'. As with art 27(b), discussed above, this provision has been incorporated into the national laws of the United Kingdom and other member states of the European Union. For example, s 60(5) of the *Patents Act 1977* (UK) provides:

> An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if— …
> (a) it is done privately and for purposes which are not commercial; …

14.60 In Canada, the existence of a defence for private and non-commercial use is recognised in s 55.2(6) of the *Patent Act 1985* (Can), which provides that Canadian regulatory review or 'springboarding' provisions[92] do not affect:

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89 Ibid, 61. In July 2003, a study of intellectual property rights within the United Kingdom healthcare sector recommended that the Department of Health 'should support the work currently being undertaken to clarify the concept of research use at the UK, EU and international levels': W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 72.

90 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 61.

91 *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01.

92 *Patent Act 1985* RS c P-4 (Canada) s 55.2(1). Springboarding (regulatory review) provisions are discussed below.

> any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose … [93]

14.61 In Australia, a defence for private and non-commercial use of a patented invention is not expressly included in the *Patents Act*. However, the Act may be said to imply such a defence on the same basis that the Act has been said to support an implied experimental use defence, namely, the definition of 'exploit' in the Act.

14.62 There has been limited consideration of the ambit of the private and non-commercial use defence and exactly how it differs from the experimental use defence.[94] It appears, however, that a private use defence will apply only where activities involving the patented invention have not been carried out in public, are intended for the benefit of the person who has conducted those activities, and do not have a commercial purpose.[95] At least in the United Kingdom, even a possible commercial application of activities involving a patented invention has been held to preclude the application of the defence.[96]

Regulatory review

14.63 The experimental use defence is broad enough in some jurisdictions to cover at least some activity connected with regulatory review and approval processes, but in others it is not. Some jurisdictions have, therefore, enacted regulatory review or 'springboarding' provisions designed expressly to permit activities directed to obtaining regulatory approval.

14.64 In the United States, these provisions are sometimes referred to as the '*Bolar* exemption', after a case bearing that name.[97] In the *Bolar* case, the United States Court of Appeals for the Federal Circuit held that an experimental use defence did not entitle a generic pharmaceutical manufacturer to conduct experiments with a patented pharmaceutical in order to prepare a regulatory application to the United States Food and Drug Administration (FDA).

14.65 Shortly after the *Bolar* decision, the United States Congress passed the *Drug Price Competition and Patent Term Restoration Act 1984* (*Hatch–Waxman Act*) to overrule it. The relevant provision states:

> It shall not be an act of infringement to make, use, or sell a patented invention … solely for uses reasonably related to the development and submission of information

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93 Ibid s 55.2(6).

94 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 59.

95 M Fysh, 'Infringement, Experimental Use and Clinical Trials: The Experience of the United Kingdom and Ireland' (Paper presented at Legal Issues in Exploiting Drug Patents in Europe, Licensing Executives Society Italy Conference, Milan, 12-13 December 2002).

96 *McDonald v Graham* [1994] RPC 407.

97 *Roche Products Inc v Bolar Pharmaceutical Co* (1984) 733 F 2d 858.

> under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.[98]

14.66 Whether an activity is 'reasonably related' to seeking FDA approval has been narrowly interpreted in the case law. The legislative history of the *Bolar* exemption indicates that only a limited amount of testing to establish the bioequivalence of a generic drug substitute is permitted.[99]

14.67 Canadian legislation contains a broader regulatory review exception, the application of which is not restricted to approval processes for drugs or veterinary products. The *Patent Act 1985* (Can) provides:

> It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.[100]

14.68 In Australia, the *Patents Act* has included a regulatory review exception since 1999.[101] This provision is applicable only to patented pharmaceutical substances and only where an extension of patent term has been granted under the Act.[102] It is not an infringement if a person exploits a patented pharmaceutical substance solely for purposes in connection with obtaining regulatory approval for therapeutic use in Australia or any foreign country. Further, during the term of the extended patent period, a patent will not be infringed if a person exploits the claimed pharmaceutical substance for a purpose other than for a therapeutic use or exploits any form of the invention other than the pharmaceutical substance per se.

Research exemption in practice

14.69 Academic researchers often assume that their use of patented inventions is immune from claims of patent infringement.[103] Research conducted by Dr Dianne Nicol and Jane Nielsen confirms that many Australian researchers and research institutions harbour erroneous assumptions about the scope of an existing experimental or research use defence. They note that some respondents to their 2003 survey of research institutions 'put forward the argument that all research as such is exempt, whether it is conducted in research institutions or private sector'.[104] Other respondents

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98 35 USC § 271(e)(1).

99 S Michel, 'The Experimental Use Exception to Infringement Applied to Federally Funded Inventions' (1992) 7 *Berkeley Technology Law Journal* 369, 374.

100 *Patent Act 1985* RS c P-4 (Canada) s 55.2(1). New Zealand enacted a similar provision in 2002: *Patents Act 1953* (NZ) s 68B.

101 *Patents Act 1990* (Cth) s 78.

102 See Ibid ss 70–79A.

103 See, eg, C Dennis, 'Geneticists Question Fees for Use of Patented "Junk" DNA' (2003) 423 *Nature* 105.

104 See D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 218. The research

commented on the difficulties of determining whether an exemption from patent infringement applies and confirmed that enforcement by patent holders is rare.[105]

14.70 Based on the survey results, Nicol and Nielsen looked at the scope of what they term the 'practice-based research exemption', that is, where the line is drawn between basic research, which is assumed to be exempt, and commercial research, about which there is no such assumption.[106]

14.71 The scope of the practice-based research exemption is dependent on the enforcement practices of patent holders. A number of company respondents said that they would not 'seek licences from participants in the research institution sector because this was not a wise decision from a business perspective'.[107] In explaining the reasons for this view, company respondents referred to the benefits to be derived from encouraging research in areas in which they have an interest; the adverse consequences of enforcing patent rights for a company's reputation in the academic community; and problems in recovering damages from public sector researchers.[108]

14.72 However, company respondents indicated that patents would be enforced once research became commercial. One respondent provided the following examples of the types of research that his company would consider sufficiently commercial to justify patent enforcement:

- if there is a fee for service;
- if an invoice is raised and there is a revenue stream;
- if the purpose of the research is for generating intellectual property; or
- if the research is done with a clear intention to lead to a commercial outcome.[109]

14.73 Submissions to the Inquiry confirmed that the existence of an experimental or research use 'exemption' is frequently relied on by Australian researchers, although the extent to which this is based on legal understandings or on expectations about the enforcement practices of patent holders is not entirely clear.[110]

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institutions surveyed included universities, government institutions, publicly funded independent research institutions and private research institutions.

105 See Ibid, 219–220.

106 See Ibid, 218.

107 Ibid, 219.

108 Ibid, 220.

109 Ibid, 221.

110 For example, the Queensland Government stated: 'Universities are often able to obtain free licences or "peppercorn" licence fees for research purposes, by adopting the research use defence': Queensland Government, *Submission P57*, 5 January 2004.

14.74 The Royal College of Pathologists of Australasia (RCPA) noted 'a long standing scientific convention that non-commercial research is exempt from patent enforcement'.[111] Davies Collison and Cave referred to evidence of 'substantial misunderstanding, and even ignorance, on the part of academic and other researchers who do not understand the rights conferred by a granted patent or the present position in relation to research or experimental use which may be exempt'.[112] The Queensland Government stated that industry seems to have adopted the practice that as long as they themselves are not commercially exploiting the patent, then the research use defence should apply.[113] The National Health and Medical Research Council (NHMRC) also observed that some researchers have assumed an implied exemption from patent protection for research as long as there are no attempts to commercialise the outcomes.[114]

14.75 Patent holders' decisions about whether or not to require licence fees from research organisations are often commercial and pragmatic, rather than legal in nature. Dr McBratney and others submitted:

> Patentees do not generally institute infringement proceedings against universities and other research institutes (because the damages are typically negligible); scientists usually conduct their research in disregard of the existence of patents. Generally, patentees favour research and development on their patented technology by universities because it adds value to their technologies.[115]

14.76 Patent holders may choose not to seek licence fees in respect of some gene patents so as not to prejudice the ongoing sale of equipment or consumables to major clients.[116] The use of patented inventions in research without a licence may be encouraged by the small size of the Australian market, which makes enforcement less worthwhile for patent holders.[117] Similarly, research organisations may make decisions about seeking licences based on their own risk or financial assessments.

Is reform needed?

14.77 Submissions to the Inquiry revealed broad support for a new experimental or research use defence,[118] although they were generally not explicit about the desirable

111 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
112 Davies Collison Cave, *Submission P48*, 24 October 2003.
113 Queensland Government, *Submission P57*, 5 January 2004.
114 National Health and Medical Research Council, *Submission P52*, 31 October 2003.
115 GlaxoSmithKline, *Submission P33*, 10 October 2003.
116 Australian Genome Research Facility, *Consultation*, Melbourne, 4 September 2003.
117 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.
118 See, eg, Cancer Council of New South Wales, *Submission P1*, 5 June 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; I Turnbull, *Submission P11*, 25 September 2003; Cancer Voices NSW Inc, *Submission P7*, 16 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Children's Cancer Institute Australia for Medical Research, *Submission P13*, 30 September 2003; Breast Cancer Network Australia, *Submission P22*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; R Barnard, *Submission*

scope of the defence. A cross-section of stakeholders indicated that it is desirable to eliminate uncertainty as to the existence of the defence and its scope.[119] Ian Turnbull wrote:

> It is all very well to talk about implied research exceptions to infringement but who will be the first to test it in court? It will generally only be when someone has achieved a valuable product resulting from their research that the original gene patent owner will be seeking to enforce his rights to share in the profits. Arguments supporting the suggested existing implied defence are not strong on my reading of it.[120]

14.78 GlaxoSmithKline stated:

> In our opinion the research community (including commercial organisations engaged in research) benefits from clarity in the scope of any research exemption from infringement, which enables them to understand the boundaries of the acts they are free to carry out with respect to a patented invention without infringement.[121]

14.79 Similar conclusions about the need for clarity were reached in Canada by CBAC, which observed that:

> the lack of clarity that currently exists in Canadian patent law can only cast a pall on university and independent researchers afraid of even the possibility of facing a patent infringement lawsuit. This chilling effect could lead to under-investment in basic research and the withholding of experimental results for fear that the disclosure of those results will draw the negative attention of the patent holder.[122]

14.80 Depending on the scope of any proposal, the justifications for an experimental or research use defence may be summarised as follows. The defence:

- enables the validity of existing patents to be properly tested by experimentation;

P32, 7 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; J Mattick, *Submission P35*, 13 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

119 See, eg, R Barnard, *Submission P32*, 7 October 2003; I Turnbull, *Submission P11*, 25 September 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

120 I Turnbull, *Submission P11*, 25 September 2003.

121 GlaxoSmithKline, *Submission P33*, 10 October 2003.

122 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 14–15. Similarly, the Ontario report noted that legal uncertainty about the extent of the experimental use exception could lead to abandonment of research projects and product development: Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 49.

- enables experiments to be conducted to determine whether a patentable invention falls within the scope of an existing patent;
- promotes attainment of new knowledge about patented inventions;
- promotes the development of new and improved inventions and reduces the likelihood of monopolisation of a new area of technology by a patent holder;
- removes a burden on researchers, who might otherwise need to conduct extensive patent searches and obtain advice from lawyers and patent attorneys; and
- involves minimal interference with the patent holder's economic interests.[123]

14.81 Submissions put forward a range of reasons for recognising an experimental or research use defence. The Australian Association of Pathology Practices Inc advocated 'exemption of basic research from patent compliance', stating:

> We feel that this not only delivers genes and other genetic material back to the true owners, i.e. the human race, but helps stimulate further ongoing research and development of better diagnostic genetic tests whilst still protecting patent holders rights in relation to pharmaceutical exploitation of their 'discoveries'.[124]

14.82 The RCPA considered that non-commercial research should be exempt from patent infringement, based on the principle that 'public institutions should be free to conduct research of a non-commercial nature'.[125] Dr Graeme Suthers referred to the need for research exemptions to prevent research being compromised by broad patents on genetic sequences.[126]

14.83 The Walter and Eliza Hall Institute of Medical Research submitted that a new research use defence should be enacted to further encourage innovation:

> In principle the purposes of the original patent acts were to exchange potential monopolies for the right of others to use the information to improve the product or produce new products. In this sense use of patent information for research purposes (even in the private domain) should not be seen as an infringement of the patent. Courts can then determine if the improved or new products themselves are in fact infringements of the original patent claims. This devolves consideration of infringement to issues of obtaining commercial advantage without impeding the further development of improved medical products.[127]

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123 See C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 15.

124 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003.

125 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

126 G Suthers, *Submission P30*, 2 October 2003.

127 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

14.84 Some submissions opposed the introduction of any new experimental or research use defence.[128] Genetic Technologies Limited (GTG) stated:

> The question is where does public domain research stop and commercial research start. Whatever the answer is, the border is not the gates of the publicly funded research institutes; these entities are collectively the biggest patenters and licencers in the world. At the end the answer lies in jettisoning the idea of a research exemption and developing a standard form of research licence that would be readily granted by 'all' patent holders for a nominal fee, but that would limit coverage to only certain types of activity. Activity beyond this limit would require a commercial licence.[129]

14.85 Dr McBratney and others submitted that:

> the research exception or defence is of little use even where it has been introduced either legislatively or at common law. It should not be introduced into Australian law. The better approach is to review and reform the compulsory licensing regime.[130]

14.86 These and other submissions highlighted the difficulties in framing an appropriate experimental or research use defence and, in particular, in distinguishing between commercial and non-commercial activity, and in dealing with the exploitation of research tools. These issues, and others related to the framing of a new defence, are examined in more detail below.

14.87 Some other approaches to the treatment of experimental or research use of patented inventions are discussed in other chapters of this Discussion Paper. One alternative approach is to introduce a statutory licensing scheme to facilitate access to gene patents for the purpose of research, however defined. Statutory licensing schemes involve the payment of a reasonable licence fee to the patent holder for use of the invention.[131] Another suggestion is that patent law could be amended to bring it in line with the 'fair dealing' exemption available in copyright law.[132] Finally, some submissions and consultations suggested that regulatory review provisions could provide useful models for reform concerning the experimental or research use of patented genetic inventions.[133]

The content of new defences

14.88 A persistent difficulty is how to define the scope of any new statutory defence. Two issues raise particular concern:

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128 A McBratney and others, *Submission P47*, 22 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.

129 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

130 A McBratney and others, *Submission P47*, 22 October 2003.

131 See Ch 28.

132 See M O'Rourke, 'Toward a Doctrine of Fair Use in Patent Law' (2000) 100 *Columbia Law Journal* 1177.

133 R Barnard, *Submission P32*, 7 October 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.

- the extent to which experimental uses may have commercial purposes; and
- the relationship between permitted experimental use and the subject matter of the patented invention.

Commercial purpose

14.89 In framing a statutory experimental use defence an important consideration is the extent to which experimental use may have a commercial purpose. If the immediate purpose of the experimentation is technical—that is, to discover more about the patented invention—to what degree should the presence of potential commercial interests be permissible?

14.90 Many submissions suggested that the defence should be available only for non-commercial research, or research conducted by not-for-profit entities. For example, the Caroline Chisholm Centre for Health Ethics submitted that no licence should be required for patented inventions used in 'pure research, ie the pursuit of scientific knowledge' but that this should not apply to research with a commercial purpose.[134] The Cancer Council Australia suggested that there should be an exemption if patented genetic sequences are used in 'bona fide, not-for-profit research'.[135]

14.91 In practice, it is difficult to distinguish between 'pure' or 'basic' research and research whose purpose or effect is to produce a commercial outcome.[136] It is often unclear when research with potential application to the development of a new product or process becomes directed to commercial purposes.

14.92 This difficulty is exacerbated by policies promoting the commercialisation of publicly funded research, as discussed in Chapters 12 and 15. These policies mean that commercial objectives are defined early in the research cycle—making it harder to argue that the research has no commercial motivation. For example, commercialisation prospects may be identified in research funding applications to bodies such as the NHMRC or the Australian Research Council (ARC).

14.93 It has been suggested that, for any new experimental or research use defence to be workable, it should avoid, as far as possible, the need to decide whether research is commercial or non-commercial in nature.[137] In many jurisdictions, courts have struggled to determine the level of commerciality that will disqualify an alleged infringer from relying on an experimental use defence.

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134 Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003.

135 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Voices NSW Inc, *Submission P7*, 16 September 2003.

136 See, eg, Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 58–59; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 60–61.

137 South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003; Gene CRC, *Consultation*, Melbourne, 3 September 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.

14.94 This difficulty was highlighted in submissions.[138] The Department of Industry, Tourism and Resources (DITR) stated that:

> care needs to be exercised in defining the phrase 'research use' as the boundaries between research and commercialisation are blurred and the potential exists for patent infringement under the guise of research.[139]

14.95 AusBiotech Ltd submitted that the defence should relate to research that might lead to a possible commercial application some time in the future, while excluding clinical or field trials undertaken to obtain regulatory approval for marketing of a product.[140]

14.96 Some submissions suggested that any attempt to construct a defence based on distinctions between commercial and non-commercial research would be unlikely to work. The RCPA submitted:

> the distinctions between public and private institutions and commercial and non-commercial research are becoming blurred. Almost all public research institutions have active programmes to commercialise their intellectual property and conversely many private companies receive substantial public funding to support their research programmes and business development. This is, therefore, likely to make such proposals unworkable.[141]

14.97 Dr McBratney and others, in opposing a new experimental or research use defence, referred to this issue as 'an almost intractable problem'.[142] A particular problem is that research may start out as non-commercial but acquire a commercial intent—raising questions about exactly when the defence would cease to apply and infringement commence.[143]

14.98 GlaxoSmithKline submitted that a research defence based on distinctions between commercial and non-commercial purposes would be misconceived. Rather, the defence should distinguish between the types of acts carried out, rather than the nature or intentions of the parties.[144]

14.99 Professor John Mattick suggested that research should be exempt from obligations to pay licence fees or royalties to patent holders where the research activity does not directly generate revenue.[145]

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138 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

139 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

140 AusBiotech Ltd, *Submission P58*, 7 November 2003.

141 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

142 A McBratney and others, *Submission P47*, 22 October 2003.

143 Ibid.

144 GlaxoSmithKline, *Submission P33*, 10 October 2003.

145 J Mattick, *Submission P35*, 13 October 2003.

Experimentation or research?

14.100 A second key issue concerns the relationship that must exist between experiments and the patented invention in order for use to be protected by an experimental or research use defence. Existing experimental use defences distinguish between experimental use 'relating to the subject matter of a patented invention'[146] and other forms of research use. Only the former category of use is covered by the defence.

14.101 This distinction has been explained in various ways. One simple explanation is that while research *on* a patented invention is exempt from claims of patent infringement, research simply involving the *use* of a patented invention is not.[147] In other words, the defence:

> does not cover any use without a licence of a patented research tool or medium which is needed for the research but is not being experimented upon for its own sake.[148]

14.102 For example, work to provide an improved polymerase chain reaction (PCR) methodology would probably qualify as experimental use, but not work which simply used PCR as a standard methodological step.[149] Inevitably, there will be doubts about where permitted experimental use merges into broader research use that is not covered by the defence. A particular issue for healthcare provision is whether experimental use may encompass clinical treatment that provides research results at the same time.[150] A 2003 report for the United Kingdom Department of Health stated:

> As research on genetic diagnosis and therapy grows in volume and effectiveness the question of clinical testing will become urgent. On balance a health authority appears to have a greater interest in ensuring (preferably by clear legislation) that the exception does apply to all testing that can reasonably be said to have research as one main purpose, provided that the prospects for further knowledge are not fanciful.[151]

14.103 There are particular complexities with regard to the application of the CPC's experimental use defence to DNA sequences and other isolated genetic materials. One view is that art 27 of the CPC:

> means that researchers will be able to conduct research on patented DNA sequences without violating that patent if the research relates to improving, further developing or testing the DNA sequence. Research aimed at discovering another function of the DNA sequence, its interrelation with another DNA sequences, or its involvement in the development of disease, for example, all arguably fall within the meaning of improving or further developing the DNA sequence.[152]

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146 These are the words used in *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01 art 27(b) and *Patents Act 1977* (UK) s 60(5).

147 See Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 60.

148 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 71.

149 Ibid, 71–72.

150 Ibid, 33.

151 Ibid, 33.

152 R Gold and A Gallochat, *The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation, and Lessons for Canada* (2001), 10.

14.104 Associate Professor Richard Gold and Alain Gallochat state that there are two schools of thought on the scope of the experimental use defence as applied to DNA sequences. The first approach is to say that much research using a patented DNA sequence as a base falls within the defence, including research aimed at discovering new biological pathways on which pharmaceuticals can act or finding pharmaceuticals that change the expression of the sequence. The second approach, however, would limit the defence to research aimed at discovering the properties of the patented DNA itself, but not involving the discovery of new products through the use of that material.

14.105 To clarify the issue, CBAC found it desirable to add the words 'to investigate its properties, improve upon it, or create a new product or process' to the wording of its proposed experimental use defence. This modification was designed to make it clear that researchers can rely on the experimental use provision 'to use a DNA sequence, for example, to find molecules that bind to it or act upon it'.[153]

14.106 Submissions to the Inquiry addressed the distinction between research on a patented invention and research involving its use. Associate Professor Ross Barnard stated:

> In my experience, researchers have to date operated with the belief that it was permissible to work 'on' an invention (for the purposes of improving the invention or making a new invention), but not to work 'with' an invention with a view to providing a service or delivering a product.[154]

14.107 Associate Professor Barnard noted that the line between these forms of research is not easy to draw 'particularly when one considers that basic research can lead in the long term, or sometimes serendipitously in the short term, to commercial products'.[155] He considered that it would be most advantageous for Australian researchers if research of any type could be permitted.[156]

14.108 However, one problem with such a broad exemption would be that patent rights over research tools could be rendered illusory: where the only use of the patented invention is in the conduct of research, the invention may not be able to be exploited effectively by the patent holder. Such a situation might penalise the Australian biotechnology industry.[157] GTG stated:

> A generic research exemption would totally devalue significant new inventions specifically directed towards assisting research … Research organisations do not get their computers free, they do not get software from Microsoft free, nor do they get their chemical lab supplies, staff, space, equipment and utilities free of charge. Why

153 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 15.
154 R Barnard, *Submission P32*, 7 October 2003.
155 Ibid.
156 Ibid.
157 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.

> should they be empowered to utilise intellectual property free of charge without consideration or benefit for the inventor … ?[158]

14.109 The Human Genetics Society of Australasia, while supporting the introduction of an experimental or research use defence, considered that the defence should be limited 'to research on an invention claimed in a gene patent'.[159] GlaxoSmithKline also submitted that the exemption should apply to experimentation or research on a patented invention. That is:

> activities carried out seeking to discover new knowledge about the patented invention, irrespective of whether that research is undertaken for commercial purposes or not and irrespective whether it is undertaken in an academic or commercial organisation. The defence would extend to the elucidation of how the invention works, improving upon it and finding new uses for it, but not to using the invention in research for the very purpose for which the patent was granted. This is the basis of the European defence of research into the subject matter of the invention.[160]

14.110 Davies Collison Cave also supported the introduction of a new experimental use defence limited to activities involving research or experiment on a patented invention. It submitted that:

> whilst the scope of the defence may encompass research or experimental use directed to improving upon the claimed invention or finding a new use for the claimed invention, if a new product or process is created *using* the claimed invention, this would not appear to be research on the patent and accordingly should be excluded from the scope of the defence.[161]

14.111 The European model received explicit support from the Australian Centre for Intellectual Property in Agriculture (ACIPA).[162] ACIPA recommended the introduction of a research use exemption intended to encourage experimental testing and follow-on innovation, and defined 'along the lines of European Union model'.[163]

Private and non-commercial use

14.112 IP 27 asked whether the *Patents Act* should be amended to include a defence for private and non-commercial use of a patented invention.[164] Submissions offered a mixed response to this question.

14.113 Some submissions supported the idea of such a defence.[165] GlaxoSmithKline stated that it would be useful in protecting the end users of patent infringing products, while leaving others in the manufacturing and supply chain liable.

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158 Genetic Technologies Limited, *Submission P45*, 20 October 2003.
159 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
160 GlaxoSmithKline, *Submission P33*, 10 October 2003.
161 Davies Collison Cave, *Submission P48*, 24 October 2003.
162 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
163 Ibid.
164 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 14–2.

> Whilst the presence of such a defence in the Patents Act would make little difference to patentees, who are unlikely to find out about or to object to any use which is truly private, or to commercial or public service organisations whose activities would be very unlikely to be covered, such a provision may give a greater sense of security to the truly private user.[166]

14.114 Other submissions opposed the introduction of a private and non-commercial use defence, mostly on the basis that such a defence would be unlikely to serve any useful purpose, given its narrow ambit.[167] DITR noted that genetic technologies are unlikely to be used for private and non-commercial purposes as they require use by experts under controlled conditions.[168] Dr McBratney and others stated that such a defence would be of 'minimal practical use' because:

> (i) the patentee would likely never learn of such private, non-commercial use; (ii) the patentee would not be likely suffer the kind of losses that would support the grant of injunction or award of damages; and (iii) the infringer in such circumstances would likely not have deep enough pockets to pay any damages that were assessed.[169]

The TRIPS Agreement and experimental use

14.115 Any proposed new experimental or research use defence needs to be consistent with Australia's obligations under the TRIPS Agreement, and in particular with art 27, which requires that member States make patent protection available without discrimination by field of technology and art 30, which allows member States to provide only limited exceptions to patent rights.[170]

14.116 The World Trade Organization Panel Report in the *Canada–Patent Protection* case[171] provides significant commentary on the interpretation of relevant provisions of the TRIPS Agreement. The complaint concerned the patent protection of pharmaceutical products and the operation of regulatory review (or springboarding) provisions contained in the *Patents Act 1985* (Canada).[172] By analogy, the case

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165 See, eg, GlaxoSmithKline, *Submission P33*, 10 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

166 GlaxoSmithKline, *Submission P33*, 10 October 2003.

167 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.

168 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

169 A McBratney and others, *Submission P47*, 22 October 2003.

170 See Ch 4.

171 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 152.

172 The approximate Australian equivalent is *Patents Act 1990* (Cth) s 78(2). However, unlike the Canadian provision, this provides a defence to the infringement of a patent only after an extension of patent has been granted under *Patents Act 1990* (Cth), ss 70, 77, and is expressly limited to the exploitation of 'pharmaceutical substances'. The Canadian provisions also included a provision allowing the 'stockpiling' of articles intended for sale after the expiry of the patent. The general regulatory review provision was found to be 'not inconsistent' with TRIPS. The stockpiling provision was found to be inconsistent and was repealed in 2001: 2001, c. 10, (Bill S-17).

provides guidance on the allowable extent of experimental or research use defences under the TRIPS Agreement.

14.117 The Panel concluded that the words 'limited exception' in art 30 of the TRIPS Agreement express a requirement that:

> the exception make only a narrow curtailment of the legal rights which Article 28.1 requires to be granted to patent owners, and that the measure of that curtailment was the extent to which the affected legal rights themselves had been impaired.[173]

14.118 The second condition of art 30 prohibits exceptions that unreasonably conflict with the 'normal exploitation' of a patent. The Panel noted it is normal exploitation 'to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'.[174]

14.119 The third condition of art 30 prohibits exceptions that unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties. The Panel rejected an argument that legitimate interests were limited to legal interests and found that the term must be defined:

> in the way that it is often used in legal discourse—as a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms.[175]

14.120 In its discussion of 'legitimate interest', the Panel referred to research use exceptions in national laws. The Panel noted that such exceptions may be 'based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge'.[176] Both society and scientists have a 'legitimate interest' in using patent disclosure to support the advance of science and technology.

14.121 The TRIPS Agreement places significant constraints on the allowable ambit of exceptions to the exclusive rights conferred by patents. While the precise extent of these constraints is uncertain, the Inquiry has reached some preliminary conclusions in relation to experimental or research use defences.

14.122 It seems clear that the enactment of an experimental use defence into Australian law, covering acts done for experimental purposes relating to the subject

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173 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 158.

174 The Panel found that the regulatory review exception did not conflict with a normal exploitation of patents. Using patent rights to preclude submissions for regulatory authorisation and exploiting an additional period of *de facto* exclusive rights should not be considered 'normal': Ibid, 161–162.

175 Ibid, 158.

176 Ibid, 165.

matter of the patented invention,[177] would not conflict with the provisions of the TRIPS Agreement, as it would constitute an appropriately limited exception to patent rights.

14.123 In the *Canada–Patent Protection* case, both parties accepted that experimental use exceptions, which are found in the law of most members of the WTO, comply with the TRIPS Agreement. The European Communities and their member states (EC) stated that such exceptions are limited in character as they apply only to one of the five patent rights in art 28.1—that is, to 'using', but not to making, offering for sale, selling or importing.[178] There was no conflict with the normal exploitation of the patent because it is a consequence of the 'basic patent deal' that others may use the patent holder's invention to further develop the state of the art. Further, no monopoly on research is included in the patent holder's legitimate interests and, therefore, there is no need to balance those interests with those of third parties.[179] Canada noted that the experimental use exception was grounded in the theory that the experimentation was either a *de minimis* use of the invention or a form of scientific experimentation—that is, a 'fair use'.[180]

> As such, the exception was well within the four corners of Article 30 of the TRIPS Agreement. It was 'limited' in that it only applied to non-commercial experimentation, i.e. testing for academic or scientific purposes, or to commercial experimentation when a licence was anticipated. It would not be worth the trouble to sue a researcher or university for patent infringement, particularly if the research did not threaten the commercial interests of the patent holder.[181]

14.124 Further, it was said that such exceptions do not conflict with the normal exploitation of the patent, or unreasonably prejudice the legitimate interests of the patent owner, in that the latter retained the right to prevent the marketing or sale of any infringing subject matter.[182] Experimental use exceptions take account of the legitimate interests of third parties in the advance of scientific and technical knowledge, to the benefit of society at large.[183]

14.125 Australia's third party arguments noted that 'purely experimental use' could be justified under the TRIPS Agreement as either:

- not falling within the scope of exclusive patent rights under art 28 (and therefore not constituting an infringing act); or

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177 That is, consistent with United Kingdom law: *Patents Act 1977* (UK) s 60(5)(b); and *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01 art 27(b).
178 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 56.
179 Ibid, 56.
180 Ibid, 75.
181 Ibid, 75.
182 Ibid, 75.
183 Ibid, 75.

- a specific limited exception to patent rights under art 30.[184]

14.126 The position becomes more uncertain where it is proposed to provide more extensive protection. The broader the classes of experimental or research activity given protection, the more likely an exception will conflict with the TRIPS Agreement.

14.127 A significant uncertainty concerns the extent to which a defence could extend beyond experimental use to broader research use. For example, is it possible to cover a broad category of research activity if the exception is limited to 'pure' or 'basic' research that does not have immediate commercial application?

14.128 Article 27 of the TRIPS Agreement does not 'prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.[185] It may be possible to craft a broader research use exception that is specific to some defined subset of gene patents, so that the provision does not discriminate by field of technology in terms of TRIPS. However, there would need to be strong arguments to justify differentiating a relevant category of gene patents from patents in other fields of technology.

14.129 The ALRC has received some comments on the implications of the TRIPS Agreement for reform relating to experimental or research use defences. In consultations it was suggested that, providing any such defence applied only to non-commercial research, there would be minimal interference with the rights of the patent holder, helping ensure the reform was TRIPS–compliant.[186] GlaxoSmithKline considered that reform along the lines of the European Union model would comply with the TRIPS Agreement, but noted:

> in order to avoid any conflict with Australia's obligations under the TRIPs agreement, any research defence should not be limited to activities involving only gene patents, as this would be to discriminate on the basis of technology.[187]

14.130 ACIPA stated that the defences mooted in IP 27 did not go beyond international norms and practices and that the European Union and the United States have long recognised research use defences as 'a legitimate limited exception to the exclusive rights conferred by a patent'.[188]

ALRC's views

14.131 The ALRC has concluded that it is desirable to remove uncertainty about the existence and scope of an experimental use defence in Australian law. Such a reform received broad support in submissions. The existing uncertainty is unhelpful to the research community and commercial organisations. It has the potential to lead to

184 Ibid, 106.
185 Ibid, 170–171.
186 Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.
187 GlaxoSmithKline, *Submission P33*, 10 October 2003.
188 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

under-investment in basic research and hinder innovation because researchers are concerned that their activities may lead to legal action by patent holders.

14.132 In the *Canada–Patent Protection* case,[189] it was noted that an experimental use defence is closely linked to the 'basic underlying deal' embodied in the grant of a patent by the state.[190] The patent holder is given the exclusive right to exploit the patent for the term of the patent but in return agrees to disclose the invention at an early stage in order to avoid research investment being duplicated, and to make the invention available as the basis for further research. In a sense, therefore, an experimental use defence may be seen as a corollary to the disclosure requirement because otherwise researchers would be allowed only to read the description of the patented invention, without being able to experiment with the invention to see if and how it works.[191]

14.133 The ALRC's view is that the *Patents Act* should be amended to incorporate an express experimental use defence. However, the full benefit of reform will not be achieved unless the scope of any new experimental use defence is carefully defined. In those jurisdictions in which common law defences are more firmly established than in Australia, significant doubts exist about the ambit of the defence. Doubts may persist even where statutory defences exist, as in the United Kingdom and other member states of the European Union, unless the scope of the defence is articulated.

14.134 There are many possible criteria that might be used to delineate the boundary between permissible and impermissible experimentation or research involving a patented invention. For example, distinctions might be drawn between:

- experimentation *on* a patented invention and research involving the *use* of a patented invention;
- the purpose or intention of experimentation or research, in terms of its technical, scientific or commercial motivations;
- the technical, scientific or commercial outcomes of experimentation or research; or
- the nature of the organisation conducting the experimentation or research, for example whether the organisation is a commercial or not-for-profit entity.

14.135 The ALRC's preliminary view is that the key element should be the first listed criterion—that is, the required relationship between the experimentation or research and the patented invention. At a minimum, experimentation that seeks further

189 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R.

190 Ibid, 55.

191 Ibid, 56. See also T Sampson, 'Madey, Integra and the Wealth of Nations' (2004) 26 *European Intellectual Property Review* 1.

knowledge about the patented invention and its uses should be covered. The defence should also extend to experimentation or research on the patented invention aimed at improving the invention, as suggested by CBAC. This appears to be consistent with the views of Professor Rebecca Eisenberg, who has suggested that the proper scope of an experimental use defence should include research 'in the field of the invention, which could potentially lead to improvements in the patented technology or to the development of alternative means of achieving the same purpose'.[192]

14.136 It has been suggested that, under an experimental use defence, the following acts should not constitute patent infringement:

> (a) testing an invention to determine its sufficiency or to compare it to prior art; (b) tests to determine how the patented invention worked; (c) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention; (d) experimentation for the purpose of 'designing around' a patented invention; (e) testing to determine whether the invention met the tester's purposes in anticipation of requesting a licence; and (f) academic instructional experimentation with the invention.[193]

14.137 In Australia, depending on the view taken of the current law, many uses of patented genetic materials and technologies in medical research would infringe gene patents. An experimental use defence should protect some of these uses from claims of patent infringement, at least where the properties of the genetic materials and technologies are being investigated.

14.138 It is not a simple matter to describe what kinds of experimental uses of genetic materials or technologies should be regarded as involving experimentation *on* a patented invention, and therefore protected by an experimental use defence. However, a good starting point is that study or experimentation on patented genetic materials or technologies for the purpose of improving, further developing, or testing them should be covered by a defence.

14.139 For example, the ALRC suggests that experimentation on patented genetic materials aimed at discovering another function of a genetic sequence or its interrelation with another genetic sequence should generally be covered by such a defence. On the other hand, the use of some genetic materials, such as gene promoters and repressors,[194] should not be covered by the defence because the material is not itself being investigated, but is being used as a research tool to investigate a gene and

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192 R Eisenberg, 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' (1989) 56 *University of Chicago Law Review* 1017, 1078. Eisenberg notes that 'it might be appropriate in some cases to award a reasonable royalty after the fact' to the patent holder. See also A Rai, 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' (1999) 94 *Northwestern University Law Review* 77, 139.

193 Statement of Legislative History of Title V of Patent Competitiveness and Technological Innovation Bill 1990 (US) in H Wegner, *Patent Law in Biotechnology, Chemicals & Pharmaceuticals* (2nd ed, 1994), 465.

194 For example, a CMV (cytomegalovirus) promoter: US Patent Nos 5,168,062 and 5,385,839.

its expression. As discussed in Chapter 13, researchers developing downstream products often require access to patented inventions, including research tools, to conduct their research. Patent holders properly view these research tools as valuable end products in themselves, for which patent protection is important. The use of patented research tools should not be covered by a new experimental use defence.

14.140 In the ALRC's view, it would be unrealistic to insist that the purpose of experimentation be solely to gain more technical or scientific knowledge and that it have no commercial motivation. As CBAC explained:

> Given that even basic research often leads to commercial products, we have not attempted to distinguish between research conducted for purely academic purposes and research with a commercial interest.[195]

14.141 An important purpose of the patent system is to promote experimentation as a stepping stone to the development of new or improved inventions. Whether experimentation is conducted by a non-profit or commercial entity, or with altruistic or commercial motivations, does not seem central to this purpose.

14.142 Whatever its exact formulation, and with one important qualification, the ALRC's view is that a statutory defence should more closely resemble the law of the United Kingdom and other member states of the European Union (which permit experimentation to have some commercial motivation, though not perhaps a dominant commercial motivation) than the more restrictive position reflected in United States case law. Member states of the European Union have included experimental use exceptions in legislation without any apparent negative effects. Moreover, basing a new defence on the European Union model would promote harmonisation of Australian patent law with the law of a major trading bloc, and would give Australian courts the benefit of considering European case law in applying the new provisions.

14.143 The qualification, however, is that the existence of a commercial purpose or intention (even if a dominant purpose) should not be relevant to the application of an experimental use defence, so long as experimentation is on, rather than simply using, the patented invention.[196] This perspective is consistent with the view that the patent system is intended to facilitate research and promote innovation. It is also consistent with views expressed by Newman J in the case of *Integra Life Sciences v Merck KgaA*[197] in the United States Court of Appeals for the Federal Circuit. Newman J stated that the patent system:

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195 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 16.

196 As we have seen, under European laws, permissible experimentation may have some commercial objective but the commercial objective, it seems, may not be the dominant motivation. The courts are thus still required to inquire into the commercial motivation for research.

197 *Integra Life Sciences v Merck KgaA* 307 F 3d 1351 (2002). The case was heard at the same time as *Madey*.

> both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or improvement. Such activities are integral to the advance of technology.[198]

14.144 In response to arguments that commercial motivations should disqualify researchers from relying on the United States common law defence, Newman J stated:

> an ultimate goal or hope of profit from successful research should not eliminate the exemption. The better rule is to recognize the exemption for research conducted in order to understand or improve upon or modify the patented subject matter, whatever the ultimate goal. That is how the patent system has always worked: the patent is infringed by and bars activity associated with development and commercialization of infringing subject matter, but the research itself is not prohibited, nor is comparison of the patented subject matter with improved technology or with designs whose purpose is to avoid the patent.[199]

14.145 For these reasons, the ALRC proposes that the Commonwealth enact a new defence under the *Patents Act* to a claim of infringement relating to the use of a patented invention to study or experiment on the subject matter of a patented invention, for example, to investigate its properties or to improve upon it (Proposal 14–1). The legislation should make it clear that the existence of a commercial purpose or intention does not affect the availability of the defence, provided the study or experimentation is on the subject matter of the patented invention.

14.146 It may be that some commercially-orientated research falls outside the scope of such a defence; if so, this is not because the research has a commercial objective but because it is not experimentation on the subject matter of the patented invention. This may be the case, for example, where trials are conducted not to find out more about the subject matter of a patented invention but simply to prove known characteristics of the invention to the satisfaction of a regulator. In practice, because the scope of the proposed defence is limited to study or experimentation on the subject matter of the patented invention, most research *using* patented inventions will not be covered by it.

14.147 As currently formulated, Proposal 14–1 applies to all patented inventions, not just those concerning genetic materials and technologies. Submissions and consultations emphasised that the problems encountered in relation to the experimental use of patented genetic technologies are similar to those applicable to other subject matter, such as business methods and pharmaceuticals.[200] For example, Davies Collison Cave submitted that any amendment should apply in all fields of technology

198 Ibid, (Newman J, dissenting).

199 Ibid.

200 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

> for the simple reason that the current difficulties are not confined to the 'gene patent' field, but apply in all fields of technology, particularly in the pharmaceutical and related fields.[201]

14.148 Similarly, DITR stated:

> The use of advanced technologies in the course of further research is a need that is common to all areas of technology and therefore there is no apparent reason why this defence needs to be instituted for genetic research only.[202]

14.149 In addition, the TRIPS Agreement imposes constraints on the extent to which the national laws of signatory countries may discriminate by 'field of technology'.[203] This provides another important reason why it is appropriate to extend this proposed reform beyond gene patents to all patented inventions.

14.150 Finally, as noted above, the CPC, the *Patents Act 1977* (UK) and the CBAC recommendations each incorporate a private and non-commercial use defence. While there may be some advantage in also incorporating this defence into the *Patents Act* in terms of promoting the harmonisation of Australian patent law with European laws, the ALRC does not find the arguments in favour of such a defence compelling. The defence would have little practical application to the use of genetic materials and technologies, and it received no significant support in submissions to the Inquiry.

Proposal 14–1 The Commonwealth should amend the *Patents Act 1990* (Cth) to establish a new defence to a claim of patent infringement based on the use of a patented invention to study or experiment on the subject matter of the invention; for example, to investigate its properties or improve upon it. The legislation should make it clear that the existence of a commercial purpose or intention does not affect the availability of the defence.

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201 Davies Collison Cave, *Submission P48*, 24 October 2003.

202 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

203 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 27.1.

15. Research Culture, Patents and Commercialisation

Contents

Introduction

15.1 The Terms of Reference direct the ALRC to consider the impact of current patenting laws and practices related to genes and genetic and related technologies on the conduct of research and its subsequent application and commercialisation.

15.2 Obtaining patent protection for new inventions in genetics is often vital to ensure the invention is developed to the stage where it has a useful application, particularly in healthcare provision. One submission commented:

> Without patents the discovery and development of new and cost effective medicines and vaccines will not [take] place, with or without public funding. Without gene patents, there would be little or no incentive to invest in this area of research and develop new innovative medicines on the basis of this research.[1]

1 GlaxoSmithKline, *Submission P33*, 10 October 2003. See also Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

15.3 Failure to patent genetic research may therefore affect healthcare provision if it is not picked up by industry. This may occur where researchers fail to obtain patent protection either due to a lack of experience with the patenting process or because of resistance to the need to protect and commercially exploit research. It may also occur if the research is made public before a patent application has been made, as the invention may no longer be novel.

15.4 This chapter considers the impact of patenting on research practice. It examines the role of academic researchers in the patenting and commercialisation process and considers some factors that may adversely affect this process.

15.5 This chapter also explores the relationship between the need for secrecy to protect the novelty of a new invention prior to obtaining a patent and the scientific tradition of peer review and replication of studies and briefly considers how this affects research practice. The effect of the provisions for non-prejudicial disclosures and the grace period prior to filing a patent application provided under the *Patents Act 1990* (Cth) (*Patents Act*) are considered in relation to early publication of research results and the ability to obtain a patent.

Researchers, patenting and commercialisation

15.6 It is Australian Government policy to promote the commercial exploitation of innovative research.[2] As discussed in Chapter 12, the responsibility to obtain intellectual property protection and pursue commercialisation of research lies with the institution that receives government funding and carries out research. Within institutions, it is researchers who are usually best placed to identify research with commercial potential.

15.7 This emphasis on commercialisation is a relatively new development in the culture of research. As John O'Connor has suggested:

> Before the advent of the commercial potential of biotechnology, researchers were not motivated to seek patent protection. This is because it was regarded as being against scientific norms to claim exclusive rights in research discoveries. Consequently, commercial potential of recent advances in biotechnology has created a conflict between traditional policies of patent law and scientific research.[3]

15.8 Dr Dianne Nicol and Jane Nielsen have also observed that academics involved in upstream research must now respond to commercial considerations, noting:

> Many of the scientists who are involved in upstream research and for whom academic kudos has in the past been sufficient reward are now required to consider the best ways to protect their intellectual property rights and transfer their technology to

2 See Ch 18.

3 J O'Connor, 'The Commercialisation of Human Tissue: The Source of Legal, Ethical and Social Problems: An Area Better Suited to Legislative Resolution' (1990) 24 *Loyola of Los Angeles Law Review* 115, 137.

> industry. This introduces sharper focus on commercial considerations in the research environment.[4]

15.9 The skills, experience and attitudes of academic researchers may affect the capture and exploitation of intellectual property in genetic research. This is particularly so in relation to genetic research, where more than 50% of Australian holders of gene patents are public sector organisations.[5]

Resistance to commercialisation

15.10 One factor that may prevent genetic research from being patented and subsequently commercialised is researcher resistance to obtaining and exploiting patents. It has been suggested that some academic researchers resist patenting and commercialisation because of perceptions that commercially-focused work is 'dirty' science.[6] A recent study of biotechnology patenting and technology transfer practices by Nicol and Nielsen (Nicol-Nielsen Study) reported:

> one respondent said that researchers hate patents, and see patenting as prostitution, but they pay the bills. Another said that some researchers just don't want to know about patents and others make jibes about the patent system. He described attempts to change attitudes about patents in the research sector as 'trying to turn around a big ship'.[7]

15.11 Some comments received in consultations also suggested that there is an anti-commercialisation attitude prevalent among researchers.[8] For example, Bio Innovation SA suggested that this might in part be because some researchers do not regard commercially-focused science as 'real' science, or because of a belief that placing research results in the public domain without patenting them will allow others to benefit from the research.[9] Another stated that:

> Observation suggests that most scientists see patents and IP generally as a necessary evil that they wish would simply go away because of the work involved and costs of administration, associated with licensing for example. All of which interferes with their actual job of doing science.[10]

15.12 Scientists may also resist commercialisation due to the need for the scientific community to freely and widely disseminate their research results. This freedom may be restricted by the need to keep results confidential prior to making a patent

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4 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 35.

5 See Ch 17, figure 17–2.

6 T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 5.

7 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 125.

8 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003; Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

9 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

10 I Turnbull, *Submission P11*, 25 September 2003.

application or due to contractual terms in licensing or collaborative agreements. The impact of secrecy requirements on scientific research is discussed further below.

15.13 However, it appears that this resistance is decreasing and that the research culture in Australia has undergone a shift over the past decade. In some consultations, it was suggested that there is now greater acceptance of the need to commercialise research results.[11] For example, the Queensland Biotechnology Advisory Council suggested that in the past, commercial application of research results had been 'frowned upon', but said that research culture is now more accepting of commercialisation.[12] One respondent in the Nicol-Nielsen Study, a technology transfer officer, stated:

> there are two types of researchers: those that always have their eye on further activities. For them, intellectual property is the currency. They know that it is an important part of their work. Others (generally older academics) find it really annoying. They find it difficult to understand corporate bodies, ownership of intellectual property and employment issues. But this culture is changing. We rarely come across problems now.[13]

15.14 Respondents in the Nicol-Nielsen Study suggested a number of causes for this change in culture. These included the preference of funding bodies such as the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) for funding research with commercial potential; the need to obtain funding from the private sector due to a lack of public sector funding; the desire for economic viability, and for some, the view that successful commercial exploitation may be lucrative.[14] Changed attitudes have also been attributed to researcher experience working within Co-operative Research Centres.[15]

15.15 However, some researchers do not seek patents and pursue commercialisation because they regard other aspects of research activity as more important. Although most publicly funded research institutions provide for researchers to share in royalties flowing from the successful commercialisation of an invention, this may not be a sufficient incentive for some researchers to put in the time required to apply for and exploit a patent.[16]

15.16 Another aspect of this resistance is that applying for patents may reduce the time available for researchers to pursue other activities that are more likely to contribute to

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11 Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

12 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003. See also Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

13 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 125–126.

14 Ibid, 126.

15 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), xxii.

16 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72.

career progression. For academic researchers, publishing research results is an important factor in career progression and obtaining funding grants, as a good publication record affords both prestige and evidence of research excellence.[17]

15.17 A 1999 survey by Toss Gascoigne and Jenni Metcalfe (Gascoigne-Metcalfe Survey) of 126 scientists across Australia demonstrated that some researchers believe that their career progression will be limited if they spend time patenting and commercialising research rather than on publication. Survey participants reported having missed promotion because time spent on commercialisation had taken them away from publishing and seeking grants.[18] However, it should be noted that this survey was carried out largely before the major government initiatives for stimulating commercialisation of research had begun. As noted above, attitudes do appear to be shifting towards greater acceptance of commercialisation as a result.

15.18 The Department of Education, Science and Training report, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (DEST Report) suggested that wariness about patenting can be partially attributed to that fact that:

> academic performance appraisal is still often based on publication or grants received rather than efforts to commercialise. Not only does this provide inadequate incentive to commercialise, but when 'commercialisation activities remove them from 'mainstream' activities' it can jeopardise academics' chances for promotion and thus act as a disincentive.[19]

15.19 Similarly, the Gascoigne-Metcalfe Survey reported that some participants criticised research organisations:

> for making promotions and appointments on the basis of the number of academic papers an applicant had published rather than commercial activities, notwithstanding formal policies to the contrary.[20]

15.20 According to the DEST Report, although some universities have begun to include commercialisation activity as a criterion for assessing performance, the practice is still not widespread: 'Instead, it seems that grants and publications are the primary criterion used in promotions'.[21]

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17 M Berry and A McBratney, *Submission to the Senate Standing Committee on Regulations & Ordinances: An Analysis of Issues Relevant to the Patents Amendment Regulations 2002 (No 1) which Introduced a Grace Period into Australian Patent Law* (2002), 16.

18 T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999).

19 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72.

20 T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 1.

21 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 82. See also R Johnston, M Matthews and M Dodgson,

15.21 More generally, in 2003, Research Australia released the *Health & Medical Researcher Opinion Poll 2003* (*Health and Medical Researcher Opinion Poll*), a survey of health and medical researcher attitudes to, among other issues, research commercialisation.[22] Respondents, who encompassed researchers at universities, hospitals, medical research institutes, and pharmaceutical and biotechnology companies, were asked to rate the importance of a variety of research outcomes. Only 55% of respondents rated patenting research results as important, while 99% rated improving health outcomes as important. The survey findings also suggested that researchers were reticent about commercialising their research. Only 40% agreed they would like to be involved in the commercialisation process, while 34% said they would not like to be involved at all.[23]

Submissions and consultations

15.22 The ALRC sought comment in consultations on whether the intention to obtain patents and other intellectual property has had adverse effects on the timely publication of research outcomes. It was generally recognised that in the increasingly commercialised research environment, publication is often delayed because organisations seek to protect their positions with regard to intellectual property.[24]

15.23 While this did not necessarily have a significant impact on the overall progress of science,[25] some concern was expressed about the possible impact of publication constraints on the careers of individual researchers.[26] It was suggested that there is a need to change the system of grant assessment to recognise experience in commercialisation and obtaining patents as well as research record as indicators of research success.[27]

15.24 On the other hand, the ALRC also heard that promotion panels and research grant committees have procedures for taking patents into account in assessing researchers' track records.[28] For example, the ARC commented in submissions that it is relatively straightforward to balance publications and patents in assessing the research record of applications for grants or before promotion panels. An assessment of an applicant's research ability can be made even where they hold patents but have no

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Enabling the Virtuous Cycle: Identifying and Removing Barriers to Entrepreneurial Activity by Health and Medical Researchers in the Higher Education Sector (2000), 17.

22 Research Australia, *Health & Medical Researcher Opinion Poll 2003* (2003), 3.

23 Ibid, 6.

24 Australian Academy of Science, *Consultation*, Canberra, 22 September 2003; Gene CRC, *Consultation*, Melbourne, 3 September 2003.

25 Australian Academy of Science, *Consultation*, Canberra, 22 September 2003; Gene CRC, *Consultation*, Melbourne, 3 September 2003.

26 Australian Academy of Science, *Consultation*, Canberra, 22 September 2003.

27 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

28 Australian Research Council, *Consultation*, Canberra, 22 September 2003; National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003; Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

publications.[29] The NHMRC pointed out that it is possible to take account of researchers' time spent on other projects in relation to their achievements in assessing funding applications.[30]

Options for reform[31]

15.25 One solution to a lack of researcher involvement in patenting and commercialisation is to foster a research culture that is positive towards commercialisation. In 1999, the Health and Medical Strategic Review report, *The Virtuous Cycle: Working Together for Health and Medical Research* (Wills Report) noted a number of factors that might affect the development of this culture. These were whether there was appropriate recognition of commercial success in the academic environment; appropriate role models for commercialisation practice; or barriers to researcher involvement in commercial enterprises. The report included recommendations that:

- Australian academic, research and funding bodies develop ways to incorporate commercial measures of research outcomes, such as patents and receipt of industry funding, when assessing the performance of a researcher, project or institution;

- successful commercialisation role models be highlighted and networks for mentorship be established and promoted to researchers; and

- researchers be provided with incentives to develop technology commercially, including royalty-sharing arrangements, the ability to hold equity and accept directorships in biotechnology companies; and the capacity to move between academia and industry be facilitated.[32]

15.26 The ARC suggested a variety of strategies for promoting commercialisation in its 2000 report, *Research in the National Interest: Commercialising University Research in Australia* (ARC report). These included creating the right academic environment, in which individuals and institutions were 'committed to increasing the opportunities and rewards for commercialisation'. It outlined a number of means of achieving this, such as improving understanding of the commercialisation process within the institution and establishing policies for intellectual property ownership and management.[33]

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29 Australian Research Council, *Consultation*, Canberra, 22 September 2003.
30 National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003.
31 This section is written on the premise that there is value in patenting genetic research. This is not, however, a statement that all genetic research ought to be patented.
32 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 125–127.
33 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 39.

15.27 The ARC also suggested that one model for reform could be to 'ensure in the conditions of award for an ARC grant that the researchers hold the licence to exploit the IP arising from the research'.[34] This approach would provide incentives for researchers to develop research to commercialisation stage. However, the report suggested it might also be a barrier to commercialisation if researchers lack the skills, the financial means and the time and networks needed to undertake this development. The ARC suggested that this might be addressed by providing support to researchers during the commercialisation process, in exchange for a share of royalties.[35]

15.28 Such arrangements are in place at many research institutions. In 2001, the ARC released the *National Principles of Intellectual Property Management for Publicly Funded Research* (*National Principles*), which stipulate that publicly funded research institutions should provide researchers with adequate incentives to participate in the commercialisation process.[36] The NHMRC's *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (*Interim Guidelines*) contain similar provisions.[37]

15.29 The DEST Report recommended implementing an expanded National Principles model placing greater emphasis on the need for institutions to ensure competing demands on researchers do not act as a disincentive to participation in commercialisation. It suggested this should include recognising commercialisation activity as a criterion for assessing performance.[38]

ALRC's views

15.30 The ALRC's preliminary view is that it endorses the policies and actions of the NHMRC and ARC in seeking to promote commercialisation in appropriate cases. While the NHMRC and ARC policies do take account of patents when considering applications for research funding, it also appears that there is a perception among some researchers that patents are not adequately valued in this process. This is particularly so because of the time required to make and support patent applications, which may lead some researchers to prioritise publication over patent protection. The ALRC is interested in comments on any disincentives to patenting of genetic research that affect researchers.

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34 Ibid, 20.
35 Ibid, 20–21.
36 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), Principle 3.
37 National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), Principle 2.6.
38 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 82.

Question 15–1 In assessing the research record of grant applicants, is sufficient weight given to the applicant's record in applying for and obtaining patents? Are there any other disincentives for researchers to seek patents over genetic research outcomes?

Question 15–2 Are any additional strategies or policies required by the National Health and Medical Research Council, the Australian Research Council, universities, or other publicly funded research institutions to encourage researchers to patent and commercialise the outcomes of genetic research?

Lack of skills and experience

15.31 As indicated above, researchers are increasingly encouraged to participate in the process of patenting and commercialising genetic research.[39] The first stage in translating genetic research into healthcare benefits is the identification of new technology with potential healthcare applications. Once identified, the next stage is obtaining patent protection and subsequently developing the technology into a usable product. Hence, the initial identification stage is crucial to ensuring the benefits of genetic research reach the community.

15.32 While researchers are obviously well-placed to identify new technologies, where they lack the skills to do so effectively, the potential health benefits of these technologies may not be realised. They may also lack the commercial skills and experience to contribute effectively to the process of commercialisation.

15.33 The Gascoigne-Metcalfe Survey suggested that:

> Thinking commercially does not come naturally to scientists. They do not see careers in the commercial world or recognise the problems that industry is trying to solve.[40]

15.34 Some participants in the Gascoigne-Metcalfe Survey commented that they found it difficult to recognise when their research had potential commercial value and that they lacked knowledge of the commercialisation process. One participant noted, 'We don't know what we don't know' and reported that lack of experience extended to obtaining patents and intellectual property management.[41]

15.35 Participants in the Gascoigne-Metcalfe Survey also reported that they needed access to advice on commercialisation and '"translators" who can speak both the language of industry and the language of research'.[42] Responses to the *Health and*

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39 T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 1.
40 Ibid, 5.
41 Ibid, 5, 7.
42 Ibid, 5.

Medical Research Researcher Opinion Poll were similar, with a significant number of respondents stating that they did not feel they had the skills to commercialise their research results. Although 50% agreed that they would know how to find help to develop their product (with only 10% strongly agreeing), 33% said they would not know how to find advice on developing the commercial potential of their discoveries.[43]

15.36 The *National Principles* and *Interim Guidelines* require institutions to inform staff of their responsibilities in relation to intellectual property protection.[44] Most publicly funded research institutions also have pre-publication review procedures, where papers to be submitted for publication are reviewed to identify potentially patentable inventions[45] and technology transfer offices to manage intellectual property and commercialisation. These offices assist academics in applying for and commercialising patents, and may take on a considerable portion of the responsibility for the process of commercialisation.[46] However, it appears that not all researchers are aware of the functions of these offices, and do not access the support available to them.

15.37 Marc Berry and Dr Amanda McBratney have also suggested that there are inadequate proper educational frameworks to 'support users of the patent system and ensure that those users are aware of their rights and obligations under that system'.[47] The ARC report stated that unless there was appropriate support for individual researchers, they could be disadvantaged because of a lack of expertise in intellectual property management and a lack of commercial and legal expertise to negotiate deals involving intellectual property.[48]

Question 15–3 Do researchers in human genetics possess sufficient expertise to participate in the process of applying for and exploiting gene patents? If not, what measures might be taken to address any lack of expertise?

Submissions and consultations

15.38 To some extent, comments received in consultations supported the view that researchers lack the skills to identify new inventions that may be commercially

43 Research Australia, *Health & Medical Researcher Opinion Poll 2003* (2003), 7.

44 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), Principle 2; National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), Principle 2.2.

45 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72.

46 See Ch 18.

47 M Berry and A McBratney, *Submission to the Senate Standing Committee on Regulations & Ordinances: An Analysis of Issues Relevant to the Patents Amendment Regulations 2002 (No 1) which Introduced a Grace Period into Australian Patent Law* (2002), 22.

48 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 21.

valuable.[49] One problem cited was that some valuable research results produced by public institutions are not protected by the patent system because it has been published before a patent application was filed. Researchers may be unaware of the need to protect their ideas, and once publication has occurred the research is no longer novel and cannot be patented.[50]

15.39 Bio Innovation SA pointed out that some researchers are unaware of the need to meet supporting research requirements for patent applications. This research differs from academic research, and encompasses experimental results that will support the invention through to commercialisation stage.[51]

15.40 However, others noted that researchers are becoming more active about commercialisation now that they are expected to make returns on their research.[52] Comments received in consultations also suggested that researchers' awareness of, and skills in dealing with, patenting and commercialisation are increasing. For example, AusBiotech Ltd stated that researchers have become more aware of the need to obtain intellectual property protection over the past ten years.[53] However, it further suggested that academic researchers need to be able to understand the commercialisation process and be aware of how to package their ideas to make them attractive to investors.[54] Others suggested that the difficulty is not a lack of awareness among researchers, but a lack of funding to support their efforts to commercialise.[55]

15.41 It was also noted that in Australia researchers are isolated from, and have less access to, industry partners and commercial support. By contrast, in the United States academic researchers have greater links with industry and therefore do not need to develop the same level of business know how required in Australia.[56]

15.42 Comments in submissions and consultations emphasised the need for ongoing skill building to ensure the value of Australian research is not lost through failure to obtain appropriate protection. Improving researcher skills at capturing and exploiting the results of research was also considered crucial to the development of a mature and internationally competitive biotechnology industry in Australia.[57] In particular, one submission suggested that:

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49 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

50 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003. This issue is discussed below.

51 Ibid.

52 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.

53 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.

54 AusBiotech Ltd, *Submission P58*, 7 November 2003.

55 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

56 Ibid.

57 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003; Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

> Usually the person who knows the most about the new innovation is the inventor, so this person's connection to the technology needs to be nurtured with appropriate financial connections.[58]

15.43 Educating scientists about patenting issues was recognised as a continuing challenge, and support was shown for including subjects covering intellectual property and commercialisation issues in health sciences and biotechnology degree programs.[59]

Education programs and support

15.44 Research institutions and industry organisations are addressing some of the concerns about researcher skills and experience with patenting and commercialisation through education programs. Many institutions provide seminars and workshops on intellectual property protection and commercialisation for researchers.[60] Advice and educational resources for staff are also provided through technology transfer offices established in most institutions.[61] Some institutions take a pro-active approach to assist researchers to identify commercially valuable technology by placing technology managers in each faculty where they are able to work closely with research staff.[62]

15.45 The Nicol-Nielsen Study reported that:

> Respondents indicated that researchers generally are conscious that the key issue when protecting intellectual property is not to publish. One university technology transfer officer said that in her view the organisation had not lost any intellectual property through publication to date. She noted that the university has a package telling scientists how to keep track of their intellectual property.[63]

15.46 A number of recent reports on patenting and research commercialisation have recommended that capture of valuable intellectual property could be improved by building researcher skills and expertise in recognising potentially patentable inventions. Suggested mechanisms for doing so include the provision of extra training and support personnel to identify inventions, the inclusion of subjects covering

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58 *Confidential Submission P54 CON*, 3 November 2003.

59 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003; Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; UniQuest, *Consultation*, Brisbane, 3 October 2003.

60 For example, the University of Melbourne Research and Innovation Office runs workshops for staff members covering commercialisation and license agreements and may tailor the contents of programs to suit the needs of faculties and departments: Melbourne Research and Innovation Office, *Workshop and Information Sessions*, University of Melbourne, <www.research.unimelb.edu.au/infosessions> at 6 January 2004.

61 The role of technology transfer offices in patenting and commercialising biotechnology research is discussed in Ch 18.

62 See, eg, UniQuest, *About UniQuest*, <www.uniquest.com.au/?id=13> at 16 December 2003.

63 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 127.

commercialisation and business skills in undergraduate and postgraduate courses, and mechanisms to encourage researchers to form links with industry partners.[64]

ALRC's views

15.47 There is evidence that the Australian research culture has shifted toward general acceptance of the role of patent protection over genetic research results. Government policy and education programs have raised awareness and improved skills, as well as ensuring that researchers appreciate the benefits of patenting and exploiting research.

15.48 Significant steps are already being taken to improve researcher knowledge and skills in patenting and commercialising research. The ALRC recognises that many universities and publicly-funded research institutions are already undertaking this task, and endorses this action. These programs should inform researchers about the basic elements of intellectual property law, including patenting, and the processes for obtaining patent protection for their research. Researchers should also be aided to improve their skills in the commercial aspects of patent exploitation and technology transfer.

15.49 The ALRC also considers there would be merit in ensuring that familiarisation with intellectual property and commercialisation begins at the undergraduate level.

Proposal 15–1 Universities and other publicly-funded research institutions should continue to take steps to raise the awareness of researchers in the health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required.

Proposal 15–2 Universities should ensure that students undertaking degrees in the health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.

Secrecy and publication

15.50 While scientific research necessarily involves a period of non-publication for proving and developing the relevant theories, scientific research is built on a tradition of peer review and replication of studies—which are dependent on the critical analysis of published research:

64 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72; T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 5.

> This public exposure has two main functions. One is to maintain high standards of quality control through peer review. This is through both the refereeing process and the later replication of the research. The other function is to promote rapid advances in critical research areas.[65]

15.51 It has been suggested that the commercialisation of research, and the consequent relationships and obligations on researchers, have the potential to constrain this tradition and result in previously open research becoming secret. Nicol and Nielsen state that:

> One of the ways in which this new commercialised research culture could affect upstream research is in its impact on the dissemination of research results. The integrity of the individual researcher is promoted by the strong communal traditions of team-work and free exchange of ideas, results and research reagents. Integrity is further assured by subjecting research results to external testing and criticism through the peer review system and the publication of results in wide circulation refereed journals. This publication tradition has been the primary reward for academic scientists and the dominant measure of academic excellence.[66]

15.52 Further, a 2002 report from the Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, suggested that:

> there is some evidence in the biomedical sciences that research delays (before the publication of research results) are increasing, although it is unclear why this is occurring. The withholding of data, research materials and research results is reputed to be more common in genetics and especially in human genetics than in other fields.[67]

15.53 Scientists who perform research with private funding may be required to delay publication of research outcomes, at least until the commercial partner has had time to evaluate an invention.[68] In the United States, the National Institutes of Health (NIH) recommends that universities allow commercial partners to prohibit publication for no more than one or two months.[69] However, survey evidence indicates that much longer delays may be common. A 1994 study found that 58% of 210 life science companies that sponsor research required delays of more than six months before publication.[70]

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65 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 249–250.

66 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 51.

67 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 13. See also Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 1.

68 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 250.

69 E Press and J Washburn, 'Secrecy and Science', *The Atlantic Online*, March 2000, <www.theatlantic.com/issues/2000/03/press2.htm>.

70 Ibid.

15.54 Another United States survey conducted in 1994–95 of 2,167 scientists in universities receiving NIH funding revealed that nearly 20% had delayed publication for more than six months at least once in the preceding three years in order to allow for a patent application, protect their scientific lead, slow the dissemination of undesired results, allow time to negotiate a patent, or to resolve disputes over the ownership of intellectual property.[71] The study concluded that while withholding of research results was not a widespread phenomenon, it was more common among the 'most productive and entrepreneurial faculty'.[72]

15.55 Problems with the withholding of research results in human genetics may extend beyond the time at which research results are published. A 2000 survey found that 47% of geneticists who had asked other academics for additional information, data, or materials regarding published research, reported that at least one of their requests had been denied in the preceding three years.[73] It has been suggested that secrecy may be more common in human genetic research than in other areas:

> Reasons may include the increased scientific competitiveness of the field and the opportunities for commercial applications. Research has shown that scientists who reported conducting research on goals similar to that of the Human Genome Project (HGP) were more likely to deny requests for information, data, and materials than other life scientists.[74]

15.56 Patent law and practice may significantly contribute to publication delays and reluctance to share information. In particular, since patent law depends on novelty, publication before a patent application has been filed may prevent a patent being granted (see Chapter 6). For this reason it is said that:

> delays in publication may arise where preliminary findings need more work before patent filing is possible or desirable, or to permit the aggregation of incremental advances over a period of time (none of which on their own would be patentable) into a patentable invention. Piecemeal publishing as research progresses is generally incompatible with any reasonable patenting strategy. If patenting is the pre-eminent concern, it will disturb this natural phasing of research papers and will necessarily result in secrecy and delay dissemination of the research.[75]

15.57 Restraints on publication may also affect the free exchange of new technology. As Nicol and Nielsen commented:

> Where, in the past, researchers often freely exchanged newly developed research reagents and other research tools, public sector institutes now often require recipients to enter into contractual arrangements in the form of material transfer agreements.

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71 D Blumenthal and others, 'Withholding Research Results in Academic Life Science' (1997) 277 *JAMA* 1224.

72 Ibid.

73 E Campbell and others, 'Data Withholding in Academic Genetics' (2002) 287 *JAMA* 473, 473.

74 Ibid.

75 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 250.

> Even if no costs are involved, limitations are placed on the range of uses to which such materials can be put.[76]

15.58 On the other hand, patents may sometimes aid research because, without patent protection, some results might be kept as trade secrets, and potentially never revealed. Information that is the subject of a patent application is available in the public domain 18 months after the application is filed, through publication in the *Official Journal of Patents*.[77] This can be a valuable source of technical information for use in further research and development.

15.59 In the United States, the NIH has taken steps to help researchers gain access to information for research through the promulgation of the NIH principles and guidelines. The principles include that institutions should:

- Ensure academic freedom and publication. 'Recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish' and 'excessive publication delays or requirements for editorial control, approval of publications, or withholding of data all undermine the credibility of research results and are unacceptable'.

- Ensure appropriate implementation of the *Bayh-Dole Act*.[78] Recipients of NIH funds 'are expected to maximize the use of their research findings by making them available to the research community and the public, and through their timely transfer to industry for commercialization'.[79]

15.60 The NIH guidelines provide that agreements to acquire materials for use in NIH funded research should address the timely dissemination of research results.

> Recipients should not agree to significant publication delays, any interference with the full disclosure of research findings, or any undue influence on the objective reporting of research results. A delay of 30-60 days to allow for patent filing or review for confidential proprietary information is generally viewed as reasonable.[80]

15.61 In the United States, the Genomic Research and Diagnostic Accessibility Bill of 2002 would have required faster disclosure of genomic sequence information in a patent application when federal funds were used in the development of the invention. The Bill required information to be released within 30 days of the patent application rather than the current 18 months.[81] The Bill's sponsor cited the example of research

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76 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 51–52.

77 *Patents Act 1990* (Cth) s 49 (standard patents), s 62(2) (innovation patents).

78 See the discussion in Ch 12.

79 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

80 Ibid.

81 The Bill was referred to the House Subcommittee on the Courts, the Internet, and Intellectual Property on 6 May 2002, but lapsed at the end of the 107th Congress.

for autism being delayed due to some researchers hoarding tissue samples in order to be the first to find the relevant gene and thus get commercial benefits.[82]

Submissions and consultations

15.62 A variety of opinions about the effect of patenting on openness in research were expressed in submissions. Some suggested that the necessity of keeping new research secret until a patent application had been filed reduced the free exchange of information between researchers. For example, the Cancer Council of New South Wales commented that:

> The increasing shift towards patenting of genetic inventions, and the necessary secrecy and confidentiality surrounding patent applications, runs contrary to the scientific tradition of publication and rapid dissemination of new knowledge. This possible barrier for the sharing of information is worthy of further investigation.[83]

15.63 The Department of Health Western Australia submission commented that the need to apply for patents may result in publication delays, slow dissemination of undesired results or suppression or selectivity in publishing results.[84]

15.64 Others were more positive about the effects of patenting requirements on research culture. GlaxoSmithKline pointed out that:

> confidential information can be shared with others without jeopardising the subsequent filing of a patent application if the disclosure takes place under an appropriate agreement. There are standard forms of such agreements, which can be executed and brought into effect rapidly.[85]

15.65 GlaxoSmithKline also noted that patenting encourages sharing of information once an application has been filed:

> Without strong patent protection, those engaged in research are far more likely to keep innovations secret for longer than they do now i.e. patenting *encourages* knowledge sharing *after* filing for patent protection … failure to provide adequate patent protection will in itself discourage both research and knowledge sharing. This raises the issue of whether failure to provide adequate patent protection is unethical as it impedes the rapid and free flow of information and the delivery of new medical treatments to society.[86]

15.66 AusBiotech Ltd suggested that delays in publication due to the need to maintain confidentiality until a patent application has been filed will be minimal:

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82 United States, *Congressional Debates, House of Representatives*, 14 March 2002, E353 (L Rivers).

83 Cancer Council of New South Wales, *Submission P1*, 5 June 2003.

84 Department of Health Western Australia, *Submission P53*, 3 November 2003, citing P Baird, 'Getting It Right: Industry Sponsorship and Medical Research' (2003) 168 *Canadian Medical Association Journal* 1267, 1267–1269.

85 GlaxoSmithKline, *Submission P33*, 10 October 2003.

86 Ibid.

> Because of the lead time involved in scientific publication, and because a submitted manuscript is still regarded as being confidential, any delay in publication will be minimal. Moreover, all patent applications are published eighteen months after their earliest priority date, and most patent specifications contain far greater detail than any corresponding literature publication.[87]

15.67 Should patent protection be eroded and the rights of patent holders weakened, the Walter and Eliza Hall Institute of Medical Research suggested that this might lead inventors to assess 'the relative value of a patent versus commercial secrecy as the means of protecting their investment in developing the invention'. It suggested that as a consequence:

> Rather than increasing public access to inventions and encouraging further improvements a weak patent system can have exactly the opposite effect … Not granting patents could encourage secrecy which would impede further research by others. Not granting patents, coupled with disclosure, would make IP unattractive to a company since it would have to invest heavily in further research and especially clinical development with no protection from competitors using the invention and underselling them because they do not have to recover extensive R&D costs. The result could be no further development of the potential health care product by anyone.[88]

The general grace period

15.68 As discussed in Chapter 5, a patent will only be granted for an invention that is 'novel' and involves an 'inventive step'.[89] The novelty of each claim in a patent application is assessed against the 'prior art base' that comprises publicly available 'prior art information' as it existed before the priority date of the relevant patent claim.[90] Whether an invention involves an inventive step is also assessed against the prior art base at that date.

15.69 An invention may be deprived of novelty by prior use, information disclosed in oral communications or information contained in documents. Similarly, prior use or publicly available information may prejudice claims that an invention involves an inventive or innovative step.[91]

15.70 The *Patents Act* provides that for the purposes of deciding whether an invention is novel or involves an inventive or innovative step certain use or information must be

87 AusBiotech Ltd, *Submission P58*, 7 November 2003.
88 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.
89 *Patents Act 1990* (Cth) s 18(1)(b) (standard patents), s 18(1A)(b) (innovation patents).
90 Ibid s 18(1)(b)(i) (standard patents), s 18(1A)(b)(i) (innovation patents), sch 1.
91 However, under the *Patents Act*, examiners are specifically directed not to include information made publicly available only through the doing of an act as part of the prior art base when examining a patent application: Ibid s 45(1A).

disregarded (disclosures of this nature are referred to below as 'non-prejudicial disclosure').[92]

15.71 Non-prejudicial disclosure includes any information made publicly available, through any publication or use of the invention, in circumstances prescribed by regulation. The circumstances prescribed are set out in the *Patents Regulations 1991* (Cth) (*Patents Regulations*) and include publication or use of the invention:

- by the showing or use of the invention at a recognised exhibition, or the publication of the invention during an exhibition where the invention was shown or used;[93]
- by the publication of the invention in a paper written by the inventor and read before a learned society or published by a learned society;[94] or
- by the working in public of the invention within a period of 12 months before the priority date for the purposes of reasonable trial.[95]

15.72 In each of these cases, the protection only applies if a patent application is made for the invention within a prescribed period. The prescribed periods range from between 6 or 12 months after the publication or public use of the invention, depending on the circumstances.[96] In order to comply with these requirements and protect patent rights, it is usual to lodge a provisional patent application to secure a priority date, after which disclosure becomes possible.[97]

15.73 The above categories of non-prejudicial disclosure are recognised in many other jurisdictions. For example, national laws dealing with disclosure at official or international exhibitions is obligatory for all member states of the Paris Convention.[98] The other categories of non-prejudicial disclosure mentioned above are harmonised in the law of member countries of the European Patent Convention.[99]

15.74 In Australia, since 2002, there are also general grace period provisions.[100] These apply to any publication or use by, or with the consent of, the prospective patent holder within 12 months of the filing date of the complete patent application provided it is

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92 Ibid s 24.
93 *Patents Regulations 1991* (Cth) r 2.2(2)(a)–(b).
94 Ibid r 2.2(2)(c)(i)–(ii).
95 Ibid r 2.2(2)(d)(i).
96 See Ibid r 2.3.
97 A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475.
98 *Paris Convention for the Protection of Industrial Property 1883*, [1972] ATS 12, (entered into force on 27 September 1975), art 11(1).
99 See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 477.
100 The provisions apply to publication or use on or after 1 April 2002: *Patents Amendment Regulations 2002 (No 1) 2002* (Cth) r 2.

filed within 12 months after the information was made publicly available.[101] These provisions are referred to in this Discussion Paper as the 'grace period provisions'. Associate Professor Ann Monotti explains the rationale for the grace period provisions as follows:

> Within the university research community, the provisional patent application makes it possible to combine the patenting process with the traditional need for academic inventors to publish their new theories and data without undue delay. However, the provisional application does not protect against public disclosures of the invention that occur before the priority date or that occur in the priority period if they go beyond the scope of the invention described in the provisional application. One way of dealing with this problem is to introduce a general 'grace period'.[102]

15.75 While some other countries have similar grace period provisions,[103] most European countries do not.[104] However, whether such provisions should be introduced into the European Patent Law has been the subject of extensive debate.[105]

15.76 The grace period provisions followed recommendations of the Intellectual Property and Competition Review Committee (IPCRC).[106] The IPCRC stated:

> [T]here is merit in introducing a grace period for public disclosure affecting the prior art base for novelty and inventive step. In the event that moves to introduce such a grace period are made by the European Patent Organisation on an expeditious basis, in the context of the European Patent Convention, then the introduction of a grace period in Australia should be coordinated with an introduction in Europe. However, if it appears that such moves in Europe will take more than five years from October 2000, then Australia should seriously consider proceeding before its European counterparts.[107]

15.77 While the primary reason for introducing the grace period was directed to problems that inventors face when they wish to publish their inventions immediately following the filing of a provisional application,[108] the potential benefits of grace periods are said to include encouraging the sharing of research results between

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101 *Patents Act 1990* (Cth) s 24(1)(a); *Patents Regulations 1991* (Cth) rr 2.2(1A), 2.3(1A).

102 A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475.

103 For example, Japan and Canada: see W Condon and R Hoad, 'Amazing Grace: New Grace Period for Patents in Australia' (2002) 15 *Australian Intellectual Property Law Bulletin* 73, 74. The position in the United States is somewhat different as it has a 'first to invent' system. The critical date is the date on which the inventor made the invention, and novelty is not prejudiced by disclosures during the year prior to the date of the application for a patent. See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 477.

104 J Straus, *Expert Opinion on the Introduction of a Grace Period in the European Patent Law: Submission to the European Patent Organisation* (2000).

105 See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475.

106 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 161.

107 Ibid.

108 See Ibid, 159–161; A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 261–262.

inventors and allowing researchers and academics to publish results in journals and peer reviewed literature without putting at risk any patentable subject matter that may be disclosed.[109]

15.78 However, disclosure permitted by the grace period provisions may destroy the novelty of the invention in countries that do not have equivalent provisions—notably in Europe. Associate Professor Ann Monotti and Professor Sam Ricketson argue that:

> The new grace period will do nothing to promote prompt dissemination of university research while significant markets operate within countries that apply the absolute novelty test. It will continue to be important to delay public disclosure of inventions until after a priority date is secured.[110]

15.79 On the other hand, Monotti and Ricketson conclude that the grace period provision provides a 'safety net' for those who make inadvertent disclosures and that the grace period must be seen as a 'positive development' from the point of view of academics and universities.[111]

Submissions and consultations

15.80 The grace period provisions were a specific focus of submissions. IP 27 asked whether the 12 month grace period encourages the publication of scientific results and overcomes problems of secrecy or delay in publication.[112]

15.81 Most submissions that addressed this question indicated that the grace period provisions do not significantly encourage early publication,[113] mainly because not all countries recognise grace periods.[114] For example, GlaxoSmithKline submitted that:

> Because of the need to take a global perspective, the introduction of a grace period in Australia has had no effect either way. No grace period exists in Europe and so, if a

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109 W Condon and R Hoad, 'Amazing Grace: New Grace Period for Patents in Australia' (2002) 15 *Australian Intellectual Property Law Bulletin* 73, 74.

110 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 264.

111 Ibid, 265.

112 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 11–4.

113 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Davies Collison Cave, *Submission P48*, 24 October 2003. The Queensland Government stated that the grace period has overcome some of the problems associated with secrecy and delay in publication of research findings: Queensland Government, *Submission P57*, 5 January 2004.

114 See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 57. Respondents noted that 'whilst it is good to have a grace period in Australia, it will not really assist them because there is a lack of uniformity with regard to this provision world wide'.

> European patent is required, the patent application must still be filed before any publication of the invention.[115]

15.82 Similarly, Genetic Technologies Limited stated that:

> The good intentions of the grace period … are completely undermined by the absence of such a grace period in Europe. Under this new rule premature publication may not prevent the issue of a patent in Australia but the same publication will prevent corresponding patents being issued in Europe. Given the relative size of the markets, the European patent is vastly more valuable than the Australian one so the Australian grace period is irrelevant to the patenting strategy.[116]

15.83 Dr Amanda McBratney and others submitted that it is 'highly doubtful' that the grace period works to encourage scientific disclosure or overcome secrecy because most scientists will want to patent not just in Australia or the United States, but in Europe as well.[117]

15.84 The motivations of academic researchers were cited as another reason why the grace period was not seen as important in encouraging scientific publication. McBratney and others stated that, based on surveys of university research practices:

> the majority of researchers tend to research those areas which are of most appeal to them personally (often for altruistic reasons) and that publication of those results is the dominant driving paradigm. Issues of secrecy, commercialisation and patentability are a distant concern. This is hardly surprising given the modus operandi of publicly funded research institutions or the criterion for promotion for University academics.[118]

15.85 Some negative effects of the grace period provisions were identified. GlaxoSmithKline stated that, from a pharmaceutical industry perspective, grace periods 'increase the uncertainty around decisions to invest without encouraging earlier publication of the invention'.[119]

15.86 Some submissions expressed concerns that researchers may not be aware or understand the implications of the grace period provisions.[120] For example, Davies Collison Cave stated:

> It is likely that early publication will not be accompanied by a proper understanding of the implications of such publication in relation to obtaining patent protection both in Australia and in overseas countries.[121]

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115 GlaxoSmithKline, *Submission P33*, 10 October 2003.
116 Genetic Technologies Limited, *Submission P45*, 20 October 2003.
117 A McBratney and others, *Submission P47*, 22 October 2003.
118 Ibid.
119 GlaxoSmithKline, *Submission P33*, 10 October 2003.
120 Department of Health Western Australia, *Submission P53*, 3 November 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.
121 Davies Collison Cave, *Submission P48*, 24 October 2003.

15.87 In contrast, AusBiotech Ltd expressed the view that scientists in Australia have become much more aware of the importance of patent protection over the last ten years, so the need to rely on the grace period is relatively rare.[122]

ALRC's views

15.88 The Australian government introduced the general 12 month grace period despite the IPCRC's recommendation that Australia should try to coordinate any changes with Europe, where the issue remains alive and unresolved.

15.89 One view is that it may be too early to assess the effect of the introduction of the grace period provisions in Australia.[123] However, many submissions highlighted the dangers that reliance on the grace period may have for patentability in other jurisdictions.

15.90 Given the limited progress towards introducing equivalent provisions in Europe,[124] the ALRC proposes that the Advisory Council on Intellectual Property should undertake a review of the grace period provisions to ascertain whether these are having an adverse impact on the commercialisation of Australian research in Australia or overseas (Proposal 15–3).

15.91 The IPCRC, in recommending the introduction of the grace period, stated that IP Australia should actively inform inventors 'of the risks that disclosure may incur to patentability in jurisdictions without a grace period'.[125] Concerns about inventors misunderstanding the grace period were raised during debate over the introduction of the grace period provisions.[126] Monotti has concluded that:

> it is critical that there be adequate education and publicity campaigns about the effect of these changes so that university (and other) inventors are not misled into believing that they can now publish before they file an Australian patent application.[127]

15.92 The ALRC proposes that universities and other publicly funded research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions, particularly in relation to the effect of publication before filing a provisional patent application, and the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions (Proposal 15–4).

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122 AusBiotech Ltd, *Submission P58*, 7 November 2003.
123 IP Australia, *Submission P56*, 4 November 2003.
124 See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 477–479.
125 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 161.
126 IP Australia, *Submission P56*, 4 November 2003.
127 A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 481.

Proposal 15–3 The responsible Minister should request the Advisory Council on Intellectual Property to review the grace period provisions in the *Patents Regulations 1991* (Cth) (*Patents Regulations*) to ascertain whether these provisions are having an adverse impact on the commercialisation of Australian research in Australia or overseas.

Proposal 15–4 Universities and other publicly funded research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the *Patents Regulations*, particularly in relation to the effect of publication before filing a provisional patent application, and the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.

16. Stem Cell Technologies

Contents

Introduction

16.1 The Terms of Reference require the ALRC to consider the impact of current patenting laws and practices related to 'gene and genetic and related technologies'. One group of such technologies relates to stem cells. As stem cell research progresses, and as understanding about the potential application of stem cell technologies improves, the role of patents in the commercialisation of such research is likely to receive more attention.

16.2 The chapter first provides an overview of stem cell science. The approach to the patentability of inventions involving stem cell technologies under Australian law is then compared to legal developments in the United States, the European Union, the United Kingdom and Canada. The chapter then examines concerns that have been raised about access to stem cell lines and licensing practices involving patented stem cell technologies.

16.3 The application of patent law and practices to stem cell technologies raises many of the same concerns that have been expressed about gene patents. It has been suggested that both genetic inventions and inventions involving stem cell technologies should be excluded from patentability on the basis of ethical considerations because both types of inventions involve the use of human biological material. Concerns about the exploitation and commercialisation of stem cell technologies are also similar to those that have been expressed about gene patents, including that access to stem cell technologies may be unduly restricted if patent protection is available.

Scientific background

16.4 This section gives an overview of stem cell science in order to provide a background for the discussion of patent issues relating to stem cell technologies. The overview is based on the ALRC's current understanding of this developing scientific area, and focuses on those aspects of stem cell science that raise particular issues for patents.

What are stem cells?

16.5 Stem cells are biological materials that are present in all human beings, and in other animals.[1] Stem cells have two characteristics that distinguish them from other cell types:[2]

- stem cells are able to differentiate into specialised cell types, a process known as differentiation; and

- stem cells are able to renew themselves, allowing stem cell populations to be maintained for long periods through cell division; a process known as proliferation.

16.6 Stem cells are typically characterised according to the tissue from which the cells are derived. As described further below, stem cells may be obtained from embryos, foetal tissue and certain adult tissue.[3] Depending on the tissue source, stem cells may have particular characteristics for potential development, which scientists call 'pluripotent' or 'multipotent'.

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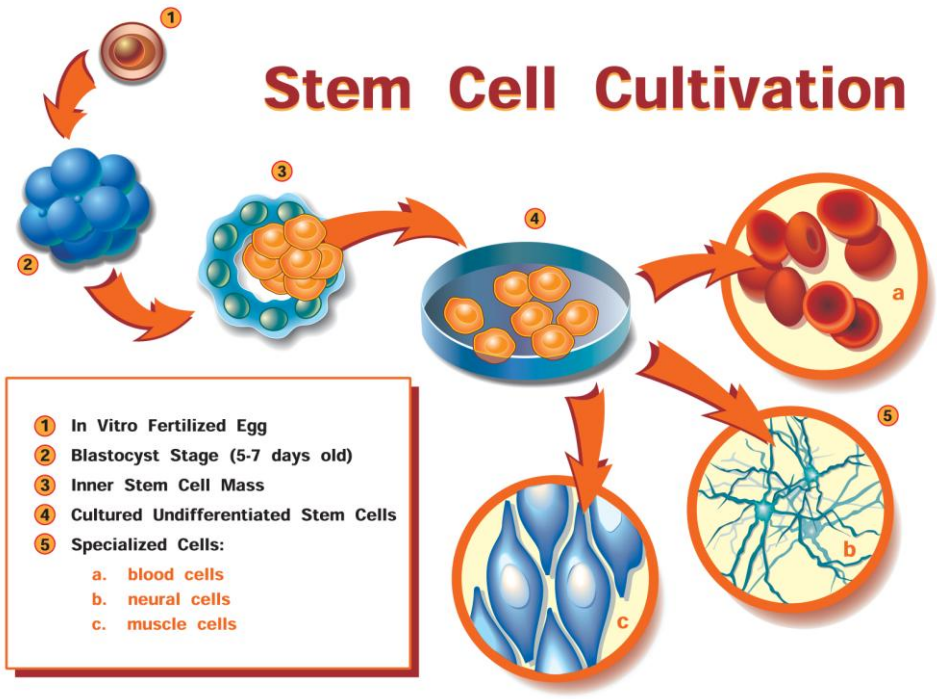
1 As discussed below, certain types of stem cells—in particular, embryonic stem cells—occur naturally only for a short period of time in the earliest stages of development. Such stem cells do not exist naturally in an isolated state.

2 For further discussion of stem cells, see House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), ch 2–4; Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), ch 2; National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/index.asp> at 28 August 2003.

3 The term 'embryo' is generally used to refer to a developing foetus up to eight weeks after fertilisation and the term 'foetus' is used for the period commencing nine weeks after fertilisation until birth.

Figure 16–1: Stem cell cultivation



Embryonic stem cells

16.7 A fertilised ovum and the cells comprising an embryo in the earliest stages following fertilisation—up until about the eight-cell stage—are 'totipotent'. These cells have the capacity to form the placenta and other supporting tissue necessary for the development of an embryo *in utero*, as well as post-embryonic tissues and organs. Some literature refers to the embryo during this stage of development as comprising 'totipotent cells'. Where necessary, this term is also used in this chapter, although scientists generally consider it inaccurate to describe totipotent cells as stem cells.

16.8 Embryonic stem cells appear at the blastocyst stage of embryonic development, approximately four days after fertilisation. A blastocyst is a hollow sphere of about 120 cells with an outer layer (which later develops into the placenta and other supporting foetal tissue) and an inner cell mass. The inner cell mass comprises embryonic stem cells that are pluripotent. Pluripotent embryonic stem cells are capable of giving rise to almost all of the different types of cells found in humans, but cannot produce the placenta and other supporting tissues necessary for foetal development in the uterus.

Thus, if placed in a woman's uterus, pluripotent embryonic stem cells do not have the capacity to develop into a human being.

16.9 Embryos from which stem cells may be obtained can be made available in different ways. The most widely used source is surplus embryos from assisted reproductive technology (ART) programs. Alternatively, embryos could be created specifically for use in research; such as by the process of somatic cell nuclear transfer[4]—commonly referred to as 'cloning'.[5] However, accounts of human embryos being successfully produced by cloning techniques are anecdotal[6] and, in some cases, have been called into question by the wider scientific community.[7] In addition, as discussed later in this chapter, following the enactment of recent legislation regulating the use of surplus embryos from ART programs in Australia, embryonic stem cells may lawfully be derived only from embryos that are produced during ART procedures and that are no longer required for reproductive purposes.

Foetal stem cells

16.10 Foetal stem cells may be isolated from primordial germ cells in the incipient gonads (ovaries and testes) of aborted foetuses and are often referred to as 'embryonic germ cells'. Embryonic germ cells are pluripotent—that is, they have the capacity to develop into many or all of the tissues in the human body, but cannot develop into a human being if placed in a woman's uterus. Multipotent stem cells—that is, stem cells that can give rise to various types of cells but only within a certain tissue type—have also been derived from foetal neural tissue and from umbilical cord blood.[8]

Adult stem cells

16.11 Adult stem cells[9] exist in human organs and tissues and are responsible for the normal replacement and repair of different organs and tissues. Currently, about 20

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4 Somatic cell nuclear transfer involves a nucleus being removed from a mature (somatic) cell and inserted into an egg cell (ovum) from which the nucleus has previously been removed.

5 The ethical and legal issues surrounding cloning technologies have been comprehensively canvassed in Australia and in other jurisdictions in recent years. See, eg, House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001); Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002); National Health and Medical Research Council and Australian Health Ethics Committee, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning Human Beings* (1998); President's Council on Bioethics, *Monitoring Stem Cell Research (Pre-publication Copy)* (2004); Royal Society, *Whither Cloning?* (1998); United Kingdom Department of Health, *Stem Cell Research, Medical Progress With Responsibility: A Report from the Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human Health* (2000).

6 See, eg, W Rohn, 'Seven Days of Creation: The Inside Story of a Human Cloning Experiment', *Wired*, January 2004, 122.

7 For example, scientists worldwide have expressed doubts about claims by the company Clonaid—which is linked to the Raelian movement—to have cloned a human.

8 Some scientists classify stem cells derived from umbilical cord blood as adult, rather than foetal, stem cells.

9 It has been suggested that the term 'adult stem cells' is something of a misnomer since adult stem cells can be found in foetuses and newborns, as well as in adults. The more accurate terms for this type of stem cells are 'multipotent stem cells' or 'progenitor cells'. The term 'adult stem cells' is, however, used in

different types of adult stem cells have been identified. Adult stem cells are multipotent. Adult stem cells are thought to be less flexible than embryonic stem cells, and to be capable of differentiating into a more restricted range of specialised cells. However, there is some evidence that adult stem cells may be able to give rise to cell types outside their own lineage—that is, cells from a different tissue type.[10] To date, scientists have found adult stem cells difficult to identify, isolate and grow in culture.[11]

Potential of stem cell research

16.12 There has been widespread discussion about the potential applications of stem cell research.[12] Research into the events that lead to cell specialisation in humans and the stages of human development may increase scientific understanding of the causes of birth defects and abnormal cell activity, such as cancer.

16.13 Stem cells may also be used to generate cells and tissue that may be used for transplantation in the treatment of diseases of the nervous system such as Alzheimer's disease and Parkinson's disease, as well as treatment for spinal cord damage, strokes and burn injuries. The use of stem cells to regenerate damaged organs or to create new organs for transplantation purposes has also been proposed. Such therapeutic applications of technologies involving embryonic stem cells are unlikely to be available for some years.[13] However, certain therapeutic applications of adult stem cells are already in use; for example, bone marrow transplants and regrowth of skin cells for burn victims.

16.14 In addition, stem cell research may change the way in which drugs are developed and tested. In the future, stem cell lines might be used for toxicology testing of candidate drugs—known as cell-based drug screening—although research use of embryonic stem cell lines for this purpose is controversial. Promising drugs might then be further tested on animals and finally in clinical trials.

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this Discussion Paper as it is the most common term used in the literature to refer to these types of stem cells.

10 National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/index.asp> at 28 August 2003.

11 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [2.48]–[2.51]; Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), [2.16].

12 See, eg, House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), ch 4; Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), [2.51]–[2.136]; National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/index.asp> at 28 August 2003; President's Council on Bioethics, *Monitoring Stem Cell Research (Pre-publication Copy)* (2004), ch 4.

13 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [4.14]–[4.17].

Issues and problems

16.15 Stem cell research has generated much controversy both in Australia and in other countries. In particular, research involving human embryonic stem cells has been objected to on the basis that the potential for an embryo to develop into a human being should preclude the use or destruction of embryos in scientific research. Critics of stem cell research also object to the patenting of inventions involving human embryonic stem cell technology. A 2002 report of the European Group on Ethics in Science and New Technologies (the EU Stem Cell Report) commented that those who are opposed to human embryo research 'cannot, a fortiori, consider any patenting in that field'.[14]

16.16 Specific objections to the patenting of inventions involving stem cell technologies have also been raised, including that stem cell patents may:

- represent an inappropriate commodification of human biological material, and in particular human reproductive material;[15]
- violate fundamental principles against the ownership of human beings, as well as the principle of free and informed consent of the donor;[16] and
- inhibit continued research and development relating to stem cell technologies.[17]

16.17 Many of the ethical objections that have been raised in relation to patenting human stem cell technologies are similar to those that have been articulated about gene patents. The variety of perspectives on these ethical concerns are canvassed in Chapter 3. In addition, as discussed in Chapter 3, ethical concerns that may be raised about whether it is acceptable to grant gene (or stem cell) patents may in fact be based upon objections to the way in which the research is conducted, or the way in which patents (if granted) are exploited.

16.18 The issues surrounding human embryonic stem cell research, and research involving human embryos generally, were recently considered in the report of the House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (the Andrews Report).[18] Following this report, legislation was introduced into federal Parliament, leading to a further report of the Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and*

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14 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 13.

15 Ibid, 13.

16 Ibid, 13.

17 Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), [4.56]–[4.61]; M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448.

18 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001).

Prohibition on Human Cloning Bill 2002.[19] A new regulatory regime governing embryo research has now been implemented at the federal level,[20] and corresponding legislation is in the process of being implemented by the various States and Territories.[21] Relevant aspects of this regime are outlined in the following section. However, beyond this, the chapter does not address in any detail the moral and ethical concerns related to the conduct of human stem cell research.

Stem cell research in Australia

16.19 Research conducted by Australian scientists has made, and continues to make, a valuable contribution to knowledge about human stem cells and the potential applications of stem cell technologies, particularly in relation to adult stem cells.[22]

16.20 Both publicly funded organisations and companies are involved in adult and embryonic stem cell research in Australia. The establishment of the National Stem Cell Centre (NSCC) in 2002 has augmented these research efforts. The NSCC initiative is part of the Australian Government's Innovation Statement, *Backing Australia's Ability*.[23] It is a national endeavour with headquarters on the Monash University campus, and will coordinate the research efforts of public and private sector institutions in a number of States and internationally.[24] Biotechnology Australia and the Australian Research Council (ARC) have jointly committed $46.5 million in funding to the NSCC over four years.[25]

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19 Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002). See also Council of Australian Governments, 'Human Cloning, Assisted Reproductive Technology (ART) and Related Matters', *Communiqué*, 5 April 2002, <www.pm.gov.au/news/media_releases/2002>.

20 *Prohibition of Human Cloning Act 2002* (Cth); *Research Involving Human Embryos Act 2002* (Cth).

21 Corresponding legislation has been adopted by New South Wales, Queensland, South Australia and Victoria: *Research Involving Human Embryos (New South Wales) Act 2003* (NSW); *Human Cloning and Other Prohibited Practices Act 2003* (NSW); *Research Involving Human Embryos and Prohibition of Human Cloning Act 2003* (Qld); *Research Involving Human Embryos Act 2003* (SA); *Prohibition of Human Cloning Act 2003* (SA); *Health Legislation (Research Involving Human Embryos and Prohibition of Human Cloning) Act 2003* (Vic). Bills addressing this issue are pending in the Australian Capital Territory and Western Australia: Human Cloning and Embryo Research Bill 2003 (ACT); Human Reproductive Technology Amendment Bill 2003 (WA); Human Reproductive Technology Amendment (Prohibition of Human Cloning) Bill 2003 (WA).

22 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [4.8]–[4.10]; Invest Australia, *Australian Biotechnology* (2003), 9. According to estimates by the University of Adelaide, Australia contributes about 25% of the world's research on stem cells, compared with about 2.5% of the world's [biotechnology] research generally: Invest Australia, *Australian Biotechnology* (2003), 9.

23 Australian Government, *Backing Australia's Ability: An Innovation Statement for the Future* (2001).

24 The core scientific participants in the NSCC are: Monash University; University of Melbourne; Peter MacCallum Cancer Institute; Institute of Molecular Bioscience, University of Queensland; University of Adelaide; National Centre for Advanced Cell Engineering; John Curtin School of Medical Research; University of New South Wales; Victor Chang Cardiac Research Institute; and Murdoch Children's Research Institute. At the time of its establishment, the NSCC's key commercial partners were ES Cell International Pte Ltd and BresaGen Ltd: Biotechnology Australia, 'Centre for Stem Cells and Tissue Repair', *Fact Sheet*, <www.biotechnology.gov.au>.

25 Ibid.

16.21 Australian companies also feature in the international arena in the research and development of stem cell technologies. A 2003 report produced by Invest Australia indicated that these companies included BresaGen Ltd, ES Cell International Pte Ltd, Norwood Abbey Ltd, and Stem Cell Sciences Pty Ltd.[26] Since the publication of the Invest Australia report, BresaGen Ltd has entered voluntary administration.[27]

Regulation of stem cell research

16.22 Various aspects of research involving stem cells are subject to federal, state and territory legislation, as well as guidelines and standards issued by the National Health and Medical Research Council (NHMRC) and the Australian Health Ethics Committee (AHEC). However, Australia does not currently have a comprehensive legislative scheme, or set of guidelines, regulating all research involving human embryonic and adult stem cells, whether conducted by publicly-funded institutions or private entities.[28]

Regulation of the use of excess ART embryos

16.23 In December 2002, the Australian Parliament passed the *Prohibition of Cloning Act 2002* (Cth) (*Prohibition of Cloning Act*) and the *Research Involving Human Embryos Act 2002* (Cth) (*Research Involving Human Embryos Act*).[29] These Acts prohibit certain unacceptable practices, including human cloning,[30] and regulate uses of excess human embryos created through ART.

16.24 Pursuant to this legislation, human embryo research (and, therefore, the use of embryos for the derivation of human embryonic stem cells) is permitted only in limited circumstances. First, the research may only involve embryos that are 'excess ART embryos'. An excess ART embryo is one that has been determined in writing by the couple for whom it was created to be excess to their needs.[31] It is an offence to use an embryo that is not an excess ART embryo for a purpose other than one relating to the

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26 Invest Australia, *Australian Biotechnology* (2003), 9. ES Cell International is incorporated in Singapore, but conducts a substantial part of its activities at facilities in Melbourne.

27 BresaGen Limited, 'BresaGen Appoints Administrator', *Press Release*, 20 January 2004, <www.bresagen.com.au>.

28 This type of legislation was proposed in the Andrews Report, but not ultimately adopted by the Council of Australian Governments: Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), recs 1, 2, 6–8; Council of Australian Governments, 'Human Cloning, Assisted Reproductive Technology (ART) and Related Matters', *Communiqué*, 5 April 2002, <www.pm.gov.au/news/media_releases/2002>.

29 Corresponding state and territory legislation has been enacted in New South Wales, Queensland, South Australia and Victoria and is pending in Western Australia and the Australian Capital Territory. The following discussion focuses on the federal legislative provisions, although corresponding requirements are contained in the state and territory legislation adopted to date.

30 *Prohibition of Human Cloning Act 2002* (Cth) ss 9–23, makes it an offence to create, implant in a woman, import or export, among other matters, a human embryo clone, a human embryo that contains genetic material provided by more than two persons, and a hybrid or chimeric embryo (that is, an embryo created using the sperm or ovum of an animal).

31 *Research Involving Human Embryos Act 2002* (Cth) s 9.

assisted reproductive treatment of a woman—for example, non-excess ART embryos could not be used to derive embryonic stem cells.[32]

16.25 Second, any use of excess ART embryos must either be conducted pursuant to a licence granted in accordance with the procedures set out in the *Research Involving Human Embryos Act*, or be subject to a statutory exemption, in which case a licence is not required.[33] Activities that may be conducted without a licence include the storage, removal and transport of excess ART embryos, and the use of such embryos by an 'accredited ART centre' to achieve pregnancy for a woman other than the woman for whom the embryo was initially created.[34] Diagnostic investigations performed by an accredited ART centre on embryos that are determined to be biologically unfit for implantation are also exempt from the requirement of a licence.[35] However, the purpose of such diagnostic investigations is limited to investigations to identify the cause of abnormal development of an embryo in order to benefit the woman for whom the embryo was created in subsequent ART treatment.[36]

16.26 Third, where research involving excess ART embryos requires a statutory licence, the licence must be granted by the Embryo Research Licensing Committee of the NHMRC (the NHMRC Licensing Committee) in accordance with the procedures set out in the *Research Involving Human Embryos Act*.[37] The NHMRC Licensing Committee is a new principal committee of the NHMRC established by the *Research Involving Human Embryos Act*[38] to consider applications for licences to use excess ART embryos and to monitor compliance with the relevant legislation.[39]

16.27 The licence requirement in the *Research Involving Human Embryos Act* applies to all uses of excess ART embryos after 19 June 2003.[40] In addition, only embryos

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32 Ibid s 11.

33 Ibid s 10(1). Activities that constitute exempt uses are set out in s 10(2) of the *Research Involving Human Embryos Act 2002* (Cth).

34 Ibid ss 10(2)(a), 10(2)(e). An 'accredited ART centre' is defined as a person or body accredited to carry out assisted reproductive technology by the Reproductive Technology Accreditation Committee of the Fertility Society of Australia, or such other body as may be prescribed by regulation: *Research Involving Human Embryos Act 2002* (Cth) s 8.

35 *Research Involving Human Embryos Act 2002* (Cth) s 10(2)(d).

36 Ibid s 10(2)(d); National Health and Medical Research Council, *General Information About the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryo Act 2002 (Doc No 1/2003)* (2003), 18.

37 *Research Involving Human Embryos Act 2002* (Cth) ss 10(1)(a), 12.

38 Ibid s 13. See also *National Health and Medical Research Council Act 1992* (Cth) ss 4, 35.

39 *Research Involving Human Embryos Act 2002* (Cth) s 14. See also Council of Australian Governments, 'Human Cloning, Assisted Reproductive Technology (ART) and Related Matters', *Communiqué*, 5 April 2002, <www.pm.gov.au/news/media_releases/2002>.

40 National Health and Medical Research Council, *General Information About the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryo Act 2002 (Doc No 1/2003)* (2003), 15. The majority of the provisions in the Acts came into effect on 16 January 2003. However, ss 10–12 of the *Research Involving Human Embryos Act 2002* (Cth) did not come into effect until 19 June 2003: *Research Involving Human Embryos Act 2002* (Cth) s 2.

created prior to 5 April 2002 may be used if the activities proposed under the licence will involve the damage or destruction of such embryos.[41]

16.28 The NHMRC Licensing Committee has indicated that eight applications for licences to use excess ART embryos had been received by 30 September 2003, but no licences have been granted by the Committee to date.[42]

Regulation of other types of stem cell research

16.29 The regulatory scheme established by the *Prohibition of Human Cloning Act* and the *Research Involving Human Embryos Act* is relevant only to the *derivation* of human embryonic stem cells from excess ART embryos, as defined in the latter Act.[43]

16.30 As noted above, *research* involving the use of human embryonic stem cell lines, including human embryonic stem cell lines that have been imported into Australia, is not subject to specific legislation. It is, however, covered by guidelines issued by the NHMRC and AHEC, which apply to all research projects funded by the NHMRC. In 2001, AHEC issued an interim advice to human research ethics committees (HRECs) relating to the review of research protocols that involve human stem cell research (the AHEC Interim Advice).[44] The AHEC Interim Advice requires that, to obtain the approval of an HREC, the stem cell lines proposed for use in the research should have been derived in a manner that is consistent with the NHMRC's *Ethical Guidelines on Assisted Reproductive Technology*[45] and the *National Statement on Ethical Conduct in Research Involving Humans*.[46] AHEC is in the process of reviewing the *Ethical Guidelines on Assisted Reproductive Technology* and related publications and intends to address the conduct of stem cell research in the revised guidelines that will flow from this review.[47]

16.31 Research involving tissue from which adult stem cells may be derived is regulated by a mixture of legislation and guidelines, including:

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41 *Research Involving Human Embryos Act 2002* (Cth) ss 21(3)(b), 24(1)(c), 24(3). This limitation will, however, be repealed on 5 April 2005, or an earlier date pursuant to a declaration by the Council of Australian Governments: *Research Involving Human Embryos Act 2002* (Cth) s 46.

42 National Health and Medical Research Council Licensing Committee, *Report to the Parliament of Australia: For the Period 1 April 2003 to 30 September 2003* (2003), 14; T Noble, 'Cloning Police to Keep Watch as Scientists Begin Embryo Experiments', *Sydney Morning Herald* (Sydney), 1.

43 The Act does not however cover uses of human embryos that have been imported in research.

44 Australian Health Ethics Committee, 'Information for HRECs: Stem Cell Research', *Information Sheet*, 1 September 2001, <www.nhmrc.gov.au/issues/hrec5.htm>.

45 National Health and Medical Research Council, *Ethical Guidelines on Assisted Reproductive Technology* (1996). See in particular ss 6 and 11.

46 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999).

47 Australian Health Ethics Committee, 'Information for HRECs: Stem Cell Research', *Information Sheet*, 1 September 2001, <www.nhmrc.gov.au/issues/hrec5.htm>.

- state and territory Human Tissue Acts, which require consent for the donation of blood, and regenerative and non-regenerative human tissue for research;[48] and

- ethical guidelines and policy statements, including the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans*.[49]

Patentability of stem cell technologies

Existing patents and patent applications

16.32 Patent applications claiming animal and human stem cells and stem cell technologies have been filed in Australia and other jurisdictions.[50] The EU Stem Cell Report indicated that, by May 2002, over 2,000 patent applications involving human and animal stem cells had been filed worldwide, one quarter of which related to embryonic stem cells.[51] Approximately one third of all stem cell patent applications have been granted.[52]

16.33 The types of products and processes claimed in filed patent applications include stem cells, stem cell lines, and differentiated and genetically modified stem cells. They also include processes for: the creation of embryos by somatic cell nuclear transfer and parthenogenesis; isolating and culturing stem cells; inducing stem cells to differentiate; and genetically modifying stem cells for particular applications.[53]

16.34 A number of granted stem cell patents have been identified as particularly significant because of the scope of the patent claims and the specific stem cell technologies covered by the patents. These include certain patents over human and primate embryonic stem cell technology held by the Wisconsin Alumni Research

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48 *Human Tissue Act 1983* (NSW); *Transplantation and Anatomy Act 1979* (Qld); *Transplantation and Anatomy Act 1983* (SA); *Human Tissue Act 1985* (Tas); *Human Tissue Act 1982* (Vic); *Human Tissue and Transplant Act 1982* (WA); *Transplantation and Anatomy Act 1978* (ACT); *Human Tissue Transplant Act 1979* (NT). Sperm, ova and foetal tissue are expressly excluded from the operation of these Acts.

49 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999).

50 As of February 2000, IP Australia had granted four patents for cloning processes applicable to non-human mammals and 'routinely grants patents for both human and animal cell lines' that satisfy the statutory requirements for patentability: IP Australia, *Submission to House of Representative Standing Committee on Legal and Constitutional Affairs Inquiry into the Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, Commonwealth of Australia, <www.aph.gov.au/house/committee/laca/humancloning/sub274.pdf> at 22 August 2003.

51 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 11. This figure does not take into account patent applications that may be filed in a number of jurisdictions but relate to the same invention.

52 Ibid, 11. For a survey of United States patents covering embryonic stem cells, see G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243.

53 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 11–12.

Foundation (WARF).[54] These patents are often referred to as the 'Thomson patents', after Dr James Thomson who led the team that first reported the isolation and differentiation of human embryonic stem cells.[55] The Thomson patents cover methods for isolating embryonic stem cells[56] and for transplanting them into human beings.[57] One of the Thomson patents also claims unmodified human embryonic stem cell lines per se, regardless of their 'creator'.[58]

16.35 In Australia, stem cell patents have been granted to a number of companies, including:

- BresaGen Limited, relating to methods of using a biological factor to produce pluripotent stem cells having different properties;[59]
- Geron Corporation, relating to a system for culturing human pluripotent stem cells in the absence of feeder cells;[60] and
- ES Cell International Pte Ltd, relating to undifferentiated human embryonic stem cells, and methods of cultivation, propagation and production of differentiated cells.[61]

16.36 A preliminary search of IP Australia's online patents databases also revealed pending applications claiming inventions involving human embryonic stem cells, or processes involving such cells.[62]

16.37 Patents have also been granted over adult stem cell lines. For example, Johns Hopkins University holds a patent on the processes for isolating adult bone marrow stem cells;[63] and MorphoGen Pharmaceuticals Inc has obtained a patent claiming 'purified pluripotent mesenchymal stem cells' obtained from cultured muscle cells.[64]

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54 WARF is an intellectual property holding entity established by the University of Wisconsin.

55 J Thomson and others, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145.

56 US Pat No 5,843,780 (granted 1 December 1998) relates to a purified preparation of primate embryonic stem cells and a method of isolating such cells. US Pat. No 6,200,806 (granted 13 March 2001) relates to a purified preparation of pluripotent primate (including human) embryonic stem cells and a method of isolating such cells.

57 US Pat No 6,280,718 (granted 28 August 2001) cl 1, 4, 6, 9–10.

58 US Pat No 6,200,806, cl 1.

59 AU Pat No 755176.

60 AU Pat No 751321.

61 AU Pat No 764684.

62 See, eg, 'Mesenchymal cells and osteoblasts from human embryonic stem cell' filed by Geron Corporation on 3 July 2002 (AU App No 2002322379); 'Isolation of Inner Cell Mass for the Establishment of Human Embryonic Stem Cell (hESC) Lines' filed by Reliance Life Sciences Pvt Ltd on 20 August 2002 (AU App No 2002334378); and 'Characterization and Isolation of Subsets of Human Embryonic Cells (HES) and Cells Associated or Derived Therefrom' filed by ES Cell International Pte Ltd on 11 November 2002 (AU App No 2002340638).

63 US Pat No 5,130,144.

64 US Pat No 5,827,735.

Application of patent law to stem cell technologies

16.38 On one view, the patenting of inventions involving stem cell technologies does not raise issues different from those raised by the patenting of other human biological material, such as genetic sequences. From another perspective, the patenting of inventions involving stem cell technologies should be treated differently from other inventions involving human biological material either because:

- the human biological material at issue has been derived from a human embryo, and embryos have a special status because of their potential to develop into a human being; or

- the capacity of stem cells to develop into various tissue types justifies the application of special rules.

Australia

16.39 As discussed in Chapters 6 and 7, s 18 of *Patents Act 1990* (Cth) (*Patents Act*) provides that a 'patentable invention' under Australian law is one that is a 'manner of manufacture', is novel, involves an inventive step, is useful, and is not expressly excluded from patentability under the Act. As a general matter, inventions involving biological materials may be patented under Australian law if they have been isolated from their natural state.[65] IP Australia has indicated that human cell lines are patentable on this basis.[66]

16.40 However, s 18(2) of the *Patents Act* excludes 'human beings and the biological processes for their generation' from patentability under Australian law. It has been suggested that this provision may prevent patent protection being available for inventions involving human embryonic stem cells.[67] The Act does not define 'human beings' or 'biological processes for their generation' and, to date, there has been no judicial consideration of this provision.

Legislative history of s 18(2) of the Patents Act

16.41 Parliamentary debates surrounding the adoption of s 18(2) provide little guidance as to whether inventions involving human embryonic stem cells were intended to be covered by this provision. This is not surprising because the ability to isolate human embryonic stem cells was not announced until 1998.

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65 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 31 March 2003.

66 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1].

67 See Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [8.70]–[8.75]; M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448.

16.42 Section 18(2) was based on a proposal by Senator Brian Harradine during consideration of the Patents Bill 1990 (Cth) (Patents Bill). Foreshadowing the amendment, Senator Harradine indicated that he was concerned that insufficient consideration was being given by Parliament to 'the possibility of patenting new forms of animal life',[68] and that the Australian Patents Office (as it then was) might grant patents on a human, or a genetically-modified human.[69] The Australian Democrats also expressed concerns about deficiencies in the Patents Bill for being 'silent on the question of the patenting of biological material', in particular genetic material.[70]

16.43 During consideration of the Patents Bill by the Senate Standing Committee on Industry, Science and Technology (the Senate Standing Committee), Senator Harradine proposed an amendment that originally provided:

> A patentable invention shall not include the following:
>
> (a) human life forms;
>
> (b) any genetic manipulations of the human species;
>
> (c) any trans-species procedure involving human cells.[71]

16.44 A majority of the Senate Standing Committee supported Senator Harradine's proposal in principle, but was concerned about its apparent breadth and ambiguity. The proposal was amended during the Senate Standing Committee's debates as follows:

- The words 'human beings' replaced 'human life forms'. The latter was deemed to be a 'broader expression' and the Senate Standing Committee wished to limit the scope of any exception to avoid uncertainty.[72]

- The phrase 'biological processes for the generation of human beings' replaced subsections (b) and (c) of Senator Harradine's proposal. The Senate Standing Committee considered that subsections (b) and (c), as originally drafted, were 'fraught with definitional problems and [caught] up in their scope unintended consequences'.[73]

16.45 Little consideration was given to the meaning of the term 'human beings' during the parliamentary debates surrounding the adoption of s 18(2) of the *Patents Act*, but

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68 Commonwealth of Australia, *Parliamentary Debates*, Senate, 22 August 1990, 1917 (B Harradine).

69 The Senator's concern arose from an Office Practice Note which stated that the Patents Office would not reject a patent application solely on the basis that a claimed product or process contains or uses a living organism: Commonwealth of Australia, *Parliamentary Debates*, Senate (In Committee), 12 September 1990, 11 (B Harradine).

70 Commonwealth of Australia, *Parliamentary Debates*, Senate, 22 August 1990, 1910 (J Coulter). The amendments proposed by the Australian Democrats to address this deficiency are discussed in Ch 7.

71 Commonwealth of Australia, *Parliamentary Debates*, Senate (In Committee), 12 September 1990, 17 (P Button).

72 Ibid, 10 (P Button).

73 Ibid, 10–11, 16–17 (P Button).

the debates provide more assistance as to the intended scope of the term 'biological processes for the generation of human beings'. Senator Harradine indicated that 'techniques for cloning an embryo at the four-cell stage'—a reference to the technique of 'embryo splitting'—would be an example of the type of invention prohibited by s 18(2).[74] The Opposition suggested that s 18(2) would preclude patenting of inventions involving 'in-vitro fertilisation and cloning for reproductive purposes'.[75] The Government did not elaborate on the intended scope of the provision, except to note that it did not represent 'a change in policy in relation to the patentability of life forms'.[76]

IP Australia's current practice

16.46 Section 18(2) has been interpreted narrowly by IP Australia. IP Australia's *Manual of Practice and Procedure* (the *Manual*) indicates that, while the precise scope of the provision is unclear, certain inventions are 'clearly encompassed'[77] by the exception, including:

- human beings, foetuses, embryos or fertilised ova;
- methods of *in vitro* fertilisation or cloning methods that generate human beings; and
- processes—beginning with fertilisation and ending with birth—that are wholly biological and result in a human being.[78]

16.47 The *Manual* also sets out the inventions that IP Australia regards as being 'clearly outside' the scope of s 18(2), namely 'human genes, tissues and cell lines', which will be patentable if the requirements for patentability set out in the *Patents Act* are satisfied.[79] In its submission to the Andrews Report, IP Australia explained why human genes, cell lines and tissues are not covered by s 18(2):

> This is premised on a widely accepted view that human genes, cell lines and tissues are not regarded as human beings, as distinct from foetuses and embryos which are regarded as human beings and hence are not patentable.[80]

16.48 A human cell line may meet the statutory requirements for patentability because:

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74 Commonwealth of Australia, *Parliamentary Debates*, Senate, 20 September 1990, 2654 (B Harradine).
75 Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 16 October 1990, 2945 (G Prosser).
76 Ibid, 2954 (S Crean).
77 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1].
78 Ibid, [8.5.1], [8.5.2].
79 Ibid, [8.5.1]. See also D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 241.
80 IP Australia, *Submission to House of Representative Standing Committee on Legal and Constitutional Affairs Inquiry into the Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, Commonwealth of Australia, <www.aph.gov.au/house/committee/laca/humancloning/sub274.pdf> at 22 August 2003.

> [it] is different from naturally occurring cells in the human body. It is capable of continuous propagation in an artificial environment by continual division of the cells, unlike naturally occurring cells which die after a limited number of divisions.[81]

16.49 However, IP Australia has indicated that what constitutes a human being or the biological processes for the generation of a human being may be ambiguous.[82] As a matter of practice, IP Australia has developed a policy by which patent applications that might fall within this 'grey area' must be referred to supervising examiners, who then discuss the matter with a Deputy Commissioner.[83] The ALRC understands that inventions involving human embryonic stem cells are currently covered by this policy.

United States

16.50 Other jurisdictions have also addressed the issue of whether patent protection should be available for stem cell technologies, though they have adopted different conclusions about this matter.

16.51 The United States has adopted arguably the most liberal approach to stem cell patenting. As discussed above, United States patents have been granted for inventions involving purified and isolated embryonic and adult stem cell lines, as well as those involving methods for isolating and purifying stem cell lines.[84]

16.52 There is no express prohibition in United States law on patents claiming human beings or the processes for their generation, equivalent to s 18(2) of the *Patents Act*. However, it has been a long-standing policy of the United States Patent and Trademark Office not to grant such patents.[85] Until recently, little substantive consideration appears to have been given to whether inventions involving human embryonic stem cells could fall within the scope of the policy against issuing patents on human beings.

16.53 However, this issue was raised for consideration by the United States Congress in July 2003. Representative Dave Weldon proposed an amendment to an appropriations Bill for the Commerce, Justice and State Departments[86] that would prohibit the use of any funds made available under that Bill in granting 'patents on

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81 Ibid.

82 IP Australia, *Submission P56*, 4 November 2003. See also IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1]; House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), 146–147.

83 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1]. The role of supervising examiners and Deputy Commissioners is discussed further in Ch 8.

84 Subcommittee on Labor Health and Human Services Education and Related Agencies of the Senate Appropriations Committee, *Statement of Q Todd Dickinson, Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks, 12 January 1999*, <www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/stemcell.pdf> at 18 September 2003.

85 United States Patent and Trademark Office, *Manual of Patent Examining Procedure: 8th edition*, <www.uspto.gov/web/offices/pac/mpep/index.htm> at 14 March 2003, [2105].

86 Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Bill 2004 (HR 2799) (US).

claims directed to or encompassing a human organism'.[87] The amendment attracted strong criticism and concern that research on stem cells may be affected if the proposal were adopted.[88] In November 2003, the House of Representatives and the Senate agreed on a compromise provision that would ban patents on genetically engineered human embryos, foetuses and human beings, but would not affect patents on genes, cells, tissue and other biological products.[89] Stem cell research is also expressly excluded from the scope of the provision.[90] The House of Representatives and the Senate have not yet voted on the Bill.[91]

European Union

16.54 The Directive of the European Parliament on the legal protection of biotechnological inventions (the EU Biotechnology Directive)[92] and the *European Patent Convention* (EPC)[93] contain provisions that may affect the patentability of stem cell technologies.[94]

16.55 Article 5(1) of the EU Biotechnology Directive provides that 'the human body, at the various stages of its formation and development' does not constitute patentable subject matter. However, art 5(2) states that 'an element isolated from the human body or otherwise produced by the means of a technical process' may be a patentable invention, even if the invention is structurally identical to a natural element. The implementing regulations of the EPC were amended in 1999 to ensure consistency

87 United States, *Congressional Debates, House of Representatives*, 22 July 2003, H7274 (D Weldon); Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Bill 2004 (HR 2799) (US) s 801.

88 R Weiss, 'Funding Bill Gets Clause on Embryo Patents', *Washington Post* (Washington DC), 17 November 2003, A04; Kaiser Network, *Sen Brownback Adds Clarifying Language to Appropriations Bill Barring Patents on 'Human Organisms', Kaiser Daily Reproductive Health Report, 18 November 2003*, <www.kaisernetwork.org/daily_reports/rep_repro.cfm> at 18 November 2003; Biotechnology Industry Organization, *New Patent Legislation Sets Dangerous Precedent and Stifles Research, 2 September 2003*, <www.bio.org/ip/cloningfactsheet.asp> at 23 December 2003.

89 United States, *Congressional Debates, House of Representatives*, 5 November 2003, E2234 (D Weldon); United States, *Congressional Debates, House of Representatives*, 22 November 2003, E2471 (D Weldon). See also Kaiser Network, *House to Vote on Provision Included in Omnibus Spending Bill that Would Ban Patents on 'Human Organisms', Kaiser Daily Reproductive Health Report, 8 December 2003*, <www.kaisernetwork.org/daily_reports/rep_repro.cfm> at 8 December 2003.

90 United States, *Congressional Debates, House of Representatives*, 5 November 2003, E2234 (D Weldon); United States, *Congressional Debates, House of Representatives*, 22 November 2003, E2471 (D Weldon).

91 Even if the provision were adopted, the fact that it is contained in an annual appropriations Bill means that the provision must continue to be adopted each year to remain in effect.

92 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998).

93 *European Patent Convention*, (entered into force on 7 October 1977).

94 The EPC applies to all member states of the EU, as well as some non-EU member states; for example, Switzerland. The EPC and its administrative body, the EPO, fall outside the legislative boundaries of the European Union (EU), but certain provisions of the EU Biotechnology Directive were adopted by the EPO for the purposes of supplementary interpretation of the EPC: see Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001) r 23(b)–23(e).

between the EPC and the EU Biotechnology Directive.[95] Rule 23e of the EPC implementing regulations contains provisions equivalent to art 5 of the Directive.

16.56 Article 6 of the EU Biotechnology Directive prohibits the grant of patents that are contrary to '*ordre public* or morality'. The article specifies particular inventions that presumptively fall within the scope of this exclusion, such as 'uses of embryos for industrial or commercial purposes'.[96] Article 53a of the EPC contains equivalent language to art 6 of the EU Biotechnology Directive.

16.57 The European Patent Office (EPO) and the European Group on Ethics in Science and New Technologies appear to have adopted different positions on the patentability of technologies involving human embryonic stem cells under the EPC and EU Biotechnology Directive.

Position of the European Patent Office

16.58 In 1999, the EPO granted a patent to Edinburgh University that related to a method of using genetic engineering to isolate animal stem cells—including embryonic stem cells—from more differentiated cells in a cell culture (the Edinburgh Patent).[97] The patent was opposed by fourteen parties—including the governments of Germany, the Netherlands and Italy—primarily on the basis that the patent did not comply with art 53(a) of the EPC.[98] Opponents argued that the claims encompassed human stem cells, including human embryonic stem cells and the genetic modification of such cells, because the term 'animal' in the claims could be interpreted as including humans.[99]

16.59 The Opposition Division of the EPO held that the patent did not comply with art 53(a) of the EPC because it involved uses of human embryos for industrial and commercial purposes.[100] The Opposition Division required the patent to be amended to exclude human and animal embryonic cells from the scope of the claims. Since 1999,

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95 Articles 5(1) and 5(2) are included in the EPC as rr 23e(1) and 23d(c) respectively.

96 The other inventions presumptively excluded from patentability pursuant to art 6 of the EU Biotechnology Directive are processes for cloning human beings, for modifying the germ line identity of human beings, or for modifying the germ line identity of animals which is likely to cause them suffering without any substantial medical benefit to humans or animals. See also *European Patent Convention*, (entered into force on 7 October 1977) rr 23d(a), 23d(b).

97 EP0695351.

98 European Patent Office, *Status of Patent No EP0695351*, 5 January 2004.

99 Some opponents also asserted that the patent claims encompassed human cloning and the creation of transgenic humans. Edinburgh University voluntarily amended the patent expressly to exclude claims to the creation of transgenic humans and human germ-line intervention. The Opposition Division of the European Patent Office determined that the patent claims did not encompass the cloning of humans or animals: European Patent Office, 'Opposition Hearing on Genetic Stem-Cell Patent at the European Patent Office', *Press Release*, 18 July 2002, <www.european-patent-office.org/news/pressrel>; European Patent Office, 'Background Information on the "Edinburgh" Patent', *Press Release* (July 2002), <www.european-patent-office.org/news/pressrel/pdf/backgr_3.pdf>; Societa Italiana Brevetti, *European Patent Decisions: 'Edinburgh' Patent to be Maintained in Amended Form*, <www.sib.it/engsib/novita/pat/270902.htm> at 21 January 2004.

100 Societa Italiana Brevetti, *European Patent Decisions: 'Edinburgh' Patent to be Maintained in Amended Form*, <www.sib.it/engsib/novita/pat/270902.htm> at 21 January 2004.

no further patents relating to human embryonic stem cells appear to have been granted by the EPO.[101]

EU Stem Cell Report

16.60 In May 2002, the European Group on Ethics in Science and New Technologies published a report that considered issues surrounding the patentability of inventions involving stem cells.[102] Unlike the EPO, the EU Stem Cell Report did not interpret the EU Biotechnology Directive (and the corresponding provisions of the EPC) as precluding all inventions involving human embryonic stem cells lines from patentability. The report stated that art 6 of the EU Biotechnology Directive leaves open the question of patentability of cells obtained from donated embryos and does not indicate which embryos, if any, are subject to the exclusion.[103]

16.61 The opinions expressed in the EU Stem Cell Report were not, however, limited to inventions involving human embryonic stem cells. The position adopted in the report as to the patentability of stem cell technologies under European law is as follows.

- Isolated stem cells that have not been modified do not fulfil the legal requirements for patentability, particularly the requirement of industrial application. Further, unmodified stem cell lines should not be patentable because the cell lines may have a large range of undescribed uses, which could result in the grant of overly broad patents.[104]

- Stem cell lines that have been modified by *in vitro* treatments, or genetically modified so that they have acquired characteristics for a specific industrial application, may satisfy the requirements for patentability.[105]

- Patents on inventions involving stem cells should be granted only if the application refers to a specific and sufficiently accurately described stem cell line and its industrial application.

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101 National Health and Medical Research Council, *International IP Laws in Relation to Stem Cells: An Information Paper* (2003), 22–23.

102 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002).

103 Ibid, 14. In particular, the report commented that some people have considered that non-viable embryos—such as those created by parthenogenesis or even by somatic cell nuclear transfer—may not be covered by this exclusion: European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 14. However, the report recommended (at 17) that processes for creating a human embryo by cloning for use in stem cell research should not be patentable.

104 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 16.

105 Ibid, 15.

- Patenting processes involving human stem cells, regardless of the source of the cells, does not raise any specific ethical obstacles if the requirements for patentability are otherwise satisfied.[106]

16.62 The EU Stem Cell Report also commented that the role of the European Group on Ethics in Science and New Technologies was to consider ethical aspects of biotechnology in general,[107] but that patent applications involving biotechnological inventions—including those involving stem cell technologies—may require specific ethical evaluation.[108] In light of this, the EU Stem Cell Report suggested that ethical evaluation of patent applications should become part of the assessment process of the EPO, or national patent offices, and that 'advisory panels of independent experts' should be established for such purposes.[109]

United Kingdom

16.63 In April 2003, the United Kingdom Patent Office (UK Patent Office) issued a Practice Note setting out its general approach to patent applications claiming stem cells derived from human embryos and processes involving human embryonic stem cells.[110] The Practice Note indicates that each patent application will be assessed on its merits, but goes on to provide as follows:

- processes for obtaining stem cells from human embryos are not patentable because the *Patents Act 1977* (UK) provides that uses of embryos for industrial or commercial purposes are not patentable inventions;[111]

- 'human totipotent cells' are not patentable because they have the potential to develop into an entire human body, and the human body at its various stages of its formation and development is excluded from patentability under the *Patents Act 1977* (UK);[112] and

- 'human embryonic pluripotent stem cells' will be patentable if such inventions satisfy the statutory criteria for patentability because such stem cells do not have the potential to develop into an entire human body.

16.64 In addition, the UK Patent Office has concluded that the commercial exploitation of inventions involving human embryonic pluripotent stem cells is not, as

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106 Ibid, 16.

107 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998) art 7.

108 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 18.

109 Ibid..

110 United Kingdom Patent Office, 'Inventions Involving Human Embryonic Stem Cells', *Practice Notice*, April 2003, <www.patent.gov.uk/patent/notices/index>.

111 *Patents Act 1977* (UK) sch A(2) para 3(d). This provision implemented art 6 of the EU Biotechnology Directive.

112 Ibid sch A(2) para 3(a). This provision implemented art 5(1) of the EU Biotechnology Directive.

a general matter, contrary to public policy or morality in the United Kingdom.[113] The Practice Note states that, despite some opposition to embryo research in the United Kingdom, a number of reports have noted the enormous potential of stem cell research.

16.65 The Practice Note does not address the patentability of inventions involving foetal and adult stem cell lines. It appears, therefore, that inventions involving foetal and adult stem cell lines may be assessed for patentability in the same manner as inventions involving any other type of technology.

16.66 The Practice Note has adopted an interpretation of the EPC and EU Biotechnology Directive—as implemented in the *Patents Act 1977* (UK)—that differs from the opinions of both the EPO and the EU Stem Cell Report in some respects. Unlike the EPO, the UK Patent Office will grant patents on inventions claiming certain types of embryonic stem cells. Further, in determining which types of inventions claiming human embryonic stem cells are eligible for patent protection, the UK Patent Office has drawn a different distinction to that adopted in the EU Stem Cell Report: the UK Patent Office distinguishes between types of cells on the basis of their potential to develop into an entire human being, rather than according to whether the cell lines are modified or unmodified.

Canada

16.67 The Canadian Biotechnology Advisory Committee report, *Patenting of Higher Life Forms and Related Issues* (the CBAC Report), recommended that the *Patent Act 1985* (Can) be amended to include a provision that: 'No patent shall be granted on human bodies at any stage of development'.[114] In proposing this amendment, the CBAC Report made reference to Australian law and, in particular, s 18(2) of the *Patents Act*.[115]

16.68 The CBAC Report indicated that the proposed provision should be narrowly construed and was not intended to prevent patent claims being granted with respect to stem cell lines, (adult) cell lines or DNA sequences.[116] CBAC commented that it selected the plural term 'human bodies', rather than 'human body', to indicate that only the entire human body was encompassed by the exclusion, not its parts.[117] Further, CBAC stated that it proposed the term 'human bodies' rather than 'human beings' (the term used in s 18(2) of the *Patents Act*) because 'human beings' is a metaphysical concept, not a biological one.[118]

113 Ibid s 1(3), 1(4).
114 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), rec 1.
115 Ibid, 9.
116 Ibid.
117 Ibid.
118 Ibid.

16.69 The CBAC Report also suggested that the phrase 'at all stages of development' in the proposed amendment would cover human bodies of infants, children and adults, as well as precursors to human bodies from zygotes to foetuses.[119] However, such a provision would not prevent the patenting of stem cells or other cells because:

> these are removed from a multi-cellular precursor of the human body (except for the zygote) and thus do not comprise a human body at any stage of development.[120]

16.70 The report of the Ontario Government, *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare* (the Ontario Report), adopted a different approach to the issue of stem cell patents to that proposed in the CBAC Report. The Ontario Report recommended that the Canadian Government 'consider adopting an [*ordre public*]/ morality clause within the Canadian *Patent Act*'.[121] The Ontario Report was particularly concerned to provide a mechanism for assessing 'contentious patent applications', such as those involving stem cells.[122] The Ontario Report regarded patenting stem cells as controversial because of the potential applications of stem cell therapies,[123] but did comment on the possible controversy arising from the fact that stem cell research may involve the use and destruction of embryos.

Options for reform

16.71 The ALRC has been considering whether the patentability of inventions involving stem cell technologies under Australian law needs to be clarified. It has been suggested that governments should 'learn from the experiences and social controversies surrounding human gene patents' and formulate coherent policies in relation to stem cell patenting to avoid such controversies recurring.[124] A clear approach to this issue is certainly desirable. In formulating such an approach, however, Stacy Kincaid has noted that:

> isolated analysis and decision making of an issue, particularly a biotechnology issue, often results in 'laws that may be drafted too vaguely, broadly, or narrowly so as to inhibit the development of scientific innovation.[125]

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119 Ibid.

120 Ibid. CBAC also noted that, in their view, the provision would not be interpreted to include ova or sperm cells.

121 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(f).

122 Ibid, rec 13(f), 50.

123 Ibid, 38–39, 50.

124 T Caulfield, 'From Human Genes to Stem Cells: New Challenges for Patent Law?' (2003) 21 *Trends in Biotechnology* 101, 103.

125 S Kincaid, 'Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research' (2003) 30 *Pepperdine Law Review* 553, citing L Knowles, 'Science Policy and the Law: Reproductive and Therapeutic Cloning' (2000) 4 *New York University Journal of Legislation and Public Policy* 13, 14.

16.72 There are a number of reform options available, including:

- leaving determinations as to the patentability of inventions involving stem cell technologies to IP Australia for case-by-case analysis on the basis of existing laws and policy;
- amending the *Patents Act* to clarify which inventions involving stem cell technologies (if any) constitute patentable subject matter; or
- requiring IP Australia to develop examination guidelines setting out its examination practices with respect to inventions involving stem cell technologies and to indicate clearly the types of inventions involving stem cell technologies (if any) for which IP Australia will grant patent protection if the statutory criteria for patentability are satisfied.

Submissions and consultations

16.73 The issue of patentability of stem cell technologies was discussed only briefly in IP 27.[126] However, the ALRC received a number of submissions that addressed this issue, and consulted with a number of organisations engaged in stem cell research in Australia, including the NSCC.[127]

16.74 A number of submissions suggested that patent protection should be available under Australian law for stem cell technologies. For example, the NHMRC submitted:

> The Council considers that it would be the clear expectation of researchers currently working (in Australia) with human stem cells to develop therapeutic application, to attempt to commercialise the outcomes of their research. Such researchers and the commercial organisation they are associated with, would in all likelihood seek patent protection of their inventions.[128]

16.75 Some submissions—primarily from companies in the pharmaceutical and biotechnology industries—indicated that patents on stem cell technologies are important to encourage investment in this research and the development of therapeutic applications for stem cells. Genetic Technologies Limited commented:

> Gene-based and stem cell-based therapies hold enormous potential, but developing proven reliable therapies will be a long, difficult and expensive exercise. Patent laws are likely to underpin any significant investment in gene-based therapies and stem cell-based therapies and, as such, are a necessary part of realising the future potential of these areas of research.[129]

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126 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), [2.51], [9.66], [12.72], Question 12–6.

127 National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003; BresaGen Limited, *Consultation*, Adelaide, 15 September 2003. See also National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003.

128 National Health and Medical Research Council, *Submission P52*, 31 October 2003.

129 Genetic Technologies Limited, *Submission P45*, 20 October 2003. See also GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003.

16.76 Two submissions addressed the application of s 18(2) of the *Patents Act* to inventions involving stem cell technologies. The Australian Centre for Intellectual Property in Agriculture (ACIPA) suggested that s 18(2) should be revised to 'remove ambiguity and uncertainty as to whether stem cell research is patentable'.[130] ACIPA also submitted:

> The Government must act to provide a clear directive as to whether stem cell research is patentable under the *Patents Act 1990* (Cth), and, if so, to what extent protection should be granted. In particular, it must determine whether unmodified and modified stem cells will be patentable. Such reforms are necessary to foster the commercialisation of stem cell research.[131]

16.77 IP Australia also addressed the scope of s 18(2) of the *Patents Act* and indicated its approach when determining whether s 18(2) is applicable to a particular invention.

> What constitutes a 'human being' according to s 18(2) is currently a very grey area, as no clear guidance on this has yet been provided by the courts. Although IP Australia's position will no doubt change as the technology evolves, *the organisation's current interpretation is that anything which has an inherent capability to mature and become a human being should be excluded.* According to this, the more complex the subject matter, the more likely it is to be excluded. Human genes, cells, tissues, ovum and sperm are generally considered patentable. However, complexities arise for subject matter such as fertilised ovum, stem cells, foetuses, genetically modified animals containing human genes, and humans treated with animal tissue.[132]

16.78 Submissions did not generally distinguish between patenting issues relevant to embryonic stem cells, foetal stem cells or adult stem cells. In consultations, however, the NSCC commented that different issues arise for different types of stem cells because of the ethical concerns associated with embryo research.[133]

16.79 A few submissions considered that Australian patent law should take ethical considerations into account. Dr Warwick Neville of the Australian Catholic Bishops Conference submitted:

> It would be remarkable if, on the one hand, the Commonwealth Parliament has so recently enacted legislation [the *Research Involving Embryos Act 2002* and *Prohibition of Human Cloning Act 2002*] which deals expressly with medical research involving embryos and stem cells, and which includes reference to ethical considerations, and on the other hand, patent law and patent office practice … continue to exclude ethical considerations.[134]

16.80 Similarly, ACIPA considered that:

> The government must also consider patent law and stem cell research within the prism of the debate over the ethics of patenting life forms. It should seek to include public

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130 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
131 Ibid.
132 IP Australia, *Submission P56*, 4 November 2003 (emphasis added).
133 National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003.
134 W Neville, *Submission P50*, 29 October 2003.

> policy considerations—such as ethical considerations in an assessment of patent applications.[135]

16.81 One submission addressed the ethics of embryonic stem cell research generally and considered that future research on embryos should not be permitted.[136]

ALRC's views

16.82 It is important to distinguish between concerns applicable to the *conduct* of stem cell research and those directed to the *patenting* of inventions that may be developed in the course of such research. In addition, issues that may relate only to patenting inventions involving embryonic stem cells need to be distinguished from issues that may relate to other types of inventions involving stem cell technologies.

16.83 Inventions involving embryonic stem cells may raise issues that are not raised by inventions involving adult stem cells. Objections to patenting inventions involving embryonic stem cells are often founded on ethical concerns about the conduct of research involving embryos and embryonic stem cells per se. As described above, regulation of embryo research is the subject of separate federal, state and territory laws, which themselves draw a delicate balance between competing interests, taking ethical considerations into account. In the ALRC's view, amendments to the *Patents Act* to address ethical concerns about the patenting of stem cells are not required at this stage as an additional layer of ethical consideration.

16.84 Existing provisions in the *Patents Act* may be used in appropriate circumstances to reject patent applications claiming human embryonic stem cells or related processes. The Commissioner of Patents has a discretion to refuse a patent application claiming an invention whose use would be contrary to law.[137] Because it is an offence under the *Research Involving Human Embryos Act* to use an excess ART embryo without a licence from the NHMRC Licensing Committee (unless the use falls within a statutory exemption),[138] inventions involving human embryonic stem cells lines that are derived from the use of an excess ART embryo without a licence, or in breach of the conditions in any such licence, could fall within the 'contrary to law' provision in the *Patents Act*. Similar considerations could apply to inventions involving human embryonic stem cell lines derived from non-excess ART embryos.[139] Further, as discussed in Chapter 7, the incorporation of the *Statute of Monopolies* into the definition of 'invention' in the *Patents Act* may provide a basis for excluding inventions that are 'generally inconvenient' from patentability under Australian law.[140]

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135 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
136 M Pryor, *Submission P60*, 6 November 2003.
137 *Patents Act 1990* (Cth) s 50(1)(a). The Commissioner may also revoke an innovation patent on equivalent grounds: *Patents Act 1990* (Cth) s 101B(2)(d). See further Ch 7.
138 *Research Involving Human Embryos Act 2002* (Cth) ss 10(1), 10(2).
139 See Ibid s 11. However, research involving human embryonic stem cell lines imported into Australia may not currently be subject to the same considerations.
140 *Patents Act 1990* (Cth) s 18, sch 1.

16.85 On the basis of information currently available, the ALRC is not inclined to propose amendments to the *Patents Act* that would expressly address the patentability of inventions involving stem cell technologies. As discussed in Chapters 6 and 7, the requirements for patentability in the *Patents Act* are nearly all technology-neutral and are therefore capable of adapting to new technologies as they arise. Technology-specific exceptions to the requirements for patentability impact on the flexibility of the current statutory framework. Further, such provisions may conflict with Australia's obligations under the Agreement on Trade-Related Intellectual Property Rights.[141] The express exclusion of inventions involving stem cell technologies is also likely to have an adverse effect on research in this burgeoning field.[142] Moreover, the emergent state of stem cell science and the uncertainty about its potential applications must be borne in mind. A specific provision in the *Patents Act* relating to the patentability of inventions involving stem cell technologies is unlikely to be sufficiently flexible to adapt to future scientific developments.

16.86 However, the ALRC recognises that uncertainty currently exists about the types of inventions involving stem cells that may be patentable under Australian law. The ALRC's preliminary view is, therefore, that IP Australia should develop clear examination guidelines setting out the types of inventions involving stem cell technologies that it regards as patentable and, to the extent that any inventions involving stem cell technologies may not be patentable, the basis on which patent protection may not be available. In the remainder of this chapter, these are called the Stem Cell Examination Guidelines.

16.87 Stem Cell Examination Guidelines are desirable for similar reasons to those set out in Chapter 8 in support of the development of guidelines for the examination of biotechnological inventions generally.[143] Currently, IP Australia's policy is to refer applications claiming stem cell technologies to a supervising examiner and then to a Deputy Commissioner. It is unclear from IP Australia's *Manual*, or submissions made by IP Australia to relevant government inquiries on this issue, exactly how Australian patent law is applied to inventions involving stem cells, particularly human embryonic stem cells.

16.88 Patent applications claiming stem cell technologies have, however, been filed with IP Australia, and in some cases patents have been granted. It would assist potential applicants in understanding the scope of patent protection available under Australian law if IP Australia's approach with respect to inventions resulting from stem cell research were more clearly articulated. The UK Patent Office's Practice Note on

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141 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

142 As similar concern was articulated in the EU Stem Cell Report: European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 15.

143 See Proposal 8–4.

the patentability of human embryonic stem cell inventions provides a worthwhile model in this regard.

16.89 Although the primary responsibility for developing the proposed Stem Cell Examination Guidelines should lie with IP Australia, that body should consult with the NHMRC and other relevant stakeholders before adopting any guidelines in final form. IP Australia should also obtain the assistance and advice from the panel of experts described in Proposal 8–2. Any guidelines should be consistent with the *Patents Act*, *Patent Regulations* and existing case law. However, it is recognised that the final interpretation of the Act and the Regulations lies with the courts, which may ultimately reject an interpretation adopted by IP Australia.

16.90 In developing the proposed Stem Cell Examination Guidelines, the distinctions drawn by the UK Patent Office between totipotent and pluripotent cells may provide a helpful way to approach the application of s 18(2) of the *Patents Act* to inventions involving embryonic stem cell technologies. Distinguishing between types of cells on the basis of their potentiality is preferable to the approach adopted in the EU Stem Cell Report of distinguishing between modified and unmodified stem cell lines. The EU Stem Cell Report does not explain why, as a general matter, isolated human biological material may constitute a patentable invention under European law,[144] but an isolated stem cell line requires an additional step—that is, further modification—in order to be patentable. It appears that the distinction between modified and unmodified stem cells lines is a response to concerns about access to patented stem cell technologies and the effect of broad claims in stem cell patents. The ALRC considers that it is preferable to address issues relating to the exploitation of stem cell technologies directly (see below).

Proposal 16–1 IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cell technologies. The examination guidelines should address, among other things, the patentability of inventions involving:

(a) totipotent, pluripotent and multipotent cells; and

(b) processes involving stem cell technologies.

144 *European Patent Convention*, (entered into force on 7 October 1977), r 23e; *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998) art 5.

Exploiting patents over stem cell technologies

16.91 In addition to concerns about the patentability of inventions involving stem cell technologies, other issues have been raised about stem cell patents. These focus on the impact of stem cell patents on access to, and the licensing of, stem cell lines and stem cell technologies. The balance of this chapter examines the issues that have been raised in this regard—including broad claims in stem cell patents, the licensing practices of stem cell patent holders, and commercialisation of stem cell technologies—and considers ways in which these matters might be addressed.

Broad stem cell patents

16.92 The EU Stem Cell Report expressed concern about the scope of the claims in stem cell patents. The Report recommended that stem cell patents should be granted only where 'the patent claim refers to a specific and sufficiently accurately described stem cell line and its industrial application'.[145] Further, the EU Stem Cell Report considered that stem cell patents may cover important research tools and that broad claims in stem cell patents might therefore have adverse effects on further innovation that might be of benefit to healthcare.[146] Similar concerns have been expressed by the Nuffield Council on Bioethics and by a Select Committee of the House of Lords.[147]

16.93 Academic commentators have also identified broad stem cell patents as a concern.[148] Professor Glenn McGee and Elizabeth Banger reviewed a number of United States patents involving stem cell technologies granted by the end of 2001 and concluded:

> The entire field of stem cell research (both in basic and clinical science) is still very much emergent, and yet patent protection is already in place that could allow a tiny number of companies to exert enormous influence over the conduct of stem cell research for many years.[149]

16.94 In particular, it has been suggested that the broad claims in the Thomson patents (described above) may be problematic. Indeed, some people have indicated that the majority of human embryonic stem cell research could fall within the scope of the claims of these patents.[150] As discussed in Chapter 6, broad claims are characteristic of

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145 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 18.

146 Ibid, 18. Concerns about patented genetic research tools are discussed in Ch 13.

147 Nuffield Council on Bioethics, *Stem Cell Therapy: The Ethical Issues* (2001); House of Lords, *Stem Cell Research: Report* (2002), [6.8].

148 See, eg, M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448; G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243.

149 G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243, 257.

150 S Shulman, 'Owning the Future: The Morphing Patent Problem' (2001) *Technology Review* 33; G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243, 259; J Lee, 'The Ownership and Patenting of Inventions Resulting from Stem Cell Research' (2003) 43 *Santa Clara Law Review* 597, 626; M Rimmer,

patents granted early in the development of a new technological field. However, broad claims in stem cell patents may not be objectionable if access to stem cell technologies covered by such claims is not unduly restricted.

16.95 Concerns about the potential breadth of existing stem cell patents and the likely impact of this on stem cell research in Australia need to be carefully evaluated. Dr Dianne Nicol and Jane Nielsen have indicated that some of the Thomson patents have not been filed in Australia.[151] Australian researchers may therefore be free to conduct research that falls within the scope of these patents without fear of infringement of these patents, although the activities may fall within and potentially infringe other issued claims.[152] Stem cell patents granted in other jurisdictions might, however, prevent the importation of a stem cell product developed in Australia using a process covered by the claims of such patents. In addition, the NSCC commented in consultations that the prior art against which any subsequent patent applications claiming stem cell technologies may be assessed may significantly limit the scope of the claims in any stem cell patents that may be granted by IP Australia in the future.[153]

16.96 Despite the broad foundational stem cell patents owned by entities such as WARF and Geron Corporation, other biotechnology companies have derived stem cell lines that may fall outside the scope of the Thomson patents. For example, BresaGen Limited, an Australian biotechnology company with facilities in Georgia, USA, has indicated that it has developed four pluripotent embryonic stem cell lines derived from embryos at a later stage of embryonic development than that claimed in the Thomson patents.[154]

Licensing stem cell patents

16.97 Concerns have also been expressed about how stem cell patents are exploited. It has been suggested that stem cell patents may impede further research and innovation in relation to stem cell technologies, particularly if stem cell patent holders license such patents exclusively, or only on restricted terms. These concerns are similar to those addressed elsewhere in this Discussion Paper about the licensing of gene patents.[155]

16.98 A few submissions to the Inquiry commented on restrictions on access to patented stem cell technologies. For example, the Walter and Eliza Hall Institute of

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'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448.

151 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 42–43. Nicol and Nielsen were unable to identify corresponding Australian patents or patent applications for US Pat Nos 6,200,806 and 6,280,718.

152 Similar observations were made by the NSCC in consultations: National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003. Freedom to conduct stem cell research without infringing patent rights will, however, need to be determined on a case-by-case basis.

153 Ibid.

154 S Kincaid, 'Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research' (2003) 30 *Pepperdine Law Review* 553, 581–582.

155 See Ch 13 and 23.

Medical Research indicated that non-exclusive licensing of stem cell patents should be encouraged.[156] Similarly, ACIPA commented that:

> The government also needs to ensure that the granting of patents in respect of stem cell research will not impair research and development in the field or prevent equitable access to therapies and drugs derived from this work.[157]

16.99 Concerns about the licensing of stem cell patents have been particularly acute in the United States, largely as a result of government policy relating to funding embryonic stem cell research.[158] On 9 August 2001, President George W Bush announced that human embryonic stem cell research using federal funds could be conducted only on the then-existing stem cell lines.[159] This policy sought to balance the potentially valuable therapies that stem cell research may produce against concerns in different sections of American society that research involving human embryos should not be permitted.[160]

16.100 President Bush indicated that there were more than 60 'genetically diverse stem cell lines' in existence, which had been created from embryos that had already been destroyed.[161] However, concerns have now been raised that an insufficient number of human embryonic stem cell lines are available and that there are deficiencies in existing cell lines.[162] Further, many of these human embryonic stem cell lines are covered by patents.[163] It has been said that President Bush's policy has rendered existing embryonic stem cell lines (and patents over such cell lines) more significant, and arguably reduced the possibility that United States scientists will derive and patent new embryonic stem cell lines.[164] Professor Rebecca Eisenberg has commented that:

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156 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

157 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

158 See, eg, S Kincaid, 'Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research' (2003) 30 *Pepperdine Law Review* 553; C Carroll, 'Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences' (2002) *Journal of Law, Technology and Policy* 435; J Lee, 'The Ownership and Patenting of Inventions Resulting from Stem Cell Research' (2003) 43 *Santa Clara Law Review* 597.

159 President Bush and United States Office of the Press Secretary, 'Embryonic Stem Cell Research', *Fact Sheet*, 9 August 2001, <www.whitehouse.gov/news>. See also National Institutes of Health, *Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Stem Cell Registry, 7 November 2001*, <http://stemcells.nih.gov/fedPolicy/NIHFedPolicy.asp> at 16 September 2003 The NIH maintains a registry of all stem cell lines that fall within the ambit of President Bush's policy: National Institutes of Health, *NIH Human Embryonic Stem Cell Registry*, <http://stemcells.nih.gov/registry> at 21 January 2004.

160 President Bush and United States Office of the Press Secretary, 'Embryonic Stem Cell Research', *Fact Sheet*, 9 August 2001, <www.whitehouse.gov/news>.

161 Ibid.

162 National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003. For example, some are frozen inner cell masses that, upon thawing and culturing, have not been viable cell lines.

163 G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243, 247, 258.

164 S Kincaid, 'Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research' (2003) 30 *Pepperdine Law Review* 553, 574; C Carroll, 'Selling the Stem Cell: The Licensing

> What constrains the monopoly power of a patent holder is the prospect of new technology being developed that will make it unnecessary to deal with them … [the] President's decision limits that threat.[165]

16.101 Access to human embryonic stem cell lines that fall within President Bush's policy does not, however, appear to have been unduly restricted to date. The United States National Institutes of Health (NIH) have developed Memoranda of Understanding with a number of entities to ensure access to proprietary embryonic stem cell lines for researchers funded by the NIH.[166] In particular, an agreement between WiCell Research Institute Inc (WiCell)[167] and the United States Department of Health and Human Services[168] permits NIH-funded researchers to access human embryonic stem cell lines covered by the Thomson patents for a fixed fee of US$5,000 for use for educational and non-commercial purposes.[169] Researchers are permitted to retain any intellectual property rights that may arise from such research without consultation with WiCell,[170] but they require an additional licence from WiCell to be able to commercialise any resulting inventions.

16.102 Licences over stem cell patents and other collaborative arrangements relating to the development of stem cell technologies have also been reported in connection with Australian commercial entities. For example, a 2003 report published by Invest Australia indicated that three Australian entities—BresaGen, ES Cell International, and Stem Cell Sciences—had entered into agreements with organisations based in the United States and Japan pursuant to which intellectual property rights would be licensed for use in human embryonic stem cell research and the development of human embryonic stem cell therapies.[171] However, the extent to which access to stem cell technologies is being restricted, particularly outside Australia, is unclear.

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of the Stem Cell Patent and Possible Antitrust Consequences' (2002) *Journal of Law, Technology and Policy* 435, 444.

165 S Stolberg, 'Patent Laws May Determine Shape of Stem Cell Research', *New York Times* (New York), 17 August 2001, A1.

166 Memoranda of Understanding have also been entered into by: ES Cell International Pte Ltd, BresaGen Inc (a United States affiliate of the Australian company BresaGen Limited); and the University of California: National Institutes of Health, *Stem Cell Transfer Agreements*, <http://stemcells.nih.gov> at 21 January 2004.

167 WiCell Research Institute is a subsidiary of WARF, which has rights to license the Thomson patents.

168 WiCell Research Institute Inc and Public Health Service of the United States Department of Health and Human Services, *Memorandum of Understanding*, 5 September 2001. See also J Lee, 'The Ownership and Patenting of Inventions Resulting from Stem Cell Research' (2003) 43 *Santa Clara Law Review* 597, 626; J Miller, 'A Call to Legal Arms: Bringing Embryonic Stem Cell Therapies to Market' (2003) 13 *Albany Law Journal of Science and Technology* 555, 562–563.

169 A fee of US$5,000 is charged to cover preparation and shipping costs.

170 As discussed in Ch 13, guidelines developed by the NIH prohibit licences to research tools developed with NIH funds to include reach-through claims: National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

171 Invest Australia, *Australian Biotechnology* (2003), 10.

Stem cell banks

16.103 Initiatives have been implemented in other jurisdictions to facilitate access to existing and newly-created stem cell lines. In the United Kingdom, the National Institute for Biological Standards and Controls has established a stem cell bank (the UK Stem Cell Bank). The UK Stem Cell Bank will be developed to supply stem cell lines of all types for use in research in the United Kingdom and other countries, as well as for direct use in the production of human therapeutic products.[172]

16.104 The NIH has also established an on-line registry of human embryonic stem cell lines that are available for use by researchers funded by the NIH.[173] Access to human embryonic stem cell lines is not available directly from the NIH, but relevant information about the stem cell lines and their availability is provided.

16.105 In Australia, the *Research Involving Human Embryos Act* and the *Prohibition of Human Cloning Act* provide for an independent review of the operation of this legislation, which will include consideration of a National Stem Cell Bank.[174] The review is scheduled to be conducted as soon as possible after 19 December 2004—being the second anniversary of the date on which the Acts received Royal Assent—and a report is to be submitted to the Council of Australian Governments and both Houses of Parliament upon completion.[175]

16.106 The EU Stem Cell Report also proposed the creation of an EU registry of unmodified human stem cell lines, which would include both embryonic stem cells and embryonic germ cells.[176] No action has been taken to implement this proposal to date.

16.107 In addition, in January 2003, the United Kingdom Medical Research Council convened the International Stem Cell Forum for the discussion of international policy issues relating to stem cells.[177] The Forum comprises nine international research agencies, including the NHMRC.[178] One of the projects under consideration by the

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172 UK Stem Cell Bank, *UK Stem Cell Bank*, <www.ukstemcellbank.org.uk> at 23 January 2004.

173 National Institutes of Health, *NIH Human Embryonic Stem Cell Registry*, <http://stemcells.nih.gov/registry> at 21 January 2004.

174 *Research Involving Human Embryos Act 2002* (Cth) s 47(4)(d); *Prohibition of Human Cloning Act 2002* (Cth) s 25(4)(d). One submission to the Senate Community Affairs Legislation Committee considered that the establishment of a similar registry in Australia was desirable: Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), [4.61]–[4.62].

175 *Research Involving Human Embryos Act 2002* (Cth) ss 47(1), 47(3); *Prohibition of Human Cloning Act 2002* (Cth) ss 25(1), 25(3).

176 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 18.

177 United Kingdom Medical Research Council, *International Stem Cell Forum*, <www.mrc.ac.uk/index/strategy-strategy/strategy-science_strategy/strategy-index.htm> at 9 February 2003; National Health and Medical Research Council, *International IP Laws in Relation to Stem Cells: An Information Paper* (2003), 32.

178 The other participants in the Forum include relevant bodies from Israel, Canada, the United States, Singapore, Finland and Sweden: United Kingdom Medical Research Council, *International Stem Cell*

Forum is opportunities for collaboration between countries in connection with stem cell banks covering all types of stem cells.

Commercialisation of stem cell technologies in Australia

16.108 To date, consideration of issues relating to stem cell technologies in Australia has focused on the circumstances in which stem cell research may be conducted and whether it is appropriate for intellectual property rights to be granted in relation to inventions involving stem cell technologies. Regulation of the way in which stem cell patents might be exploited and commercialised has not been addressed in any detail.

16.109 Proposals have been made to address specific aspects of the commercialisation of stem cell technologies. For example, in 2003, the *Therapeutic Goods Regulations 1991* (Cth) were amended to include provisions requiring manufacturers of prescription medicines to provide consumers with information about whether medicines have been manufactured or tested using human embryonic stem cells.[179] In addition, the Andrews Report recommended that a licensing body be established to regulate any research involving the isolation, use and creation of embryonic stem cell lines.[180] The Andrews Report contemplated that this licensing body should have regard to 'the potential commercialisation of the products' of such research and would 'issue guidelines to other Commonwealth agencies'.[181]

16.110 The functions of the licensing body contemplated by the Andrews Report were more extensive than those ultimately conferred upon the NHMRC Licensing Committee pursuant to the *Research Involving Human Embryos Act*, the *Prohibition of Human Cloning Act* and corresponding state and territory legislation.[182] In addition, the scope of activities that the Andrews Report considered that the proposed licensing body would regulate applied to human cloning and stem cell research generally.[183]

16.111 The *Research Involving Human Embryos Act* and corresponding state legislation does not currently provide for the NHMRC Licensing Committee to exercise this type of responsibility. In issuing a licence to use excess ART embryos, the NHMRC Licensing Committee is required to consider, among other matters, whether appropriate procedures are in place to obtain consent if a licence to use excess ART embryos is granted, and whether the proposed use has been approved by an HREC.[184]

Forum, <www.mrc.ac.uk/index/strategy-strategy/strategy-science_strategy/strategy-index.htm> at 9 February 2003.

179 *Therapeutic Goods Amendment Regulations (No 3) 2003* (Cth); AusBiotech Ltd, *Proposed Amendments to Therapeutic Goods Regulations 2003*, <www.ausbiotech.org/policy.php> at 23 January 2004.

180 Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), recs 6 and 7.

181 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [12.82].

182 Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), rec 8, [12.55].

183 Ibid recs 1, 2, 5–8, [12.41]–[12.55].

184 *Research Involving Human Embryos Act 2002* (Cth) ss 20, 21.

In addition to certain licence conditions stipulated in the legislation,[185] the NHMRC Licensing Committee may also impose licence conditions relating to: the persons authorised to use the excess ART embryos; the number of embryos authorised to be used; reporting and monitoring requirements; and information to be provided by the licence holder to persons authorised to use the excess ART embryos.[186]

16.112 There is no provision in the legislation that would allow the NHMRC Licensing Committee to impose conditions on the way in which the results of any inventions arising from the use of excess ART embryos are exploited or commercialised. Nor does the NHMRC Licensing Committee have jurisdiction to require the owner of any stem cell patents to grant access to such technology, similar to the rights exercisable by the NIH in relation to stem cell technology developed using NIH funds.[187]

Guidelines for access to stem cell technologies

16.113 One alternative to legislative provisions regulating access to stem cell technologies would be to develop national guidelines relating to patenting and exploiting stem cell technologies by Australian entities. Such guidelines might apply to embryonic stem cells, as well as to adult and foetal stem cells, to address issues that may arise from time to time.

16.114 In Victoria, a draft code of practice for the propagation and use of human stem cell lines has been developed by a working group within the Biotechnology Safety and Ethics Interdepartmental Committee (the Victorian Draft Code of Practice). The Draft Code gave some consideration to the issue of proprietary rights in stem cell lines and the exploitation of such inventions.[188] The Victorian Draft Code of Practice is a set of voluntary guidelines, designed to apply to the use of adult, foetal and embryonic stem cell lines in both the public and private sectors. The Draft Code of Practice indicated that:

> the public good is best served by a situation in which private ownership of unmodified stem cell lines does not inhibit or prevent basic or non-commercial research on stem cells.[189]

16.115 Further, the Draft Code commented that the biotechnology industry has a responsibility to avoid developing proprietary interests such that 'the potential for basic

185 Ibid ss 24(1), 24(2), 24(3).

186 Ibid s 24(5). Conditions may be imposed at the time a licence is granted by the NHMRC Licensing Committee or, with notice, during the licence term, either following an application by the licence holder or upon the Committee's own motion: *Research Involving Human Embryos Act 2002* (Cth) ss 25, 28.

187 See further Ch 12.

188 The Draft Code of Practice was released for public comment in February 2003. Further information about the status of the Draft Code of Practice has not been published to date.

189 Department of Human Services (Vic) Stem Cell Code of Practice Working Group, *Propagation and Use of Approved Human Stem Cell Lines: Draft Code of Ethical Practice and Discussion Paper* (2003), [2.8.2].

research outcomes is limited',[190] and that the government should 'facilitate the availability of stem cell lines and donated tissue in the public domain.'[191] However, neither the Draft Code of Practice, nor the discussion paper that was released in conjunction with it, proposed a mechanism by which such outcomes could be ensured.

16.116 In Chapter 13, the ALRC proposed that the ARC and NHMRC develop guidelines for researchers to ensure that the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in wide dissemination of research tools.[192] There is scope for considering whether stem cell research funded by the ARC or the NHMRC should also be covered by such guidelines, or whether guidelines specifically relating to stem cell technologies should also be developed.

ALRC's views

16.117 The ALRC has been considering whether mechanisms should be established to facilitate the monitoring of commercial applications of patented stem cell technologies and access to associated inventions.

16.118 Proposals made elsewhere in this Discussion Paper to facilitate access to genetic materials and technologies could also be invoked to facilitate access to stem cell technologies. These proposals include amendments to the existing compulsory licensing regime in the *Patents Act*; use or acquisition of patented technologies pursuant to the Crown use provisions in the *Patents Act*; and amendments to the *Patents Act* to incorporate a specific experimental use defence.[193]

16.119 Specific proposals may also be desirable to address concerns that have been articulated about the way in which stem cell patents are exploited. A range of reform options are available, including:

- establishing an Australian stem cell bank, or collaborative agreements with existing stem cell banks in other countries, to facilitate and regulate access to stem cell lines by researchers;

- conferring responsibility on some new or existing body (for example, the NHMRC Licensing Committee), to consider the potential exercise of any patent rights that may arise from research involving human stem cell lines conducted by Australian entities; or

- requiring the ARC and NHMRC to develop guidelines and principles for researchers that would ensure the public interest in the commercial exploitation

190 Ibid, [3.2.3].
191 Ibid, [3.3.7].
192 See Proposal 13–1.
193 See Ch 14, 26 and 27.

of inventions involving stem cell technologies is balanced with the public interest in dissemination of such technologies.

16.120 There are limitations in each of the reform options outlined above, and a combination of these options, or alternative approaches, may be desirable. In particular, if responsibility is to be conferred upon a new or existing body to consider the potential exercise of any patent rights that may arise from research involving stem cell lines conducted in Australia, the issues that would need to be taken into account include the following:

- the type of research that will be regulated;
- the time at which an assessment of the exercise of patent rights should be made;
- the appropriate composition of a body that would assess and determine how to manage the potential exercise of patent rights; and
- the legislative or regulatory framework that would be required to establish such a body or confer additional power on an existing body.

16.121 Given the limitations discussed in this chapter on the functions conferred on the NHMRC Licensing Committee under the *Research Involving Human Embryos Act*, the *Prohibition of Human Cloning Act* and corresponding state and territory legislation, the NHMRC Licensing Committee may not be the most appropriate body to exercise such a role, even if regulation of the potential exercise of stem cell patent rights is considered desirable. It may be more appropriate for the NHMRC and ARC to establish other mechanisms to examine the potential impact of patents over stem cell technologies, such as through the issuing of guidelines.

16.122 The ALRC is interested in obtaining further information and comments on these proposed options, and any other mechanisms by which the exploitation of stem cell technologies might be regulated.

Question 16–1 Should specific mechanisms be established to regulate the exploitation of patented stem cell technologies? If so, would any of the following initiatives be desirable:

(a) establishing an Australian stem cell bank or collaborating with existing stem cell banks in other countries;

(b) conferring responsibility on a new or existing body to consider the potential exercise of any patent rights that might arise from research conducted by Australian entities using human stem cell lines; or

(c) developing guidelines and principles by the National Health and Medical Research Council and the Australian Research Council to ensure that the public interest in the commercial exploitation of inventions involving stem cell technologies is balanced with the public interest in dissemination of such technologies?

PART D

Patents and Commercialisation of Biotechnology

17. Overview of the Biotechnology Industry

Contents

Introduction

17.1 The Terms of Reference require the ALRC to consider the impact of current patenting laws and practices related to genes and genetic and related technologies on the Australian biotechnology sector. The biotechnology sector, including pharmaceutical companies, is heavily dependent on patents because of the large costs involved in developing products and because many products are readily copied.

17.2 This chapter describes the structure and features of the biotechnology sector in Australia. It also describes the pharmaceutical industry in Australia, as the pharmaceutical industry is part of the biotechnology sector, and biotechnology drug products form an important output of the sector. However, the pharmaceutical industry also operates in areas outside biotechnology and the industry is often differentiated from other biotechnology companies in statistics about the biotechnology sector.

17.3 The biotechnology sector also encompasses areas outside the scope of this Inquiry, including agriculture, food processing, manufacturing and environmental management. The *Australian Biotechnology Report 2001* defines biotechnology as:

> The application of all natural sciences and engineering in the direct or indirect use of living organisms or parts of organisms, in their natural or modified forms, in an innovative manner in the production of goods and services (including for example therapeutics, foodstuffs, devices, diagnostics, etc) and/or to improve existing industrial processes. The market application of outputs is typically in the general areas

> of human health, food production, industrial bio-processing and other public good and environmental settings.[1]

17.4 As the Terms of Reference require the ALRC to focus on the human health implications of gene patenting, this definition of biotechnology encompasses areas that fall outside the scope of this Inquiry. Consequently, much of the description in this chapter is of the sector as a whole as it is not always possible to find statistics that differentiate between industries within the sector.[2]

Global context

17.5 Biotechnology is one of the world's fastest growing industrial sectors[3] and is worth an estimated US$296 billion.[4] The United States Department of Commerce has described biotechnology as 'the most research-intensive industry in civilian manufacturing'.[5] Ernst & Young estimates that well over US$16 billion was spent on global research and development (R&D) in biotechnology from October 2000 to September 2001.[6] During the same period, global biotechnology revenue accounted for almost US$39 billion, despite generating a net loss of almost US$6 billion for that year.[7]

17.6 The United States dominates the biotechnology sector. In 2003, the Biotechnology Industry Organization reported that the United States biotechnology industry comprised 1,475 companies, of which 342 were publicly held,[8] and generated 72% of global revenue in biotechnology. In 2002, these revenues amounted to US$33.6 billion.[9] The United States sector spends around three and a half times more on biotechnology than Europe and 25 times more than the Asia-Pacific region.[10] In 1999, the sector invested US$11 billion in R&D growing to US$15.6 billion in 2001.[11]

17.7 Most companies in the global biotechnology sector are privately owned. According to Ernst & Young, from October 2000 to September 2001, there were 3,662

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1 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 3. The Australian Bureau of Statistics is currently considering the development of a formal definition for biotechnology to work as a generally accepted standard: Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 310.

2 The Australian Bureau of Statistics has recognised the lack of statistical information about biotechnology in Australia, and has indicated that it will undertake a survey of biotechnology in 2003–04. Australian Bureau of Statistics, 'Biotechnology', *Science and Technology Statistics Update*, June 2003, [4], [4.2].

3 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 1.

4 Access Economics Australia, *Pharmaceuticals and Australia's Knowledge Economy* (1998).

5 Office of Technology Policy, *The US Biotechnology Industry* (1997), 30.

6 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 10.

7 Ibid.

8 Biotechnology Industry Organization, *Editors' and Reporters' Guide to Biotechnology* (2003), 3.

9 Ernst & Young, *Resilience: Americas Biotechnology Report 2003* (2003), 3.

10 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 10.

11 B Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, <http://genethics.ca/personal/HistoryPatent.pdf> at 17 April 2003, 3.

private companies, compared with only 622 public companies operating worldwide in the biotechnology sector.[12]

17.8 Globally, the sector has been characterised by a high attrition rate especially among the start up firms whose only assets may be patents or patent applications. Capital-raising and cash flow may also present problems and many companies have become insolvent after a few years or have been absorbed by larger companies.[13] A recent study found that of the 24 companies that listed publicly on the Australian Stock Exchange between 1998 and 2002, seven had enough funding for only one year of operation, and a further nine had funding for only two years. The study suggested this problem might be attributed to a lack of scale and financial liquidity in the Australian industry.[14]

Australian biotechnology sector

17.9 There are four types of companies or organisations within the Australian biotechnology sector:

- core biotechnology companies;[15]
- pharmaceutical companies;
- genomic companies; and
- public research institutions.[16]

17.10 The sector comprises a mix of small and medium sized enterprises (SMEs) together with larger companies, including subsidiaries of multinationals. Most major international pharmaceutical companies have Australian subsidiaries. In 2003, there were more than 300 core biotechnology companies, with an industry growth rate of over 50% in the previous two years.[17] There were also around 450 'diversified' biotechnology companies. The sector employs about 6,400 full-time equivalent employees.[18]

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12 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 10.

13 B Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, <http://genethics.ca/personal/HistoryPatent.pdf> at 17 April 2003, 6.

14 D Sparling and M Vitale, *Australian Biotechnology: Do Perceptions and Reality Meet?* (2003) Australian Graduate School of Management, 2.

15 The *Australian Biotechnology Report 2001* used the expression 'core' to describe companies whose business depends on 'exploiting intellectual property embedded in molecular, cellular and tissue biology': Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 4.

16 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 353.

17 Invest Australia, *Australian Biotechnology* (2003), 1.

18 Invest Australia, *A Snapshot of Biotech and Pharma in Australia*, <www.investaustralia.gov.au> at 18 December 2003.

17.11 Total revenue generated by the core biotechnology companies is estimated to be almost $1 billion annually.[19] The biggest contributors to revenue growth have been royalties, licensing and milestone fees.[20] The *Australian Biotechnology Report 2001* suggested that 'one of the challenges for most Australian biotechnology companies is generating sufficient funds to achieve their product development objectives'.[21] It described the sector as growing, but small in global terms.[22]

17.12 Internationally, Australia compares favourably with the United States in terms of the number of biotechnology companies relative to the size of the labour force, and is well ahead of the European Union. Australia now ranks sixth in the world for the number of biotechnology companies, behind the United States, Canada, the United Kingdom, Germany and France.[23] However, revenue as a proportion of the labour force is well below the United States but ahead of the European Union.[24]

17.13 The *Australian Biotechnology Report 2001* described the Australian biotechnology sector as being numerically 'dominated by small to medium players',[25] lacking geographic proximity to a large market, and therefore also lacking the 'wealth of information' provided through conferences, workshops, networking and industry associations.[26] Larger companies are frequently involved with the smaller ones through strategic alliances, in particular licence agreements.[27] The Report noted that alliances are the main means by which Australian biotechnology companies gain access to international markets:

> The best Australian companies are now able to joint venture with, or even acquire entities overseas … Low and slow commercialisation successes are still, however, an ongoing issue for many Australian companies.[28]

17.14 Dr Dianne Nicol and Jane Nielsen suggest the strongest reason for the alliance and merger activity within the sector:

> is the high cost of research and development together with the increased marketing power of the allied or merged entity … Financing is difficult for most start-up biotechnology companies, and the high cost of research and development force many companies to enter either into strategic alliances with, or be acquired by, larger

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19 Ibid.

20 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 20. Milestone fees are lump sum payments that may be made by a licensee upon reaching specified stages in the development or commercialisation of a product.

21 Ibid.

22 Ibid, 8.

23 Invest Australia, *Australian Biotechnology* (2003), 5; Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 6.

24 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 22.

25 Ibid, 8.

26 Ibid.

27 This is also a feature of the industry in the United States and increasingly, the European Union: Department of Industry Science and Resources Business Competitiveness Division, *Invisible Value: The Case for Measuring and Reporting Intellectual Capital* (2001), 354.

28 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 46.

> biotechnology companies or pharmaceutical companies. In addition, the high technical and commercial risks of product development mean that the companies need to share risk and have significant product pipelines. These agreements result in the sharing of IPRs [intellectual property rights] over genomic information and bioinformatics tools in return for funds for research and development. Indeed, access to IPRs may be a major factor influencing a company's decision to enter into an alliance.[29]

17.15 In a 2002 survey, Kelvin Hopper and Lyndal Thorburn reported that 50% of Australian core biotechnology companies aim to develop new therapeutic or diagnostic products directed at human diseases.[30] The survey also found that human health and therapeutics dominated among the new companies, with a significant increase in the number of companies established to supply to the sector in areas such as protein and gene sequencing.[31]

17.16 The *Australian Biotechnology Report 2001* found that most core biotechnology companies in the field of human health intend to develop their intellectual property, technology or products to the pre-clinical stage (and less frequently to a clinical stage) before licensing to an offshore multinational company.[32] This is particularly likely to be the case for drug discovery companies. Interview data from a recent study of the Australian medical biotechnology sector by Nicol and Nielsen suggests that this could be attributed to a lack of infrastructure and resources to exploit patents within the Australian sector.[33]

17.17 Companies that produce other downstream products (such as tests, therapies or devices) or those that produce intermediate products (such as reagents, formulations and bioinformatics tools) may not necessarily seek to license offshore.

17.18 Spin-off companies are the preferred approach to commercial development of biotechnology innovations in the Australian industry. This approach may be preferred in part because most Australian scientific research that results in new technologies occurs in the public sector. It may also be due to the support for new companies available through the Biotechnology Innovation Fund.[34] Government grants are the largest source of capital for the new companies, followed by funds from parent

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29 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 354.

30 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 29.

31 Ibid, 11.

32 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 46.

33 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 103.

34 In one recent study of 24 biotechnology companies listed on the Australian Stock Exchange between 1998 and 2002, all but two were developing technology originating from academic institutions, medical research institutes or the Commonwealth Scientific and Industrial Research Organisation: D Sparling and M Vitale, *Australian Biotechnology: Do Perceptions and Reality Meet?* (2003) Australian Graduate School of Management, 5.

organisations and venture capital.[35] It has been suggested that the Australian industry is overpopulated with small companies relying on a single idea to be successful.[36]

17.19 The *Australian Biotechnology Report 2001* described funding for R&D as 'an ongoing challenge'[37] for SMEs. It suggested that a problem for the sector is the capacity to generate sufficient funds to achieve its objectives, whether in licensing or manufacture.[38] R&D expenditure by Australian companies is well below those in the United States and the European Union.[39] Publicly listed core biotechnology companies invest about $3.2 million a year each in R&D, whereas unlisted and private core biotechnology companies invest an average of $1 million each.[40]

17.20 However, the Report noted that government programs have caused a 'sharp increase' in expenditure.[41] The Australian Government currently contributes around $300 million in R&D funding to the sector each year.[42] Government funding programs for the biotechnology industry are discussed in Chapter 11.

Pharmaceutical industry

17.21 As noted above, for the purposes of this Inquiry, the biotechnology sector is taken to include pharmaceutical companies. The pharmaceutical industry undertakes the development, production and supply of pharmaceutical products. The Australian pharmaceutical industry has been described as:

> an integrated part of the global industry. Subsidiaries of MNEs [multinational enterprises] undertake a significant proportion of pharmaceutical activity in Australia, although there are also some large Australian owned companies within the industry (particularly producers of out of patent drugs).[43]

17.22 Globally, the pharmaceutical industry is dominated by horizontally and vertically integrated multinational entities.[44] Some of these are engaged in joint ventures with universities, other research institutions, or smaller biotechnology firms.

17.23 Australia's population represents 0.3% of the world's population yet consumes around 1% of total global pharmaceuticals sales. In 2002, revenue of the Australian

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35 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 3.
36 D Crowe, 'Testing Time for Biotech', *Australian Financial Review* (Sydney), 7 October 2003, 61.
37 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 11.
38 Ibid, 20.
39 Ibid, 22.
40 Ibid, 10.
41 These programs are described below.
42 Invest Australia, *Australian Biotechnology* (2003), 1.
43 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), [1.2]. For the purpose of the Productivity Commission's report, the pharmaceutical industry was defined as 'all those who contribute to the discovery, development, manufacture and supply of human-use pharmaceutical products and services in Australia, including the biomedical sector'.
44 Department of Industry Tourism and Resources, *Pharmaceuticals Industry Profile*, <www.industry.gov.au> at 17 December 2003.

human-use pharmaceuticals manufacturing industry was about $6.1 billion. There are around 143 separate firms listed as suppliers to the Pharmaceutical Benefits Scheme, which employ up to 16,000 people.[45] (See Chapter 20.)

17.24 The Productivity Commission has described R&D as the 'lifeblood' of the pharmaceutical industry, which relies on developing new products to maintain and sustain growth.[46] Pharmaceutical research and development involves drug discovery, pre-clinical testing and clinical trials to test new drugs for their effectiveness and safety. Total R&D spending by pharmaceutical companies in Australia is around $300 million annually.[47]

17.25 The pharmaceutical industry is strongly dependent on patent protection. The lead time and costs involved in research and clinical trials are cited as one of the strong arguments in support of patents in this area. It is estimated that it can cost more than $900 million to bring a new pharmaceutical drug to market.[48]

Biotechnology patents

17.26 Patents are highly important to the biotechnology industry. The Organisation for Economic Co-operation and Development (OECD) has noted:

> Patents are especially important for biotechnology firms as many of them have no activity other than R&D and therefore do not directly exploit their inventions: they sell them, or the right to exploit them, to other firms. A legal property right is therefore needed for the seller to be protected.[49]

17.27 Biotechnology products are often easily copied and regulatory requirements mean the time required to develop technology into a marketable product can be long and costly. As one biotechnology sector analyst has commented, companies need 'tons of time and buckets of money' to bring products to market.[50] Intellectual property rights afford producers protection during this period and the period of monopoly gained as a result of a patent allows for the high initial investment in development to be recouped.

17.28 The majority of all biotechnology patents originate in the United States. The United States' share of biotechnology patents accounts for 65.5% of all biotechnology patents issued by the United States Patent and Trademark Office (USPTO) and almost

45 Ibid.
46 Government programs to support R&D in the pharmaceutical industry are discussed in Ch 11.
47 Department of Industry Tourism and Resources, *Pharmaceuticals Industry Profile*, <www.industry.gov.au> at 17 December 2003. Clinical trials comprise the largest component of such spending.
48 Ibid.
49 Organisation for Economic Co-operation and Development, *An Overview of Biotechnology Statistics in Selected Countries* (2003), 13.
50 D Crowe, 'Testing Time for Biotech', *Australian Financial Review* (Sydney), 7 October 2003, 61, 61.

50% of those issued by the European Patent Office (EPO).[51] The OECD reports that the number of biotechnology patents issued in the United States and Europe has grown substantially in comparison with the total number of patents overall. In the years 1990–2000, the USPTO recorded an increase of 15% in biotechnology patent applications, compared with an increase of just 5% for patents overall. Similarly, in Europe, the EPO recorded a 10.5% increase in biotechnology patents from 1990–1997, compared with a 5% increase overall.[52]

17.29 It is difficult to obtain reliable figures on the number of gene patents granted, or the number of applications pending in Australia or overseas. A threshold complexity concerns the definition of gene patent. As outlined in Chapter 1, this Discussion Paper uses 'gene patent' to refer to patents on genetic materials or technologies, and not just to patents on isolated genetic material. Others may use the term more narrowly to refer only to patents that assert claims on isolated genetic materials and the genetic sequences they contain. Complexities also arise because of the way in which patents and applications are classified under the International Patent Classification (IPC)[53] system, and because of the limited amount of published patent information.

17.30 Biotechnology Australia is currently undertaking a detailed analysis of gene patenting activity in Australia over the last decade, with a view to compiling reliable statistics on the number of gene patents granted in the various IPC classes.

17.31 It appears clear, however, that most gene patents granted in Australia relate to inventions that are developed overseas. One research study, conducted for the United States National Science Foundation,[54] examined the source of patent applications in relation to 'international patent families' covering human DNA sequences.[55] The study assumed that the priority application (the first application filed anywhere in the world) was the country in which the invention was developed. The study found that, from 1995–1999, 736 applications related to inventions developed in the United States, compared with 150 in Japan, 107 in the United Kingdom, 42 in Australia and 28 in Canada (see Figure 17–1).[56]

17.32 Of the 42 applications filed in Australia, 16 were filed by corporations, 16 by universities, six by other not-for-profit entities, three by government agencies and one by an individual (see Figure 17–2).[57]

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51 Organisation for Economic Co-operation and Development, *Biotechnology Statistics in OECD Member Countries: Compendium of Existing National Statistics* (2001), 12.

52 Ibid, 11.

53 See explanation about the IPC in Ch 8.

54 L Rausch, 'International Patenting of Human DNA Sequences: InfoBrief (NSF 02–333)', *Dvision of Science Resource Statistics, National Science Foundation*, September 2002, 1.

55 A 'patent family' was defined as consisting of all patent documents published in a country and associated with a single invention. An 'international patent family' was defined as an invention for which patent protection has been sought in more than one country: see Ibid, 1–2.

56 Ibid, Table 2.

57 Ibid, Table 2.

Figure 17–1 Country of origin of patent applications on human DNA sequences 1995–1999

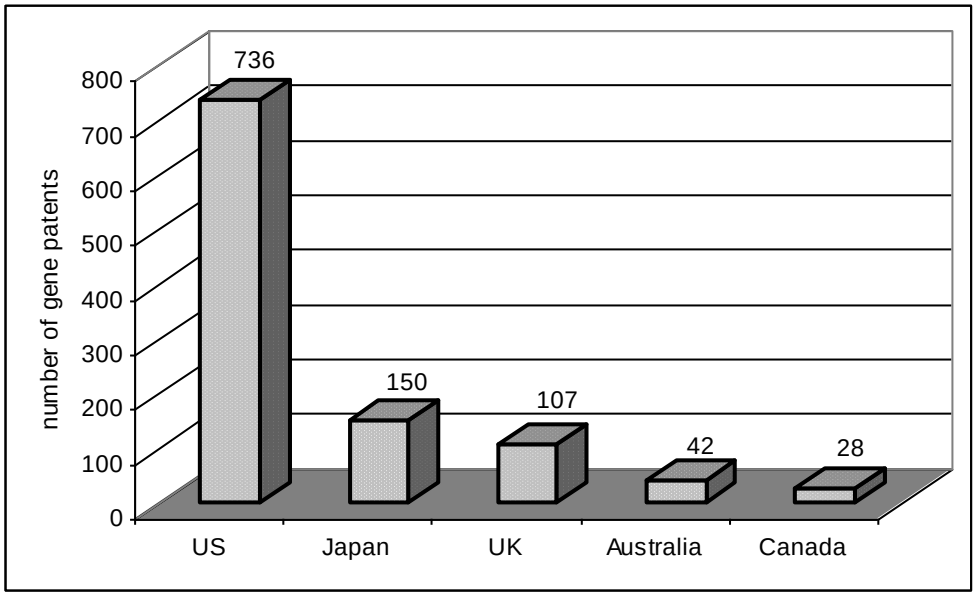
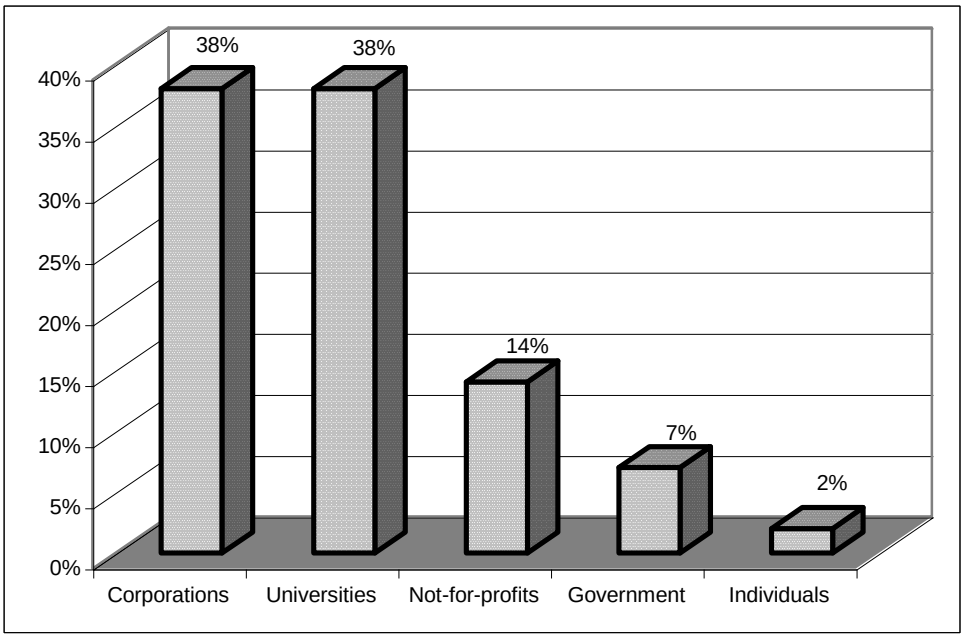


Figure 17–2 Organisations filing Australian patent applications on human DNA sequences 1995–1999



17.33 Studies relating to Australian biotechnology patents also indicate that most such patents are foreign owned. Nielsen reports that only about 2% of biotechnology applications filed in Australia originate from Australian inventors.[58] She notes that 'by far the greatest number of biotechnology patents are held by US inventors, both in the US and in other jurisdictions including Australia'.[59] However, the recent study conducted by Nicol and Nielsen indicates that the number of biotechnology patents filed by Australian-based inventors rose from 26 in 1988 to 46 in 1998.[60]

17.34 Nielsen also notes that of the biotechnology patent applications in the United States, around 2% originate from Australia.[61] A report by CHI Research Inc found that of Australian patents granted in the United States, Australia was 'relatively strong in pharmaceuticals and biotechnology and quite weak in most other high-tech areas'. The report suggested that 'combined pharmaceuticals and biotech AIUS patents [Australian-invented US patents] … may in fact represent an area of actual or potential great strength for Australia'.[62]

17.35 Hopper and Thorburn report that 50 United States patents were granted to Australian biotechnology firms in 2002. Of these, less than 10 were gene patents. Hopper and Thorburn suggest that one measure of the strength of the Australian biotechnology sector is the number of United States patents granted because holding an Australian patent or having an Australian patent application is usually not sufficient for entry into international markets.[63] They also note, however, that many established Australian biotechnology firms hold no United States patents and conclude that 'many Australian firms may not be serious about intellectual property protection in what may be their major market'.[64]

Licences

17.36 The number of patents granted does not tell the whole story in relation to the biotechnology sector. Licensing is the means by which technology is made available to others, and is discussed in Chapter 23. A patent holder, without the inclination or capacity to commercialise a product, may licence others to do so. Licences are also acquired in order to gain access to patented inventions, and are used for further

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58 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 39.

59 Ibid, 39.

60 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 39.

61 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 39.

62 CHI Research Inc, *Inventing Our Future: The Link between Australian Patenting and Basic Science* (2000), 29.

63 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 30.

64 Ibid. However, the number of patent applications far exceed the number of United States patents granted. There is a large backlog in the United States Patent Office (see Ch 8). Patents granted reflect previous applications not current activity.

research or product development. It is difficult to obtain comprehensive information in Australia about the licensing of gene patents since the details of such licences are often confidential. However, some information can be obtained from IP Australia[65] and from company reports or stock exchange announcements.

17.37 Nicol and Nielsen report prolific licensing activity in the biotechnology sector, noting that in 1999, 219 licences were issued and 181 were acquired.[66] Of those acquired, 45% were from overseas companies, and of those issued, 78% went to international companies. Nicol and Nielsen suggest the figures on international involvement indicate that 'Australian companies are compelled to seek alliances and financing arrangements with overseas companies'.[67]

17.38 Chapter 23 discusses licensing practices and issues that have been identified as impediments to licensing in the biotechnology industry.

Submissions and consultations

17.39 In submissions and consultations, the Australian biotechnology industry was generally regarded as youthful, buoyant and undergoing an expansionary phase.[68] Only one submission suggested that the current success of the biotechnology industry in Australia was probably overrated.[69] It was also noted that many of the people involved in running biotechnology companies in Australia are scientists, rather than business professionals.[70]

65 IP Australia is the Commonwealth organisation that administers patent, trademark and design rights. See IP Australia, *Annual Report* (2003).

66 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 363 citing Ernst & Young, *Australian Biotechnology Report* (1999), 35.

67 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 363.

68 Australian Competition and Consumer Commission, *Consultation*, Canberra, 23 September 2003, Queensland Department of Innovation and Information Economy, *Consultation*, Brisbane, 2 October 2003.

69 *Confidential Submission P54 CON*, 3 November 2003.

70 Queensland Department of Innovation and Information Economy, *Consultation*, Brisbane, 2 October 2003.

18. Technology Transfer from Publicly Funded Research Institutions

Contents

Introduction

> The ivory tower academy has had to learn the language of business economics.[1]

18.1 Most upstream genetic research undertaken in Australia occurs in publicly funded research institutions. This chapter considers the transfer of this upstream research to the biotechnology sector for commercial development. It focuses on the interface between publicly funded research institutions and the biotechnology industry.

18.2 Some of the potential impediments to transfer for commercialisation are addressed in this chapter. These include lack of commercial experience or institutional support, researcher attitudes, difficulty in finding industry receptors and lack of resources. Variability in transfer practices and lack of clear ownership of patented technology may also hamper effective transfer for commercialisation. A variety of options for addressing these issues are examined.

18.3 This chapter also considers transfers that are not specifically aimed at commercialisation and briefly discusses issues surrounding materials transfer agreements.

Technology transfer and research commercialisation

18.4 Basic research is only the first stage in the development of genetic tests and therapies that will eventually have healthcare benefits for the community. Moving from idea to product requires considerable investment to fund further research into the medical applications of the technology; to undertake validation research and clinical trials; and to develop and produce a marketable test or therapy. The cost of this developmental phase will usually be high and require specialised skills and facilities.

18.5 Most publicly funded research institutions lack the financial capacity and skill base to undertake this phase, and it is generally considered that the industry sector is better placed to take on this role to ensure that the community receives the benefits of genetic research.

18.6 Technology transfer is the process of moving new technology from one person or organisation to another, to enable sharing of resources or to facilitate further development and commercialisation. This may include transfers of materials, information or the details of new technologies.

18.7 In the past, the transfer of research results out of research institutions to industry was generally conceived of as a linear progression from basic research to applied research, followed by commercial financing, manufacturing and marketing.[2] The

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1 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 50.

2 J Merson, 'Epistemic Capture: Industry and Government in the Setting of Medical Research Priorities' (Paper presented at 28th International Congress on Law and Mental Health, Sydney, 29 September 2003).

process of knowledge creation and product development is now regarded as a more complex interaction where market needs and commercialisation possibilities inform and modify the conduct of basic research and technology development.[3] Interaction between publicly funded research institutions and industry is a recent development. Prior to the 1980s they had little to do with one another.[4]

18.8 As discussed in Chapter 11, it is government policy for public sector institutions to work with industry to commercialise the products of their research. This policy is based on the view that patenting by public sector institutions and licensing of technologies to the private sector will increase the rate of commercial application of knowledge.[5] This is said to be important because:

> Effective research commercialisation, and more broadly the capture of ownership and exploitation of intellectual property, has become of paramount importance in global competitiveness.[6]

18.9 The 1999 Health and Medical Research Strategic Review Committee report, *The Virtuous Cycle: Working Together for Health and Medical Research* (the Wills Report),[7] emphasised the need to promote technology transfer from the research sector to industry:

> Australia has traditionally been very good at research, but deplorably bad at capturing the value of its intellectual property. Australia can no longer accept this condition and must adjust its culture and mechanisms urgently before the opportunities of the biotechnology and pharmaceutical industries pass us by.[8]

18.10 This view has also been endorsed by Australia's peak research funding bodies, the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC). The NHMRC's *Interim Guidelines on Intellectual Property Management for Health and Medical Research* (*Interim Guidelines*) state:

> To ensure Australia captures the benefits of publicly funded health and medical research, it is essential to have the skills and appropriate mechanisms to identify, value, protect, develop and commercialise these resources.[9]

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3 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), 17.

4 Australian Research Council, *Mapping the Nature and Extent of Business-University Interaction in Australia* (2001), 14.

5 Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001), 18.

6 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 50.

7 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998).

8 Ibid, 110.

9 National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), v. See also Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001).

18.11 Similarly, the ARC's *National Principles of Intellectual Property Management for Publicly Funded Research* (*National Principles*) state that, as part of ensuring the benefits of research are captured, 'the good management of intellectual property (IP) becomes one of the most critical steps in the translation of research into national wealth'.[10]

Patent protection

18.12 Chapter 17 noted the importance of patent protection in attracting commercial interest in developing technology to allow companies to recoup financial outlays for the process of product development.[11] This is particularly true for genetic research and the biotechnology industry because of the time and expense required to develop a product to a marketable stage.[12]

18.13 The link between intellectual property protection and the ability to obtain investment funding was also noted in submissions and consultations. As the Department of Industry, Tourism and Resources pointed out:

> Patents define the IP developed by researchers and constitute the 'property' that is exchanged to raise the capital needed for the commercialisation of research results. Attracting venture capital for further research or commercialisation of inventions is not possible without an effective and enforceable patent system.[13]

18.14 As discussed in Chapter 12, since most publicly funded research institutions claim ownership over intellectual property developed within their organisation, the capacity and the responsibility to obtain patent protection and develop or transfer their intellectual property therefore lies with the institution.

18.15 As a result of government policy, institutions are now more inclined to patent the results of research rather than simply allowing them to be published and placed in the public domain. A recent study by Dr Dianne Nicol and Jane Nielsen (Nicol-Nielsen Study) reported that the research sector considers that obtaining patents promotes ongoing investment in research programs[14] and encourages the development of scientific advances into useful applications.[15]

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10 National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), v.

11 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 2.

12 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), i.

13 Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

14 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 85.

15 Ibid, 60.

18.16 It was also observed in consultations that research institutions are becoming more sophisticated in their approach to intellectual property and are often holding on to it longer to add value and get better returns by licensing at a later stage.[16]

Technology transfer offices

18.17 In recent years, most research institutions have established dedicated units or companies to facilitate technology transfer. These units take a variety of forms and have differing responsibilities, including obtaining patent protection, negotiating licensing and materials transfer agreements and, in some cases, establishing spin-off companies. They are also referred to by a range of titles, including 'business liaison offices', 'technology transfer units' or 'commercialisation arms'. They may be units within the institution or companies wholly owned by the institution. They will be collectively referred to as 'technology transfer offices'.

18.18 The overall functions of these units include:

- identifying technology developed within the institution that may have commercial application;
- managing intellectual property issues, including facilitating patent applications, licensing university innovations to the commercial sector and advising on the terms of research agreements;
- co-ordinating industry access to research projects within the university that require financial investment to develop the commercial potential of innovative technologies and products; and
- offering assistance with gaining government support for research and development, including tax incentives and grant and loan schemes, such as the Federal Government R& D Start program.[17]

18.19 Technology transfer offices take different approaches to aiding technology identification and transfer. One method is a decentralised approach where managers of innovation and commercial development are appointed to each faculty to assist with identifying innovative technology, to work with the faculty on business development matters and to liaise with the technology transfer office's staff.[18] As discussed below, this is regarded as preferable to a centralised approach because it allows for the development of expertise around particular areas of research and commercialisation.

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16 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; UniQuest, *Consultation*, Brisbane, 3 October 2003.

17 See, eg, UniQuest, *About Commercialising Your Research*, <www.uniquest.com.au/?id=15> at 16 December 2003. The R&D Start program is outlined in Ch 5.

18 See, eg, UniQuest, *About UniQuest*, <www.uniquest.com.au/?id=13> at 16 December 2003.

18.20 Some offices maintain a register of companies and consultants who are willing to assist university researchers in the management and commercial development of intellectual property.[19] Others take an active role in helping researchers through the process of transfer and commercialisation, including through the provision of educational programs.[20]

Facilitating transfer for commercialisation

18.21 Research commercialisation begins with the identification of new technology and an evaluation of its possible applications and commercial potential. Patents may be sought and, if obtained, the technology may be transferred to other researchers or industry for further development.[21] There is a broad range of approaches to transferring technology for commercialisation, which include research-industry linkages, creating spin-off companies to develop the technology, licensing-out and assignment. Each of these approaches is discussed below.

18.22 The most appropriate approach will depend on the nature of the technology and the capacity of the institution to develop it further.[22] There was some difference of opinion in submissions and consultations about the capacity of universities and publicly funded research institutions to commercialise research results effectively. Some suggested that universities and research institutions are becoming better at commercialisation, but doubts were expressed about whether these organisations would develop the same level of skill and experience as industry.[23]

18.23 The Department of Education, Science and Training's 2002 report, *Best Practice Processes for University Research Commercialisation* (DEST Report), noted that some research-focused universities are developing a new approach to technology transfer and subsequent commercialisation that takes account of Australia's strengths in basic research and lack of strong industry capability to translate innovation successfully into commercial success. This new approach, according to DEST, features a more decentralised process of intellectual property identification and development; increased focus on growing start-ups; direct equity investment by universities and selection and pursuit of strategic commercialisation areas.[24]

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19 Melbourne Research and Innovation Office, *Technology Transfer*, University of Melbourne, <www.research.unimelb.edu.au/ridg/techtrans> at 16 December 2003.

20 For example, the Garvan Institute of Medical Research's Business Development Unit works closely with researchers to keep abreast of research progress and runs small, focused educational seminars on intellectual property and commercialisation issues to raise awareness and skills: Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003; Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003.

21 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 15.

22 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.

23 Ibid.

24 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 5.

18.24 There is also evidence that the nature of business-university interactions is undergoing a shift from 'the traditional donor-recipient contracts' to formalised joint projects between universities and businesses.[25] The ARC has suggested that this shift has resulted from changes in the business and economic environment that have made the process of developing new products for commercialisation more costly and specialised. These changes have meant that:

> the concept of the individual inventor or research laboratory achieving commercial success on the basis of one activity, and without expert management, marketing and substantial ongoing financial support, is a misrepresentation of the nature of innovation. Innovation requires cooperation and collaboration within an organisation as well as with organisations external to it.[26]

18.25 As discussed above, transfer and commercialisation are also increasingly understood as two-way processes, rather than as a linear movement of technology from the research sector to industry for development. The research and industry sectors appear to be working more closely together to shape research objectives to fit economic objectives. This approach fosters research that is more readily exploitable by industry.[27]

Linkages

18.26 The ARC has noted that 'successful commercialisation of university research requires a champion … a lot of hard work is involved in finding and developing the initial partner in the commercialisation of a new discovery'.[28] Strong, well-developed linkages between publicly funded research institutions and the industry sector facilitate identification of such 'champions'.

18.27 The Wills Report noted that the emergence of geographic clusters of technology-based industries with research institutions had provided a 'well-recognised model for biotechnology success'. It recommended that state development departments and local government work with research and biotechnology groups to remove barriers to the growth of such clusters.[29]

18.28 Linkages can take the form of relationships between individual institutions and commercial bodies, personal networks between researchers and entrepreneurs, or more formalised and broad-reaching relationships through overarching arrangements supported by institutions, industry or government.

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25 Australian Research Council, *Mapping the Nature and Extent of Business-University Interaction in Australia* (2001), 14.

26 Ibid, 14.

27 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 5.

28 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), xxiii.

29 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 128–129.

18.29 An example of the latter type of relationship is the New South Wales project, BioLink, a business initiative designed to improve commercialisation of medical research. BioLink's stated aim is 'to complete the development chain by establishing [a] platform for a research-industry-government partnership providing world's best practice business development service for NSW medical researchers'.[30] The initiative involves linkages between research institutions, government and industry partners.

18.30 There is a range of similar programs and initiatives across Australia directed at facilitating and improving linkages between the biotechnology industry sector and research institutions. These include networking forums and linkage initiatives. Nicol and Nielsen's results show that 'one of the dominant features of the biotechnology industry in Australia is widespread alliance activity between the public and private sectors'.[31] The ARC has commented that 'the traditional boundaries between education and commercialisation, basic research and applied research, and universities and industry are all blurring'.[32]

18.31 Government policy has also led to the development of Cooperative Research Centres (CRCs) and other linkage programs between the public and private sector. A CRC for the Discovery of Genes for Common Human Diseases was established in 1997, linking the Murdoch Children's Research Institute, the Walter and Eliza Hall Institute of Medical Research, the Menzies Centre for Population Health Research and a number of other publicly funded research institutions with Cerylid Biosciences Ltd as an industry partner.

Licensing-out

18.32 According to the DEST Report, across the university sector generally, licensing-out patented technology to established companies is 'the most common form of research commercialisation and generates by far the most revenue' for universities.[33] Licensing-out agreements may be exclusive or non-exclusive, and may include upfront payments, milestone agreements, royalty payments or a combination of these.[34]

18.33 However, the Nicol-Nielsen Study reported a low level of licensing-out activity in relation to gene patents. While 82% of responding research institutions indicated they owned biotechnology patents, only 52% reported they licensed-out patented genetic technologies. Of the eight who did not license, only one had no patents.[35] Nicol

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30 Garvan Institute of Medical Research, *Bio-Link*, <www.garvan.org.au/garvan.asp?sectionid=48> at 16 December 2003.

31 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 75, 85.

32 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 9.

33 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii.

34 See discussion of licensing practices in Ch 23.

35 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 100.

and Nielsen suggest that this level of licensing-out activity can be explained partially by the growth phase currently experienced by the industry. A number of respondents reported that they are in the process of finding parties to whom they can license, while institutions may still be developing technology to a point where it is capable of being licensed. Nicol and Nielsen also suggest that institutions face difficulties in finding parties to license to, with some respondents reporting that it was challenging to attract commercial interest.[36]

Assignment

18.34 Assignment of gene patents is generally not the preferred approach to technology transfer by patent holders. This may be because patent owners do not wish to lose all control of the technology and because assignment will reduce their patent portfolio. Conversely, industry recipients of technology may prefer assignment because it involves complete transfer of all rights.[37]

Spin-off companies

18.35 Research institutions create spin-off companies as a means of holding and developing patented technology, generally either because of a lack of industry receptors or because large returns are expected from developing the technology. Spin-off companies are also thought to 'contribute to innovation, growth, employment and revenues' while 'the prospects of winning big make spin-offs an attractive gamble'.[38]

18.36 Spin-off companies may take one of a number of forms. Research institutions may establish a new company to develop technology arising out of its research activities or may move technology into a company already established by the institution for the purpose of value-adding and subsequent transfer. In other cases, staff or former staff of the institution may establish their own company if ownership of the technology has been assigned to them.

18.37 Research institutions may favour establishing spin-off companies over other approaches to technology transfer because they are capable of generating revenues for the institution if it retains a share in the company. With this in mind, institutions often hold an equity interest.

18.38 In consultations, UniQuest emphasised that spin-off companies are more effective than licensing for moving technology out of universities and into industry.[39] Kelvin Hopper and Lyndal Thorburn have commented that 'the continued fast growth in start-ups is essential to capture the public sector research outputs and ensure there is a pipeline for the industry as a whole'.[40] Establishing spin-off companies is a

36 Ibid, 102.
37 Ibid, 103–104.
38 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 7.
39 UniQuest, *Consultation*, Brisbane, 3 October 2003.
40 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 67.

particularly important mechanism for transfer in Australia due to the lack of industry receptors for biotechnology innovations coming out of the public research sector.[41] Despite this, smaller institutions appear to prefer licensing to establishing spin-off companies.[42]

18.39 A large proportion of Australian biotechnology companies were established as spin-offs from universities and other research institutions. The rate of establishing spin-off companies is increasing. Figures from one survey show that 38 spin-off companies were established by universities and CRCs in 2000, a 40% increase on the previous year.[43] However, despite this growth in the actual number of spin-offs, such companies are declining as a proportion of the biotechnology sector as a whole. According to the 2002 Bioindustry Review, in 2000–2001 these companies made up 55% of the biotechnology sector in Australia, dropping to 41% in the following year.[44]

18.40 Although spin-offs may be effective in facilitating technology transfer, they may not always be the best mechanism for generating returns for the research institution. The DEST Report stated that:

> While a great deal of attention has been directed to spin-offs at least partly driven by a small number of spectacular successes, the major return to universities remains through licensing to well-established firms.[45]

18.41 Spin-offs established around one patent or product face a high failure rate, as the company stands or falls on the success of that one product. If the company fails, the institution that generated the technology will likely lose all control of it as the patent will be sold off during liquidation.[46] Spin-offs are also often staffed by researchers, as they lack the funds to employ professional managers. There is consequently often a lack of commercial expertise within the company.

Other mechanisms

18.42 Technology also moves between publicly funded research institutions and industry through a range of other mechanisms. These include joint industry-institution research projects, research contracts, public/private sector partnerships, shared infrastructure and the movement of personnel.[47]

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41 Ibid, 50.

42 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 33.

43 Ibid, 33.

44 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 18.

45 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 28.

46 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 75.

47 Prime Minister's Science Engineering and Innovation Council, *University–Industry Linked Research in Australia* (1998), 4; Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 11.

Potential impediments to transfer for commercialisation

18.43 There is a danger of repeating outdated perceptions of Australia's ability to commercialise research, including genetic research, when considering potential impediments to technology transfer. As noted above, many publicly funded research institutions have substantially increased their skills in technology transfer and commercialisation over the past five years.[48]

18.44 Two years after the release of the Wills Report and a paper by the Prime Minister's Science, Engineering and Innovation Council (PMSEIC),[49] the NHMRC, the ARC and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) carried out a study into the performance of Australian public research institutions in commercialising their research. The study suggested that Australia performed better than both Canada and the United States in commercialising its research, measured in terms of income generated from licences and start-up company formation relative to research expenditure and the size of the national economy. However, Australia lags behind both countries in terms of the number of licences executed and behind the United States in terms of the number of patents issued.[50]

18.45 The DEST Report commented that there has been a tendency in Australia to perpetuate a view of Australian institutions as performing behind their overseas counterparts in research commercialisation. DEST referred to this view as a 'myth', pointing out that:

> The data available demonstrate that the best-performing Australian universities are achieving research commercialisation outcomes broadly comparable with the best in the US and Europe, and way above their average … Australian universities have significantly strengthened their research commercialisation capacities and performance in the past five years.[51]

18.46 The ALRC is also aware that a number of programs are currently in place to address some of the impediments considered below.

18.47 However, a number of potential impediments to transfer of genetic technology for commercialisation remain. These include:

- lack of commercial experience;

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48 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), v.

49 Prime Minister's Science Engineering and Innovation Council, *University–Industry Linked Research in Australia* (1998).

50 Australian Research Council, Commonwealth Scientific and Industrial Research Organisation and National Health and Medical Research Council, *National Survey of Research Commercialisation* (2002), 43–44.

51 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vi.

- lack of institutional support for commercialisation;
- institutional decision making structures and attitudes;
- researcher attitudes and experience;
- difficulty in finding industry receptors; and
- lack of resources.

Lack of commercial experience

18.48 Effective commercialisation is promoted where research groups have developed business skills and experience with intellectual property. These groups are then more able to produce sound business plans, appreciate patenting laws, establish workable commercial structures for spin-off companies and negotiate agreements.[52]

18.49 Lack of experience in managing intellectual property and dealing with the biotechnology industry may be an impediment to effective transfer of technology from publicly funded research institutions. The Wills Report suggested that:

> professional business development management within the research enterprise is crucial and generally lacking in Australia. Together with increased investment in fundamental research … it is probably the most important initiative for developing a dynamic industry sector. Commercialisation success depends on an intimate knowledge of the industry, intense commitment to researchers and the research, and high-level management skills that can match the research to a commercialisation strategy and negotiate a favourable agreement.[53]

18.50 This potential impediment was also highlighted in a number of submissions and consultations.[54]

18.51 Lack of experience may occur in part because technology transfer within an institution is dealt with by one central office covering all areas of research, which may not have the experience to deal with issues particular to individual areas of research such as the commercialisation of genetic research. As might be expected, it appears that smaller institutions are more likely to lack transfer and commercialisation expertise. The DEST Report noted that there is a relationship between the productivity

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52 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 5.

53 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 128.

54 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.

of technology transfer offices and scale, with large institutions generating greater returns.[55]

18.52 Inexperience in technology transfer offices might also stem from a failure to employ people with adequate or appropriate skills. For example, DEST reported that employing staff with business and entrepreneurial skills, rather than legal skills, appears to promote new business formation.[56]

18.53 Lack of appropriate skills and experience with gene patenting and technology transfer may result in a variety of problems, including inefficient management of patents, failure to add sufficient value to technology before licensing and inappropriate business strategies. The ALRC has also received suggestions that institutional technology transfer offices can actually hinder the process of commercialisation where they lack the appropriate expertise.[57]

18.54 As an example, AusBiotech Ltd commented in consultations on the need for clear discussion of how intellectual property is to be dealt with at the early stage of licensing negotiations. It provided an example of an Australian university that had licensed its patented technology to an Australian biotechnology company. The company sought to open an office in the United States and obtained investment from the United States. To open the overseas office, the patent had to be relocated, however the original licence agreement entitled the university to retain ownership of the patent, and as a result the investors dropped out. AusBiotech Ltd suggested that situations of this kind could be avoided by adequate early stage discussion.[58] Awareness of these issues and the ability to deal with them is more likely to exist in technology transfer offices with adequate skills and experience.

Lack of institutional support

18.55 Research may fail to be commercialised where institutions choose not to pursue commercialisation but do not assign the patented technology elsewhere to enable others to do so.[59] This may also create a disincentive for researchers in future to work with commercialisation offices if the institutions are unreceptive to potential commercialisation.

18.56 Effective technology transfer requires an integrated approach, with transfer office staff working closely with researchers to identify, protect and develop technology. Lack of institutional support, either due to lack of funding to provide sufficient staff and facilities, or lack of support for integrative programs may prevent this interaction from occurring. As the DEST Report has commented:

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55 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 35.
56 Ibid, 35.
57 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.
58 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.
59 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

> What emerges strongly from experience is that if the research commercialisation function is set up without strong links with, and support from, the institution, it will be marginalised and, in all probability, fail. Research commercialisation is not simply an 'add-on' function; it requires a reworking of strategy and resource allocation to make it an integral part of the university's objectives and operations.[60]

Institutional decision making structures and attitudes

18.57 Negotiations for technology transfer between research institutions and commercial organisations may be slow due to the sometimes complex decision making structures within publicly funded research institutions.[61] Publicly funded research institutions may also be risk-averse, which may lead them to be overly cautious in making decisions about the transfer and commercialisation of patented research.[62]

Researcher attitudes and experience

18.58 The Wills Report suggested that Australian researchers had a relatively low rate of involvement in research commercialisation in comparison with other countries.[63] Consequently, Australia's failure to commercialise its intellectual property was in part attributed to a lack of researcher involvement in new business ventures to exploit technology. Researchers may resist commercialisation and hence not facilitate transfer or work in co-operation with technology transfer offices.

18.59 The value of research is also sometimes lost when information about a new technology is shared or published before patent protection is obtained. This may occur if researchers are unaware of the need to keep information confidential until a patent application has been made, or because they have not identified the information as having potential commercial value that should be protected by seeking a patent.[64]

18.60 Informal sharing of materials and research results may pose further problems where the technology was originally licensed-in, by infringing the terms of the licence. Reach-through claims to subsequent inventions based on the original shared material may also arise, which may be difficult to resolve in the absence of a formal transfer arrangement. It was also suggested in consultations that a lack of researcher understanding about patents sometimes leads to patents being licensed too early.[65]

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60 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 52.

64 Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003.

62 UniQuest, *Consultation*, Brisbane, 3 October 2003.

63 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 121, 123. Lack of venture capital to support new companies and low levels of industry investment in research and development were also cited as barriers to commercial development of biotechnology research. These issues are discussed further in Ch 19 in the context of the biotechnology sector.

64 UniQuest, *Consultation*, Brisbane, 3 October 2003; Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003.

65 UniQuest, *Consultation*, Brisbane, 3 October 2003.

18.61 However, the Australian research community's attitude to patenting and commercialisation appears to be changing, with researchers more receptive to the need to patent and commercially develop the results of genetic research. This perception was largely supported in submissions and consultations, some of which suggested that there are researchers with considerable experience and interest in commercial development of technology.[66] These issues, and proposed reforms, are discussed further in Chapter 15.

Difficulty in finding industry receptors

18.62 As noted in Chapter 17, the Australian biotechnology industry is small, and consists largely of upstream companies that license their patented technology to larger international companies for further development. The industry is also quite fragmented and characterised by relatively low research and development spending by international standards.[67]

18.63 DEST has concluded that consequently, Australian industry has a fairly poor capacity to absorb technology generated within universities.[68] As a result, research institutions may sometimes face a lack of industry receptors to which they can transfer technology.[69] This may make it difficult for publicly funded research institutions to establish working partnerships with industry, and may require them to negotiate with overseas firms. The ARC has expressed concern about this shortage of industry receptors for Australian research, suggesting that some of the benefits of Australia's public investment in genetic research might consequently be lost overseas.[70]

18.64 Publicly funded research institutions also report difficulty in identifying appropriate commercial partners.[71] However, the ALRC is aware that a variety of mechanisms to address this issue have been developed, including state and federal government initiatives and organisations, which are discussed below.

Lack of resources

18.65 Some institutions may lack the funds to support a patent application.[72] The Nicol-Nielsen Study reported that 'although quality research may be performed in

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66 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; UniQuest, *Consultation*, Brisbane, 3 October 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.

67 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii. See also Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 318.

68 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii.

69 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 3.

70 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 18.

71 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 106.

72 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

Australian research institutions, there are insufficient resources to support large scale patenting'.[73] This may be generally attributed to the cost of applying for and maintaining a patent, and in many cases research institutions may choose not to support an application beyond the provisional stage without external financial support. An inability to obtain appropriate patent protection may prevent institutions from transferring technology.

18.66 As noted above, successful technology transfer rests in part on technology transfer offices having staff with the appropriate skills and experience to do so. Lack of resources may prevent technology transfer offices from employing staff with the specific expertise to deal with gene patenting and negotiations with the biotechnology industry.[74]

Other issues and concerns

18.67 The impediments outlined above will, in some cases, inhibit technology transfer. This may have a variety of consequences, such as the inadequate capture and exploitation of Australia's research outputs. This in turn may prevent the Australian community from deriving maximum benefit from public spending on genetic research in the form of tests and therapies and in economic growth.

18.68 Two other specific concerns arise in relation to technology transfer practices—variability in practice across institutions, and lack of clear ownership of patents. These are discussed below.

Variability in practice between institutions

18.69 DEST and the ARC have each suggested that skills and experience of technology transfer offices vary between institutions. This may leave technology transfer to what has been called 'a lottery' based on the skills and resources of each institution.[75]

18.70 This concern is more likely to arise in relation to universities rather than other research institutions. Universities undertake research across a broad spectrum of activities in diverse fields, and may not build up sufficient expertise in transferring genetic research and dealing with the biotechnology industry. Research institutions focusing specifically on scientific or biotechnology research may have greater experience with the particular features of the biotechnology sector and therefore be better equipped to manage gene patents and transfer technology.

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73 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 78.

74 UniQuest, *Consultation*, Brisbane, 3 October 2003.

75 D Nicol, *Consultation*, Sydney, 21 October 2003.

Lack of clear ownership of patents

18.71 It is not always clear where ownership of intellectual property generated through public research lies. This is largely due to the cumulative nature of many breakthroughs in genetic research, and the favouring of collaborative research efforts across a number of research institutions. This section examines issues that may arise where ownership of intellectual property is shared across a number of institutions or with industry partners.[76]

18.72 The Nicol-Nielsen Study reported that 19 of the 23 research institutions that responded to its survey were involved in collaborative research arrangements, of which, by far the greatest number were, with biotechnology and pharmaceutical companies.[77] Thirteen institutions also reported collaborations with other research institutions, of which five included at least one overseas collaborator.[78] The problem of unclear ownership may be exacerbated where researchers have joint appointments to several organisations or research is conducted by visiting researchers or students.

18.73 The Nicol-Nielsen Study reported that four institutions responded that the only ownership arrangement they had with collaborators was to give them sole ownership. The remaining institutions reported a wide variety of arrangements, including 11 institutions indicating shared ownership agreements.[79]

18.74 These results suggest there may be instances in which ownership of gene patents is either shared or unclear. Unencumbered ownership of patents is of considerable importance in attracting investment for further development. Fragmented or unclear ownership of patents may therefore deter potential investors.[80] Also, as Bio Innovation SA commented in consultations, difficulties in determining ownership contribute to the frustratingly long time it can take to move intellectual property out of the public sphere into industry.[81]

Support programs

18.75 A variety of programs to support transfer for commercialisation have been established, including a number of dedicated organisations. Some of these focus specifically on the biotechnology industry and provide specialised expertise to aid transfer and commercial development of innovation in biotechnology research. These include educational materials, industry initiatives, government incubator programs and funding support, and other organisations that provide specialised expertise.

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76 Issues about ownership of research within institutions, rather than ownership shared between institutions, are considered in Chapter 12.

77 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 94.

78 Ibid, 95 (Table 8).

79 Ibid, 99.

80 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 51.

81 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

18.76 Biotechnology Australia and the Department of Foreign Affairs and Trade, among others, have released educational materials to promote understanding of intellectual property issues in biotechnology.[82] For example, the *Biotechnology Intellectual Property Manual* released by Biotechnology Australia gives an overview of the types of intellectual property, the patent procedure in Australia and overseas and issues in patenting biotechnological inventions. It also includes information on identifying inventive subject matter, strategic management of intellectual property resources and commercial exploitation.[83]

18.77 Examples of support organisations include:

- Knowledge Commercialisation Australasia (KCA), an organisation representing organisations and individuals associated with knowledge transfer from the public sector;[84]

- Aussie Opportunities, 'a web enabled database which actively matches Australian research and technology projects with potential investors and partners who can help in the project development';[85] and

- AusBiotech Ltd, 'the peak body for the Australian Biotechnology industry', which provides a "platform" to bring together all the relevant players involved in the Australian biosciences community. Its mission is to facilitate the commercialisation of Australian bioscience in the international marketplace.[86]

18.78 One example of a state government organisation developed to provide particular expertise on the development and exploitation of biotechnology innovations is Bio Innovation SA. Bio Innovation SA is a South Australian public corporation established in 2001 with the task of creating 50 new bioscience companies over ten years—it has established 18 to date. Bio Innovation SA has developed strategies to identify research being produced by its public institutions. It provides free advice on intellectual property protection and commercial development to researchers, and may guide them through the patent application process, including helping them to meet the requirements for experimental support of the invention.[87] It does not hold patents itself.[88] It also works with research institution commercialisation offices where they lack the necessary expertise to develop an invention.

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82 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001); Department of Foreign Affairs & Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001). IP Australia provides more general information on intellectual property issues at its website: IP Australia, *What is Intellectual Property?*, <www.ipaustralia.gov.au/ip/index.shtml> at 23 December 2003.

83 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001).

84 Knowledge Commercialisation Australasia, *Home Page*, <www.kca.asn.au> at 16 December 2003.

85 Aussie Opportunities, *About Us*, <www.aussieopportunities.com.au> at 16 December 2003.

86 AusBiotech Ltd, *What is AusBiotech?*, <www.ausbiotech.org/whataus.php> at 16 December 2003.

87 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

88 Ibid.

Submissions and consultations

18.79 Submissions and consultations generally acknowledged that publicly funded research institutions are becoming more adept at protecting and commercialising research. For example, the Royal College of Pathologists of Australasia (RCPA) suggested that universities are adopting business-like practices toward the research results they generate. It suggested this was partially the result of government policy.[89] In one consultation it was noted that, in the past, universities had tended to license technology too early and before adding significant value, but that this situation had begun to improve.[90] Consultations also confirmed that Australian scientists are becoming more aware of intellectual property and commercialisation issues.[91]

18.80 Despite this continuing improvement, it appears from comments received that there is still considerable variation in skill and experience with commercialisation across technology transfer offices. While some researchers and technology transfer offices have developed considerable expertise, others are less able.[92] The Queensland Biotechnology Advisory Council emphasised the need for technology transfer offices to employ staff with appropriate skills and experience to promote effective commercialisation.[93] The Council also noted that in some cases technology transfer offices lack the funding needed for effective commercialisation of intellectual property.[94] GlaxoSmithKline suggested that governments could support commercialisation by 'distinct and separate funding for technology transfer offices in academic institutions' and suggested there was a need for training programs for technology transfer offices.[95]

18.81 There were some suggestions that research institutions pursue commercialisation largely because they are required to do so as a condition of research funding. As a result, they approach commercialisation in a 'rhetorical manner', rather than because they are committed to the process.[96] In one consultation it was suggested that commercialisation is not a mainstream activity within research institutions and is given little support.[97]

18.82 Another problem raised in consultations was that publicly funded research institutions and public sector organisations may have different approaches to, and policies for, intellectual property management. This can create problems for technology transfer and commercialisation where institutions cannot agree on how to

89 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
90 Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003.
91 Ibid.
92 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.
93 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.
94 UniQuest, *Consultation*, Brisbane, 3 October 2003.
95 GlaxoSmithKline, *Submission P33*, 10 October 2003.
96 UniQuest, *Consultation*, Brisbane, 3 October 2003.
97 Ibid.

address transfer issues.[98] Similarly, researchers are sometimes employed at more than one institution, and the diversity of approaches may cause confusion.

18.83 Some submissions supported the introduction of guidelines similar to the United States National Institutes of Health (NIH) commercialisation guidelines.[99] The RCPA suggested such guidelines could be supported by the NHMRC.[100]

Options for reform

18.84 As noted above, some of the impediments to technology transfer and commercialisation are caused by the size of the Australian biotechnology industry and potential reforms for these issues fall outside the Inquiry's Terms of Reference. Others arise from a lack of expertise, but as recent surveys demonstrate, this problem is diminishing as research institutions increase their skills and experience. Where there are problems these might therefore best be addressed through facilitating continued education. Similarly, problems of weak linkages between industry and research institutions can be addressed by continued promotion of the need to create linkages and opportunities for doing so.

Education and support programs

18.85 A wide variety of education and support programs are already in place to promote the development of expertise and it is likely that improvements in technology transfer practices over the past five years can be in part attributed to these programs. However, from submissions and consultations, it appears that there is room for further continuing education to improve skills across the research sector. This includes education and support programs for technology transfer offices to aid them in improving the specific skills needed to deal with transferring and commercialising genetic research.

18.86 Such programs and materials should focus on building skills that will enable technology transfer offices to overcome the impediments outlined above, including:

- the basics of intellectual property with specific reference to genetic research;
- techniques for identifying, protecting and managing technology with commercial potential;
- methods for encouraging researchers to identify and prevent premature disclosure of such technology;
- strategic management of intellectual property resources;

98 Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.
99 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
100 Ibid.

- approaches to commercialisation of technology; and
- aspects of good commercial practice, such as good licensing practice and approaches to attracting commercial interest in new technologies.

18.87 Programs might also include training in basic science where appropriate. For example, the Wills Report recommended programs to cross-train managers in science.[101]

18.88 One possible model for such a training website is the technology transfer training website created by the NIH. The site provides information about patenting, co-operative research and development arrangements, materials transfer agreements (MTAs), licensing, royalties and ethics and includes links to any relevant NIH policies. It also takes the participant through a series of interactive scenarios that apply the knowledge gained in the information sections.[102]

18.89 However, education programs alone may not provide sufficient skills. PMSEIC has pointed out that it is difficult to instil all the expertise required for successful research commercialisation through education programs.[103] Other programs might therefore be directed at helping researchers and industry to draw on each other's experiences.[104] This might be achieved through developing fora for exchanging know-how and improving institution-industry interaction.[105]

Best practice models

18.90 Best practice for transfer and commercialisation involves researchers and technology transfer offices working closely to identify, protect and exploit research. Researchers are better placed to understand what is new or unique about the research, while transfer office staff should have the appropriate skills in intellectual property and commercialisation to obtain patents and undertake the commercialisation process.

18.91 DEST has advised that potentially valuable intellectual property is best identified 'through decentralised processes close to the researcher, but with effective partnership with the research commercialisation office. Researchers hence need to be assisted to develop these skills'.[106] This might include practices such as the UniQuest model of placing a 'commercialisation manager' in each faculty to identify and

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101 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 128.

102 National Institutes of Health, *Welcome to the NIH On-line Technology Transfer Training*, <http://137.187.206.145/cbttng_ott/cbts/tesweb/login.asp> at 23 December 2003.

103 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 6.

104 Ibid, 6.

105 Ibid, 5–6.

106 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii.

develop potentially valuable intellectual property.[107] AusBiotech Ltd has also suggested that researchers should be involved earlier in the planning stages of commercialisation.[108]

18.92 Publication of guidelines for best practice in technology transfer and commercialisation might aid the dissemination of knowledge and expertise to less experienced institutions.

Clarifying ownership of patents

18.93 One solution to the issue of 'dirty IP', including patents that do not have a clearly defined, single owner, is to revise the *National Principles for IP Management* to provide guidance on negotiation of ownership where the research leading to the patented invention was conducted jointly, or with funds from overseas bodies that have staked an ownership claim.[109]

Addressing problems of scale

18.94 DEST has suggested that the problems of scale faced by smaller and regional research institutions should be addressed by encouraging networking to share their expertise. It suggested that this might be facilitated by the KCA or the Australian Institute for Commercialisation, and by case managers involved in local incubators.[110]

Other options

18.95 The DEST Report suggested some approaches that might encourage greater commercialisation of research results. These were to:

- give academics greater rights over the inventions they produce when publicly funded; or
- revert ownership of inventions to the government or the government funding body.[111]

18.96 Commercialisation might be promoted by assigning the intellectual property to the inventor where the research institution has chosen not to transfer or commercially develop it. The inventor will have an incentive to pursue commercial development, as any profits from exploitation will now flow to them directly. These options are considered in Chapters 15 and 12 respectively.

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107 Ibid, ix.
108 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.
109 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), ix.
110 Ibid, ix.
111 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 75.

18.97 Finally, there may be a need to conduct a study of technology transfer office practice that focuses specifically on the commercialisation of biotechnology. Although a number of studies of technology transfer practice have been carried out, these have been general in scope. A more directed survey could identify any particular difficulties faced by technology transfer offices when commercialising genetic research.

ALRC's views

18.98 The ALRC acknowledges that Australian publicly funded research institutions have markedly improved their performance in capturing the value of intellectual property and commercialising research. Technology transfer practices within research institutions appear to be improving, particularly because institutions, government and industry are recognising and acting on the need to build skills and linkages.

18.99 However, it appears that there is still variability in practice between institutions, and in skill levels between technology transfer offices. During consultations, the ALRC heard many comments suggesting that there is a need to continue the process of skill-building within technology transfer offices especially, thereby improving institutional capacity for technology transfer.

18.100 The ALRC considers that patent management in relation to genetic research and interaction with the biotechnology industry, requires specialised knowledge. This knowledge should encompass a basic understanding of genetics to enable offices to recognise potentially valuable technology and an understanding of the commercial issues particular to the biotechnology industry. This may include an understanding of the time frames for product development in biotechnology; regulatory requirements such as clinical trial requirements and regulation of medical therapies; and awareness of industry structure. Technology transfer offices may sometimes lack this specialised knowledge because they are charged with managing intellectual property and commercialisation across a broad spectrum of research fields.

18.101 For these reasons, the ALRC is of the view that there is a need to continue to improve awareness of, and skills for dealing with, patent management and technology transfer in relation to gene patents. To facilitate this, the ALRC proposes that Biotechnology Australia, in consultation with relevant stakeholders, should continue to develop and implement programs to assist technology transfer offices in developing these skills.

18.102 Such programs should include the provision of educational seminars and resource materials that focus on issues specific to patenting and commercialising genetic technologies. These could present models of best practice for technology transfer and commercialisation, including methods for identifying innovative technology and developing business liaisons. These programs should also encourage networking and sharing of expertise between institutions.

18.103 Potential lack of clear ownership of patents over technology developed through collaborative research or funding arrangements is regarded by the ALRC as a significant impediment to the transfer and commercialisation of genetic technologies. The ALRC considers that these issues would best be dealt with through requirements that ownership of intellectual property be clearly delineated in the early stages of research. Such requirements are best incorporated into the *National Principles* and the *Interim Guidelines*, which should be revised to include clear guidance on the need to negotiate ownership of patents where there is more than one potential owner.

Proposal 18–1 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should:

(a) continue to develop and implement programs to assist technology transfer offices in universities and publicly-funded research institutions in commercialising inventions involving genetic materials and technologies; and

(b) develop strategies to ensure widespread participation of technology transfer offices in these programs. (See also Proposals 19–1 and 23–1.)

Proposal 18–2 The Australian Research Council and the National Health and Medical Research Council should review their principles and guidelines on intellectual property and research to emphasise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research. (See also Proposals 12–1 to 12–3.)

Proposal 18–3 Universities and other publicly funded research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research. (See also Proposals 12–4 and 18–2.)

Question 18–1 Are there any other measures that could be implemented to improve technology transfer practice in relation to genetic research?

Materials transfer agreements

18.104 The sharing of genetic materials within the research community is important for the progress of research. Living organisms are difficult to describe and often impossible to duplicate from a written patent description.[112] While some genes may be isolated easily, cloning into vectors and generating transgenic cell lines and animals

112 S Jong and R Cypress, 'Managing Genetic Material to Protect Intellectual Property Rights' (1998) 20 *Journal of Industrial Microbiology and Biotechnology* 95, 99.

can be costly and time consuming. In fact, it may be impossible to improve upon a biotechnology invention without a physical exchange of genetic material.

18.105 In the past, this often occurred informally, however, the increased commercialisation of research results has created a need to develop more formalised arrangements, often referred to as MTAs. An MTA is a written agreement defining the terms and conditions governing the transfer of biological or other research materials from the owner or authorised licensee to a third party for internal research purposes only. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives created during the course of the ensuing research.

18.106 For the provider, the advantages of having an MTA include the ability to restrict the use of the material to non-commercial research and reduce legal liability for the recipient's use of the material.[113] Importantly, the terms of an MTA may enable the provider of material to gain access to the results of research and to manage and extend its intellectual property rights. A provider may be entitled to outright ownership or to a licence in respect of intellectual property generated by the recipient's research.[114]

18.107 Most commercial organisations, and an increasing number of research institutions, will only release genetic materials if there is an MTA in place between the provider and the recipient.[115]

18.108 It was suggested in consultations that although Australian universities sometimes negotiate MTAs, this is not always the case.[116] Informal transfers may exacerbate problems involving patent ownership and reach-through claims to subsequent inventions.

Model materials transfer agreements

18.109 One Australian approach to streamlining processes for materials transfer for research purposes is that initiated by the Garvan Institute of Medical Research (Garvan). Garvan uses an MTA based on the uniform agreement recommended by the United States Association of University Technology Managers and has created an automated, web-based system to streamline processes for agreeing the terms of MTAs with researchers wishing to have access to Garvan's research materials.[117]

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113 Technology Transfer Office, *Facts about Materials Transfer Agreements (MTAs)*, University of Cambridge, <www.admin.cam.ac.uk/offices/tto/material/mta.html> at 26 August 2003.

114 Ibid.

115 Ibid.

116 Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.

117 Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003; see also Garvan Institute of Medical Research, *Garvan Technology Transfer*, Garvan Institute of Medical Research, <www.garvan.org.au/garvan.asp?sectionid=13> at 16 September 2003.

ALRC's view

18.110 The ALRC is of the view that there is a need to encourage better practice in the transfer of technology and materials between research institutions. The ALRC considers that some of the concerns surrounding materials transfer could be met by the introduction of model MTAs to reduce arbitrary variation across agreements and to encourage institutions to formalise transfer arrangements. To address this concern, the ALRC proposes that Biotechnology Australia, in consultation with relevant stakeholders, should develop model MTAs by drawing on those developed by the United States Association of University Technology Managers.

Proposal 18–4 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should develop model materials transfer agreements for use by universities and other publicly funded research institutions, along the lines of the models developed by the United States Association of University Technology Managers.

19. Patents and the Biotechnology Industry

Contents

Introduction

19.1 Chapter 17 described the structure and features of the biotechnology industry in Australia. As discussed in that chapter, the biotechnology sector (including pharmaceuticals) is heavily dependent on patents. Chapter 17 noted that the Australian biotechnology sector is primarily an upstream industry, with many companies holding intellectual property is their only or main asset.

19.2 This chapter examines the impact of patents on the downstream section of the biotechnology sector. It considers a number of ways in which gene patents may act as a barrier to commercial development of genetic research results, including patent thickets, royalty stacking, broad patents, reach-through provisions, blocking and dependent patents. The chapter also considers licensing practices, investment issues and commercialisation expertise within the sector.

Upstream and downstream issues

19.3 As discussed in Chapter 13, the process of moving new technology from the research stage through to product development is sometimes divided into 'upstream' and 'downstream' phases. However, this division does not form a bright line between

genetic research and commercialisation. Upstream research takes place across the entire biotechnology sector, in commercial ventures as well as research institutions. Hence, many of the issues discussed in Chapter 13 are also relevant to the sector as a whole.

19.4 Some of the potential barriers to commercialisation considered in this chapter may be more likely to affect downstream companies—royalty-stacking and reach-through provisions are examples. Other concerns will however be relevant to upstream genetic research. For example, blocking patents and patent thickets may prevent researchers from accessing technology for research purposes, either for use in research (such as research tools) or to improve upon a particular technology. The cumulative nature of genetic research means that reach-through provisions in licences to foundational patents or patents on research tools may affect further research. These issues are discussed in Chapter 13.

Importance of patents for industry

19.5 Gene patents play an important part in enabling biotechnology companies to develop healthcare products. As Biotechnology Australia has pointed out:

> a biotechnology company's value is very dependent on its intellectual property. Biotechnology companies rely heavily on strong patent protection due to the high costs of research and commercialisation in this sector.[1]

19.6 The limited monopoly provided by patents gives biotechnology companies an opportunity to recoup the investment in developing the patented invention further, including the creation of a marketable healthcare product. The importance of gene patents in the biotechnology industry is also recognised in the Australian Government's National Biotechnology Strategy, which states that:

> The development of capabilities for the effective management of Intellectual Property (IP) is an important element in securing the benefits of public and private sector research in biotechnology for the Australian community, industry and the environment.[2]

19.7 However, it is important to bear in mind that gene patents will have varying effects on companies depending on each company's structure and commercial activities. Most biotechnology companies are both consumers and producers of technology, as the biotechnology industry is characterised by companies using the inventions of others in their own research and as part of the products they market, such as tests or therapies. The gene patents of others might therefore block a company's activity if access to the patented technology is necessary for its research or creation of products it seeks to sell. However, at the same time it might also be motivated by the

1 Biotechnology Australia, *IP Management*, <www.biotechnology.gov.au> at 20 January 2004.
2 Biotechnology Australia and Commonwealth Biotechnology Ministerial Council, *Australian Biotechnology: A National Strategy* (2000), 19.

possibility of obtaining patent protection for its own products. As Professor Rebecca Eisenberg has commented:

> firms welcome the patents that allow them to charge higher prices, while cursing the patents that require them to pay higher prices. At any given point in the stream, downstream patents motivate R&D, while upstream patents make it more costly.[3]

19.8 Eisenberg commented further:

> In the absence of patents on DNA sequences, are we likely to lose out on the development of new products? Or can firms be expected to welcome free access to DNA sequences generated with government funds as a subsidy for their own research? There is no simple, obvious answer to this question, but we can engage in a bit of cautious speculation. In all likelihood the bottom line will be uneven, favouring incentives to develop some types of products, while diminishing others.[4]

Barriers to commercialisation

19.9 The *Australian Biotechnology Report 2001* includes the results of a survey of Chief Executive Officers within the biotechnology sector regarding what they saw as barriers and impediments to commercialisation and success. Of the four main issues identified, one was 'effective protection of intellectual property'.[5]

19.10 Dr Dianne Nicol and Jane Nielsen have suggested that:

> Australia has a number of strengths in medical biotechnology, including world class expertise in research, geographical advantages in terms of expanding regional markets, appropriate structures to promote close cooperation between the public and private sectors and an internationally recognised clinical trial system. Despite this, development and commercialisation of scientific discovery is generally weak. One factor behind this is inadequate management and understanding of intellectual property.[6]

19.11 Nicol and Nielsen argued that 'the regimes protecting IPRs [intellectual property rights] may prove to be a significant barrier for the development of the Australian industry'.[7] They noted that the patent system is:

> crucial to the biotechnology industry in order to reward and encourage innovation … [but] it is becoming apparent that the same regime may hinder the research efforts of Australian companies by restricting access to research tools and technologies.[8]

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3 R Eisenberg, 'Genomic Patents and Product Development Incentives' in B Knoppers, C Laberge and M Hirtle (eds), *Human DNA: Law and Policy: International Comparative Perspectives* (1997), 373, 374.

4 Ibid, 375.

5 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 49. The others were access to capital, the availability of skilled human resources, and the relatively small size of the domestic market.

6 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 356.

7 Ibid, 348.

19.12 As has been discussed elsewhere in this Discussion Paper, the purpose of patent laws is to provide an incentive for innovation. Intellectual property rights generally, and patent rights in particular, are attractive to firms because they create the prospect of charging others monopoly prices for access to their intellectual capital and prevent others ('free riders') from taking advantage of their investment.

19.13 However, as discussed in Chapter 13, patents may also act as a barrier to research and a disincentive to commercialisation. The problems cited in that chapter are as relevant to product development as they are to further research. Nicol and Nielsen suggested that biotechnology companies 'face unique challenges'. They cited the following reasons:

- the research intensive nature of the industry;
- the massive increase in patent activity in the area of biotechnology;
- the preponderance of upstream patents with broad claims;
- the reliance of downstream companies on access to patented research tools and techniques.[9]

19.14 A report of the Organisation for Economic Co-operation and Development (OECD Report) identified the following as issues relevant to commercialisation:

- patent thickets and royalty stacking;
- reach-through claims; and
- dependence and uncertainty.[10]

19.15 Other issues include:

- refusals to licence;
- blocking patents;
- lack of commercial expertise in the biotechnology sector; and
- lack of available investment funds.

19.16 The following discussion addresses the issues raised by the OECD Report together with other issues that have the potential to impede the commercialisation of

8 Ibid, 348–349.
9 Ibid, 374.
10 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 15–16.

research in the area of human genetics. The discussion also notes mechanisms that might assist to overcome these barriers.

Patent thickets

19.17 'Patent thickets' are a consequence of multiple upstream patents.[11] A patent thicket has been described as:

> a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.[12]

19.18 Such multiple patents have also been described as the 'tragedy of the anti-commons', namely, the under-use of a scarce resource where multiple owners exclude others and no one has an effective privilege to use the resource.[13] The OECD Report suggested that:

> The proliferation of gene patents, including multiple patents on research tools, can necessitate negotiating multiple licences when developing a single product or process. Such patent thickets have the potential to raise the transaction costs of doing research and possibly the ultimate cost of products owing to stacking of royalties … for example, the development of a medicine may require licences to access genomics technologies, targets such as receptors, assays and high-throughput technologies. Companies report that royalty exposure to net sales of a given product can in some cases exceed 20%.[14]

19.19 Patent thickets may result in increased production costs, and affect commercial incentives for pursuing downstream product development and marketing. However, the issue is not confined to gene patents and is an issue across a number of fields.

19.20 The issue arises in relation to gene patenting because different patents over the same gene may contain overlapping claims. A gene contains coding DNA sequences (exons), non-coding regulatory DNA sequences, and functionless introns.[15] Separate patent claims could be made on each of the exons as expressed gene fragments; another claim could be made over the complete expressed sequence; another on a promoter sequence; and others over mutations known to have the potential to cause diseases. Patent thickets could present a problem in this area, for example in the development of genetic diagnostic tests or therapeutic proteins, where access is required to genetic information covered by multiple patents.

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11 For example, patents over isolated genetic materials that might be used to develop further inventions such as diagnostic tests or pharmaceutical products (downstream products).

12 C Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting* (2001), 1–2.

13 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 698. See also Ch 3.

14 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 15.

15 The majority of introns serve no currently identifiable function.

19.21 A second potential consequence of a proliferation of upstream patents is that it may impede downstream research and innovation by adding to the cost and time of biomedical invention. For example, in the United States, the National Human Genome Research Institute (NHGRI) stated that:

> patent applications on large blocks of primary human genomic DNA sequence could have a chilling effect on the development of future inventions of useful products. Companies are not likely to pursue projects where they believe it is unlikely that effective patent protection will be available. Patents on large blocks of primary sequence will make it difficult to protect the fruit of subsequent inventions resulting from real creative effort.[16]

19.22 Similarly, Nicol and Nielsen have suggested that:

> The existence of an anti-commons in the medical biotechnology industry is likely to be particularly problematic because of the important role that this industry has in providing innovative diagnoses, treatments and therapies to alleviate human suffering caused by disease. An anti-commons in this industry has the capacity to slow the pace of innovation, which is most unlikely to be in the public interest.[17]

19.23 In extreme cases projects may even be abandoned.

> If negotiations are required to be undertaken with a number of parties, the risk of negotiation breakdown is increased. If negotiations break down with any one of these parties, the investment of time, effort and money in the project will need to be reassessed. Depending on the stage at which breakdown occurs, this may mean that projects are either not commenced or are abandoned at some stage into the research process. The later projects are abandoned, the greater the waste of resources. In other instances, considerable research effort may need to be put into inventing around the area protected by intellectual property rights in order to enable the project to proceed. As the number of relevant intellectual property rights increases, the task of inventing around becomes more onerous, and project abandonment may become inevitable.[18]

19.24 Professors Michael Heller and Eisenberg suggest that patent rights for upstream discoveries may help attract private funds for basic research and 'may fortify incentives to undertake risky research projects and could result in a more equitable distribution of profits across all stages of R&D'.[19] However, they also argue that this can 'go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research'.[20] Heller and Eisenberg suggest that such barriers could be 'transitional phenomena'[21] and the costs may be worth incurring if 'fragmented privatisation allows upstream research to pay its own way and helps

16 National Human Genome Research Institute, *NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence* (1996).

17 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 174.

18 Ibid, 174.

19 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

20 Ibid, 698.

21 Ibid, 700.

ensure its long term viability'.[22] They express concern that 'a patent anticommons could prove more intractable in biomedical research than in other settings'.[23]

19.25 One of the questions Nicol and Nielsen addressed in their empirical study of patents and the medical biotechnology industry was whether an anti-commons had emerged in Australia.[24] They reported that respondents to the Study did not describe significant problems with the enforcement of multiple research tool patents. They suggested that:

> In part this is because a number of the most aggressively enforced research tool patents do not exist in Australia, or, if they do exist, they do not appear to be enforced. However, we expect that these or other patents may well be enforced in the future. Hence, it would be premature to say that the Australian industry is free from the rigors of research tool patent enforcement.[25]

19.26 Nicol and Nielsen also reported that although the Australian patent landscape is becoming increasingly complex, the number of problematic patents is quite small. They suggested that:

> in part the reason for this is that if there is a higher level of encumbrance research will be redirected. We are unable to state with any level of precision the number of research projects that are abandoned because there are too many problematic patents in the area. However, we know that this problem does exist.[26]

19.27 On balance, Nicol and Nielsen concluded that their results did not provide conclusive evidence of either the existence or absence of an anti-commons in Australia, although they did note the potential for one to develop:

> In general the Australian industry seems to be avoiding an anti-commons situation, but the potential still exists for its emergence. Ongoing increases in the number of patents, more vigilant enforcement and the increasing complexity of research paths may result in the development of an anti-commons.[27]

Royalty stacking

19.28 Royalty stacking is a problem caused by a multiplicity of overlapping patents, especially over upstream products. The need to pay multiple licence fees and royalties may force up prices and discourage innovation and product development. In the context of pharmaceutical patents, Mr Phillip Grubb suggests royalty payments for the use of research tools may be problematic because:

> it will often be the case that a number of different tools or technologies have contributed to the drug development, and whereas a single royalty of one or two per

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22 Ibid, 700.
23 Ibid, 700. See discussion of the anti-commons in research in Ch 13.
24 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, x.
25 Ibid, 255.
26 Ibid, 255.
27 Ibid, xi–xii, 194.

> cent may be an acceptable burden, an accumulation of such royalties soon adds up to an unacceptable amount.[28]

19.29 The OECD Report linked concerns about patents over research tools[29] with the problem of patent thickets and royalty stacking and suggested that together these have the potential to raise the costs of conducting research and ultimately the costs of products. As noted above, the OECD Report suggested that royalties could comprise up to 20% of the net price of some products.[30]

19.30 Often, however, companies are able to address stacking problems by contractual solutions. Industry representatives canvassed in the OECD Report identified provisions for:

> **Variable rates.** Different rates apply depending on how much additional work is done by the licensee (eg analogue development). The smaller the role the technology plays, the lower the rate the licensor receives.
>
> **Joint venture expense.** This model deducts any third-party royalty rate from gross revenues, prior to determination of net sales on which royalties or profit splits are made. A licensor with a 10% net sales royalty would only bear one-tenth the cost of a third-party payment under this structure.
>
> **Creditable percentage.** The parties share the third-party royalty, down to a floor rate.
>
> **Maximum royalty rate.** The parties put a top limit on all combined royalties. If a third-party royalty must be paid, previous rates are adjusted downwards to stay below the limit.
>
> **Royalty-free.** The technology is licensed outright, with some combination of up-front and/or interim payment, but no royalties are owed downstream on products sold.[31]

19.31 The OECD Report noted that contractual solutions are generally pursued because it is in the interests of companies to accommodate reduced royalties to enable agreements for patent use to be made. It suggested that biotechnology industry projects that require patented technology to be in-licensed rarely fail due to royalty stacking concerns.[32]

19.32 It is unclear whether royalty stacking is a serious problem for the Australian biotechnology industry. However, given that the industry is largely comprised of upstream companies, it may be a lesser problem here than in overseas industries with a more significant downstream component. Of respondents to the Nicol-Nielsen Study:

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28 P Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (3rd ed, 1999), 375.

29 See also the discussion on concerns raised by patents on research tools in Ch 13.

30 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 15.

31 Ibid, 62.

32 Ibid.

> Most said that they were aware of the potential for royalty stacking to arise and that they guarded against it. Indeed, one upstream company respondent said that this is one of the first issues that is addressed.[33]

19.33 However, respondents' experience of royalty stacking appeared to be mixed. One intermediate company stated they had not encountered royalty stacking, while one upstream company 'predicted that in the future, when conducting licensing negotiations, companies may well be exposed to licence stacking and overlapping royalty structures'. In addition, mixed views were expressed about the reactions of downstream pharmaceutical company to royalty-stacking:

> One respondent said that large pharmaceutical companies abhor royalty stacking. However, a pharmaceutical company respondent noted that although reach-through royalties and divided ownership don't help in the drug development process, 'they are not showstoppers'.[34]

19.34 The Nicol-Nielsen Study also reported that a number of respondents commented that:

> it is vital that intermediate companies have to keep an eye on their capacity to on-license when agreeing to royalty rates. This has to be factored into the commercialisation process and it can be a significant impost on revenue stream, because each one to two percent adds up. If an intermediate-level company has a number of obligations to pay royalties, this detracts both from their capacity to on-license and from the profits they are likely to get from further downstream licensing.[35]

19.35 Patent pools[36] are a mechanism for overcoming some of the difficulties of access to research tools and technologies caused by a multiplicity of patents.[37] Commercial products such as therapeutic proteins or diagnostic genetic tests are likely to require access to many gene fragments; a bundle of licences collected in a single licence arrangement can overcome the problem of dealing with multiple patent holders or licensees.[38]

19.36 Heller and Eisenberg suggest that:

> Because patents matter more to the pharmaceutical and biotechnology industries than to other industries, firms in these industries may be less willing to participate in patent pools that undermine gains from exclusivity.[39]

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33 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 191.

34 Ibid, 192.

35 Ibid.

36 Patent pools are cooperative arrangements that allow the owners of several patents, all of which are necessary for the development of a product, to license or assign their rights at a single price. See Ch 23.

37 See J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office.

38 See further Ibid.

39 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700.

19.37 Patent pools also raise competition issues, which are discussed in Chapter 24.

Broad patents

19.38 Chapter 13 described broad patents as 'patents that grant broad rights to the patent holder and which may be seen as covering applications invented later by someone else'. As noted in that chapter, such patents may discourage further research and innovation because researchers may be concerned about infringing them, or because of the cost of licence fees associated with the use of the patented invention. These concerns are also relevant to industry, both as constraints on further research, and more particularly, because the cost of licence fees or royalty payments may decrease the possible returns on products developed using the patented technology. Companies may then attempt to offset this decrease through charging higher prices for products.

19.39 The flow on effect of these problems may include:

- increases in the cost of healthcare products;
- fewer products available if development of some products is abandoned; and
- inefficient use of resources due to paying licence fees or inventing around unnecessarily.[40]

19.40 The Nicol-Nielsen Study reported that 24% of respondents to the company survey believed the grant of broad patents had an inhibitory effect on research. Study respondents also noted that, despite this, they continued to seek patents that were as broad as possible.[41]

19.41 However, some respondents commented that for some companies, inventing around may be a workable strategy for dealing with broad patents. In particular, respondents from the pharmaceutical sector:

> were generally of the view that it is not possible to obtain broad patents that block research in the pharmaceutical industry because of the ability of researchers to invent around.[42]

Reach-through provisions

19.42 Chapter 13 discussed the problem of reach-through provisions in licence agreements in the context of research. This section discusses the implications of reach-through licence agreements for the biotechnology industry.[43]

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40 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 86.

41 Ibid, 86–87.

42 Ibid, 144.

19.43 Reach-through provisions are claims by patent holders to future intellectual property in new products that might result from the use of a patented invention. Reach-through provisions may include rights to a licence to, or ownership of, the intellectual property, or rights to royalties from future inventions. Reach-through provisions are usually included as licence conditions, when the holder of a patent over an upstream technology licenses it to other companies further downstream. They may also be included in Materials Transfer Agreements.[44] Reach-through provisions in a licence agreement therefore effectively give the patent holder what Heller and Eisenberg have described as, 'a continuing right to be present at the bargaining table as a research project moves downstream toward future product development'.[45]

19.44 The Human Genome Organisation (HUGO) has expressed concerns that:

> *reach-through patent claims* and *reach-through licenses*, as partly accepted in the current practice, will not only seriously affect further research and development but could, eventually, discredit the entire patent system as an invaluable incentive to invent, innovate and invest in new technologies.[46]

19.45 Reach-through provisions may present difficulties for companies negotiating for access to gene patents, either to develop them further or because they may form an input into the companies' products. The Nicol-Nielsen Study suggests that reach-through provisions appear to be problematic in a large number of negotiations:

> Respondents from most industry sectors made some reference to these provisions, a large number of respondents involved in licensing-out stating that they insisted on such rights, other respondents stating that they tried to avoid them … Most respondents who were involved in a high volume of deals did encounter these provisions regularly. A number of respondents specifically stated that they try to keep away from such terms when licensing-in because they can be so problematic. In instances where they licensed-in, research institution respondents tried to avoid such terms because they would have the effect of detracting from their exploitation of any improvements or new technology developed by them … In a significant number of cases, however, provisions giving reach-through rights were still included, and one public sector researcher we interviewed stated that in his experience there is a general trend toward these sorts of agreements becoming more restrictive.[47]

19.46 One comment cited in the Study aptly summed up why reach-through provisions can present problems during negotiations: 'The patentee wants as much as possible whereas the licensee wants as little as possible'.[48]

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43 These provisions are to be distinguished from reach-through patent claims which are discussed further in Ch 6.

44 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 163.

45 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700.

46 HUGO Ethics Committee, *Statement on Patenting of DNA Sequences* (2000).

47 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 164.

48 Ibid.

19.47 Reach-through provisions may deter future development by restricting the rights of the licensee to exploit new technology that results from working with the patented technology. This may be particularly problematic if a number of reach-through rights are stacked on downstream technologies. Heller and Eisenberg suggest that reach-through provisions may contribute to the emergence of an anti-commons.[49] However, the Nicol-Nielsen Study stated:

> Despite this theoretical risk of accumulated reach-through rights, we did not hear complaints of them from any of our respondents. This does not mean they do not exist in practice; as there were many complaints about provisions giving reach-through rights in licences, it may well be the case that some downstream licensees are encountering stacking licences giving numerous parties rights to future inventions. It is also fair to assume given the comments from respondents, that licensees are baulking at the inclusion of such terms in licences.[50]

19.48 Some concern about reach-through provisions was expressed in submissions and consultations, although this concern was also extended to claims in patents to reach-through rights. The Queensland Clinical Genetics Service suggested that a patent on a genetic sequence should not necessarily provide reach-through rights to diagnostic or therapeutic applications of the sequence.[51] The Walter and Eliza Hall Institute of Medical Research (WEHI) suggested that investment in developing patented technology might be deterred where it is unclear whether the patent can be freely exploited.[52]

19.49 AusBiotech Ltd commented in consultations that licences are most often structured to give the licensor the first offer on the commercialisation of any new product resulting from the use of the patented invention.[53] As an example, Benitec Ltd, a Queensland biotechnology company, stated in consultations that it would want reach-through rights to drugs developed through its target validation technology. However, Benitec Ltd typically agrees to waive reach-through rights for use of the technology for small molecular development, such as drug development, on the understanding that it will have reach-through rights to RNAi therapies and be a partner in the development of these therapies.[54] By contrast, the Australian Genome Research Facility stated in consultations that it has no licence agreements that contain reach-through rights.[55]

Blocking patents

19.50 Broadly defined, blocking patents are patents which stifle developments by others. They may occur where one patent holder holds a broad patent over an invention

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49 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700.

50 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 193.

51 Queensland Clinical Genetics Service, *Consultation*, Brisbane, 2 October 2003.

52 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

53 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.

54 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.

55 Australian Genome Research Facility, *Consultation*, Melbourne, 4 September 2003.

(a dominant patent) and another patent holder holds a narrower patent over an improvement to that invention or a new invention that relies on access to the original invention (a dependent patent).[56] The holder of a dependent patent will be precluded from practising the improved invention unless they have obtained a licence from the holder of the dominant patent. The dominant patent holder may not exploit the improved invention without a licence from the dependent patent holder.[57]

19.51 Blocking patents also include patents that cover a broad or fundamental technology—a patent over a gene sequence is an example—but are not exploited or licensed, blocking others from using the technology. The effect of a broad blocking patent may be to block off whole areas of research, particularly where the patent holder chooses not to practise the patent themselves. In such cases, or where the patent is foundational to other research, the capacity for others to undertake further research may be curtailed and the benefits from the technology may not flow to the public.[58]

19.52 In submissions, WEHI commented that the value of a patent is highly dependent on the patent holder's ability to practise it.[59] Blocking patents that prevent a patent holder from exploiting their patent may therefore also devalue the patent, and consequently affect the holder's ability to attract investment.

19.53 Nicol and Nielsen noted:

> it has been estimated that over 90% of current US patents are never exploited, suggesting that many of them are obtained for blocking purposes. Given that most biotechnology patents in Australia are held by foreigners, it is likely that a large number are obtained for blocking purposes and will lie dormant. Although there are many reasons why technology may not be exploited, the result is clearly detrimental to the industry and to the healthcare sector as a whole.[60]

19.54 The existence and effects of blocking patents were examined in the Nicol-Nielsen Study. The Study found that a significant number of respondents regarded blocking patents as a real issue in the biotechnology industry, although many commented that they could not see the value of companies obtaining patents purely for blocking or defensive purpose.[61] However, Nicol and Nielsen commented:

> Having said this, 21 respondents to the company survey had applied for a patent for strategic reasons, that is, to allow them freedom to operate (43 percent). In most cases, that patent had been granted. It was not clear whether those particular patents were

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56 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 141.

57 It should be noted that 'blocking patents' has a specific legal meaning in the United States which refers to dominant and subservient (dependent) patents, rather than the broader definition, used in this chapter, as any patents that block access to technology: see further Ibid, 141.

58 Ibid.

59 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

60 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 362.

61 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 142.

> subsequently exploited or licensed-out, however many respondents who participated in interviews either had patents that they did not currently exploit, or knew of companies who did not currently exploit. In many cases, these patents were not licensed or otherwise transferred, although this may have been due to a number of reasons.[62]

19.55 The Nicol-Nielsen Study asked companies whether they had had to alter their research program due to a patent blocking access to research tools or materials:

> Nine respondents reported that they had changed their research program, (18 percent) and as would be expected, several of these respondents indicated that existing patents heavily influenced their research programs, with one other commenting that only slight changes in the scope of their research were required to avoid infringing patents. One indicated that they left the field completely if they were unable to work with patent holders to enable them to access necessary patents. Another four respondents provided comments that indicated they had come across patents that would potentially impact on their research programs.[63]

19.56 Some respondents commented that they avoided areas of research where they did not think they would be able to get access to necessary technology due to the presence of blocking patents. Others changed the direction of research where they found themselves blocked, or invented around the patented technology.[64]

19.57 Despite the reported concerns, there were also responses suggesting that participants in licensing negotiations were used to deal with potentially blocking patents:

> In a considerable number of cases where a licence was required and the researcher approached the patent holder, respondents indicated that a successful licensing outcome was eventually negotiated. One licensing manager contended that 99.99 percent of licensing deals within the industry run smoothly, and only about 0.01 percent stand out as anomalies. In his view, it is not correct to say that there is any blockage to research except in exceptional cases.[65]

19.58 However, Nicol and Nielsen commented that:

> in many instances, respondents did not even try to negotiate a licence as they were of the view that the patent holders would be unlikely to enter into negotiations with them.[66]

19.59 A possible mechanism for dealing with blocking patents is compulsory licensing, where the holder of the patent can be required to license the technology to allow others in the industry to exploit it or to practise their own patents. The compulsory licensing provisions in the *Patents Act 1990* (Cth) (*Patents Act*) are

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62 Ibid, 142.
63 Ibid, 140–141.
64 Ibid, 143.
65 Ibid, 143–144.
66 Ibid, 144.

discussed in Chapter 27. There may also be competition issues, which are discussed in Chapter 24.

Dependency and uncertainty

19.60 A dependent patent is a patent on an invention, the exploitation of which would encroach on an earlier patent. The OECD Report suggested that the rapid proliferation of gene patents could cause commercial uncertainty and cited the example of different patents for inventions claiming 'a partial gene sequence (for example, an EST), the full-length cDNA or gene, and the protein encoded'[67] leading to uncertainty about which patent holder would be able to prevent the others from using the later invention. The OECD Report stated that:

> While licensing under uncertainty about the extent of property rights is not new to the pharmaceutical industry, too much litigation could again slow progress, raise end-product costs or discourage entry to certain fields of enquiry.[68]

19.61 The OECD Report also noted that:

> While official statistics show that the number of patent applications and grants is on the rise, little is known about who is licensing what technologies to whom and under what conditions. Firms claim that it is increasingly difficult to assess whether they have 'freedom to use' their own in-house or licensed technologies as the web of patents becomes more complex and overlapping.[69]

19.62 However, the OECD Report also indicated difficulties in assessing whether this was really an issue for industry.[70]

19.63 Compulsory licences can be a solution to the problem of dependent patents. Chapter 27 discusses the provisions in the *Patents Act 1990* for compulsory licences over dependent patents.

Refusals to license

19.64 As discussed in Chapter 23, licensing is a means by which rights in patented technology may be transferred.[71] There are two main types of licences:

- those where a researcher needs to acquire a licence in order to do further research or development (licence-in); and

67 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 16.
68 Ibid, 16.
69 Ibid, 45.
70 Ibid, Ibid.
71 Chapter 23 discusses licences and Part E discusses the role of licensing in healthcare, particularly in relation to genetic tests.

- those where technology is transferred from a patent holder to another to allow further research or the development of a new product or the exploitation of a product (licence-out).

19.65 The development of a product may require cross-licences, and the need for cross-licences may encourage alliances and mergers. Chapter 17 noted that the level of licensing in the Australian biotechnology sector is 'prolific' but it also noted a finding by Ernst & Young that more than 20% of firms surveyed reported abandoning a project because of an inability to obtain a licence.[72]

19.66 Only 6 of the companies (12%) that responded to the Nicol-Nielsen Study reported being refused licenses.[73] Interview responses reinforced the perception that refusals to licence are not a pervasive problem.[74] One reason for refusal was that exclusive licences had been granted to other companies. Competition between the patent holder and the company seeking to licence was also cited. In some cases, refusals also occurred because of an inability to agree on reasonable licence terms.[75] Nicol and Nielsen commented that:

> One interpretation of this data is probably that refusals to license were not encountered because often it did not get to the stage that licences were requested. This was acknowledged by many of our respondents. As reported elsewhere, researchers and companies stated that they avoided particular areas of research if patents were held by competitors, or if it looked as though obtaining a licence might prove to be too problematic … in line with the survey results a few interview respondents expressed frustration at difficulties in licensing-in enabling technologies, but these were greatly outnumbered by the number of respondents who had not experienced any problems. Some respondents complained that owners of research tool patents, while willing to license, unreasonably demanded reach-through royalties.[76]

19.67 The need to licence-in patented technology may be a barrier to commercialisation if licences are not widely available. In particular, exclusive licences have the potential to be anti-competitive either because they allow prices above the market rate to be charged or because they restrict access to important genetic materials or research tools.[77] Compulsory licensing, discussed in Chapter 27, may provide some solutions to problems resulting from refusals to license. That chapter also proposes that an additional ground for obtaining a compulsory licence based on a competition test be included in the *Patents Act* (Proposal 27–2).

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72 Ernst & Young, *Australian Biotechnology Report* (1999), 35.

73 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 145.

74 Ibid, 145.

75 Ibid, 145–146.

76 Ibid, 146.

77 Competition issues are addressed in Ch 24.

Lack of experience with commercialisation

19.68 It has been suggested that there is a lack of appropriate commercialisation experience related to biotechnology within the Australian industry.[78] In consultations, AusBiotech Ltd suggested that investors need to be aware that there is a logic to intellectual property protection strategies.[79]

19.69 Benitec Ltd refuted the view that Australia is not good at commercialising its research, but suggested that the problems for Australia lay in a lack of people with the skills to manage intellectual property effectively. Benitec Ltd stated that this is a serious problem for the effective commercialisation of biotechnology and in some cases leads to the failure of biotechnology companies. It is suggested that this lack of managerial skill is particularly evident in companies managed largely by academics, who may not possess the skills to commercialise adequately the technology they have developed.[80] This concern was also raised in the Australian Science and Innovation Mapping Taskforce report, *Mapping Australian Science and Innovation*, which stated that scientists, when taking on the role of Chief Executive Officer, 'often do not have the specialist business skills to enable the company to survive in early-stage commercialisation'.[81]

19.70 Benitec Ltd noted, however, that Australia's ability to commercialise its research will improve as the country's skill base improves as a result of experience.[82] In its submission, AusBiotech Ltd pointed out that it was attempting to educate the industry about patents, but commented that, for the most part, only listed companies and companies that needed patents to protect their intellectual property were currently obtaining good patent protection.[83]

19.71 Benitec Ltd also suggested that Australia has, to date, regarded biotechnology companies as essentially research institutions funded by commercial investment. It stated that part of the transition from being a research institution to a company is the possession of a strong commercial focus. This is a crucial shift because investors are commercially focused, rather than seeking to fund further research.[84]

Lack of investment and venture capital

19.72 One possible barrier to effective commercialisation of genetic research within the biotechnology industry in Australia is the lack of long term venture capital

78 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.
79 Ibid.
80 See also D Sparling and M Vitale, *Australian Biotechnology: Do Perceptions and Reality Meet?* (2003) Australian Graduate School of Management, 6–7.
81 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 318.
82 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.
83 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.
84 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.

funding.[85] It has been suggested that it is very difficult to attract venture capital in Australia due to the lack of a mature venture capital base in this country.[86] It has also been suggested that there is a need for venture capital with at least a five-year term.[87]

19.73 Seed funding[88] rates are also much lower in Australia compared with the United States. In Australia, the usual level of seed funding is around $1,000, while in the United States the level is closer to $1 million.[89] In consultations, UniQuest suggested that higher funding at this stage enables United States companies to establish effective management structures, initially staffed by professional managers.[90] Lack of investment can lead small, early stage companies to licence their intellectual property too early in an effort to maintain cash flow. This is sometimes done before the company has undertaken sufficient value adding, and the original intellectual property is therefore undervalued.[91]

19.74 Insufficient early stage funding prevents new companies from establishing effective management structures.[92] As a result, some biotechnology start-up companies in the Australian industry are managed by the academic researchers who developed the technology, instead of by professional managers with experience in commercial negotiations and intellectual property management.

19.75 Many Australian biotechnology inventions fail to be exploited effectively because of a lack of funding at the proof-of-concept stage. At this stage, an invention has been created and its commercial potential must be demonstrated to attract investment for its development into a marketable product. Passing the proof-of-concept stage involves demonstrating the commercial potential of an invention to attract investment for development of a marketable product.

19.76 In some cases, an invention at this stage will not be exploited at all. In others, the invention is licensed to an international company prematurely and its potential value to Australia is lost.[93] Biotechnology Australia has suggested that this

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85 'Venture capital funding' is funding provided by investors to early stage companies, generally after they have demonstrated strong growth potential and good management. Venture capital differs from seed funding (see below) because it is often provided in return for equity in the company and the investor will expect greater control of the company and a quicker return on the investment. See: D Zahorsky, *Venture Capital*, What You Need to Know About: Small Business Information, <http://sbinformation.about.com/library/glossary/bldef-venture.htm> at 16 February 2004.

86 UniQuest, *Consultation*, Brisbane, 3 October 2003.

87 Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

88 'Seed funding' is an initial or early stage investment in a start up company or project, which is usually used to develop an idea to proof of concept stage, to conduct market research or for initial product development. See: InvestorWords.com, *Seed Capital*, <www.investorwords.com/4453/seed_capital.html> at 16 February 2004.

89 UniQuest, *Consultation*, Brisbane, 3 October 2003.

90 Ibid.

91 Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

92 UniQuest, *Consultation*, Brisbane, 3 October 2003.

93 Biotechnology Australia, *Australian Biotechnology: Progress and Achievements* (2000), 13.

commercialisation gap 'is widely recognised as the most critical barrier to biotechnology development in Australia'.[94]

19.77 The range of funding programs designed to support the biotechnology industry are outlined in Chapter 11.

Submissions and consultations

19.78 IP 27 asked what effects Australia's patent laws and licensing practices have on the development of the Australian biotechnology industry as it relates to human health.[95]

19.79 Submissions generally recognised the importance of the biotechnology industry in facilitating the delivery of healthcare benefits from genetic research.[96] Some, such as the Children's Cancer Institute Australia for Medical Research, recognised the role that the industry plays in medical research and innovation.[97] A South Australian Member of Parliament, Dr Duncan McFetridge, stressed the need to ensure the biotechnology industry does not deteriorate in any way.[98]

19.80 Submissions and consultations also recognised that patents are vitally important for the biotechnology industry.[99] For example, one submission referred to intellectual property as 'essential for stimulating technological innovation, whether in industry or academic institutions'.[100] Associate Professor Ross Barnard, co-ordinator of the Biotechnology Program at the University of Queensland, submitted it was important that genetic research remain patentable for the prosperity of the biotechnology industry.[101] In contrast, one submission argued that Australian patent laws have only a neutral effect on the local biotechnology industry, as most patented products developed or supplied in this country are foreign patents.[102]

19.81 Others highlighted the importance of patents for attracting investment.[103] Intellectual property is the main asset of some smaller biotechnology companies, particularly in the predominantly upstream Australian biotechnology sector. Without

94 Ibid, 13.
95 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 13–1.
96 D McFetridge, *Submission P23*, 30 September 2003.
97 Children's Cancer Institute Australia for Medical Research, *Submission P13*, 30 September 2003.
98 D McFetridge, *Submission P23*, 30 September 2003.
99 Queensland Department of Innovation and Information Economy, *Consultation*, Brisbane, 2 October 2003; *Confidential Submission P54 CON*, 3 November 2003; A Johnston, *Submission P15*, 30 September 2003; Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003; D Jackson, *Submission P43*, 20 October 2003; R Barnard, *Submission P32*, 7 October 2003.
100 *Confidential Submission P54 CON*, 3 November 2003.
101 R Barnard, *Submission P32*, 7 October 2003.
102 A McBratney and others, *Submission P47*, 22 October 2003.
103 Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003; A Bankier, *Submission P19*, 30 September 2003; R Barnard, *Submission P32*, 7 October 2003.

patent protection, such companies have little on which to pin their value and nothing to market.[104] As one submission from Dr Amanda McBratney and others commented:

> it would be impossible to obtain commercial funding and licensing of products without IP protection. An investor requires a potential monopoly to warrant investment.[105]

19.82 However, others raised concerns about gene patents and the biotechnology industry. The Cancer Foundation of Western Australia warned of the need for controls to ensure that the profit motive driving industry does not override the pursuit of affordable healthcare.[106] The Royal College of Pathologists of Australasia (RCPA) suggested that:

> Holders of gene patents and licenses need to recognise that they have ethical and social responsibilities and be responsive to government, health care provider and community concerns as well as their shareholders' interests. Socially responsible patent and license holders strive to return a reasonable profit without disrupting the existing healthcare framework and by maintaining equitable and affordable access to testing. Size appears to be an important factor which seems to dictate how patent and license holders behave. Large pharmaceutical and biotechnology companies and universities are able to balance their patent portfolios to return a reasonable and sustainable profit (eg Roche PCR patent, Stanford University's Cohen-Boyer patent on recombinant DNA) without impeding research or health care provision. Smaller biotechnology companies (especially single patent holders) do not have this luxury and their economic reality and commercial aspirations sometimes force some to adopt more aggressive practices (eg exclusive testing licenses, monopoly laboratories, higher license and royalty fees, and to threaten legal proceedings for alleged patent infringement) that limit choice and affect equitable and affordable access to research tools and clinical testing.[107]

19.83 Professor John Mattick noted the potential conflict between the public interest and the inappropriate exploitation of patents.[108] Another submission suggested that:

> It is difficult to submit that such patent practices stifle innovation although it is recognised that certain types of research in certain 'crowded' fields may be curtailed due to commercial realities.[109]

19.84 Dr Graeme Suthers suggested that the exclusive rights afforded by patents created a strong incentive for patent holders to establish and maintain monopoly control over an invention.[110] He commented that monopolies created by exclusive patent rights may lead to a loss of price competition, stating:

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104 South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.
105 A McBratney and others, *Submission P47*, 22 October 2003.
106 Cancer Foundation of Western Australia Inc, *Submission P34*, 10 October 2003.
107 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
108 J Mattick, *Submission P35*, 13 October 2003.
109 A McBratney and others, *Submission P47*, 22 October 2003.
110 G Suthers, *Submission P30*, 2 October 2003.

> Current patent practices have resulted in a flood of investment in biotechnology companies, but the potential return from these investments is often related to the anti-competitive nature of gene patents. If a company holds a patent on a gene, this effectively removes the testing of this gene from the marketplace because the patent-holder can have a testing monopoly.[111]

19.85 IP 27 also asked whether there is any evidence that broad patents, trivial patents, defensive patents, dependent patents, multiple patents or reach-through claims may adversely affect the development of Australia's biotechnology industry as it relates to human health.[112]

19.86 In consultations, the Queensland Clinical Genetics Service expressed concerns about 'reach-through' claims. The service suggested that a patent on a genetic sequence should not necessarily provide reach-through rights to diagnostic or therapeutic applications of the sequence.[113]

19.87 The Australian Health Ministers'Advisory Council warned that broad patents may stifle innovation.[114] Similarly, the Queensland Government submitted:

> Broad, trivial and defensive patents tend to stifle innovation, lead to royalty stacking and affects the ability of industry to freely and successfully commercialise their intellectual property. Broad patents create uncertainty and a litigious environment. There is a problem in relation to broad patents particularly if holders of broad (gene) patents also follow restrictive licensing practices.[115]

19.88 However, AusBiotech Ltd stated that:

> Overly-broad patents are unlikely to be enforceable, and there is unlikely to be motivation or funding to enforce trivial patents. There is no evidence that the development of the industry in Australia is being adversely affected.[116]

19.89 Dr Amanda McBratney and others also commented:

> Anecdotal evidence may suggest that broad patents, trivial patents, defensive patents, dependent patents, multiple patents or reach-through claims affect the scope of research being conducted in private companies but not so for research within the University context. It is difficult to submit that such patent practices stifle innovation although it is recognised that certain types of research in certain 'crowded' fields may be curtailed due to commercial realities. Freedom to operate patent searches are frequently *de rigour* in patent prosecution strategies for many companies and University commercialisation companies.[117]

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111 Ibid.
112 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 13–2.
113 Queensland Clinical Genetics Service, *Consultation*, Brisbane, 2 October 2003.
114 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.
115 Queensland Government, *Submission P57*, 5 January 2004.
116 AusBiotech Ltd, *Submission P58*, 7 November 2003.
117 A McBratney and others, *Submission P47*, 22 October 2003.

19.90 A variety of comments were received on the operation of the biotechnology industry in Australia generally. It was suggested that the Australian biotechnology industry is somewhat risk averse in commercialising technology, preferring to license its patents to overseas firms rather than developing them to product stage.[118] AusBiotech Ltd suggested in consultations that the Australian biotechnology industry suffers from an inward looking culture.[119] In addition, the Department of Health and Ageing noted that the commercial sector is not good at research into gene function, which requires access to patient data and longitudinal studies.[120]

19.91 Submissions and consultations also highlighted a range of factors that may impede commercial development of gene patents. Bio Innovation SA commented that state-based programs to develop critical mass in biotechnology in one state would fragment the development of the industry, but in time the stronger sectors would develop, while other initiatives would fail.[121]

19.92 In consultations, AusBiotech Ltd identified a range of impediments to commercialisation facing the Australian biotechnology industry, including the distance from large markets and having a small domestic market.[122] Australia's ability to be internationally competitive in this industry rests on its capacity for inventiveness.[123] AusBiotech Ltd commented that Australia needs to have a stable regulatory framework governing the industry, as regular change will reduce overseas investor confidence and the Australian industry's credibility overseas.[124]

19.93 Others commented that Australian biotechnology companies face difficulties when attempting to move from proof-of-concept stage to the commercialisation stage. This may be due to the lack of a well-developed venture capital industry in this country.[125] In one consultation it was suggested that companies need to be more aware that for the value of technology to be increased, the risks in commercially developing it into a product need to be reduced by developing the technology to a more advanced stage, at which point venture capitalists will be inclined to pay more for it.[126]

19.94 One submission stated:

> One of the reasons the development of new products is under pressure is that intellectual property has a limited life (20 years) and quite often several years have already elapsed by the time the importance of new technology has been realised. For similar reasons, the injection of adequate capital into the development of new biotech products is important. In under-funded projects, even those with considerable potential, the development time has to be stretched out as funds become available, and

118 South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.
119 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.
120 Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.
121 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.
122 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.
123 Ibid.
124 Ibid.
125 Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003.
126 Ibid.

> thus the ultimate value of the product for the investors is shortened by the number of years the intellectual property has been 'wasted' during the development.[127]

19.95 Submissions and consultations provided a number of suggested measures to address some of the problems raised by gene patents for the biotechnology industry, while others made more general comments about how these problems might be approached. For example, the Department of Health and Ageing made the overarching statement that concerns about gene patents have arisen from the way patent holders behave, and that there needed to be policy solutions to control 'rogue players'.[128] The Human Genetics Society of Australasia cited a need to collect data about the impact of patents and licensing practices on the biotechnology sector.[129]

19.96 Professor Alec Morley called for government to be cautious in intervening in commercial transactions, and suggested that:

> companies which exert too heavy a monopoly for their intellectual property will, I suspect, prove to have counterproductive business plans which result in the driving away of their market.[130]

19.97 One suggested solution to the problem of inadequate venture capital was for government to provide investment-equity schemes, like the Biotechnology Innovation Program.[131] In relation to patent thickets and overlapping licences, patent pools were also suggested as a possible solution.[132] The RCPA favoured the creation of guidelines similar to the United States National Institutes of Health commercialisation guidelines that discourage restrictive and anti-competitive practices. It suggested these could be supported by the National Health and Medical Research Council (NHMRC).[133] The Department of Health Western Australia also supported introducing guidelines of this kind.[134]

ALRC's views

19.98 Many of the problems facing the biotechnology industry, and possible reforms to address them, lie beyond the scope of the Terms of Reference. However, the ALRC considers that continuing current education programs, and developing further programs to address particular issues faced by the Australian biotechnology sector, are the most effective solutions to improving the ability of Australian biotechnology firms to compete in the world market.

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127 *Confidential Submission P54 CON*, 3 November 2003.
128 Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.
129 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
130 A Morley, *Submission P18*, 30 September 2003.
131 Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003.
132 Ibid.
133 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
134 Department of Health Western Australia, *Submission P53*, 3 November 2003.

19.99 The ALRC recognises that considerable efforts are being made at both the federal and state levels to support the biotechnology industry, including the provision of information and training about intellectual property issues. These programs should continue, and should focus on providing companies with the specific skills and knowledge to deal with the issues raised by gene patents. (See Proposal 19–1.)

19.100 Solutions to some of the other concerns raised in this chapter are discussed elsewhere in this Discussion Paper. Broader licensing issues, including support for skill development in relation to negotiation, are covered in Chapter 23. Compulsory and statutory licensing, as mechanisms for dealing with other licensing issues are considered in Chapters 27 and 28 respectively.

19.101 Further, Proposals 12–1 to 12–3 suggest that the Australian Research Council (ARC) and NHMRC should review their principles and guidelines to provide for conditions to be placed on research funding, in some circumstances. These conditions may be used to promote the dissemination of research results by wide licensing or precluding patenting entirely.

19.102 Chapter 13 proposes that, as part of this review, the ARC and NHMRC should include principles and guidelines that ensure the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.[135] Some industry concerns about access to research tools should be met by this proposal.

19.103 In addition, the role of competition law for addressing patenting issues within the biotechnology sector is considered in Chapter 24 and a number of proposals are made. Proposal 24–1 suggests the Australian Competition and Consumer Commission (ACCC) should develop guidelines regarding the relationship between Part IV of the *Trade Practices Act 1974* (Cth) and intellectual property, with particular regard to patented genetic materials and technologies. The guidelines should extend to patent pools and cross-licensing involving patented genetic materials and technologies. Proposal 24–2 suggests the ACCC should review the conduct of firms dealing with patented genetic materials and technologies, as the need arises, to determine whether their conduct is anti-competitive. In doing so, the ACCC should liaise with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns.

19.104 Taken together, this set of proposals addresses some of the issues raised in submissions suggesting that commercialisation guidelines about restrictive and anti-competitive practices in the biotechnology industry are required.

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135 Proposal 13–1.

Proposal 19–1 Biotechnology Australia, in consultation with State and Territory governments and other relevant stakeholders, should:

(a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and

(b) develop strategies to ensure widespread participation of biotechnology companies in these programs. (See also Proposals 18–1 and 23–1.)

PART E

Patents and Human Health

20. Gene Patents and the Healthcare System

Contents

Introduction

20.1 The Terms of Reference refer to the potential for rapid advances in human genome research and genetic technologies to improve human health. The ALRC is required specifically to examine and report on the impact on 'the cost-effective provision of healthcare in Australia' of current patent laws and practices related to genetic materials and technologies.

20.2 This chapter discusses the possible impact of gene patents on the healthcare system and begins by presenting background information on the Australian healthcare system, how it is funded, and how decisions are made about funding medical services or pharmaceuticals through the Medicare Benefits Scheme (MBS) or the Pharmaceutical Benefits Scheme (PBS).

20.3 The chapter discusses how gene patents may contribute to the cost of healthcare, and the possible implications of gene patents for healthcare funding. Options are examined for ensuring that the healthcare system is able to manage the introduction of new genetic medical technologies and, in particular, any problems of cost or access attributable to gene patents. In this context, the chapter discusses:

- the need for economic and financial evaluation of the impact of gene patents on healthcare in Australia;

- the possible role of government funding and purchasing power in controlling the cost to the healthcare system of genetic materials and technologies; and

- how Commonwealth, state and territory health departments, with advice from the proposed Human Genetics Commission of Australia (HGCA),[1] may better manage legal and other issues relating to gene patents.

Overview of the Australian healthcare system

20.4 The healthcare system in Australia is complex, involving many funders and healthcare providers.[2] Responsibilities are split between different levels of government, and between the government and non-government sectors. As a generalisation, the Australian Government is primarily responsible for the funding of healthcare, through health insurance arrangements and direct payments to the States and Territories, while the States and Territories are primarily responsible for the direct provision of services.[3]

20.5 The Australian Government operates universal benefits schemes—the MBS for private medical services and the PBS for pharmaceuticals. It also contributes to the funding of public hospitals in the States and Territories through the Australian Health Care Agreements.

20.6 Public hospital services, including outpatient clinics such as those that are part of clinical genetics services, are usually delivered by state and territory governments. The private sector's provision of healthcare includes private medical practitioners, private hospitals, pathology services and pharmacies.

Healthcare funding

20.7 The Australian Institute of Health and Welfare has estimated that total Australian health expenditure was $66.6 billion in 2001–2002.[4] This represented 9.3% of gross domestic product (GDP).[5]

20.8 The healthcare system is largely government funded. In 2001–2002, an estimated 68.4% of the total amount spent on health services was funded by

1 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1.
2 See Australian Institute of Health and Welfare, *Australia's Health 2002* (2002), 238–243.
3 See G Palmer and S Short, *Health Care and Public Policy in Australia: An Australian Analysis* (3rd ed, 2000), 10.
4 Australian Institute of Health and Welfare, *Health Expenditure Australia 2001–02* (2003), 6.
5 Ibid, 8.

governments. The Australian Government met 46.1%, and state, territory and local governments met 22.3% of total funding.[6]

20.9 Most of the Australian Government's healthcare funding was applied to medical services, including those provided under the MBS (30.7% of federal funding), and public hospitals (27.3%).[7] A further 16% of federal funding was directed to pharmaceuticals, including those provided under the PBS. Most state, territory and local government healthcare funding was applied to public hospitals (64.4% of state, territory and local government funding).[8]

Funding decisions under the MBS and PBS

20.10 Decisions about Australian Government funding under the MBS and PBS are made by applying clinical and economic criteria to determine whether, and in what circumstances, the cost of new medical services or pharmaceuticals should be subsidised.[9] These evaluation processes apply, for example, if funding is sought under the MBS for the provision of medical genetic tests or under the PBS for drugs based on therapeutic proteins.

20.11 The Medical Services Advisory Committee (MSAC) provides advice to the federal Minister for Health and Ageing about the strength of evidence relating to the safety, effectiveness and cost-effectiveness of new and emerging medical services and technologies and under what circumstances public funding, including listing on the MBS, should be supported. Applications for funding under the MBS can be made to MSAC by the medical profession, medical industry or others,[10] including health consumer interest groups.

20.12 Similarly, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations on the suitability of drug products for subsidy, after considering the effectiveness, cost-effectiveness and clinical place of a product compared with other products already listed on the PBS, or with standard medical care. PBAC considers submissions from industry sponsors of drug products, but also from medical bodies, health professionals and private individuals. However, for new products or new clinical

6 Ibid, 23.
7 Ibid, 27.
8 Ibid, 29.
9 See Medicare Services Advisory Committee, *Funding for New Medical Technologies and Procedures: Application and Assessment Guidelines*, Department of Health and Ageing, <www.health.gov.au/msac/pdfs/guidelines.pdf> at 1 April 2000; Pharmaceutical Benefits Advisory Committee, *1995 Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee: Including Major Submissions Involving Economic Analyses*, Department of Health and Ageing, <www.health.gov.au/pbs/general/pubs/pharmpac/gusubpac.htm> at 1 December 2003.
10 Medicare Services Advisory Committee, *Funding for New Medical Technologies and Procedures: Application and Assessment Guidelines*, Department of Health and Ageing, <www.health.gov.au/msac/pdfs/guidelines.pdf> at 1 April 2000.

indications, it is normally the sponsor or manufacturer who will hold the necessary data required for a submission.[11]

20.13 Where items are recommended by PBAC for listing on the PBS, the Pharmaceutical Benefits Pricing Authority makes recommendations on the price to be paid. In doing so, the Pricing Authority takes account of a range of factors, including PBAC advice on clinical and cost-effectiveness; prices of alternative brands; comparative prices of drugs in the same therapeutic group; cost data information; prescription volume and economies of scale.[12] The pricing methodology does not provide any mechanism for the recognition of patent rights by way of a price premium. As stated by the Department of Industry, Tourism and Resources (DITR):

> The process of price determination under the PBS system in Australia is based on price referencing using therapeutic and cost effectiveness relativities. This process does not take into consideration the patent status of a drug.[13]

20.14 Another perspective, expressed by Dr Dianne Nicol and Jane Nielsen, is that:

> It is likely that many of the new products arising out of biotechnology research and development will be considered by the PBAC to be too expensive for inclusion on the PBS, in which case the cost must be borne by the individual consumer … Without PBS listing, it is only when patents expire and when competing generic products become available that the Australian community as a whole will get the full benefit of new pharmaceutical developments.[14]

20.15 The Minister for Health and Ageing cannot list pharmaceuticals on the PBS without a positive PBAC recommendation, but is not obliged to comply with a positive PBAC recommendation for listing.[15] Although PBS listing is determined on the basis of clinical and economic criteria, decisions about which drugs are funded by government can become 'political'.[16] For example, Herceptin, a drug derived from monoclonal antibodies and used in treatment for breast cancer, was rejected by PBAC on cost grounds. The drug was nevertheless made available to eligible patients through a program separate to the PBS, following lobbying by patient groups.

20.16 More recently there has been controversy about PBS listing of Glivec (Imatinib), a drug that inhibits an enzyme responsible for aberrant genetic instructions. Glivec has been reported as costing about $50,000 for one year's treatment. While Glivec has been listed as a treatment for chronic myelogenous leukaemia (at a cost to

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11 Pharmaceutical Benefits Advisory Committee, *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC: Part I*, Department of Health and Ageing, <www.health.gov.au/pbs/general/pubs/pharmpac/part1.htm> at 1 December 2003.

12 Pharmaceutical Benefits Pricing Authority, *Procedures and Methods* (2003).

13 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

14 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 60.

15 *National Health Act 1953* (Cth) ss 85, 101.

16 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 60.

patients of $36 per month), PBAC has refused to list the drug as a treatment for gastrointestinal stromal tumour, a rare stomach cancer.[17]

The challenge of new medical technology

20.17 New medical technologies have the potential to place strain on the capacity of the economy to afford them. There are concerns that new technology, in the context of fixed budgets set by governments, may distort the balance of resources devoted to various aspects of the healthcare system.

20.18 Most experts believe that new technology is a driving force behind the long-term rise of healthcare spending.[18] The Australian Government's Intergenerational Report 2002–2003 states:

> Technological change accounts for a significant proportion of non-demographic growth in health spending per person. As the Commonwealth exercises significant controls over whether to adopt new technology in the health system, past increases in spending partly reflect the Commonwealth's choice to fund new technologies.[19]

20.19 Costs attributable to recognition of patent rights are only one component of the costs that may be involved when new medical technologies are introduced. For example, while it is sometimes claimed that patents are the predominant cause of high prices for new pharmaceuticals, the price of pharmaceuticals depends on a wide variety of factors, including the cost of research and development, production, distribution and marketing.[20] One United States' estimate is that patent protection for pharmaceuticals adds only 5–10% to the value of patent holders' financial returns.[21]

20.20 The effect of technological developments on the practice of medicine is one of the most important problems facing health policy makers in Australia.

> New technologies offer new opportunities for treatment or raise the quality or outcome of treatment, and thus increase the number of people who may benefit, even though particular items of new technology may be cost saving. New technologies consequently tend to create pressure to increase spending.[22]

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17 See ABC Radio National, 'Glivec (Imatinib)', *The Health Report*, 21 July 2003, <www.abc.net.au/rn/talks/8.30/helthrpt/stories/s905390.htm>; Novartis Oncology, *About Glivec*, <www.glivec.com/about> at 2 December 2003; J Walker, 'Fight over Cancer Drug Price', *The Australian* (Sydney), 28 July 2003, <www.theaustralian.news.com.au/common/story_page/0,5744,6823070%255E23289,00.ht>.

18 Other factors include population growth, demographic changes, increasing fees and costs of delivering health care services, growth in the medical workforce and greater community expectations. See M Fett, *Technology, Health and Health Care* (2000) Department of Health and Ageing.

19 Australian Government, *Budget Paper No 5: Intergenerational Report 2002–03* (2002), Pt III.

20 Biotechnology Australia, *Consultation*, Sydney, 22 May 2003.

21 M Schankerman, 'How Valuable is Patent Protection? Estimates by Technology Field' (1998) 29 *RAND Journal of Economics* 77: compared to 15% for mechanical and electronic goods. AusBiotech Ltd observed that, as a result of the special requirements for Commonwealth funding under the MBS and PBS, the 'cost differential may well be lower': AusBiotech Ltd, *Submission P58*, 7 November 2003.

22 M Fett, *Technology, Health and Health Care* (2000) Department of Health and Ageing.

20.21 Much of the debate about the cost implications of new medical technology has focused on the high capital cost of technologies such as computerised axial tomography (CAT) or magnetic resonance imaging (MRI). However, new medical technology is not limited to equipment. Genetic diagnostics and therapeutics are also capable of creating cost pressures.

20.22 It has been asserted that genetic technologies will come to affect every sector of healthcare provision.[23] If so, health expenditure attributable to genetic technology may increase.[24] However, the extent of any increase in expenditure, or compensating savings, in other areas is uncertain.

20.23 The Ontario Government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (the Ontario Report), concluded that:

> [m]any genetic technologies while offering promise of longer term savings through better disease management will in the short-to-medium term likely contribute to the rising costs of healthcare.[25]

20.24 Whether new genetic diagnostics and therapeutics will be as costly to bring to the market as the products of today, or whether greater knowledge of genetic sequences will shorten development times and reduce their costs is a matter for debate. It is also uncertain whether patients will demand new genetic tests or new medicines that give only marginal health benefit.[26]

Gene patents and healthcare

20.25 Gene patents are relevant to the provision of healthcare in two broad categories:

- medical genetic testing, including testing for pharmacogenetics; and
- novel therapies, such as gene therapy, the production of therapeutic proteins, and the use of stem cells.

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23 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 61.

24 See Ibid, 61; R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), 3–4.

25 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 61. While certain medical genetic tests may allow disease prevention to be practised, and consequent health care costs reduced, the clinical benefits may not be observable for many years.

26 R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), 4. It has been said that 'Pharmacogenetics could help to reduce costs in the provision of medicines by enabling more efficient treatment, allowing prescription only for those patients who are like to be responsive to a particular treatment. Alternatively, it may be that pharmacogenetics increases costs because of the additional administrative burden': Nuffield Council on Bioethics, *Pharmacogenetics: Ethical Issues* (2002), 11.

20.26 Medical genetic testing can be categorised in various ways.[27] Relevant types of testing include diagnostic testing, predictive or presymptomatic testing, genetic carrier testing, screening testing and pre-implantation or prenatal testing.[28] The uses of genetic testing in healthcare are likely to expand over time as testing processes become easier to undertake and their practical uses become clearer. For example, pharmacogenetics—the study of how genetic characteristics affect the body's response to drugs—may result in medical genetic testing in order to prescribe 'individualised' drugs or dosages.

20.27 Gene therapy involves the use of a gene carrier or 'vector' to carry a gene into somatic (non-reproductive) cells to integrate the gene into chromosomal DNA, with a view to its long-term expression.[29] Currently, gene therapy is an experimental procedure.[30] However, in the future it may be used to treat ailments such as heart disease, inherited diseases or cancers.[31]

20.28 Gene patents are also relevant to the use of therapeutic proteins and stem cells in medical treatment. Isolated genetic materials and the sequences they contain might be used to produce therapeutic proteins, namely, drugs based on proteins produced by the body. These drugs include beta interferon and Epo (erythropoietin).[32]

20.29 Stem cells are cells that have the potential to develop into different types of cells and tissues. Human stem cells can be derived from adult stem cells, foetal stem cells, embryonic stem cells and umbilical cord blood.[33] Stem cells may be useful in the

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27 In this Discussion Paper, the term 'medical genetic testing' refers to molecular genetic testing that directly analyses DNA or RNA. Other biochemical tests of non-genetic substances, as well as some medical imaging processes, may provide strong indicators of particular genetic disorders, particularly in combination with other tests or clinical observations. However, these biochemical tests are not covered by the term 'medical genetic testing' because gene patents are unlikely to have direct impact on the availability or cost of such tests.

28 For a full description of these terms, see Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [10.7]–[10.8].

29 Gene therapy may also refer to therapies, such as where DNA is introduced into somatic cells in order to generate an immune response to treat or prevent a chronic viral infection such as HIV, or as part of a cancer treatment: National Health and Medical Research Council, *About Gene and Related Therapies Research Advisory Panel (GTRAP)*, <www.nhmrc.gov.au/research/gtrap.htm> at 9 May 2003.

30 As at March 2003, the Gene and Related Therapies Research Advisory Panel (GTRAP) of the National Health and Medical Research Council had approved 10 gene therapy studies, including studies related to use of gene therapy to treat mesothelioma, melanoma and leukaemia: National Health and Medical Research Council, *Australian Gene Therapy Studies Approved by GTRAP*, <www.health.gov.au/nhmrc> at 9 May 2003. Regulatory authorities in China have recently approved a form of gene therapy for the treatment of head and neck squamous tumours: See S Westphal, 'Cancer Gene Therapy is First to be Approved', *New Scientist*, 28 November 2003, <www.newscientist.com/news/news.jsp?id=ns99994420>.

31 See Biotechnology Australia, 'Gene Therapy', *Fact Sheet 24*, December 2001, <www.biotechnology.gov.au/library/content_library/BA_24_Gene_therapy.pdf>.

32 Beta interferon is used to treat multiple sclerosis. Epo is used as a treatment for persons with certain types of anaemia.

33 See Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 38.

therapy of degenerative diseases or injuries, as well as for toxicological testing and drug design.[34] They are discussed in detail in Chapter 16.

Patents and the cost of healthcare

20.30 The existence of gene patents may make the provision of healthcare more expensive. A patent grants exclusive rights to exploit the patented invention. This exclusivity may enable the patent holder to charge higher prices and make greater profits than would otherwise be possible. However, the extent to which this applies depends on whether the patent holder has effective monopoly control and, in particular, on the availability of alternative and substitute products and processes.[35]

20.31 It will also depend on the nature of demand. In the case of healthcare, demand is strongly influenced by government funding decisions—for example, decisions about whether a certain medical genetic test will be funded through the MBS are likely to influence consumer demand for the test. Demand may also be influenced by the marketing and other activities of suppliers of healthcare products and services.

20.32 As well as enabling a patent holder to charge a higher price for a patented product, gene patents may increase healthcare costs if:

- healthcare providers are obliged to pay licensing fees or royalties in order to provide healthcare services—such as where a state or territory clinical genetics service is obliged to pay licence fees in order to provide medical genetic testing;

- recognition of gene patents on research tools contributes to the time and expense involved in developing new healthcare products or services and, therefore, their ultimate cost; or

- any additional cost of, or restriction on access to, medical genetic testing means that preventable or treatable genetic diseases are not identified and, as a consequence, further healthcare costs are incurred.

Gene patents and the funding of healthcare

20.33 Concerns about the implications of gene patents for public healthcare funding have arisen primarily in relation to medical genetic testing (see Chapter 21). Most medical genetic tests are ordered as part of healthcare services provided by state and territory clinical genetics services. Testing itself is most often carried out by public

34 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 4.

35 See Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 138.

sector laboratories, often attached to public hospitals or significantly funded by state or territory governments.[36]

20.34 As discussed in Chapter 21, there are presently around 220 medical genetic tests available in Australia[37]—but the scope of MBS funding support is quite limited. The MBS funds medical genetic testing under only six MBS items, which concern testing for haemochromatosis, factor V Leiden, protein C or S deficiencies, antithrombin 3 deficiency, and fragile X syndrome.[38] Professor Ron Trent has observed that most tests are funded:

> ad hoc through cost recovery or public hospital laboratories. This is a difficult situation particularly in relationship to patents when DNA tests may not be generating income but may actually lose money for the labs.[39]

20.35 This situation may change in future as genetic medicine develops. The Australian Health Ministers' Advisory Council (AHMAC) observed:

> A small number of genetic tests are delivered privately but the majority are provided by States through their public hospital laboratories with access to testing through outpatient settings. As genetic technologies become more mainstream it is likely that the private sector will play a greater role in provision, with rebates under the Medicare Benefits Schedule.[40]

20.36 Another element of funding for genetic healthcare services is private health insurance. The extent to which private health insurance covers the cost of medical genetic testing will depend on the terms of particular insurance policies and on conditions of registration, which provide that health insurance funds must offer some types of products and benefits, but cannot offer others.[41] In general, private patients are charged for the small number of tests that are scheduled on the MBS, with private insurance covering the gap between the MBS rebate and the cost of the service. Private insurance does not cover genetic tests that are not scheduled on the MBS.

Submissions and consultations

20.37 IP 27 asked whether gene patents pose any distinct problems of cost for the Australian healthcare system beyond those applicable to new technologies generally.[42]

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36 In turn, half of all public hospital funding comes from the Commonwealth through the Australian Health Care Agreements.

37 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html> at 19 February 2003. Not all tests are available from all laboratories. The register does not include newborn screening laboratories.

38 Department of Health and Ageing, *Medicare Benefits Schedule (MBS)* (2003). These tests are funded by Medicare under two categories: diagnostic testing to confirm a clinical observation (for example, in the case of haemochromatosis the patient must have raised iron levels); and screening of asymptomatic individuals where the patient is a first-degree genetic relative of another individual who is known to have the condition.

39 R Trent, *Correspondence*, 23 September 2003.

40 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

41 *National Health Act 1953* (Cth) ss 73BA, 73B(1), sch 1.

42 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 7–1.

In response, a number of submissions suggested that cost problems are not unique to genetic technologies.[43] For example, AusBiotech Ltd submitted that there is no difference between therapeutic agents or diagnostic tests based on gene patents and those in other fields, such as pharmaceuticals, and noted:

> The cost of a patented therapeutic or diagnostic is far more dependent on research and development, production, distribution and marketing costs than it is on whether or not the product or method is patented.[44]

20.38 Similarly, DITR stated:

> As with most new technologies, the initial price for a genetic technology is likely to reflect the cost of development. Experience with the relatively small number of genetic technologies that have been available over the last several years indicates that prices tend to decline over time due to normal market forces and competition.[45]

20.39 Submissions expressed different views on the extent to which recognition of patent rights contribute to the cost of genetic medical technologies, as compared to other cost components. The Human Genetics Society of Australasia (HGSA) submitted:

> Gene patents are likely to inflate prices, though their precise impact is not yet known. There is clearly a potential for patent holders to charge exorbitant prices for genetic testing kits or licences when the cost of gene discovery and kit development is not that great (certainly not as great as drug and other treatment development).[46]

20.40 In relation to genetic testing, Dr Graeme Suthers submitted that gene patents did not pose problems provided there is 'healthy competition between private sector companies and public sector organisations'. Such competition will help 'keep costs manageable and access reasonable'.[47]

20.41 DITR submitted that any link between the patenting of genes and the potential for health care cost increases has not been established.[48] DITR observed:

> Ideally, the price of patented health care technologies should be equal to the benefit that it creates for the patient relative to all alternative technologies. This price may

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43 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Queensland Government, *Submission P57*, 5 January 2004; GlaxoSmithKline, *Submission P33*, 10 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; IP Australia, *Submission P56*, 4 November 2003; G Suthers, *Submission P30*, 2 October 2003; Queensland Government, *Submission P57*, 5 January 2004; A McBratney and others, *Submission P47*, 22 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

44 AusBiotech Ltd, *Submission P58*, 7 November 2003.

45 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

46 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

47 IP Australia, *Submission P56*, 4 November 2003.

48 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

> bear little or no relationship to production costs, or to the costs of research and development.[49]

20.42 Genetic Technologies Limited (GTG) suggested that, while patents may enable patent holders to charge higher prices than would otherwise be possible, the characteristics of the Australian market, including its small size, have an important influence.[50]

20.43 Some submissions highlighted concerns about the future costs of genetic medical technologies given the growing importance of genetics in healthcare. The Department of Health and Ageing stated that the cost impacts of gene patenting could affect the Commonwealth and State health budgets, health insurance, and health consumers. On the other hand, the Department accepted that 'practice and technologies will change constantly and that our funding systems and decision making processes need to adapt to those changes and the associated costs'.[51]

20.44 The South Australian Government expressed concern about future inequalities in access to healthcare services, if costs due to licence fees or royalties have an impact on the capacity of state governments to fund services currently provided free to patients.[52] In this context, it observed:

> As genetic research provides information which identifies individuals, groups and populations at risk of various conditions, demands will be created for a range of health services including predictive testing, counselling and interventions … Access to and uptake of these services by individuals and groups with differing interests and needs will be influenced by factors including socio-economic disadvantage.[53]

20.45 IP 27 also asked what problems gene patents and future developments in genetic technologies pose for the cost and funding of clinical genetics services specifically.[54]

20.46 The mix of Commonwealth, state and territory healthcare funding may present challenges for clinical genetics services in responding to demands for recognition of gene patent rights. Dr Suthers stated:

> The Federal Government is shielded from the immediate financial impact of decisions about the patentability of genes. The States will feel the impact more immediately but lack the responsibility for addressing the matter. The same issue lies at the heart of difficulties in developing a national familial cancer program; the States pay for genetic testing but Medicare is a major beneficiary because of the reduction in unnecessary colonoscopies. There are no national programs in clinical genetics.[55]

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49 Ibid.
50 Genetic Technologies Limited, *Submission P45*, 20 October 2003.
51 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.
52 South Australian Government, *Submission P51*, 30 October 2003.
53 Ibid.
54 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 7–2.
55 G Suthers, *Submission P30*, 2 October 2003.

20.47 The South Australian Government stated that, if patent holders charge licence fees or royalties when 'in-house' genetic tests are performed by state clinical genetics services without charge to patients,[56] the extra cost will need to be funded in one of three ways:

> (i) increased State funding to cover licence fees, by redirecting funding from some other area of health care (ii) reduced testing to maintain laboratory costs within budget, by redirecting funds used for provision of testing services to families towards licence fees for patent holders (iii) charging families affected by genetic abnormalities an amount to cover the licence fees, redirecting family resources from caring for affected family members to licence fees for patent holders.[57]

20.48 Dr Duncan McFetridge MP, who has introduced a private member's Bill into the South Australian Parliament to stop companies charging fees for genetic testing in hospitals,[58] expressed specific concern about maintaining public testing services.[59] On the other hand, GTG submitted that, for existing state and territory clinical genetics services, the cost of obtaining access to patented inventions 'pales into insignificance' when compared with other problems compromising the quality and efficiency of public testing services.[60]

20.49 DITR noted that at least some genetic tests are likely to replace the use of more expensive or inaccurate non-genetic tests, giving rise to cost reductions and improved health outcomes.[61] The Department of Health and Ageing stated that it expects:

> increasing demand for genetic testing and screening in the future, with potential for improvements in the quality of healthcare and, in some instances, for savings in healthcare costs.[62]

Evaluating the economic and financial impact of gene patents

20.50 IP 27 asked what steps, if any, should be taken to facilitate the economic evaluation of the impact of gene patents on genetics services and other healthcare in Australia.[63] The term 'economic evaluation' is used to encompass a wide range of techniques used for comparing the costs and benefits of an activity. These techniques are used to evaluate interventions in healthcare and other contexts.

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56 Where commercial test kits are not financially viable: South Australian Government, *Submission P51*, 30 October 2003.

57 Ibid.

58 Gene Testing Services (Public Availability) Bill 2003 (SA).

59 D McFetridge, *Submission P23*, 30 September 2003.

60 These were stated to include 'the hidden costs of duplication, organizational fragmentation, and the fact that most existing services are extensions of research infrastructure rather than purpose designed service organizations': Genetic Technologies Limited, *Submission P45*, 20 October 2003.

61 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

62 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

63 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 7–3. It is probably not practicable to conduct economic evaluation of the impact of gene patents on healthcare, as suggested by IP 27, separately from economic evaluation of a genetic medical technology as a whole.

20.51 The techniques applied in the economic evaluation of healthcare are derived from the same theoretical base as in other contexts, but differ in how benefits are measured and valued. For example, the 'benefits' of health services usually include both the extension and the quality of life.

20.52 Costs, outcomes and quality of life measurements are usually included in an economic evaluation.[64] Three types of economic evaluation of health services are cost-benefit analysis, cost-effectiveness analysis, and cost-utility analysis.[65] Cost-benefit analysis requires the value of lives saved or quality of life enhanced by a medical program to be measured in dollars. To overcome this difficulty, cost-effectiveness analysis measures benefits in natural units such as lives saved or life years gained. Cost-utility analysis is a form of cost-effectiveness analysis that allows the value of life years to be weighted by an index of the quality of life or, more precisely, by an index of the strength of people's preferences (utility) for different health states.[66]

20.53 Economic evaluation involves comparing costs and benefits for maximum societal wellbeing. Therefore, anything that adds to or subtracts from wellbeing can be included in the framework. Professor Jeff Richardson has pointed out that, in practice, as ethical, distributional and other intangible considerations are often difficult to quantify, economic evaluation, narrowly defined, may deal only with readily measurable costs and benefits.[67] Another characteristic of economic evaluation of health services is that its validity depends on clinical or epidemiological analysis of health impacts.[68]

20.54 While the economic evaluation of health services is complex, there have been developments in agreeing standard approaches to the measurement of costs and benefits, particularly where this has been linked to funding decisions, such as those under the PBS. However, as Professor Jane Hall has noted, the application of economic evaluation to genetic services presents several challenges beyond those relevant to other health service interventions. These include the following:

- the health impact may not be immediate or related directly to the intervention, such as when a test reveals a susceptibility to the development of a disease that will be manifest only if certain environmental conditions prevail and, even then, only at some considerable time in the future;

- even if the condition cannot be prevented, more careful monitoring may lead to earlier intervention and less severe cases of the disease;

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64 J Richardson, 'The Economic Framework for Health Service Evaluation and the Role for Discretion' (Paper presented at Health Outcomes Conference, Canberra, 21 July 1999), 1.
65 Ibid, 4.
66 Ibid, 4.
67 Ibid, 2.
68 Ibid, 3.

- more careful monitoring will add to healthcare costs, even though these may be offset by savings in future treatment; and

- some genetic testing will not affect the health of the patient, but rather the health of the patient's children, so that there is an inter-generational effect, which may make discounting for time preference inapplicable.[69]

20.55 Many submissions indicated that examining options for economic evaluation of the impact of gene patents, or genetic health technologies more generally, would be desirable.[70] However, there was no common understanding about what economic evaluation would involve, the scope of such evaluation, or who should be responsible for it. Most submissions commented on the need for economic evaluation of genetic medical technologies generally, rather than evaluation of the impact of gene patents specifically.

20.56 The complexity of economic evaluation of health services was highlighted by DITR, which noted there is no precise methodology available to evaluate costs and benefits of new healthcare technologies. In particular, DITR commented:

> While the estimation of costs can be carried out with a relatively high level of accuracy, the estimation of direct and indirect benefits through health gains to the community and reductions in 'opportunity costs' is more difficult because they are diffuse.[71]

20.57 DITR noted that genetic tests cannot be meaningfully evaluated as 'one monolithic technology'.[72] Rather, evaluation of the costs of genetic technologies needs to be carried out 'on a case by case basis, taking into consideration factors such as the accuracy of the test and the potential population that might benefit from the technology'.[73] DITR highlighted the opportunity to improve current processes of assessment and economic evaluation carried out by the Therapeutic Goods Administration (TGA) and PBAC. DITR added:

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69 See J Hall, R Viney and M Haas, 'Taking a Count: The Evaluation of Genetic Testing' (1998) 22 *Australian and New Zealand Journal of Public Health* 754; J Hall, 'Evaluation of Genetic Testing: How are We Going to Assess the Costs, Risks and Benefits of this New Technology?' in G O'Sullivan, E Sharman and S Short (eds), *Good-bye Normal Gene* (1999), 30. Genetic testing also involves complex ethical, privacy and discrimination issues: see Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003).

70 Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003; G Suthers, *Submission P30*, 2 October 2003; D McFetridge, *Submission P23*, 30 September 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

71 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

72 These comments apply to all evaluation of healthcare services since each service or program has to be considered in relation to each target group.

73 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003. See also F Miller and others, *Predictive Genetic Tests and Health Care Costs: Final Report Prepared for the Ontario Ministry of Health and Long Term Care* (2002).

> It may be appropriate to assign the proposed Human Genetics Commission the task of commissioning such evaluations and assessment of cost implications in their role as an advisory body to government on genetic technologies.[74]

20.58 Dr Suthers suggested a new Commonwealth program to evaluate clinical genetics services and programs:

> There are no national programs in clinical genetics and hence no vehicle for national evaluation of issues such as this. All of the costing analyses in clinical genetics services being done in Australia at present are done with limited resources at the level of individual States. Genetic testing is still new and services vary greatly in different States and regions. Hence an econometric evaluation in one State will not necessarily provide an accurate reflection of the situation nationally. There is an urgent need for a Federal program addressing service delivery and evaluation in clinical genetics. This program should include, but not be limited to, economic evaluation of the impact of gene patents on the delivery of clinical genetics services.[75]

20.59 Dr Suthers provided an example of possible savings in future healthcare costs attributable to testing for the BRCA genes associated with breast and ovarian cancer. Savings maybe derived from cancer prevention, earlier diagnosis and better targeting of surveillance. However, he observed:

> Of course, this looks nicer on paper than in practice because we are offsetting today's costs against tomorrow's savings. For most policy makers and their masters, the challenge is to avoid drowning today; a potential lifeboat is not very useful … If the costs of these genetic tests were to increase and testing had to be curtailed, there would be financial and social costs associated with late diagnoses of cancer in those who didn't realise they are at high genetic risk. There would also be costs associated with unnecessary cancer surveillance in those who didn't realise they are not at high risk.[76]

20.60 In relation to medical genetic testing, the HGSA stated that government needs to establish mechanisms for the 'rigorous evaluation' of new technology and indications for its use. The HGSA considered that the MSAC system 'does not have the capacity to undertake the task' and that an 'Office of Health Technology Assessment' could be established within the TGA.[77]

20.61 The Department of Health Western Australia is undertaking an economic evaluation of the Familial Cancer Program in Western Australia, in collaboration with Genetic Services of Western Australia. This study aims to measure the cost-effectiveness of current models of service delivery for colorectal, breast and ovarian cancers, looking at costs of testing, counselling, surveillance, intervention and

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74 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
75 G Suthers, *Submission P30*, 2 October 2003.
76 Ibid.
77 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

treatment.[78] The Department highlighted the challenges involved in determining the economic impact of such programs and submitted:

> Economic evaluation of genetic services is in its infancy in Australia … While additional funding would be required to expand the [Familial Cancer Program] study to include other genetic services, we believe that the familial cancer model could be useful in assessing the costs and benefits of other genetic diseases. With an already financially stretched health system and a consumer demand for genetic tests that far exceeds supply, there is a clear need for the economic evaluation of genetic testing services. Funding is desperately required to enable effective evaluation.[79]

20.62 GlaxoSmithKline emphasised that assessing the benefit of gene patents should be part of any such evaluation and should include healthcare savings (for example, from reduced hospitalisation) derived from the innovative therapeutic and diagnostic products covered by gene patents.[80]

20.63 The Queensland Government advised that Queensland Health favoured evaluation by the Australian Government of the impact of gene patents on the cost of genetic services and other healthcare in Australia. It was suggested that such evaluation be conducted by or under the aegis of MSAC.[81] The South Australian government emphasised the need for a national approach to evaluation of the impact of gene patents on healthcare costs. Evaluation should identify the different potential scenarios, in terms of licensing models and enforcement by patent holders.[82]

20.64 Some submissions opposed new processes for the economic evaluation of gene patents and healthcare. GTG considered such evaluation would be likely to be 'hijacked by special interests which would lead to flawed or politicized outcomes'.[83]

ALRC's views

20.65 Gene patents have the potential to create cost problems for particular health services—for example, where state clinical genetics services are obliged to pay licensing fees or royalties for medical genetic testing from existing fixed budgets. In these circumstances, governments will either have to reduce service provision, increase user charges, or obtain increases in their budget allocations.

20.66 However, the extent to which increased expenditure on medical genetic testing and novel therapies will pose a challenge to overall healthcare funding is not clear; nor is it clear what contribution gene patents may make to this increased expenditure. Dealing with additional expenditure attributable to the recognition of gene patents is one component of a broader health policy challenge.

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78 Department of Health Western Australia, *Submission P53*, 3 November 2003.
79 Ibid.
80 GlaxoSmithKline, *Submission P33*, 10 October 2003.
81 Queensland Government, *Submission P57*, 5 January 2004.
82 South Australian Government, *Submission P51*, 30 October 2003.
83 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

20.67 Economic evaluation may assist in planning and resource allocation relating to genetic technologies. The Australian healthcare system is regarded by some as a world leader in carrying out detailed economic evaluation of the costs and benefits of pharmaceuticals and other medical technologies prior to inclusion in the MBS and PBS,[84] and these skills may usefully be applied more broadly.

20.68 A need for economic evaluation of new genetic medical technologies has been identified by inquiries overseas.[85] The Ontario Report suggested that Canadian Health Ministers should establish a plan for better economic evaluation of genetic technology and testing.[86] Similarly, a report for the Nuffield Trust Genetics Scenario Project recommended that the use of health economics should be encouraged in assessing the impact of genetic science on health services.[87]

20.69 The impact of new genetic technologies on healthcare in Australia clearly needs to be monitored closely by health policy makers. The ALRC highlighted aspects of the need for long term planning regarding genetics in the 2003 report, *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC 96). ALRC 96 recommended the development of strategies to assess and respond to the need for genetic counselling services throughout Australia and approaches to ensure that medical practitioners are appropriately trained and equipped in clinical genetics and in the use of relevant genetic counselling and genetic services.[88]

20.70 It is also desirable to anticipate and plan for the impact of genetic medicine on healthcare costs and funding. While the ALRC's Terms of Reference are directed to the impact of patent laws and practices, submissions and consultations have highlighted a more general need for economic evaluation of genetic medical technologies. The ALRC proposes that Commonwealth, state and territory health departments should establish a process for economic evaluation of medical genetic testing and other new genetic medical technologies (Proposal 20–1).

20.71 Separately assessing the impact of gene patents as part of an economic evaluation of genetic medical technologies may be problematic because of the many intangibles including, for example, whether the benefit of a particular genetic medical technology would have become available, or become available when it did, without the

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84 Biotechnology Australia, *Consultation*, Sydney, 22 May 2003.

85 See Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002); R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000). In relation to pharmacogenetics, see Nuffield Council on Bioethics, *Pharmacogenetics: Ethical Issues* (2002); P Lipton, 'Pharmacogenetics: The Ethical Issues' (2003) 3 *Pharmacogenomics Journal* 14, 14–15.

86 See Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 84.

87 R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), 76.

88 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 23–1; 23–4, 23–5.

incentive of patent protection. A financial or budgetary analysis of the impact of gene patents specifically may, therefore, be more practical. Such an analysis would estimate current and projected costs of providing genetic healthcare services, taking patent rights into account.

20.72 The ALRC proposes that Commonwealth, state and territory health departments should also establish a process for examining the financial impact of gene patents on the delivery of healthcare services in Australia. A financial analysis may assist decision making about how to absorb any future costs attributable to patent licence fees or royalty payments. It may also assist health departments in decision making about whether to recognise or challenge patent rights, and in developing strategies for negotiations with patent holders, consistent with the more active role in managing patent issues proposed by the ALRC.[89]

20.73 The ALRC considers that AHMAC is the appropriate body to take this proposal forward. AHMAC is a committee of the heads of the Commonwealth, state and territory health departments. It is the major policy making body on national health matters, advising the Australian Health Ministers' Conference on policy, resource and financial issues. In May 2002, AHMAC established an AHMAC Advisory Group on Human Gene Patents and Genetic Testing. Its terms of reference include advising and making recommendations to AHMAC on matters relating to the planning, management, regulation, provision and delivery of human genetic testing and screening services. In addition, AHMAC may be assisted by MSAC. MSAC's terms of reference include undertaking health technology assessment work referred to it by AHMAC, and reporting its findings to AHMAC.[90]

Proposal 20–1 The Australian Health Ministers' Advisory Council (AHMAC) should establish processes for: (a) an economic evaluation of medical genetic testing and other new genetic medical technologies; and (b) an examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

Control through government funding and purchasing

20.74 Government decisions about healthcare funding can indirectly influence patent holders' decisions about licensing and the level of licence fees. IP 27 noted that government funding and purchasing power may provide mechanisms to control the availability and cost of medical genetic testing and other aspects of healthcare, including those costs that may be attributable to recognition of patent rights. It asked whether government funding and purchasing power should be used to control the cost

89 See Proposal 20–3.

90 Department of Health and Ageing, *Medicare Services Advisory Committee Terms of Reference*, <www.health.gov.au/msac/terms.htm> at 3 December 2003.

of medical genetic testing that is subject to gene patents and, if so, how this might best be achieved.[91]

20.75 Government funding decisions can help determine the availability of medical genetic testing. The HGSA has stated that the cost of genetic testing to individuals, including testing that is subject to gene patents, should be minimised 'through a national funding program that is limited to tests of proven clinical utility and cost-effectiveness', with the price to be negotiated by government.[92]

20.76 The AHMAC Working Group on Human Gene Patents recommended in 2001 that government funding for genetic testing should be restricted initially to genetic testing performed by publicly funded facilities, in part to assist in controlling healthcare costs.[93] Restricting government funding of medical genetic testing to tests performed in public sector laboratories is seen by some as necessary to ensure 'a robust Australian genetic testing infrastructure'.[94]

20.77 The PBS has been cited as an example of how government purchasing power may assist in controlling the cost of healthcare.[95] There is evidence that the PBS allows relatively low prices for drugs to be maintained through the government being the single buyer (a monopsony) in a market with a number of pharmaceutical sellers.[96] In 2003, in reviewing the Pharmaceutical Industry Investment Program, the Productivity Commission concluded that bargaining power arising from Australia's PBS arrangements almost certainly leads to lower prices, but the exact price effect is unknown given other influences.[97]

20.78 The ALRC received comments about possible adverse effects of the PBS on biotechnology research and development. One submission stated that, while the PBS results in 'excellent bargains in bulk purchase and pricing':

> it jeopardises the ability of Australian biotech to receive funding within Australia since margins for Australian drug companies are extremely tight and they prefer to do most of their R&D overseas where they are more appropriately funded.[98]

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91 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 12–7.

92 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001).

93 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 27, rec 7.

94 P Dawkins and others, *Human Gene Patents: The Possible Impacts on Genetic Services Health Care* (2003) unpublished manuscript.

95 In 1999–2000 the Commonwealth Government contributed $3,522 million in benefits under the PBS and the Repatriation Pharmaceutical Benefits Scheme, out of a total expenditure on all pharmaceuticals of $7,563 million: Australian Institute of Health and Welfare, *Australia's Health 2002* (2002), 255.

96 See M Rickard, *The Pharmaceutical Benefits Scheme: Options for Cost Control: Current Issues Brief No 12 2001–02 (28 May 2002)*, Parliament of Australia, <www.aph.gov.au/library/pubs> at 6 April 2003; Productivity Commission, *International Pharmaceutical Price Differences: Research Report* (2001).

97 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), [3.12].

98 *Confidential Submission P54 CON*, 3 November 2003.

20.79 The United States pharmaceutical industry pressed for changes to the PBS scheme in the context of negotiations for an Australia–United States Free Trade Agreement (AUSFTA)[99]—in part on the basis that United States consumers, who pay higher prices for drugs, support drug research and development that benefits consumers in the rest of the world.[100]

20.80 Many submissions expressed approval for the use of government monopsony purchasing power to control the cost of genetic medical technologies.[101] Dr McBratney and others noted that the MBS and PBS are already used to control the cost of medical procedures and pharmaceuticals and submitted that:

> The burden of such systems therefore rests with society universally, at least via distributive allocation across the tax base.[102]

20.81 The Walter and Eliza Hall Institute of Medical Research stated that government purchasing power should be used:

> through a mixture of incentives (eg through a PBS and P3-like scheme) and restrictions for use based on evidence and cost-effectiveness in order to qualify for the incentives.[103]

20.82 DITR asserted that there are adequate mechanisms available through health benefits administration and competition law to address any concerns about the potential for sharp rises in health care cost attributable to the exercise of patent rights.[104] DITR stated that the perception that the costs of clinical genetics services will escalate appears to be based on 'the potential for broad uptake and inappropriate use of genetic tests'. DITR submitted:

> This problem can be managed through the adoption of appropriate policy measures using criteria-based public coverage (referral protocols, designated accredited test providers and by disallowing direct consumer marketing) to ensure access for those in need and those who are likely to benefit most while limiting the potential for broad and inappropriate uptake.[105]

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99 See Ch 4.

100 See E Becker, 'Drug Industry Seeks to Sway Prices Overseas', *New York Times* (New York), 27 November 2003, A1. However, following the conclusion of negotiations for the AUSFTA, it appears that the PBS will be maintained: Department of Foreign Affairs & Trade, *Australia–United States Free Trade Agreement: Key Outcomes*, <www.dfat.gov.au/trade/negotiations/us_fta/outcomes/02_key_outcomes.html> at 9 February 2004.

101 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Genetic Support Council WA (Inc), *Submission P59*, 7 November 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003. The Royal College of Pathologists of Australasia rejected the use of government funding and purchasing power to control the cost of medical genetic testing: Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

102 A McBratney and others, *Submission P47*, 22 October 2003.

103 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

104 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

105 Ibid.

ALRC's views

20.83 Governments have considerable control over healthcare expenditure in Australia through budget appropriations,[106] fixing health benefit levels, taxation arrangements, and setting the parameters for private health insurance arrangements.

20.84 The MBS and PBS are relevant where funding is sought through federal funding programs. There are also funding and other mechanisms that may be used by state and territory health departments. AHMAC noted:

> Jurisdictions regularly make decisions in order to manage the costs resulting from new health technologies through the application of appropriate efficacy and cost effectiveness analysis, funding and targeting mechanisms.[107]

20.85 There may be other ways in which funding mechanisms might be used to address concerns about the impact of gene patents on healthcare provision, including by placing conditions on the public funding of new medical services. For example, Medicare funding of a medical genetic test might be made conditional on broad licensing of the test.

20.86 The ALRC proposes that options for using government funding and purchasing power to control the cost of genetic medical technologies subject to gene patents should be examined by Commonwealth, state and territory health departments.

Proposal 20–2 AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

Role of health departments

20.87 Health departments and other public health organisations are directly affected by the patenting of genetic materials and technologies. Health departments are the major funders and users of these technologies and, therefore, have a major stake in the outcomes of the patent system for healthcare provision and for medical research.

20.88 The ALRC has been examining whether health departments should take a more active role in monitoring the application of patent law to genetic materials and technologies and, where appropriate, intervening in patent processes.

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106 In the case of the Australian Government, appropriations include grants to the States and Territories that are specifically targeted to healthcare purposes, payments of health benefits to individuals, subsidies paid to providers of healthcare services, and reimbursements to private health insurance funds.

107 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

20.89 Recommendations made in 2003 to the United Kingdom Department of Health provide an important lead. The report *Intellectual Property Rights (IPRs) and Genetics*, by Professor William Cornish, Dr Margaret Llewelyn and Dr Michael Adcock (the UK Report)[108] was commissioned by the United Kingdom Department of Health because of its 'serious concern' about the impact of intellectual property rights upon 'research and the use of novel developments in genetics affecting health care'.[109]

20.90 The remit of the project was to undertake a study into the impact and management of intellectual property rights within the healthcare sector. This included looking at ways in which the Department of Health could manage intellectual property rights and, in particular, deal with the protection and patentability of genetic material.[110] Relevant recommendations[111] of the UK Report were that the Department of Health should:

- recognise its unique position with regard to healthcare related intellectual property and take an active role in monitoring developments in relevant areas of intellectual property law (most notably patent law).[112]

- have in place a mechanism for assessing whether (a) to send information to patents offices during the examination of a patent application which would restrict the scope of any patent on the disclosed genetic invention; (b) to challenge the validity of a genetic patent once granted; and (c) to challenge any abuse of monopoly rights using competition law.[113]

- instigate a policy for 'licensing in' designed to moderate excessive demands by licensors by considering, as possible options, the use of compulsory licensing, competition law and Crown use.[114]

- make full use of existing monitoring and horizon scanning work being undertaken by groups such as the Human Genetics Commission, the Nuffield Council on Bioethics, and the Intellectual Property Advisory Committee and make representations to these groups where necessary.[115]

20.91 While IP 27 did not ask specific questions about health departments taking a more active role in monitoring patent law and practices, a number of submissions made relevant comments.

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108 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003).
109 Ibid, 8.
110 Ibid, 87.
111 Another significant focus of the recommendations in the UK Report was on 'licensing out' and commercialisation of genetic materials and technologies by the Department.
112 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), rec 1.
113 Ibid, rec 4.
114 Ibid, rec 7.
115 Ibid, rec 10.

20.92 The Cancer Council of Australia proposed that governments should have a mechanism for challenging gene patents and suggested that AHMAC may be the appropriate body to assume responsibility for this.[116]

20.93 In relation to scrutiny of applications for gene patents, the South Australian Government referred to the UK Report and suggested that IP Australia should 'make full use of the advice that would be available to it' from the National Health and Medical Research Council (NHMRC), the Australian Health Ethics Committee (AHEC) and the HGCA, once it is established. The submission also noted that:

> it would be difficult for Health Departments at every level to monitor health-related patent applications in Australia. There may be a role for the HGCA in monitoring applications for gene-related patents, but that would work most effectively if IP Australia was required to advise the HGCA on receipt of such an application …[117]

20.94 The establishment of the HGCA was recommended by the ALRC and AHEC in ALRC 96.[118] The ALRC and AHEC recommended that the HGCA should be established under federal legislation as an independent statutory authority. The role of the HGCA would be to provide, among other things, on-going, high-level, technical and strategic advice to Australian governments about current and emerging issues in human genetics, including on the ethical, legal and social implications arising from these developments.

ALRC's views

20.95 The possibility of Commonwealth, state and territory health departments undertaking new roles in monitoring and challenging gene patents was canvassed by the ALRC in consultations. A common response was that health departments currently lack the expertise and resources to do so. In any case, it is often unclear at the time of application or grant, even to experts, what the impact of granting a patent will ultimately be. The vast majority of patents are never exploited or enforced—and therefore will be unlikely ever to have adverse consequences on the provision of healthcare.

20.96 It is often only many years after the grant of a patent that healthcare providers become aware of its existence and its possible implications. For example, the patents on methods of using non-coding DNA polymorphisms (the non-coding patents) held by GTG were first granted in 1994.[119] It was eight or nine years before the possible implications of these patents for the provision of medical genetic testing became a focus of health department concern.[120]

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116 Cancer Council Australia, *Submission P25*, 30 September 2003.
117 South Australian Government, *Submission P51*, 30 October 2003.
118 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1 to 5–9.
119 US5851762.
120 Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.

20.97 Notwithstanding the practical challenges, the ALRC considers that health departments should develop the capacity to monitor patent processes and intervene where appropriate. Depending on the circumstances, health departments may have an interest in monitoring or intervening in patent processes at the point of patent application, on examination, or during the term of the patent.[121] Health departments should be willing to challenge patents in the public interest because of possible adverse effects on the conduct of medical research or the cost or quality of healthcare.

20.98 There are precedents overseas of governments intervening in patent processes, motivated by public health policy considerations. For example, the Ontario provincial government recently intervened in a court case involving genetically modified crops, in part because of concern about the impact of gene patents on healthcare and research.[122] In New Zealand, the Pharmaceutical Management Agency—the Crown entity responsible for managing New Zealand's equivalent of the PBS—has challenged the grant of patent claims directed to methods of medical treatment.[123]

20.99 The ALRC proposes that where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on the cost-effective provision of healthcare, Commonwealth, state and territory health departments actively consider whether to: request re-examination of a patent; initiate proceedings to oppose a patent; make application for revocation of a patent; apply for the grant of a compulsory licence; or exploit or acquire a patent under the Crown use and acquisition provisions of the *Patents Act 1990* (Cth) (Proposal 20–3).

20.100 As well as being skilled-up to monitor patent developments and intervene where necessary, health departments need to be sophisticated in their commercial dealings with patent holders and need to ensure that they have appropriate strategies in place to manage intellectual property issues across the entire health portfolio. The UK Report observed:

> In understanding what options are available to the Department, it is essential that, in addition to noting the problems which IP is commonly perceived as causing, the Department also appreciates the limits which the law places upon patent rights (these take the form of the requirements for validity and disclosure, various exceptions, compulsory licences etc …). The single most effective option available to the Department is to take a central role in ensuring that these are properly observed in those situations where the Department has an interest.[124]

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121 Opportunities to challenge the grant of patent rights exist at each stage of the patenting process—prior to acceptance of a standard patent application, after the Commissioner of Patents has accepted an application, and after a patent has been sealed (see Ch 9).

122 C Freeze, 'Ontario Seeks to Intervene in Biofoods Court Case', *The Globe and Mail* (Toronto), 9 October 2003, A5.

123 See, eg, *Pharmaceutical Management Agency Limited v The Commissioner of Patents & Ors* [2000] 2 NZLR 529.

124 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 46.

20.101 Health departments need to have the expertise and resources to play a more active role in the patent system. This will be more easily achievable for the larger States. The ALRC proposes that the Commonwealth, States and Territories establish specialist offices within their health departments to monitor and manage intellectual property issues relating to genetic materials and technologies. The offices should be staffed by qualified individuals who are capable of giving specialist legal and policy advice to the departments about intellectual property, biotechnology and human health (Proposal 20–4). The functions of the specialist office would be broad ranging and could include, for example, the negotiation of licences with patent holders. Health departments should also be able to draw on expertise in other government departments and agencies to advise and assist them in dealing with intellectual property issues arising from gene patents.

20.102 In practice, the implications of gene patents are likely to affect all health departments in similar ways. To avoid duplication of activities, some initiatives should be coordinated at a national level. The ALRC proposes that the HGCA should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for human health, both generally and in specific cases (Proposal 20–5). For these purposes, the HGCA could make use of the new searchable online database of patents and published patent applications proposed in Chapter 9.

20.103 The membership, structure and proposed functions of the HGCA, as recommended by the ALRC and AHEC, make the HGCA potentially well equipped to perform the sort of monitoring and horizon-scanning work that is undertaken in the United Kingdom by the UK Human Genetics Commission and the Nuffield Council on Bioethics. There would be a synergy with the HGCA functions recommended in ALRC 96. For example, one of the roles of the HGCA is to 'identify genetic tests that have particular concerns or sensitivities attached to them, and thus may require special treatment'.[125]

20.104 In addition, the HGCA should advise and liaise with Commonwealth, state and territory health departments in relation to opposition to, and re-examination or revocation of, gene patents and obtaining access to patented inventions under the compulsory licensing or Crown use and acquisition provisions. Pending the establishment of the HGCA, AHMAC should undertake these roles, as the major policy making body on national health issues (Proposal 20–6).

20.105 Undertaking proceedings in respect to patent rights—whether it be through challenging the patentability of specific genetic materials or technologies, making application for revocation of a patent, or invoking Crown use—should be the province of individual health departments or related bodies. Health departments and other

125 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–3.

healthcare providers are the bodies most likely to incur liability for patent infringement where patented inventions are used in healthcare, or to take any financial advantage arising from a successful challenge to patent rights and, therefore, seem the most appropriate bodies to undertake patent proceedings. Neither the HGCA nor AHMAC (which have only advisory and policy making roles) are appropriate bodies to initiate and prosecute litigation involving patents in their own right.

20.106 However, strategies for patent negotiations or proceedings, or for the funding of proceedings, could usefully be coordinated at a national level, for example, through the Department of Health and Ageing or AHMAC, even though proceedings are ultimately taken by an individual health department or other body, such as a hospital or medical research institute.

Proposal 20–3 Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should actively consider whether to: request re-examination of a patent; initiate proceedings to oppose a patent; apply for revocation of a patent; apply for the grant of a compulsory licence; or exploit or acquire a patent under the Crown use and acquisition provisions of the *Patents Act 1990* (Cth) (*Patents Act*).

Proposal 20–4 Commonwealth, state and territory health departments should establish specialist offices to monitor and manage intellectual property issues relating to genetic materials and technologies. The offices should be staffed by qualified individuals who are capable of giving specialist legal and policy advice about intellectual property, biotechnology and human health. Health departments should also establish mechanisms to enable them to draw on expertise in other government departments and agencies to advise and assist them in dealing with intellectual property issues arising from gene patents.

Proposal 20–5 The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. In conducting such monitoring, the HGCA should have the following functions:

(a) providing information to IP Australia during the examination of a patent about the proper scope of the patent, in appropriate cases;

(b) liaising with AHMAC, health departments, and other relevant stakeholders about the advisability of opposition, re-examination or revocation of a patent under the *Patents Act*, and about who might take such action and in what circumstances; and

(c) liaising with AHMAC, health departments, and other relevant stakeholders about whether access to patented genetic inventions should be obtained under the Crown use, Crown acquisition or compulsory licensing provisions of the *Patents Act*.

Proposal 20–6 Pending the establishment of the HGCA, AHMAC should establish a mechanism for monitoring the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases.

21. Gene Patents and Healthcare Provision

Contents

Introduction

21.1 Gene patents may have an impact on the development and provision of healthcare involving medical genetic testing and novel therapies such as gene therapy, the production of therapeutic proteins, and the use of stem cells. This chapter focuses on the impact of patent laws and practices on medical genetic testing. In Australia and overseas, concerns about the impact of gene patents on healthcare have most often been expressed in relation to this aspect of healthcare.[1] This chapter also presents background information on factors affecting the availability and cost of medical genetic testing in Australia and describes the nature and extent of relevant patents.

21.2 IP 27 noted that there is a range of possible adverse consequences of existing patent laws and practices, including: monopoly control and the cost of testing; the quality of testing and medical practice; and innovation in the development of new or

1 A particular focus has been on gene patents over the BRCA1 and BRCA2 genes, mutations of which are implicated in the development of some forms of breast and ovarian cancer.

improved testing techniques. This chapter discusses these concerns and the ALRC's preliminary views in relation to them.

21.3 IP 27 asked a number of questions about the impact of gene patents on various aspects of healthcare provision and presented a number of options for reform. Submissions and consultations comprehensively addressed these issues. This chapter discusses the responses received by the Inquiry and the implications for reform of patent law and practice.

Medical genetic testing

21.4 This section briefly describes factors affecting the availability and cost of medical genetic testing in Australia. This background is necessary to understand the possible impact of patent laws and practices on the provision of medical genetic testing in the Australian healthcare system.

Availability of medical genetic testing

21.5 Medical genetic tests are generally ordered by medical practitioners. Some genetic testing may involve referral of the patient to a clinical geneticist as well as to a genetic counsellor for pre-test and post-test counselling. Genetic testing for research purposes may also be conducted in concert with medical practitioners, who liaise with participating patients.

21.6 Individuals generally cannot obtain direct access to medical genetic testing by laboratories in Australia. At present, most medical genetic testing is provided through state and territory clinical genetics services and the public sector laboratories associated with these services,[2] and individuals must be referred to them by a medical practitioner. However, the range of genetic testing available to the public is likely to expand in the future.[3]

21.7 The Human Genetics Society of Australasia (HGSA) maintains a register of medical genetic tests that are available in Australasia and a list of the laboratories that provide them. According to the HGSA, there are presently around 220 medical genetic tests available from 44 laboratories across Australia.[4] Some genetic tests offered overseas are not available in Australia. Likewise, some types of tests offered in Australia are not available, or not widely performed, in other countries.

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2 Of those laboratories listed on the HGSA's website as offering diagnosis of genetic disorders, 81% were located in public hospitals (as at November 2002): D Nicol, 'The Impact of Patents on the Delivery of Genetic Tests in Australia' (2003) 15(5) *Today's Life Science* 22, 25.

3 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [11.50]–[11.63].

4 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html> at 19 February 2003. Not all tests are available from all laboratories. The register does not include newborn screening laboratories.

21.8 A range of factors, other than patent laws and practices, affect the availability of medical genetic testing. These include cost, whether the test is listed on the Medicare Benefits Schedule (MBS), the level of funding provided for testing by state and territory governments, technical and ethical standards, laboratory protocols and accreditation, and regulation of testing provided direct to the public (rather than through a medical practitioner).[5]

21.9 The availability of genetic testing in Australia may be dependent on decisions about which tests are ethically acceptable,[6] and on a cost-benefit analysis of a particular test. Medical genetic testing is still a relatively slow and expensive process. However, the technology is advancing rapidly. The development of automated 'DNA chip' technology[7] may soon make it technically possible and financially practicable to test for numerous genetic mutations simultaneously in a single procedure.

21.10 The availability of a genetic test in a particular laboratory may also reflect the research interests of that laboratory. For example, a laboratory that undertakes research into a particular genetic disease might also offer, as part of its research work, a diagnostic service for that disease.

Cost of medical genetic testing

21.11 As with other health services, access to medical genetic testing depends on the cost to consumers of testing procedures and on the rebates provided by public and private health insurers.

21.12 The cost of genetic testing procedures varies, from less than $100 to more than $1000, depending on a number of factors including the complexity and methodology of the testing procedure.[8]

21.13 In 2002, a report by the Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (the OECD Working Party on Biotechnology Report) noted factors that may affect the cost of medical genetic tests:

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5 In ALRC 96, the ALRC and the Australian Health Ethics Committee (AHEC) made a number of recommendations with implications for the future availability of medical genetic testing. These included recommendations: for the enactment of new legislation to require laboratories that conduct genetic testing to be accredited; to amend the *Therapeutic Goods Act 1989* (Cth) and regulations to enable the Therapeutic Goods Administration to regulate more effectively genetic testing products provided directly to the public; and for the development of genetic testing and counselling practice guidelines, which identify genetic tests, or categories of genetic tests, requiring special treatment in relation to procedures for ordering, testing and ensuring access to genetic counselling. See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 11–1, 11–5, 23–3.

6 For example, predictive testing of minors for late onset disorders (such as Huntington's disease) may be considered unethical.

7 Also known as 'gene chips', 'biochips' and 'DNA microarrays'.

8 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [10.20]–[10.21].

> Creating economies of scale may help reduce costs in the long term, but … certain pressures are likely to increase prices. In particular, the need for more and higher-quality epidemiological and genetic population data, increasing regulatory costs, including stricter quality assessment and quality control requirements, laboratory certification costs, increased needs for counselling, and, potentially, liability costs can push up the price of tests.[9]

21.14 In Australia, depending on the test and the laboratory, testing may be free to the patient or fees may be charged.[10] In some cases, genetic testing is funded by Medicare. However, Medicare funding is limited in its coverage. The MBS currently funds medical genetic testing under only six MBS items (see Chapter 20).

Patents and medical genetic testing

21.15 Patents may be granted over isolated genetic material that has been separated from the human body or manufactured synthetically, provided the patent application satisfies the threshold tests for patentability.[11] Genetic sequences in this material provide the basis for diagnostic tests—that is, mutations in genes can be detected by testing techniques based on knowledge of the genetic sequence.

21.16 Patents may be granted over isolated genetic material or over methods or products used in testing for mutations in a gene or genetic sequence. For example, a United States company, Myriad Genetics Inc (Myriad), holds patents internationally on isolated genetic materials associated with breast and ovarian cancer.[12] Myriad's patents also cover methods for predictive testing[13] and products and processes involved in its breast cancer predisposition test, which is called 'BRACAnalysis'. Similarly, another United States company, Bio-Rad Laboratories, holds patents on isolated genetic materials associated with hereditary haemochromatosis covering isolated genetic materials and methods for testing.[14]

21.17 A patent that asserts rights to isolated genetic material *per se* may cover all uses of that material. These uses often include diagnostic or predictive testing for genetic conditions. For example, Myriad is said to have a dominant patent position covering the use of the BRCA1 genetic sequence for predictive testing relating to breast and

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9 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 71.

10 See D Nicol, 'The Impact of Patents on the Delivery of Genetic Tests in Australia' (2003) 15(5) *Today's Life Science* 22, Table 2.

11 See Ch 6.

12 In the United States: US 5753441; in Australia: AU 691958, AU 686004 and AU 691331. As discussed below, Myriad has granted an exclusive licence in Australia and New Zealand relating to predictive genetic testing for breast and ovarian cancer to Australian biotech company Genetic Technologies Limited.

13 See M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20, 21–23.

14 In the United States: US 5705343; US 5712098; US 5753438; in Australia AU 733459. A list of United States and equivalent Australian patents associated with medical genetic testing can be obtained from D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, Table 1.

ovarian cancer.[15] In other words, any technique for BRCA1 testing is likely to require use of Myriad's patents.

21.18 Patents may be granted on general methods for identifying genetic sequences, mutations or deletions in an individual's genetic sequence. For example, United States patents for the process known as polymerase chain reaction (PCR), which enables the DNA from a genetic sample to be reproduced in large quantities for testing, were granted to Cetus Corporation in 1989, and assigned in 1991 to Roche Diagnostics.[16]

21.19 Genetic testing that is protected by patents asserting rights over isolated genetic material and the use of genetic sequences in diagnostic or predictive testing has been the subject of most concern. The possible adverse effects of such patents on healthcare provision are discussed in more detail below. It has been stated that such patents may confer on the owner of the patent

> not only a monopoly on their own diagnostic methods, but also the ability to prevent others from competing with them through the development of improvements in the diagnostic methods, using the same DNA sequence.[17]

21.20 As noted above, there are about 220 medical genetic tests available in Australia.[18] Many of these medical genetic tests, particularly the common ones, are likely to be subject to patents on isolated genetic materials.[19] Recent research conducted in the United States confirms that 12 common genetic tests are subject to United States patents.[20] Research conducted by Dr Dianne Nicol and Jane Nielsen (the Nicol-Nielsen Study) confirms that most of these United States patents have equivalent Australian registered patents or patent applications.[21]

21.21 The ALRC understands that these patents generally include claims over isolated genetic materials containing sequences that code for proteins. However, patents over methods for using so-called 'junk' or non-coding genetic sequences are also relevant to

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15 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 33.

16 A division of F Hoffmann-La Roche Ltd: Roche Diagnostics, *Roche Molecular Diagnostics Patents Portfolio*, <www.roche-diagnostics.com/ba_rmd/patent_list.html> at 11 June 2003.

17 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 48.

18 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html> at 19 February 2003.

19 Research conducted by the Centre for Law and Genetics reveals that over 40% of the diseases listed in the HGSA-listed medical genetic tests appear in the titles of patent applications filed with the Australian Patent Office: D Nicol, 'The Impact of Patents on the Delivery of Genetic Tests in Australia' (2003) 15(5) *Today's Life Science* 22.

20 Including in relation to genes associated with Alzheimer's disease (Apo E); hereditary breast and ovarian cancer (BRCA1, BRCA2); Duchenne/Becker muscular dystrophy; hereditary haemochromatosis; myotonic dystrophy; Canavan disease; spinocerebellar ataxia; adenomatous polyposis; Charcot-Marie-Tooth Disease type 1A; Fragile X syndrome; Huntington's disease; and Factor V Leiden: M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3, 6.

21 See D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, Table 1.

medical genetic testing. The use of non-coding genetic sequences is integral to medical genetic testing because they are used to design primers for PCR assays.

Enforcement of patents and medical genetic testing

21.22 The most publicised instance of a patent holder seeking to enforce rights to isolated genetic materials used in medical genetic testing is that of Myriad and the BRCA1 and BRCA2 patents associated with testing for pre-disposition to breast and ovarian cancer.[22] Myriad has sought to enforce its patent rights against Canadian provincial health authorities.[23] In the United Kingdom, the Department of Health has entered into an agreement with Rosgen Limited, the exclusive licensee of the Myriad patents in the United Kingdom. Rosgen went into liquidation and the Department of Health remains in negotiation with Myriad.[24] Myriad's patents are being opposed in Europe[25] and have led to calls for patent law reform in France and Canada.[26]

21.23 In the United States, research indicates that gene patent holders are actively enforcing their rights against laboratories.[27] A national survey of laboratory directors found that 65% of respondents had been contacted by a patent or licence holder regarding the laboratory's potential infringement of a patent through the performance of a genetic test.[28] Thirty laboratories (25% of those surveyed) reported that they had been prevented by patent considerations from performing a medical genetic test that they had developed.[29]

21.24 In contrast, the results of a 2002–2003 survey of Australian laboratories that perform medical genetic testing found that, compared with the United States, there was 'little indication that holders of patents related to disease genes were actively enforcing their patents against Australian genetic test laboratories'.[30]

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22 In Australia, Cancer Research Centre Technologies Limited and Duke University have filed for patent protection on the BRCA2 genetic sequence. This patent application has been challenged by Myriad: M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20, 23.

23 As of mid-2002, all but one Canadian province (British Columbia) had decided to continue to provide genetic testing that might infringe on patents granted to Myriad: R Gold, 'Gene Patents and Medical Access' (2000) 49 *Intellectual Property Forum* 20, 23. British Columbia resumed testing in February 2003: British Columbia Government Decision to Ignore Myriad Patent', *CanWest News Service*, 16 February 2003.

24 M Llewelyn, *Intellectual Property Rights on Public Healthcare: A UK Response* (2003).

25 See Institut Curie and Assistance Publique Hopitaux de Paris and Institut Gustav-Roussy, *Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer Associated with the BRCA1 Gene* (2002).

26 See R Gold, 'Gene Patents and Medical Access' (2000) 49 *Intellectual Property Forum* 20, 23.

27 M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

28 Ibid, 5.

29 Ibid, 5.

30 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 201. The survey was based on questionnaires sent to laboratories listed on the HGSA website in November 2002, and on a supplementary telephone survey conducted in March–April 2003: See D Nicol and J Nielsen, *Patents and*

21.25 Eleven respondent laboratories reported payments of licence fees or royalties with respect to genetic testing. However, nine of these payments were royalties for the use of Taq polymerase in PCR and the other two involved the use of another reagent and a test kit.[31] Only eight laboratories had received notifications from patent holders (or licensees) about the existence of patents, and almost all of these were related to PCR.[32]

21.26 Consultations confirmed that, while there is a high degree of concern about the potential impact of patents over isolated genetic materials on public sector laboratories, enforcement by patent holders has been limited.[33] The ALRC understands that Australian public sector laboratories currently do not pay licence fees for the use of isolated genetic materials in medical genetic testing, and generally have not been approached by patent holders seeking to enforce their rights over such materials. The situation is different with respect to gene patents over genetic technologies, such as PCR, where royalties are commonly paid, often as part of the purchase price of equipment or consumables.[34]

21.27 There has been much conjecture about the future enforcement of gene patents against public sector laboratories. Much of this conjecture has concerned patents held by Australian biotechnology company Genetic Technologies Limited (GTG). There are two sets of patents involved. The first set of patents is the patents associated with testing for pre-disposition to breast and ovarian cancer (the BRCA patents). The second set of patents is patents on methods of using non-coding DNA polymorphisms (the non-coding patents).[35]

21.28 In May 2003, Myriad granted GTG an exclusive licence in Australia, New Zealand and South East Asia relating to predictive genetic testing for breast and ovarian cancer using the BRCA patents.[36]

21.29 GTG has stated publicly that the rights it has obtained from Myriad for breast cancer testing 'will not be enforced against other health service providers in Australia

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Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry (2003) Centre for Law and Genetics Occasional Paper No 6, 67.

31 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 200–201.

32 Ibid, 201, Table 18.

33 Department of Human Services (Vic), *Consultation*, Melbourne, 3 September 2003; New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003.

34 Issues relating to the enforcement and licensing of gene patents are also discussed in Ch 9 and 14.

35 Sometimes referred to as GTG's 'intron sequence patents'.

36 Genetic Technologies Limited, 'Genetic Technologies and Myriad Genetics Announce Strategic Licensing Agreement', *Press Release*, 28 October 2002, <www.gtg.com.au/Announcements2002.html>. As part of this arrangement GTG granted Myriad a non-exclusive licence for the use of GTG's non-coding patents.

and New Zealand'.[37] In July 2003, GTG reiterated that it did not intend to enforce the BRCA patents and confirmed that it has allowed the existing public hospital cancer genetics laboratories in both Australia and New Zealand to continue to perform tests on the BRCA genes unhindered.[38]

21.30 The position is different with regard to enforcement of the non-coding patents. In March 2003, GTG advised public sector laboratories in Australia and New Zealand that they would need to negotiate licences in relation to its non-coding patents.[39] GTG claimed that its non-coding patents may be infringed by medical genetic testing for a range of genetic conditions, including cystic fibrosis, Duchenne muscular dystrophy, Friedreich's ataxia, fragile X syndrome, haemophilia, myotonic dystrophy and prothrombin (Factor II). In the United States, a major biotechnology company, Applera Corporation, is facing an infringement action for refusing to obtain a licence to use GTG's non-coding patents for, among other things, a diagnostic test for cystic fibrosis.[40]

21.31 There is growing concern in Australia about the possibility that gene patent holders and licensees might enforce their patents against medical genetic testing laboratories. However, actual enforcement activity remains more limited than in the United States. Nicol and Nielsen comment:

> Could Australian testing laboratories face demands for licence fees from a number of different patent holders in the future? The small size of the Australian market suggests that it may not be worthwhile for foreign companies to pursue Australian laboratories. In addition, most laboratories are in public hospitals and many do not charge for their services, further suggesting that there may be little financial incentive in targeting them.[41]

The need for patents on medical genetic testing

21.32 An important justification for patent law is to provide an incentive to invest in the research and development of new products by providing a limited monopoly on the manufacture, use or sale of the patented invention. In the context of medical genetic testing, patent rights may be justified if they encourage investment in research that leads to the development of new, clinically useful, medical genetic tests.

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37 Genetic Technologies Limited, 'Genetic Susceptibility Testing: A Third Progress Report', *Press Release*, 22 May 2003, <www.gtg.com.au/Announcements.html>. See Ch 9 for a discussion of the possible effect of such a declaration in creating an estoppel.

38 Genetic Technologies Limited, 'Letter from GTG to Medical and Scientific Colleagues', *Press Release*, 21 July 2003, <www.gtg.com.au/Announcements.html>.

39 See also Genetic Technologies Limited, 'Licensing the "Non-Coding" Patents: A Third Report to the ASX', *Press Release*, 2 April 2003, <www.gtg.com.au/Announcements.html>.

40 Z Moukheiber, 'Junkyard Dogs', *Forbes Magazine*, 29 September 2003.

41 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 203.

21.33 An incentive, in the form of the patents, may be required for the development of some medical genetic tests.[42] IP 27 noted that even some of the most outspoken critics of gene patents concede that, in some cases, it may require significant effort to convert a known genetic sequence into a reliable and clinically useful medical genetic test. The Nicol-Nielsen Study found that some individuals who work in public sector laboratories have a positive view of the impact of patents on medical genetic testing, depending on what the patents are and how they are exploited.[43]

21.34 It has been suggested that patent law incentives may not be as necessary to the development of genetic tests as they are to the development of other therapeutic goods, notably drugs. Professor Lori Andrews has argued that, while proponents of gene patents have tried to justify such patents by reference to arguments in favour of patenting drugs, drug patenting is not the appropriate analogy:[44]

> The discovery of genes does not require the same incentives as drug development. Molecular biologists were attempting to identify genes long before the [USPTO] made it clear that genes could be patented. Moreover, there are no expensive clinical trials when a gene is discovered and knowledge about the sequence of the gene is used to identify whether a particular patient has a mutation in that gene. In some cases, a disease gene has been identified one day and testing begun almost immediately.[45]

21.35 Andrews has also noted that gene patents may have negative effects, not present in the case of patented drugs or medical devices. While other researchers can create alternatives to patented drugs or medical devices, 'there are no alternatives to the patented human genes in genetic diagnosis and gene therapy'.[46]

21.36 A recent study of clinical laboratories in the United States found that laboratories are able to translate published data into clinical tests quickly, without the incentive provided by patents.[47] The study suggested that

> patents are not critical for the development of an invention into a commercially viable service when the invention is the finding of an association between a genetic variant and a particular condition.[48]

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42 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 51.

43 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 202.

44 L Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 77–79.

45 Ibid, 77–79. This was the case with testing for haemochromatosis. See J Merz and others, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577. However, medical genetic tests may require regulatory approval prior to marketing.

46 L Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 78–79.

47 M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3, 9. See also D Leonard, 'Medical Practice and Gene Patents: A Personal Perspective' (2002) 77 *Academic Medicine* 1388.

48 M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3, 9.

21.37 One view is that gene patents on genetic sequences associated with disease are unnecessary because such patents are 'an end in themselves':

> No further development is generally needed for dissemination among medical practitioners, and broad adoption [of testing] often follows first publication by only a short time. Moreover, these patents are not necessary to promote downstream development of therapeutics; in fact they may stifle such development by restraining competition.[49]

21.38 IP 27 asked whether gene patents are necessary to encourage investment in research that leads to the development of new, clinically useful, medical genetic tests.[50] In response, the HGSA noted that many genetic tests are not expensive to develop and, for some tests, the costs involved in determining the gene sequence 'are not the issue'. Instead, the real expense 'relates to the cost of developing the platform that is used to perform the test eg sequencing or array technology or meeting regulatory requirements prior to marketing'.[51] The HGSA and others doubted whether patents are necessary to the development of new genetic tests.[52] The HGSA stated:

> This has certainly not been the case in the past. Numerous gene discoveries have been driven by the wish to find the cause of a disorder, to understand it and to improve treatment, rather than to profit financially from the discovery. They have often been funded by the public sector through the standard funding channels. The possibility of patenting was not an issue and indeed, many of the patents taken out have never been enforced. Sometimes the patent has been taken out to protect the innovation from commercialisation.[53]

21.39 In this context, the Royal College of Pathologists of Australasia (RCPA) contrasted medical genetic tests with other medical tests. As many tests can be easily copied, patent protection allows companies to prevent 'free-riding' but, according to the RCPA, this rationale for patent protection does not necessarily apply to genetic tests:

> The vast majority of diagnostic genetic laboratories develop tests 'in house' using genetic sequences freely available form public domain databases and publications as well as equipment and reagents obtained from commercial suppliers … Most clinically useful genetic tests, therefore, are presently based on discoveries made by public institutions and involve payment of appropriate royalties for use of patented reagents and methods.[54]

21.40 Other submissions were clear about the importance of patents to genetic testing research and development, and focused on the role of patents in facilitating the

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49 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 325.

50 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 12–5.

51 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

52 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003.

53 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

54 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

development of research results into usable tests or therapeutics.[55] For example, GlaxoSmithKline observed that

> if improved technologies and hardware, faster or less laboratory-bound tests (e.g. tests which may be performed in the GP's surgery without [the] sample being sent away) are to be developed, this will require significant investment. If it is thought desirable for the testing industry to advance, rather than to continue using basic (home brew) tests only then patenting will be essential.[56]

21.41 Some submissions contested the idea that the time and cost needed to develop new genetic tests may mean that the incentive of patent protection may not be as essential as in other fields of biotechnology. Dr Amanda McBratney and others submitted:

> just because a process is not costly does not mean it does not need, or should be excluded from, the incentives provided by the patent system. Monetary rewards for costly activities are not the only incentive provided by the patent system … Other incentives provided by the patent system are to encourage others to participate in inventive activity and, importantly, to disseminate full details of the invention to the public for free use upon expiry of the patent.[57]

21.42 GlaxoSmithKline observed that limiting patent protection by reference to the amount of effort, time or expenditure that is incurred would be to 'reward inefficiency' and penalise the 'flash of inspiration' that sometimes leads to important inventions.[58]

Impact of gene patents on medical genetic testing

21.43 There has been worldwide concern about the possible adverse consequences of existing patent laws and practices on the provision of healthcare. In Australia, concern about the effect of gene patents on health and the healthcare system led to the establishment of an Australian Health Ministers' Advisory Council (AHMAC) Working Group on Human Gene Patents (AHMAC Working Group).

21.44 The AHMAC Working Group concluded that any attempt to enforce exclusive control over BRCA1 testing raised issues including: the financial impact of an increase in testing costs; the effects on clinical priorities and resource allocation for genetic testing; the effects on compliance with best practice guidelines for conducting genetic testing and genetic counselling; the provision of incomplete testing by patent holders while restricting others from providing testing; and the potential to hinder innovation

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55 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

56 GlaxoSmithKline, *Submission P33*, 10 October 2003.

57 Ibid.

58 Ibid.

and research.[59] Similar concerns have been expressed in position statements on gene patents prepared by the HGSA and the RCPA.[60]

21.45 The following section describes concerns about the impact of patent laws and practices on medical genetic testing and asks about the extent to which these concerns apply to the Australian healthcare system. Many of these concerns are traceable to concerns about monopoly control of genetic testing. The section thus begins by discussing monopoly control and then examines the effects of this on:

- the cost of medical genetic testing;
- access to public sector testing and related services;
- access to genetic counselling;
- the quality of medical genetic testing;
- the professional relationships between medical practitioners and laboratory scientists; and
- the further development of medical genetic testing.

Monopoly control and competition

21.46 In the case of medical genetic testing, any test for a gene or genetic sequence associated with a genetic condition needs to identify a mutation in the relevant sequence in the individual being tested. This requires the use of the genetic sequence of the normal gene, as well as that of the mutation. Where the genetic sequence is contained in patented genetic material, the use of the sequence in genetic testing may constitute an infringement of patent rights, unless a licence is obtained from the patent holder or testing is conducted through another licensee.

21.47 The patent holder (or an exclusive licensee) may exercise monopoly control over a particular genetic test by licensing a single service provider. Alternatively, a number of laboratories may be licensed to perform the test. The factors that influence the market structure for genetic testing have been said to include the following.

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59 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 3. In accordance with the key recommendation of the AHMAC Working Group report, an AHMAC Advisory Group on Human Gene Patents and Genetic Testing was established in May 2002. The AHMAC Advisory Group will advise and make recommendations to AHMAC on matters relating to the planning, management, regulation, provision and delivery of human genetic testing and screening services, for the purposes of the diagnosis, prevention and treatment of human disease and the improvement of human health.

60 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001); Royal College of Pathologists of Australia, *Position Statement: Patenting of Human Genes* (2001).

- The number of patents related to a test. One or few patents will favour monopolisation. Several patents held by different patent holders may lead to limited cross-licensing, which can create an oligopoly.

- The complexity of a test. Where any laboratory can quickly develop and validate a clinically useful test, this will favour open competition and make it harder to enforce any patent rights.

- The prevalence and penetrance of the genetic disease related to a test. Larger demand by healthcare consumers will favour broader licensing. However, providers may only be willing to develop a test for a rare condition if enough testing volume can be generated to make it commercially viable, including by enforcing monopoly patent rights.[61]

21.48 Particular concerns have been expressed about exclusive licensing of gene patents relating to genetic testing.[62] In this chapter, 'exclusive licensing arrangements' refers to situations where the patent holder grants exclusive rights to one licensee to exploit the patent for the purposes of medical genetic testing. The exclusive licensee may require that all testing, regardless of its geographical origin, be performed at a single laboratory. At least in the United States, exclusive licensing of gene patents for medical genetic testing is common[63]—the BRCA patents being a notable example, where all testing must be done by Myriad.

21.49 While a patent grants a patent holder the right to exclude or control the exploitation of a patented invention by others for the term of the patent, patents do not inevitably lead to monopolies. Patents may promote competition if the goods and services created pursuant to a patent compete with other like goods and services. The relationship and tension between patent and competition law is discussed in Chapter 24.

21.50 IP 27 asked whether existing patent laws and practices favour the development of genetic testing monopolies in Australia and, if so, whether reforms are needed to address this situation.[64]

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61 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 325–326. Because it is inefficient to send samples to different laboratories in order to test for different mutations on the same gene, gene patents may help create an effective monopoly over genetic testing for unpatented DNA sequences. Merz states that this has occurred with testing for Charcot-Marie-Tooth disease. He notes that a monopoly is also favoured because it may 'be malpractice to test for the most prevalent mutation without testing for the patented ones'.

62 See the discussion of patent licensing in Ch 23.

63 J Merz and others, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577, 578.

64 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 12–1.

21.51 Some submissions stated that, even if patent and other intellectual property laws favour the development of monopolies in medical genetic testing, this is not necessarily detrimental to society.[65] For example, GlaxoSmithKline stated:

> The time limited exclusive rights conferred by patents are justified because of the advantages they bring in terms of dissemination of knowledge and the incentive to innovate. The fact that genes and genetic tests are patentable incentivises investment in the development and exploitation of such tests.[66]

21.52 Patent law is only one of many factors that may contribute to monopolistic behaviour.[67] The OECD Working Party on Biotechnology Report noted that:

> licence exclusivity may be necessary to make a genetic testing service economically viable, depending on the market and the rarity of the disease … highly complex and specialised tests are more likely to be licensed exclusively. Only high volumes and automation allow genetic testing companies to achieve economies of scale and reduce costs for such tests. Given the competition from academic institutions and hospitals as well as other firms, genetic testing companies may have difficulty creating economies of scale.[68]

21.53 In the Australian context, GTG stated that the size of markets in medical genetic testing will be the most significant factor in determining their structure.[69] Associate Professor Agnes Bankier observed that:

> Whilst national/state reference laboratories for rare disorders are highly desirable for cost-efficient service delivery this is not the case for more common conditions where the commercial concerns are the driver for high throughput testing which may be detrimental to the health care system.[70]

21.54 IP 27 noted that one view is that commercial pressures are leading patent holders to develop new strategies and business models for the exploitation of their inventions for the purpose of taking 'maximum advantage of the very broad claims often included in patents relating to human genes and functional genetic sequences'.[71]

21.55 In this context, submissions highlighted particular characteristics of genetic testing that favour monopolies. For example, Dr Graeme Suthers stated that:

> Current patent practices in Australia do favour the development of genetic testing monopolies. If a patent-holder is granted an exclusive right to analyse a gene, that

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65 GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

66 GlaxoSmithKline, *Submission P33*, 10 October 2003.

67 A McBratney and others, *Submission P47*, 22 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

68 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 71.

69 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

70 A Bankier, *Submission P19*, 30 September 2003.

71 I Walpole and others, 'Human Gene Patents: The Possible Impacts on Genetic Services Health Care' (2003) 179 *Medical Journal of Australia* 203, 203.

> decision provides a strong incentive to monopolise the testing of that gene. The high cost of genetic testing equipment necessitates high throughput to keep the cost-per-test manageable. The natural consequence is to centralise testing at one facility. This is not a good move. Medical testing by any means requires transparency and accountability, and this cannot be achieved with a monopoly.[72]

21.56 The HGSA submitted that the 'ease of developing genetic tests and the ease with which substantial profits can be made is an incentive to use the monopoly rights that come with a patent'. The HGSA expressed concern that patents may provide:

> a monopoly over all uses of the gene, thus potentially affecting both healthcare services and research. The nature of the monopoly created is of particular concern as it relates to totally new products entering the healthcare market. This is not simply an improvement to a device already in the medical health market. Rather, we are talking about genetic tests that have not existed before and have great utility for healthcare. The potential of patents to create 20 year monopolies over all uses of a gene sequence is of great concern in that setting.[73]

21.57 Many submissions focused on the possible adverse effects of monopoly genetic testing on healthcare. For example, the Cancer Council Australia stated:

> One of the key concerns with the use of gene patents is the risk of the creation of monopolistic genetic health services which are able to dictate the costs of genetic tests to patients, the availability of such tests and timely access to services. Such a situation could occur where a gene patent limits diagnostic testing to only specified licensed tests and no others are permitted by the patent holder.[74]

21.58 While it was thought acceptable that patents 'favour a time-limited monopoly', the Walter and Eliza Hall Institute of Medical Research submitted that:

> The problem is with generic technology or tool patents with broad claims that impinge on every genetic test so that the monopoly is extended to multiple applications each of which requires further innovative steps that are not fully rewarded.[75]

21.59 The South Australian Government stated that the 'one-to-one' relationship between gene patents and disease, which is not the case for other biotechnology patents, poses particular problems:

> An in-house test which is an alternative to a patented test can be used legally as it is not subject to licence or royalty fees provided the method used is different from any patented method. However, where a gene is subject to a patent, low cost in-house tests cannot be legally used without compensating the patent holder.[76]

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72 G Suthers, *Submission P30*, 2 October 2003.
73 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
74 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.
75 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.
76 South Australian Government, *Submission P51*, 30 October 2003.

21.60 The RCPA emphasised that the RCPA, the HGSA and the American College of Medical Genetics all recommend that 'diagnostic genetic tests' be 'broadly and non-exclusively' licensed.[77] The RCPA submitted that monopolistic genetic testing is 'fundamentally wrong' because of its effects on equitable access to healthcare and innovation in testing.[78]

21.61 Many other submissions expressed concerns about patents promoting medical genetic testing monopolies and the consequences for healthcare.[79] Specific concerns about the effects of patents on medical genetic testing, including those said to derive from monopoly testing, are discussed in more detail throughout this chapter.

Cost of medical genetic testing

21.62 If access to medical genetic testing is severely restricted by patent laws and practices, the implications for healthcare can be serious. People may die if they are not identified as susceptible to serious but preventable genetic diseases, such as some breast, ovarian or colon cancers. Children may be born with incurable inherited diseases.[80] On the other hand, if patent rights are a necessary incentive for the development of medical genetic tests, the absence of patent rights may also have serious implications if important medical genetic tests are not developed and made available.

21.63 Once a test is available, the cost of medical genetic testing is an important factor affecting access to testing. One consequence of patent rights is that genetic tests may be more expensive. The extent of any increased cost will depend on many factors, including the licensing model used by the patent holder.

21.64 Submissions and consultations reflected concern about the impact of monopoly control on the cost of genetic testing to patients and the healthcare system, and about cost limiting access to medical genetic testing.[81] For example, the HGSA stated that:

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77 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

78 Ibid.

79 R Edson, *Submission P9*, 23 September 2003; Children's Cancer Institute Australia for Medical Research, *Submission P13*, 30 September 2003; D McAndrew, *Submission P14*, 30 September 2003; Australian Huntington's Disease Association (NSW) Inc, *Submission P27*, 1 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Cancer Foundation of Western Australia Inc, *Submission P34*, 10 October 2003; A Bankier, *Submission P19*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Genetic Support Council WA (Inc), *Submission P59*, 7 November 2003.

80 For example, in relation to United States screening programs for Canavan disease, a serious and incurable neurological disorder: see L Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 91–92.

81 Cancer Council of New South Wales, *Submission P1*, 5 June 2003; Cancer Voices NSW Inc, *Submission P7*, 16 September 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; D McFetridge, *Submission P23*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Australian Huntington's Disease Association (NSW) Inc, *Submission P27*, 1 October 2003; G Suthers,

> Gene patents are likely to inflate prices, though their precise impact is not yet known. There is clearly a potential for patent holders to charge exorbitant prices for genetic testing kits or licences when the cost of gene discovery and kit development is not that great (certainly not as great as drug and other treatment development) … In contrast, when no patent is involved, once a gene's sequence is known and published, it becomes possible for laboratories around the world to develop the test quickly and cheaply and to improve on it over time. This results in rapid access to tests at minimum cost.[82]

21.65 The RCPA stated that royalties affect the cost and availability of clinical diagnostic testing and noted:

> These are often in addition to substantial up front payments for permission to perform the test. Mostly the royalty fees are modest (eg $US20 for haemochromatosis testing). Of particular concern is the effect of multiple royalty payments on a single gene or royalty payments on multiple genes being tested for in certain ethnic groups. Such 'royalty stacking' occurs for laboratories that offer a panel of tests such as those for the Ashkenazi Jewish population, including testing for Tay-Sachs disease, Gaucher's disease, Niemann-Pick Disease and Canavan's Disease.[83]

21.66 The BRCA patents have often been used to illustrate concerns about the future cost of genetic testing in Australia. IP 27 noted that, in 2001, the AHMAC Working Group estimated that if testing for the BRCA1 gene were to be performed by Myriad rather than by Australian public health system laboratories, the cost of such testing would rise from between A$1.2 and A$2 million to A$4.5 million per annum.[84] The Department of Health Western Australia stated that:

> Myriad charges AUD$4800 for tests that are conducted in local laboratories in Western Australia for AUD$1300-1800 (although, currently in Australia, costs are met by government funding).[85]

Submission P30, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; South Australian Government, *Submission P51*, 30 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

82 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003. Improvements in testing may themselves be patented.

83 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

84 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 11. This estimate assumed that the cost of each test would rise from A$1,200–2,000 to US$2,400. Similar estimates of the potential increased cost have been made elsewhere. For example, in 2002 the French Institut Curie stated that tests performed by Myriad cost €2,744 compared with an estimated cost of €914 for testing in other laboratories, and that testing French patients through Myriad could cost an additional €5.5 million per annum: Institut Curie and Assistance Publique Hopitaux de Paris and Institut Gustav-Roussy, *Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer Associated with the BRCA1 Gene* (2002), 6. As at 30 June 2002, Myriad stated that the price of its BRCA1 and BRCA2 test was $US2,760: Myriad Genetics Inc, *United States Security and Exchange Commission Form 10-K*, United States Security and Exchange Commission, <www.sec.gov> at 5 November 2003.

85 Department of Health Western Australia, *Submission P53*, 3 November 2003. The Department also noted that, in the United States, the patent holder for haemochromatosis testing was asking US$2,500 and

21.67 In the event, no such increase in the cost of providing BRCA1 and BRCA2 testing has eventuated. As discussed above, GTG—the exclusive licensee of the BRCA patents in Australia—has elected not to prevent public sector laboratories from continuing to provide testing.

21.68 There are reasons to doubt that cost increases of this scale would be likely to eventuate, were patents on medical genetic testing to be enforced. The Department of Industry, Tourism and Resources (DITR) stated:

> The assumption that patented medical tests will always be excessively priced is not supported by available facts. Companies' pricing considerations are part of a long term business strategy and include considerations such as market acceptance and market share.[86]

21.69 One view expressed in consultations was that, given relevant differences in markets for medical genetic testing, it was always unlikely that Myriad would have sought to charge a similar price in Australia as in the United States for the use of BRCA1 and BRCA2 testing.[87] Further, the ALRC understands that GTG is able to offer BRCA testing conducted in its Melbourne laboratory for a lower price than that charged by Myriad in the United States, and anticipates that future costs will be reduced further through investment in new robotic technology.[88]

21.70 A number of submissions expressed concern about increases in the cost of medical genetic testing attributable to future enforcement of GTG's non-coding patents.[89] As discussed above, the position with regard to the enforcement of these patents remains uncertain.

Access to public sector testing and related services

21.71 Leaving aside issues directly relating to cost, concerns have also been expressed about the implications of patents for other aspects of access to testing and related healthcare services, such as clinical advice and genetic counselling. IP 27 asked about these implications.[90]

21.72 In submissions and consultations, access issues were most often raised in relation to the viability of public sector genetic testing and related services.[91] For

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US$25,000 for licence fees from academic laboratories and commercial laboratories, respectively. See J Merz and others, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577.

86 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

87 Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003.

88 Genetic Technologies Limited, *Consultation*, Melbourne, 5 September 2003.

89 New South Wales Health Department, *Submission P37*, 17 October 2003. Such concerns were frequently raised in consultations: New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003; Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.

90 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 12–2.

91 Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Human Genetics Society of Australasia, *Submission*

example, Breast Cancer Action NSW stated that patent law should be amended to ensure that existing public genetic testing facilities are not adversely affected by the establishment of private testing services:

> The present system, which ensures access to best practice and comprehensive genetic services must be protected in the public interest. Access to private services should be an alternate option.[92]

21.73 The Cancer Council Australia expressed concern that monopoly provision of medical genetic testing would have adverse ramifications for the public health system:

> by enabling some health providers with sole control over testing for several genetic conditions to dominate the market. Equally it places the public health system at a significant disadvantage in terms of providing genetic testing as part of a subsidised health care system.[93]

21.74 The Department of Health Western Australia stated that, where genetic testing monopolies exist:

> Publicly funded genetic services will still be required to provide other non-patented and thus not commercially attractive tests, as well as counselling and clinical services, compromising their budgetary capacity to maintain viability and expertise.[94]

21.75 A specific focus of concern was on the possible diversion of expertise from public sector testing facilities.[95] IP 27 noted suggestions that access to public sector genetic testing may be affected adversely if private laboratories are able to 'cherry-pick' profitable genetic tests or divert professional expertise away from public sector laboratories.

> Gene patents threaten to disrupt the public laboratory services in Australia, by diverting selected commercially viable gene tests from the public sector to private laboratories and impacting the viability of public sector testing of the other disease genes.[96]

21.76 The HGSA's 2001 position statement noted that exclusive licensing of genetic testing could result in irreplaceable loss from the public sector of a large part of its genetic testing workload and, as a consequence, of its genetic testing skills and

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P31, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

92 Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003.

93 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

94 Department of Health Western Australia, *Submission P53*, 3 November 2003.

95 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

96 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 6.

molecular genetics expertise.[97] Further, in the event that a sole licensee for a genetic test were to cease to operate, this could result in Australia being left without an expert testing service, at least for a time.[98]

21.77 The HGSA re-emphasised these concerns in its submission to the Inquiry.[99] Similarly, Dr Suthers observed:

> There is a limited number of genetic scientists in Australia who currently provide genetic testing in public sector laboratories. The scientists provide both a diagnostic service and act as [an] expert resource for other scientists and clinicians in the hospitals. If genetic testing moves to private sector laboratories, then these scientists will have to leave the public laboratories. The indirect impact in terms of genetic expertise in teaching hospitals would be substantial but would take time to quantify.[100]

21.78 Another perspective is that, in many other areas of medical and pathology practice there is a mix of public and private sector provision, and personnel move freely from one sector to another. While there may be short term negative effects, the development of new services in the private sector may not in fact reduce the expertise available in the public system, but deepen the pool.[101]

21.79 Further, it is clear that most concern about access is predicated on the existence of private sector monopolies on genetic tests, supported by patent rights. The possibility of an expanded role for private medical genetic testing services did not attract criticism in itself.

21.80 There is wide acceptance that some level of private provision is inevitable, and may even be desirable. For example, the Cancer Council Australia stated:

> We consider that a dual health system where both public and private providers support genetic services is the best outcome subject to public interest requirements (such as equality of access, affordability, quality assurance/validation procedures) being met'.[102]

21.81 In the future, there could be advantages in state clinical genetics services sub-contracting genetic testing to private providers, particularly if there are benefits in cost or speed of delivery.[103] GTG observed that as medical genetic testing evolves:

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97 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), 4.

98 Ibid, 4.

99 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

100 G Suthers, *Submission P30*, 2 October 2003.

101 Genetic Technologies Limited, *Consultation*, Melbourne, 5 September 2003.

102 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

103 Department of Human Services (Vic), *Consultation*, Melbourne, 3 September 2003; New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003. GTG pointed to existing problems in some States with turnaround times for BRCA1 and BRCA2 testing: Genetic Technologies Limited, *Consultation*,

> current providers need to make policy decisions as to whether the performance of routine genetic testing is an essential component of the services delivered via the public health system or whether the more routine parts of it better belong in the private sector in the same way that other pathology services do.[104]

21.82 Further, there was no fundamental objection to the idea that individuals who may not qualify for public testing services should be able to seek private testing, if they so wish.[105] However, private service provision should not be at the expense of accepted standards, especially those relating to the interpretation of test results and the provision of genetic counselling.[106]

Access to genetic counselling

21.83 State and territory genetics services provide comprehensive services in relation to diagnosis, testing, counselling and the ongoing management of genetic conditions, through medical practitioners, genetic counsellors and social workers. Concerns have been expressed that 'commercial testing might disassociate genetic testing from proper screening and genetic counselling'[107] and have consequences in relation to access to genetic counselling.[108] In particular, it has been suggested that exclusive licensing of genetic tests may disrupt closely linked publicly funded testing, clinical and counselling services by requiring that the genetic testing component be performed elsewhere.[109] For example, the Department of Health Western Australia expressed its opposition to 'commercialisation strategies that serve to disrupt the comprehensive genetic testing services that have been developed over the past decades for diagnostic and predictive genetic testing' and expressed concern about the maintenance of best practice guidelines for testing and counselling.[110]

Melbourne, 5 September 2003. The Queensland Government noted that 'Genetic testing monopolies already exist with State laboratories because of enterprise bargaining and funding arrangements. Due to these constraints, state laboratories must do the test regardless of whether other laboratories are capable of doing the tests more efficiently or cost effectively': Queensland Government, *Submission P57*, 5 January 2004.

104 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

105 For reasons of funding and testing capacity, public clinical genetics services may restrict access to genetic testing to individuals who fit certain criteria, for example, based on family history or clinical indications.

106 Cancer Councils of NSW and Australia, *Consultation*, Sydney, 8 September 2003; New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003.

107 See M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20, 26.

108 The role and importance of genetic counselling is described in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 23.

109 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 11; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

110 Department of Health Western Australia, *Submission P53*, 3 November 2003.

21.84 Breast Cancer Action NSW stated commercial testing does not 'provide for counselling, interpretation of data or advice for clinical management' and 'would not require quality risk assessment'.[111]

> Our members are at potential risk of not being able to access tests to establish whether their breast cancer is familial, with the appropriate range of support and counselling that this requires for optimal care.[112]

21.85 However, other commentators suggested that private sector testing will not necessarily mean that individuals will face problems in accessing related medical and other services.[113] Rather, this will depend on the model of service delivery—for example, if a private laboratory conducts the genetic testing component of services provided by a public clinical genetics service there is no reason why other elements of healthcare delivery need be affected.

21.86 The ALRC agrees there is no real basis for claims that private genetic testing services will necessarily lead to substandard service delivery. All medical genetic testing, like other forms of health and pathology service, is subject to regulation and standards, including the national laboratory accreditation scheme,[114] standards and guidelines issued by the National Pathology Accreditation Advisory Council and ethical and other standards applying to health professionals.[115] If there are inadequacies in service delivery, mechanisms exist to deal with them.

Quality of testing

21.87 IP 27 noted concerns about the possible impact of patent laws and practices on the quality of genetic testing and associated medical practice. For example, the AHMAC Working Group expressed concern that where testing is performed by a sole commercial entity, it may 'dictate testing practice, methodology and standards without regard for best medical practice'.[116]

21.88 IP 27 asked whether medical practice may be compromised by exclusive licensing arrangements that limit the types of medical genetic tests that can be performed using a genetic sequence covered by a gene patent. Concerns about the quality of testing and medical practice include those relating to the technical quality

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111 Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003.

112 Ibid.

113 New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003.

114 Administered by the National Association of Testing Authorities Australia and the Royal College of Pathologists of Australasia, and based on policy guidance provided by the National Pathology Accreditation Advisory Council: See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 11.

115 In ALRC 96, the ALRC and AHEC recommended a number of reforms to enhance laboratory accreditation standards to promote high ethical standards in genetic testing, to provide an enhanced level of oversight for ordering genetic tests and ensure better access to genetic counselling: See Ibid, Ch 11; Ch 23; rec 11–1 to 11–4; rec 23–1; rec 23–3.

116 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 19–20.

and quality assurance of genetic testing and communication and information transfer between medical practitioners and laboratory scientists.

21.89 It has been claimed that patent laws or practices may prevent the use of more appropriate tests for the same genetic condition and thereby prejudice medical practice.

> [D]isease gene patents have the very real ability to prescribe nationwide medical practices and to dictate the medical standard of care. Patents may grant [patent holders or licensees] the ability to dictate what kinds of test may be done … or limiting the conditions for which testing may be done … Simply, this is an unacceptable outcome of medical process patenting and again highlights the fundamental incompatibility between diagnostics process patents and medical care.[117]

21.90 Laboratories in Australia and elsewhere use a range of different methodologies for medical genetic testing.[118] There are concerns that exclusive licensing of medical genetic testing may constrain laboratories from choosing the most clinically appropriate test.[119] The HGSA contended that medical practice may be adversely affected where patents and licensing operate to limit testing to technologies that detect 'only a proportion of mutations in a gene'.[120] The RCPA submitted:

> Ultimately, commercial considerations will dictate priorities and products, not the public need. Patents grant companies the ability to dictate what kind of test may be done (eg sequencing instead of less sensitive but substantially less costly screening methods such as dHPLC or protein truncation tests) or limit the condition in which testing may be done (eg refusing to perform prenatal testing for late-onset diseases).[121]

21.91 IP 27 noted that questions have been raised in France and elsewhere about the technical quality of Myriad's method of BRCA1 testing. In 2001, the Institut Curie claimed that the direct sequencing technology used by Myriad failed to detect 10–20% of all expected mutations in the BRCA1 gene (which were detected by an alternative testing technique).[122] It has been said that this situation jeopardises the quality of test results. The Institut Curie concluded that:

> The Curie test for large scale deletions should be used at least as a supplement, if not an alternative, to the full sequencing approach used by Myriad. The broad nature of

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117 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 327.

118 Department of Human Services (Vic), *Consultation*, Melbourne, 3 September 2003; South Australian Department of Human Services, *Consultation*, Adelaide, 15 September 2003.

119 Department of Health Western Australia, *Submission P53*, 3 November 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003; Queensland Government, *Submission P57*, 5 January 2004.

120 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

121 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

122 Institut Curie and Assistance Publique Hopitaux de Paris and Institut Gustav-Roussy, *Against Myriad Genetics's Monopoly on Tests for Predisposition to Breast and Ovarian Cancer Associated with the BRCA1 Gene* (2002), 5.

> the European BRCA patents—which cover any diagnostic or therapeutic use of the BRCA1 and BRCA2 genes—means that clinicians using this new technique would be infringing the patents and thus open to legal suits, thereby undermining their ability to provide patient services.[123]

21.92 Submissions also noted quality assurance as a concern.[124] IP 27 observed that quality assurance in medical testing is often pursued through external quality assessment schemes that allow participating laboratories to test the reliability and accuracy of their testing methods by testing, on a scheduled basis, material of known or consensus-agreed composition.[125] Such programs may be difficult to establish where only one or a small number of laboratories perform genetic testing.

21.93 The HGSA submitted that restricted licensing can 'make independent assessment of quality assurance more difficult, by reducing relevant independent expertise'.[126] Dr Suthers stated that testing monopolies can result in the loss of quality assurance programs.

> A key component of the QA program in any laboratory is comparison of test results between laboratories. This is particularly important in the comparatively new area of genetic diagnostics. Over the last five years, two NATA-accredited laboratories with HGSA-accredited scientists have provided genetic testing in familial cancer in South Australia. The two labs routinely swap samples. Discrepancies in test results are rare but revealing. A testing monopoly precludes this form of QA.[127]

Professional relationships

21.94 Another issue related to genetic test quality regards the relationships between medical practitioners and laboratory scientists. It has been claimed that monopoly control of genetic testing may have adverse effects on medical practice by changing the interface between medical practitioners, who order genetic testing for their patients, and those who conduct the tests.[128] The HGSA has stated that genetic testing monopolies

> will disrupt the professional relationships that exist within regional genetic services between laboratory scientists, medical consumers of testing services and clinicians

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123 See B Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, <http://genethics.ca/personal/HistoryPatent.pdf> at 17 April 2003, 23.

124 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

125 National Coordinating Committee for Therapeutic Goods In Vitro Diagnostic Device Working Group, *A Proposal for a New Regulatory Framework for In Vitro Diagnostic Devices: Discussion Paper* (2003), 42.

126 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

127 G Suthers, *Submission P30*, 2 October 2003.

128 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.

> whose expertise covers both areas and, by doing so, reduce the quality of medical services.[129]

21.95 Communication between practitioners and scientists is said to develop mutual expertise, particularly in interpreting scientific information and this is important in providing best practice medical care.[130] For example, clinicians often provide relevant patient history and results from earlier investigations to the testing laboratory, and in many cases directly to the scientists performing the testing.[131] The interpretation of results may 'suffer from lack of discussion regarding abnormalities in testing the accuracy of the test results'.[132] In its submission, the RCPA emphasised that genetic testing should be performed by 'laboratories with close links to clinical genetics services'.[133]

21.96 It may be that these comments overstate the extent of communication between medical practitioners and laboratories. In any case, there may be no reason why good communication cannot be developed between medical practitioners and private laboratories operating under an exclusive licence to use a particular genetic testing technology. GlaxoSmithKline noted that 'public laboratories do not have a monopoly on good customer service'.[134]

Further development of medical genetic testing

21.97 IP 27 noted that where patents contain claims to all or most conceivable diagnostic tests related to a particular gene, there may be less incentive to develop new or improved tests.[135] Innovation in medical genetic testing at the clinical and laboratory level may be hindered.[136] The RCPA submitted that

> there is little or no incentive to improve diagnostic testing by the patent holder and the development of complementary or alternative testing methods, by third parties, can be retarded.[137]

21.98 Concerns about the development of new tests were highlighted in the OECD Working Party on Biotechnology Report:

> When clinical testing centres are also research laboratories investigating the genetic basis of a disease, the inability to obtain a licence impedes research and can mean that higher-quality tests may not emerge.[138]

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129 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001).
130 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 19.
131 Ibid, 19.
132 Ibid, 20.
133 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
134 GlaxoSmithKline, *Submission P33*, 10 October 2003.
135 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 4.
136 The ways in which gene patents may restrict the conduct of research more generally are discussed further in Ch 13.
137 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

21.99 One reason for this is that genetic sequences covered by gene patents are typically the single most prevalent sequence carried by healthy individuals. Medical genetic testing is directed at identifying mutations in this sequence that are associated with disease. Medical practitioners with access to family pedigrees discover many such mutations over time. It this way, medical genetic testing is routinely subject to incremental improvement as more is learned about the genetics of a disease.[139] It has been suggested that 'limiting the number of laboratories permitted to do the testing could slow this incremental process of discovery'.[140]

21.100 A recent study of clinical laboratories in the United States concluded that the development of new genetic tests for clinical use, based on published data on disease-gene associations, and information sharing between laboratories, has been inhibited by gene patents and licences.[141]

21.101 Submissions confirmed negative views about the impact of gene patents on the development of new or improved genetic tests.[142] AHMAC submitted:

> lack of competitive pressure in human genetic and related technologies caused by the uniqueness of genes may limit the development of alternative and higher quality technologies. In turn this may affect the quality, accessibility and cost of genetic tests and related technologies.[143]

21.102 The Walter and Eliza Hall Institute of Medical Research stated that medical best practice may be compromised by exclusive licensing arrangements in the sense that:

> the patented or alternative test or procedure may not be optimal. In a perfect world the patent system is meant to promote innovative improvements to that test or procedure (via publication followed by further research) and the new improved test or procedure should be patentable in its own right. In practice very broad [patent] claims can prevent this …[144]

21.103 Submissions and consultations highlighted constraints on the conduct of clinical research where a patent holder has exclusive rights to test for a genetic

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138 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 18.

139 R Eisenberg, 'Why the Gene Patenting Controversy Persists' (2002) 77 *Academic Medicine* 1382, 1382–1383.

140 Ibid, 1383.

141 M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3, 8.

142 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Breast Cancer Network Australia, *Submission P22*, 30 September 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

143 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

144 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

disease.[145] Dr Suthers expressed concern about patent holders or exclusive licensees maintaining private holdings of population genetic data compiled from test results. This, it is claimed, may constrain the further development of tests on the gene, resulting in genetic tests of limited utility and efficiency, and lack of data about genetic variants in populations.[146]

21.104 Similarly, the HGSA stated that gene patents and restricted licensing may:

- enable the licence holder to control details of the variations detected in a given gene, enhancing the monopoly by controlling the means of interpreting test results;

- slow the accumulation of information about variations in genes and the relationship of the variations to the disorder in question, by reducing the number of laboratories providing testing; and

- restrict rapid publication of information about variations in the gene and their relationship to the disorder in question.[147]

21.105 The Department of Health Western Australia expressed concern that licence terms for testing laboratories where research and development are undertaken may 'exclude the development and use of complementary or alternative technologies for mutation detection, which may have a better sensitivity than the current patented method'.[148]

21.106 In this context, the RCPA confirmed that European researchers have discovered that deletions account for around 28% of all BRCA1 mutations associated with breast cancer risk in Dutch families.[149] The RCPA stated that:

> In other nations, including Australia, such exon deletions may account for 5-10% of all the mutations identified in the BRCA genes. These mutations may have remained undiscovered had Myriad successfully enforced its patents in Europe because Myriad's testing methodology is unable to detect these deletions.[150]

21.107 Another example cited by the RCPA involves haemochromatosis testing. The RCPA stated that two mutations account for 99% of cases of hereditary haemochromatosis in Caucasians, but that different mutations are more prevalent in

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145 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003.

146 G Suthers, *Submission P30*, 2 October 2003.

147 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003. See also Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

148 Department of Health Western Australia, *Submission P53*, 3 November 2003.

149 F Hogervorst and others, 'Large Genomic Deletions and Duplications in the BRCA1 Gene Identified by a Novel Quantitative Method' (2003) 63 *Cancer Research* 1449.

150 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

other ethnic groups, who therefore require different tests. However, the test developed by Bio-Rad tests only for the presence of the Caucasian mutations and does not detect the rarer mutations.[151]

21.108 Particular concerns were expressed about the barriers gene patents may pose for the development of new forms of comprehensive genetic testing using DNA microarrays, which are capable of testing thousands of genes on a single chip at a time. The Medical Genetics Elective Group of the University of Newcastle stated that such testing will be a viable diagnostic tool in the near future but the need for multiple licences may make this development economically impractical.[152]

21.109 Other submissions contested the idea that gene patents adversely affect the development of new or improved tests.[153] GlaxoSmithKline noted that concerns outlined in IP 27 were 'founded on the assumption that the existence of the patent necessarily limits the numbers of users'—which was not necessarily the case.[154] More recognition should be given to the likelihood that gene patenting might 'improve medical practice by encouraging the investment needed to develop improved medical genetic tests'.[155] It has been suggested that those expressing concern about patents hindering innovation in genetic testing disregard the incentive that patents provide to new test development. The likelihood that any single gene patent could be enforced over all conceivable testing methodologies relating to a gene may also be overstated.

Impact of gene patents on novel genetic therapies

21.110 IP 27 noted that patent laws and practices may have an impact on the development and provision of other forms of healthcare, including novel therapies such as gene therapy, the production of therapeutic proteins, and the use of stem cells.

21.111 Any treatment based on gene therapy will require the use of a gene carrier or 'vector' and a genetic sequence. Patents on the use of vectors may be a constraint on the development of gene therapy in Australia. Further, if the gene is patented, treatment for gene therapy will depend, at least in part, on the availability of a licence from the patent holder. The Nuffield Council has stated:

> Many patents which assert rights over human DNA sequences include claims to the use of the sequence for gene therapy, even though such applications have almost never been demonstrated. This is because patents applicants have been allowed to assert rights over uses which are judged theoretically credible without having

151 Ibid.
152 E Milward and others, *Submission P46*, 20 October 2003.
153 GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.
154 GlaxoSmithKline, *Submission P33*, 10 October 2003.
155 Ibid.

> evidence from research to show that they have made experimental progress towards realising this theoretically obvious possibility.[156]

21.112 The use of therapeutic proteins in healthcare may be affected by gene patents. Patents over therapeutic proteins generally assert rights over the genetic sequence as well as the protein itself because the genetic sequence is crucial to the production of the protein.[157]

21.113 Gene patents may also be relevant to the use of stem cells in medical treatment (see Chapter 16). By 2002, there had been over 2,000 patent applications worldwide involving human and non-human stem cells, one quarter of which referred to embryonic stem cells. Over one third of the total applications and one quarter of all embryonic stem cell applications have been granted.[158]

21.114 The Ontario Government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, has commented that:

> Since stem cells have the potential to be developed into tissues and organs, the potential use of them for curing and treating many conditions and diseases is enormous. The patenting of stem cells may well mean that exclusive royalty fees will have to be paid in the future for replacement organs and tissues, developed in this manner, raising significant implications for publicly funded healthcare systems.[159]

21.115 IP 27 asked what impact might patent laws and practices have on the future provision of gene therapy, medicines based on therapeutic proteins, and medical treatment involving stem cells.[160]

21.116 The RCPA stated that gene patents have potential both to encourage and to limit the development of genetic medicine. While patent rights are essential in encouraging investment in the development of novel genetic therapies, the RCPA submitted that the 'broad scope of many patents on genetic material' is likely to discourage such investment.[161] The RCPA referred to the BRCA patents, in which Myriad claims rights in relation to both diagnosis and potential therapies, and noted:

> There is no obligation on Myriad to develop gene-based therapies based on BRCA1 and BRCA2, while the threat of legal proceedings for infringement or the imposition of licence fees could discourage others.[162]

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156 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 61.
157 Ibid, 63.
158 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 10.
159 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 39.
160 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 12–6.
161 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
162 Ibid.

21.117 Dr McBratney and others submitted that patenting these kinds of therapeutics raises the same kind of issues as the patenting of drugs or medical methods generally and should be treated no differently.[163]

21.118 DITR observed that restricting gene patenting would be likely to have a negative impact on capital inflows into Australia, which may deny the community the benefit of new gene based therapies.[164] Similarly, GlaxoSmithKline referred to the major investment needed to develop new treatments based on genetics. It stated:

> We believe that patents are essential to the future provision of gene therapy, medicines based on therapeutic proteins and medical treatment involving stem cells, all of which are essentially new medicines … Treatments such as these, based on genetics, will need to go through the same development and regulatory approval processes as more traditional drugs based on chemistry. Just as patents are essential to the pharmaceutical industry in relation to the development of more traditional chemical drug treatments, they will be no less essential in relation to these new forms of treatment.[165]

Reform and healthcare provision

21.119 The ALRC is required to report on what changes may be required to address the adverse impact, if any, of current patent laws and practices on the cost-effective provision of healthcare in Australia. If gene patents are found to have an adverse impact on healthcare provision there are a number of possible reform options.

21.120 A range of reform options is discussed in detail elsewhere in this Discussion Paper. The following material highlights some of the other comments made in submissions about reform to address concerns about gene patents and healthcare specifically.

21.121 Many submissions focused on mechanisms to address the adverse consequences of exclusive licensing of gene patents used in medical genetic testing. The RCPA submitted that legislation should be introduced that 'prohibits the exclusive licensing of diagnostic genetic tests'.[166]

21.122 The Breast Cancer Network Australia suggested that 'exclusions or exemptions should be granted from patents for specific public health purposes'.[167] Similarly, the Cancer Council Australia, Cancer Council Tasmania and Cancer Council South Australia[168] stated that an exemption from breach of patent should be granted in respect of 'human genetic sequences and the tests dependent on them' if testing is

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163 A McBratney and others, *Submission P47*, 22 October 2003.
164 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
165 GlaxoSmithKline, *Submission P33*, 10 October 2003.
166 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
167 Breast Cancer Network Australia, *Submission P22*, 30 September 2003.
168 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

conducted in a 'public, not-for-profit institution'. Other organisations also stated that medical genetic testing in the public health system should be able to continue 'without penalty'.[169]

21.123 Some submissions suggested reform to address the cost of medical genetic testing. For example, the Cancer Council Australia, Cancer Council Tasmania and Cancer Council South Australia recommended that the ALRC should 'identify law reform options to prevent gene testing from becoming unaffordable for the community'.[170]

21.124 Two submissions focused specifically on measures to 'cap' licence fees. Associate Professor Bankier suggested that, to ensure health services to the public are not compromised, licence fees or royalties should be capped to no more than 5–10% of the cost of providing the test.[171] The Medical Genetics Elective Group of the University of Newcastle suggested licence caps for multi-gene tests.[172] Neither submission elaborated on the mechanism for enforcing such caps.

21.125 Other submissions opposed any reforms directed specifically to gene patents and medical genetic testing.[173] Instead, existing mechanisms to address problems relating to access to medical genetic testing were highlighted.[174] Dr McBratney and others stated that if there are problems with the availability of genetic tests on fair terms, the compulsory licensing provisions of the *Patents Act* could be used.[175] GlaxoSmithKline also emphasised the possible role of compulsory licensing.[176] DITR noted that means for dealing with the potential for increased cost and demand for genetic testing include using the Australian Government's monopsony buying power, public education about the value of genetic testing, and reviewing the operation of the *Trade Practices Act 1974*.[177] DITR stated:

> There is no evidence to suggest that gene patents are causing unreasonable cost increases of genetic testing in Australia. Anti-competitive practices may be addressed by the *Trade Practices Act 1974*. Using the patent system to address this issue would be ineffective.[178]

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169 Cancer Council of New South Wales, *Submission P1*, 5 June 2003; Cancer Voices NSW Inc, *Submission P7*, 16 September 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003.

170 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

171 A Bankier, *Submission P19*, 30 September 2003.

172 E Milward and others, *Submission P46*, 20 October 2003.

173 GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

174 GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

175 A McBratney and others, *Submission P47*, 22 October 2003.

176 GlaxoSmithKline, *Submission P33*, 10 October 2003.

177 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

178 Ibid.

ALRC's views

21.126 The ALRC's preliminary view, based on submissions and its extensive consultation and research program, is that there is limited evidence to date that gene patents and licensing practices with respect to genetic testing have had any significant adverse impact on the cost of healthcare provision in Australia. Similarly, there is currently no firm evidence of any impact on access to medical genetic testing, the quality of such testing, or clinical research and development.

21.127 Expressions of concern about gene patents from health authorities, health consumer groups, health professionals and others have generally been based on assumptions about the future development of the market in medical genetic testing and about the intentions of patent holders with regard to the exploitation and enforcement of gene patents—in particular, the assumptions that patent holders will use exclusive licences as their business model and that such licensees will charge monopoly prices. The extent to which this business model will be adopted in Australia is unclear and it is problematic to extrapolate from the experience in other countries such as the United States, which have very different healthcare systems.

21.128 The position with regard to GTG and the BRCA and non-coding patents has been discussed above, and will continue to be monitored during the course of the Inquiry. How GTG will decide to exploit or enforce these patent rights in the future is not known, particularly with regard to the non-coding patents. In any case, there are limits to what may be learnt from experience in relation to any particular patent holder or set of patents. As GlaxoSmithKline stated:

> rights-holders are free to establish their own licensing and enforcement strategies and … the activities of one company do not necessarily indicate a trend within an industry.[179]

21.129 IP 27 noted that one view on the impact of gene patents on medical genetic testing is that the problem does not lie in the patenting of isolated genetic material but in the way in which such patents are commercially exploited. While some individuals and organisations involved in the healthcare sector hold 'in principle' objections to the patentability of isolated genetic materials,[180] it is the level of future royalties or licence fees, and how these may be funded, that provokes most anxiety within this sector.

21.130 It is clear that concerns about the cost of, and access to, medical genetic testing are influenced by broader concerns about Australian healthcare policy, applicable to all new medical technologies. These concerns include the future of Medicare, the respective roles of tax-financed healthcare and private health insurance, and the mix of public and private healthcare provision generally. For example, Dr

179 GlaxoSmithKline, *Submission P33*, 10 October 2003.

180 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

Amanda McBratney and others observed, in relation to the cost of genetic health technologies, that:

> The issue is more about equity in welfare payment and in how the health care burden should be distributed in Australia rather than the price of an individual 'gene based' technology.[181]

21.131 The ALRC recognises that, while adverse effects of gene patents may not yet be manifest, this position may change, particularly if patent holders become more active in enforcing patent rights. The nature of this change, and whether existing legal mechanisms such as those in patent law and competition law may be used effectively to address problems for healthcare, is not entirely clear.

21.132 There are many existing mechanisms through which problems might be addressed. These include use of the compulsory licensing and Crown use provisions of the *Patents Act*, laws dealing with anti-competitive conduct, and prices surveillance.[182] There are also ways in which Commonwealth, state and territory governments, as funders and purchasers of healthcare services, may be able to influence the way in which patent holders exploit or enforce patent rights (Chapter 20).

21.133 While there is limited evidence that gene patents are having any present impact on the cost-effective provision of healthcare, genuine concerns are held about the potential for future negative effects on access to medical genetic testing, the quality of such testing, and clinical research and development. As a result, more detailed consideration of options to address the impact of gene patents on healthcare is justified.

21.134 Elsewhere in this Discussion Paper, the ALRC has proposed reforms that address the potential for future harm, including with respect to healthcare provision. Some of these reforms are intended to ensure that problems are identified at an early stage, for example, through monitoring of anti-competitive conduct and informal prices surveillance by the Australian Competition and Consumer Commission (see Chapters 24 and 25). The ALRC also proposes processes for examining the economic and financial impact of gene patents on healthcare services and the monitoring of gene patents by specialist offices within Commonwealth, state and territory health departments (Chapter 20).

21.135 Other proposed reforms, which are intended to address possible adverse effects of gene patents on healthcare provision, are addressed in other chapters of this Discussion Paper. These include:

- changes to Patent Office practice relevant to some gene patents (Chapter 8);
- enacting a new experimental use defence (Chapter 14);

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181 A McBratney and others, *Submission P47*, 22 October 2003.
182 See Ch 24–27.

- encouraging health departments or other agencies to challenge questionable gene patents that may impact adversely on healthcare (Chapter 20);

- establishing a role for the proposed Human Genetics Commission of Australia in monitoring the application of intellectual property laws to genetic materials and technologies, where these may have implications for human health (Chapter 20);

- model licensing guidelines to encourage broad access to genetic inventions (Chapter 23); and

- clarification of Crown use and compulsory licensing provisions (Chapters 26 and 27).

22. Medical Treatment Defence

Contents

Introduction

22.1 Chapter 21 examined the impact of gene patents on the provision of healthcare. There is some evidence that gene patents may, in future, have some adverse effects on healthcare. In particular, the exclusive licensing of patents relating to medical genetic testing may have adverse consequences for the cost of testing, access to testing, the quality of testing, and innovation in the development of new or improved testing techniques.

22.2 This evidence justifies more detailed consideration of patent law reform. This chapter examines the introduction of a medical treatment defence—a reform option directed specifically to healthcare provision. Other chapters discuss reforms that might help address possible adverse effects of gene patents on healthcare provision, as well as effects on the conduct of research, and its subsequent commercialisation.

22.3 This chapter describes the existing law in Australia and other jurisdictions in relation to patents and medical treatment and examines reforms that have been proposed overseas. The chapter examines the issues involved in framing any new medical treatment defence and the implications of reform for Australia's compliance with its obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[1]

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1 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

A defence or an exclusion from patentability?

22.4 Some jurisdictions have addressed concerns about the impact of patents on healthcare by excluding certain diagnostic, therapeutic or surgical methods of treatment from the scope of patentable subject matter—that is, by treating methods of medical treatment as an exclusion from patentability. This is the case, for example, in the United Kingdom[2] and in the Canadian province of Ontario. Australia has not adopted this approach. As discussed in Chapter 6, provided an invention meets the requirements for patentability set out in the *Patents Act 1990* (Cth) (*Patents Act*), the Patent Office will allow patents on diagnostic, therapeutic or surgical methods of treatment.

22.5 As discussed in Chapter 7, the ALRC does not propose that a new exclusion from patentability for methods of medical treatment be introduced in Australia. In particular, the ALRC is concerned that such an exclusion would have adverse effects on investment in biotechnology, medical research and innovation in healthcare.

22.6 However, an exclusion from patentability differs from a defence to a claim of infringement. Where an exclusion from patentability exists, a patent cannot be granted and no question can arise about infringement of patent rights. By contrast, a defence does not affect the existence of patent rights but constrains the enforcement of these rights by providing protection against actions for infringement in specified circumstances. For this reason, a defence may involve a less dramatic diminution in the rights of inventors: while an exclusion from patentability means that the relevant subject matter is not patentable at all, a defence may be drafted to permit patents to be enforced in some circumstances but not in others. Yet, if its scope is broad, a defence may also have adverse effects on investment and innovation.

22.7 One advantage of a defence, as opposed to an exclusion from patentability, is that while art 27(3)(a) of the TRIPS Agreement permits World Trade Organization (WTO) member states to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability, the permissible exclusion may be limited to methods performed on or inside the body (*in vivo* procedures).

22.8 As discussed in Chapter 7, gene patents most often relate to products and processes for use outside the human body, notably in connection with genetic sequencing and diagnostic genetic testing. Even in the case of gene therapy, patents are most likely to relate to processes carried out *in vitro*—such as inserting genes into a gene carrier (or 'vector') and using the vector to carry the genes into somatic cells. However, some procedures for introducing vectors, modified cells or stem cells into the human body (for example, by injection) are performed on the human body and may be considered methods of medical treatment as understood by patent law.

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2 See *Patents Act 1977* (UK) s 4(2).

22.9 The ALRC has concluded that if reform in relation to gene patents and medical treatment is justified, the introduction of a new defence—as opposed to an exclusion from patentability—would be the preferable approach. Such a defence could apply to both *in vivo* and *in vitro* procedures and be more targeted in its application. However, as discussed below, there are many difficulties in introducing such a defence.

A medical treatment defence

22.10 The United States, like Australia, allows patent protection to be obtained for diagnostic, therapeutic or surgical methods of treatment. However, United States law has sought to address some of the objections that have been raised to such patents by introducing a limited statutory defence to infringement claims asserted against a 'medical practitioner' or a 'related health care entity' in connection with their performance of a 'medical activity'.[3] This provision is referred to in this chapter as 'the United States medical treatment defence', and it is the only defence of its kind to be found in the patent laws of developed nations.

22.11 The United States medical treatment defence covers any 'medical practitioner', defined as any natural person who is licensed by a State to provide the medical activity and any person who is acting under the direction of such a person.[4] The defence also covers a related health care entity, namely, an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity 'including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic'.[5]

22.12 The term 'medical activity' is defined as the performance of a medical or surgical procedure on a body, including a human body, organ or cadaver, or an animal used in medical research directly relating to the treatment of humans.[6] Certain activities are expressly excluded from the ambit of the defence. These include:

- the use of a patented machine, manufacture, or composition of matter in violation of the patent;
- the practice of a patented use of a composition of matter in violation of the patent;
- the practice of a process in violation of a biotechnology patent;[7] and

3 35 USC § 287(c). This defence was introduced in 1996 and does not apply to any patent with an effective filing date before 30 September 1996: 35 USC § 287(c)(4).
4 35 USC § 287(c)(2)(B).
5 35 USC § 287(c)(2)(C).
6 35 USC § 287(c)(2)(A), (E), (F).
7 35 USC § 287(c)(2)(A)(i)–(iii).

- clinical laboratory services (other than those provided in a physician's office).[8]

22.13 While the term 'biotechnology patent' in the third listed exclusion is not defined, the use of isolated genetic materials would generally be considered a core element of biotechnology. The Congressional Record indicates that the term includes a patent on a 'biotechnological process',[9] as well as a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated *ex vivo* (*in vitro*) at the cellular or molecular level.[10]

22.14 In summary, the United States defence has been described as limited to 'patents claiming "pure" medical, diagnostic or surgical methods—those which do not encompass the novel uses of drugs, chemicals or biological reagents'.[11] The limited ambit of the defence means that, in practice, it does not apply to most medical applications of genetic materials and technologies. As discussed above, medical treatment involving gene patents can be expected to be conducted mostly outside the body and in a laboratory. Further, relevant gene patents cover isolated genetic materials and genetic products and their uses, which are patents on biotechnology.

22.15 The drafting of the United States medical treatment defence reflects its legislative history. The defence was proposed in the aftermath of the United States District Court case of *Pallin* v *Singer*,[12] in which it was claimed that a physician had infringed certain patents in performing cataract surgery. The claims were in respect of a method for making self-sealing incisions in the episclera of the eye—that is, a means of surgery that eliminated the need for sutures to close the wound.[13]

22.16 The case caused a great deal of controversy within the medical community in the United States and provoked an immediate push for legislation. Originally, it was proposed that medical procedures should be an exclusion from patentability. This was opposed by the biotechnology and pharmaceutical industries, resulting in compromise legislation that addressed the remedies available to patent holders.[14]

22.17 There have been proposals to extend the scope of the United States medical treatment defence, notably in the Genomic Research and Diagnostic Accessibility Bill 2002.[15] This Bill proposed to extend the definition of medical activity covered by the

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8 35 USC § 287(c)(3).

9 As defined in 35 USC § 103(b).

10 E Lee, '35 USC §287(c): The Physician Immunity Statute' (1997) 79 *Journal of the Patent and Trademark Office Society* 701, 709.

11 V Bennett, *Limitation on Patents Claiming Medical or Surgical Procedures*, Myers Bigel, <www.myersbigel.com/pat_articles/pat_article3.htm> at 14 November 2003.

12 *Pallin v Singer* 36 USPQ 2d 1050 (1995).

13 E Lee, '35 USC §287(c): The Physician Immunity Statute' (1997) 79 *Journal of the Patent and Trademark Office Society* 701.

14 See Ibid, 702–709. The legislation was eventually enacted late at night as part of a complex appropriations Bill: A McBratney and others, *Submission P47*, 22 October 2003.

15 The Bill was referred to the House Subcommittee on the Courts, the Internet, and Intellectual Property on 5 May 2002, but lapsed at the end of the 107th Congress. See also S Minwalla, 'A Modest Proposal to

defence to include 'performance of a genetic diagnostic, prognostic, or predictive test'.[16] The co-sponsor of the Bill, the Hon Lynn Rivers, stated that this provision would 'exempt medical practitioners utilizing genetic diagnostic tests from patent infringement remedies'.[17] She stated:

> To those who argue that medical innovation will be stifled by this approach, I would point out that surgeons have been refining their techniques for centuries without patent protection.[18]

Reform proposals in other jurisdictions

22.18 Other jurisdictions have also examined the possible introduction of a medical treatment defence to address concerns about the impact of gene patents on the provision of healthcare.

22.19 Methods of medical treatment are currently excluded from patentability under Canadian law.[19] The 2002 Ontario Government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (the Ontario Report), recommended that this exclusion be replaced with a medical treatment defence.

22.20 The Ontario Report stated that adopting the United States approach, with an extension to cover diagnostic procedures, could address concerns about access to patented genetic technologies. It recommended an amendment preventing patent holders from bringing an action for infringement against a medical practitioner for providing medical services (including treatment and diagnosis) to patients.[20] The Ontario Report noted that such an approach 'while providing protection would still allow the full patenting of genetic testing technologies'.[21] It also observed that given the realities of contemporary biotechnology, the distinction between *in vivo* and *in vitro* procedures was theoretical and difficult to maintain.[22]

22.21 In 2002, a report by the Organisation for Economic Co-operation and Development (the OECD Working Party on Biotechnology Report)[23] noted suggestions that 'clinical use' exceptions should be enacted into national laws. The

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Amend the Patent Code 35 USC §287(c) to Allow Health Care Providers to Examine their Patients' "DNA"' (2002) 26 *Southern Illinois University Law Journal* 471. Minwalla proposed that 'genetic diagnostic' should be added to the definition of medical activity and that the medical treatment defence should apply to procedures on 'parts of the body', including tissue and other genetic materials: 503.

16 Genomic Research and Diagnostic Accessibility Bill 2002 (HR 3967) (US) s 3.

17 United States, *Congressional Debates, House of Representatives*, 14 March 2002, E353 (L Rivers), E354.

18 Ibid, E354.

19 See further Ch 7.

20 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(e), 51.

21 Ibid, 51.

22 Ibid, 51.

23 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002).

report observed that a difficulty with such an approach would be to 'distinguish clinical use from commercial use'.[24]

22.22 A 2003 report for the United Kingdom Department of Health referred to a 'groundswell of opinion' in countries that exclude methods of medical treatment from patentability that the exemption should be removed.[25] It concluded that, if this were done in the United Kingdom, clinicians would require the benefit of a defence against infringement. The report recommended:

> The Department should consider whether the exclusion [from patentability] should be lifted only upon the condition that the activities of clinicians should not constitute infringement of any patent claim. This would put the EPO member countries in broadly the same position as now prevails in the US.[26]

22.23 The report did not provide any formulation for such a defence, but it did observe that:

> Whether in practice the American approach does anything more than impose financial responsibility on the health authority alone, rather than the medical staff in person, must remain a controversial matter.[27]

Framing a new defence

22.24 If a new medical treatment defence were introduced, it would need to be carefully framed to remedy specific problems resulting from the enforcement, or potential enforcement, of gene patents against healthcare providers. There are many difficulties involved in framing the scope of a new medical treatment defence.

22.25 What medical activities should be covered by the defence? For the defence to be of practical application to the infringement of gene patents in the provision of healthcare, it seems clear that it would need to apply to *in vitro* testing and other procedures, and not just to procedures performed on or inside the body. Yet, the implications of exempting a broad class of diagnostic or therapeutic methods from claims of patent infringement would be significant, especially in relation to effects on investment and innovation in healthcare technology. These implications would have to be the subject of specific investigation and consultation. On the other hand, as discussed below, enactment of a new medical treatment defence specific to gene patents would need to be carefully justified in order to be consistent with Australia's obligations under the TRIPS Agreement, which provides that patent rights shall be enjoyable without discrimination as to field of technology.[28]

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24 Ibid, 73.
25 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 23.
26 Ibid, 83.
27 Ibid, 23.
28 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 27.1.

22.26 The second major question in framing a new medical treatment defence is how to define the class of persons or organisations who should be able to invoke the defence. As discussed above, the United States medical treatment defence applies to medical practitioners, their assistants, and 'related healthcare entities'—entities with which a medical practitioner has a professional affiliation under which the medical practitioner performs a medical activity[29]—for example, a hospital or clinic.

22.27 An important consideration in defining the class of persons protected from infringement proceedings is that most genetic testing is conducted by laboratories, rather than by medical practitioners. In Australia, most medical genetic tests are ordered by a clinical geneticist or other medical practitioner as part of healthcare services provided by state and territory public clinical genetics services. The testing itself is usually, but not always, carried out by public sector laboratories attached to public hospitals.[30] If the intention of the defence is to protect the delivery of healthcare services—rather than to protect only medical practitioners from liability—laboratories should also be covered by the defence.

22.28 Whether medical practitioners need special protection in relation to gene patent infringement is an open question. It may be argued that medical practitioners should be entitled to refer patients for medical genetic testing as they see fit, without having to concern themselves with the existence or otherwise of relevant patent rights. It is not clear whether a medical practitioner would infringe a patent simply by referring a patient to a laboratory for testing. A medical practitioner can be liable for indirect infringement of a patent where he or she has:

- procured the infringement through inducement, incitement or persuasion (that is, contributory or indirect infringement);
- joined in a common design with someone else to engage in acts that infringe a patent (that is, as a joint tortfeasor); or
- authorised the infringement.[31]

22.29 For liability to be established, the medical practitioner must have done something more than merely facilitate the infringement of the patent by another. He or she must have made himself or herself a party to the act of infringement by taking part in it, such as by taking some positive step designed to produce the infringement, even though further action by others (that is, the laboratory) is also required.[32] Referral of a patient to a testing laboratory may be regarded as contributory infringement, but this

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29 35 USC § 287(c)(2)(C).

30 In these cases, the medical practitioner and the laboratory will often be part of the same public health organisation (eg in New South Wales, the same area health service or statutory health corporation). See *Health Services Act 1997* (NSW) ch 2.

31 See J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [18,270].

32 See Ibid, [18,270].

may depend on the exact relationship between a referring medical practitioner and the testing laboratory.[33]

22.30 It is possible that patent holders may protect patents by seeking injunctions or other remedies against medical practitioners who refer patients for unauthorised testing, as well as by taking action directly against the offending laboratory. However, the ALRC has received no evidence that patent holders have adopted such an approach to patent enforcement in Australia. Indeed, it is uncertain whether it would serve any useful purpose for a patent holder to do so, given the remedies available against laboratories.

The TRIPS Agreement and medical treatment defences

22.31 Any proposed new medical treatment defence needs to be consistent with Australia's obligations under the TRIPS Agreement, and in particular with art 27 and 30. The TRIPS Agreement places significant constraints on the permitted scope of exceptions to the exclusive rights conferred by patents.

22.32 Article 27.1 of the TRIPS Agreement provides that patent rights shall be enjoyable without discrimination as to the field of technology. This non-discrimination provision places constraints on the extent to which gene patents may be singled out for special treatment, including through new defences to claims of patent infringement.[34]

22.33 As discussed in Chapter 14, art 27 of the TRIPS Agreement does not 'prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.[35] As with an experimental or research use defence, it may be possible to craft a medical treatment defence that is specific to some defined subset of gene patents, such that the provision does not discriminate by field of technology within the terms of art 27. However, there would need to be strong arguments to justify differentiating a relevant category of gene patents from patents in other fields of technology.

22.34 Article 30 of the TRIPS Agreement provides that there may be limited exceptions to the exclusive rights conferred by a patent. Such exceptions must not unreasonably conflict with the normal exploitation of the patent and must not

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33 Another consideration in such circumstances is the concept of innocent infringement. If a defendant has infringed a patent, it does not matter whether he or she knows of the existence of the patent, or whether he or she intended to infringe. However, a court will take account of the defendant's innocence in determining the nature of the relief to be awarded. The extent to which a medical practitioner knows about the existence of patent rights may therefore be relevant to the remedies available against him or her: See Ibid, [18,345]; *Patents Act 1990* (Cth) s 123.

34 See Ch 4.

35 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 170–171.

unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.[36]

22.35 Unlike experimental use exceptions, which are found in the laws of most members of the WTO, only the United States has enacted a medical treatment defence to claims of patent infringement. This provision is quite different in scope from the kind of defence that would be necessary to address infringement of gene patents in healthcare provision because it is limited to medical activities 'on a body'.

22.36 The Office of the United States Trade Representative opposed the legislation that eventually became the United States medical treatment defence.

> Although TRIPS Article 27.3 permits Members to exclude diagnostic, therapeutic and surgical techniques from patentability, we believe that if a member makes patents available in this field of technology, a member must accord full rights under the TRIPS Agreement.[37]

22.37 The United States medical treatment defence has come under scrutiny as part of review of the implementation of the TRIPS Agreement. The European Communities and their member states asked the United States to explain how this provision complies with the TRIPS Agreement.[38] The United States responded that the provisions fell within the limited exceptions authorised by art 30 of the TRIPS Agreement and noted:

> The effect of the provision … is very limited, and is designed to ensure that doctors performing life saving or health enhancing medical or surgical procedures are not inhibited by fear of lawsuits for patent infringement.[39]

22.38 The TRIPS Agreement allows member States to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability.[40] It might be argued that, as an exclusion from patentability is permissible, a defence cast in similar terms should also be permissible, as it is less prejudicial to patent rights than an exclusion. However, as discussed in Chapter 7, it is not not clear whether the TRIPS Agreement permits exceptions for *in vitro* procedures.

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36 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

37 See J Duffy, 'Harmony and Diversity in Global Patent Law' (2002) 17 *Berkley Technology Law Journal* 685, 722, fn 122.

38 Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: United States, 1 May 1998*, World Trade Organization, <www.wto.org/english/tratop_e/trips_e/intel8_e.htm> at 17 November 2003.

39 Ibid, 13.

40 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 27(3)(a).

Submissions and consultations

22.39 IP 27 asked whether the *Patents Act* should be amended to include a defence to allow the use of a patented genetic material or technology by a medical practitioner for the purposes of medical treatment of humans.[41]

22.40 Many submissions favoured the introduction of some form of medical treatment defence.[42] The scope of the desirable defence was expressed in varying ways. The Australian Association of Pathology Practices Inc advocated the 'exemption of diagnostic testing from patent compliance'.[43] The Caroline Chisholm Centre for Health Ethics Inc considered that 'diagnostic tests, like surgical procedures, should be exempt from patent law'.[44] The Cancer Council Australia recommended that 'an exemption from breach of patent should be granted in respect of human genetic sequences and the tests dependent on them' if genetic testing is conducted 'in a public, not-for-profit institution'.[45] The Royal College of Pathologists of Australasia (RCPA) recommended new legislation to exempt laboratories from patent infringement for 'performing non-commercial genetic testing on patients for private purposes'.[46]

22.41 The submission from the South Australian Government stated that 'genetic testing for diagnosis, prognosis and predictive testing' should be expressly excluded from claims of patent infringement.[47] It also suggested that other specific medical activities appropriate for exclusion should be identified by peak medical bodies, in collaboration with the proposed new Human Genetics Commission of Australia[48] and ethics committees. The Breast Cancer Network Australia stated that 'exclusions or exemptions should be granted from patents for specific public health purposes'.[49]

22.42 In addition to these broad prescriptions for reform, which tended to focus on ensuring that medical genetic testing conducted by public sector laboratories was covered by the defence, submissions suggested a range of ways in which the defence

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41 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 14–3.

42 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Breast Cancer Network Australia, *Submission P22*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

43 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003.

44 Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003.

45 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

46 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. The exemption should apply to the approved pathology authority, pathology laboratory and pathology practitioner.

47 South Australian Government, *Submission P51*, 30 October 2003.

48 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1.

49 Breast Cancer Network Australia, *Submission P22*, 30 September 2003.

should be framed. These submissions sometimes referred to the United States medical treatment defence.

22.43 The Human Genetics Society of Australasia (HGSA) emphasised that any defence under Australian law should include diagnosis, as well as treatment, in its definition of protected medical activity. In the HGSA's view, the definition of 'medical practitioner' should be at least as broad as that in the United States and needs to encompass medical practitioners who request genetic tests from any laboratory.[50]

22.44 GlaxoSmithKline also supported a medical treatment defence covering medical practitioners carrying out treatment and diagnosis.[51] GlaxoSmithKline stated that the defence should apply to registered health professionals (medical practitioners and registered nurses) and their assistants and the healthcare organisations for whom they work when providing the relevant healthcare services.[52] However

> the supply, manufacture, sale and importation of patented items required to carry out patented methods of treatment should not be exempt from infringement. Australian law should though continue to provide that contributory infringement is itself an infringing act to ensure that method of treatment and diagnostic claims can be effectively enforced against the manufacturers and suppliers.[53]

22.45 The Australian Centre for Intellectual Property in Agriculture recommended that the *Patents Act* should be amended to include

> a defence to allow for the use of a patented genetic material or technology by a medical practitioner for the purposes of medical treatment of humans. The definition of a medical practitioner should be broad for the purposes of the legislation, and the activities protected would include medical procedures as well as the administration of genetic testing.[54]

22.46 Similarly, AusBiotech Ltd stated:

> If any such exemption is introduced it should apply only to medical practitioners who are registered to practice by state medical practice boards, and to para-medical staff such as nurses acting under their direction, as well as bodies with which such medical practitioners are professionally affiliated, such as hospitals or area health services. This would be analogous to the situation in the United States.[55]

22.47 Other submissions considered there was no need for a medical treatment defence because the problems that it would be intended to address are able to be dealt with more appropriately using other mechanisms. The Queensland Government stated that further evidence would be required to justify any new defence and that, in any case,

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50 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
51 GlaxoSmithKline, *Submission P33*, 10 October 2003.
52 Ibid.
53 Ibid. The application of the concepts of indirect liability for infringement of a patent and contributory infringement to medical practitioners using patented genetic technologies is discussed below.
54 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
55 AusBiotech Ltd, *Submission P58*, 7 November 2003.

such a defence may not be necessary as compulsory licensing and crown use provisions may be able to achieve the same outcome.[56]

22.48 A number of submissions were opposed outright to the idea of a new medical treatment defence.[57] The Walter and Eliza Hall Institute of Medical Research was concerned that such a reform might unjustifiably undermine patents on genetic technologies:

> Delivery of most therapeutics will always be by a medical practitioner for the purposes of medical treatment of humans. The only exceptions we could think of would be medical procedures that do not involve a novel product but rather a series of surgical or other steps.[58]

22.49 Dr Amanda McBratney and others stated that such a provision would be discriminatory and permit 'free-riding in relation to these inventions to the detriment of patentees, especially if their main target market is the medical use market'.[59] Davies Collison Cave considered there to be no justification for introducing a medical treatment defence. Such a defence had never been considered necessary to protect the use of pharmaceuticals by medical practitioners and was unlikely to be needed in respect to genetic materials and technologies.[60]

ALRC's views

22.50 The ALRC acknowledges the strong support in submissions for the introduction of some form of medical treatment defence. Not surprisingly, much of this support was from organisations involved in providing healthcare or representing the interests of healthcare consumers. However, even within this group of stakeholders, support for the idea was not universal: some submissions presented reasons for rejecting a medical treatment defence because of concerns about the effect of such a defence on investment and innovation in genetic medical technologies, or medical technologies generally.

22.51 It has not been established that gene patents have had any significant adverse impact, to date, on healthcare provision in Australia. Patent holders have not been active in enforcing gene patents against healthcare providers. While this situation may change, the ALRC considers that it would be premature to propose a significant diminution of patent rights where there is no demonstrated harm.

22.52 If gene patents are found to have an adverse impact on healthcare provision, a number of reforms are available to address the problem, other than the enactment of a new medical treatment defence. These include: changes to Patent Office practices

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56 Queensland Government, *Submission P57*, 5 January 2004. See Ch 26–27.

57 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

58 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

59 A McBratney and others, *Submission P47*, 22 October 2003.

60 Davies Collison Cave, *Submission P48*, 24 October 2003.

relevant to gene patents (Chapter 8); encouraging health departments to challenge questionable gene patents that may impact adversely on healthcare (Chapter 20); model licensing agreements to encourage broad access to genetic inventions (Chapter 23); and clarification of the Crown use and compulsory licensing provisions in the Patents Act (Chapters 26 and 27). Many of these options appear to present fewer practical difficulties than the introduction of a medical treatment defence.

22.53 As discussed in this chapter, there are genuine difficulties in framing the scope of any new medical treatment defence. These include defining what medical activities should be covered by the defence, and the persons or organisations who should be able to invoke it. There may also be problems in framing the defence in a way that is consistent with Australia's obligations under the TRIPS Agreement.

22.54 At present, the United States is the only country to have enacted a medical treatment defence. There is little experience in the practical application of the provision and, in any case, the limited ambit of the United States defence means that it probably does not apply to any medical treatment involving gene patents.

22.55 There may be sound arguments for a United States-style medical treatment defence in order to protect medical practitioners who engage in medical or surgical procedures on the human body from patent infringement actions. However, this is not an appropriate matter for this Inquiry, with its limited focus on patents over genetic materials and technologies. Gene patents most often relate to products and processes for use outside the human body, notably in connection with genetic sequencing and diagnostic genetic testing. While gene patents are sometimes used in procedures on the human body, for example in connection with gene therapy, such use is rare and still largely experimental.

22.56 The ALRC is currently not inclined to propose a new medical treatment defence to claims of patent infringement. However, it remains interested in further submissions and comment on whether the enactment of such a defence may be justified and, if so, how such a defence should be framed.

Question 22–1 In the absence of a general defence relating to medical treatment, should the *Patents Act 1990* (Cth) be amended to enact a new defence to claims of patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment?

PART F

Licensing and Commercial Arrangements

23. Licensing of Patent Rights

Contents

Introduction

23.1 Much of the concern about the potential adverse impact of gene patents has entailed criticism of the way in which gene patent rights are exploited and the possibility that licences for gene patents may be granted only on a restrictive basis. Chapters 13 and 21 considered the way in which these concerns apply in the context of licences to genetic research tools and gene patents used in diagnostic genetic tests.

23.2 This chapter provides a more general consideration of issues relating to the licensing of gene patents. The various types of patent licences and the typical terms of such agreements are outlined. The chapter then examines available evidence about licensing practices relating to genetic materials and technologies in Australia. It concludes with a discussion of particular issues that have been identified as impediments to the licensing of gene patents in the Australian biotechnology sector, and considers whether reform is necessary in this area.

23.3 Other chapters of this Discussion Paper address specific aspects of gene patent licensing practices are also addressed in other chapters of this Discussion Paper. Chapter 18 outlines the licensing practices of Australian publicly funded research institutions. Chapters 24 and 27 consider the remedies that may be available if patent holders unreasonably restrict access to patented genetic inventions or engage in anti-

competitive conduct. Finally, Chapter 28 examines whether introducing a statutory licensing scheme for certain types of gene patents would be beneficial.

Licensing patent rights

23.4 As discussed in Chapter 9, the grant of a patent confers upon a patent holder the exclusive right to exploit an invention, or to authorise another person to exploit an invention, during the patent term.[1] A patent holder may license any or all of its patent rights to a third party. A licence of a patent does not transfer ownership of the patent rights, as is the case if a patent is assigned; rather it establishes terms upon which a third party (the 'licensee') may exercise specified patent rights without such use constituting infringement.[2]

23.5 A licence to exploit one or more gene patents may be a stand-alone transaction or part of a larger commercial arrangement. Patent licences are frequently an aspect of the establishment of a spin-off company, a joint venture or a strategic alliance. Patent licences are also typical in collaboration and consortium arrangements, sponsored research agreements, and manufacture and supply agreements.[3]

23.6 Patent licence agreements may be divided into two categories: in-licences and out-licences. An 'in-licence' is an agreement by which a party acquires the rights to use a patent. An 'out-licence' is an agreement by which a patent holder grants the right to use a patent to a third party.

23.7 The decision to license gene patents may be based on a number of factors.[4] Licensing arrangements allow companies to exchange resources and information, thereby reducing research and development expenditure and time delays in bringing a product to market. Licensing of patent rights may also be necessary to gain access to domestic or foreign markets, by providing access to manufacturing facilities or distribution networks without additional expense, or lowering the cost and risk associated with entry into a market through partnership with a more experienced entity. A company's strategic patent licensing may also result in the establishment of profitable, long-term alliances leading to future research collaborations. Finally, a patent licence may provide a company with access to significant third party intellectual

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1 *Patents Act 1990* (Cth) s 13(1). The right to exploit an invention is subject to earlier patents not owned by the patent holder, as well as any necessary government approvals.

2 'Licence' is defined in the *Patents Act 1990* (Cth) as 'a licence to exploit, or to authorise the exploitation of, a patented invention': Ibid sch 1. The grant of an exclusive licence may carry with it some of the indicia of ownership, for example the right to enforce the licensed patent rights. A patent holder must also seek a licensee's consent to amend a patent specification (unless this requirement is waived by the Commissioner of Patents): *Patents Act 1990* (Cth) ss 103, 120(1), 187.

3 An express or implied licence to use a patented product may also be included with the purchase of any such product.

4 For a general discussion of the relevant factors, see Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Ch 8; Department of Foreign Affairs & Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001), Module 9; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 97–99.

property, or provide a means of avoiding or settling patent litigation—particularly where an agreement involves cross-licences of patent rights among competitors.

Types of patent licences

23.8 A licensee may be granted exclusive, sole or non-exclusive rights to a gene patent. An exclusive licence provides that only the licensee (and, where permitted, persons authorised by the licensee) may exploit the rights licensed under the agreement—even the patent holder is prevented from exploiting such rights. Exclusive licences may be limited to a territory (for example, a particular country or group of countries), to a particular field of use, or to a specified period of time. Therefore, a patent holder may retain the right to exploit the invention in other territories or fields of use, or to license patent rights to a different entity, perhaps also on an exclusive basis.

23.9 A sole licence permits the patent holder and a licensee to exploit a patented invention, but prevents the patent holder from licensing the rights to any other entity. A non-exclusive licence allows the patent holder to license some or all of the rights under a patent to an unlimited number of third parties, and also to retain the right to exploit a patented invention itself. Like exclusive licences, licences that authorise the use of gene patent rights on a sole or non-exclusive basis may be restricted to a particular territory, field of use, or period of time.

Common terms in patent licences

23.10 The *Patents Act 1990* (Cth) (*Patents Act*) does not specify any formalities that must be satisfied for a patent licence to be valid and enforceable. However, as a matter of commercial practice, the terms of a patent licence are typically set out in a written document executed by the parties to the agreement.

23.11 Patent licences usually address the following matters:[5]

- licensed property—identifying the particular patents and patent applications subject to the licence;
- territory within which the licensee may exercise its rights;
- scope of rights granted—whether exclusive, sole, or non-exclusive, as well as any restrictions on the use of the licensed patent rights (for example, restrictions on the right to sub-license, or rights retained by the licensor);
- duration of the licence;
- financial terms—such as licence fees,[6] payment terms and liability for taxes;

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5 This list is not comprehensive and is intended only as a guide to issues that a patent holder may wish to regulate by the licence.

- termination of the licence;
- obligations of the licensor—for example, maintenance and enforcement of the licensed patent rights, continued prosecution of relevant patent applications, and provision of technical assistance and know-how related to the inventions covered by the licensed patent rights;
- obligations of the licensee—such as performance obligations to exercise best efforts to develop and exploit the technology covered by the licensed patents;[7]
- ownership of (and the right to use) any intellectual property that may arise from activities conducted under the licence—for example, improvements on, or new applications for, inventions covered by the licensed patent rights, as well as new inventions that may be developed;
- reversion of rights in the licensed patents—for example, upon termination of the licence, or upon failure of the licensee to satisfy performance obligations stipulated in the agreement;
- reporting and record keeping requirements—including the ability of the licensor to conduct periodic audits of the licensee's records;
- confidentiality obligations; and
- responsibility for liability claims—typically addressed in the form of indemnification provisions covering issues such as patent infringement and product liability claims.

23.12 While most patent licences address the issues identified in the preceding paragraph, parties to a licence typically negotiate the precise terms of the arrangement, including the scope of the licence granted, the obligations and liabilities of each of the parties, and the quantum and terms of payment. These negotiations will be influenced by a number of factors such as the nature of the technology being licensed, the identity and business of the patent holder and potential licensee, the proposed use of the patented technology, and revenue considerations. The way in which these factors affect licences of Australian gene patents is considered in the following section.

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6 Licence fees may be structured in a number of ways and may include payments in one or more of the following forms: royalty payments, fixed fees, minimum guaranteed payments, and milestone payments.

7 An agreement may also provide that a licensee is responsible for matters that are typically the obligation of the licensor—such as maintenance and enforcement of the licensed patent rights—particularly if patent rights are licensed on an exclusive basis.

Licensing of gene patents in Australia

23.13 The size and character of the Australian biotechnology industry (which is discussed in Chapter 17) means that patent licensing is particularly important to facilitate further research and to allow the development and commercialisation of products. The relatively limited size of the Australian market means that it is unlikely that companies will be able to sustain long-term growth or profitability based solely on activities in the domestic market.[8] In addition, the primary expertise of many Australian biotechnology companies is in the area of research. The resources and expertise of more established—and frequently foreign-owned—companies are typically required to commercialise the results of research and produce a diagnostic or therapeutic product.[9] Australian biotechnology entities are, therefore, unlikely to raise substantial revenue from the sale of genetic products or processes and are often dependent upon licence fees as a primary source of revenue.[10]

23.14 A recent empirical study of patenting and technology transfer practices in the Australian medical biotechnology industry conducted by Dr Dianne Nicol and Jane Nielsen (the Nicol-Nielsen Study) concluded that the majority of participants in the Australian medical biotechnology industry—particularly in the drug discovery sector—need to transfer their technology 'downstream' to develop a commercial product.[11] The Nicol-Nielsen Study found, however, that participants in the medical device and non-human research sectors of the Australian medical biotechnology industry are more likely to have the capacity to bring a product to market.[12]

23.15 Apart from the Nicol-Nielsen Study, publicly available information about gene patent licensing practices in Australia is limited and, to date, has been largely anecdotal.[13] It has, therefore, been difficult to obtain a clear picture of what patented genetic materials and technologies are being licensed in Australia, which entities are acquiring such rights, and on what terms.[14]

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8 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 115.

9 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 358–360; J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating The New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 39, 43; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 93. See further Ch 17.

10 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 110.

11 Ibid, 253.

12 Ibid, 103.

13 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

14 Limitations on the availability of information about gene patent licensing practices have also been noted by the Organisation for Economic Co-operation and Development: Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 45.

23.16 While there is no comprehensive source of information about gene patent licensing, some information about patent licence agreements may be gleaned from the following sources:

- the records of IP Australia—including, patent licences that are filed with the Patent Office;[15]

- disclosures made by publicly-listed Australian companies pursuant to the Australian Stock Exchange listing rules[16] (and equivalent disclosure requirements imposed by securities exchanges in other jurisdictions); and

- an individual company's press releases.

23.17 Such sources will, however, reveal only a portion of concluded transactions. Moreover, public sources of information about patent licences generally exclude details of the commercial terms of such agreements to preserve confidentiality.[17]

Nicol-Nielsen Study

23.18 The Nicol-Nielsen Study examined licensing practices relating to biotechnological inventions, including genetic materials and technologies, among publicly-listed and private companies, research organisations and genetic testing laboratories within the Australian medical biotechnology sector.[18] While the focus of the Study was broader than gene patents, its findings in relation to licensing practices are instructive.

23.19 The Nicol-Nielsen Study reported significant levels of collaborative and licensing activity on the part of each of the types of entities surveyed.[19] Respondents to the survey from the 'research institute' and 'company' sectors reported lower levels of licensing-out of patent rights than might be expected.[20] However, Nicol and Nielsen commented that this result was 'reflective of an industry in a growth phase'.[21] Some entities are still developing their technology and are not yet in a position to enter into licence agreements. Others favour assignment or co-ownership of patents, or the

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15 *Patents Act 1990* (Cth) ss 187, 193; *Patents Regulations 1991* (Cth) r 19.1.

16 Subject to certain exceptions, the listing rules of the Australian Stock Exchange require disclosure of information that may have a material effect on the price or value of an entity's securities: see ASX Listing Rules, ch 3.

17 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

18 Survey responses were received from 49 companies, 23 research institutions and 18 diagnostic testing facilities. Forty interviews were also conducted with representatives from research institutes, companies, and diagnostic testing facilities: D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 64–71.

19 Ibid, 95–97, 104, 123.

20 Ibid, 100–101.

21 Ibid, 102.

establishment of a spin-off entity, as a means of providing access to patented technology. Nicol and Nielsen concluded that:

> most patent holders are able to find ways to license-out their technology or to find other means of transferring their technology to other sectors of the industry.[22]

23.20 In addition, Nicol and Nielsen concluded that 'licensing on an exclusive basis is commonplace' within the Australian medical biotechnology sector,[23] and that there is some evidence of restricted access to patented biotechnological inventions. However, their Study found that Australian entities currently have little difficulty accessing broadly applicable research tools and technologies because there is liberal licensing of foundational biotechnological inventions.[24] To the extent that access to biotechnological inventions is being restricted, Nicol and Nielsen suggested that it typically occurs where providing a third party with access to patented technology could result in a competing product.[25]

23.21 Responses to the survey and interview data collected by Nicol and Nielsen suggest that a variety of factors affect the terms on which a biotechnology patent will be licensed. The principal considerations are as follows.[26]

- The nature of the technology—non-exclusive licences are more common for patents on research tools and gene sequences than for a genetic invention that might result in a drug based therapy; and patent holders are likely to be more willing to license technology that is not critical or central to their business plan.

- Identity and business of the patent holder—academic institutions and biotechnology start-ups appear to be more likely to license patented technology to a third party on an exclusive basis.

- Identity and number of potential licensees—'downstream' entities such as pharmaceutical companies often insist on exclusive licences to justify investment in the research and development of a drug target or therapeutic product, but favour non-exclusive licensing of research tools; universities and research institutions are likely to enter into exclusive licences in order to find a partner for the commercial development of the research;[27] and the scope of rights granted under a licence and the fees payable may differ if the licensee is an academic institution rather than a commercial enterprise.

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22 Ibid, 102.
23 Ibid, 150.
24 Ibid, 254.
25 Ibid, 254.
26 Ibid, 109–122, 149–155.
27 Similarly, a United States study of entities operating in the biotechnology field has suggested that non-profit entities (including universities) are more likely to rely on exclusive licensing arrangements than private companies: M Henry and others, 'DNA Patenting and Licensing' (2002) 297 *Science* 1279.

- Payment considerations—the larger the licence fees sought by a patent holder, the more likely a potential licensee is to require exclusive rights to the patented technology. In the case of research tool patents, requiring a modest fee from multiple licensees may be the best means to maximise profits derived from such a patent.[28]

23.22 Respondents to the Nicol-Nielsen Study indicated that refusals to license gene patents are relatively low.[29] In the small number of cases in which a licence had been refused, respondents suggested that a justifiable commercial explanation might exist. These include that: a licence would conflict with a patent holder's own business strategy or an agreement already in place with another party; the potential licensee was problematic (in terms of their financial position or reputation in the market place); the proposed terms of the licence (for example, financial terms) were unsatisfactory; or the proposed application of the patented technology by the potential licensee was unethical.[30] However, Nicol and Nielsen noted that statistics relating to the frequency with which licences are refused in the Australian medical biotechnology sector do not take into account instances in which an entity chooses not to request a licence because it expects the licence to be refused or offered on unreasonable terms.[31]

Submissions and consultations

23.23 In IP 27, the ALRC sought information about licensing practices relating to Australian gene patents, including the type of entities that are seeking and granting such licences, the purpose for which licences are being obtained, and whether the terms on which gene patents are being licensed are perceived to be fair and reasonable.[32]

23.24 In conformity with responses to the Nicol-Nielsen Study, a number of submissions and consultations indicated that licences are being granted to a broad range of gene patents and that the inventions claimed in these patents are being further developed.[33] For example, Davies Collison Cave, submitted:

> Based on anecdotal evidence available to us, we believe that licences are regularly being sought and granted, and the associated inventions are being exploited, across

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28 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 151–152.

29 Six out of 49 companies and two out of 23 research institutes surveyed by Nicol and Nielsen indicated that their request for a patent licence had been refused; no diagnostic facilities that responded to the survey had been refused a licence: Ibid, 145–146. Information provided in interviews conducted by Nicol and Nielsen reinforce the survey data: D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 146–148.

30 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 145, 148–149.

31 Ibid, 161.

32 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Questions 10–1, 10–2 and 10–3.

33 GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

> the full spectrum of patented technologies, including all types of biotechnology and more specifically 'gene patent' technology.[34]

23.25 Submissions also supported Nicol and Nielsen's conclusion that refusals to license gene patents do not appear to be a significant issue in the Australian biotechnology market at this stage.[35] Submissions suggested that failures to negotiate a licence generally reflected the normal operation of the market, rather than concerted efforts by Australian patent holders to limit access to gene patents.[36]

23.26 A few submissions suggested that Australian entities might be using patented genetic technologies without a licence from the relevant patent holder. In particular, comments indicated that Australian universities may operate on the understanding that any research conducted by them involving a patented genetic material or technology does not require a licence.[37] In addition, diagnostic testing laboratories in Australia may make use of patented genetic inventions in performing diagnostic tests without obtaining a licence. The Royal College of Pathologists of Australasia (RCPA) stated that, as a matter of practice, licences to patents covering genetic materials are 'rarely requested by the testing laboratory or demanded by the patent holder'.[38] These observations are consistent with the conclusions of the Nicol-Nielsen Study:

> [One] option when a particular area of research is discovered to be infringing a patent is to ignore it. Many respondents in research institutions rely on the argument that their research is exempt. There is also some evidence of patents being ignored in the company sector. Similarly, in the diagnostics area, it appears that most patents are ignored.[39]

23.27 Although available evidence suggests that licensing practices in Australia are not unduly restrictive, a few submissions nonetheless encouraged the ALRC to address

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34 Davies Collison Cave, *Submission P48*, 24 October 2003. See also GlaxoSmithKline, *Submission P33*, 10 October 2003.

35 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

36 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

37 A McBratney and others, *Submission P47*, 22 October 2003. The impact of patents on genetic research is addressed in Ch 13. In addition, Ch 14 considers whether the *Patents Act* should be amended to include an 'experimental use' defence to patent infringement claims.

38 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. The RCPA indicated that approximately 40 out of the approximately 200 tests that are listed on the website of the Human Genetics Society of Australasia are covered by patents. However, the RCPA was not aware of any Australian company seeking licences from, or granting licences to, Australian diagnostic laboratories.

39 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 257.

the potential adverse effects if patent holders refused to license gene patents or offered licences on unreasonable terms.[40] Dr Graeme Suthers submitted:

> There may be limited evidence of problems relating to gene patenting as yet, but the ALRC must evaluate not only the previous or current problems but also the potential problems.[41]

Impediments to gene patent licensing in Australia

23.28 The Nicol-Nielsen Study suggests that, in addition to the financial factors that might have an impact on an entity's ability to commercialise its gene patents, impediments continue to exist in the licensing of genetic inventions.[42] Respondents to the Nicol-Nielsen Study commented that Australian gene patent holders and potential licensees of gene patents in Australia face difficulties in negotiating licence agreements, particularly if the other party is a more experienced commercial entity.

> One of the big problems identified for Australian companies is lack of the ruthlessness that many of their international counterparts have developed. Hence they tend to cave in too easily when negotiations become difficult. In part this may be because they don't appreciate the value of what they are acquiring and giving.[43]

23.29 In interviews conducted in connection with the Nicol-Nielsen Study, many respondents made reference to 'difficulties in negotiating' patent licences and that 'often these difficulties stemmed from the fact that they held an inferior bargaining position'.[44] Nicol and Nielsen also concluded that Australian entities 'lack deal precedents' and that 'one of the biggest problems is naivety in bargaining'.[45] The Study also found that a relatively standard set of licence terms are at issue in most negotiations,[46] and certain terms are consistently matters of substantial disagreement and negotiation—in particular, payment provisions, field of use restrictions, and provisions claiming reach-through rights.[47]

23.30 Australian entities may also have difficulties in identifying the patents for which a licence is needed. Respondents to the Nicol-Nielsen Study indicated that identifying patents that may need to be licensed is an onerous and expensive exercise, and is becoming more so as the gene patent landscape becomes more complex.[48] In

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40 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003

41 G Suthers, *Submission P30*, 2 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

42 See further Ch 18.

43 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 114.

44 Ibid, 158, 162.

45 Ibid, 108.

46 Ibid, 115–119, 158.

47 Ibid, 160, 162–163. Reach-through claims in patent licences may provide for the licensor to obtain ownership, licence rights or royalty payments to inventions arising as a result of activities conducted under a licence: see further Ch 13.

48 Ibid, 181–182.

Chapter 9, the ALRC proposed reforms to IP Australia's on-line databases for the purpose of assisting patent holders and users of patent rights in conducting preliminary prior art searches.[49] The following section also considers the desirability of establishing mechanisms to assist patent holders and patent users in identifying relevant patents and licensing them as a bundled package.

Facilitating gene patent licensing

23.31 The ALRC has been considering ways to facilitate access to genetic materials and technologies by participants in the Australian biotechnology sector. Later chapters in this Discussion Paper address the use of the compulsory licensing provisions in the *Patents Act* and consider whether introducing a statutory licensing scheme (comparable to schemes under the *Copyright Act 1968* (Cth)) for certain types of gene patents would be beneficial.[50]

23.32 In addition, the ALRC has been considering other government and industry initiatives that might facilitate gene patent licensing in Australia and reduce associated transaction costs, including:

- the development of education programs for biotechnology companies and research institutions relating to the licensing of gene patents;
- the development of model licence agreements; and
- encouraging industry-based initiatives, such as patent pools and patent clearinghouses, to facilitate gene patent licensing and technology transfer.

Education programs about licensing practices

23.33 Chapters 15 and 18 outlined the variety of programs that exist to support commercialisation of research by Australian entities, including programs directed specifically to the Australian biotechnology sector. To date, the focus of these programs has been to provide support (including funding) to aid the commercial development of innovation in biotechnology research.

23.34 Biotechnology Australia and the Department of Foreign Affairs and Trade (DFAT), among others, have also published educational materials to promote an understanding of intellectual property issues in biotechnology, including how intellectual property rights in biotechnological inventions can be used and managed most effectively.[51] The involvement of these government agencies in intellectual property issues is an indication of the importance of intellectual property in fostering economic growth and international trade.

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49 Proposal 9–1.

50 See Ch 27 and 28.

51 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001); Department of Foreign Affairs & Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001).

23.35 DFAT has published the *Intellectual Property & Biotechnology: A Training Handbook* (DFAT IP Handbook).[52] Its purpose is to provide an introduction to key intellectual property concepts, as well as an understanding of how they apply in practice. The DFAT IP Handbook comprises ten self-contained modules, nine of which focus on particular issues in intellectual property law relevant to the biotechnology sector and on managing intellectual property rights. The tenth module contains case studies that illustrate the way in which particular issues may arise in practice.[53]

23.36 The DFAT IP Handbook contains a separate module on licensing and enforcing intellectual property rights, which provides an overview of issues that Australian organisations may encounter in negotiating licences to gene patent rights.[54] The module outlines factors relevant to the decision to commercialise an invention and the various ways in which patent rights can be exploited. It also includes information relating to negotiating biotechnology licences—from conducting due diligence on a potential licence partner, to the type of provisions that commonly appear in patent licence agreements and the purpose of these provisions.

23.37 Biotechnology Australia has also released a manual providing a practical guide to the identification, protection and management of biotechnology-related intellectual property (Biotechnology IP Manual).[55] The manual is a resource for research institutions, companies and entities funding biotechnology research, to be used in conjunction with such entities' existing intellectual property management policies and practices. The Biotechnology IP Manual includes a separate chapter on commercial exploitation of intellectual property, which addresses topics such as conducting due diligence, valuation of intellectual property, factors relevant to a decision whether to license patent rights, as well as common terms in patent licences and their significance.[56]

23.38 Organisations have also been established to develop the commercial skill base of Australian entities, including those in the biotechnology sector. These organisations and the type of programs offered include the following.

- The Australian Institute for Commercialisation is a not-for-profit company that 'delivers programs to improve commercialisation of Australia's research investment';[57] offers courses on technology commercialisation for managers in

52 Department of Foreign Affairs & Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001).

53 The DFAT IP Handbook indicates that it is intended for use as a resource in connection with a training course, either in a group or on an individual basis: Ibid, vii.

54 Ibid, Module 9.

55 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001).

56 Ibid, ch 8.

57 Australian Institute for Commercialisation Ltd, *About the AIC*, <www.ausicom.com> at 12 January 2004.

public and private sector organisations; and conducts a 'commercialisation bootcamp' for doctoral students and early career researchers.[58]

- AusBiotech Ltd is a national industry body whose membership includes entities from all aspects of the Australian biotechnology sector.[59] AusBiotech is aimed at facilitating the commercialisation of Australian bioscience in the international marketplace and provides its members with access to training and information resources, as well as opportunities to network with other members.[60]

Licensing guidelines and model agreements

23.39 A 2002 report of the Organisation for Economic Co-operation and Development (the OECD Report) concluded that concerns about gene patents are often about access to patents through licensing arrangements, rather than about the grant of gene patents *per se*. In light of this, the report proposed that:

> governments [should] consider the development of good practice guidelines or codes of conduct. Good licensing practices are already being developed by public-sector research organisations for internal use (e.g. MTAs [Materials Transfer Agreements], policies on research tools and licensing clauses). Guidelines could also be developed in consultation with industry to determine the limits of acceptable licensing practices.[61]

23.40 Similarly, in a report released in 2004, the Organisation for Economic Co-operation and Development (OECD) commented that:

> Licensing guidelines or model contracts are self-regulatory solutions to some of the perceived problems associated with the patenting of biotechnology.[62]

23.41 The OECD's Working Party on Biotechnology is currently developing best practice guidelines for the licensing of genetic inventions.[63] It is anticipated that the guidelines will be voluntary, non-binding recommendations and serve as examples of good practices.[64] In November 2003, a steering group of experts met to discuss this issue, and a draft of the licensing guidelines is scheduled to be released in mid-2004.

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58 Australian Institute for Commercialisation Ltd, *AIC Professional Development*, <www.ausicom.com/02_service_centre> at 12 January 2004.

59 AusBiotech Ltd, *What is AusBiotech?*, <www.ausbiotech.org> at 21 January 2004; AusBiotech Ltd, *AusBiotech's Corporate Members*, <www.ausbiotech.org> at 21 January 2004.

60 AusBiotech Ltd, *Membership Benefits*, <www.ausbiotech.org> at 21 January 2004.

61 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 82.

62 Organisation for Economic Co-operation and Development, *Patents and Innovation: Trends and Policy Challenges* (2004), 23.

63 Organisation for Economic Co-operation and Development, *Guidelines for Good Licensing Practices*, <www.oecd.org> at 22 October 2003.

64 Organisation for Economic Co-operation and Development, *Brief Explanation of the Working Party on Biotechnology's Project on Best Practice Guidelines for the Licensing of Genetic Inventions*, <www.oecd.org/dataoecd/2/39/9230380.PDF> at 29 August 2003.

23.42 Best practice guidelines and model agreements are already an aspect of technology transfer in the United States. As discussed in Chapter 13, the United States National Institutes of Health (NIH) have developed *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (NIH Principles and Guidelines).[65] While the NIH Principles and Guidelines apply specifically to the recipients of NIH research grants and contracts, the NIH has expressed its hope that 'these Principles and Guidelines will be adopted by the wider research community'.[66] The NIH has also developed a 'Simple Letter Agreement for the Transfer of Materials' in conjunction with the NIH Principles and Guidelines. In addition, a model Materials Transfer Agreement developed by the United States' Association of University Technology Managers (AUTM) is widely used by entities in the United States and other countries.[67] Industry organisations—such as the Licensing Executives Society—and industry publications may also be a source of examples of standard form licence agreements.

Patent pools and other industry initiatives

23.43 Patent pools, patent clearinghouses, or collective rights organisations have also been proposed as a self-regulatory solution to address difficulties in obtaining access to patented genetic materials and technologies. The OECD Report has suggested that:

> Novel solutions, such as patent pools, clearinghouses and collective licensing organisations, should be further explored to understand their potential utility and their real impact on the biopharmaceutical sector.[68]

Patent pools

23.44 A 'patent pool' is an agreement between two or more patent holders to license their respective patents to one another, or to third parties, on a non-exclusive basis.[69] Participants in a patent pool typically retain ownership of their respective patent rights, and license the pooled patents directly, or through an administrative intermediary established for the purpose.

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65 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

66 Ibid, 72090.

67 Materials Transfer Agreements are discussed in Ch 18.

68 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 82. See also Organisation for Economic Co-operation and Development, *Patents and Innovation: Trends and Policy Challenges* (2004), 23.

69 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 4; Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 66. See also Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

23.45 Patent pools have been created in relation to other technologies, including in connection with sewing machines, aircraft and radio parts, semiconductors and DVD technology.[70] However, there is limited precedent for patent pools in bioscience.[71]

23.46 The purpose of a patent pool is to facilitate the use of other entities' intellectual property. In principle, patent pools could be employed by patent holders to facilitate access to complementary, blocking or other patented tools for use in genetic research and development, or to facilitate access to various medical genetic tests or other genetic therapies.

23.47 A number of benefits may flow from the pooling of patent rights. The OECD Report has suggested that patent pools may:

> (i) help integrate complementary technologies; (ii) reduce transaction costs; (iii) clear blocking positions; (iv) avoid costly infringement litigation; and (v) promote the dissemination of technology.[72]

23.48 However, patent pools have also been criticised on the basis of the perceived anti-competitive effects of such arrangements. It has been suggested that patent pools may inflate the costs of competitively priced technologies and encourage collusion and price fixing.[73] These issues are discussed in Chapter 24. In addition, some critics have suggested that patent pools may shield invalid patents.[74]

23.49 Questions have been raised about the feasibility of establishing patent pools in the biotechnology sector. The OECD Report has commented that, while there appears to be a growing interdependence among gene patents, and while licensing transaction costs may be burdensome, the biotechnology industry is unlike the electronics sector. In the latter sector, defining standards and interoperability of technologies is important and may act as an incentive to the development of patent pools.[75]

23.50 Professor Arti Rai has argued that patent pools are most likely to arise when horizontal competitors, who share similar values and are engaged in repeat-play transactions, each hold similar portfolios of blocking patents. Where the relevant parties have disparate patent positions and consequently differing attitudes towards patents, patents pools are less likely to arise. Rai has commented that:

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70 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 4–5.

71 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 66.

72 Ibid, 66–67. See also J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 8–10.

73 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 10–11.

74 Ibid, 11.

75 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 67.

> the relevant players in the biotechnology industry include institutions ranging from federal agencies and academic institutions to various types of private companies, each of which has a different agenda. In the context of a patent pool, these heterogeneous parties would probably have difficulty reaching agreement on the licensing policy the pool should adopt.[76]

23.51 However, Rai considered that a patent pool might be formed in the biotechnology context where multiple patents are absolutely necessary to conduct basic research on a gene or a particular disease.[77] The OECD Report also commented that some of the impediments to patent pools in the biotechnology sector may be overcome if limited fields of application and essential patents can be defined.[78]

Patent clearinghouses

23.52 Patent clearinghouses—or collective rights organisations—are, in effect, a more formalised patent pool.[79] Clearinghouses may cover a broader range of technologies than a particular patent pool and are more likely to rely on a single entity to coordinate the administrative functions associated with the licensing of patent rights.

23.53 Patent clearinghouses are analogous to collecting societies that administer licences over certain types of copyright works.[80] Professor Robert Merges has identified a number of distinctive features of such arrangements, including:

- the establishment of the clearinghouse by knowledgeable industry participants;
- the division of intellectual property rights into categories based on the participants' knowledge and experience; and
- the establishment of a price for the rights within each category (either individually or as a package), which applies equally to all similarly-situated licensees.[81]

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76 A Rai, 'Intellectual Property Rights in Biotechnology: Addressing New Technology' (1999) 34 *Wake Forest Law Review* 827, 840–841. See also F Scherer, 'The Economics of Human Gene Patents' (2002) 77 *Academic Medicine* 1348, 1363–1364.

77 A Rai, 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust' (2001) 16 *Berkeley Technology Law Journal* 813, 847.

78 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 67.

79 The terms 'collective rights organisations' and 'clearinghouses' are sometimes used interchangeably and at other times in conjunction. For the purposes of this Discussion Paper, the term 'clearinghouses' is used to refer to arrangements with the features identified in this section: see, eg, G Graff and D Zilberman, 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 3 *IP Strategy Today* 1, 3–4.

80 See Ch 29.

81 R Merges, 'Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations' (1996) 84 *California Law Review* 1293, 1296, 1327.

23.54 In addressing the benefits of patent clearinghouses in the agricultural biotechnology industry, Gregory Graff and David Zilberman have suggested that an effective clearinghouse mechanism would provide the following services:[82]

- identification of all relevant intellectual property, together with an indication of whether such rights are available for licensing;
- establishment of a pricing scheme, contractual terms, and royalty distribution arrangements; and
- an arbitration mechanism for monitoring and enforcing contracts.

23.55 The advantages of patent clearinghouses are similar to those identified in the case of patent pools, namely:

> the consolidation of intellectual property rights by intellectual property holders so that negotiating contracts with numerous rights holders is streamlined and transaction costs are consequently reduced.[83]

23.56 Nicol and Nielsen have suggested that the use of patent clearinghouses in the Australian biotechnology industry warrants further consideration. They considered that patents clearinghouses—perhaps in conjunction with a statutory licensing scheme—might address problems caused by licensing transaction costs and the need to obtain authorisation to use an increasing number of patent rights in order to pursue a particular line of research.[84] They commented that, while a clearinghouse arrangement may not be suitable for patent licences relating to drug development, it may be useful in the context of patented genetic sequences and genetic research tools.[85]

Submissions and consultations

23.57 IP 27 asked whether patent pools or clearinghouses should be created to make it easier for laboratories to obtain licences for patented genetic inventions, and how this might best be achieved.[86]

23.58 Several submissions expressed support for the creation of patent pools or clearinghouses in this context.[87] For example, the Walter and Eliza Hall Institute of Medical Research commented that:

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82 G Graff and D Zilberman, 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 3 *IP Strategy Today* 1, 9. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6,

83 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 242.

84 Ibid, 242–244.

85 Ibid, 243.

86 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 12–9.

> this would help both the patent holders (increased attractiveness to users) and the users (increased ease of dealing with all existing patents and licences). This would be most important for generic tools, technologies and procedures where specific packages could be put together for different applications. This might best be achieved by creating a commercial opportunity for patent and licence packaging companies who would investigate the most attractive packages somewhat like insurance brokers and negotiate the best prices because they can deal in bulk.[88]

23.59 Addressing the desirability of patent pools and clearinghouses in relation to diagnostic genetic testing, the Human Genetics Society of Australasia submitted that:

> Where a licence is necessary and royalties are payable on a 'number of tests done' basis, patent pools and clearinghouses could reduce the difficulties for laboratories. For Australia, one could envisage a single 'entity' that would act for all patent holders. Laboratories would deal with that 'entity' in relation to all patent issues. 'Bundled licences' that meet the needs of the laboratory could be provided, with responsibility for dividing up the revenue generated and forwarding it to patent holders resting with the 'entity'.[89]

23.60 Several submissions, while supporting voluntary arrangements, expressed concern or opposition to the creation of compulsory patent pools or clearinghouses.[90] For example, GlaxoSmithKline submitted that:

> Voluntary patent pools can help reduce patent thickets and transaction costs, although patentees unwilling to license their patents widely may well be unwilling to add their patents to the pool. Compulsory patent pools should not be created as this would serve to reduce the incentive to innovate.[91]

23.61 McBratney and others submitted that patent pools could 'fall foul' of competition law. They suggested that the compulsory licensing regime may be just as effective, and with less risk of competition law complications.[92] Chapter 24 addresses these issues further.

ALRC's views

23.62 The results of the Nicol-Nielsen Study, as well as submissions and consultations to the ALRC's Inquiry, suggest that restrictive licensing of gene patents is not currently pervasive in the Australian biotechnology industry. Further, as outlined in other chapters of this Discussion Paper, no significant adverse impact on genetic research, commercialisation, or the healthcare system in Australia has been demonstrated at this

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87 For example, South Australian Government, *Submission P51*, 30 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; G Suthers, *Submission P30*, 2 October 2003.

88 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

89 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

90 GlaxoSmithKline, *Submission P33*, 10 October 2003; G Suthers, *Submission P30*, 2 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

91 GlaxoSmithKline, *Submission P33*, 10 October 2003.

92 A McBratney and others, *Submission P47*, 22 October 2003.

stage. In light of this, the ALRC is not inclined to make proposals aimed specifically at regulating gene patent licensing practices, or prohibiting certain types of licensing arrangements.

23.63 However, available evidence does suggest that some participants in the Australian biotechnology sector may find the negotiation of patent licences to be problematic. These difficulties stem from a variety of causes, including lack of commercial experience in licensing patents generally, the unequal bargaining power of the parties, and inadequate resources to commit to extended licence negotiations.[93] In addition, the increasing complexity of the Australian patent landscape may create difficulties for entities in identifying relevant patents and in negotiating licences.

Education programs

23.64 The ALRC considers that an effective way to address these matters is to assist Australian entities in developing commercial and negotiation skills by enhancing education programs about licensing inventions involving genetic materials and technologies. Biotechnology Australia would be an appropriate body to co-ordinate the development of such programs, in consultation with state and territory governments and other relevant stakeholders.

23.65 Education programs about patent licensing would expand upon projects already undertaken by Biotechnology Australia and other federal, state and territory departments to assist Australian entities in commercialising the results of biotechnology research. In Chapter 18, the ALRC proposed that Biotechnology Australia continue to develop and implement programs to assist technology transfer offices in commercialising inventions involving genetic materials and technologies (see Proposal 18–1). Education programs about patent licensing directed to Australian research institutions and biotechnology companies would complement these initiatives.

23.66 The education programs should address issues such as structuring deals aimed at the licensing of inventions involving genetic materials and technologies; alternative mechanisms by which rights to a patent may be obtained by a third party (such as a patent assignment) and when these mechanisms might be preferable to licensing patent rights; common terms in gene patent licences; typical licensing practices; and negotiation strategies for gene patent holders and licensees of gene patent rights. The programs should also address other issues relevant to the licensing and enforcement of patent rights, including patent litigation insurance.[94]

Model licence agreements

23.67 Transaction costs in negotiating licences to gene patents have also been identified as an issue for Australian entities. The Nicol-Nielsen Study suggested that

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93 Other difficulties faced by Australian research institutions and biotechnology companies in patenting and commercialising research results are considered in Ch 15, 18 and 19.

94 Patent litigation insurance is discussed in Ch 9.

licence negotiations often follow a well-trodden path in which certain types of terms generate recurrent controversy. The ALRC agrees in principle with the solutions proposed by the OECD and considers that these problems would be minimised by the development of model agreements for the licensing of inventions involving genetic materials and technologies. Model licence agreements would reduce the financial costs and time involved in negotiating licences to gene patents, and would be particularly useful for small and medium sized Australian entities, which have limited resources.

23.68 The ALRC considers that AusBiotech Ltd would be an appropriate body to coordinate the development of such model agreements. As the peak industry body in the Australian biotechnology sector, AusBiotech's membership includes entities whose businesses involve diverse aspects of the research, development and commercialisation of genetic materials and technologies. AusBiotech appears, therefore, to be well-placed to seek opinions about the issues that model agreements should address and to balance the interests of patent holders and licensees in developing these agreements. Government involvement in this process (at federal, state and territory levels) would also be desirable to ensure that the public interest in maintaining access to genetic materials and technologies—for example, to genetic research tools—is taken into account in developing model agreements.

23.69 The ALRC envisages that a number of model agreements could be developed to address the particular issues raised by different types of gene patents and the various purposes for which a licence may be required. Entities that choose to use the model agreements would be able to adopt the terms of an appropriate agreement in full, or to modify an agreement by negotiation in a manner that best suits the needs of the parties. Some terms of the model agreements—for example, financial provisions—are more likely than others to require adaptation to meet the particular needs of the parties. However, model agreements could nonetheless offer useful examples of the way in which financial terms might be structured, as a starting point in negotiations.

23.70 Uniform agreements developed by bodies such as the NIH and AUTM in the United States, as well as the licensing guidelines currently being developed by the Biotechnology Working Group of the OECD, may be useful resources in developing the proposed model agreements.[95] The ALRC considers that model agreements would include provisions relating to: definitions of particular types of genetic materials and technologies; the scope of rights granted under a licence (including both exclusive and non-exclusive licences); restrictions on the exercise of licence rights (such as reservations of rights for research use); and payment terms (including desirable royalty structures, fixed fee and milestone payment provisions). The agreements might also include model provisions relating to more controversial licensing issues, such as reach-through terms. Interpretative guidelines should be developed in conjunction with the model agreements to assist users in understanding the circumstances in which each of

95 Aspects of these agreements that address particular requirements of United States law would, however, need to be appropriately adapted for the Australian context.

the agreements could be used and the scope and purpose of particular terms in the agreements.

Industry initiatives

23.71 The ALRC considers that the development of education programs and the creation of model licence agreements will address some of the issues faced by Australian biotechnology companies and research institutions in licensing gene patent rights. However, these reforms are unlikely to address all the difficulties that Australian entities face in identifying relevant gene patents to which a licence may be required, and in meeting the high transaction costs of negotiating multiple licences. Additional mechanisms may be required to facilitate licensing in relation to genetic materials and technologies within the Australian biotechnology sector.

23.72 The ALRC believes that a representative industry body should consider the feasibility of establishing patent pools or patent clearinghouses over particular types of patented genetic materials or technologies. As noted above, AusBiotech Ltd is the peak biotechnology industry body in Australia, with a diverse membership base. It would be an appropriate body to encourage and coordinate the consideration of industry-based initiatives to facilitate the licensing of genetic materials and technologies.

Proposal 23–1 Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should continue to develop and implement education programs to assist research institutions and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies. (See also Proposals 18–1 and 19–1.)

Proposal 23–2 AusBiotech Ltd should develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. The model agreements should be developed in consultation with Biotechnology Australia, state and territory governments, and other relevant stakeholders as a non-binding model of desirable licensing practices. (See also Proposals 13–1 and 18–4.)

Proposal 23–3 AusBiotech Ltd should consider ways in which industry initiatives can facilitate the licensing of patent rights over genetic materials and technologies, for example through the establishment of patent pools or patent clearinghouses.

24. Patents and Competition Law

Contents

Introduction

24.1 This chapter discusses the relationship between patent law and competition law, and considers to what extent competition law can be used to prevent or remedy anti-competitive conduct in relation to patented genetic materials and technologies.

24.2 The two key pieces of legislation in this area are Part IV of the *Trade Practices Act 1974* (Cth) (TPA), which proscribes a range of anti-competitive conduct; and the *Patents Act 1990* (Cth) (*Patents Act*), which limits the inclusion of certain anti-

competitive conditions in contracts, leases or licences to exploit a patent,[1] and provides remedies for unjustified threats of infringement proceedings.[2]

Competition and patent law

Intellectual property laws and competition laws

24.3 Competition law seeks 'to enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection'.[3] The promotion of competition and fair trading can enhance dynamic efficiency and motivate technological innovation, which in turn promotes competition between market participants. Intellectual property laws seek to encourage innovation by granting exclusive statutory property rights to certain creative and inventive efforts.[4]

24.4 One commentator has noted that although competition law and intellectual property law both seek to increase competition and efficiency within markets to the benefit of consumers, their modes of achieving this goal differ:

> competition law strives to maintain a consistently competitive market whilst intellectual property law is content to allow mild distortions in market conditions to realise long term benefits. Thus, despite the common goal, intellectual property law's mode of achieving market efficiencies is antithetical to competition law's view of acceptable behaviour. It is this ideological impasse that produces tension.[5]

24.5 According to the Australian Competition and Consumer Commission's (ACCC) submission to this Inquiry:

> The interaction between competition laws and intellectual property laws raises a crucial question about the types of incentives that are required to encourage innovation efforts to the level that is best for society. Another question is whether society benefits most if it rewards initial innovation efforts through broad intellectual property protection, or if it fosters successive innovation by requiring access to the intellectual property of the initial innovator. The answers to such questions help to define the appropriate scope of statutory IP rights. The scope of IP rights can have a significant bearing on the structure of markets.[6]

24.6 The Intellectual Property and Competition Review Committee (IPCRC) considered the interaction between competition and patent law in its report, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (IPCRC Report). The IPCRC commented that:

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1 *Patents Act 1990* (Cth) ss 144–146.
2 Ibid ss 128–132.
3 *Trade Practices Act 1974* (Cth) s 2.
4 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.
5 P Tucker, 'Refusal to Licence Intellectual Property Rights and Misuse of Market Power: Where is the Line in the Sand?' (1999) 10 *Australian Intellectual Property Journal* 78, 79–80.
6 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

> The major concerns of competition policy in regard to intellectual property rights are the market power that may result from granting such rights, and the detrimental effects caused by the anti-competitive exercise of IP rights. At its simplest, market power can harm consumers by setting prices which are higher than those needed to secure cost-effective production. Moreover, the harm caused by market power may extend beyond this, when the protection granted to firms allows them to slow or distort innovation. Under these circumstances, market power will limit the growth of productivity over time, and reduce the scope for sustainable increases in living standards.[7]

24.7 The IPCRC considered that there are genuine grounds for concern when intellectual property rights are used to slow the process of innovation, thereby hindering future competition. In its opinion, mechanisms were needed to prevent firms from using intellectual property rights to camouflage conduct involving price fixing, dividing markets or monopolising supply in other ways. The IPCRC concluded that, overall:

> the system of intellectual property laws acts to promote competition by maintaining the incentives to innovate, while striving to strike a balance—through the nature and content of the rights it grants—between those incentives and society's interest in the widespread diffusion of ideas. [The Committee] believes that the terms of the balance are properly specified in the intellectual property laws themselves … However, the Committee recognises that the rights granted by the intellectual property laws can be used to anti-competitive ends. This occurs when the rights are used to claim for the creator not merely a share of the gains society obtains from the creation, but also rents that arise from market power …[8]

Submissions and consultations

24.8 IP 27 asked whether, following the IPCRC Report and the Australian Government's response to it, there were any competition issues specifically relevant to gene patents that needed to be dealt with in the course of this Inquiry.[9]

24.9 Several submissions suggested that the ALRC should consider the competition issues that may arise from conduct relating to patented genetic materials and technologies.[10] The Walter and Eliza Hall Institute of Medical Research submitted that there is a natural antagonism between patent law, which grants potential time-restricted monopoly rights, and competition policy:

> For single products (eg therapeutic goods or specific diagnostic tests) exclusive licensing is required for commercial viability of the R&D program (ie you only get one bite of the cherry). For generic technologies, tools and methods of doing

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7 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 25.

8 Ibid, 26–27.

9 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 17–1.

10 For example, Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

> something one could argue that exclusive licensing is not necessary for commercial viability, is anti-competitive and not in the public interest.[11]

24.10 The ACCC submitted that, to the extent possible, it would prefer solutions that are capable of general application across all patents and sectors of the economy. It commented that:

> the licensing or assignment of IP rights is often pro-competitive as it enables IP to be exploited to a greater extent than would occur if the rights are not licensed or assigned at all. In these instances, licensing or assigning IP rights can increase production, geographic distribution and the rate of new product introduction. The licensing or assignment of IP rights can also be pro-competitive if it enables the licensee to engage in commercial activity that would otherwise be closed to it, or which could only be engaged in by duplicating or 'inventing around' the existing IP rights.
>
> In some instances, however, a condition of an IP license or assignment may have a detrimental impact on competition. A key concern for the ACCC with intellectual property licensing and assignment conditions is that they are not used to inappropriately constrain competition.[12]

24.11 The Australian Centre for Intellectual Property in Agriculture (ACIPA) submitted that the potential for gene patents to be anti-competitive is a real concern. ACIPA commented that the IPCRC and the National Competition Council (NCC)[13] had both failed to address these concerns in any detail:

> In the past most pharmaceutical products were chemical entities, while future products promise to be based on genetic materials (for the diagnosis and treatment of genetic conditions). This makes gene and gene sequence patents a key factor in sustaining pharmaceutical prices and ensuring the financial return to the pharmaceutical industry, and [is] a significant issue in considering the likely impact of patenting on competition. [The] failure of the Intellectual Property and Competition Review Committee to examine the role of patenting in different industries was a significant oversight. The inability to substitute or imitate broadly claimed genetic material patents and the concentration of the exclusive rights in large vertically integrated corporations can be expected to extract high social costs in Australia through a prolonged period of higher prices, restricted access and curtailed innovation …[14]

24.12 The Australian Health Ministers' Advisory Council submitted that:

> If research institutions find their capacity to engage in research and development affected by gene patents, this could reduce the pressure to improve genetic tests and pharmaceuticals based on an understanding of gene structure. This has the potential to perpetuate patent-based monopolies by limiting competition in the development of

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11 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

12 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

13 See National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999).

14 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

> new knowledge based on existing gene patents. This may add unnecessarily to the costs of these services and products.
>
> These issues do not automatically arise and many early genetic and related technology patents have been subject to broad licensing arrangements. The human genetic and related technology industry, however, relies more heavily on patents in their strategic business planning than most other industries. The industry is currently diverse, with a large number of small to medium enterprises. As a result many companies are dependent on a small number of patents to maintain commercial viability. In such circumstances there are good commercial reasons to vigorously protect their broad patents.[15]

24.13 Several submissions contended that gene patents do not raise any competition issues that are not relevant to patents in other fields of technology.[16] AusBiotech Ltd submitted that:

> Any changes in the light of the Intellectual Property and Competition Review Committee's report of 2000 and the Federal Government's response thereto should apply to all fields of technology. If anything, restrictions should be less rigorous in view of the small numbers of companies in the biotechnology field.[17]

Patent or competition law?

24.14 The ALRC received several submissions suggesting that the primary focus of concern should be on the breadth of gene patents, rather than the potentially anti-competitive use of them. They commented that the granting of narrower patents over upstream genetic inventions would minimise both the patent holder's monopoly, and the impact on competition in downstream research and healthcare provision.[18]

24.15 Several commentators have discussed the interaction between competition and patent law in relation to broad patents. Jane Nielsen of the University of Tasmania's Centre for Law and Genetics, has suggested that:

> Biotechnology raises new hopes in terms of public health, improved economy and consumer welfare. Much upstream research is now being conducted, but downstream research and production may be hindered if the patent laws are given too free a rein. This is due to the breadth of patents being granted, and the fact that courts are more likely at the present time to enforce patent laws over competition laws.[19]

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15 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

16 See, eg, GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

17 AusBiotech Ltd, *Submission P58*, 7 November 2003.

18 See, eg, L Palombi, *Submission P28*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003.

19 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating The New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 47.

24.16 Dr Charles Lawson of ACIPA has expressed concern that:

> an analysis of gene and gene sequence patenting in Australia has illustrated the potential for very broad claims to both sequences and sequence applications to effectively confound competitors using the basic patented genetic materials at all or inventing around the patents … This brings the effectiveness of competition law into focus and poses the question whether Australian patent and competition law will be effective in delivering to the Australian economy reasonably priced access to, and use of, the basic patented genetic materials, on which a competitive domestic pharmaceutical and agricultural industry, and further economically useful innovations depend.[20]

24.17 Patent law has several mechanisms that may be used to address competition concerns. For example, Chapter 6 discusses the criteria for patentability in relation to genetic materials and technologies, and Chapter 26 discusses the potential for compulsory licensing. This chapter focuses on the use of competition law, rather than patent law, to address competition concerns.

Trade Practices Act

Anti-competitive conduct

24.18 Part IV of the TPA deals with restrictive trade practices.[21] It prohibits anti-competitive agreements between competing firms, such as price fixing ('horizontal agreements');[22] anti-competitive agreements between firms at different stages of the production chain, such as exclusive dealing and resale price maintenance ('vertical agreements');[23] misuses of market power;[24] and mergers or acquisitions that are anti-competitive in nature.[25] Certain conduct is prohibited if it has the purpose or effect of 'substantially lessening competition' in a market, while other conduct is prohibited on a 'per se' basis.[26]

24.19 Section 45 of the TPA prohibits contracts, arrangements or understandings that have the purpose, effect, or likely effect of substantially lessening competition; or which contain an 'exclusionary provision'[27] which is prohibited on a 'per se' basis.

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20 C Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, 101–102.

21 Part IV of the TPA has been the subject of several reviews, including the National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999); Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000); Trade Practices Act Review, *Review of the Competition Provisions of the Trade Practices Act* (2003); and the Senate Economics References Committee's current inquiry into the effectiveness of the TPA in protecting small business.

22 *Trade Practices Act 1974* (Cth) ss 45, 45A.

23 Ibid ss 47, 48.

24 Ibid s 46.

25 Ibid ss 50, 50A.

26 'Per se' breaches do not involve an analysis of the impact of the conduct on competition because the conduct is presumed, by its nature, to have the effect of substantially lessening competition.

27 See *Trade Practices Act 1974* (Cth) s 4D.

Sections 45A–45EB regulate specific types of conduct, including price-fixing and secondary boycotts.[28]

24.20 Section 46 provides that a firm with a substantial degree of power in a market must not take advantage of that power for the purpose of eliminating or substantially damaging a competitor, preventing entry into that market or into any other market, or deterring or preventing a person from engaging in competitive conduct in that or any other market.[29]

24.21 Section 47 prohibits exclusive dealing in relation to a number of vertical restraint practices, where this has the purpose or effect of substantially lessening competition in a market.

24.22 Section 48 prohibits resale price maintenance, for example where a supplier sets the minimum price at which its goods or services are resold to a third person. Maximum price limits are not prohibited by this provision.[30]

24.23 Section 50 prohibits mergers or acquisitions that would have the effect or likely effect of substantially lessening competition in a substantial market.[31]

Intellectual property exemption

24.24 Section 51(3) of the TPA provides a limited exemption from some of the Part IV prohibitions for certain conditions in intellectual property licences and assignments. This section exempts conditions that relate to the subject matter of the intellectual property, which might otherwise constitute collusive conduct or price fixing (ss 4D, 45, 45A), exclusive dealing (s 47) or an acquisition which would result in a substantial lessening of competition in a market (ss 50, 50A).[32]

24.25 The exemption does not extend to the misuse of market power (ss 46, 46A) or resale price maintenance (s 48). As the exemption applies only to conditions in licences and agreements, it also does not cover refusals to license intellectual property, or infringement or enforcement actions.

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28 See generally R Steinwall, *Butterworths Australian Competition Law* (2000), 149–152.

29 See below for more detail.

30 See also *Trade Practices Act 1974* (Cth) s 96.

31 Section 50A prohibits the acquisition outside Australia of a controlling interest in a corporation that would lead to a substantial lessening of competition in a market.

32 See Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 202–203; National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999), 169–170.

Authorisation and notification

24.26 The ACCC may authorise conduct that might otherwise breach particular provisions of ss 45, 47, 48 and 50 of the TPA.[33] The ACCC applies different tests when determining authorisations, depending on the nature of the conduct in question. Generally, the ACCC may authorise conduct if it is satisfied that the proposed agreement or arrangement would be likely to result in a public benefit that outweighs the detriment to the public caused by any lessening of competition. The ACCC may authorise certain conduct that is per se illegal if the public benefit resulting from the conduct justifies the grant of the authorisation.[34]

24.27 A firm may notify the ACCC of proposed conduct constituting exclusive dealing (s 47). Generally, the notified conduct is taken not to have the purpose, effect or likely effect of substantially lessening competition until the notification is cancelled.[35] The ACCC may issue a notice to the firm withdrawing such protection if it is satisfied that the conduct has the purpose or effect of substantially lessening competition and that no public benefit will result from the conduct, or that such public benefit would not outweigh the public detriment constituted by the lessening of competition.[36]

Misuse of market power

24.28 As noted above, s 46 of the TPA provides that a firm with a substantial degree of power in a market must not take advantage of that power for the purpose of eliminating or substantially damaging a competitor, preventing entry into that market or into any other market, or deterring or preventing a person from engaging in competitive conduct in that or any other market.[37] The purpose of this section is to protect competition in the market, rather than individual competitors.[38]

The relevant market

24.29 To determine the degree of power a corporation has in a market, it is necessary to define the relevant market within which it is operating. The Trade Practices Tribunal articulated the principles on which markets are identified and defined in *Queensland Co-op Milling Association Ltd v Defiance Holdings Ltd*:

> A market is the area of close competition between firms, or putting it a little differently, the field of rivalry between them … Within the bounds of the market there

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33 Section 46 is not directly subject to the authorisation and notification provisions. However, s 46(6) provides that the section does not prevent a corporation from engaging in conduct that does not constitute a breach of ss 45, 45B, 47 or 50 of the TPA by reason of a current authorisation; or which is lawful under s 47 due to a notification to the ACCC. Accordingly, if conduct is lawful pursuant to an authorisation or notification, s 46 does not render it unlawful.

34 *Trade Practices Act 1974* (Cth) s 88.

35 With the exception of third line forcing, in which case other notification provisions apply.

36 *Trade Practices Act 1974* (Cth) s 93.

37 Ibid s 46(1).

38 *Queensland Wire Industries Pty Ltd v The Broken Hill Proprietary Co Ltd* (1989) 167 CLR 177, 191; *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2003) 178 ALR 253; *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 625, 639–640, 647, 663; *Rural Press Limited v Australian Competition and Consumer Commission* (2003) 203 ALR 217.

> is substitution between one product and another, in response to changing prices. So a market is the field of actual and potential transactions between buyers and sellers amongst whom there can be strong substitution, at least in the long run, if given sufficient price incentive … Whether such substitution is feasible depends ultimately on customer attitudes, technology, distance and cost and price incentives …[39]

24.30 This formulation is reflected in s 4E of the TPA, which defines a 'market' as:

> a market in Australia and, when used in relation to any goods or services, includes a market for those goods or services and other goods or services that are substitutable for, or otherwise competitive with, the first-mentioned goods or services.

24.31 Substitutability within a market has four dimensions: product differentiation; geographic; functional market level; and dynamic and temporal dimensions.[40]

24.32 Substitutability is determined by reference to the 'price elevation test' or the 'price incentive test'. This involves considering the likely responsiveness of both buyers and sellers to a small percentage increase in price for the relevant product. If users would shift to other products or if other producers could quickly and easily alter their product mix to provide an alternative supply, these products and the suppliers should be included in the same market as the products of the producer under investigation.[41]

Market power

24.33 To determine whether a corporation has a substantial degree of power in the relevant market, the court must consider the extent to which the conduct of the corporation is constrained by the conduct of competitors (or potential competitors), suppliers or customers.[42]

24.34 The traditional test of market power was formulated by Mason CJ and Wilson J in *Queensland Wire Industries v BHP*:

> the ability of a firm to raise prices above supply cost without rivals taking away customers in due time, supply cost being the minimum cost an efficient firm would incur in producing the product.[43]

24.35 The Trade Practices Commission's background paper, *Misuse of Market Power*, defined 'market power' as:

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39 *Queensland Co-op Milling Association v Defiance Holdings Ltd* (1976) 8 ALR 481, 517. In *Boral*, Gleeson CJ and Callinan J stated that a market is 'an area of close competition; a field of rivalry': *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 634.

40 National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999), 171.

41 R Steinwall, *Butterworths Australian Competition Law* (2000), 119.

42 *Trade Practices Act 1974* (Cth) s 46(3).

43 *Queensland Wire Industries Pty Ltd v The Broken Hill Proprietary Co Ltd* (1989) 167 CLR 177, 188.

> the ability of a corporation to make decisions with some degree of independence from the discipline of the market place, ie the ability to be able to act with some degree of freedom from the competitive constraints, exerted by its actual or potential competitors, suppliers and customers.[44]

24.36 In *Boral Besser Masonry Limited v ACCC*, Gleeson CJ and Callinan J stated that market power is the capacity to act without constraint. While pricing is usually regarded as the critical test of market power, the capacity to withhold supply or to decide the terms and conditions (apart from price) upon which to supply, also manifests market power. Their Honours commented that:

> Power, that is, the capacity to act without constraint, may result from a variety of circumstances. A large market share may, or may not, give power. The presence or absence of barriers to entry into a market will ordinarily be vital. Vertical integration may be a factor.[45]

24.37 In *Universal Music Australia Pty Ltd v ACCC*, the Full Federal Court held that a corporation's conduct in a market refers to its conduct in the market generally, rather than in relation to a particular market participant. However, the latter may be of evidentiary value in establishing the former. In addition, market power is determined by reference to persistent rather than temporary conditions.[46]

Taking advantage

24.38 A firm with a substantial degree of market power may breach s 46 if it 'takes advantage of' that power for a proscribed purpose. Section 46 requires not merely the co-existence of market power, conduct and proscribed purpose, but a connection such that the firm whose conduct is in question can be said to be taking advantage of its power.[47]

24.39 The term 'take advantage of' means 'use', and does not require conduct that is predatory or morally blameworthy.[48] In *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd*, the High Court held that where a firm acts in a manner that is consistent with the way it could have acted in a competitive market, its conduct is unlikely to constitute a taking advantage of market power.[49]

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44 Trade Practices Commission, *Misuse of Market Power: Section 46 of the Trade Practices Act 1974 (Background Paper)* (1990) Commonwealth of Australia, 16. The Trade Practices Commission is now known as the Australian Competition and Consumer Commission.

45 *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 635.

46 *Universal Music Australia Pty Ltd v Australian Competition and Consumer Commission* (2003) 201 ALR 636, 667, 672–673.

47 *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2003) 178 ALR 253, 264 (Gleeson CJ; Gummow, Hayne and Callinan JJ).

48 *Queensland Wire Industries Pty Ltd v The Broken Hill Proprietary Co Ltd* (1989) 167 CLR 177.

49 *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2003) 178 ALR 253, 269. See also *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609; *Rural Press Limited v Australian Competition and Consumer Commission* (2003) 203 ALR 217.

Proscribed purpose

24.40 A 'proscribed purpose' under s 46 means eliminating or substantially damaging a competitor, preventing or deterring a person from entering, or engaging in competitive conduct in that or any other market.[50]

24.41 A firm's purpose may be inferred from its—or any other relevant person's—conduct or from other relevant circumstances.[51] It must be a 'substantial' purpose, but need not be the sole or dominant purpose.[52] In its submission to this Inquiry, the ACCC commented that:

> in an IP context, the ACCC believes that proof of a proscribed purpose (in the absence of a 'smoking gun') would be particularly difficult.[53]

24.42 The Trade Practices Act Review, which was chaired by Sir Daryl Dawson (Dawson Committee), considered that proving purpose is generally not an unnecessarily onerous hurdle.[54] The Dawson Committee considered several proposals for reform of s 46, including the ACCC's proposal that an 'effects' test be added in addition to the 'purpose' test. It recommended that s 46 should be retained without amendment, and that the ACCC should give consideration to issuing guidelines on the application of Part IV to intellectual property.[55] The Australian Government has expressed support for these recommendations.[56]

Access to services

24.43 Part IIIA of the TPA provides a legislative regime to facilitate third party access to the services of essential facilities of national significance.[57] Part IIIA does not, however, apply to a service that is the use of intellectual property except to the extent that this is an integral, but subsidiary part of the service.[58] The ACCC submitted that, as a result of this exception, court-enforced access to intellectual property that may be essential for competition can currently only be achieved under the TPA where a breach of s 46 can be shown.[59]

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50 *Trade Practices Act 1974* (Cth) s 46(1).
51 Ibid s 46(7).
52 Ibid s 4F.
53 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.
54 Trade Practices Act Review, *Review of the Competition Provisions of the Trade Practices Act* (2003), 79.
55 Ibid, recs 3.1, 3.3. In March 2003, the Dawson Committee reaffirmed its recommendations in light of the High Court decision in *Boral*, maintaining that no amendment should be made to s 46, although the position could be reviewed after a number of other cases are determined: Australian Government, *Commonwealth Government Response to the Review of the Competition Provisions of the Trade Practices Act 1974* (2003), 4.
56 Australian Government, *Commonwealth Government Response to the Review of the Competition Provisions of the Trade Practices Act 1974* (2003), 5.
57 The provisions apply where the third party fails to secure access to the services through commercial negotiations, or where the parties cannot reach agreement regarding the terms and conditions of access.
58 *Trade Practices Act 1974* (Cth), s 44B.
59 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

Patents Act

24.44 Section 144 of the *Patents Act* makes void contracts that have 'tie-in' conditions that require the buyer, lessee or licensee to acquire a product from the patent holder which is not covered by the patent, or that prohibits or restricts him or her from using a product or process supplied or owned by a third party.[60] It is a defence to patent infringement proceedings that the patent agreement contains such a void condition, provided the patent holder inserted the condition.[61]

24.45 Section 146 permits certain behaviour that might be considered anti-competitive. For example, s 146(a) provides that a patent holder may stipulate that a person selling his or her product cannot sell competing products supplied by a third party.[62]

24.46 The IPCRC considered these provisions in its review. It commented that although 'tie-in' conditions were once considered to be automatically anti-competitive, economists now recognise that they may have certain benefits—including enhancing efficiency and reducing the social costs arising from a patent grant. The IPCRC recommended that these provisions be repealed and that such conduct be dealt with through its suggested amendments to s 51(3) of the TPA.[63] The Australian Government has accepted this recommendation, but has not yet implemented legislation to effect it.[64]

24.47 Section 128 of the *Patents Act* provides that where a person threatens another person with infringement or other similar proceedings, an aggrieved person may apply to a court for a declaration that the threats are unjustifiable, an injunction against the continuance of the threats, and the recovery of any damages sustained by that person as a result of the threat.

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60 *Patents Act 1990* (Cth) s 144(1), subject to the exceptions specified in s 144(2). See Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 161.

61 *Patents Act 1990* (Cth) s 144(4).

62 In addition, s 146(d) provides that the patent holder may insert a condition in a contract for the lease of, or a licence to exploit a patented product that reserves to the lessor or licensor the right to supply new parts of the patented product required to be put into it, or to keep it in repair.

63 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 161–162. The Industrial Property Advisory Committee made a similar recommendation in relation to a similar provision of the *Patents Act 1952* (Cth): Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 27.

64 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003.

Other jurisdictions

United States

24.48 The United States' antitrust laws are set out in several statutes. The *Sherman Act* prohibits contracts, combinations and conspiracies in restraint of trade, which affect United States commerce. The *Clayton Act* prohibits acquisitions of stock or assets where the effect may be to lessen competition substantially, or to create a monopoly in any line of commerce. The *Federal Trade Commission Act* deals with unfair methods of competition, and unfair or deceptive acts or practices in, or affecting, commerce.[65]

Guidelines for licensing intellectual property

24.49 The United States' Department of Justice and the Federal Trade Commission (the Agencies) enforce the federal antitrust laws. The Agencies have issued *Antitrust Guidelines for the Licensing of Intellectual Property* (*Licensing Guidelines*), to assist those involved in intellectual property licensing.[66]

24.50 The *Licensing Guidelines* embody three principles: (a) for the purpose of antitrust analysis, the Agencies regard intellectual property as being essentially comparable to any other form of property; (b) the Agencies do not presume that intellectual property creates market power in the antitrust context; and (c) the Agencies recognise that intellectual property licensing allows firms to combine complementary factors of production and is generally pro-competitive.[67]

24.51 The *Licensing Guidelines* provide that licensing arrangements raise antitrust concerns if they are likely to adversely affect the prices, quantities, qualities, or varieties of goods and services either currently or potentially available.[68] Most restraints in intellectual property licensing arrangements are evaluated under the 'rule of reason'. The Agencies consider whether the restraint is likely to have anticompetitive effects and, if so, whether the restraint is reasonably necessary to achieve pro-competitive benefits that outweigh these anti-competitive effects.[69] By contrast, some licensing arrangements are so anti-competitive that they are treated as unlawful 'per se'. These include naked price fixing, output restraints, market division among horizontal competitors, and certain group boycotts and resale price maintenance.[70]

24.52 The *Licensing Guidelines* also establish antitrust 'safety zones' in which the Agencies generally will not challenge a licence arrangement. In the absence of

65 See generally A Gutterman, *Innovation and Competition Policy* (1997), 71–72.
66 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), 2.
67 Ibid, 2–3.
68 Ibid, 7.
69 Ibid, 16.
70 See Ibid, 16; C Carroll, 'Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences' (2002) *Journal of Law, Technology and Policy* 435, 450.

extraordinary circumstances, the Agencies will not challenge a restraint in an intellectual property licensing arrangement if: (a) the restraint is not facially anti-competitive;[71] and (b) the licensor and its licensees collectively account for no more than 20% of each relevant market significantly affected by the restraint.[72]

24.53 The *Licensing Guidelines* refer to technology and innovation markets. A 'technology market' consists of the intellectual property that is licensed and its close substitutes.[73] An 'innovation market' consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development.[74]

24.54 Generally, in the absence of extraordinary circumstances, the Agencies will not challenge a restraint that may affect competition in a technology market if: (a) the restraint is not 'facially' anti-competitive; and (b) there are four or more independently controlled technologies, in addition to the technologies controlled by the parties to the arrangement, that may be substitutable for the licensed technology at a comparable cost to the user.[75]

Guidelines for collaborations

24.55 In 2000, the Agencies issued the *Antitrust Guidelines for Collaborations Among Competitors* to complement the *Licensing Guidelines*. These guidelines apply to agreements, other than merger agreements, between or among competitors to engage in economic activity, and the economic activity resulting from such agreements.[76]

24.56 Agreements that always or almost always tend to raise price or reduce output are per se illegal. These include agreements for price fixing, output fixing, bid rigging, sharing or dividing markets by allocating customers, suppliers, territories, or lines of commerce. Other agreements are assessed under the 'rule of reason' to determine their overall competitive effect.[77]

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71 'Facially anti-competitive' means restraints that normally warrant per se treatment, and other restraints of a kind that would always, or almost always, tend to reduce output or increase prices.

72 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), 22. This 'safety zone' does not apply to those transfers of intellectual property rights to which a merger analysis is applied.

73 When rights to intellectual property are marketed separately from the products in which they are used, the Agencies may rely on technology markets to analyse the competitive effects of a licensing arrangement.

74 If a licensing arrangement may adversely affect competition in developing new or improved goods or processes, the Agencies will analyse this impact either as a separate competitive effect in relevant goods or technology markets, or as a competitive effect in a separate innovation market.

75 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), 23.

76 'Competitors' includes both actual and potential competitors. Competitor collaborations involve one or more business activities, such as research and development; production; marketing; distribution; sales or purchasing; information sharing; and various trade association activities: United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for Collaborations* (2000), 2.

77 Ibid, 8–11.

24.57 The guidelines also include two 'safety zones' in which the anti-competitive effects are so unlikely that the Agencies presume the arrangements are lawful without further inquiry. This includes a safety zone for research and development.[78]

European Union

24.58 The European Community's Rules of Competition are set out in Title VI of the *European Community Treaty* (EC Treaty). Articles 81 and 82 are the primary Treaty provisions dealing with competition law. The European Commission is in the process of instituting major reforms to its competition policy, which are due to commence operation on 1 May 2004.[79]

Anti-competitive agreements and practices

24.59 Article 81 prohibits restrictive agreements and concerted practices between firms that may affect trade between the Member States and which have anti-competitive objects or effects.[80] Article 81(3) provides a mechanism for authorising certain prohibited agreements.[81]

24.60 The technology transfer block exemption provides a block exemption for certain categories of intellectual property licensing conditions.[82] The European Commission has released a new draft block exemption for technology transfer, which provides a short list of restrictive provisions that generally will be prohibited; a 'safe harbour' below certain market share thresholds—20% for licensing agreements between competitors and 30% for agreements between non-competitors—and a new set of guidelines to explain how art 81 applies to agreements that fall outside the safe harbour. The Commission aims to finalise the revised exemption before a modernised competition regime commences in May 2004.[83]

Abuse of dominant position

24.61 Article 82 prohibits any abuse by one or more firm of a dominant position within the common market or in a substantial part of it to the extent that it may affect

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78 Ibid, 25–27.

79 These reforms include the modernisation of competition enforcement framework, the review of the system of merger control, and various internal reforms: M Monti, 'EU Competition Policy after May 2004' (Paper presented at Fordham Annual Conference on International Antitrust Law and Policy, New York, 24 October 2003), 1.

80 A 'restrictive agreement' is an agreement between two or more firms that requires one or more of the parties to adopt a specific type of conduct. A 'concerted practice' involves co-ordination among firms that falls short of a formal agreement.

81 See *Council Regulation (EC) No 1/2003 of 16 December 2002 on the Implementation of the Rules of Competition Laid down in Articles 81 and 82 of the Treaty* (2002).

82 *Commission Regulation (EC) No 240/96 of 31 January 1996 on the Application of Article 85(3) of the Treaty to Certain Categories of Technology Transfer Agreements* (1996).

83 M Monti, 'EU Competition Policy after May 2004' (Paper presented at Fordham Annual Conference on International Antitrust Law and Policy, New York, 24 October 2003), 4–5. See also *Draft Commission Regulation (EC) No .../ 2004 of [...2004] on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements* (2004).

trade between Member States.[84] A firm abuses its dominant position if, for example, it imposes unfair prices or other unfair trading conditions; limits production, markets or technical development to the prejudice of consumers; applies dissimilar conditions to equivalent transactions with other trading parties; or uses 'tying' conditions in contracts.

24.62 European Community law traditionally applied an 'existence/exercise' dichotomy in relation to the interface between intellectual property and competition laws. This provided that aspects of an intellectual property right's existence generally could not be challenged by competition law, while the way in which the right was exercised could be challenged. The exercise of a right that fell within the specific subject matter of an intellectual property right was deemed to relate to the existence of the right.[85]

24.63 Several recent cases suggest that the courts' focus has shifted to considering whether 'exceptional circumstances' exist for regarding behaviour as anti-competitive.[86] In *Radio Telefis Eireann v EC Commission* (*Magill*), the European Court of Justice held that a copyright holder's refusal to license its copyright information in a derivative market constituted exceptional circumstances, as the refusal had prevented the emergence of a new product and monopolised a derivative market. Exceptional circumstances existed because the copyright information protected an essential facility in the derivative market,[87] and the refusal to license the information eliminated competition in that market.[88] Therefore, the refusal to license constituted an abuse of the copyright holder's dominant position in the market.[89]

24.64 In October 2003, Advocate General Tizzano of the Court of First Instance delivered a preliminary opinion on several questions of law referred by a German court in copyright infringement litigation between IMS Health, and its competitor, NDC Health. The Advocate General concluded that a refusal to license an intellectual property right could breach art 82 where there is no 'objective justification' for the

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84 In EC law, a 'dominant position' is a situation of economic power held by a firm that allows it to hinder effective competition in the relevant market.

85 A van Melle, 'Refusals to License Intellectual Property Rights: The Impact of RTE v EC Commission (Magill) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4, 7–8.

86 National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999), 269.

87 The 'essential facilities' doctrine provides that if a facility supplied in one market is an essential input for the production of goods or services in a downstream market, a competitor which has or obtains control of that facility would not be legitimately competing in the downstream market if it restricts access to the facility, or cuts off access to its competitors in that market: J Temple Lang, *Compulsory Licensing of Intellectual Property in European Community Antitrust Law: Paper prepared for the Department of Justice/Federal Trade Commission Hearings, Washington DC* (2002), 11. See below for more detail.

88 F Fine, 'NDC/IMS: A Logical Application of the Essential Facilities Doctrine' (Paper presented at Intellectual Property Antitrust 2002, New York, June 2002), 22.

89 C Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, 118. See also A van Melle, 'Refusals to License Intellectual Property Rights: The Impact of RTE v EC Commission (Magill) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4, 7–9.

refusal, and the use of the right is essential for development of a derivative market, with the consequence that all competition would be eliminated in that market. However, the licensee cannot merely reproduce goods or services already produced by the right holder, but must seek to market products with different characteristics that—while they may compete with the right holder's goods—meet other discrete demands by consumers who are not satisfied by the right holder's products.[90]

24.65 The European Commission is currently examining the operation of art 82 of the EC Treaty to evaluate the existing policy and possible means to make it more effective and transparent.[91]

The TRIPS Agreement

24.66 Article 31 of the TRIPS Agreement provides Members with a limited right to grant compulsory licences over patents.[92] The TRIPS Agreement also contains two specific provisions dealing with the interaction between intellectual property law and competition law.

24.67 Article 40(1) provides that Members agree that some licensing practices or conditions relating to intellectual property rights which restrain competition may have adverse effects on trade, and may impede the transfer and dissemination of technology. Under art 40(2), Members may specify in legislation those licensing practices or conditions that may constitute an abuse of intellectual property rights due to their anti-competition nature. Members may adopt appropriate measures to prevent or control such practices, provided these are consistent with other provisions in the TRIPS Agreement.

Competition law and gene patents

24.68 The grant of a patent effectively gives the patent holder a monopoly over the exploitation of the patented invention. Chapter 21 noted examples of patents creating monopolies over the provision of medical genetic testing.[93] Healthcare providers and other sectors of the community have expressed concern about the implications of granting monopoly rights over patented medical genetic tests and other genetic

90 *IMS Health GmbH v OHG/NDC Health GmbH*, Case C-418/01, Court of First Instance, Opinion of Advocate-General Tizzano, October 2, 2003. See the discussion in F Fine, 'NDC/IMS: A Logical Application of the Essential Facilities Doctrine' (Paper presented at Intellectual Property Antitrust 2002, New York, June 2002), 11.

91 M Monti, 'EU Competition Policy after May 2004' (Paper presented at Fordham Annual Conference on International Antitrust Law and Policy, New York, 24 October 2003), 2.

92 See Ch 27 for more detail.

93 For example, Myriad Genetics Inc (Myriad) holds patents internationally on isolated genetic materials associated with breast and ovarian cancer. Myriad's patents also cover methods for predictive testing and products and processes involved in its breast cancer predisposition test. Any technique for BRCA1 testing is likely to require use of Myriad's patents.

technologies.[94] By contrast, some submissions suggested that monopolies in medical genetic testing are not necessarily of concern.[95]

24.69 The way in which a patent holder exploits the patent may affect competition within the relevant market for that product or process, or within a related downstream market.[96] Generally, a patent holder might engage in the following types of conduct in relation to a gene patent:

- refusal to license, or a constructive refusal to license by charging an unreasonably high licence fee;
- exclusive licensing—by licensing the research tool to only one party; and
- restrictive licensing—by including certain restrictive conditions in the licence agreement.

24.70 While such dealings may not necessarily be anti-competitive, a patent holder could engage in conduct that may, in some circumstances, breach competition law. Dr Dianne Nicol and Jane Nielsen have suggested that there are two particular concerns regarding the potentially anti-competitive nature of biotechnology licensing:

> firstly that the patent monopoly may effectively be extended through these post-grant contractual arrangements, and secondly that the patent holder may restrict the ability of the licensee to practise the invention as fully as the patent holder was entitled to practice.[97]

24.71 Nielsen has commented that certain terms in both licensing-in and licensing-out agreements for biotechnology inventions may give rise to competition implications. The terms commonly found in licensing-out agreements that may have competition implications are exclusivity provisions; future assignment provisions;[98] tying provisions; and restrictive termination provisions.[99] The terms commonly found in licensing-in agreements that may have competition implications are sub-licence

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94 For example, Cancer Council Australia, *Submission P25*, 30 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

95 GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

96 See Ch 23 for a discussion of the licensing arrangements commonly employed in relation to patented genetic inventions, and the terms that such agreements commonly contain.

97 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 246.

98 These require the patent holder to continue research on the invention, and include all future intellectual property relating to the invention in the original patent licence.

99 Restrictive termination provisions may provide that there is no effective termination date for the licence, or may include an obligation to provide confidential information relating to the patent beyond the duration of its term. See J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating The New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 43–44.

restrictions; post-termination restrictions; grant-back provisions;[100] no challenge restrictions; leveraging arrangements;[101] and price, quantity and territorial restrictions.[102]

Anti-competitive conduct

24.72 Where a licence agreement for a patented research tool or medical genetic test includes an exclusive or restrictive condition that is prohibited per se; or that has the purpose, effect or likely effect of substantially lessening competition within the relevant market, this may constitute a breach of Part IV of the TPA.

24.73 But for the exemption under s 51(3), an exclusive licence to exploit a genetic research tool or medical genetic test could constitute an anti-competitive agreement under s 45 of the TPA if it prevents the grant of further licences, thereby limiting the number of competitors in a market in respect of the licensed product.

24.74 Similarly, where a licence agreement for a research tool includes 'reach-through' provisions this could discourage potential licensees from entering into an agreement, which could have a detrimental effect on competition.[103]

Intellectual property exemption

24.75 As noted above, s 51(3) of the TPA exempts certain restrictive licence conditions from the operation of Part IV of the Act.[104] However, the scope of this exemption is uncertain due to ambiguity regarding the meaning of the term 'relates to'. Nicol and Nielsen have commented that:

> it is far from clear which terms are likely to be caught by s 51(3), and it is likely that the widespread use of potentially anti-competitive terms is commonplace. Policing the use of these terms would involve considerable resources, and there are a number of other reasons why monitoring the use of particular terms in licence agreements is

100 These are a form of 'reach-through' provision, which oblige the licensee to license back improvements that it makes to the invention as a result of using the intellectual property right.

101 These include bundling together patented and non-patented products into licences, extending the licence territories in which no intellectual property rights exist, and requiring the payment of royalties until the last intellectual property right in a composite licence expires.

102 These restrict the price that the licensee may charge for goods, the quantity that may be sold, and the territories in which they may be sold. See J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating The New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 46–47.

103 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 246. See Ch 19 for more detail about 'reach-through' provisions.

104 The Trade Practices Commission suggested that, generally, territorial restraints, price, quota and quality restrictions, and minimum royalty requirements are likely to be exempt under s 51(3) because they relate to the licensed product. In contrast, post-termination restrictions, sub-licence restrictions, licence-back provisions, 'non competition' provisions, and full or third line forcing are unlikely to be exempt because these conditions generally do not relate to the licensed product: Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property: Background Paper* (1991).

> difficult, not least of which is that many agreements are entered into on a confidential basis.[105]

24.76 The High Court made some brief observations on the section in *Transfield Pty Ltd v Arlo International Ltd.* Mason J commented that:

> In bridging the different policies of the *Patents Act* and the *Trade Practices Act* section 51(3) recognises that a patentee is justly entitled to impose conditions on the granting of a licence or assignment of a patent in order to protect the patentee's legal monopoly … conditions which seek to gain advantages collateral to the patent are not covered by sec 51(3).[106]

24.77 The Trade Practices Commission's background paper, *The Application of the Trade Practices Act to Intellectual Property*, stated that where there is any doubt about whether a condition 'relates to' the subject matter of a licence, the Commission would consider the purpose and scope of the exclusive rights granted by the patent to determine whether the licence condition has obtained an advantage outside the scope of these rights.[107]

24.78 The exemption has been subject to review by several bodies.[108] The IPCRC concluded that the exemption is inappropriate due to the uncertainty surrounding its scope, and the possibility that it may exempt virtually all agreements that touch on intellectual property.[109] It recommended that the section be reframed to achieve an appropriate balance between the needs of the intellectual property system and the wider goals of competition policy.[110]

24.79 The Australian Government has announced its intention to narrow the exemption so that it will apply only if the relevant licensing or assignment arrangement does not have the effect or likely effect of substantially lessening competition.[111] At the time of writing, legislation has not yet been introduced into Parliament to implement this reform. The ACCC has commented that the proposed amendment means that:

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105 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 247.

106 *Transfield Pty Ltd v Arlo International Ltd* (1980) 144 CLR 83.

107 Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property: Background Paper* (1991), 13.

108 National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999); Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000).

109 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 212.

110 Ibid, 213, 215. The IPCRC recommended that: s 51(3) and related sections be repealed; s 51(1)(a)(i) be amended to list all the relevant intellectual property statutes; and that the TPA be amended to provide that conditions in a licence, contract, arrangement or understanding that relate to the subject matter of an intellectual property statute should not constitute a breach of Part IV or s 4D of the TPA—provided those conditions do not result, or are not likely to result, in a substantial lessening of competition.

111 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003.

> IP licensing and assignment conditions will be subject to Part IV of the TPA to a greater extent than is currently the case. In particular, licensing and assignment conditions which constitute anti-competitive agreements, including price fixing, exclusionary provisions or exclusive dealing, will breach Part IV if they substantially lessen competition.[112]

24.80 The IPCRC also recommended that the ACCC be required by legislation to issue guidelines as to the manner in which it will implement any enforcement activities relating to these provisions.[113] The ACCC has stated that it will release guidelines on the application of Part IV of the TPA to intellectual property once s 51(3) has been amended.[114]

24.81 Nicol and Nielsen have commented that, although an amended s 51(3) would provide more certainty to intellectual property owners when entering into contracts, it 'will not be without its problems'. In their opinion, it is important to avoid dampening the incentive to innovate or enter into pro-competitive licence agreements.[115]

24.82 Dr Amanda McBratney and others also submitted that even after the proposed amendments, s 51(3) will remain unclear and unworkable. They suggested that the section should be substantially redrafted to make it more clear and certain.[116]

Authorisation process

24.83 Where a contract or arrangement for a patented genetic invention falls outside the intellectual property exemption, those involved could apply to the ACCC for authorisation of the conduct.

24.84 For example, in 2003 the New South Wales Department of Health applied for authorisation in respect of its policy that public pathologists exclusively provide pathology services to private inpatients in New South Wales public hospitals. The ACCC concluded that the public benefit resulting from the policy would outweigh the public detriment (provided certain conditions were imposed) and granted the authorisation for a period of five years, subject to the specified conditions.[117]

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112 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

113 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 215.

114 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003. The ACCC also suggested that these amendments be reviewed after a period of three years, and that such review could canvass any concerns arising specifically in relation to gene patents.

115 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 247.

116 A McBratney and others, *Submission P47*, 22 October 2003.

117 Australian Competition and Consumer Commission, 'Final Determination: Application for Authorisation Lodged by the NSW Department of Health (Public Register No C20000/1680), 27 June 2003' (2003).

Misuse of market power

24.85 In certain limited circumstances, the refusal to grant a licence or other conduct in relation to a patented genetic research tool or medical genetic test could constitute a misuse of market power under s 46 of the TPA.

24.86 For example, where an organisation holds the patent over an upstream research tool such as a particular genetic sequence (and all its known applications), and refuses to license the tool to third parties involved in downstream research and development, depending on the circumstances, this might constitute a misuse of market power.[118]

24.87 In order to determine whether a patent holder has misused its market power it is necessary to define the market within which it is operating. Depending on factors such as substitutability, a biotechnology invention might exist in its own market or within a broader market. The grant of a patent will not necessarily confer market power because substitutes may be readily available within the relevant market. The Trade Practices Commission's background paper stated that:

> A patented process may constitute such an improvement or advance that competitors will be forced to discover alternative technological means to achieve the same or similar result in order to compete successfully. In advanced technologies, the cost involved may limit the number of potentially competitive corporations engaging in such research.[119]

24.88 Where market power is established, the court must determine whether the firm has taken advantage of its power for a proscribed purpose.[120] The court will determine whether a firm has taken advantage of its market power by considering whether it could have engaged in the conduct if it lacked market power and were operating under competitive conditions.[121]

24.89 According to the Trade Practices Commission's background paper, conduct that may amount to a misuse of market power includes the refusal to license intellectual property rights, the imposition of restrictive conditions on a licence and abusive infringement suits. While a firm with a substantial degree of market power has no

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118 For example, in October 2003, the South African Competition Commission found that two pharmaceutical firms had abused their dominant position in the market when they refused to license their patents over anti-retroviral drugs to generic manufacturers in return for a reasonable royalty. The Commission found that these firms had engaged in denying a competitor access to an essential facility; excessive pricing; and an exclusionary act. The Commission referred the matter to the Competition Tribunal for determination: Competition Commission of South Africa, 'Competition Commission Finds Pharmaceutical Firms in Contravention of the Competition Act', *Media Release*, 16 October 2003.

119 Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property: Background Paper* (1991), 16.

120 In one case a Full Federal Court found that a firm's use of an intellectual property right could breach s 46 if undertaken for a proscribed purpose: *Australasian Performing Right Association Limited v Ceridale Pty Ltd* (1991) ATPR 41; see also R Steinwall, *Butterworths Australian Competition Law* (2000), 286.

121 See *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2003) 178 ALR 253; *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609.

general duty to license an intellectual property right to existing or potential competitors:

> this is not to say that a proprietor of intellectual property rights can never be guilty of conduct that infringes s 46(1). This is most likely to occur where a corporation with a substantial degree of market power seeks to obtain an advantage greater than that conferred by the relevant statute or seeks to extend the monopoly conferred by the relevant statute into markets other than those protected by the statutory grant.[122]

24.90 Accordingly, where a patent holder with substantial market power refuses to license in a secondary market, for the purpose of extending the scope of its right beyond that granted, this is likely to constitute a misuse of its market power. However, it is doubtful that a refusal to license in the primary market would generally amount to a misuse of market power.

24.91 Nicol and Nielsen have suggested that a refusal to license or exploit a biotechnology patent would rarely constitute a breach of s 46.[123] Nielsen has stated that:

> The only circumstance in which the grant of [intellectual property] will give rise to market power is in the rare instance where there is no effective substitute for the patented product. Markets … are defined in fairly broad terms, for example, in the pharmaceutical sector a patented headache tablet will compete in the same market as alternative and herbal therapies. There has, as yet, been no consideration of the market into which upstream genomic information, including gene sequences, falls.[124]

24.92 Even if a patent holder has a substantial degree of market power, a court generally will not find that it has misused its power if there is evidence that it could have refused to license or exploit the patent even if it lacked the market power and was operating under competitive conditions.

24.93 According to Nielsen, s 46 generally would apply only where a patent holder stifles competition by refusing to license its patent to a competitor in a downstream or secondary market, preventing that competitor from preventing a new product.[125] While s 46 applies where patent holders misuse their market power in relation to their gene patents, it appears to have only a narrow application.

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122 Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property: Background Paper* (1991), 35.

123 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 245.

124 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating The New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 45.

125 Ibid, 45.

Mergers and acquisitions

24.94 Organisations involved in genetic research and development could engage in anti-competitive conduct by forming alliances, entering into agreements, or obtaining assignments or exclusive licences of all the patent rights in a particular market in order to maximise their market dominance.

24.95 As noted above, s 50 of the TPA prohibits mergers or acquisitions that would have the effect, or likely effect, of substantially lessening competition in a substantial market for goods and services.[126] To determine whether an acquisition has this effect, courts must take into account a number of matters, including: actual or potential import competition; the ease with which other businesses may enter the market; the availability of substitute products in the market; and the dynamic characteristics of the market, including growth, innovation and product differentiation.[127]

24.96 Accordingly, where a firm seeks to acquire assignments or exclusive licences of all the patent rights in a substantial market, it may breach s 50 if its acquisition has the effect, or is likely to have the effect, of substantially lessening competition in that market.[128] However, such conduct is subject to the operation of the s 51(3) exemption applying to intellectual property. According to Nicol and Nielsen:

> companies entering into mergers should be wary of the effect of bundling their IP rights. Although it is difficult to conceive of a situation where a merger between an upstream company or intermediate biotechnology company and a downstream or pharmaceutical company has the effect of dominating a particular market, each case should be individually assessed.[129]

Patent pools and cross-licensing

24.97 Chapter 23 discussed the use of patent pools and cross-licensing arrangements in relation to patented genetic materials and technologies.[130] The purpose of both patent pooling and cross-licensing is to facilitate each party's use of the others' intellectual property.[131] Depending on their nature, patent pools and cross-licensing arrangements could have either positive or negative implications for competition within a market.

24.98 The United States' *Licensing Guidelines* state that pooling may be pro-competitive when it integrates complementary technologies, reduces transaction costs,

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126 In addition, s 50A prohibits the acquisition outside Australia of a controlling interest in a firm that would lead to a substantial lessening of competition in a market.

127 *Trade Practices Act 1974* (Cth) s 50(3).

128 See National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999), 181–182.

129 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 247.

130 A 'patent pool' is an aggregation of patent rights held by an individual or organisation for the purpose of licensing the patents as a joint package. 'Cross-licences' are mutual arrangements between rights holders granting rights to use the intellectual property owned by each party to the other parties.

131 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

clears blocking positions, avoids costly infringement litigation, and promotes the dissemination of technology. For example, granting patents over gene and protein sequences can create blocking patents. By creating a patent pool over these basic patents, third parties can obtain all the necessary licences required to use the particular technology from a single entity. This can facilitate the rapid development of new technology by saving the time and resources required to negotiate individual licences.[132]

24.99 Several commentators have discussed the potentially anti-competitive nature of patent pools and cross-licensing arrangements.[133] The *Licensing Guidelines* state that pooling may be anti-competitive if: the excluded firms cannot compete effectively in the relevant market for the good that incorporates the licensed technologies; the pool participants collectively possess market power in the relevant market; the limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies; or the patent pool deters participants from engaging in research and development, thus retarding innovation.[134]

24.100 Nicol and Nielsen have suggested that a collaborative arrangement may potentially be anti-competitive if it involves collusion and has the effect of substantially lessening competition.[135] Professor William Cornish, Dr Margaret Llewelyn and Dr Michael Adcock have commented that:

> It may be that, as patents on proteins, receptors and related procedures build towards effective forms of diagnostics and gene therapy, collaborations between the different right owners arise which amount to a pool of patents against users which has a cumulative monopoly effect. Conduct of this kind could well amount to an unlawful restrictive practice between firms, which could not be justified and therefore exempted for the countervailing benefits which could be said to stem from that conduct.[136]

24.101 Patent pools and cross-licensing agreements are subject to Part IV of the TPA. Professor Warren Pengilley has identified several factors that may be relevant to determining whether a patent pool breaches the TPA, including whether:

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132 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995). See also J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office.

133 See, eg, D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 247; W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003).

134 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), 28–29. These have been 'collapsed' into two overarching questions: whether the proposed licensing program is likely to integrate complementary patent rights; and if so, whether the resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program.

135 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 247.

136 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003).

- the pool contains price fixing agreements;
- there are territorial or customer restraints;
- any agreement contains clauses that would be illegal if practised by a single owner—for example, attempts to control commerce in goods outside the patent;
- the arrangement attempts to exclude others and the nature of any access arrangements for competitors or future competitors;
- the pool encourages innovation or seeks to stifle it; or
- the arrangement constitutes a misuse of substantial market power.[137]

24.102 However, where a cross-licensing arrangement breaches Part IV of the TPA (with the exception of s 46), it could fall within the scope of the s 51(3) exemption for intellectual property or be subject to an application to the ACCC for authorisation of the conduct.[138]

Submissions and consultations

24.103 IP 27 asked how competition law and policy should deal with patent pools relating to gene patents.[139] Several submissions suggested that such patent pools should be regulated in the same way as patent pools are regulated generally.[140] The Department of Industry, Tourism and Resources submitted that patent pools for gene patents do not raise any specific issues when compared with other technologies.[141] GlaxoSmithKline submitted that:

> Competition law should not deal with patent pools relating to gene patents in a manner that is any different to patent pools that may exist in other areas of technology. Although a patent pool may result in increased market power by the pool members in relation to a particular technology, it is also important to remember that in many instances important technologies would not reach the market if it is not possible for a web of licensing or cross-licensing arrangements to be put into place.[142]

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137 W Pengilley, 'Patents and Trade Practices: Competition Policies in Conflict?' (1977) 5 *Australian Business Law Review* 172, 194–197.

138 *Trade Practices Act 1974* (Cth), s 88. Alternatively, the patent pool participants could notify the ACCC of proposed conduct that might breach the prohibition against exclusive dealing under s 47 of the TPA.

139 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 17–2.

140 For example, Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003.

141 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

142 GlaxoSmithKline, *Submission P33*, 10 October 2003.

24.104 AusBiotech Ltd submitted that, if anything, restrictions on patent pooling should be less rigorous in relation to gene patents due to the small number of companies in the biotechnology field.[143]

24.105 Some submissions highlighted the potential benefits of patent pools and cross-licensing arrangements. For example, the Department of Health and Ageing considered that:

> any arrangements that facilitate easier cross licensing of gene patents in order to reduce transaction costs, avoid costly infringement litigation and promote dissemination of gene technologies should be encouraged. To the extent that patent pools promote these objectives they should be carefully considered.
>
> Health considers that competition law and policy could make provision for patent pools on a case-by-case basis, with a view to approval where they have the effect of creating efficiency and competition in the application of human gene technology. However, it notes that there has been little if any action in respect of the formation of patent pools, and little private sector coordination of information other than the Single Nucleotide Polymorphism Consortium.[144]

24.106 By contrast, several submissions were cautious about the use of patent pools and cross-licensing arrangements in this context. McBratney and others submitted that there are preferable, less complicated solutions to restrictive patent commercialisation practices than patent pools.[145] ACIPA submitted that it had serious concerns about whether patent pools are appropriate to gene patents:

> there is ongoing debate about whether patent pools have anti-competitive effects in the marketplace. Therefore it is necessary that patent pools are subject to proper scrutiny by the Australian Competition and Consumer Commission.[146]

24.107 A number of submissions suggested the need for guidelines to deal with patent pool arrangements.[147] The Queensland Government commented that the United States' *Licensing Guidelines* have merit, and suggested that Australian legislation should be clarified to enable access to patent pools subject to guidelines issued by the ACCC.[148]

24.108 The ACCC's submission contained a detailed discussion of this issue. It noted that arrangements which combine complementary technologies can reduce transaction costs for potential licensees, clear bocking positions in downstream markets and avoid costly infringement litigation. However, potential competition may be foregone in technology markets, if the parties to the pool would likely compete in the absence of pooling arrangements.

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143 AusBiotech Ltd, *Submission P58*, 7 November 2003.
144 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.
145 A McBratney and others, *Submission P47*, 22 October 2003.
146 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
147 For example, Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Queensland Government, *Submission P57*, 5 January 2004.
148 Queensland Government, *Submission P57*, 5 January 2004.

> While pooling and cross-licensing can be pro-competitive, there is also the potential for arrangements to be used for blatant price fixing, or market sharing, agreements among competitors without any possible pro-competitive justification. If these arrangements raised prices for products and/or services that use the licensed intellectual property, or restrict output in those downstream markets then the ACCC is likely to consider that they have the effect of substantially lessening competition in breach of s 45.
>
> Patent pools can be anti-competitive by foreclosing competition in related markets or raising entry barriers to competitors of the license holders. This may occur if the licensing arrangements contain exclusionary provisions that restrict licensing to the pool's members or the nominated parties. Such arrangements may breach s 45 of the TPA … if the parties to the arrangements collectively possess market power then in some circumstances the exclusion of third parties from the arrangements may have anti-competitive effects …
>
> Patent pools may also raise competition concerns, if they provide the opportunity for licensors to share competitively sensitive information or to gain access to the competitively sensitive information of actual or potential competitors in downstream markets. [149]

24.109 The ACCC suggested that patent pools would be less likely to raise competition concerns if:

- they combine complementary patents;
- licensing arrangements do not restrict access to the pool's technology by competitors, potential entrants or third parties; and
- pooling arrangements do not facilitate sharing or access to competitors commercially sensitive information in the relevant or downstream markets.[150]

24.110 The ACCC submitted that it sees no need to distinguish patent pool arrangements relating to gene patents from other patent pool arrangements. It noted that any gene related patent pool arrangements that may give rise to potential breaches of Part IV of the TPA would be assessed on a case-by-case basis.[151]

Options for reform

24.111 There are several options for reforming the application of competition law to patented genetic materials and technologies. These include:

- adopting an 'essential facilities' doctrine;

149 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.
150 Ibid.
151 Ibid.

- amending the TPA; and

- developing new guidelines to clarify the application of Part IV of the TPA to intellectual property dealings.

Essential facilities

24.112 One option is to broaden the Part IIIA regime in the TPA to include patented genetic materials and technologies within the definition of essential facilities.[152] As noted above, Part IIIA of the TPA provides a framework for facilitating third party access to the services of essential national facilities. A third party can seek access to eligible services in several ways, and the ACCC has the power to require the service provider to give access to the third party. This regime does not, however, apply to the use of intellectual property, except to the extent that it is an integral but subsidiary part of the service provided by the facility.

24.113 European Community law has recognised an 'essential facilities' doctrine under art 82 of the EC Treaty, which deals with abuse of a dominant position within a market. Unlike the Australian position, intellectual property rights have been recognised as an essential facility within EC law.[153] Professor John Temple Lang has stated that where a dominant company operates in only one market, it does not have a duty to use its intellectual property right in that market. However, the firm has a duty to contract on non-discriminatory grounds when

- the firm is dominant in the market for the supply of a product or service that is essential for competitors operating in the second market;

- there is no other actual or possible source of the essential product or service;

- competitors cannot operate in the second market without access to the product or service;

- the company is also dominant in the second market and a refusal to supply the product or service would confirm or strengthen its dominant status;

- there is scope for substantial competition in the second market; and

- there is no objective justification for the refusal to contract.[154]

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152 See Ch 27 for more discussion.

153 C-7/97 *Bronner v Mediaset* [1998] ECR I-7791, 7806–7807 (Advocate General Jacobs), cited in J Temple Lang, *Compulsory Licensing of Intellectual Property in European Community Antitrust Law: Paper prepared for the Department of Justice/Federal Trade Commission Hearings, Washington DC* (2002), 6.

154 Ibid, 2–3.

24.114 Under the essential facilities doctrine, a compulsory licence could be granted as a remedy where a gene patent holder seeks to use its patent rights in a secondary, downstream market for anti-competitive purposes.

24.115 The IPCRC considered whether the Part IIIA regime under the TPA should be expanded to apply to intellectual property. It considered there was a case for the existing exception in relation to intellectual property on the basis that the intellectual property statutes already provide for third party access (for example, through compulsory licensing of patented inventions); and the design of Part IIIA seemed poorly suited to handle intellectual property rights, as they do not fit easily into the 'facility' and 'service' concepts that underpin the regime.

24.116 Accordingly, the IPCRC considered that the best approach was to review and, where appropriate, amend the relevant provisions in the intellectual property statutes. It also recommended reforms to the compulsory licensing provisions of the *Patents Act* to include a competition-based test.[155] The ACCC submitted that it considers that:

> the introduction of a competitive effects test is likely to assist in addressing some of the specific concerns that have been expressed about gene patents–including the need to enure access to patents on reasonable terms.[156]

Amend the TPA

24.117 Another option is to amend Part IV of the TPA to clarify its application to the patented genetic materials and technologies. The s 51(3) exemption could be amended to clarify its application to conditions in licence agreements and assignments. As noted above, the Australian Government has announced its intention to amend this exemption so that it will apply only if the relevant licensing or assignment arrangement does not have the effect, or likely effect, of substantially lessening competition. Once amended, it appears that s 51(3) would effectively provide a 'safety zone' or 'safe harbour' for certain licence conditions that relate to intellectual property, but only to the extent that they do not substantially lessen competition within the market. The ACCC has commented that:

> In general terms, the proposed amendment to s 51(3) means that IP licensing and assignment conditions will be subject to Part IV of the TPA to a greater extent than is currently the case. In particular, licensing and assignment conditions which constitute anti-competitive agreements, including price fixing, exclusionary provisions or exclusive dealing, will breach Part IV if they substantially lessen competition … The ACCC considers that the proposed amendments to s 51(3) of the TPA will significantly enhance the ability of the ACCC to deal with anti-competitive conduct resulting from licensing and assignment of patent rights. The ACCC encourages the Government to expedite the introduction of amending legislation.[157]

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155 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 215. See Ch 27 for more detail.

156 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

157 Ibid.

24.118 It has been suggested that the Australian Government's proposal may not adequately address the concerns raised in relation to this exemption.[158] The ALRC considers that legislative clarification of the exemption is desirable, and that the proposed amendment, combined with guidelines on its application, may be sufficient to address these concerns.

Intellectual property guidelines

24.119 Several review bodies, including the IPCRC and the Dawson Committee, have recommended the development of guidelines to clarify the application of Part IV of the TPA to intellectual property. The Australian Government has asked the ACCC to issue such guidelines,[159] and the ACCC has advised this Inquiry that it intends to do so after s 51(3) of the TPA has been amended.[160]

24.120 McBratney and others submitted that:

> A more in-depth comparative analysis of other jurisdictions' approaches would assist the proper formulation of an effective intellectual property exception in the *Trade Practices Act* and a clear set of guidelines. The much-anticipated release of the draft guidelines on s51(3) for public comment will at least be a step in the right direction.[161]

24.121 As noted above, both the United States and the European Union have released policy guidelines on the application of antitrust and competition laws to licensing agreements and other collaborations involving intellectual property. These guidelines advise intellectual property rights holders and other market participants about the possible competition implications of certain licence arrangements. As a result, they may provide greater certainty to the parties to these agreements that their arrangements are likely to comply with competition law. While the approaches in these two jurisdictions have differed, the European Union's new draft guidelines now appear more closely aligned with the United States' approach.

ALRC's views

24.122 At this stage, it is difficult to evaluate whether Part IV of the TPA adequately addresses the anti-competitive concerns arising from the patenting and licensing of genetic materials and technologies.

24.123 On the face of it, but for the effect of the s 51(3) intellectual property exemption, certain anti-competitive licence conditions (or other arrangements) could be prohibited either per se, or due to their effect on competition. However, the uncertain scope of the exemption makes it difficult to predict which conditions are

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158 A McBratney and others, *Submission P47*, 22 October 2003; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 247.

159 Trade Practices Act Review, *Review of the Competition Provisions of the Trade Practices Act* (2003), 87.

160 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

161 A McBratney and others, *Submission P47*, 22 October 2003.

exempt. If the exemption is interpreted broadly, certain otherwise anti-competitive conditions will be exempt. Further, although a patent holder's refusal to license its patent (or certain other anti-competitive conduct) might amount to a misuse of market power, s 46 would only apply to such conduct in very limited circumstances.

24.124 As noted above, the Australian Government has asked the ACCC to issue guidelines on the application of Part IV of the TPA to intellectual property, and the ACCC has advised the Inquiry that it will do so after s 51(3) has been amended. The ALRC proposes that, in drafting these guidelines, the ACCC should address the application of Part IV of the TPA to patented genetic materials and technologies, including in relation to patent pools and cross-licensing arrangements. The guidelines should also provide guidance about the type of conduct that might be authorised under Part VII of the TPA.

24.125 The ALRC has considered the option of proposing an amendment to Part IIIA of the TPA to include intellectual property. This does not appear necessary since an amended s 51(3), new guidelines on its application, and the insertion of a competition test into the compulsory licensing provisions of the *Patents Act* may adequately address the competition concerns arising from dealings in gene patents.

24.126 However, if in future there is evidence that Part IV of the TPA and a competition test for a compulsory licence in the *Patents Act* do not address concerns adequately, the ALRC considers that the essential facilities approach may warrant further consideration.

24.127 Accordingly, the ALRC proposes that the ACCC should develop guidelines regarding the relationship between Part IV of the TPA and intellectual property, with particular regard to patented genetic materials and technologies. The guidelines should extend to patent pools and cross-licensing.

Proposal 24–1 The Australian Competition and Consumer Commission (ACCC) should develop guidelines regarding the relationship between Part IV of the *Trade Practices Act 1974* (Cth) and intellectual property, with particular regard to patented genetic materials and technologies. The guidelines should extend to patent pools and cross-licensing involving patented genetic materials and technologies.

Monitoring and enforcement

24.128 The ACCC is the statutory authority responsible for enforcing the TPA. Generally, it deals with complaints and inquiries about possible breaches of the Act; proposed mergers; applications for authorisation and notifications; determinations and

undertakings under the access regime; inquiries made on its own initiative; and government directions and references.[162]

24.129 The Australian Competition Tribunal is the appeal body for the ACCC's determinations in relation to authorisations and notifications, and the Federal Court has exclusive jurisdiction in relation to all matters arising under Part IV of the TPA.

24.130 Nielsen has commented that although various forms of conduct in relation to gene patents could contravene Part IV of the TPA, very few of these dealings are ever queried or litigated. She suggested several possible reasons for this, including:

- the resources necessary to monitor the licensing practices of companies;
- the confidential nature of most patent licence agreements;
- the resources necessary to challenge the terms on which a patent licence is granted, or a refusal to licence a patent; and
- the uncertain outcome of any proposed litigation, which may deter potential litigants from bringing proceedings.[163]

Submissions and consultations

24.131 IP 27 asked whether there is a role for the ACCC in monitoring the impact on competition of gene patents and licences.[164] Most of the submissions addressing this question supported such a role for the ACCC.[165] McBratney and others commented that the information collected through such monitoring:

> would be useful provided that the scope of any such enquiry, terms of reference and the appropriate skills and resources are provided for this complex, emotive and difficult area of study.[166]

24.132 The Queensland Government submitted that:

> in conjunction with its price-monitoring role, the ACCC could also monitor the impact of competition on gene patents and licences as well as patents and licences over biomedical products and services generally. In a rapidly changing environment,

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162 R Baxt, R Blunt and A Tonking, *Australian Trade Practices Reporter: Looseleaf Service* (1980) Vol 1, [800], [910]. Remedies that may be sought by the ACCC in the event of a contravention of Part IV of the TPA include injunctions, declarations, enforceable undertakings and pecuniary penalties.

163 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating The New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 48–49.

164 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 17–4.

165 For example, Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; A McBratney and others, *Submission P47*, 22 October 2003; Queensland Government, *Submission P57*, 5 January 2004; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; A Johnston, *Submission P15*, 30 September 2003.

166 A McBratney and others, *Submission P47*, 22 October 2003.

> this monitoring would be useful in keeping guidelines current and addressing any new issues that may emerge.[167]

24.133 Adam Johnston submitted that the ALRC should request the ACCC to conduct an inquiry into the emerging market in gene technology and the desirability of one firm holding such a dominant position within that market.[168] Luigi Palombi submitted that a new Part should be inserted into the TPA directing the ACCC to scrutinise and challenge granted patents because of the negative impact of invalid patents on the economic wellbeing of Australia, and because the existence of invalid patents 'creates pockets of anti-competitive activities which are likely to be illegal under the existing provisions' of the TPA.[169]

24.134 Several submissions suggested that it is not necessary to monitor the impact of gene patents and licences on competition.[170] The ACCC submitted that it has developed a series of enforcement priorities to address trends in the economy and strategically targeted areas that it identifies as important, including new areas of the law or industries resulting in technological change. It also has specific objectives and priorities for anti-competitive conduct in developing and innovative markets.

24.135 The ACCC commented that it has not specifically targeted intellectual property as an enforcement priority but, in the light of the proposed amendments to s 51(3) of the TPA, it is possible that it will expand its activities in this area in the future. It submitted that this would enable the ACCC to assess the impact of intellectual property licensing on competition and the adequacy of the TPA to deal with these concerns. If the ACCC identifies inadequacies in the legislation it will bring these concerns to the Australian Government's attention.[171]

ALRC's views

24.136 Chapter 25 discusses the regulatory framework, and proposals for reform, regarding prices surveillance of patented genetic materials and technologies. In addition to prices oversight, the ALRC also considers that there would be merit in some form of independent oversight of dealings involving patented genetic inventions.

24.137 While long-term monitoring may not be necessary, the ALRC considers that at this early stage in the development of genetic technologies (and dealings with them), there is a public interest in ensuring that patent or licence holders with a concentration of market power in relation to their gene patents or licences do not abuse this power for anti-competitive purposes, where this will adversely affect healthcare provision or further research and development.

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167 Queensland Government, *Submission P57*, 5 January 2004.
168 A Johnston, *Submission P15*, 30 September 2003.
169 L Palombi, *Submission P28*, 1 October 2003.
170 GlaxoSmithKline, *Submission P33*, 10 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.
171 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

24.138 The ACCC, as the competition regulator, is the most appropriate body to conduct such oversight. The ALRC proposes that the ACCC should liaise with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns in this field. Should it be apparent that problems are emerging, the ACCC should review the conduct of firms dealing with patented genetic materials and technologies, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act*. Most of the submissions received by this Inquiry supported a role for the ACCC in this context.

24.139 While the ACCC does not consider such monitoring necessary in relation to gene patents and licensing, in light of the proposed amendment to s 51(3) of the TPA, the ALRC considers it would be appropriate, at least in the short term, for the ACCC to adopt this role but that it should be guided by information from health authorities.

24.140 Accordingly, the ALRC proposes that the ACCC should review the conduct of firms dealing with patented genetic materials and technologies, as the need arises, to determine whether their conduct is anti-competitive within the meaning of Part IV of the TPA. The ACCC should liaise, on an ongoing basis, with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns in this field.

Proposal 24–2 The ACCC should review the conduct of firms dealing with patented genetic materials and technologies, as the need arises, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act.* The ACCC should liaise, on an ongoing basis, with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns in this field.

25. Prices Surveillance

Contents

Introduction

25.1 This Discussion Paper has outlined the various concerns arising from the grant of gene patents. One of these concerns is the potential for patent and licence holders to charge prices for these patented inventions that are above market rates, and the potential impact that this may have on equitable access to healthcare services.

25.2 This chapter discusses the existing regulatory framework for prices surveillance in Australia, and considers what reforms may be necessary to ensure reasonably priced access to medical genetic tests and other genetic inventions involved in the provision of healthcare services.

Prices surveillance

25.3 Prices surveillance is a regulatory tool of government that may take several forms.

- Price control involves requiring nominated businesses to provide a range of financial information to a regulator, who then determines the permitted prices or the rate of permitted price increases or decreases. Compliance with price control is generally mandatory.

- Price notification involves requiring nominated businesses to notify a regulator of proposed price increases. The regulator examines these proposals and makes

determinations as to whether the price increases are acceptable or not. Compliance with the regulator's determinations is generally voluntary.

- Price monitoring involves requiring nominated businesses to provide price, cost and profit information to a regulator periodically. The regulator may report on the performance of firms, but it does not have the authority to make price determinations.

- Pricing inquiries may investigate market situations to determine the nature, significance and causes of alleged pricing problems. The inquiry body makes recommendations to government as to the appropriate response.[1]

Current law and practice

Prices Surveillance Act

25.4 The *Prices Surveillance Act 1983* (Cth) (PSA) currently provides the regulatory framework in Australia for prices surveillance, monitoring and inquiry in relation to selected goods and services. The Australian Competition and Consumer Commission (ACCC) is the regulatory body for prices surveillance in Australia. The PSA provides for three forms of prices oversight.

- **Monitoring and reporting**. The Minister directs the ACCC to monitor the prices, costs and profits relating to the supply of goods or services in any industry or business and to report the results to the Minister.[2]

- **Prices notification**. The Minister, or the ACCC with the Minister's approval, declares that specified companies must notify the ACCC of a proposed price increase for specified goods and services.[3] The ACCC must make a determination about the notified price increase within 21 days (unless the company agrees to an extension). The determination is not enforceable, but there is a penalty for increasing prices during the 21-day period without approval.

- **Public inquiries**. The Minister directs the ACCC to conduct a public inquiry into matters relating to the prices for the supply of goods and services and to report the results of the inquiry to the Minister. Alternatively, the ACCC may conduct an inquiry on its own initiative with the Minister's approval. Those who

1 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), 3.

2 The ACCC's formal price monitoring is currently restricted to stevedoring and airport services: Department of the Parliamentary Library, *Trade Practices Legislation Amendment Bill 2003 (Bills Digest No 9, 2003–04)* (2003), 3.

3 Services that have been declared for price notification are harbour towage services, letter services reserved to Australia Post, air services and aeronautical services: Ibid, 4.

> increase prices during the period without the ACCC's approval may be penalised.[4]

25.5 The PSA provides that, in performing its functions, the ACCC must have particular regard to the need to:

- maintain investment and employment, including the influence of profitability on investment and employment;
- discourage a firm, which is in a position to substantially influence a market for goods or services, from taking advantage of that power in setting prices; and
- discourage cost increases arising from increases in wages and changes in conditions of employment inconsistent with principles established by relevant industrial tribunals.[5]

25.6 The ACCC also conducts informal monitoring as part of its general objective to promote greater transparency of pricing and price competition. The areas subject to informal monitoring include public liability, professional indemnity and medical indemnity insurance; bank fees and charges; and petrol prices. This informal monitoring relies on publicly available information, and the co-operation of the monitored organisations.[6]

Trade Practices Act

25.7 The Productivity Commission conducted a review of the PSA during 2000–01. The Commission recommended that the PSA be repealed, and that a new Part be inserted into the *Trade Practices Act 1974* (Cth) (TPA) to provide for inquiries and prices monitoring in nationally significant markets where there may be concern about monopolistic pricing.[7]

25.8 The Trade Practices Legislation Amendment Bill 2003 (Cth) was the Australian Government's response to the Productivity Commission's report. The Explanatory Memorandum to the Bill states that:

> The PSA was introduced in 1983 to promote price restraint as part of the prices and incomes policy. An object was to reduce inflation and inflationary expectations. Since then, the economic environment has changed considerably. Transferring prices

4 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), 4. See *Prices Surveillance Act 1983* (Cth).

5 *Prices Surveillance Act 1983* (Cth) s 17(3).

6 Australian Competition and Consumer Commission, *Industry Regulation and Price Monitoring*, <www.accc.gov.au/content/index.phtml/itemId/3671> at 10 December 2003; see also Department of the Parliamentary Library, *Trade Practices Legislation Amendment Bill 2003 (Bills Digest No 9, 2003–04)* (2003), fn 6.

7 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), rec 5.1.

> surveillance to the TPA recognises that it has become part of Australia's competition policy, rather than a tool to reduce general price inflation.[8]

25.9 The *Trade Practices Legislation Amendment Act 2003* (Cth) received Royal Assent on 17 December 2003 and is due to commence operation in 2004.[9] Upon commencement, the Act will repeal the PSA and insert a new Part VIIA into the TPA. The new Part VIIA essentially replicates the PSA, with some differences.[10]

25.10 Like the PSA, the new Part provides for selected surveillance of the prices of certain goods and services at the Minister's discretion. Declared companies and authorities must notify the ACCC before increasing the prices of notified goods or services, and must wait a statutory period before implementing an increase. At the Minister's direction, the inquiry body may inquire into prices charged and conduct certain other price inquiries.[11]

25.11 In addition to the new Part VIIA, the TPA contains a number of provisions that directly and indirectly provide for prices oversight. Part IV of the TPA seeks to protect competition by prohibiting certain anti-competitive agreements, the misuse of substantial market power, and certain mergers and acquisitions. (See Chapter 24.)

25.12 Part IIIA of the TPA establishes a legislative regime to facilitate third party access to the services of essential facilities of national significance. Part IIIA applies to the services provided by essential facilities, but not the facilities themselves. It does not extend to the supply of goods, the use of intellectual property or the use of the production process, except to the extent that these are an integral but subsidiary part of the service. This Part provides some scope for price control, for example through the ACCC's arbitration powers.[12] (See Chapter 24.)

Issues and problems

25.13 Chapter 21 discussed the potential impact of gene patenting on the cost of medical genetic tests and other healthcare services. The grant of exclusive rights over patented genetic inventions could result in prices higher than market value being charged for these inventions. This could have implications both for the conduct of medical research and development within Australia, and for equitable access to medical genetic tests and related healthcare services.

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8 Explanatory Memorandum, Trade Practices Legislation Amendment Bill 2003 (Cth), 1.

9 The Act will commence operation upon proclamation or, at latest, by 17 June 2004.

10 For example, the new Part VIIA contains an objects clause, and permits bodies other than the ACCC to hold public inquiries: see *Trade Practices Legislation Amendment Act 2003* (Cth); Department of the Parliamentary Library, *Trade Practices Legislation Amendment Bill 2003 (Bills Digest No 9, 2003–04)* (2003), 8.

11 See Explanatory Memorandum, Trade Practices Legislation Amendment Bill 2003 (Cth), 1.

12 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), 35–36, 38.

25.14 Submissions and consultations reflected concern about the impact that monopoly control might have on the cost of genetic testing to patients and the healthcare system.[13] For example, the Human Genetics Society of Australasia (HGSA) commented that:

> Gene patents are likely to inflate prices, though their precise impact is not yet known. There is clearly a potential for patent holders to charge exorbitant prices for genetic testing kits or licences when the cost of gene discovery and kit development is not that great (certainly not as great as drug and other treatment development) …[14]

25.15 The Queensland Government submitted that:

> Major concerns relating to gene patents are that the patent holder may engage in restrictive licensing practices, such as charging excessive licence fees … These actions may increase costs of genetic tests or other products or services to the extent that some citizens on low incomes may be unable to receive the benefit of the technology. The burden of some of these charges may impact on the health benefits system or on social services.[15]

25.16 Concerns about cost limiting access to medical genetic testing were also commonly expressed in submissions and consultations.[16]

25.17 Chapter 21 noted that the BRCA patent has been used as an example of concerns about the potential impact of gene patents on the cost of genetic testing in Australia. Concerns were initially expressed that if Myriad Genetics Inc, rather than the public health system laboratories, conducted testing for the BRCA1 gene in Australia, the cost of such testing would rise dramatically.[17]

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13 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Cancer Council of New South Wales, *Submission P1*, 5 June 2003; Australian Huntington's Disease Association (NSW) Inc, *Submission P27*, 1 October 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

14 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

15 Queensland Government, *Submission P57*, 5 January 2004.

16 Cancer Voices NSW Inc, *Submission P7*, 16 September 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; D McFetridge, *Submission P23*, 30 September 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

17 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 11.

Submissions and consultations

25.18 IP 27 asked whether there is a role for the ACCC in monitoring the prices charged for medical genetic tests or any other products or services arising from the grant of gene patents or licences.[18]

25.19 Several submissions commented that the ACCC should engage in such price monitoring.[19] The HGSA submitted that the ACCC

> may have a role in monitoring the prices charged for tests, products and services arising from the grant of gene patents or licences. In addition the ACCC may have a role in monitoring the impact on competition of gene patents and licences. It would be important for the ACCC to consult with interested parties (for example expert health professionals and consumers) if it takes on these monitoring roles.[20]

25.20 The Queensland Government submitted that:

> While governments should be wary of setting charges, the rapidly changing nature of the industry is such that there is a need for ongoing monitoring of prices in the industry. The ACCC, through its normal inquiry and monitoring process, could be asked to monitor prices of medical tests and any other products or services arising from the grant of gene patents (along with other biomedical products and services) and report on a regular basis to the relevant federal Minister. This may have the effect of restricting excessive prices or, if not, the Minister will have evidence that remedial action is required.
>
> Consumers need to be informed of their rights concerning the use of their genetic material and it is suggested that a consumer education program could be undertaken by the ACCC.[21]

25.21 Dr Graeme Suthers submitted that there should be mechanisms to vet patent applications and to monitor subsequent licensing to ensure that the patenting process does not harm society. While he considered that societal evaluation and monitoring is essential, he did not suggest what organisation should have the responsibility and authority for fulfilling this role.[22]

25.22 Several submissions did not support a role for the ACCC in price monitoring. The Walter and Eliza Hall Institute of Medical Research submitted that:

> the ACCC is about competition and should focus on pricing behaviour between suppliers. The ACCC should not be able to force an exclusive licensee to modify prices since they have the right to get a reasonable return on the investment. The

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18 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 17–3.

19 For example, Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

20 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

21 Queensland Government, *Submission P57*, 5 January 2004.

22 G Suthers, *Submission P30*, 2 October 2003.

> licensee could then elect not to market in Australia. Alternative schemes comparable to the PBS could be considered to address this issue.[23]

25.23 AusBiotech Ltd and GlaxoSmithKline both suggested that the position in relation to patented genetic products and services is no different from the position for other patents in terms of price monitoring.[24] GlaxoSmithKline further submitted that:

> Even in situations where there is limited competition in a specific technology area, the market will dictate that prices are at an appropriate level … The ACCC does not have a price monitoring role across any other area of commercial life (other than in exceptional circumstances), and certainly not in relation to other patent areas. There is no need for the ACCC to have such a role in relation to gene patents.[25]

25.24 The ACCC provided a detailed submission noting the difficulties with price regulation. These include that if the price is set too low or too high this can either stifle innovation or reduce a firm's incentive to increase efficiency. Price regulation also imposes costs on both the regulated firms and on the regulator. Despite these difficulties, the ACCC submitted that in certain limited circumstances price regulation may be appropriate to constrain excessive pricing and its consequent effects. It stated that:

> the role of price regulation should be limited to very specific circumstances where the industry is characterised by high market power, the benefits of regulation exceed the costs, and when no other appropriate policy measures can be taken.[26]

25.25 The ACCC recognised that in some circumstances the grant of a patent over a genetic invention will give the holder the ability to charge very high prices for the use of that invention. It also noted that from time to time there are likely to be areas of the economy where there is considerable public concern about particular pricing outcomes. The public health aspects of the patenting of genetic materials and technologies may be an example of this.[27]

25.26 However, the ACCC submitted that price regulation should be a measure of last resort for two reasons: the ACCC cannot compel a regulated firm to reduce its prices; and price regulation can stifle innovation. It argued that price monitoring is not a suitable alternative to finding an appropriate balance within intellectual property legislation between the conflicting needs of producers and users of patented genetic products. However, it noted that where legislators are uncertain whether the balance is correct, price monitoring may be an option.

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23 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.
24 AusBiotech Ltd, *Submission P58*, 7 November 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003.
25 GlaxoSmithKline, *Submission P33*, 10 October 2003.
26 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.
27 Ibid.

25.27 The ACCC concluded that:

> At this stage, the ACCC sees no reason to advocate a role for itself in specifically monitoring prices that are charged for medical genetic tests or any other products or services arising from the grant of gene patents or licences. Nor does the ACCC consider there is a need for it to specifically monitor the impact of competition on gene patents and licences. Ultimately, however, these are matters for the Australian Government.[28]

Options for reform

25.28 There is limited evidence to date that gene patents or exclusive licensing of genetic testing have had any significant adverse impact on the cost of healthcare in Australia. Similarly, there is no firm evidence as yet of any current impact on access to medical genetic testing, the quality of such testing, or clinical research and development.[29]

25.29 While the ACCC has submitted that it does not consider that price monitoring is necessary in relation to patented genetic inventions, several other submissions favoured some form of independent prices surveillance in this area. Due to community concern about the potential impact of gene patenting on access to healthcare services, the ALRC considers that it is desirable to propose some form of surveillance or monitoring of prices in this area but only if there is evidence of problems.

Price surveillance

Price control

25.30 One option is to grant the ACCC price control powers in relation to patented genetic inventions generally, or specific categories of these inventions such as genetic research tools and medical genetic tests. This would permit the ACCC to set the price of certain patented genetic inventions, such as medical genetic tests.

25.31 The Productivity Commission considered the use of price control powers in its review of the PSA. The Commission stated that in markets where competition is not strong

> regulators attempt to set prices at the levels they estimate would occur if there were more active competition. Yet this is a complex task requiring information that typically is not available. So, in practice, regulators are likely to end up setting prices above or below the efficient level.[30]

25.32 The Productivity Commission noted the trend to pro-competitive reform and the increasingly diminishing role that price control has played over the last two decades in Australia. It found that price control generally should be applied only to markets that display substantial market power and that are significant to the national economy. In

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28 Ibid.
29 See Ch 21.
30 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), xvii.

other markets where competition is not strong, the long-running costs of regulatory failure are likely to outweigh the cost of the market failure.[31] It concluded that:

> Given the limitations and potential costs of price control, it should be considered the remedy of last resort, applied only in important markets, after careful evaluation of the options.[32]

Price notification

25.33 Price increase notifications are another possible option for monitoring the prices of patented genetic inventions generally, or specific categories such as medical genetic tests.

25.34 The Minister could declare companies or authorities holding patents over certain genetic products and services. These companies would be required to notify the ACCC of proposed price increases for their goods and services. However, while a declared company is required to observe the procedures of the PSA, it is not required to comply with the ACCC's decisions in response to price notifications.

25.35 The Productivity Commission considered the role and effectiveness of price notifications in its review of the PSA. The Commission concluded that price notification is an indirect form of price control and should be removed from the legislation.[33] Despite this recommendation, these provisions were retained in the new Part VIIA of the TPA.[34]

Price monitoring

25.36 Price monitoring involves the formal and informal monitoring of prices, costs and profits relating to the supply of goods or services in any industry or business. The ACCC conducts such monitoring and reports the results to the Minister.

25.37 The Productivity Commission considered the role of price monitoring in its review of the PSA. It noted that in imperfectly or potentially competitive markets, the publication of key information about prices and market performance can enable customers, the community, policy makers and regulators to monitor market outcomes and gain a better understanding of the market's operation. Monitoring can enhance market transparency; assist the competitive process; and ease public concerns about the exercise of market power in some industries.[35]

25.38 The ACCC indicated that if price monitoring of patented genetic inventions were to be considered, it should be borne in mind that:

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31 Ibid, 44, Finding 3.1.
32 Ibid, 30, Finding 2.2.
33 Ibid, 49.
34 See *Trade Practices Legislation Amendment Act 2003* (Cth).
35 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), 46–47.

- expected benefits from monitoring should be greater than expected costs, including the administrative and compliance costs for monitored firms; and

- monitoring may induce monitored firms or industries to price in a particular, desirable way. However, once monitoring ceases and public scrutiny is eased, there may be no incentive for them to continue to price appropriately, where competition is weak.[36]

Price inquiries

25.39 The Minister could direct the ACCC, or another body, to hold an inquiry into the pricing of patented genetic inventions generally, or medical genetic tests or other specified inventions. The inquiry body would report its findings to the Minister who would then make decisions on these recommendations.

25.40 The Productivity Commission has noted that public inquiries have been used for several purposes, including: to determine whether pricing outcomes reflect competitive market forces; to advise the Minister on what types of prices oversight, if any, should be applied to the company or companies under inquiry; to assess price notifications in greater depth; to encourage compliance with determinations about notified price increases; and to play an educational role by bringing information into the public domain, facilitating public understanding of the pricing matters at issue.[37] There have not been any public inquiries under the PSA since 1996.[38]

Role of government and health departments

25.41 Chapter 20 discussed the potential for controlling pricing through government funding and purchasing. It noted that governments have considerable control over healthcare expenditure in Australia, and proposed that the Australian Health Ministers' Advisory Council (AHMAC) should examine options for using government funding and purchasing power to control the cost of genetic medical technologies subject to gene patents (Proposal 20–2).

25.42 Chapter 20 also discussed the role of health departments in monitoring the application of patent law to genetic materials and technologies. As health departments are the major funding providers and users of these technologies, they are directly affected by such patenting. The ALRC proposed that AHMAC should establish a process for examining the financial impact of gene patents on the delivery of healthcare services in Australia (Proposal 20–1).

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36 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

37 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), 4.

38 Department of the Parliamentary Library, *Trade Practices Legislation Amendment Bill 2003 (Bills Digest No 9, 2003–04)* (2003), 4.

ALRC's views

25.43 As noted above, the ALRC's preliminary view is that there is limited evidence to date that gene patents or exclusive licensing of genetic testing have had any significant adverse impact on the cost of healthcare provision in Australia. Similarly, there is no firm evidence of any current impact on access to medical genetic testing, the quality of such testing, or clinical research and development. However, there appears to be considerable concern amongst both the Australian community and the healthcare sector that prices might adversely affect these areas in the future.

25.44 The ALRC considers that some form of independent prices surveillance in relation to patented genetic products and processes may be desirable if evidence emerges that the pricing of these inventions is having a negative impact on equitable access to healthcare services within Australia.

25.45 The Terms of Reference direct the ALRC to have regard to the objective of 'protecting intellectual property rights to contribute to the promotion of technological innovation, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.

25.46 The use of price control powers on patented genetic inventions could unduly favour users of patented genetic inventions at the expense of the producers of those inventions. If the price is set too low to be financially attractive to patent holders, this could present a disincentive to future investment in genetic research and development. Accordingly, the ALRC does not consider this a useful option for reform. Prices notification or a public inquiry could be useful tools for prices surveillance, but in the absence of any evidence of unfair pricing, these do not appear necessary at this stage.

25.47 The ALRC considers that informal prices monitoring could be a desirable vehicle for addressing community concern regarding the pricing of medical genetic tests and other genetic inventions involved in the provision of healthcare services, if there is evidence that prices are having an adverse effect on these services.

Proposal 25–1 The Australian Competition and Consumer Commission should conduct informal price monitoring of patented medical genetic tests and other genetic inventions involved in the provision of healthcare services if evidence emerges that such prices are having an adverse impact healthcare services.

PART G

Non–Voluntary Uses

26. Crown Use and Acquisition

Contents

Introduction

26.1 This chapter discusses the Crown use and acquisition provisions of the *Patents Act 1990* (Cth) (*Patents Act*). It examines how these may be applied to address concerns that gene patents may impede access to genetic materials and technologies for use in research and hinder the provision of healthcare, and it discusses options for reform.

26.2 The Crown use provisions allow the Commonwealth or a State[1] either to exploit a patented invention (or an invention that is the subject of a patent application) without infringement, or to authorise another person to do so. The Crown acquisition provisions allow the Commonwealth to acquire compulsorily all rights in a patented invention (or an invention that is the subject of a patent application).

26.3 The Crown use provisions are similar to those relating to compulsory licensing (discussed in Chapter 27) in allowing the exploitation of an invention without the consent of the patent holder or applicant—in effect creating a compulsory licence in favour of the Crown. Like compulsory licensing, the terms of remuneration or compensation are agreed or, in the absence of agreement, determined by a court.

1 For the purposes of the Crown use provisions, 'State' includes the Australian Capital Territory, the Northern Territory and Norfolk Island: *Patents Act 1990* (Cth) sch 1.

However, unlike compulsory licensing, the Crown use and acquisition provisions may be invoked by the Crown without first seeking the authorisation or agreement of the patent holder.

26.4 For reasons discussed in this chapter, the Crown use provisions seem to be used only rarely. They may nevertheless be important in ensuring that patent protection does not have an adverse impact on significant public interests, including those in the conduct of research and the cost-effective provision of healthcare.

Crown use

26.5 Crown use provisions were introduced into English patent legislation in 1883.[2] Earlier case law had held that the Crown may retain rights to exploit inventions for which a patent had been granted, although this depended on the terms of the particular 'letters patent' issued under the *Statute of Monopolies 1623*.[3] With the enactment of the Crown use provisions in 1883, the Crown agreed to be bound by patents, but obtained the protection of these provisions when using patented inventions.[4]

26.6 In 1903, Crown use and acquisition provisions were included in Australian patents legislation.[5] Barwick CJ described the purpose of the Crown use provisions in the *Patents Act 1952* (Cth) as being to 'ensure that the governments of the Commonwealth and of the States have the invention available to them for the benefit of the services of the respective governments at once, rather than at the end of the term of the letters patents'.[6]

26.7 In its submission to the Inquiry, the South Australian Government characterised the Crown use provisions as being intended to 'provide a balance between the rights of an inventor and the rights of the Crown, representing the public interest'.[7]

26.8 In December 2003, the Advisory Council on Intellectual Property (ACIP) released a Discussion Paper on review of the Crown use provisions in patents and designs legislation (ACIP Discussion Paper). The ACIP Discussion Paper stated that, historically, the two main justifications for Crown use provisions have been:

> (i) the Crown should not be impeded by patents (which are, in effect, Crown grants) from acting in the public interest, particularly in relation to matters of national defence; and

2 *Patents, Designs, and Trade Marks Act 1883* (UK) s 27.
3 *Feather v The Queen* (1865) 6 B & S 257, cited in *Pfizer Corporation v Ministry of Health* [1965] AC 512, 533.
4 See *Pfizer Corporation v Ministry of Health* [1965] AC 512, 533.
5 *Patents Act 1903* (Cth) ss 92–93.
6 *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125, 133–134.
7 South Australian Government, *Submission P51*, 30 October 2003.

> (ii) unlike private traders, the Crown, through its departments and authorities is ordinarily engaged in public services, rather than commercial activities, and therefore should be in a special position in regards to use of patented inventions.[8]

26.9 At the time the Crown use provisions were first enacted, the scope of government activities was more limited than at present. In *Pfizer Corp v Ministry of Health*[9] (*Pfizer*), Lord Reid observed:

> In Victorian times [the services of the Crown] were the armed services—the navy and the army—the Civil Service, the foreign colonial and consular services, the Post Office, and perhaps some others. Now there are many more Government activities which are staffed and operated by servants of the Crown, and are subject to the direction of the appropriate Minister.[10]

26.10 Expansion in government services, including the provision of healthcare, has greatly broadened the scope for use of the Crown use provisions. However, the frequency with which the provisions have been used is difficult to establish. Evidence that the provisions have been used may be found in the reported cases in which the application of the Crown use provisions has been contested. There are two reported cases in Australia, from 1964 and 1994, involving the use of patented inventions in water meters by local government[11] and in central bearing structures for railway carriage construction by a state Commissioner for Railways,[12] respectively.

26.11 In response to questions about how frequently Crown use is authorised in Australia, Australia stated in a 1997 report to the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) that:

> If the Crown use provisions were invoked the case would be between the relevant instrumentality of the Crown and the patentee and would not involve any of the administrative bodies responsible. As such it is difficult to determine the frequency of use, though we expect this has been minimal.[13]

26.12 While the Crown use provisions have been used only rarely, their importance may lie more in their potential for use. One view is that the primary purpose of the Crown use provisions is 'to force an unwilling licensor to the negotiating table' and that the 'threat of resort to the Crown use provisions may assist in ensuring an acceptable result from those negotiations'.[14]

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8 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 2.

9 *Pfizer Corporation v Ministry of Health* [1965] AC 512.

10 Ibid, 533.

11 *Stack v Brisbane City Council* (1994) 131 ALR 333.

12 *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125.

13 Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997*, World Trade Organization, <www.wto.org/english/tratop_e/trips_e/intel8_e.htm> at 17 December 2003.

14 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 74.

26.13 There are various reasons why the Crown might seek to exercise the Crown use or acquisition provisions in respect to genetic inventions used in scientific research or healthcare provision, including:

- to facilitate genetic research by organisations such as the Commonwealth Scientific and Industrial Research Organisation (CSIRO);
- to provide medical genetic testing through public sector genetics laboratories; or
- to provide novel therapies (such as those involving gene therapy, therapeutic proteins or stem cells) through public sector health organisations or other healthcare providers.

26.14 The Crown use provisions involve significant interference with the rights that patent holders otherwise have under the patent system. It is arguable that the Crown use and acquisition provisions should not be relied upon too readily and should be invoked only in exceptional circumstances if confidence in the patent system is to be preserved. For example, reliance upon the provision may be justifiable in the case of public health emergencies, such as those in which the United States and Canadian governments contemplated compulsory use of Bayer's patent on the ciprofloxacin antibiotic following bioterror attacks using the anthrax organism in the United States.[15]

26.15 However, even in these circumstances, Crown use or acquisition of a patent may be controversial and this factor may act as a political constraint on the exercise of these provisions of the *Patents Act*. Another constraint is that, as discussed below, where the provisions are invoked, adequate remuneration or compensation must still be paid to the patent holder.

The Patents Act

26.16 Section 163(1) of the *Patents Act* allows the exploitation of a patented invention by the Commonwealth or a State, or by a person authorised by the Commonwealth or a State, without liability for infringement of the patent, provided that exploitation is 'for the services of the Commonwealth or the State'.[16] The permitted exploitation by the Crown expressly includes exploitation by an authority of the Commonwealth or of a State.[17]

26.17 The relevant Crown authority must notify the patent holder of the exploitation as soon as practicable after the invention has been exploited and give the patent holder information about the exploitation, as reasonably required from time to time.[18] The

15 Consumer Project on Technology, *Ciprofloxacin: The Dispute over Compulsory Licenses*, <www.cptech.org/ip/health/cl/cipro> at 3 June 2003.

16 The right to exploit an invention under s 163(1) includes the right to sell products made in exercise of that right: *Patents Act 1990* (Cth) s 167(1).

17 Ibid s 162.

18 Ibid s 164.

terms of the exploitation, including remuneration payable to the patent holder, are to be agreed between the patent holder and the relevant authority or determined by a prescribed court.[19] The exploitation of the patented invention by the Crown must cease upon a prescribed court declaring that the exploitation of the invention is no longer necessary for the proper provision of services of the Commonwealth or the State.[20]

26.18 The *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement) contains detailed provisions dealing with the use of patented inventions 'without the authorization of the right holder, including use by the government or third parties authorized by the government'.[21] These provisions, which are discussed in more detail in the context of compulsory licensing,[22] apply to Crown use of patented inventions.

26.19 Importantly, art 31(b) of the TRIPS Agreement provides that use without the authorisation of the patent holder may only be permitted if, prior to the use, the proposed licensee has made previous efforts for a reasonable period to obtain authorisation from the right holder on reasonable commercial terms and conditions.[23] This requirement may be waived in the case of a national emergency or other circumstances of extreme emergency, or in cases of public non-commercial use.[24] Crown use is considered to be 'public non-commercial use' for the purposes of the TRIPS Agreement.[25] Crown use may, therefore, be permitted without efforts being made to obtain authorisation from the patent holder.

Who is the Crown?

26.20 The Crown use provisions may be exercised by the Commonwealth or a State, an authority of the Commonwealth or a State,[26] or a person authorised in writing by the Commonwealth or a State.[27]

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19 Ibid s 165.

20 Ibid s 165A.

21 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31. See also Ch 4.

22 See Ch 27.

23 Contracting states need not apply this condition where such use is permitted to remedy a practice that is determined after a judicial or administrative process to be anti-competitive practice. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases: *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31(k).

24 See Ibid art 31(b).

25 See Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997*, World Trade Organization, <www.wto.org/english/tratop_e/trips_e/intel8_e.htm> at 17 December 2003.

26 *Patents Act 1990* (Cth) s 162.

27 Ibid s 163(1).

26.21 Case law provides some guidance on the entities that may constitute 'an authority of the Commonwealth or of a State' for the purposes of the Crown use provisions.[28] In *Stack v Brisbane City Council*[29] (*Stack*), the Federal Court of Australia considered the position of the Brisbane City Council, which had installed water meters in homes in Brisbane, which incorporated assemblies in respect of which the applicants were beneficially entitled to a patent. The applicants sought an injunction restraining the Council from infringing the patent. The Council relied on the Crown use provisions as a defence to the claim of infringement.

26.22 The Federal Court held that the primary focus in determining whether a body was an authority of the State was on the functions of government. A body would be an authority of the State if its functions were 'impressed with the stamp of government' or if the body had been given the power to direct or control the affairs of others on behalf of the State. The role and involvement of the executive, through the Governor in Council or the appropriate Minister, was also a relevant factor.[30] The Federal Court stated that in determining whether a body satisfied the test, no one consideration was decisive. It was a question of fact and degree in the circumstances and depended on the structure, powers and functions of the body.[31]

26.23 The Federal Court found that the Brisbane City Council was an authority of the State. Relevant factors were that the Council was a statutory body, established and ultimately controlled by State legislation, and its functions and powers were State governmental functions and powers, which the State had delegated to it in legislation, and which were to be exercised in the interests of the community. The State executive retained a prominent role and a practical involvement in the functions of the Council.[32]

26.24 In considering what entities may constitute the Crown or a Crown authority, IP 27 referred to the ALRC's work on Commonwealth immunity (sometimes referred to as the 'shield of the Crown')[33] conducted in the context of its review of the *Judiciary Act 1903* (Cth).[34] The issue of whether an entity is the Crown, for these purposes, is straightforward if legislation establishing the entity states that an entity is entitled to the privileges and immunities of the Crown. In the absence of an express statutory provision, the question of whether an entity is entitled to the immunities of the Crown is determined by implication according to two criteria, established in the common law.

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28 See *Stack v Brisbane City Council* (1994) 131 ALR 333; *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125; *Committee of Direction of Fruit Marketing v Delegate of the Australian Postal Commission* (1980) 144 CLR 577.

29 *Stack v Brisbane City Council* (1994) 131 ALR 333.

30 Ibid, 339.

31 Ibid, 339.

32 See Ibid, 339–344.

33 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, DP 64 (2000), Ch 5.

34 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [29.6]–[29.17].

These involve the nature of the activities carried out by the entity and the degree of control exercised by the executive (usually a Minister) over the entity.[35]

26.25 In *Stack*, Cooper J stated that the long line of cases relating to Crown privileges and immunities were of limited relevance because the phrase 'authority of a State' carried a 'different emphasis'.[36] However, he conceded that there is some overlap in the concepts of Crown entities for immunity purposes and authorities of the Commonwealth or of a State for the purposes of the *Patents Act*.[37] It seems likely that most Crown entities for immunity purposes will also be authorities of the Commonwealth or a State for *Patents Act* purposes.

26.26 The ACIP Discussion Paper observed that case law suggests the Crown use provisions are applicable to a 'vast number of municipal councils and statutory authorities throughout Australia'.[38] ACIP stated:

> The vast range of entities that may be considered the Crown is the basis of some arguments that the Crown use provisions, whilst justified, apply to too many entities that have more commercial interests such as profits rather than the proper provision of Government services to the public.[39]

26.27 The ACIP Discussion Paper suggested that consideration should be given to limiting the range of government bodies that can exploit patents under the Crown use provisions—in particular so that 'deregulated and corporatised' statutory bodies do not obtain an 'unfair advantage in the market place'.[40] The ACIP Discussion Paper noted:

> One possible option that may address this risk is to amend the legislation to require any Crown use of patents by any council, statutory corporation or any other like body to require Ministerial approval. This would centre the responsibility for invoking the Crown use provisions and would ensure that they are not commercially abused contrary to competition principles such as competitive neutrality.[41]

Services of the Commonwealth or the State

26.28 The Crown use provisions apply to exploitation 'for the services of the Commonwealth or the State'.[42] An invention is taken to be exploited for the services of the Commonwealth or the State if the exploitation is 'necessary for the proper provision of those services within Australia'.[43]

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35 Ibid, [29.6].
36 *Stack v Brisbane City Council* (1994) 131 ALR 333, 337.
37 Ibid, 337.
38 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 6.
39 Ibid, 6–7.
40 Ibid, 7.
41 Ibid, 6.
42 *Patents Act 1990* (Cth) s 163(1).
43 Ibid s 163(3).

26.29 The ACIP Discussion Paper noted that there are some uncertainties about the circumstances in which the Crown use provisions can be used and stated that 'the over use or incorrect use of this right may be seen as an abuse of power by the Government and possibly an easy and convenient method of acquiring technology on the cheap'.[44]

26.30 In *Stack*,[45] the Federal Court considered the meaning of the phrase 'services of the Commonwealth or the State'. The applicant submitted that the installation of the water meters by the Brisbane City Council was a revenue-gathering function of the Council and not for the services of the State.[46]

26.31 This argument was rejected by the Federal Court, which found that the water meters were an asset of the Council that enabled it to quantify and charge for water supplied and were a component part of the apparatus by which water was supplied as a function of local government.[47] The exploitation of the meters was 'for the services of the State' for the purposes of s 163 of the *Patents Act*.

26.32 In arriving at its decision, the Federal Court considered the reasoning of the House of Lords in *Pfizer*,[48] in which it was held that the use of a patented drug (tetracycline) in National Health Service hospitals for patients was 'for the services of the Crown'.[49] The House of Lords held that the phrase was not to be limited to the internal activities of Crown authorities but that the services at issue could ultimately benefit individual members of the public.[50]

26.33 The facts of *Pfizer* were that the Ministry of Health had invited tenders for the supply of tetracycline from various firms and offered protection to tenderers by relying on the Crown use provisions of s 46 of the *Patents Act 1949* (UK).[51] The successful tenderer imported the drug from Italy, where it was not patented and thus could be legally produced by a supplier without the patent holder's authority.

26.34 The House of Lords held, by majority, that an act was done 'for the services of the Crown' if it was done for the purpose of performing a duty or exercising a power

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44 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 7.

45 *Stack v Brisbane City Council* (1994) 131 ALR 333.

46 Ibid, 344.

47 Ibid, 348.

48 *Pfizer Corporation v Ministry of Health* [1965] AC 512.

49 Ibid.

50 For example, Lord Reid indicated that it would not be workable for the purposes of the Crown use provisions to distinguish between the use of patented articles for the benefit of the government department or service that uses them, and use for the benefit of others: 'Most, if not all, activities of Government departments or services are intended to be for the benefit of the public, and few can be regarded solely, or even mainly, for the benefit of the department or of members of the service': Ibid, 534.

51 *Patents Act 1949* (UK) s 46(1) provided: 'Notwithstanding anything in this Act, any Government department and any person authorised in writing by a Government department may make use and exercise any patented invention for the services of the Crown in accordance with the following provisions of this section'.

which was imposed upon or invested in the executive government by statute or by prerogative, including providing services to the general public.[52]

26.35 The ACIP Discussion Paper referred to *Pfizer* and noted that the case shows how the Crown use provisions could be applied to the supply of drugs used in the treatment of disease.[53] The ACIP Discussion Paper questioned whether the sale of patented products to members of the public should be characterised as a use necessary for the proper provision of Commonwealth or State services.[54] It also suggested that one option was:

> to categorise and condense the broad range of circumstances in which the Government can invoke the [Crown use provisions]. Making approval based on a national interest basis, with associated criteria could do this. For example the provisions could be restricted to use in time of national emergency, for defence purposes, and/or health purposes.[55]

Crown use in research and healthcare

26.36 The Crown use provisions are of broad potential application and include the conduct of research and the provision of healthcare. However, as discussed below, there are some limitations on, and uncertainties about, the application of the Crown use provisions to the use of patented genetic materials and technologies in research and healthcare. These relate to whether: (a) particular bodies are the Crown and (b) exploitation is for the services of the Crown.

Application to research

26.37 The use of patented genetic materials or technologies in research by a Commonwealth or State organisation, such as the CSIRO or a State public teaching hospital, would quite clearly involve exploitation by the Commonwealth or a State for the services of the Commonwealth or a State.

26.38 However, as discussed in Chapter 11, while more than half of human health-related biological research in Australia is funded by the Australian Government, much of this research is conducted by bodies that may not constitute the Commonwealth or a State, or an authority of the Commonwealth or of a State, for the purposes of the *Patents Act*.

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52 See *Pfizer Corporation v Ministry of Health* [1965] AC 512, 535, 543, 551–552; *Stack v Brisbane City Council* (1994) 131 ALR 333, 345.

53 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 10–11.

54 Ibid, 10–11. The minority in *Pfizer* considered that re-supply by a government department to members of the general public in competition with the patent holder should not be covered by the Crown use provision: *Pfizer Corporation v Ministry of Health* [1965] AC 512, 568. In *Stack*, Cooper J stated that he was not required to express a view as to which view more closely reflected the law in Australia: *Stack v Brisbane City Council* (1994) 131 ALR 333, 348.

55 See Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 8.

26.39 For example, publicly funded research is often conducted by medical research institutes, such the Garvan Institute for Medical Research (Garvan) and the Walter and Eliza Hall Institute of Medical Research (WEHI). Such institutes may be established by state legislation[56] and may be affiliated with public sector universities or hospitals.[57] However, they are self-governing, set their own research priorities, and receive some funding from non-government sources, including private donations.

26.40 Following the approach taken by the Federal Court in *Stack*,[58] it seems likely that such bodies would not constitute authorities of a State for the purposes of the *Patents Act*. They are not 'impressed with the stamp of government' because their functions are not governmental or delegated by the State. Further, while institutes such as the Garvan may be established by state legislation, the State executive generally does not retain a prominent role or practical involvement in their operation.[59]

26.41 This conclusion is consistent with comments made in a submission from the Medical Genetics Elective Group of the University of Newcastle, which stated that most research is not conducted by entities that would qualify for the benefit of the Crown use provisions—the CSIRO constituting a significant exception.[60]

26.42 Another issue that arises is whether research is 'for the services of the Commonwealth or the State'. Where research is conducted by an authority of the Commonwealth or of a State, such as the CSIRO or a public teaching hospital, it could be expected the research would be considered to be 'for the services of the Commonwealth or the State'. A government authority would be using the patented invention directly for government research purposes.

Application to healthcare

26.43 There are similar questions about the application of the Crown use provisions to the use of patented genetic materials and technologies in the provision of healthcare.

26.44 In Australia, responsibility for the provision of healthcare is divided between Commonwealth, state and territory governments, and between the government and non-government sectors.[61]

26.45 In most cases, it will be clear that the use of patented genetic materials or technologies in healthcare involves exploitation by an authority of the Commonwealth or of a State—for example, where medical genetic testing of patients is carried out by a public sector laboratory attached to a state public hospital. It seems equally clear that

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56 For example, *Garvan Institute of Medical Research Act 1984* (NSW).
57 For example, WEHI is affiliated with the University of Melbourne and the Royal Melbourne Hospital.
58 See *Stack v Brisbane City Council* (1994) 131 ALR 333, 344.
59 The New South Wales Minister for Health nominates two directors for membership of the 15-person Garvan Institute Board: *Garvan Institute of Medical Research Act 1984* (NSW) sch 1, cl 2(1)(e).
60 E Milward and others, *Submission P46*, 20 October 2003.
61 See Ch 20.

the same testing carried out by a private sector laboratory or a private medical practitioner would not involve exploitation by an authority of the Commonwealth or of a State.

26.46 A more problematic issue is whether the provision of healthcare to patients is 'for the services of the Commonwealth or the State'. As Dr Amanda McBratney and others have observed, if the question were to be considered by an Australian court, the House of Lords decision in *Pfizer* may constitute persuasive authority, but much would turn on the circumstances of the case.[62]

26.47 Following the reasoning in *Pfizer* and *Stack*,[63] it seems likely that the use of a patented genetic test by a public hospital would be held to be for the services of a State. The provision of healthcare by public hospitals to their patients is a function of the State and its health authorities. However, the position is not beyond doubt.

Other jurisdictions

26.48 The patents legislation of other jurisdictions, including the United Kingdom, New Zealand and Canada, contains Crown use provisions similar to those in the *Patents Act*.

26.49 In the United Kingdom, the *Patents Act 1977* (UK) provides for the exploitation of a patented invention 'for the services of the Crown' by 'any government department and any person authorised in writing by a government department'.[64] The Act provides specifically that the term 'services of the Crown' includes, among other things, 'the production or supply of specified drugs and medicines'.[65] This provision was not present in the *Patents Act 1949* (UK) and may have been considered desirable in order to remove any doubt about the effect of the decision in *Pfizer*.[66] The Act also includes detailed provisions as to Crown use during an emergency.[67]

26.50 In New Zealand, the *Patents Act 1953* (NZ) provides for the exploitation of a patented invention by 'any Government Department and any person authorised in writing by a Government Department … for the services of the Crown'.[68]

26.51 In Canada, the *Patent Act 1985* (Can) provides that the Commissioner of Patents may 'on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government',[69] on terms set by the

62 A McBratney and others, *Submission P47*, 22 October 2003.
63 *Stack v Brisbane City Council* (1994) 131 ALR 333.
64 *Patents Act 1977* (UK) s 55(1).
65 Ibid s 56(2).
66 *Pfizer Corporation v Ministry of Health* [1965] AC 512.
67 *Patents Act 1977* (UK) s 59.
68 *Patents Act 1953* (NZ) s 55(1).
69 *Patent Act 1985* RS c P-4 (Canada) s 19(1).

Commissioner.[70] There is no requirement in the Act that the use must be for the services of the Government.

26.52 There is no evidence that the Crown use provisions in the United Kingdom, New Zealand or Canada have been used any more frequently than in Australia. There is a small number of reported United Kingdom cases in which the Crown use provisions were at issue. These include *Pfizer*, and two cases from the 1920s involving the supply of fire extinguishers to the Ministry of Munitions during the First World War,[71] and the welding of aluminium articles for use by government.[72]

26.53 In a 1998 report to the Council for TRIPS, the United Kingdom stated that, at least since 1996, no Crown use authorisations had been made.[73] The report implies that, in the United Kingdom, the Crown use provisions are most likely to be asserted by the Ministry of Defence.[74] Similarly, New Zealand reported in 1997 that, at least since 1993, there had been no exercise of Crown use provisions.[75]

Acquisition by the Crown

26.54 In addition to Crown use, s 171 of the *Patents Act* provides for compulsory acquisition by the Commonwealth of an invention covered by a patent or patent application.[76] The Act does not stipulate any limitations on the circumstances in which the Commonwealth may acquire an invention, but the Commonwealth must compensate a patent holder.[77] The section does not extend to compulsory acquisition by a State or Territory.

26.55 There are several situations in which the Commonwealth might wish to acquire a gene patent, such as in dealing with national emergencies or for defence purposes.[78] It is also conceivable that the Australian Government may wish to acquire gene patents so as to provide open access to specific genetic materials or technologies. However, in

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70 Ibid s 19(2). The terms must comply with principles set out in that subsection.

71 *Pyrene Co Ltd v Webb Lamp Co Ltd* (1920) 37 RPC 57.

72 *Aktiengesellschaft für Autogene Aluminium Schwiessung v London Aluminium Co Ltd (No 2)* (1923) 40 RPC 107.

73 Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: United Kingdom, 7 January 1998*, World Trade Organization, <www.wto.org/english/tratop_e/trips_e/intel8_e.htm> at 7 January 2004.

74 Ibid.

75 Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: New Zealand, 24 October 1997*, World Trade Organization, <www.wto.org/english/tratop_e/trips_e/intel8_e.htm> at 7 January 2004.

76 *Patents Act 1990* (Cth) s 171.

77 Ibid s 171(4).

78 Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997*, World Trade Organization, <www.wto.org/english/tratop_e/trips_e/intel8_e.htm> at 17 December 2003.

1997 the Australian delegation to the World Trade Organization stated that there are no instances of this provision having been used.[79]

Submissions and consultations

26.56 IP 27 asked whether the Crown use provisions in the *Patents Act* are capable of applying to the provision of healthcare services using patented genetic materials and technologies.[80] In response, some submissions suggested that the Crown use provisions are adequate in scope and do not require amendment.[81]

26.57 For example, GlaxoSmithKline submitted that Crown use provisions are 'potentially extremely broad in their operation' and that, in relation to healthcare, these provisions:

> could be used in a wide variety of ways which would of course be adverse to the rights originally afforded to the patentee under the patent system. In view of the fact that the Crown use provisions would appear to be contrary to the general public policy intention of the Act to reward inventors and encourage innovation, it is perhaps not surprising that these provisions have not been utilised to any significant extent. This is evidence that the patent system is not abused so as to necessitate resort to these provisions and there is no reason to suppose that gene patenting will change the position.[82]

26.58 Other submissions suggested that legislative amendment is desirable to make it clear that the Crown use provisions apply to healthcare services.[83] For example, the Human Genetics Society of Australasia submitted that, while the Crown use provisions appear capable such application, it might still be advisable:

> to amend the legislative provisions to ensure that the definition of service includes health care activities and that health care providers fall under the definitions of Commonwealth, State or an authority of such.[84]

26.59 The Commonwealth Department of Health and Ageing noted that while Crown use of gene patents may address problems of accessibility, it would not necessarily address cost issues.[85] The Department stated:

> it would be preferable to ensure that the operation of the Act in relation to gene patents ensures appropriate levels of competition. This would obviate the need to

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79 Ibid.

80 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 15–1.

81 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003.

82 GlaxoSmithKline, *Submission P33*, 10 October 2003.

83 Cancer Council Australia, *Submission P25*, 30 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Queensland Government, *Submission P57*, 5 January 2004; South Australian Government, *Submission P51*, 30 October 2003.

84 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003. The South Australian Government highlighted the absence of definitive Australian case law: South Australian Government, *Submission P51*, 30 October 2003.

85 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

> apply Crown use or compulsory licensing provisions except in extraordinary circumstances.[86]

26.60 The Medical Genetics Elective Group of the University of Newcastle submitted that the Crown use provisions should be amended to apply to situations where research is 'funded by the Commonwealth and is not intended for profit'.[87] However, they also cautioned that the Crown use provisions should only be used 'in extreme circumstances'.

> An over use of this defence could undermine the patent system and be more detrimental to research and healthcare in the long term. The threat of use may be enough to encourage patentees to provide general licences thus benefiting both the patentee and the public.[88]

ALRC's views

26.61 As discussed in Chapter 2, patent law seeks to achieve a balance between the desirability of encouraging the provision of new and useful goods by rewarding inventiveness, and the undesirability of ongoing monopolies for critical processes or products.

26.62 In some circumstances, the exercise of patent rights may have adverse implications for governmental or public interests. Where this is the case, the Crown use provisions ensure that governments can step in to exploit a patent or authorise others to do so. These provisions may be seen as a 'safety valve' in particular cases, preventing the public interest from being subverted by the patent system.

26.63 Where important public interests are involved, the Australian Government could potentially legislate to permit the use or acquisition of property, including patents, so as to address the particular problem at hand. However, the Crown use provisions may offer a more expeditious and efficient mechanism,[89] and one that is also available to state and territory governments and their health authorities.

26.64 In practice, as is the case with the compulsory licensing provisions, the Crown use provisions are not often used. However, they may be important in encouraging patent holders to negotiate on reasonable terms with prospective licensees, including government authorities.

26.65 The Inquiry proposes a pattern of laws and practices that is flexible enough to anticipate and respond to any future problems for research or healthcare delivery attributable to gene patents. The potential use of the Crown use provisions by

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86 Ibid.
87 E Milward and others, *Submission P46*, 20 October 2003.
88 Ibid.
89 See Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 11–12.

Commonwealth, State and Territory governments may contribute desirable flexibility to the patent system.

26.66 The ALRC's proposals anticipate that Commonwealth, state and territory governments may, in future, consider exercising the Crown use and acquisition provisions of the *Patents Act* more actively, and that there may be circumstances in which it is appropriate to do so. Notably, in Chapter 20, the ALRC proposed a more active role for Commonwealth, state and territory health departments, in liaison with the Australian Health Ministers' Advisory Council (AHMAC), in considering whether to exploit or acquire a patent under the Crown use or acquisition provisions of the *Patents Act*.[90] The ALRC also proposes that AHMAC and the Commonwealth Department of Health and Ageing should develop policies regarding the circumstances in which is it is appropriate for the Crown to exploit a patented invention under these provisions for the purpose of promoting human health (Proposal 26–1).

26.67 In the light of this, the ALRC considers that it would be desirable to amend the *Patents Act* to clarify that 'the services of the Commonwealth or of a State' includes the provision of healthcare services or products to members of the public (Proposal 26–2). While the case law suggests this interpretation, the position is not beyond doubt and it would be helpful to clarify that the Crown use provisions are able to be used, where appropriate, in healthcare delivery.[91] The ALRC is interested in comments on how such an amendment might be drafted. For example, should a distinction be drawn between the exploitation of a patent to provide a service, such as medical genetic testing, and situations involving the re-supply or sale of a patented product to others?

26.68 There appears to be no similar need for an amendment directed at research use by the Crown of patented genetic materials or technologies. The problem in this context relates more to whether a particular research organisation constitutes 'an authority of the Commonwealth or of a State'. There are existing solutions to this problem. Where there is some doubt about its status, a research institution may be authorised in writing by the Commonwealth or a State (before or after the patented invention is exploited).[92] Alternatively, the institution may be able to invoke the compulsory licensing provisions.[93]

26.69 The ALRC also considers that the *Patents Act* should be amended to clarify that, when the Crown exploits or acquires a patent under the Act, the compensation payable must be just and reasonable. Commonwealth acquisition of a patent under s 171 of the *Patents Act* would, in any case, fall within the scope of s 51(xxxi) of the Australian

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90 See Ch 20.

91 In this context, it is noted that United Kingdom legislation defines 'services of the Crown' as including certain specific activities. These are: (a) the supply of anything for foreign defence purposes; (b) the production or supply of specified drugs and medicines; and (c) purposes relating to the production or use of atomic energy or research: *Patents Act 1977* (UK) s 56(2).

92 *Patents Act 1990* (Cth) ss 163(1), 163(2).

93 See Ch 27.

Constitution, which requires that any acquisition of property—including intellectual property—by the Commonwealth must be on 'just terms'.

26.70 The compulsory licensing provisions state that a patent holder is entitled to be paid for use of a patent under a compulsory licence at an agreed rate or, failing agreement, such amount as is determined by a prescribed court to be 'just and reasonable having regard to the economic value of the licence'.[94] This provision was inserted by the *Patents (World Trade Organisation Amendments) Act 1994* (Cth), which made a suite of amendments to the *Patents Act* to enable Australia to ratify the TRIPS Agreement, by ensuring that Australian patents legislation was consistent with it.[95]

26.71 Article 31 of the TRIPS Agreement, which deals with both Crown use and compulsory licensing, as those terms are understood in Australian law, requires the patent holder to be paid 'adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'.[96]

26.72 Following the 1994 amendments, the *Patents Act* now refers to the fact that remuneration for Crown use is payable to the patent holder.[97] However, there is no guidance on the quantum of remuneration, but only on the mechanism by which any dispute about remuneration is to be resolved. The ALRC considers that a legislative standard is desirable and proposes that an amendment to the Crown use and Crown acquisition provisions follow the language of the equivalent compulsory licensing provision (Proposal 26–3).

26.73 The ALRC recognises that questions have been raised about whether the Crown use provisions are already too broad in their potential application. For example, the ACIP Discussion Paper highlights the broad ambit of the Crown use provisions and asks, among other things, whether the availability of the provisions should be limited or denied to certain entities and whether it would be advantageous to restrict the circumstances in which government can invoke them.[98] These are important questions. However, the central focus of the ALRC's Terms of Reference is on the desirability of reforms to address the possible adverse impact of gene patents on research and healthcare. Questions about whether the Crown use provisions should be wound back have not been a focus of consultation.

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94 *Patents Act 1990* (Cth) ss 133(3)(a), 133(5).

95 *Patents (World Trade Organisation Amendments) Act 1994* (Cth). Being an original Member of the World Trade Organisation with effect from 1 January 1995, Australia was obliged to bring its laws in conformity with the TRIPS Agreement by January 1996.

96 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31(h).

97 *Patents (World Trade Organisation Amendments) Act 1994* (Cth) s 15(c); *Patents Act 1990* (Cth) s 165(2).

98 See Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 6–9.

Proposal 26–1 The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the *Patents Act 1990* (Cth) (*Patents Act*) for the purposes of promoting human health. Similarly, the Commonwealth Department of Health and Ageing should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health.

Proposal 26–2 The Commonwealth should amend the *Patents Act* to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or the State' if the exploitation of the invention is for the provision of healthcare services or products to members of the public.

Proposal 26–3 The Commonwealth should amend the *Patents Act* to provide that when a patent is exploited or acquired under the Crown use or Crown acquisition provisions of the *Patents Act*, the Crown must pay such remuneration or compensation as is:

(a) agreed between the parties; or

(b) determined by a prescribed court to be just and reasonable having regard to the economic value of the patent.

Transfer of 'know-how'

26.74 A patent application must fully disclose an invention. The *Patents Act* provides that a complete specification must 'describe the invention fully, including the best method known to the applicant for performing the invention'.[99] However, the patent holder may later acquire valuable know-how and experience that is necessary to exploit the invention effectively or optimally.

26.75 Where Crown use or acquisition rights are asserted over a patented invention, the Crown, or the person authorised by the Crown, may encounter problems in exploiting the patented product or process if it does not have the necessary know-how to do so. Thus, the mere right to exploit without infringement may be insufficient to enable the Crown to use a patented invention effectively or optimally. Access to the patent holder's know-how may also be required, for example through the provision of additional information by the patent holder, or access to documentation about the invention. This issue has arisen more frequently in the context of compulsory licences

99 *Patents Act 1990* (Cth) s 40(2)(a). This is known as the 'sufficiency requirement': see Ch 6.

over patented inventions, rather than in relation to Crown use, and is discussed in further in Chapter 27.

Question 26–1 Should the Commonwealth amend the *Patents Act* to require a patent holder to transfer 'know-how' relating to the patented product or process to the Crown when the Crown uses or acquires a patent under the Act?

27. Compulsory Licensing

Contents

Introduction

27.1 A compulsory licence is an authorisation given by a national authority, without or against the consent of the patent holder, for the exploitation of a particular patented product or process, or other intellectual property right.[1]

1 C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 3.

27.2 This chapter considers the circumstances in which compulsory licences may be granted under the *Patents Act 1990* (Cth) (*Patents Act*) to facilitate access to patented genetic inventions for use in scientific research or healthcare provision. The chapter considers particular issues and problems arising from the existing test for granting a compulsory licence, and proposes several reforms.

Compulsory licensing

27.3 The compulsory licensing provisions of the *Patents Act* allow the exploitation of a patented invention without the consent of the patent holder. The terms of remuneration or compensation are agreed or, in the absence of agreement, determined by a court. The Act stipulates the conditions upon which a court may grant a licence.[2]

27.4 The concept of a compulsory licence over patents arose from the historical requirement that a patent holder must 'locally work' a patented product or process. This meant that the patent holder was required to use or produce the patented invention within the country in which the patent was registered.[3] Where a patent holder failed to 'work' the invention locally, the patent was subject to forfeiture. Compulsory licences were developed as a less drastic means to ensure a patent was exploited.[4]

27.5 Compulsory licensing provisions were included in the first Australian patents legislation.[5] Menzies J described the objects of similar compulsory licensing provisions in the now repealed *Patents Act 1952* (Cth) as:

> (1) fostering Australian manufacturing industry to make the patented article or to use the patented process and (2) ensuring that the Australian demand for the patented article or articles made in accordance with the patented process should be reasonably met whether from local production or from imports.[6]

27.6 However, in its report, *Review of Intellectual Property Legislation under the Competition Principles Agreement*, the Intellectual Property and Competition Review Committee (IPCRC) suggested that these objectives may no longer be appropriate:

> The current terms … hark back to a period where the primary concern was the promotion of domestic industry, rather than securing the best use of resources and achieving high levels of productivity. Moreover, they lack an explicit competition

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2 See below for more detail.

3 This requirement was introduced in the *Statute of Monopolies 1623* (UK) and many other national patent laws during the 19th century.

4 C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 3–4. See also M Halewood, 'Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law' (1997) 35 *Osgoode Hall Law Journal* 243, 251–254; J Reichman and C Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America: Issue Paper No 5* (2003) UNCTAD–ICTSD Capacity Building Project on IPRs and Sustainable Development, 10–11.

5 *Patents Act 1903* (Cth) s 87.

6 *Fastening Supplies Proprietary Limited v Olin Mathieson Chemical Corp* (1969) 119 CLR 572, 575.

> test, and do not seem to allow for the legitimate interests of the rights owner to be adequately protected.[7]

27.7 Compulsory licences have been granted on a diverse range of grounds in other countries, including: to address local working and lack of appropriate supply; to remedy a refusal to deal;[8] to remedy anti-competitive conduct; in the public interest;[9] to facilitate dependent patents; to facilitate government use;[10] and to facilitate access to medicines.[11]

27.8 The United Kingdom's Nuffield Council on Bioethics (Nuffield Council) has suggested that compulsory licensing may be one way of ameliorating the problems arising from the grant of patents on genetic diagnostic tests. For example, compulsory licensing may be an appropriate remedy if the patent holder's monopoly is such that an important diagnostic tool is available only from the inventor at an unreasonably high cost, and the patent holder is unwilling to license others to provide a cheaper alternative.[12]

27.9 The Nuffield Council also outlined the main arguments against compulsory licensing. These were that such licensing would decrease the incentive to develop new inventions and encourage secrecy among inventors; increase the cost and complexity of the patent system; and result in fewer challenges to the validity of gene patents, meaning that invalid patents may never be challenged. It recognised the strong opposition to compulsory licensing within the pharmaceutical industry, and emphasised the need to strike a careful balance of rights.[13]

27.10 Compulsory licensing also raises several practical concerns. For example, national governments that allow compulsory licences may face censure from major

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7 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 162.

8 For example, the United Kingdom provides for the grant of a compulsory licence on this ground where an export market is not being supplied, the working of any other patented invention that makes a substantial contribution is prevented or hindered, or the establishment or development of commercial or industrial activities in the country is unfairly prejudiced: C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 10–11.

9 For example, European Union member states permit the grant of compulsory licences on public interest grounds, but define the public interest differently: J Reichman and C Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America: Issue Paper No 5* (2003) UNCTAD–ICTSD Capacity Building Project on IPRs and Sustainable Development, 12.

10 See Ch 26.

11 See generally, C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 10–21. Canada previously permitted the grant of compulsory licences for the importation, manufacture, use and sale of patented medicines. In France, compulsory licences may be granted when medicines are 'only available to the public in insufficient quantity or quality or at abnormally high price': Ibid, 19–21.

12 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 54–55.

13 Ibid, 55.

trading partners under pressure from powerful patent holding interests.[14] In addition, it may be difficult to exploit the patented invention under a compulsory licence without the co-operation of the patent holder, unless the necessary 'know-how' to work the invention is included in the licence.[15]

27.11 Several commentators have discussed the benefit of using the threat of compulsory licensing as a means of inducing patent holders to enter into voluntary licences for their patented inventions.[16] In its review of similar provisions in *Patents Act 1952* (Cth), the Industrial Property Advisory Committee (IPAC) commented that:

> there is anecdotal evidence that compulsory licences have an impact on licence negotiations, notably between foreign rights owners and potential users of patents in Australia. It is claimed that the threat of acquiring a compulsory licence often encourages parties to reach agreement where they otherwise would not have.[17]

27.12 In contrast, AusBiotech Ltd submitted to the Inquiry that:

> There is no solid evidence that the mere existence of the compulsory licence provisions does encourage patentees to negotiate with potential licensees as only a handful of such cases were flagged by AusBiotech Members. This is so for all fields of technology.[18]

27.13 It is difficult to obtain empirical information about the use of these provisions in licence negotiations in Australia. In one recent international example, the South African Competition Commission announced that it had reached a settlement with GlaxoSmithKline, and was in discussion with Boehringer Ingelheim, regarding the grant of voluntary licences to several generic manufacturers to produce anti-retrovirals for sale throughout sub-Saharan Africa. The South African Competition Commission had previously found that the companies had abused their dominant position in the market. It had referred the matter to the Competition Tribunal, which had the power to grant compulsory licences.[19]

Relationship to Crown use

27.14 As discussed in Chapter 26, the *Patents Act* permits the Commonwealth or a State, or a person authorised by the Commonwealth or a State, to exploit a patented

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14 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 372.

15 See the discussion below for more detail.

16 See, eg, D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6; C Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97; Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984); IP Australia, *Submission P56*, 4 November 2003; Australian Centre for Intellectual Property in Agriculture, *Consultation*, Brisbane, 3 October 2003.

17 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 28.

18 AusBiotech Ltd, *Submission P58*, 7 November 2003.

19 Competition Commission of South Africa, 'Competition Commission Concludes an Agreement with Pharmaceutical Firm', *Media Release*, 10 December 2003.

invention without infringing the patent, provided that exploitation is 'for the services of the Commonwealth or the State'. The permitted exploitation by the Crown expressly includes exploitation by an authority of the Commonwealth or of a State.[20]

27.15 A public organisation seeking access to patented genetic materials or technologies may be able to choose whether to invoke either the Crown use provisions or apply for a compulsory licence under the *Patents Act*. For example, where a state health department or other public sector healthcare authority seeks to use a patented medical genetic test, in circumstances where the patent holder has refused to provide a licence, the health authority may have the option of asserting Crown use, or applying to a court for a compulsory licence.

27.16 There may be an advantage in exercising Crown use as compared with seeking a compulsory licence. The costs and delay involved in prior negotiation and court proceedings may be avoided. On the other hand, there may be more uncertainty about the remuneration, ultimately payable to the patent holder, where Crown use is involved.

Patents Act

27.17 Section 133(1) of the *Patents Act* provides that a person may apply to a prescribed court for a compulsory licence to work a patent after a period of three years has lapsed since the patent was granted. The court may make the order if it is satisfied that:

- the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied; and
- the patent holder has not given a satisfactory reason for failing to exploit the patent.[21]

27.18 Section 135 sets out the circumstances in which the 'reasonable requirements of the public' will be deemed not to have been satisfied:

- A new or existing trade or industry in Australia is unfairly prejudiced, or the demand in Australia for the patented product[22] is not reasonably met, because of the patent holder's failure to: manufacture sufficient quantities of the patented product and supply it on reasonable terms; carry on a patented process to a reasonable extent; or grant licences on reasonable terms.

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20 *Patents Act 1990* (Cth) s 162.

21 Ibid s 133(2); *Patents Regulations 1991* (Cth) r 12.1. However, a person cannot apply for a compulsory licence in respect of an innovation patent that has not been certified: s 133(1A).

22 Or for a product resulting from the patented process.

- A trade or industry in Australia is unfairly prejudiced by the conditions the patent holder has attached to the purchase, hire or use of a patented product or to the use or working of a patented process.

- The patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.[23]

27.19 Additional provisions apply where the patent in question is a 'dependent patent', that is, an invention that cannot be worked without infringing another patent.[24]

27.20 A compulsory licence must not be in the nature of an exclusive licence.[25] The patent holder is entitled to be paid for use of the patent at an agreed rate or, failing agreement, 'such amount as is determined by a prescribed court to be just and reasonable having regard to the economic value of the licence'.[26] A compulsory licence may be revoked where the circumstances that justified its grant have ceased to exist and are unlikely to recur, and the interests of the licensee are not likely to be adversely affected by the revocation.[27]

27.21 Few, if any, compulsory licences have been granted under Australian patent law, and the compulsory licensing provisions have received little judicial consideration.[28] A report of the House of Representatives Standing Committee on Industry, Science and Technology in 1992 stated that 'no compulsory licences have been granted since Federation'.[29] The ALRC is not aware of any compulsory licences having been granted since that date.

The TRIPS Agreement

27.22 Article 31 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement) deals with the use of patented inventions without the authorisation of the patent holder. Such use includes Crown use and use pursuant to the grant of a compulsory licence. Article 31 does not specify or limit the grounds upon which a compulsory licence may be granted, but outlines the procedures that

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23 *Patents Act 1990* (Cth) s 135(1). However, if it appears that the patent is not being worked on a commercial scale in Australia, the patent is capable of being worked in Australia, and the reason for non working is due to the nature of the invention or some other cause, the court may adjourn the hearing of an application for a compulsory licence for a period sufficient to permit working on a commercial scale: *Patents Act 1990* (Cth) s 135(2).

24 *Patents Act 1990* (Cth) s 133(3B). See Ch 19 and the discussion below for more detail about dependent patents.

25 Ibid s 133(3)(a).

26 Ibid s 133(5).

27 Ibid s 133(6).

28 See *Fastening Supplies Proprietary Limited v Olin Mathieson Chemical Corp* (1969) 119 CLR 572; *Wissen Pty Ltd v Lown* (1987) AIPC 90. In Bristol-Myers v Faulding, Finkelstein J made a brief reference to the provisions, commenting that 'they may be cumbersome and expensive to apply': *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439, 480.

29 House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), 227.

governments must follow when they grant a licence, and specifies certain provisions to be respected.[30] These include:

- each case must be considered on its individual merits;
- the proposed licensee must have made previous efforts for a reasonable period to obtain authorisation from the right holder on reasonable commercial terms and conditions[31]—however, this requirement may be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use;
- the use must be non-exclusive;
- any such use must be predominantly for the supply of the domestic market of the authorising Member;
- the authorisation must be liable, subject to adequate protection of the legitimate interests of the persons so authorised, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur;
- the right holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation; and
- where such use is authorised to permit the exploitation of a patent (dependent patent) that cannot be exploited without infringing another patent (original patent), the invention claimed in the dependent patent must involve an important technical advance of considerable economic significance in relation to the invention claimed in the original patent; the owner of the original patent must be entitled to a cross-licence on reasonable terms to use the invention claimed in the dependent patent; and the use authorised in respect of the original patent must be non-assignable except with the assignment of the dependent patent.[32]

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30 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 123.

31 Members need not apply this condition where such use is permitted to remedy a practice that is determined after a judicial or administrative process to be anti-competitive practice. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases: *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31(k).

32 Ibid art 31.

Application to research and healthcare

27.23 There are various reasons why a person or organisation might seek a compulsory licence for a patented genetic invention for use in scientific research or healthcare provision, including:

- a researcher or research institution might seek access to an upstream genetic research tool to develop a downstream product such as a pharmaceutical drug;
- a researcher or research institution that has developed an improvement on a patented research tool might seek a licence over the primary tool in order to exploit the patented improvement;
- a pharmaceutical company or other private organisation might seek to provide novel therapies, such as gene therapy, the production of therapeutic proteins, or the use of stem cells to the Australian community where the patent holder has failed to do so; or
- a public sector health authority might seek to provide a patented medical genetic test or other healthcare service where the demand in Australia is not being met.[33]

27.24 IP 27 asked whether the compulsory licensing provisions in the *Patents Act* encourage patent holders to exploit or license gene patents; and whether the grant of a compulsory licence is an adequate and appropriate mechanism to remedy the possible adverse impacts of gene patents on access to healthcare or the ability to conduct research related to human health.[34]

27.25 One submission suggested that the compulsory licence provisions do not appear to assist in this context due to 'the legalities in pursuing them'.[35] In contrast, the Department of Industry, Tourism and Resources submitted that:

> The *Patents Act* provides an appropriate mechanism for the application of compulsory licensing of gene patents and adequate compensation to the Patentee.
>
> Even though compulsory licensing has rarely been applied, its potential has provided incentive for the exploitation and licensing of patent across technologies.[36]

27.26 Several submissions supported the use of compulsory licensing provisions as a means to facilitate access to gene patents for the provision of healthcare services.[37] The Department of Health and Ageing submitted that the compulsory licence provisions

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33 However, as noted above, public healthcare providers could invoke the Crown use provisions of the Patents Act as an alternative to seeking a compulsory licence.

34 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 15–2.

35 I Turnbull, *Submission P11*, 25 September 2003.

36 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

> may in principle be applied to the provision of healthcare services. However, as these provisions have not been used for this purpose it is unclear whether they would operate effectively … Health believes that the Inquiry should seek to address the circumstances in which it would be appropriate to use these mechanisms and whether any changes to the Act are necessary to allow access to the mechanisms.[38]

27.27 The Human Genetics Society of Australasia submitted that:

> The current provisions of the Patent Act 1990 (Cth) relating to compulsory licences should be amended to contain specific reference to issues relating to access to health care and ability to conduct research related to human health. In this way it may be possible to grant a compulsory licence where patent holders are not acting in the best interest of public health (akin to French law). It seems that by amending the Patent Act in such a positive fashion we may limit or remove the ambiguities surrounding 'the reasonable requirements of the public' clause in the Patent Act.[39]

27.28 Several other submissions expressed support for a French law that permits the Minister of Health to grant a compulsory licence over a patented invention on public health grounds.[40] In fact, this law appears to provide for a form of Crown use of patented inventions, in which the Crown may authorise a third party to work a patented invention for the services of the Crown—including public health purposes.[41]

27.29 The Walter and Eliza Hall Institute of Medical Research submitted that although the threat of compulsory licensing is a major incentive for the patent holder to exploit its patent, in practice the provisions have been very rarely used. It considered that 'this is probably a good thing because frequent use of this capacity would undermine the entire patent system and its value in the innovation system'.[42]

27.30 Davies Collison Cave, an Australian patent attorney firm, did not support amending the compulsory licensing provisions specifically for gene patents. It noted that the IPCRC had already considered the question of the appropriate test for the grant of a compulsory licence, and suggested that any amendment of this test should be applied in relation to patents in all fields of technology.[43]

27.31 Finally, GlaxoSmithKline submitted that:

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37 For example, Cancer Council Australia, *Submission P25*, 30 September 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; E Milward and others, *Submission P46*, 20 October 2003.

38 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

39 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

40 For example, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; G Suthers, *Submission P30*, 2 October 2003.

41 See Ch 26.

42 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

43 Davies Collison Cave, *Submission P48*, 24 October 2003.

> Where it is not possible to deal with any problems which are genuinely associated with patents by means outside the patent system, the application of compulsory licensing laws can be an appropriate means of dealing with the problem and will generally be adequate. In this regard, we regard the provisions of Sections 133 and 135 of the Patents Act as being appropriately framed.
>
> We emphasise, however, that provisions such as these should not be regularly applied but only applied in exceptional cases where the patents concerned are clearly being exercised in an abusive manner to the detriment of society. Regular application of compulsory licensing laws by any country will have a chilling effect on long-term innovation and competition and of direct investment into the country concerned.
>
> Further, like other weak patent laws, regular use of compulsory licensing could also delay or prevent introduction onto the Australian market of innovative products … Thus, excessive use of compulsory licensing can in fact impede access to healthcare.[44]

The legislative test

27.32 As noted above, s 133 of the *Patents Act* provides that a person may apply to a prescribed court for a compulsory licence order three years after the grant of a patent where the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied; and the patent holder has not given a satisfactory reason for failing to exploit the patent.[45]

27.33 Section 135 sets out the circumstances in which the 'reasonable requirements of the public' will be deemed not to have been satisfied. It is not clear whether the circumstances outlined in s 135 constitutes an exhaustive list or whether they are merely illustrative.

27.34 In any case, s 135 appears to accommodate many of the circumstances in which an applicant might seek access to a patented genetic invention. For example, where a patent holder refuses to grant a licence for a research tool on reasonable terms, a scientific researcher or research institution could apply for a compulsory licence on the basis that the demand in Australia for that tool is not being reasonably met. In *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation*, Menzies J interpreted a similar provision in the *Patents Act 1952* (Cth) as follows:

> The demand for the patented article has not been reasonably met if the Court should be satisfied that, because of its superiority over articles already on the market, potential purchasers would have bought it had it been available. A market for a less efficient article indicates, other things being equal, a market for a more efficient article.[46]

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44 GlaxoSmithKline, *Submission P33*, 10 October 2003.

45 *Patents Act 1990* (Cth) s 133(2); *Patents Regulations 1991* (Cth) r 12.1. However, a person cannot apply for a compulsory licence in respect of an innovation patent that has not been certified: s 133(1A).

46 *Fastening Supplies Proprietary Limited v Olin Mathieson Chemical Corp* (1969) 119 CLR 572, 575.

27.35 As noted above, few (if any) compulsory licences have been granted in Australia since Federation. Commentators have suggested several reasons why these provisions have been rarely invoked. IPAC suggested that this might be due to the formulation of the 'reasonable requirements of the public' test and the broad discretion granted to the court in applying it:

> It is something of an enigma that, despite the apparent number of situations in which the compulsory licensing provisions could be invoked, only 2 cases of petitions for compulsory licences are known to have gone to court in Australia. One reason for this might be that in fact the provisions in question are ineffectual; that persons who would be prospective applicants for compulsory licences perceive, and are advised, that the grounds are so hedged with qualifications, discretion on the part of the court, difficulties of proof, and expense, that to petition would be too onerous or useless.[47]

27.36 Dr Dianne Nicol and Jane Nielsen have expressed concerns about the lack of judicial guidance on what constitutes the 'reasonable requirements of the public', what remuneration must be paid, and what amounts to reasonable remuneration for a compulsory licence. They commented that:

> The circumstances in which an application can be made could also be clarified, rather than having to rely on the argument that the reasonable requirements of the public have not been met.[48]

27.37 In consultations, Professor Jill McKeough noted the difficulty for an applicant in establishing that a patent holder has no satisfactory reason for failing to exploit the patent. The patent holder could offer a wide range of explanations as to why the patent had not been exploited or licensed to third parties.[49]

27.38 Several submissions expressed support for the clarification or broadening of the test to encourage applications for compulsory licences in the future.[50] The ALRC considers that there may be merit in clarifying the circumstances in which an individual or organisation can apply for a compulsory licence. This could be done by amending the *Patents Act* to replace the 'reasonable requirements of the public' test with a new test. Alternatively, the existing test may be retained, but the Act amended to provide that s 135 is not exhaustive as to the circumstances in which the reasonable requirements of the public have not been met.

27.39 As the ALRC has received few submissions addressing the formulation of the 'reasonable requirements of the public' test, it is not in a position to formulate a reform proposal at this time.

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47 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 28.

48 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 237–238. See also C Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, 114.

49 J McKeough, *Consultation*, Sydney, 15 October 2003.

50 For example, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

Question 27–1 Should the Commonwealth amend the *Patents Act 1990* (Cth) (*Patents Act*) to clarify the test for the grant of a compulsory licence? If so, should the Commonwealth

(a) clarify the circumstances in which the 'reasonable requirements of the public' will not have been satisfied; or

(b) specify that s 135 is not an exhaustive list of the circumstances in which a patented invention would fail to satisfy the 'reasonable requirements of the public'?

Anti-competitive conduct

27.40 Chapter 24 discussed the competition law implications of the patenting of genetic materials and technologies. It noted that, given the unique nature of many biotechnology inventions, and their lack of substitutability, if a patent holder engages in anti-competitive conduct in relation to its patent this could have significant implications for downstream research or access to certain healthcare services.

27.41 An individual or organisation might seek a compulsory licence over a patented genetic invention in response to a patent holder engaging in anti-competitive conduct. The ALRC has heard concerns that the compulsory licence provisions may be too narrow to address all of the circumstances in which such an order may be warranted on competition grounds.

27.42 The *Patents Act* currently does not specifically provide for the grant of a compulsory licence as a remedy for anti-competitive conduct.[51] In some circumstances, the 'reasonable requirements of the public' test may permit the grant of a compulsory licence where there is anti-competitive conduct in relation to gene patents. For example, where the patent holder of an upstream genetic research tool, for which there is no substitute, refuses to grant a licence on reasonable terms and this prejudices a trade or industry unfairly, the court may grant a compulsory licence on the basis that the reasonable requirements of the public have not been satisfied. However, certain anti-competitive conduct may fall outside the scope of this test.

27.43 The *Trade Practices Act 1974* (Cth) (TPA) may provide a mechanism for the grant of a compulsory licence as a remedy for anti-competitive behaviour under Part IV of the Act. Section 87 provides that the court may make such orders 'as it thinks fit'

51 In contrast, United States courts and regulatory agencies have the power to impose compulsory licences in relation to intellectual property rights to remedy various anti-competitive practices: J Reichman and C Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America: Issue Paper No 5* (2003) UNCTAD–ICTSD Capacity Building Project on IPRs and Sustainable Development, 21.

in proceedings for a breach of Part IV. Relevant conduct might include entering into anti-competitive agreements, the misuse of market power, the use of exclusionary provisions, and exclusive dealing. The court has a wide discretion to make orders for compensatory or pre-emptive purposes, and this could extend to the grant of a compulsory licence.[52] However, the ALRC is not aware of any cases under the TPA in which a compulsory licence has been granted for a patented invention.

Compulsory licensing

Competition-based test

27.44 In its review, the IPCRC noted that the compulsory licensing provisions lack an explicit competition test. The Committee commented that:

> We accept that, at a conceptual level, there may be instances when a compulsory access right is warranted. These include situations in which bargaining between parties is not able to achieve an outcome or, more appropriately, situations in which the access right acts as a pro-competitive remedy that tempers the exclusivity that the patent right primarily provides. Experience in other jurisdictions with compulsory licences … demonstrates that these can, in carefully defined circumstances, lead to more efficient and immediate outcomes without harming long-term incentives to innovate. Indeed, the threat of compulsory licensing may lead to innovations being worked sooner, and more widely than they would otherwise have been.[53]

27.45 As noted above, the IPCRC recommended that the existing 'reasonable requirements of the public' test for granting a compulsory licence be replaced with a competition-based test. The competition-based test would contain the following conditions:

- access to the patented invention is required for competition in the (relevant) market;
- there is a public interest in enhanced competition in that market;
- reasonable requirements for such access have not been met;
- the order will have the effect of allowing these reasonable requirements to be better met; and
- the order will not compromise the legitimate interests of the patent owner, including that owner's right to share in the return society obtains from the

52 See H Ergas, *Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia* (2002), 3–4.

53 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 162.

> owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.[54]

27.46 The IPCRC suggested that the conditions for granting a compulsory licence should be stringent. The term 'required for competition in the (relevant) market' should mean that there is no other option for competition in that market, and that the enhancement of competition that would be secured by the grant would have to be material and substantial. It commented that:

> We believe that subject to safeguards such as these, a compulsory licensing scheme is likely to promote efficiency in the use of patents and to promote competition. We note that such a scheme is fully consistent with Australia's international obligations.[55]

27.47 The Australian Government accepted this recommendation in part. The Government stated that it would adopt the competition-based test in addition to, rather than instead of, the existing 'reasonable requirements of the public test'.[56] At the time of writing, this recommendation had not been implemented.

'Essential facilities' test

27.48 An alternative approach would be to amend Part IIIA of the TPA, which deals with access to the services of essential facilities, to cover patented genetic materials and technologies. This would provide a legislative basis for access to gene patents that are considered 'essential facilities' within a certain market.[57]

27.49 In European Community law, the 'essential facilities' doctrine provides for the grant of a compulsory licence as a remedy for an abuse of a dominant position within a secondary, downstream market. Under that doctrine, a compulsory licence could be ordered where:

- by refusing to licence, a dominant company is monopolising a downstream market and preventing users from accessing a new kind of product for which there is an unsatisfied demand;
- a dominant company has previously granted licences, and had allowed its licensees to build up downstream activities on that basis, and subsequently refuses to grant licences for anti-competitive purposes; or

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54 Ibid, 163.
55 Ibid, 163.
56 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003.
57 The Part IIIA regime does not apply to the use of intellectual property, except to the extent that it is an integral but subsidiary part of the service provided by the facility. Intellectual property rights have been recognised as an 'essential facility' in European Community law: J Temple Lang, *Compulsory Licensing of Intellectual Property in European Community Antitrust Law: Paper prepared for the Department of Justice/Federal Trade Commission Hearings, Washington DC* (2002), 6. See Ch 24.

- a dominant company refuses to licence and charges prices that are so high as to be 'unfair'.[58]

27.50 The IPCRC considered whether the Part IIIA regime under the TPA should be expanded to apply to intellectual property. It considered that there was merit in having provisions for granting access to intellectual property rights similar to those provided in Part IIIA and XIC[59] of the TPA. However, it concluded that a better approach was to address the need for reform through intellectual property statutes. Accordingly, the IPCRC recommended an amended compulsory licensing provision in the *Patents Act*, incorporating a competition-based test.[60]

Submissions and consultations

27.51 IP 27 did not ask any specific questions about the grant of compulsory licences to remedy anti-competitive conduct. However, several submissions provided general statements about the application of compulsory licensing in this context.

27.52 The Australian Centre for Intellectual Proeprty in Agriculture (ACIPA) commented that compulsory licensing and forfeiture provide potentially useful tools to implement competition objectives where a patent holder seeks to impose high prices and restrict access to its invention. It recommended that the compulsory licensing provisions be revised in accordance with the IPCRC's recommendations.[61]

27.53 Dr Amanda McBratney and others submitted that compulsory licensing is the most appropriate mechanism to deal with patentees who exercise their rights in an anti-competitive manner. However, they submitted that the current system is likely to be too expensive and too slow to be of much benefit to those who need it most, even after the introduction of the new competition-based test.[62]

27.54 The Australian Competition and Consumer Commission (ACCC) suggested that any amendments to the compulsory licensing provisions be reviewed after three years to assess their effectiveness in assisting with competition concerns arising from patents in general. It commented that such a review could canvass any concerns specifically arising in relation to gene patents.[63]

ALRC's views

27.55 In the absence of reported use of the compulsory licensing provisions, it is difficult to evaluate the effectiveness of the 'reasonable requirements of the public' test as a remedy for anti-competitive conduct.

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58 Ibid, 3–4.
59 Part XIC of the *Trade Practices Act 1974* (Cth) provides an access regime for telecommunications.
60 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 163.
61 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
62 A McBratney and others, *Submission P47*, 22 October 2003.
63 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

27.56 While the courts' general powers to remedy breaches of Part IV of the TPA could permit the grant of a compulsory licence, this power does not appear to have been used for this purpose. In any case, such a power is only available if the court has already found a breach of Part IV of the TPA.

27.57 The IPCRC's proposed test would appear to cover a wider range of anti-competitive conduct than might be available under Part IV of the TPA, including at least some of the type of conduct addressed by the European Community's 'essential facilities' doctrine. The ALRC proposes that the Australian Government should implement the IPCRC's recommended test for the grant of a compulsory licence, in addition to the existing 'reasonable requirements of the public' test.

27.58 The ALRC agrees with there may be merit in the ACCC's suggestion that the compulsory licensing provisions should be reviewed at a later date to assess their effectiveness in addressing the competition concerns arising from patents. Given the infrequency with which these provisions are used, the ALRC proposes a period of five years before such a review. This would provide a greater opportunity for use of the provisions prior to their review.

Proposal 27–1 The Commonwealth should amend the *Patents Act 1990* (Cth) to insert the competition-based test that was recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence. The amendment should also provide for an independent review of the operation of the compulsory licensing provisions in addressing competition concerns arising in relation to patented inventions. This review should be conducted five years after the new test commences operation.

Dependent patents

27.59 Where a patented invention ('dependent patent') cannot be worked without exploiting an earlier patented invention ('original patent'), the owner of the dependent patent generally must obtain a licence for the original patent. If this is not granted, the owner of the dependent patent might seek authorisation through a compulsory licence to use the original patent.

27.60 The *Patents Act* makes specific provision for the grant of a compulsory licence over an original patent in circumstances where an applicant has sought access to a dependent patent. That is, where an applicant seeks a compulsory licence for a patented invention that cannot be worked without exploiting an earlier patented invention, the court may grant a compulsory licence in relation to *both* inventions. The court must be satisfied that the dependent patent involves an important technical advance of

considerable economic significance on the original patent.[64] This provision is consistent with art 31(l) of the TRIPS Agreement.[65]

27.61 In contrast, where an applicant seeks a compulsory licence over an original patent in order to work his or her own dependent patent, the applicant would need to satisfy the 'reasonable requirements of the public' test.[66] There is no provision in the *Patents Act* specifically permitting the owner of a dependent patent to apply for a compulsory licence over an original patent.

27.62 In some circumstances the owner of a dependent patent could satisfy the 'reasonable requirements of the public' test in relation to the original patent. For example, where the dependent patent involves a new medical genetic test, and the original patent is a broad patent over a genetic sequence, the applicant could argue that the original patent holder's refusal to licence its patented sequence means that the demand in Australia for the sequence is not being reasonably met.

27.63 In its submission, AusBiotech Ltd commented that:

> at present the legislation does not provide for a compulsory licence in the situation where a patented invention cannot be used by the patentee without also using an earlier invention, which was patented by another party. In contrast, a party who owns neither an original patent nor a later dependent patent can seek a compulsory licence to both patents. To exclude the former situation is completely illogical.[67]

27.64 Richard Hoad has described this as 'clearly an illogical result'.[68] Hoad has suggested that the *Patents Act* should be amended to provide that where a dependent patent cannot be worked without exploiting the original patent, the holder of the dependent patent should be granted a compulsory licence to work the original patent if the invention claimed in the dependent patent constitutes a significant technological advance over the prior art:

> Absent a voluntary cross-licensing agreement, the advance would otherwise be delayed during the term of the original patent, a result that is clearly inefficient and carries real social costs that outweigh any potential damage to the incentive to innovate.[69]

27.65 Nicol and Nielsen have also discussed this concern:

> Given that circumstances of dependency are likely to arise frequently in the area of biotechnology, there may be justification for amending the existing provisions,

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64 *Patents Act 1990* (Cth) s 133 (3B).

65 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31(l).

66 *Patents Act 1990* (Cth) s 133(1).

67 AusBiotech Ltd, *Submission P58*, 7 November 2003.

68 R Hoad, *Compulsory Licensing of Patents: Balancing Innovation and Competition* (2003) unpublished manuscript, 7.

69 Ibid, 7.

> making special provision for issuance of compulsory licences to dependant patent holders where the invention covered by the dependant patent 'involves an important technical advance of considerable economic significance' over the invention for which the compulsory licence is sought.[70]

27.66 The ALRC's preliminary view is that there may be merit in amending the *Patents Act* to expand the scope of the compulsory licensing provisions to permit an applicant who holds a dependent patent to apply for a compulsory licence over the original patent in order to exploit his or her invention where the dependent patent involves an important technical advance of considerable economic significance over the original patent. This approach would provide greater clarity and certainty. However, as few submissions addressed this issue, the ALRC is not in a position to formulate a proposal at this time.

Question 27–2 Should the *Patents Act* be amended to allow a compulsory licence to be granted to a patent holder who cannot work his or her patent without using another patent for which authorised use cannot be obtained? If so, in what circumstances?

Emergency and public non-commercial use

27.67 The *Patents Act* provides that an applicant for a compulsory licence must first try, for a reasonable period, to obtain a licence from the patent holder on reasonable terms and conditions.[71]

27.68 This requirement is consistent with art 31(b) of the TRIPS Agreement, which provides that, subject to certain circumstances, a compulsory licence may be granted only if the applicant has first made attempts, for a reasonable time, to obtain authorisation from the patent holder on reasonable commercial terms and conditions. According to a commentary on the TRIPS Agreement:

> The reasonable time for negotiations may depend on the purpose for which the licence is sought. As [an] example, a negotiator seeking to commence production of a life-saving pharmaceutical would be justified in seeking a more rapid conclusion of negotiations than a negotiator seeking to commence production of an improved fishing rod.
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> It seems unlikely that in the general case negotiations for a commercial patent licence could not reasonably be concluded within six months from the initial request for a licence.[72]

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70 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 239.

71 *Patents Act 1990* (Cth) s 133(3A).

72 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical*

27.69 The requirement of prior negotiation reflects the nature of a patent right, which is an exclusive right to exploit a new invention for a specified period. However, it necessarily delays the process of obtaining a compulsory licence while an individual or organisation seeking a licence attempts to negotiate with the patent holder.

27.70 In some circumstances, this delay may not be in the public interest. For example, an individual or organisation might seek an urgent compulsory licence in the following circumstances:

- A public health department might seek a compulsory licence over a medical genetic test or genetic therapy to address a public health crisis. However, as noted above, invoking the Crown use provisions in these circumstances may be preferable as there is no need for prior negotiation.

- A pharmaceutical company might seek a compulsory licence over a gene-related therapy that the patent holder has failed to make available to the Australian community.

- A researcher or research institution might seek a compulsory licence over a broad upstream patent for use in genetic research. Where the research involves the use of several patented research tools, the process of negotiation with each patent holder could delay the research.

TRIPS Agreement

27.71 Article 31(b) of the TRIPS Agreement provides that prior negotiation may be waived in the case of a national emergency or other circumstances of extreme emergency, or in cases of public non-commercial use.

27.72 In November 2001, a special session of the World Trade Organization (WTO) at Doha, Qatar, released a *Ministerial Declaration on the TRIPS Agreement and Public Health* (Doha Declaration)[73] which provided that, among other things, Members have the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted, and what constitutes a national emergency or other circumstances of extreme urgency.[74]

27.73 The concept of 'public non-commercial use' is said to leave governments considerable flexibility in granting licences without requiring commercial negotiations

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Guide to the TRIPS Agreement (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 131.

73 *Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, World Trade Organization 4th Ministerial Conference, WT/MIN (01)/DEC/2. The Doha Declaration is a political statement and a Ministerial decision. It does not appear to have any specific legal status in the framework of World Trade Organization law: see C Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health: Health Economics and Drugs EDM Series No 12* (2002) World Health Organization, 40.

74 *Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, World Trade Organization 4th Ministerial Conference, WT/MIN (01)/DEC/2 art 5.

in advance.[75] There are many ways the term 'public non-commercial use' may be defined in good faith.[76] For example, 'public use' could refer to use by the government (as opposed to use by a private sector entity) or to use (by any entity) for the public benefit.[77] 'Non-commercial' may refer to use by public institutions that are not functioning as commercial enterprises—for example, public hospitals operating on a non-profit basis.

27.74 Commentary on art 31(b) of TRIPS has suggested that, in the context of national emergency or extreme urgency, waiver of prior negotiation applies to grants of compulsory licences for private commercial, as well as public non-commercial purposes.[78]

Submissions and consultations

27.75 While IP 27 did not directly address the circumstances in which the requirement of prior negotiation might be waived, several submissions addressed the issue, particularly in relation to public health concerns. For example, the South Australian Government described the requirement of prior negotiation as a 'fairly high threshold' requirement, and noted that it may be unworkable in the case of urgent medical need.

> Furthermore, the fact that an application must be made to a court means that it is an expensive and possibly time consuming process. There is probably a need to make compulsory licensing more accessible in the area of human health.[79]

27.76 The Department of Health Western Australia submitted that gene patent holders can restrict the provision of public health services, and noted the danger involved in governments assuming that patent holders will not seek to enforce their right when population health is at risk or where already disadvantaged families, such as those afflicted with a genetic disorder, require equitable access to testing. The Department suggested that the *Patents Act* be amended in accordance with the waiver of negotiation provisions of art 31(b) of the TRIPS Agreement.[80]

27.77 The Caroline Chisholm Centre for Health Ethics submitted that WTO Member states:

> should be able to protect and optimise public health and overly burdensome or uncooperative patent holders may be forced to accept a compulsory licence for their invention. Greater use could be made of this provision to ensure broader public access

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75 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 132.

76 Ibid.

77 Ibid.

78 Ibid, 132.

79 South Australian Government, *Submission P51*, 30 October 2003.

80 Department of Health Western Australia, *Submission P53*, 3 November 2003.

> to vital patented technology. This is not unprecedented and offers a solution to overly protective and/or aggressive license holders.[81]

27.78 ACIPA commented that:

> The debate over access to essential medicines is not just the exclusive concern of developing countries. As the SARS outbreak in China, Singapore, Hong Kong and Canada demonstrated, developed countries as well as developing countries can suffer from public health epidemics. The race to patent the SARS virus raised important questions about access to essential medicines. There is therefore a need to ensure that the Australian patent system is appropriately adapted to providing compulsory licenses to patents in national emergencies.[82]

27.79 ACIPA submitted that the compulsory licensing provisions in the *Patents Act* should be revised in line with the TRIPS Agreement (and the Doha Declaration).[83]

ALRC's views

27.80 As noted above, the TRIPS Agreement provides that the requirement of prior negotiation may be waived in the case of a national emergency or other circumstances of extreme emergency, or in cases of public non-commercial use.[84]

27.81 The compulsory licensing provisions in the *Patents Act* do not provide for circumstances in which the obligation of prior negotiation may be waived. Any individual or organisation seeking a compulsory licence for a patented invention must have attempted, for a reasonable period, to negotiate a licence before applying for the compulsory licence. In contrast, the Crown use provisions do not require prior negotiation before they are invoked.

27.82 In future it is possible that Australia could face a public health crisis or bio-terror attack, requiring a rapid and efficient response. As ACIPA commented in its submission, the SARS outbreak showed that developed countries also may be threatened by public health epidemics. The bio-terror attacks using the anthrax organism in the United States[85] could be characterised as a circumstance of extreme emergency.

27.83 In most cases, the ALRC considers that the Australian Government, or a state or territory government or health department, would take the initiative in responding to these situations. Where access to a gene patent is needed, the relevant government or health department could invoke the Crown use provisions to work the patent itself, or

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81 Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003.

82 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

83 Ibid.

84 See *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31(b).

85 Consumer Project on Technology, *Ciprofloxacin: The Dispute over Compulsory Licenses*, <www.cptech.org/ip/health/cl/cipro> at 3 June 2003. See Ch 26 for more detail.

authorise another body to do so. In these circumstances there would be no need to seek a compulsory licence.

27.84 However, there may be circumstances where the Crown, for whatever reason, does not act. In such circumstances, it may be desirable for a pharmaceutical company or other private organisation to be able to urgently provide genetic tests or therapies to the Australian community where the patent holder has failed to do so. The requirement that the applicant must have tried for a reasonable period to obtain a licence could be onerous and, in the absence of legislative or judicial guidelines, it is unclear what constitutes 'a reasonable period' of negotiation.

27.85 Whether it would be appropriate, however, to grant a compulsory licence even in a national or other emergency in circumstances where the applicant has not tried at all to obtain a licence from the patent holder is more problematic. The ALRC would welcome comments about this.

27.86 Under the TRIPS Agreement, the requirement of prior negotiation may also be waived for 'public non-commercial use' of a patented invention. The Australian Government has stated that it considers Crown use as an example of the 'public non-commercial use' of a patented invention.[86] Accordingly, where a state or territory health department seeks compulsory access to a patented medical genetic test or other genetic technology for the 'services of the Crown', it could invoke the Crown use provisions. As these provisions do not involve an application to a court, they are more likely to be used than the compulsory licensing provisions.

27.87 The term 'public non-commercial use' appears capable of broader interpretation than Crown use. For example, a not-for-profit research organisation might argue that the use of a patented genetic research tool or a medical genetic test is non-commercial, and for the benefit of the public, particularly if being used for research. The difficulty in this circumstance might be in determining at what point non-commercial research becomes commercial.

27.88 Therefore, while Australian governments and public authorities may invoke the Crown use provisions, including in cases of national emergency, extreme urgency or public non-commercial use, the ALRC considers that there remain certain limited situations in which it might be appropriate to permit a compulsory licence to be granted instead.

27.89 Accordingly, the ALRC asks whether the *Patents Act* should be amended to provide that a compulsory licence may be granted over a patented product or process in circumstances of 'a national emergency or other circumstances of extreme urgency or

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86 See Council for Trade-Related Aspects of Intellectual Property Rights, *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997*, World Trade Organization, <www.wto.org/english/tratop_e/trips_e/intel8_e.htm> at 17 December 2003.

in cases of public non-commercial use'; and if so, whether a compulsory licence should be available whether or not the applicant has tried for a reasonable period to obtain a licence from the patent holder.

Question 27–3 Given the provision in the *Patents Act* for Crown use of patented inventions, should the Act also make provision for the grant of a compulsory licence over a patented invention in circumstances of 'a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use'? If so, should a compulsory licence be available whether or not the applicant has tried for a reasonable period to obtain a licence from the patent holder?

Jurisdiction

27.90 An applicant for a compulsory licence must apply to a 'prescribed court', which is the Federal Court or a state or territory Supreme Court.[87] The ALRC has heard concerns that the potential cost of court proceedings to obtain a compulsory licence and uncertain outcome, may deter potential applicants.

27.91 One option for reform would be to transfer jurisdiction to grant a compulsory licence from the courts to a tribunal or other administrative body. This would generally be consistent with the IPCRC's recommendation that compulsory licensing orders should be obtained through the Australian Competition Tribunal, with rights of appeal to the Federal Court.[88]

Submissions and consultations

27.92 IP 27 asked whether compulsory licences should be available only by order of a court, or whether the *Patents Act* should be amended to allow the Commissioner of Patents, or a tribunal or agency, to grant compulsory licences.[89]

27.93 Several submissions expressed the view that courts would be best placed to determine whether to grant a compulsory licence.[90] For example, GlaxoSmithKline submitted that:

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87 *Patents Act 1990* (Cth) ss 3, 133, sch 1.

88 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 163. However, the Australian Government did not accept this recommendation, stating that it would be inappropriate for the Tribunal to consider applications for compulsory licences in the first instance because it is essentially a review body. The Government also considered that the Tribunal would not be the appropriate body to hear applications under the 'reasonable requirements of the public' test: IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003, 9.

89 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 15–2.

> the Courts, particularly those comprising judges with experience in patent law and commercial patent practice, are the best arbiters of whether compulsory licences should be granted.[91]

27.94 The Royal College of Pathologists of Australasia (RCPA) submitted that:

> serious consideration should be given to create or appoint a patent ombudsman, tribunal or commissioner to hear such cases and to grant compulsory licenses, determine appropriate fees and compensation, and to be empowered to penalise companies that behave in a socially irresponsible manner.[92]

27.95 The ACCC submitted that it 'flags a concern as to whether the Federal Court's processes are well adapted to resolving what, at their heart, are "terms of access" disputes'.[93] McBratney and others submitted that the most appropriate body to determine such applications would be a tribunal or agency within the ACCC:

> it would make sense to establish a separate tribunal or agency within the ACCC to administer the compulsory licensing system. It would fit well with the intent behind the compulsory licensing system. The ACCC is already perceived as the 'corporate watchdog' and it would be more likely than the Patent Office to have the relevant resources and personnel trained for the task.
>
> The choice is more preferable than administering the compulsory licensing system through the Patent Office, as there might be some perception that its decisions may be to some extent biased towards the patentee.
>
> The choice is also more preferable than the current system. The time, cost and effort of obtaining a court order is likely one of the reasons why the system has not been used to any significant extent to date.[94]

ALRC's views

27.96 Submissions did not reveal any broadly based support for transferring jurisdiction to a tribunal or other administrative body. Due to the small number of applications that are likely to be made for the grant of a compulsory licence, the ALRC considers it would not be feasible to establish a new body for this purpose.

27.97 While there were suggestions that the ACCC be given jurisdiction to determine applications for compulsory licences, a regulator in the field of competition law may not have sufficient expertise to apply the 'reasonable requirements of the public' test, which deals with issues broader than competition.

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90 For example, South Australian Government, *Submission P51*, 30 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

91 GlaxoSmithKline, *Submission P33*, 10 October 2003.

92 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

93 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

94 A McBratney and others, *Submission P47*, 22 October 2003.

27.98 IP Australia is another administrative body that could be given jurisdiction to determine such applications. However, IPAC previously recommended that such jurisdiction be removed from the precursor of that body. It recommended that jurisdiction for compulsory licensing be vested exclusively in the Federal Court, without provision for preliminary consideration by the Commissioner of Patents.[95] In making this recommendation, IPAC commented that:

> Cases could be expected to be decided faster and better, with lower costs, if all such matters were dealt with by the one court. That would permit the judges (or a particular division) of that court to develop (and perhaps in due course to be appointed for) expertise and experience in relation to the relevant subject matter and both legal and economic principles.[96]

27.99 The Australian Government stated, in its response to the IPCRC's recommendations, that all applications for compulsory licences should be considered by the Federal Court in the first instance.[97]

27.100 As discussed in Chapter 10, the ALRC considers it important that a consistent body of patent law develops in Australia, particular in relation to new technological areas such as genetics, where the application of patent law principles might not be clear. The Federal Court has already developed substantial expertise in determining patent cases generally. A coherent and consistent interpretation of the *Patents Act* will be facilitated by concentration of judicial experience and expertise with respect to patent matters in a single court system.

27.101 Accordingly, the ALRC considers that federal courts should have original jurisdiction to determine applications for compulsory licences. Proposal 10–1 already addresses this concern, by proposing that original jurisdiction in matters arising under the *Patents Act* should be conferred exclusively on federal courts.

Remuneration

27.102 Section 133(5) of the *Patents Act* provides that, when a compulsory licence is granted, a patent holder must be paid an amount that is agreed between the patent holder and applicant, or an amount that the court determines to be just and reasonable having regard to the economic value of the licence.

27.103 Several commentators have discussed the difficulty of determining a reasonable royalty for use of genetic research tools—particularly those involved in upstream research—and have suggested that medical researchers should be permitted

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95 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), rec 8.

96 Ibid, 32.

97 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 2 May 2003, 9.

to use patented genetic search tools without paying a royalty unless or until the researcher develops a commercially valuable product.[98]

27.104 In the United States, Professor Rebecca Eisenberg has suggested that third parties should be permitted to use patented upstream research tools free of charge for improvement research; that is, for research to improve upon the patented tools. If the improvement becomes commercially valuable, the improver should then be required to pay a reasonable royalty to the patent holder.[99] Assistant Professor Donna Gitter has proposed that the compulsory licence fee for gene patents should be dependent on the commercial value of the product developed as a result of the research.[100]

27.105 The Ontario Government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* recommended that compulsory licences should be granted in return for a reasonable royalty to be established by the Commissioner of Patents. The royalty should include an amount for the use of the invention, and not the profit gained by the patent holder in providing the test.[101]

27.106 Article 31(h) of the TRIPS Agreement provides that, where compulsory licences are granted, the rights holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.

27.107 Professor Warren Pengilley has expressed concerns about courts' ability to determine a 'reasonable price' for goods in the context of proceedings brought under s 46 of the TPA. He commented that:

> The court record in setting 'reasonable' prices is depressing … All courts have expressed their general inability to determine the reasonable price in any useful way.[102]

27.108 While this comment relates to a different legislative regime, similar difficulties may arise where courts attempt to determine what is a just and reasonable royalty in relation to a licence over a biotechnology patent. A patent holder might argue that the economic value of its patented genetic research tool cannot be determined until the value of any downstream product developed from its use is known.

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98 For example, D Gitter, 'International Conflicts over Patenting Human DNA Sequences in the United States and The European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption' (2001) 76 *New York University Law Review* 1623, 1679.

99 R Eisenberg, 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' (1989) 56 *University of Chicago Law Review* 1017, 1076–1077.

100 D Gitter, 'International Conflicts over Patenting Human DNA Sequences in the United States and The European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption' (2001) 76 *New York University Law Review* 1623, 1679.

101 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 52.

102 Professor Pengilley cited *Pont Data Australia Pty Ltd v ASX Operations Pty Ltd* (1990) 21 FCR 385: W Pengilley, 'Misuse of Market Power: The Unbearable Uncertainties Facing Australian Management' (2003) 8 *Trade Practices Law Journal* 56, 64–65.

27.109 However, the ALRC notes that courts are regularly asked to make difficult assessments as to the amount of financial compensation to be paid to a party in proceedings, such as in awarding damages in personal injury cases. The use of expert evidence may assist the court in making these determinations.

Submissions and consultations

27.110 IP 27 asked whether, if compulsory licences were to be granted more frequently, the *Patents Act* should be amended to provide increased protection for patent holders, such as mechanisms for determining the compensation due, or whether certain mandatory terms should be included in such licences.[103]

27.111 In response, the RCPA submitted that guidelines should be established to determine reasonable fees and compensation; for example, these could be limited to 5–10% of the cost of performing the test.[104]

27.112 The South Australian Government submitted that compensation should be determined on a case by case basis depending on the technology, and that a generic compensation scheme or mandatory licence terms would be too restrictive.[105] McBratney and others submitted that:

> it would be extremely difficult to settle on a formula or mechanism for determining compensation. Similar provisions are contained in the German *Employee Inventions Act 1957* and they are considered some of the most difficult provisions of the law. In addition, since the compulsory licensing system would apply across the board and not just to patented gene-related inventions, it would be almost impossible to find a formula that could be applied across the entire range of possible patentable subject matter. The matter should be decided on a case by case basis, taking into account all relevant circumstances.[106]

27.113 GlaxoSmithKline submitted that:

> the law should provide (whether through statute or otherwise), that the compensation payable should be that which would be agreed between a willing licensor and licensee for the invention in question. All other requirements of TRIPS should, of course, be complied with.[107]

ALRC's views

27.114 The ALRC considers it appropriate that, where the parties cannot agree on the appropriate royalty for a compulsory licence, federal courts should have the power to determine this amount. While the parties themselves are best placed to identify the commercial value of a licence, where necessary the court would have the power to hear evidence from the parties, and expert witnesses, to determine this value. As noted

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103 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 15–2.
104 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
105 South Australian Government, *Submission P51*, 30 October 2003.
106 A McBratney and others, *Submission P47*, 22 October 2003.
107 GlaxoSmithKline, *Submission P33*, 10 October 2003.

above, courts are required to make similarly difficult determinations of financial compensation in other areas of law. Therefore, the ALRC does not propose any reform of the provision relating to remuneration for compulsory licences.

Licensing of 'know-how'

27.115 A patent application must fully disclose an invention. Under the *Patents Act*, a complete specification must 'describe the invention fully, including the best method known to the applicant for performing the invention'.[108] However, the patent holder may later acquire valuable know-how and experience that is necessary to exploit the invention effectively or optimally.

27.116 Where a compulsory licence is granted over a patented invention, the licensee may encounter significant problems in exploiting the patented product or process if it does not have the necessary know-how to do so. The *Patents Act* currently does not make specific provision for the inclusion in a compulsory licence of the know-how that may be necessary to work the patented product or process properly.

27.117 In some jurisdictions, know-how has been subject to a compulsory licence in connection with, or independently of, the compulsory licensing of patents. For example, in the United States case *FTC v Xerox Corporation*, a consent decree eliminated Xerox's patent and know-how barriers to competition by requiring the company to license some of its patents free of royalty, and the rest at low royalties, and to offer all of its office copier know-how free of royalty to United States patent licensees.[109]

27.118 IPAC recommended that, in ordering the grant of a compulsory licence, the court be given a discretionary power to order the transfer of related know-how as part of the reasonable terms on which the licence is granted.[110] IPAC acknowledged that there was no evidence to support this argument, but considered the proposal was worth applying on a trial basis.[111] It noted that, if this recommendation were implemented, it would be left to the court's discretion to determine whether any and what know-how should be transferred in conjunction with a compulsory licence. The court would also need to formulate appropriate directions for arranging its transfer, meeting the costs involved, and providing suitable compensation, as part of the reasonable terms upon which the compulsory licence is granted.[112]

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108 *Patents Act 1990* (Cth) s 40(2)(a). This is known as the 'sufficiency requirement': see Ch 6.

109 C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 6.

110 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), rec 7.

111 Ibid, 31–32. One Committee member dissented, arguing that such a provision would act as a disincentive to patenting, so that manufacturers would resort to secrecy to protect innovations, rather than to the patent system.

112 Ibid, 32.

27.119 The Australian Government did not accept this recommendation, citing concerns regarding:

- the imprecise scope of the term 'know-how';
- the uncertainty with which the proposal would operate in the absence of parallel legislation overseas; and
- the uncertainty as to whether Australian courts can set enforceable terms for such a compulsory licence, particularly where the licensee has operations outside Australia.[113]

Submissions and consultations

27.120 IP 27 did not ask about the possible incorporation of know-how in a compulsory licence for a patented invention, and the ALRC has received few comments in submissions or consultations on this issue.

27.121 As discussed in Chapter 29, the ALRC has been informed that a number of researchers and companies have engaged in the licensing of know-how, and that in some circumstances know-how licensing can be more important than patent protection. One company commented that it prefers to do the work for others, rather than to licence-out the know-how associated with its processes, because of concerns about maintaining the confidentiality of information once it has been disclosed.[114]

27.122 In consultations, the Institute of Patent and Trade Mark Attorneys of Australia commented that in some circumstances it can be important to include know-how in the terms of a compulsory licence, provided that commercial terms are paid for it.[115]

ALRC's views

27.123 In circumstances where it is not possible to effectively work a patented invention without the know-how associated with it, the ALRC considers that there may be merit in permitting courts to require the transfer of the know-how when granting a compulsory licence for a patented invention. However, the ALRC recognises that there is a difference between granting a compulsory licence over an intellectual property right that has been granted by the state, and granting compulsory access to know-how that is not the subject of the patent. The ALRC has not heard sufficient information to formulate a proposal for reform, and seeks further information to determine whether reform is required.

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113 J Lahore, *Copyright and Designs: Looseleaf Service* (1996), [5190].
114 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.
115 Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.

Question 27–4 Should the Commonwealth amend the *Patents Act* to authorise a prescribed court, when granting a compulsory licence, to require the transfer of 'know-how' relating to the patented product or process?

28. A Statutory Licensing Scheme

Contents

Introduction

28.1 This Discussion Paper has discussed the concern that the patenting or licensing of genetic materials and technologies could impact negatively on scientific research or healthcare provision.

28.2 Various chapters have discussed different models for facilitating access to patented genetic materials and technologies. Chapters 14 and 22 discussed the existence, scope and limitations of defences to patent infringement for the purpose of experimental use and medical treatment. Chapter 23 discussed the possibility of establishing voluntary industry-based licensing schemes for patented genetic inventions. Chapters 26 and 27 discussed the framework for access through Crown use and compulsory licensing.

28.3 This chapter discusses another possible option for facilitating access to such patented inventions, in the form of a statutory licensing scheme under the *Patents Act 1990* (Cth) (*Patents Act*). The primary difference between industry-based licensing and statutory licensing is that the latter is a more formal framework that operates pursuant to statutory requirements and conditions.

28.4 Chapter 29 outlines the statutory licensing schemes operating under the *Copyright Act 1968* (Cth) (*Copyright Act*), and Chapter 30 discusses the possibility of introducing a statutory licensing scheme in relation to databases of genetic information.

Current law and practice

28.5 The *Patents Act* currently permits the use of a patented invention without the patent holder's consent pursuant only to a court-ordered compulsory licence, or under the Crown use provisions. By contrast, the *Copyright Act* makes much broader provision for use of copyright material without consent through a number of statutory licensing schemes.

Patents Act

28.6 The *Patents Act* also provides for Crown use of patented inventions. Where the Commonwealth or a State (or a person authorised by the Commonwealth or a State) exploits a patented invention 'for the services of the Commonwealth or the State', this does not constitute an infringement of the patent rights. The Crown must inform the patent holder as soon as practicable of the exploitation, and provide any information that is reasonably required, unless this is contrary to the public interest. The remuneration and terms for exploitation must be agreed between the parties or, in the absence of agreement, determined by a prescribed court.[1]

28.7 The *Patents Act* also provides that a prescribed court may grant a compulsory licence for a patented invention where the patent holder has not satisfied the 'reasonable requirements of the public' in relation to that invention. These licences are granted on a case-by-case basis, provided the applicant has first attempted to negotiate a licence with the patent holder. The licensee must pay the patent holder a reasonable royalty in exchange for the compulsory licence.[2] As noted in Chapter 27, it appears that few, if any, compulsory licences have been granted under Australian patent law.

Copyright Act

28.8 The *Copyright Act* contains several statutory licensing schemes that permit the use of copyright material without the copyright owner's consent, subject to the payment of equitable remuneration and compliance with certain statutory conditions. These licences are sometimes referred to as 'statutory licences' because statute, rather than a court or other body, confers them.

28.9 The Act includes statutory licensing schemes for the reproduction of a work or sound recording for the purpose of broadcasting;[3] making of sound broadcasts of literary and dramatic works by holders of a print disability radio licence;[4] recording of

1 *Patents Act 1990* (Cth) ss 163–165. See Ch 26 for more detail.
2 Ibid ss 133(1), 135. See Ch 27 for more detail.
3 *Copyright Act 1968* (Cth) ss 47, 70, 107.
4 Ibid s 47A.

musical and literary works;[5] reproduction and communication of broadcasts by educational institutions and institutions assisting people with an intellectual disability;[6] reproduction and communication of works and published editions by educational institutions and institutions assisting people with a print or intellectual disability;[7] retransmission of free to air broadcasts;[8] public performance and broadcasts of sound recordings;[9] and Crown use of copyright material.[10] The *Copyright Act* also provides for voluntary licensing of copyright material in addition to, and as an alternative to, reliance on statutory licences.[11]

28.10 Statutory licensing schemes are generally administered through collecting societies, which collect and distribute fees on behalf of the copyright owners.[12] The Commonwealth Attorney-General declares certain organisations to be the collecting society for a particular licensing scheme.[13] Other collecting societies are not declared under the Act, but conduct similar activities for their members. For example, the Copyright Agency Limited (CAL) is the declared society for the reproduction and communication of works by educational institutions under statutory licence, and represents its author, publisher and journalist members in licensing their copyright works.

28.11 The Copyright Tribunal has jurisdiction to settle disputes regarding the determination of royalties or equitable remuneration for uses under the statutory licences, and arbitration of some other disputes between licensors and those seeking a licence.[14]

28.12 Professor Sam Ricketson and Chris Creswell have suggested that the purpose of statutory licensing is to provide a legislative balance between the rights of the copyright owner and the interests of third parties who desire access to the copyright owner's material:

> Basic to each of these licences is the assumption that, if left to themselves, the parties will be unable to reach a satisfactory resolution of the terms for the access desired. The reasons for this differ, ranging from unacceptably high transaction costs in cases where individual users would be too difficult to identify and control, to instances where the user is in a powerful initial position and has been able to impose a statutory solution in its favour … Ultimately, however, each of the statutory licences established under the *Copyright Act 1968* (Cth) can be seen as attempts to stimulate

5 Ibid Pt III Div 6.
6 Ibid Pt VA.
7 Ibid Pt VB.
8 Ibid Pt VC.
9 Ibid ss 108(1), 109(1).
10 Ibid Pt VII Div 2.
11 For example, despite the statutory licensing regime under Part VB, individual copyright owners are free to grant licences authorising the use of their material by educational and other institutions covered by the licensing scheme: Ibid s 135ZZF.
12 J McKeough, K Bowrey and P Griffith, *Intellectual Property: Commentary and Materials* (2002), 161.
13 See, eg, see *Copyright Act 1968* (Cth) s 135P.
14 J McKeough, K Bowrey and P Griffith, *Intellectual Property: Commentary and Materials* (2002), 160.

> market solutions, i.e., to allow use subject to the kinds of rates and conditions that would have been arrived at in hypothetical and freely negotiated bargain.[15]

28.13 The Intellectual Property and Competition Review Committee (IPCRC) reviewed the statutory licensing schemes under the *Copyright Act* in its report, *Review of Intellectual Property Legislation under the Competition Principles Agreement*. The IPCRC commented that these schemes are more limited than compulsory licensing under the *Patents Act*, particularly as they do not generally apply to most commercial uses. The IPCRC recognised that statutory licensing could reduce the transaction costs otherwise involved in negotiating licences, and recommended that the statutory licensing scheme remain unchanged.[16]

28.14 The IPCRC also considered the operation of copyright collecting societies. It noted that these societies provide creators with an administrative option for effectively enforcing their rights, both in relation to copyright use and for the collection and distribution of copyright licence fees. They also play an advocacy role for their members, representing owners' interests in public debate and lobbying for relevant changes to copyright laws. The IPCRC considered that if a proper balance is struck in defining copyright rights, it is desirable to have effective mechanisms for enforcing those rights, including through collective management and enforcement mechanisms.[17]

28.15 The IPCRC also noted concerns about the impact of collecting societies on competition, including the potential abuse of market power to extract higher licence fees. The IPCRC recommended several mechanisms to address these concerns.[18]

Statutory licensing for patents

28.16 This Discussion Paper has examined the concern that the patenting of genetic materials and technologies could negatively affect scientific research or healthcare provision. For example, a researcher or research institution could be hindered from conducting certain genetic research due to the time and costs involved in identifying the patent holder and negotiating a licence for each genetic research tool, or where the patent holder refuses to grant a licence for the tool. A healthcare provider might be deterred from conducting certain medical genetic tests, or using genetic therapies, for similar reasons.

28.17 The Discussion Paper has discussed various options for addressing these concerns, including:

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15 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [12.0].

16 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 117–118.

17 Ibid, 118–119, 124.

18 Ibid, 124–127.

- Experimental and medical use defences to infringement of a patented invention.[19]

- Industry-based facilitation of licensing of patented inventions, for example through patent pools.[20]

- Crown use of a patented invention 'for the services of the Commonwealth or a State'.[21]

- Compulsory licensing of a patented invention.[22]

28.18 Dr Dianne Nicol and Jane Nielsen, of the University of Tasmania's Centre for Law and Genetics, have suggested the possibility of a statutory licensing scheme under the *Patents Act* as another option to facilitate third party access to certain types of biotechnology patents, where such access is in the public interest.[23] They suggested that the statutory licensing schemes operating in copyright law should be examined 'with a view to implementing equivalent use strategies' in patent law:

> It may be more appropriate to think of this area in the same way as the educational and other automatic licensing provisions under the *Copyright Act.* Educational institutions have to pay remuneration for the use of copyright material, but they do not have to negotiate individual licences. Nor do they have to apply for compulsory licences. They merely fill out the appropriate remuneration form and pay the appropriate remuneration to approved collection agencies. There are generally standard rates for fees, and if there are disputes these are resolved by the Copyright Tribunal.[24]

Submissions and consultations

28.19 IP 27 did not discuss a potential statutory licensing scheme for patented inventions, and therefore most of the submissions did not address the issue.

28.20 Luigi Palombi suggested the creation of a new 'genetic sequence right',[25] and proposed a form of statutory licensing for that right:

> The Registered GSR [genetic sequence right] would grant to the owner the right to receive a royalty on any use of the genetic material defined by the sequence of the GSR … Users would be required to register such use with the patent office and a

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19 See Ch 14 and 22 for more detail.
20 See Ch 23 for more detail.
21 See Ch 26 for more detail.
22 See Ch 27 for more detail.
23 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 240. *Copyright Act 1968* (Cth) s 40. See Ch 29 for more detail.
24 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 240.
25 Mr Palombi submitted that genetic sequences should not be patentable, but should be eligible for protection through a 'genetic sequence right'.

> record of such use would be kept by the patent office and communicated to the GSR owner. The amount of the royalty to be paid for such use would be determined by a published scale and collected by GSR collecting organisations. Provision could be made for owners to seek specific royalties above the approved published royalties if the owner could establish that due to factors relating to the nature of the GSR or unforeseeable events in the market, the amount of royalties would be insufficient to recoup the owners investment in the research and development … The life of the GSR would be 20 years from the date of registration …[26]

28.21 The Department of Health Western Australia submitted that the ALRC should investigate the possibility of instituting a statutory licensing scheme for some types of biotechnology patents, equivalent to the educational licensing scheme in the *Copyright Act*.[27]

28.22 The ALRC raised the proposal for a statutory licensing scheme in a number of its consultations, and heard 'in principle' support for a statutory licensing scheme in several meetings.[28] Some stakeholders, while expressing an interest in such a scheme, raised some practical concerns with it. One concern was that, because there would be fewer patent holders with whom to negotiate than in the copyright field, a statutory licensing scheme might not be necessary. That is, as the system is designed to deal with multiple users, it might be overly complicated in the context of gene patents, where there are fewer patent holders, and fewer third parties likely to seek access to the patented invention.[29] However, another stakeholder commented that the fact that a scheme might not be subject to widespread use should not be fatal to it.[30]

28.23 Concerns were also raised regarding the means of calculating and collecting licence fees;[31] and whether a statutory licensing scheme would be TRIPS compliant.[32] At least one stakeholder suggested that informal patent pooling might be a better alternative to a statutory licensing scheme.[33]

Possible models

28.24 There are several possible models for a statutory licensing scheme under the *Patents Act.*

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26 L Palombi, *Submission P28*, 1 October 2003.
27 Department of Health Western Australia, *Submission P53*, 3 November 2003.
28 For example, Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003; Intellectual Property Research Institute of Australia, *Consultation*, Melbourne, 4 September 2003; J McKeough, *Consultation*, Sydney, 15 October 2003.
29 Australian Centre for Intellectual Property in Agriculture, *Consultation*, Brisbane, 3 October 2003.
30 J McKeough, *Consultation*, Sydney, 15 October 2003.
31 Australian Copyright Council, *Consultation*, Sydney, 9 September 2003; J McKeough, *Consultation*, Sydney, 15 October 2003.
32 Intellectual Property Research Institute of Australia, *Consultation*, Melbourne, 4 September 2003.
33 Australian Centre for Intellectual Property in Agriculture, *Consultation*, Brisbane, 3 October 2003.

Nicol and Nielsen model

28.25 Nicol and Nielsen have suggested a voluntary statutory licensing scheme, which could involve:

- patent holders registering patents—putting the onus on them to notify users that they have a patent and will pursue infringers;
- the payment of standard licence fees;
- the collection of fees by approved collecting agencies; and
- the creation of a Patent Tribunal to resolve disputes and determine fee structures.[34]

28.26 They suggested that this type of scheme would reduce the time and cost involved in searches, lessen the risk of anti-competitive conduct, increase certainty and decrease individual licence fees. It would also provide an ongoing income for the patent holder through licence fees. However, they note that statutory licensing would not necessarily be appropriate for the licensing of all types of biotechnology patents:

> In most instances freedom of contract should be maintained. However, where broad access to patented products or processes is clearly in the public interest, this sort of regime may provide a suitable means of balancing access and incentive to innovate. Examples might include patented research tools and diagnostic tests.[35]

Gitter model

28.27 In the United States, Assistant Professor Donna Gitter has also proposed a form of statutory licensing for patented DNA sequences. Under her proposed scheme, the patent holder would be required to license a patented sequence to any scientist pursuing commercial research in return for a reasonable licence fee. The scientist would be required to give the patent holder written notice before commencing research using or on the sequence, and the licence fee would be dependent on the commercial value of the end product developed through the research. This would eliminate the need for licence negotiations and up-front payments while still protecting the patent holder's right to a reasonable royalty.[36]

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34 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 240; see also D Nicol, 'Gene Patents: The Ultimate Snatch' (Paper presented at Hatching, Matching, Snatching and Dispatching, AIHLE 7th Annual Conference, Newcastle, 27–30 June 2002), 13.

35 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 240–241.

36 D Gitter, 'International Conflicts over Patenting Human DNA Sequences in the United States and The European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption' (2001) 76 *New York University Law Review* 1623, 1679, 1683. Gitter has suggested that scientists conducting non-commercial research should be subject to an experimental use exemption.

Copyright models

Educational licensing

28.28 The Nicol and Nielsen model appears to be based on the statutory licensing scheme for educational and other institutions under Part VB of the *Copyright Act*. Under that scheme, educational and other institutions may make both analogue and electronic reproductions of works, and communicate them, for the proper purposes of the institution provided that this is done in accordance with the procedures specified in the Act for recording, noting, giving notice, and limiting access to the work. 'Equitable remuneration' is paid for such reproduction and communication.[37]

28.29 There are several conditions for the application of the statutory licence under the Part VB scheme. First, the reproductions must be made for the 'educational purposes of the institution or of another educational institution'. Second, the institution must give the collecting society a 'remuneration notice', undertaking to pay equitable remuneration to the society for the licensed copies and communications that it makes. It must also specify how the equitable remuneration will be determined.[38] Third, the institution must comply with the marking and record keeping, or notice giving and access limiting, requirements of whichever system is adopted.[39] The scheme also acknowledges individual copyright owners' continuing right to enter into voluntary arrangements for the use of their material.

28.30 As noted above, the CAL is the declared collecting society under the Part VB statutory scheme. It collects the licence fees from the educational institutions under the statutory licence. Where the licence fees and other conditions of use cannot be agreed between the institutions and the collecting society, the Copyright Tribunal may determine these issues.[40]

28.31 The primary difference between Nicol and Nielsen's suggested model and the educational statutory licensing scheme is that participation in the former would be voluntary, while the latter permits voluntary licensing but is principally a compulsory licensing scheme.

Part VI licences

28.32 Part VI of the *Copyright Act* deals with voluntary licences entered into between copyright owners and third parties. Under Part VI, a licensor (or collecting society)

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37 *Copyright Act 1968* (Cth) Pt VB. Educational reproduction is covered by Div 2 and 2A; reproduction by institutions assisting persons with a print disability is covered by Div 3; and reproduction by institutions assisting persons with an intellectual disability is covered by Div 4. See generally, S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [12.100].

38 This may be done on the basis of a records system, a sampling system or an electronic use system. See below for more detail.

39 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [12.115].

40 Ibid, [12.100].

may refer a 'licence scheme' to the Copyright Tribunal for its approval. A 'licence scheme' is a scheme formulated by the licensor (or licensors) which sets out classes of cases in which it would be willing to grant a licence, and the fees and conditions applying to such use.[41] The Copyright Tribunal may also determine disputes arising under a licence scheme.

28.33 In practice, a potential licensee approaches the licensor (or collecting society) for a licence and, if the licensor refuses to license or insists on an unreasonable licence condition, the licensee may refer the matter to the Tribunal for a determination. The Tribunal may make an order specifying the fees and conditions that it considers reasonable in the circumstances.[42]

28.34 The main difference between the Part VB scheme and the Part VI form of licence is that the latter form of licence must be sought from the licensor (or collecting society), who can offer it on conditions or refuse it. By contrast, a person seeking to operate under a statutory licence need not have any prior negotiations with the copyright owner. While the licences dealt with under Part VI are of a commercial nature, the Part VB licensing scheme reflects a balance between the commercial interests of copyright owners and the public interest in facilitating access to copyright works for educational purposes.

Voluntary or compulsory?

28.35 A statutory licensing scheme for patented inventions could be structured to provide access to inventions where this is required in the public interest or, more broadly, for commercial purposes. In either case, an important issue is whether patent holders' participation in such a scheme should be voluntary or compulsory.

28.36 As noted above, Nicol and Nielsen have suggested a voluntary scheme in which patent holders would register their patented inventions for the purpose of statutory licensing. The patent holder could choose not to register an invention for various reasons, for example if it wishes to negotiate an exclusive licence for the invention or to use the invention exclusively itself.

28.37 However, where a patent holder wishes to license a patented invention widely, a statutory licensing scheme could provide an effective and efficient mechanism to facilitate such licensing. For example, the holder of a patent over a generic research tool might choose to participate in a statutory licensing scheme in order to notify all other researchers that the product has been patented, and to provide a mechanism for determining and collecting an appropriate licence fee from each licensee. This would avoid the time and cost involved in identifying each individual user.

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41 *Copyright Act 1968* (Cth) s 136(1).

42 See Ibid Pt VI; see also R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 216.

28.38 An alternative model would be compulsory participation in a statutory licensing scheme. As noted above, the *Copyright Act's* educational licensing scheme is based primarily on compulsory participation. Educational institutions are authorised by statute to use copyright work for certain purposes without the copyright owner's authorisation, provided they satisfy the statutory conditions for such use.

28.39 A statutory licensing scheme for patented inventions could be made compulsory for certain types of inventions, or for certain purposes or uses of those inventions. For example, it may be considered in the public interest to introduce a compulsory scheme to facilitate access to patented upstream genetic research tools. Under such a scheme, a third party could use the research tool without prior authorisation, while allowing for payment of a set remuneration. Any such scheme must comply with the TRIPS Agreement, which is discussed below.

Reasonable remuneration

28.40 Another important issue is how to determine the appropriate remuneration for the use of a patented invention subject to statutory licence.

28.41 Nicol and Nielsen have suggested that standard licence fees might be payable under a statutory licence scheme. These fees could be collected by approved collecting agencies, and a new Patent Tribunal could be established to resolve disputes and determine fee structures.[43]

28.42 The Part VB statutory licensing scheme under the *Copyright Act* provides that the educational institution must pay the relevant collecting society 'equitable remuneration' for the making of licensed copies and communications. The amount of remuneration is determined between the institution and the collecting society or, failing agreement, by the Copyright Tribunal.[44] By contrast, under Part VI 'licence schemes', the licensor sets the amount of remuneration, but the licensee may refer the matter to the Copyright Tribunal for its determination.

TRIPS Agreement

28.43 Any proposed statutory licensing scheme for patented inventions would need to comply with Australia's international obligations under the TRIPS Agreement.[45]

28.44 Article 27.1 of the TRIPS Agreement provides that patent rights generally must be enjoyable without discrimination as to the field of technology.[46] However, the

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43 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 240.

44 *Copyright Act 1968* (Cth) ss 135ZU, 135ZV(1), 135ZW(1), 135ZWA(1).

45 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

46 See Ibid art 27.1.

Canada-Patent Protection case confirmed that this article does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas.[47]

28.45 It is unlikely that a voluntary licensing scheme would be inconsistent with art 27 because a voluntary scheme would not adversely affect a patent holder's enjoyment of the patent rights. A compulsory scheme that applied only to patented genetic inventions could be inconsistent if it constituted 'discrimination' by field of technology. Therefore it may be that, in order to be TRIPS compliant, a proposed statutory licensing scheme would need to apply to categories (or uses) or patented inventions generally, rather than being limited to patented genetic materials and technologies only.[48]

28.46 Chapter 4 discussed the TRIPS Agreement's permissible legislative exceptions to the exclusive rights granted by a patent. Article 30 deals with exceptions to the patent rights conferred, and art 31 deals with other uses without the patent holder's authorisation.

28.47 Article 30 permits Members to provide limited exceptions to the exclusive rights conferred by a patent, provided that these exceptions do not unreasonably conflict with the normal exploitation of the patent, and do not unreasonably prejudice the patent holder's legitimate interests, taking into account the legitimate interests of third parties. Article 31 permits Members to provide for 'other uses' of a patented invention without the right holder's authorisation, subject to specified conditions. For example, authorisation of such use must be considered on a case-by-case basis;[49] and the applicant generally must have previously attempted to negotiate a licence from the patent holder on reasonable terms and conditions—except in circumstances of national emergency, other extreme urgency, or for public non-commercial use.[50]

28.48 It appears doubtful that arts 30 or 31 would be breached by a statutory licensing scheme based on voluntary participation. Such a licensing scheme does not appear to constitute an 'exception' to the rights conferred by a patent, or a use without the right holder's authorisation. Instead, the scheme would be better characterised as a mechanism to facilitate the exercise of patent holders' rights in relation to their patented inventions.

28.49 A compulsory statutory licensing scheme potentially could comply with art 30, provided the scheme satisfies each of its requirements. By contrast, it is unlikely that such a scheme would comply with art 31. As statutory licensing schemes are generally

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47 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 170–171.

48 See Ch 4 for more discussion about art 27.1 of the TRIPS Agreement.

49 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 31(a).

50 Ibid art 31(b). See Ch 4, 27 for more detail. See also, D Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2nd ed, 2003), 250–253.

based on the statutory authorisation of a category of inventions, or uses of an invention, this is unlikely to comply with the requirement that the authorisation of any proposed use be considered on its individual merits, or that the parties had attempted prior negotiation.

ALRC's views

28.50 The ALRC considers that the establishment of a statutory licensing scheme under the *Patents Act* is worthy of consideration. Such a scheme could provide an efficient and effective mechanism to facilitate third party access to certain patented inventions. It could potentially apply to:

- certain categories of patented inventions—such as research tools or medical diagnostic tests generally, or specific categories of these tools and tests; or

- certain uses of patented inventions, such as use for public non-commercial research or healthcare provision.

28.51 Such a scheme could strike an effective balance between the rights and interests of both the patent holder and third parties by ensuring reasonable access to the patented invention in exchange for reasonable remuneration. This remuneration could be determined by negotiation or, failing agreement, by a tribunal or court.

28.52 The scheme would be likely to reduce the time and cost of searches in relation to biotechnology patents, increase certainty and decrease individual licence fees. At the same time, it would provide an ongoing income for the patent holder through licence fees.[51] While competition concerns have been raised about collecting societies operating under copyright law, the ALRC considers that the practical and other benefits of a statutory licensing scheme are likely to outweigh these potentially negative aspects.[52]

28.53 The ALRC has not formed a view as to whether any statutory scheme should be based on voluntary or compulsory participation on the part of patent holders, although it notes significant difficulties with a compulsory scheme. Under a voluntary model, a third party could access any patented inventions that have been included on a register for these purposes, in exchange for reasonable remuneration. The weakness with this approach is that some patent holders may refuse to participate in the scheme, particularly where the patented invention has few substitutes and is therefore a highly valuable commodity. In those circumstances, third parties would have to attempt to negotiate an individual licence with the patent holder or, failing that, invoke the Crown

51 D Nicol, 'Gene Patents: The Ultimate Snatch' (Paper presented at Hatching, Matching, Snatching and Dispatching, AIHLE 7th Annual Conference, Newcastle, 27–30 June 2002), 13.

52 See Ch 24 for more discussion about the interaction between intellectual property and competition laws.

use provisions (where appropriate) or seek a compulsory licence under the *Patents Act*.[53]

28.54 The alternative is a statutory scheme based on compulsory participation, to apply in very limited circumstances. For example, where a patent holder has a broad patent over a patented upstream genetic research tool, but refuses to license the tool to other researchers, there may be a public interest in facilitating such access. However, this would represent a significant exception to the exclusive right of exploitation generally granted by a patent, and could potentially be inconsistent with the TRIPS Agreement.

28.55 Under either model, one or more collecting societies could represent patent holders in negotiating the licence fees, and in collecting and distributing these payments. This would streamline the process and minimise the transaction costs involved in negotiating licences with numerous patent holders.[54] Alternatively, the *Copyright Act* provides for the payment of remuneration direct to the copyright owner in certain circumstances.[55] Given the relatively small numbers of patent holders who are likely to be involved in such a scheme, direct payment may be more appropriate.

28.56 Where the parties cannot agree on the reasonable remuneration, an independent body should determine the matter. There are several options for such a body, including a new Patent Tribunal, an expanded and renamed Copyright Tribunal or a court. The ALRC considers that, assuming this power is judicial in nature, the federal courts may be appropriate for this role. The Federal Court already exercises similar powers in other patent matters, in particular in ordering compulsory licences and determining an appropriate remuneration.

28.57 The ALRC considers that there is merit to consideration being given to a statutory licensing scheme for certain patented inventions, and seeks further views on this. Accordingly, the ALRC asks whether the Commonwealth should amend the *Patents Act* to insert a statutory licensing scheme for patented inventions. If so, the ALRC asks whether the scheme should be available only in a limited class of patents, or to a limited class of users; whether it should be voluntary or compulsory in nature; how a reasonable royalty should be determined; and who should administer the scheme.

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53 Or, in some circumstances, under the *Trade Practices Act 1974* (Cth). See Chs 24 and 27 for more detail.

54 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6.

55 See, eg, *Copyright Act 1968* (Cth) s 108.

Question 28–1 Should the Commonwealth amend the *Patents Act 1990* (Cth) to include a statutory licensing scheme for patented inventions? If so:

(a) should the scheme be available only to a limited class of patents or a limited class of users;

(b) should the scheme be voluntary or compulsory in nature; and

(c) how should a reasonable royalty for the scheme be determined and who should administer the scheme?

PART H

Other Intellectual Property Issues

29. Copyright, Trade Secrets and Designs

Contents

Introduction

29.1 This chapter discusses the potential application of copyright, trade secrets and designs law to genetic materials and technologies, and considers the possible implications of such intellectual property protection. Chapter 30 discusses the application of copyright and other intellectual property rights to databases of genetic information.

Copyright law

29.2 IP 27 noted that scientific researchers might rely on copyright protection of certain research tools and results rather than other forms of intellectual property protection. For example, copyright might protect a computer program developed for

use in genetic research or it might protect collections of research data, such as a database of genetic sequences.[1]

29.3 Copyright protection for some research tools and data may be an attractive alternative to an application for patent protection, particularly where the researcher has little knowledge of the function of the material, and because copyright does not require that a work have a practical application.

29.4 However, the recognition of copyright in research tools could have significant implications for scientific research, due to the duration and exclusive nature of copyright protection. For example, if copyright subsists in the representation of a molecular sequence, this could present an impediment to its use by other researchers—unless the use falls within the scope of a fair dealing exception to copyright infringement.[2] On the other hand, the copyright owner cannot prevent researchers from independently sequencing the same biological information.

Current law and practice

29.5 Copyright protects the form of expression of ideas, rather than the ideas, information or concepts expressed. The *Copyright Act 1968* (Cth) (*Copyright Act*) regulates copyright in Australia in relation to original literary, dramatic, musical and artistic works, and 'subject matter other than works'.

29.6 On 8 February 2004, Australia and the United States finalised the Australia–United States Free Trade Agreement (AUSFTA). This provides, among other things, that Australia will amend several aspects of its copyright law to bring it into greater harmony with United States' copyright law. As these amendments are not yet part of Australian law, they are not discussed below.

Subsistence of copyright

29.7 Copyright in literary, dramatic, musical or artistic works is the exclusive right to reproduce the work in a material form; publish the work; perform the work in public; communicate the work to the public; make an adaptation of the work; enter into a commercial rental arrangement in respect of the work reproduced in a sound recording of the work; and for computer programs, to enter into a commercial rental arrangement in respect of that program.[3]

29.8 Copyright subsists in an unpublished literary, dramatic, musical or artistic work if the author was a 'qualified person'[4] at the time the work was made or for a

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1 See Ch 30 for more detail about copyright in databases of genetic information.

2 See the discussion below.

3 *Copyright Act 1968* (Cth) s 31(1). See ss 85–88 for the nature of copyright in subject matter other than works.

4 A 'qualified person' is an Australian citizen, resident or an Australian protected person. An 'Australian protected person' is a person who is under the protection of the Australian government: Ibid ss 32(4), 10(1).

substantial part of this time. Copyright subsists in a published work if the work is first published in Australia;[5] if the author was a 'qualified person' at the time the work was first published; or if the author died before that time but was a 'qualified person' immediately before his or her death.[6]

29.9 In order to attract copyright, a work must be a literary, dramatic, musical, or artistic 'work', and the work must be 'original'. Literary works include tables and compilations expressed in words, figures or symbols, computer programs and compilations of computer programs.[7] A literary work need not display literary merit, however it is usually intended to convey information and instruction, or pleasure, in the form of literary enjoyment.[8] This requirement has been interpreted broadly, and has been held to include codes comprising foreign or invented words, and computer source codes.[9] By contrast, the word 'EXXON' has been held not to be a literary work because, while the word is new and original, it 'has no meaning and suggests nothing in itself'.[10]

29.10 The work need not be the expression of original or inventive thought, but it must originate with an author and must not be a copy. A work originates with an author if it is the product of the author's skill, labour and expertise or experience. The requisite degree of labour, skill and expertise will depend on the facts of the case and will be a question of degree.[11] In Australia, the Federal Court has held that originality can flow purely from the 'sweat of the brow' involved in collecting, verifying and presenting information in a compilation, even if there is no creativity involved in its selection or arrangement.[12]

29.11 Generally, copyright subsists until 50 years after the end of the calendar year in which the author died.[13] Where a literary work was not published before the author's

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5 'Publication' is the authorised supply of reproductions of a work to the public: Ibid s 29(1).

6 Ibid s 32. In addition, the *Copyright (International Protection) Regulations 1969* (Cth) confer a similar protection on most works that are made or published overseas.

7 *Copyright Act 1968* (Cth) s 10(1).

8 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 42–44, citing *Hollinrake v Truswell* [1894] 3 Ch 420.

9 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 44–45.

10 *Exxon Corporation v Exxon Insurance Consultations International Ltd* [1981] 2 All ER 495, 503 (Graham J). See J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed, 1997), 142.

11 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [7.50], [7.60].

12 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433. See also J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [10,065], [10,115]. See Ch 30 for more detail.

13 *Copyright Act 1968* (Cth) s 33(2). By contrast, the European Union and the United States have extended the duration of copyright in works to 70 years after the author's death: see *Directive 93/98/EEC of the European Council on Harmonising the Term of Protection of Copyright and Certain Related Rights*, (entered into force on 29 October 1993); *Copyright Act Title 17* (US). See R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 69.

death, copyright subsists until the end of 50 years after the end of the calendar year in which it was first published.[14]

Ideas and expression

29.12 In the United States, courts have held that copyright does not subsist in facts or ideas, and where the idea and its expression merge, copyright does not subsist in the expression. Therefore, where an idea has only one possible form of expression, copyright protection does not extend to the protection of the expression.[15] It is unclear whether this 'merger doctrine' applies in Australia. Some commentators have suggested that Australian courts have accepted the principle,[16] while others suggest that the High Court has impliedly rejected it.[17] In a recent Federal Court case, Lindgren J commented that the doctrine does not apply in Australian law in relation to 'whole of universe' factual compilations, such as a telephone directory.[18]

Copyright infringement

29.13 Copyright is infringed if a person does or authorises the doing, in Australia, of any act falling within the copyright of a work without the copyright owner's permission.[19] Such reproduction or other conduct must relate to the whole or a 'substantial' part of the work, and the test of substantiality refers primarily to the quality of what is taken.[20]

Fair dealing provisions

29.14 The *Copyright Act* provides for certain acts of 'fair dealing' with a copyright work, that constitute exceptions to infringement of copyright. One such exception is fair dealing for the purpose of research or study.[21]

29.15 The Federal Court has interpreted the terms 'research' and 'study' in accordance with their ordinary dictionary meanings. 'Research' means diligent and systematic enquiry or investigation into a subject in order to discover facts or principles. 'Study' has several meanings, including the application of the mind to the acquisition of knowledge, and a thorough examination and analysis of a particular subject. The

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14 *Copyright Act 1968* (Cth) s 33(3).

15 See J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed, 1997), 137–138.

16 See Ibid.

17 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 21–22, citing *Data Access Corporation v Powerflex Services Pty Ltd* (1999) 202 CLR 1. However, Reynolds & Stoianoff note that in *Autodesk Inc v Dyason*, Dawson J had made a statement supporting the existence of the doctrine in Australian law: *Autodesk Inc v Dyason* (1992) 173 CLR 330.

18 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474. In that case, Telstra's telephone directory was a 'whole of universe' compilation because there was no selection of the subscribers to be included. The universe for each regional directory constituted all subscribers in the region, except those who had a silent number. Therefore, any persons exploring the same universe would discover the same factual information: Ibid, 440.

19 *Copyright Act 1968* (Cth) s 36(1).

20 J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed, 1997), 191.

21 *Copyright Act 1968* (Cth) s 40(1).

research or study must be carried on by the person who actually claims the benefit of the fair dealing provision.[22]

29.16 Section 40(2) of the *Copyright Act* provides guidelines for determining whether the reproduction of the whole or a part of a work constitutes a fair dealing for the purposes of research or study.[23] These factors include:

- the purpose and character of the dealing;
- the nature of the work or adaptation;
- the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;
- the effect of the dealing upon the potential market for, or the value of, the work or adaptation; and
- where only a part of the work is copied, the amount and substantiality of that part compared to the whole work or adaptation.[24]

29.17 In addition, s 40(3) places limits on the amount of reproduction that will be deemed to be a fair dealing under s 40(1), provided it is made for the purpose of research or study:

- in the case of a work comprising an article in a periodical publication, the whole or part of the work; or
- in any other case, not more than a 'reasonable portion' of the work.[25]

29.18 The Australian courts are yet to determine whether fair dealing for the purpose of research or study applies only to non-commercial research or study.[26] Professor Sam Ricketson argues that there appears to be no reason to limit the purposes for which research or study is conducted to basic, non-commercial research, provided the activity

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22 *De Garis v Neville Jeffress Pidler Pty Ltd* (1990) 37 FCR 99; see also S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [11.30].

23 The Copyright Law Review Committee has commented that although s 40(2) and (3) use the expression 'a dealing by way of copying', it considers that these fair dealing provisions are not limited to the right of reproduction, but apply to the exercise of all rights: Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), 34.

24 *Copyright Act 1968* (Cth) s 40(2).

25 Ibid s 40(3). A 'reasonable portion' generally means 10% of the work, determined either by page number or, in the case of digital copies, word count: ss 10(2), 10(2A).

26 See Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), 37; see also S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [11.30].

falls within the scope of the dictionary meanings.[27] However, the Commonwealth Attorney-General's Department has submitted that this remains an open question.[28]

29.19 An important issue in relation to fair dealing is whether, in practice, an individual or organisation is able to gain access to the copyright work for fair dealing purposes. In the genetic research field, this concern arises primarily in relation to genetic databases. Chapter 30 discusses the issues arising from the protection of genetic databases by contract and other forms of protection.

Statutory licensing provisions

29.20 The *Copyright Act* contains several statutory licensing schemes that permit third party use of copyright works without prior negotiation or permission, in exchange for a reasonable royalty. These schemes include: copying by educational and other institutions;[29] recording of musical works;[30] broadcasting sound recordings or causing them to be heard in public;[31] retransmitting free to air broadcasts;[32] recording or filming works for the purpose of ephemeral broadcast by another person, or copying such a recording;[33] and Crown use of copyright material.[34]

29.21 The statutory licensing regime for Crown use of copyright permits the reproduction or other act comprised in the copyright of a work or other subject matter 'for the services of the Commonwealth or State'. The Crown must, as soon as possible (unless contrary to the public interest), inform the copyright owner of the doing of the act and provide the owner with information that he or she may reasonably require. The Crown and the copyright owner must agree to the terms of such use, and if an agreement cannot be reached, the Copyright Tribunal may determine these terms.[35]

Application to genetic research

Genetic materials and products

29.22 IP 27 noted that scientific researchers might seek to assert copyright over the written representation of a sequence of natural or modified genetic material, or an amino acid sequence of a natural or modified protein molecule.[36]

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27 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [11.30].

28 Attorney-General's Department, *Submission P61*, 11 November 2003.

29 *Copyright Act 1968* (Cth) Pt VA, VB.

30 Ibid ss 54–64.

31 Ibid ss 108–109.

32 Ibid Pt VC.

33 Ibid ss 47, 70, 107.

34 Ibid s 183. See generally, J McKeough, K Bowrey and P Griffith, *Intellectual Property: Commentary and Materials* (2002), 159–160; H Ergas, *Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia* (2002), 4.

35 *Copyright Act 1968* (Cth) s 183. See Ch 26 for a discussion of the meaning of the term 'for the services of the Commonwealth or the State'.

36 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), 243.

29.23 Sue Coke has suggested that the written representation of a sequence of modified DNA or protein may be protected as an original literary work under the *Copyright Act*. As the legislative definition of a 'literary work' includes a table or compilation expressed in words, figures or symbols, the written representation of a genetic sequence or product—being a string of letters representing the four nucleotides, adenine, thymine, guanine and cytosine (A, G, T and C)—is likely to be a 'literary work' within the meaning of the *Copyright Act*. Coke has commented that:

> Since copyright was held to subsist in the list of numbers in the 'newspaper bingo' game used to promote the circulation of a Sunday newspaper, it can hardly be asserted that a sequence of letters (which may not be meaningful to a lay person but would be to a molecular biologist) denoting nucleotides of modified DNA or the amino acids making up the protein the product of that modification would not be protected by copyright, provided sufficient skill, labour and effort was involved in elucidating the sequence.[37]

29.24 In other jurisdictions, commentators have suggested that copyright may not subsist in such a written record because there is only one established way of representing a sequence of nucleotides (or amino acids). In this case, the idea and expression merge.[38] According to Professor Gunnar Karnell:

> It is an internationally recognised, distinguishing feature of copyright that no-one should be allowed to appropriate for himself, by means of copyright law, either the only way to express or describe a certain type of real matter (here: a DNA sequence, recombinant or other) or such matter as can only be described in such a way.[39]

29.25 As noted above, while it is unclear whether the merger doctrine applies generally in relation to copyright in Australia, it does not apply to 'whole of universe' factual compilations.[40] Therefore, copyright could potentially subsist in the representation of a genetic sequence provided sufficient skill, labour and effort is involved in creating that expression.

29.26 In other jurisdictions several commentators have suggested that copyright may subsist in a modified nucleotide or amino acid molecule itself, in addition to its written representation.[41] This is unlikely under Australian law because the molecule, by itself, is not in writing and provides no information, instruction or entertainment to human beings—unlike its written representation.

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37 S Coke, 'Copyright and Gene Technology' (2002) 10 *Journal of Law and Medicine* 97, 102.

38 See the discussion in Ibid, 101, 108.

39 G Karnell, 'Protection of Results of Genetic Research by Copyright or Design Rights?' (1995) 17 *European Intellectual Property Review* 355, 357.

40 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474 (Lindgren J).

41 See, eg, I Kayton, 'Copyright in Living Genetically Engineered Works' (1982) 50 *George Washington Law Review* 191; N Derzko, 'Protecting Genetic Sequences under the Canadian Copyright Act' (1993) 8 *Intellectual Property Journal* 3131, 39. See also S Coke, 'Copyright and Gene Technology' (2002) 10 *Journal of Law and Medicine* 97; J Silva, 'Copyright Protection of Biotechnology Works: Into the Dustbin of History?', *Boston College Intellectual Property and Technology Forum*, 28 January 2000, <www.bc.edu/itpf>, 2, 4.

Computer programs

29.27 Computer programs may be designed to conduct various steps in the identification or modification of genetic or protein sequences, or in the storage of such sequences or associated information. Copyright may be asserted in computer programs developed for these purposes.

29.28 A computer program or a compilation of computer programs, may attract copyright as an original 'literary work'.[42] The *Copyright Act* defines a computer program as 'a set of statements or instructions to be used directly or indirectly in a computer in order to bring about a certain result'.[43] Therefore, copyright protects the expression of the set of statements and instructions that constitute an original literary work in the form of a computer program.[44]

29.29 As copyright does not protect the functional elements of a computer program, a competitor could avoid infringement by using different object or source codes to achieve the same functional result.[45] It has been suggested that as most of the commercial value in bioinformatics machines lies in their functional elements, copyright law may provide insufficient protection to have any real application in this area.[46]

Submissions and consultations

29.30 IP 27 asked what role copyright law should play in dealing with genetic materials and technologies in relation to human health.[47]

29.31 Several submissions suggested that copyright law would be an inappropriate means of protecting genetic materials and technologies.[48] The Department of Industry, Tourism and Resources submitted that:

> Copyright law protects the form of ideas. Patent law protects inventions. Copyright law is an inappropriate vehicle for the protection of genetic materials and technologies in relation to human health, except for databases that contain specific gene sequences.[49]

29.32 Several submissions submitted that although copyright protection applies to databases and software programs used to analyse, sort and record genetic material and

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42 *Copyright Act 1968* (Cth) s 10(1).

43 Ibid. This definition was inserted into the *Copyright Act* by the *Copyright Amendment (Digital Agenda) Act 2000* (Cth). The Commonwealth Attorney-General's Department is currently conducting a review of the operation of this legislation and is due to report to the Attorney-General in 2004.

44 S McBride, 'Bioinformatics and Intellectual Property Protection' (2002) 17 *Berkeley Technology Law Journal* 1331, 1350.

45 Ibid, 1350.

46 Ibid, 1350.

47 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 16–1.

48 For example, Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

49 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

information, it has a limited role in dealing with the actual genetic materials and technologies themselves.[50] In addition, AusBiotech Ltd submitted that:

> Since copyright applies only to the specific form of expression, it is not suitable for protection of inventions relating to nucleic acids, because copyright could not accommodate for sequence variations. Although this copyright protection has frequently been proposed as being suitable for this purpose, it would be completely impracticable. Moreover, copyright would not be amenable to protection of uses of the sequence information. Similarly copyright could protect the depiction of the three-dimensional structure of a protein, but would not protect the protein molecule itself or its uses.[51]

29.33 The Department of Health and Ageing submitted that it would be concerned about any application of copyright law that tended to inhibit medical research or the application of such research in healthcare.[52] The South Australian Government also expressed concern about the potential impact of copyright law on research and healthcare provision.[53]

29.34 The Human Genetics Society of Australasia submitted that, rather than copyright, the focus should be on reforming patent laws to protect the intellectual property rights (if any) attached to genetic materials and products.[54]

29.35 Dr Amanda McBratney and others submitted that:

> there would be a serious policy question as to whether the Australian government would want to confer the significantly longer protection of copyright to genetic materials and technologies. In so far as industry is concerned, the untested nature of copyright protection for gene-related inventions makes it an unattractive option.[55]

29.36 The Australian Centre for Intellectual Property in Agriculture (ACIPA) submitted that Australian copyright law 'should promote the primary public interest in the free flow and exchange of scientific information amongst researchers and scientists'. ACIPA commented that:

> Copyright law needs to be much more sensitive and responsive to the need to facilitate the dissemination of scientific information amongst scientists. It should ensure that scientists are not burdened by additional imposts levied by scientific publishers. There is a need to reform the defence of [fair] dealing to recognise that the use of academic journals and scientific databases are productive and transformative uses.[56]

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50 For example, Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

51 AusBiotech Ltd, *Submission P58*, 7 November 2003.

52 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

53 South Australian Government, *Submission P51*, 30 October 2003.

54 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

55 A McBratney and others, *Submission P47*, 22 October 2003.

56 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

Options for reform

29.37 The ALRC has not identified any particular concerns with the potential subsistence of copyright in the written representation of a genetic or protein sequence, or a computer program. However, as this is a developing area of technology, it is possible that concerns may arise in the future.

29.38 As noted in Chapter 30, copyright may subsist in factual compilations of genetic information, and this may give rise to concerns regarding third party access for scientific research. In particular, ACIPA identified an issue fair dealing in relation to scientific research that may have commercial implications.

29.39 This section discusses whether it may be desirable to amend the fair dealing provisions in the *Copyright Act* to clarify whether fair dealing for the purpose of research or study applies to research of a commercial nature, which would include genetic research. Such an amendment would remove the existing uncertainty for researchers who wish to rely on the fair dealing provisions, but who are involved in research that is either commercial from the outset, or may become commercial at some point within the life of the project.

29.40 Such clarification could be achieved by amending the *Copyright Act* to provide greater guidance as to what extent the fair dealing provisions for research or study applies to commercial research; or by adopting the United States' concept of 'transformative use' in relation to fair use of copyright works.

Commercial/non-commercial research

29.41 As noted above, Ricketson argues that there appears to be no reason to limit the purposes for which research or study is conducted to basic, non-commercial research, provided the activity falls within the scope of the dictionary meanings.[57] However, the Commonwealth Attorney-General's Department has submitted that this remains an open question.[58]

29.42 The European Union has recently provided for a voluntary fair dealing exemption from copyright infringement for 'non-commercial' research. For some member states, implementing this provision would mean limiting the scope of their existing fair dealing exceptions. The United Kingdom's Royal Society has noted the difficulty in defining the commercial character of research, particularly as many research ventures and collaborations only subsequently become commercial. It commented that such a limitation would give rise to uncertainty, not be useful, and be complex to operate.[59]

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57 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [11.30].

58 Attorney-General's Department, *Submission P61*, 11 November 2003.

59 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 20, citing *Directive 2001/29/EC of the European Parliament and of the Council on the*

29.43 The Commonwealth Attorney-General's Department submitted that an expansion of the existing fair dealing provisions to cover commercial research could, potentially, minimise some of the concerns arising from the protection of factual databases. However, the Department suggested that it would be difficult to envisage a broad exclusion for scientific research that would comply with the *Berne Convention for the Protection of Literary and Artistic Works* (Berne Convention).[60]

29.44 The Berne Convention contains a 'three step test' for exceptions to the exclusive rights of copyright owners. Art 9(2) provides that:

> It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.[61]

29.45 This test has been incorporated, in a slightly amended form, into art 13 of the *Agreement on the Trade-Related Aspects of Intellectual Property Rights 1994* (the TRIPS Agreement). The first condition requires that a limitation or exception be clearly defined in national legislation and be narrow in scope and reach. The second condition is breached if the use would put the user into economic competition with the way that the right holder would normally extract economic value from the right, thus depriving the right owner of significant tangible economic gains.[62] Under the third condition, the right holder's legitimate interests would be unreasonably prejudiced if an exception causes, or has the potential to cause, an unreasonable loss of income for the copyright holder.[63]

Transformative use

29.46 In consultations, Professor Jill McKeough suggested that the concept of 'transformative use' under the United States' fair use provisions might be an alternative to the commercial/non-commercial distinction for fair dealing.[64] ACIPA

Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society, (entered into force on 22 May 2001).

60 Attorney-General's Department, *Submission P61*, 11 November 2003.

61 *Berne Convention for the Protection of Literary and Artistic Works* (1886) art 9(2). This test has been incorporated into the TRIPS Agreement through art 9(1), which incorporates the obligations under arts 1–21 of the Berne Convention, and art 13, which restates the test in a slightly wider form that applies to all the exclusive rights of copyright owners. It has also been incorporated into the WIPO Copyright Treaty: *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995) art 9(1), 13; *WIPO Copyright Treaty*, 20 December 1996, WIPO/CRNR/DC/94, art 1(4), 10.

62 In determining the normal exploitation, it is necessary to consider both the existing and the potential uses of a copyright work.

63 D Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2nd ed, 2003), 147–150, citing the WTO Panel's decision in *United States—Section 110(5) of the US Copyright Act*, document WT/DS160/R. See Copyright Law Review Committee, *Copyright and Contract* (2002), [3.08]–[3.14].

64 J McKeough, *Consultation*, Sydney, 15 October 2003.

also suggested that the fair dealing provisions should be reformed to recognise that the use of academic journals and scientific databases is 'productive and transformative'.[65]

29.47 Section 107 of the *Copyright Act 1976* (US) provides that 'fair use' of a copyright work for research (or other specified purposes) is not an infringement of copyright. In determining whether the use is a fair use the factors to be considered include the purpose and character of the use, including whether such use is of a commercial nature or is for non-profit educational purposes.

29.48 The Copyright Law Review Committee (CLRC) discussed the fair use doctrine in its report, *Simplification of the Copyright Act 1968: Part 1: Exceptions to the Exclusive Rights of Copyright Owners*. The Committee commented that the concept of 'transformative use' is relevant to the examination of the purpose and character of the use. This concept refers to the distinction between 'productive' and 'reproductive' uses of a work. It assesses the value generated by the secondary use and the means by which such value is generated. An untransformed copy or 'reproductive use' of a work is likely to be used for the same purpose as the original, while a 'productive use' makes some contribution of new intellectual value and therefore promotes the advancement of the arts and sciences.[66] The United States' Supreme Court has held that although

> a transformative use is not absolutely necessary for a finding of fair use ... the more transformative the new work, the less will be the significance of the other factors, like commercialism, that may weigh against the finding of fair use.[67]

29.49 The CLRC recommended that the fair dealing provisions be amended by consolidating the current fair dealing provisions into a single provision; expanding fair dealing to an open-ended model that specifically refers to the current exclusive set of purposes but is not confined to them; and applying the non-exclusive set factors provided for in s 40(2) of the *Copyright Act* to all fair dealings.

29.50 The Committee commented that these amendments would result in a fair dealing provision similar to, but more precise than, the United States' fair use provision.[68] The Australian Government has not implemented this recommendation.

ALRC's views

29.51 As noted above, it has been argued by some that copyright could apply to the written representation of a sequence of nucleotides or amino acids in a genetic or protein molecule. This issue does not appear to have been considered by an Australian court to date, and the state of the law is not settled. It appears very unlikely that

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65 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

66 Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), 41–44.

67 Ibid, 44, citing *Campbell v Acuff-Rose Music Inc* 114 S Ct 1164 (1994), 1171; *American Geophysical Union v Texaco Inc* 29 IPR 381 (1994), 396.

68 Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), 61.

copyright would subsist in a genetic or protein molecule itself. Copyright protection might also apply to the computer software used in genetic research. Chapter 30 notes that, in Australian law, copyright may subsist in factual compilations of genetic information and this may have significant implications for researchers.

29.52 The ALRC has not identified any particular concerns with the potential application of copyright law to an original written representation of a genetic or protein sequence, or to a computer program. However, as copyright may subsist in a database of genetic information, it is possible that copyright could in future have some impact on the conduct of genetic research. Therefore, the ALRC considers that the fair dealing provisions for the purpose of research or study would benefit from clarification.

29.53 The ALRC proposes that the Commonwealth should amend the *Copyright Act* to clarify the extent to which 'fair dealing for the purpose of research or study' applies to commercial research using genetic research tools and results that are protected by copyright.

29.54 The concept of 'transformative use' could be an attractive alternative to the commercial/non-commercial distinction in fair dealing for the purpose of research or study. It is arguable that there is a public interest in facilitating third party access to a copyright work—whether for commercial or non-commercial purposes—for use in developing an entirely new product that will contribute to scientific and intellectual knowledge. However, at this stage the ALRC has insufficient information about this option to suggest any reform.

Proposal 29–1 The Commonwealth should amend the *Copyright Act 1968* (Cth) to clarify the extent to which 'fair dealing for the purpose of research or study' applies to commercial genetic research.

Trade secrets

29.55 A scientific researcher might seek to protect particular research tools or results as a trade secret while pursuing patent protection, or as an alternative to other forms of intellectual property protection. Trade secrets may also protect certain background information about a patented invention, which makes it possible to use the new product or process most effectively.

Current law and practice

29.56 Trade secrets are a form of confidential information that arises in a commercial context.[69] Trade secrets law is based primarily in the common law. An individual may

69 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [33,080]. By contrast, 'know-how' represents the confidant's (ie employee's) accumulated experience and knowledge in a

bring an action either in contract or in equity for breach of confidence in relation to a trade secret.

Trade secret protection

29.57 In order to attract protection as a trade secret, the information must be secret, and there must have been an understanding at the time of receiving the information that it is confidential. The recipient of confidential information breaches confidence when he or she discloses or uses that information beyond the purpose for which it was given—whether the misuse is intentional, unintentional, subconscious or negligent.[70]

29.58 This protection may be lost if the information is disclosed (for example by a person who is given access to the information, such as a former employee) or otherwise enters the public domain.

Breach of confidence

29.59 Actions for breach of confidence may be based on contract or in equity. An action for breach of contract may be based on an express or implied condition of the contract that information be treated as confidential. However, where a contract purports to protect trivial or mundane information in the public domain as 'confidential information', a court may consider whether the presumption against contracts in restraint of trade should apply. Alternatively, the defendant might argue that a contract is harsh and unconscionable if it has the effect of unreasonably restraining the use of information that is freely available to the public.[71]

29.60 The basis of an equitable action for breach of confidence 'lies in the notion of an obligation of confidence arising from the circumstances in or through which the information was communicated or obtained'.[72] The equitable obligation of confidence has four elements:

- the confidential information for which protection is sought must be identified with specificity, and not merely in global terms;
- the information must have the necessary quality of confidence;
- the circumstances in which the information was received must have imported an obligation of confidence; and

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particular position or field. This is usually more peculiar to the industry than the particular employer: R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 520–521.

70 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 531.

71 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [33,010].

72 Ibid, [33,000], citing *Moorgate Tobacco Co Limited v Philip Morris Limited (No 2)* (1984) 156 CLR 414, 437–438.

- misuse of that information must be actual or threatened, without the confider's consent.[73]

29.61 In some cases, the owner of the trade secrets will clearly be able to show that he or she was the source of the information. However, in those cases where the owner is not able to prove how the information was obtained, but the similarity between the product or process allegedly disclosed and that used is so marked as to defy coincidence, the courts have drawn an inference of misuse.[74]

Defences to breach of confidence

29.62 There are several defences to an action for breach of confidentiality, including legal compulsion,[75] disclosures in respect of which privilege is claimed,[76] equitable defences,[77] and disclosures made in the public interest.[78]

29.63 In respect of private litigants, the public interest exception appears to apply only where information discloses an iniquity in the sense of a crime, civil wrong or serious misdeed of public importance.[79] Professor James Lahore and Ann Dufty have commented that there is no clear definition of an iniquity, nor any clear indication of the criteria to be used in determining whether the disclosure of particular information might be excused on this basis. They suggested that the precise scope of the public interest defence in Australia is unclear.[80]

29.64 In cases involving government information, the courts appear to have adopted a balancing test to determine whether the public interest in disclosure outweighs the public interest in observing trust and confidences.[81]

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73 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [33,000], citing *Smith Kline & French Laboratories (Australia) Ltd v Secretary, Department of Community Services and Health* (1990) 95 ALR 87. It is not clear whether the plaintiff must also show that use or disclosure of the information will be detrimental to the plaintiff.

74 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [33,260].

75 For example, where a statutory provision expressly or by necessary inference directs that information be disclosed; or a court orders discovery of the information: Ibid, [39,010], [39,020].

76 For example, a lawyer is not required to disclose confidential information if the information is covered by legal professional privilege and the client chooses not to waive that privilege: Ibid, [39,040].

77 For example, the court may reject an application for relief if the plaintiff has allowed an unreasonable time to elapse between the alleged breach of confidence and commencement of proceedings; or where the plaintiff has been guilty of some impropriety and has not come to the court with 'clean hands': Ibid, [39,100], [39.110].

78 Ibid, [39,000].

79 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 534.

80 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [39,130], [39,170]. Information which Australian courts have held to be of such public importance to justify disclosure includes: a breach of national security, the commission of a crime or fraudulent conduct, a breach of a statute, and other serious misdeeds of public importance.

81 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 534.

Application to genetic research

29.65 Scientific researchers or industry might choose to protect a new invention or research results through trade secrets law for various reasons, including because trade secrets protection is not limited to a specific duration; trade secrets do not require the time and financial resources involved in obtaining patent protection;[82] and, where the invention does not satisfy the criteria of patentability, trade secrets may be the most effective alternative form of protection.

29.66 However, the protection of genetic research through trade secrets law may have several disadvantages both for the inventor, and for the conduct of further research and development. Trade secrets protection can be easily lost by the release of the confidential information into the public domain. In addition, a trade secret cannot be enforced against third parties who independently develop the invention. Trade secrets can also inhibit the conduct of further research and development by third persons because the knowledge is not available in the public domain.

29.67 In consultations, the ALRC heard that a number of researchers and companies have engaged in the licensing of 'know-how', and that in some circumstances know-how licensing can be more important that patent protection. By contrast, one company commented that it prefers to conduct its commercial process for others, rather than to licence-out the know-how associated with the process, due to concerns about maintaining the confidentiality of the information once it has been disclosed.[83]

Submissions and consultations

29.68 IP 27 asked whether trade secrets law has any significant application to the conduct of genetic research and its commercialisation; and if so, whether the law requires reform.[84]

29.69 ACIPA submitted that trade secrets law has a significant impact upon the conduct of genetic research and its commercialisation, and that the law may need reform to allow for greater access to scientific information. It proposed an expansion of the defences available under trade secrets law, and suggested a general public interest defence to claims of infringement of trade secrets, instead of the much more limited iniquity defence.[85]

29.70 McBratney and others commented that, in practice, the cost and time taken to develop genetic inventions usually means that the investors will require much more certainty than trade secrets law could provide. They discussed the potential advantages and disadvantages of trade secrets protection of genetic inventions:

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82 B Arnold and E Ogielska-Zei, 'Patenting Genes and Genetic Research Tools: Good or Bad Innovation?' (2002) *Annual Review of Genomics and Human Genetics* 415, 419.

83 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

84 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 16–3.

85 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

> There are three major attractions of protecting an invention by trade secrecy or the law of confidence: (i) it is free; (ii) its protection is potentially perpetual; and (iii) it may allow sufficient time for certain 'enabling experiments' to be conducted to adequately protect the invention via patenting. However, on balance these advantages do not outweigh the disadvantages, except in special circumstances where delaying publication may provide competitive advantage to the incumbent or when 'enabling experimentation' may be required to fairly base the invention.[86]

29.71 McBratney and others commented that although keeping an invention secret appears to be 'free', there is a very real cost involved. In order to protect the trade secret in court the inventor must be able to show that the information was confidential; that sufficient steps were taken to prevent that information from entering the public domain; and that the information is adequately defined. They suggested that it may be necessary to implement various mechanisms to achieve secrecy, such as marking documents; training employees; and implementing physical, technical or contractual barriers to prevent unauthorised personnel from obtaining the information. They noted that:

> probably the most significant disadvantage of protecting an invention by trade secrecy is that the law of confidence does not provide the inventor with any property rights. If the inventor takes their invention to market and others who owe no duty of confidence can copy or reverse engineer it freely, in the absence of other intellectual property protection or causes of action the inventor has no recourse against the free-rider. Even contractual obligations of confidence may not assist the inventor if the provisions have been drawn too broadly.[87]

29.72 The Queensland Government also noted some of the shortcomings with trade secrets protection, being that:

> trade secrets do not provide protection that is certain. In contrast to patents, once the substance of the trade secret is revealed, the owner has no real recourse in relation to the material or a right that can be asserted against others. Therefore, generally, industry prefers to patent intellectual property rather than maintaining it as a trade secret.[88]

29.73 Several submissions suggested that trade secrets law has only a very limited application to genetic research and its commercialisation, and therefore does not require reform.[89] AusBiotech Ltd submitted that:

> Because of the difficulty in maintaining trade secrets, particularly in relation to living material, which is readily replicated, most innovations in the biotechnology field are protected via patents. Consequently confidentiality is essential only until a patent application has been lodged. The patent application will automatically be published eighteen months after its priority date, unless it is explicitly withdrawn beforehand.

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86 A McBratney and others, *Submission P47*, 22 October 2003.

87 Ibid.

88 Queensland Government, *Submission P57*, 5 January 2004.

89 For example, Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

> Moreover, the inability to enforce a trade secret against a third party who develops the invention independently is a further limitation on trade secret protection in the highly-competitive biotechnology field.[90]

29.74 Several submissions and consultations suggested that any attempt to weaken this area of law would result in a greater amount of information being kept out of the public domain.[91] For example, the Walter and Eliza Hall Medical Research Institute submitted that:

> The use of trade secrets law and confidentiality agreements allows parties to negotiate agreements prior to the patent being awarded (if the information is not in the public domain). Weakening of this protection would simply delay development until the patent is awarded and would not be in the public interest.[92]

29.75 GlaxoSmithKline submitted that trade secrets law applies to genetic research and its commercialisation in the same way as to any other field of technology:

> So, for example, a patent owner of a mechanical device will often make adjustments to its manufacturing process over time to improve the efficiency of the manufacturing process or to improve the quality of the marketed product. Depending on the nature of the improvements and the priorities of the patent owner, those improvements may be patented or may be kept secret (and thus subject to trade secrets law). Exactly the same applies in the field of genetic research.[93]

ALRC's views

29.76 The ALRC recognises that trade secrets protection, and 'know-how' licensing, play an important part in research and development in Australia. In the interests of fostering future research it is important to strike an appropriate balance between the need to protect research results prior to—or as an alternative to—patent protection, and the need to ensure that important research information becomes publicly available for use by other researchers.

29.77 Most of the submissions stated that there was no need to reform trade secrets law in relation to genetic materials and technologies. However, ACIPA proposed broadening the defences to a claim of infringement of trade secrets, for example through a general public interest defence.[94] While the existing defences to infringement arise in the common law, such expansion presumably would take statutory form. The ALRC notes the caution expressed by Lahore and Dufty about such an approach:

> [If] a breach of confidence is permitted simply because the court considers that there is something unsavoury about the plaintiff's conduct and that the public is entitled to have details of it, the action for breach of confidence will be significantly changed.

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90 AusBiotech Ltd, *Submission P58*, 7 November 2003.

91 For example, Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003.

92 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

93 GlaxoSmithKline, *Submission P33*, 10 October 2003.

94 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

> The balance of public interest which traditionally favoured the protection of information disclosed in confidence, will be tipped in favour of disclosure unless the court can find nothing objectionable in the plaintiff's case.[95]

29.78 As the ALRC has not heard any significant problems with the application of trade secrets law in relation to genetic materials and related technologies, at this stage it does not consider it necessary to propose any reform of the common law public interest defence, or to the applicaton of trade secrets law generally. Chapters 26 and 27 discuss the possibility of amending the *Patents Act 1990 (Cth)* to include the know-how necessary to work a patented invention within the scope of the Crown use and compulsory licensing provisions.

Designs

29.79 Design registration is another form of intellectual property right that may apply to genetic research. The purpose of the industrial designs system is to encourage innovation by giving designers the exclusive right to exploit their designs for a limited time and prevent competitors free-riding on their design innovations.[96]

29.80 The industrial designs registration system protects the appearance of articles, rather than their function. In contrast, the patent system grants exclusive rights relating to devices, substances, methods or processes that have a use or function. Therefore, articles that are innovative because of their visual appearance would qualify for protection under the designs registration system, rather than the patent system.[97]

29.81 IP 27 noted suggestions that design protection might be useful in product development in the biotechnology field, for example by protecting the distinctive appearance of products such as genetic diagnostic kits and analytical tools.[98]

Current law and practice

29.82 The *Designs Act 1906* (Cth) currently regulates the industrial designs registration system in Australia. This Act is in the process of being repealed and replaced by new legislation which implements the Australian Government's response to the ALRC's report, *Designs* (ALRC 74).[99]

29.83 The *Designs Act 2003* (Cth) (new *Designs Act*) and *Designs (Consequential Amendments) Act 2003* (Cth) received Royal Assent on 17 December 2003 and will commence operation upon proclamation or, at latest, by 17 June 2004. The new *Designs Act* will replace the existing Act with a new designs registration system.

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95 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [39,190].
96 Revised Explanatory Memorandum to the Designs Bill 2003 (Cth), 2.
97 Ibid, 2.
98 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), 256–257.
99 Australian Law Reform Commission, *Designs*, ALRC 74 (1995).

29.84 The main changes that will be effected by the new *Designs Act* are:

- higher threshold for obtaining registration;
- broader infringement test;
- more streamlined registration process;
- reduced term of registration from 16 to 10 years; and
- amended enforcement and dispute resolution procedures.[100]

29.85 The new *Designs Act* defines a 'design' in relation to a product, as the overall appearance of the product resulting from one or more visual features of the product.[101] A 'product' includes a thing that is manufactured or handmade, and a component part of a complex product, if it is made separately from the product.[102] A 'visual feature' includes the shape, configuration, pattern and ornamentation of the product. It may, but need not, serve the functional purpose.[103]

29.86 A design is registrable if it is new and distinctive when compared with the prior art base for the design, as it existed before the design's priority date. The prior art base consists of designs publicly used in Australia, and published in a document within or outside Australia.[104]

29.87 The owner of a registered design has the exclusive right, during the term of registration, to: make (or offer to make) a product, in relation to which the design is registered, which embodies the design; import such a product into Australia for sale, or for use for the purposes of any trade or business; sell, hire or otherwise dispose of (or offer to do so) such a product; use such a product in any way for the purposes of any trade or business; keep such a product for specified purposes; and authorise another person to do any of these things.[105]

29.88 Generally, a person infringes a registered design if, without appropriate authority, the person deals in certain ways with a product that embodies the design, or a design that is substantially similar to it.[106]

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100 See Revised Explanatory Memorandum to the Designs Bill 2003 (Cth), 1.
101 *Designs Act 2003* (Cth) s 5.
102 Ibid s 6.
103 Ibid s 7(1), (2).
104 Ibid s 15. The prior art base for a design also consists of designs in relation to which each of the following criteria is satisfied: the design is disclosed in a design application; the design has an earlier priority date than the designated design; and the first time documents disclosing the design are made available for public inspection is on or after the priority date of the designated design.
105 Ibid s 10(1).
106 Ibid s 71.

Application to genetic research

29.89 While the potential application of designs registration to genetic materials appears somewhat limited, it could be useful in certain biotechnology product development, for example by protecting the distinctive appearance of diagnostic kits and analytical tools.

29.90 Design protection (as with patent protection) is unlikely to cover naturally occurring DNA or protein sequences. Such a sequence represents a set of nucleotides in their naturally occurring state. The shape or configuration that these make is determined by principles of chemistry, not through any innovation on the part of the scientist. However, commentators in the United Kingdom have suggested that recombinant genetic or protein sequences may be eligible for design protection in that jurisdiction where there has been some creation of shape or configuration.[107]

29.91 Microarrays, diagnostic kits and analytical tools are genetic products that could potentially be eligible for designs registration. Although the underlying function might be patentable, the visual appearance of the product may be commercially valuable and may therefore warrant design protection.

Submissions and consultations

29.92 IP 27 asked whether the existing or proposed design laws have any significant application to the conduct of genetic research and its commercialisation; and if so, whether these laws require reform.[108]

29.93 Most of the submissions that addressed this question suggested that design laws would have not have any significant application to the conduct of genetic research and its commercialisation.[109] The South Australian Government suggested that although design law is unlikely to apply to genetic material, it could possibly apply to diagnostic kits or analytic tools:

> The requirements for registration under the *Designs Act 1906* (Cth) are that the design must be new or original and must be applied to an article. Genetic material does not readily meet the criteria for design registration. It may apply to provide protection to diagnostic kits or analytic tools. However the requirement that a design be different from a design that is already registered and is not an obvious adaptation of an existing design may mean that many standard genetic tests do not meet the criteria for design registration.[110]

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107 H Laddie and others, *The Modern Law of Copyright and Designs* (3rd ed, 2000), 1751.

108 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 16–4.

109 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; IP Australia, *Submission P56*, 4 November 2003; Queensland Government, *Submission P57*, 5 January 2004.

110 South Australian Government, *Submission P51*, 30 October 2003.

29.94 Finally, ACIPA submitted that 'it would be inapposite to apply the registration system of Australian designs law to deal with biological inventions'.[111]

ALRC's views

29.95 The ALRC recognises that there may be some potential application for designs registration in relation to genetic materials and technologies. It has been suggested that such protection could extend to the visual appearance of modified genetic or protein molecules, and genetic technologies such as microarrays and diagnostic tests. As the ALRC has not heard any concerns arising from the potential application of designs law in this context, it does not propose any reforms in this area.

111 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

30. Protection of Genetic Databases

Contents

Introduction

30.1 This chapter discusses the various means by which owners of genetic databases may seek to protect their investment in those databases, and considers whether reform is necessary to ensure reasonable third party access to these databases for the purpose of scientific research.

Genetic research databases

30.2 Genetic databases may hold compilations of the sequences of the human genome or other genomes—including whole genomes, single genes and gene fragments, such as single nucleotide polymorphisms (SNPs) and expressed sequence

tags (ESTs)—or information about the biochemical pathways related to the expression of genes.[1]

30.3 In recent years, there has been a proliferation of both public and private databases created for use in scientific research. They have become essential for research biologists because:

> First, the increasing rate of discovery and the increasingly varied publication options make it difficult for scientists to keep abreast of new knowledge. Second, most of the new scientific data, such as [a] nucleic acid sequence, is no longer being published by conventional means, such as in scholarly journals. Third, an electronic cataloguing of the sequence information within a database facilitates the emerging need for computational analysis of genetic information.[2]

30.4 Genetic databases may be compiled by academic or government institutes, or by biotechnology or pharmaceutical companies.[3] Access may be free, or it may be subject to a price. Database owners have sought to protect and commercially exploit their genetic databases through a variety of means, including copyright and contract law.[4]

Public databases

30.5 One of the features of public genomic research has been the creation of public or quasi-public databases to make genomic information widely and rapidly available. Public funding of the sequencing of the human genome was predicated on the public availability of the data, although it was expected that patents would be sought for products derived from such public genomic information.

30.6 Internationally, publicly available databases include the International Human Genome Sequencing Consortium; the Mammalian Gene Collection; the International Nucleotide Sequence Database Collaboration; the SNP Consortium; and the International HapMap Project.

30.7 The Wellcome Trust—the world's largest biomedical research funding charity—is a source of funding for the creation of some databases, particularly in the United Kingdom. GenBank is the United States National Institutes of Health (NIH) genetic sequence database. It provides access to all publicly available genetic sequences, but does not guarantee that all the information it provides is free from

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1 E Baba, 'From Conflict to Confluence: Protection of Databases Containing Genetic Information' (2003) 30 *Syracuse Journal of International Law and Commerce* 121, 128–132.

2 Ibid, 127.

3 Ibid, 124.

4 Database owners also protect their databases through trade secrets laws: see Ch 29 for more information. In addition, the Australian Centre for Intellectual Property in Agriculture's submission stated that biotechnology firms also have applied for patents over databases of genetic information: Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

patent, copyright or other intellectual property claims. The NIH also has a program to develop a library of clones of all human genes.[5]

30.8 The SNP Consortium Ltd (known as TSC) is a non-profit foundation that was established to provide a public resource of single nucleotide polymorphisms SNPs in the human genome. The TSC comprises academic institutions, biomedical, pharmaceutical and biotechnology companies, and the Wellcome Trust. The TSC has stated that it will file patent applications solely to establish the relevant date of the discovery and it will not allow any patents to issue. However, it notes that discoveries made using the data could be patented.[6]

30.9 The International HapMap Project was established to develop a haplotype map of the human genome, which will also be placed in the public domain. The HapMap will describe the common patterns of human DNA sequence variation to assist researchers to identify genes affecting health, disease and responses to drugs and environmental factors. Once SNPs have been genotyped densely enough to define regions of strong association, the haplotypes, individual genotypes, and tag SNPs in those regions will be released publicly without restriction. Before this, the individual genotype data will be made available under a 'data access policy', under which users must agree not to reduce others' access to the data, and to share the data only with those who have made the same agreement.[7]

Private databases

30.10 Private genetic databases have also been established. A feature of the private databases is that access comes at a price. Their attraction lies in the additional information that they contain—that is, the annotations that have been added to the sequence information.

30.11 In June 2000, the National Health and Medical Research Council (NHMRC) negotiated a three-year agreement between the Australian Government and Celera Genomics to provide Australian researchers with subsidised access to five of Celera's databases, including its Human Genome Database, Human Gene Index and Human SNP Reference Database. Access was available for publicly funded researchers, including those with Australian Research Council (ARC) funding, and other publicly funded bodies such as the Commonwealth Scientific and Industrial Research

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5 However, one writer has argued that the United States Government and those who use some of the clones may be infringing patents over specific genes: J Merz, 'A Note from the Editor' (2002) 10(3) *PennBioethics* 1, 1.

6 SNP Consortium Ltd, *The SNP Consortium: Frequently Asked Questions*, <http://snp.cshl.org/about/faq.shtml> at 10 April 2003.

7 The HapMap is a collaboration among scientists in Japan, the United Kingdom, Canada, China, Nigeria and the United States: *International HapMap Project*, <www.hapmap.org/abouthapmap.html> at 25 November 2003.

Organisation (CSIRO). Each participating institution paid an annual licence fee based on the number of teams wanting database access and which databases they required. [8]

30.12 The NHMRC recently negotiated a new three-year academic subscription agreement on behalf of Australian researchers, which commenced operation on 1 July 2003. The NHMRC is no longer involved in the administration of the new agreement. Instead, the Applera Corporation (through its Applied Biosystems Group)[9] administers all subscriptions directly with individual users and institutions. Subscription fees under the new agreement are US$2,000 per annum for each individual user per database.[10]

30.13 The Australian Genomic Information Centre operates the Australian National Genomic Information Service (ANGIS), which provides access to a comprehensive system of bioinformatics databases, software, documentation, training and support. This includes Internet-based access to various publicly available nucleotide, protein, structure and reference databases, and other services.[11]

30.14 Access to ANGIS is based on a yearly fee. Academic pricing is available to universities and non-government not-for-profit organisations, including hospitals. Government pricing is available to federally and state funded organisations and institutions. Subscription fees are charged at a base rate for the first 15 users, and an additional rate for each additional group of 50 users, being: $1,300/$1,300 (academics); $3,000/$1,500 (government); and $5,000/$2,500 (commercial).[12]

Protection of rights in genetic databases

30.15 The creation of databases of genetic information has highlighted the tensions between the need to provide sufficient incentive and protection for investment to encourage the creation of new databases for use in research, and the need to facilitate researchers' access to such data on reasonable terms, to advance scientific knowledge.[13]

Copyright protection

30.16 The *Copyright Act 1968* (Cth) (*Copyright Act*) regulates copyright in Australia in relation to original literary, dramatic, musical and artistic works, and 'subject matter

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8 See generally D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 351.

9 The Celera Genomics group and Applied Biosystems group are both part of the Applera Corporation: see <www.applera.com> at 13 February 2004.

10 National Health and Medical Research Council, *About Celera and NHMRC Celera Subscription*, <www.nhmrc.gov.au/research/special/celdesc.htm> at 10 December 2003.

11 Australian Genomic Information Service, *About ANGIS*, <www.angis.org.au/new/about/index.html> at 12 December 2003. The Australian Genomic Information Centre operates ANGIS with funding from subscriptions, and NHMRC and ARC grants.

12 Australian Genomic Information Service, *Subscription and Costs*, <www.angis.org.au/new/about/subscription.html> at 12 December 2003. These prices are exclusive of goods and services tax.

13 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 23.

other than works'. Chapter 29 discussed Australian copyright law in detail and noted its relevance particularly to genetic databases.

30.17 As discussed in Chapter 29, in order to attract copyright, a 'work' must be a literary, dramatic, musical, or artistic work, and it must be 'original'. A literary work need not display literary merit, but is usually intended to convey information and instruction, or pleasure, in the form of literary enjoyment.[14] The work need not be the expression of original or inventive thought, but it must originate with an author and must not be a copy. A work originates with an author if it is the product of the author's skill, labour and expertise or experience. The requisite degree of labour, skill and expertise will depend on the facts of the case and will be a question of degree.[15]

30.18 In Australia, the Full Federal Court has held that originality can flow purely from the 'sweat of the brow' involved in collecting, verifying and presenting information in a compilation of facts, even if there is no creativity involved in its selection or arrangement.[16] In *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd*, the court held that copyright subsists in Telstra's telephone directory, as an original literary work. Lindgren J stated that a factual compilation will be original if the compiler has exercised sufficient labour and expense in collecting, verifying, recording and assembling the information.[17] Sackville J stated that a factual compilation will be original if the compiler has undertaken substantial labour or incurred substantial expense in collecting the information recorded in the compilation.[18] The High Court refused special leave to appeal against this decision.[19]

30.19 Therefore, in Australia copyright may subsist in a database of factual information on the basis of the 'sweat of the brow' involved in obtaining and compiling the information, as well as the selection and arrangement of the information. In addition, copyright may subsist in the individual items contained within the database. The Commonwealth Attorney-General's Department submitted that:

> The consequence of the decision in *Desktop Marketing v Telstra* is that raw data, including raw data that may only be represented in one particular way, will be subject to protection under the *Copyright Act 1968*, at least where substantial independent skill, labour and effort have been used to compile the data. This would cover most, if not all, databases in existence in Australia.[20]

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14 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 42–44, citing *Hollinrake v Truswell* [1894] 3 Ch 420.

15 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [7.50], [7.60].

16 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433. See also J Lahore, *Copyright and Designs: Looseleaf Service* (1996), [10,065], [10,115].

17 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474.

18 Ibid, 532–533.

19 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (Unreported, High Court of Australia, Hayne and Callinan JJ, 20 June 2003).

20 Attorney-General's Department, *Submission P61*, 11 November 2003.

30.20 The Australian approach to originality has been criticised: as amounting to protection of the information and facts contained in a work, rather than the form of expression of the work; for preventing 'second comers' from building on ideas; and for potentially conflicting with competition law.[21]

Contract and other protection

30.21 As discussed in Chapter 29, the *Copyright Act* provides that certain acts of fair dealing with a copyright work constitute exceptions to infringement of copyright. One such exception is fair dealing for the purpose of research or study.[22] Several commentators have suggested that, where database owners use contract law to restrict access to a database, this could override the fair dealing exceptions applying in copyright law.[23]

30.22 Online databases frequently have technological protection measures[24] to restrict or control access to, or copying of, their contents. Examples of such measures are encryption, password protection, or 'read only' technology.[25] Generally, access is permitted on individual contractual terms, either by a written licence agreement or a click-through agreement on the website.[26] In practice therefore, while a scientific researcher may have a legal right to reproduce information held in a genetic database for fair dealing purposes, the database owner could nonetheless block physical access to its contents, or limit access or copying subject to contractual terms.

30.23 This could thwart the policy behind the fair dealing provisions and may give a database owner effective control over the data and information beyond his or her legal entitlement.[27] According to Associate Professor Mark Davison:

> Increasingly, the contract providing for access to a database dictates the relationship between the owner and user, rather than laws concerning databases. This is particularly the case in a digital environment, where technological devices can be

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21 S Givoni, 'Pushing the Boundaries of Copyright: Protection of Databases' (2003) 15 *Intellectual Property Law Bulletin* 8, 15. See Ch 24 for more information about the interaction between intellectual property and competition law.

22 *Copyright Act 1968* (Cth) s 40(1).

23 For example, Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 24; see also the discussion in Phillips Fox, *Digital Agenda Review: Circumvention Devices and Services, Technological Protection Measures and Rights Management Information: Issues Paper* (2003) Paper prepared for the Commonwealth Attorney-General's Department; Copyright Law Review Committee, *Copyright and Contract* (2002).

24 Under the *Copyright Act*, a 'technological protection measure' is a device or product, or a component incorporated into a process, that is designed to prevent or inhibit the infringement of copyright in a work by ensuring that access to the work is only available by use of an access code or process with the copyright owner's authority; or through a copyright control mechanism: *Copyright Act 1968* (Cth) s 10(1).

25 E Dellit and C Kendall, 'Technological Protection Measures and Fair Dealing: Maintaining the Balance between Copyright Protection and the Right to Access Information' (2003) 4 *Digital Technology Law Journal* 1, 17.

26 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 24.

27 Ibid, 24.

> used to prevent access to anyone who has not formed a contractual relationship with the owner.[28]

30.24 In practice, a researcher or other individual could use a circumvention device to avoid the effect of a technological protection measure. Under the *Copyright Act*, a 'circumvention device' is a device (including a computer program) that has only a limited commercially significant purpose or use, or no such purpose or use, other than the circumvention, or facilitating the circumvention, of a technological protection measure.[29]

30.25 While the *Copyright Act* does not prohibit the use of circumvention devices, s 116A prohibits the making, importing, selling, distribution and promotion of such devices and services, subject to certain 'permitted purposes'.[30] The 'permitted purposes' under s 116A do not include fair dealing. Therefore, while it might be lawful for an individual to use a circumvention device to access and reproduce copyright works for the purpose of fair dealing for research or study, it would be difficult to obtain such a device within Australia for this purpose.[31]

30.26 In addition it has been suggested that database owners could use contractual arrangements to prevent the use of a circumvention device to gain access to copyright works for the purpose of fair dealing.[32]

30.27 The Intellectual Property and Competition Review Committee (IPCRC) considered the regulation of circumvention devices in its report, *Review of Intellectual Property Legislation under the Competition Principles Agreement*. The IPCRC noted that some copyright owners had increased the use of technological means to 'lock up' works, for example by relying on encryption devices. It concluded that:

> The Committee is broadly satisfied that the Government's approach to the issues associated with technological protection measures preserves a reasonable balance between competing interests. However, we would be concerned if the use of

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28 M Davison, *The Legal Protection of Databases* (2003), 11.

29 *Copyright Act 1968* (Cth) s 10(1). In addition, a 'circumvention service' means a service, the performance of which has only a limited commercially significant purpose, or no such purpose or use, other than the circumvention, or facilitating the circumvention, of a technological protection measure.

30 Ibid s 116A. This provision reflects art 11 of the *WIPO Copyright Treaty*, which provides that member states must provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors in connection with the exercise of their rights, and that restrict acts in respect of their works, which are not authorised by the authors concerned or permitted by law: *WIPO Copyright Treaty*, 20 December 1996, WIPO/CRNR/DC/94.

31 Phillips Fox, *Digital Agenda Review: Circumvention Devices and Services, Technological Protection Measures and Rights Management Information: Issues Paper* (2003) Paper prepared for the Commonwealth Attorney-General's Department, 23.

32 Ibid, 27. This issues paper was released as part of the Commonwealth Attorney-General's Department's review of the operation of the *Copyright Amendment (Digital Agenda) Act 2000* (Cth) and aspects of the *Copyright Amendment (Computer Programs) Act 1999* (Cth). The review is due to report to the Attorney-General of Australia in 2004.

> technological locks, perhaps accompanied by greater reliance on contract, were to displace or in any way limit the effectiveness of fair dealing provisions.[33]

30.28 The Copyright Law Review Committee (CLRC), in its report, *Copyright and Contract*, considered the extent to which trade in copyright material is subject to contracts that purport to exclude or modify the copyright exceptions. The CLRC found that contracts have been used to exclude or modify the copyright exceptions in Australia, and that overseas contracts that purport to do so may be indicative of norms of behaviour in the e-marketplace.[34]

30.29 The CLRC considered that it would be impractical to expect copyright users to assume the risk of expensive litigation to maintain the copyright exceptions where individual contracts purport to exclude or modify them. In its view, risk management practices would, more often than not, dictate that organisations simply refrain from exercising the exception or pay for the right to use copyright material, even though they may be entitled to that use under the *Copyright Act*.[35]

30.30 In order to maintain an appropriate balance between the rights of copyright owners and the rights of copyright users, the CLRC recommended that the *Copyright Act* be amended to provide that an agreement (or a provision of an agreement) that excludes or modifies the operation of certain statutory provisions—including the fair dealing provisions—has no effect.[36] The Australian Government has not yet implemented this recommendation.

30.31 The Australian Copyright Council has expressed opposition to this recommendation for several reasons. In particular, the Council has queried the CLRC's view that a contractual provision that may be inconsistent with the application of an exception to copyright infringement is necessarily unfair.[37] By contrast, the United Kingdom's Royal Society has expressed support for the CLRC's recommendation, and has recommended that copyright and database laws in that jurisdiction be changed to prevent the possibility of contract overriding exceptions to infringement.[38]

30.32 An alternative approach might be to amend s 116A of the *Copyright Act* to expand the list of 'permitted uses' for which a circumvention device or service may be imported, made, sold or distributed and so on in Australia, to include fair dealing for the purpose of research or study. This would permit scientific researchers to obtain circumvention devices within Australia for use for fair dealing purposes. However, this

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33 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 100–101.

34 Copyright Law Review Committee, *Copyright and Contract* (2002), [7.03].

35 Ibid, [7.13].

36 Ibid, [7.49].

37 Australian Copyright Council, *Response to Report of Copyright Law Review Committee on Copyright and Contracts* (2003), 3.

38 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 24.

would not protect against copyright owners using contract to prevent the use of these devices; and it could facilitate copyright infringement if individuals were to obtain such devices for purposes other than fair dealing.

30.33 The ALRC notes that the Commonwealth Attorney-General's Department is currently dealing with this matter in its review of the *Copyright Amendment (Digital Agenda) Act 2000* (Cth) which is due to report to the Attorney-General in 2004. The ALRC did not canvass these issues in IP 27, and has not received any significant comment on them. However, as issues of access to genetic research and data are directly relevant to this Inquiry, the ALRC seeks further views on this matter.

30.34 Accordingly, the ALRC asks whether the Commonwealth should amend the *Copyright Act* to provide that, in relation to genetic databases protected by copyright, the operation of the fair dealing for the purpose of research or study provisions must not be excluded or modified by contract or technological protection measures. While the issue may be relevant to all copyright works, the ALRC has confined the question to genetic information in accordance with the Terms of Reference.

Question 30–1 Should the Commonwealth amend the *Copyright Act 1968* (Cth) to provide that, in relation to genetic databases protected by copyright, the operation of the provisions for fair dealing for the purpose of research or study must not be excluded or modified by contract or technological protection measures?

Other jurisdictions

United States

30.35 In the United States, the legal protection of databases is based on copyright, the tort of misappropriation and contract.[39] The United States has rejected the 'sweat of the brow' approach to originality in copyright law. It extends copyright protection only to those factual compilations that display a degree of creativity, and can therefore be considered intellectual creations.[40]

30.36 In *Feist Publications Inc v Rural Telephone Service*, the United States Supreme Court held that a white pages telephone directory was not sufficiently original to attract copyright protection. The Supreme Court noted that copyright did not subsist in the individual telephone book entries, but could subsist in an original selection, co-

39 M Davison, *The Legal Protection of Databases* (2003), 160.
40 Ibid, 15.

ordination or arrangement of these facts provided this involved independent creation and a minimum degree of creativity.[41]

30.37 In the absence of copyright protection, database owners tend to protect their investment through other measures including licensing arrangements, contract and technological protection measures.[42] Since 1996, several bills have been introduced into Congress to create a form of *sui generis* protection for databases or collections of information, however none of these has been implemented.[43]

30.38 On 8 October 2003, the Database and Collection of Information Misappropriation Bill 2003 (HR 3261) was introduced into the House of Representatives. If passed through both Houses, this Bill would impose substantial civil penalties on anyone who made available 'in commerce' a 'quantitatively substantial' part of an existing database or information collection.[44]

European Union

30.39 In 1996, the European Parliament and Council of the European Union (EU) adopted a directive on the legal protection of databases (Database Directive).[45] The purpose of the Directive was to harmonise copyright law among EU member states in relation to original databases; and to introduce a new database right to protect non-original databases, or factual compilations, which were not protected by copyright in most member states.

30.40 The Database Directive defines a 'database' as a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means.[46] Chapter II of the Directive deals with copyright protection for databases that, by virtue of the selection or arrangements of their contents, constitute the author's own intellectual creation. Copyright protection does not extend to the database contents, and does not affect any rights subsisting in those contents.[47]

30.41 Chapters I and IV of the Directive provide for a *sui generis* database right that applies to databases for which the owner has made a substantial investment—either quantitatively or qualitatively—in obtaining, verifying or presenting the contents of the

41 *Feist Publications Inc v Rural Telephone Service* 499 US 340 (1991). See also E Baba, 'From Conflict to Confluence: Protection of Databases Containing Genetic Information' (2003) 30 *Syracuse Journal of International Law and Commerce* 121, 134–135.

42 Attorney-General's Department, *Submission P61*, 11 November 2003.

43 M Davison, *The Legal Protection of Databases* (2003), 213.

44 Attorney-General's Department, *Submission P61*, 11 November 2003.

45 *Directive 96/9/EC of the European Parliament and of the Council on the Legal Protection of Databases*, (entered into force on 11 March 1996).

46 Ibid art 1(2).

47 Ibid art 3(2).

database. The Directive prohibits the unauthorised extraction[48] and/or re-utilisation[49] of the whole or a substantial part of the database contents, whether evaluated quantitatively or qualitatively.[50] The term of protection is 15 years, which may be extended by a substantial change—in qualitative or quantitative terms—to the database contents.[51]

30.42 The Database Directive permits three different sets of rights in relation to a database. First, copyright may subsist in the structure of the information in a database; that is, the selection and arrangement of the database. Second, copyright may subsist in the individual items constituting the database contents. Third, the database right may protect the contents of the database.[52]

30.43 The Database Directive contains several exceptions to both copyright and the database right.[53] This includes a limited form of fair dealing provision that permits the extraction of database contents for the purpose of illustration for teaching or scientific research, to the extent justified by the non-commercial purpose to be achieved.[54]

30.44 European courts have been asked to interpret several provisions of the Database Directive including the meaning of a 'database', the 'substantiality' of the investment required to attract the right, the status of the database 'maker',[55] and the test of infringement.[56] According to Professor Bernt Hugenholtz:

> [I]t is far too early to draw conclusions, except, perhaps, that non-European countries contemplating the introduction of a database right or similar regime would be well advised to wait and see—*wait* until the European Court of Justice has had the opportunity to clarify the key notions of the Directive; and *see* if what ensues is beneficial to the information industry, and in the public interest.[57]

30.45 The protection provided by the database right may be higher than copyright protection in several ways. First, the protection is potentially perpetual. While the database right lasts for 15 years only, it may be renewed whenever there is a substantial

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48 'Extraction' is defined as the permanent or temporary transfer of all or a substantial part of the contents of a database to another medium by any means or in any form: Ibid art 7(2)(a).

49 'Re-utilisation' is defined as any form of making available to the public all or a substantial part of the contents of a database by the distribution of copies, by renting, by online or other forms of transmission: Ibid art 7(2)(b).

50 Ibid art 7(1).

51 Ibid art 10.

52 M Davison, *The Legal Protection of Databases* (2003), 50–51.

53 *Directive 96/9/EC of the European Parliament and of the Council on the Legal Protection of Databases*, (entered into force on 11 March 1996) art 6, 9.

54 Ibid, art 6(2)(b), 9(b).

55 B Hugenholtz, *The New Database Right: Early Case Law from Europe* (2001) Ninth Annual Conference on International IP Law & Policy, Fordham University School of Law, New York, 3.

56 M Davison, *Report on the Protection of Databases* (2002), 9–10.

57 B Hugenholtz, *The New Database Right: Early Case Law from Europe* (2001) Ninth Annual Conference on International IP Law & Policy, Fordham University School of Law, New York, 9.

change in the database contents. Second, the extraction of small amounts of data over time is prohibited where those small amounts together constitute a substantial taking.[58]

30.46 Third, the exceptions to the database right are more limited than those available under Australian copyright law. For example, the directive provides that the database may be used for the purpose of 'illustration' for teaching and scientific research, but does not define this term; and, unlike the fair dealing provisions applying to Australian copyright, it is specifically limited to non-commercial purposes.[59] Davison has commented that:

> Many teaching and research institutions have a commercial aspect of their operations, partly in response to reductions in public funding. The potential for a mix of commercial and non-commercial purposes for which teaching or research may be undertaken has dramatically increased as a result.[60]

30.47 The Database Directive provides that the EU may conclude agreements to extend the database right to databases made in third countries, such as Australia.[61] It appears that protection will be offered only on the basis of reciprocity; that is, where the third country offers comparable protection to the database right.[62]

30.48 The United Kingdom's Royal Society has concluded that the database right is inappropriate for scientific data and has recommended that it be repealed or substantially amended.[63] The Human Genome Organisation's (HUGO) Ethics Committee has recommended that the Database Directive be amended to provide for compulsory licensing of access to genetic databases under certain conditions, such as a public health emergency.[64]

International treaties

30.49 The *Berne Convention for the Protection of Literary and Artistic Works 1886* (Berne Convention) and the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement) provide copyright protection for collections of works, including compilations of data.[65]

30.50 In 1996, the World Intellectual Property Organization (WIPO) adopted the *WIPO Copyright Treaty*, which extends copyright protection to compilations of data or

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58 Attorney-General's Department, *Submission P61*, 11 November 2003.
59 M Davison, *The Legal Protection of Databases* (2003), 79–80.
60 Ibid, 80.
61 *Directive 96/9/EC of the European Parliament and of the Council on the Legal Protection of Databases*, (entered into force on 11 March 1996) art 11(3).
62 Ibid recital 56.
63 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 27.
64 H Pearson, 'Human Genome Organisation Meeting, Cancun, Mexico, April 2003: Database Free for All', *Nature*, 30 April 2003, <www.nature.com/nsu/030428/030428-10.html>.
65 *Berne Convention for the Protection of Literary and Artistic Works* (1886); *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

other material that, by reason of the selection or arrangement of their contents, constitute intellectual creations.[66] Australia has not yet signed this treaty.

30.51 WIPO has also considered adopting a draft treaty that would create a special protection regime similar to that provided in the Database Directive. To date, the treaty has not been adopted.[67] However, database protection remains on the agenda of the WIPO Standing Committee on Copyright and Related Rights.[68] The Commonwealth Attorney-General's Department's submission commented that:

> The issue of database protection remains outstanding, and although it remains on the agenda for the international intellectual property community, no consensus is likely to be reached until the United States makes a firm commitment either way.[69]

International principles

30.52 Specific concerns have been expressed about the possible impact of intellectual property laws on access to information about the human genome. A number of international initiatives have sought to overcome some of these concerns.

The Bermuda Principles

30.53 The Bermuda Principles are a set of principles that seek to ensure that genomic sequence data is made as freely available as possible. The principles were established in 1996 at an International Strategy Meeting on Human Genome Sequencing,[70] and endorsed in Bermuda the following year. The Bermuda Principles state that:

- primary genomic sequences should be in the public domain;
- primary genomic sequences should be rapidly released; and
- HUGO should be advised of large-scale sequencing of particular regions of the genome.[71]

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66 *WIPO Copyright Treaty*, 20 December 1996, WIPO/CRNR/DC/94.

67 E Baba, 'From Conflict to Confluence: Protection of Databases Containing Genetic Information' (2003) 30 *Syracuse Journal of International Law and Commerce* 121, 145–146. See also World Intellectual Property Organization, *Draft Treaty on Intellectual Property in Respect of Databases* (1996).

68 Attorney-General's Department, *Submission P61*, 11 November 2003.

69 Ibid.

70 Those taking part in the meeting included the Wellcome Trust, the United Kingdom Medical Research Council, the United States National Centre for Human Genome Research, the United States Department of Energy, the German Human Genome Program, the European Commission, the HUGO and the Human Genome Project of Japan: Wellcome Trust, *Genome Data Release*, <www.wellcome.ac.uk/en/1/awtvispoldat.html> at 10 April 2003.

71 The Principles noted that some data would be released on a daily basis and other data, as soon as sequencing was finished: Wellcome Trust, *Summary of Principles Agreed at the International Strategy Meeting on Human Genome Sequencing*, University College London, <www.gene.ucl.ac.uk/hugo/bermuda.htm> at 10 April 2003.

HUGO Statement

30.54 In December 2002, HUGO's Ethics Committee released a *Statement on Human Genomic Databases*, which declared there was a need to place primary genomic sequences rapidly in the public domain. The Statement also recognised the potential global good arising from genetic research; the scientific and clinical uses of genomic databases; the potential for conflicts between the free flow of information that is crucial to research advances and the legitimate rights to return from research expenditure; and the potential risk of misusing genetic data.[72]

Issues and problems

30.55 The legal protection of genetic databases raises significant policy considerations. Limiting access to, and the use of, such information can stifle potentially useful scientific research. However, it is also necessary to provide sufficient incentive for a database owner to collect and arrange the data, and to make it available for use in scientific research.

30.56 As genetic databases are protected by a mixture of copyright and contract law in Australia, third party researchers who seek access to the database contents would generally need to negotiate a licence with the database owner. As noted above, even if the proposed use falls within the scope of fair dealing for the purpose of research or study, the researcher could be barred from physically accessing the database contents if they are protected by technological protection methods.

30.57 If a database owner refuses researchers access to the database contents, or places unreasonable conditions on such access, this could potentially hinder publicly useful research. Therefore, it is desirable to ensure that the law strikes an appropriate balance between protecting the investment involved in developing such databases, and ensuring reasonable third party access to their contents.

Submissions and consultations

30.58 IP 27 asked whether Australian copyright law provides adequate protection of databases that hold factual compilations of genetic sequences and other genetic data.[73] Most of the submissions addressing this question suggested that copyright law does provide adequate protection. The Human Genetics Society of Australasia submitted that:

> Australian copyright law does provide adequate protection of databases that hold factual compilations of genetic sequences and other genetic data. If we introduce a special data base right into Australian law … it would be important to ensure that we

72 HUGO Ethics Committee, *Statement on Human Genomic Databases* (2002).

73 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 16–2.

> do not increase the legal protections afforded to such databases to the point that access to data that may have been publicly funded is severely limited or denied.[74]

30.59 Dr Amanda McBratney and others submitted that:

> Australia already provides adequate protection for database creators. As the *Telstra v Desktop Marketing* case shows, the threshold for what will constitute an original copyright work in Australia is very low ... Given the decision in this case, and the refusal of the High Court to entertain an appeal, the 'sweat of the brow' doctrine is firmly entrenched in Australian law. In operation it can produce similar results to the European database right.[75]

30.60 They suggested that possibly the only major advantage of enacting legislation on this issue would be to strengthen Australia's negotiating position with the EU to provide Australian citizens with reciprocal protection under the European database right.[76]

30.61 The Queensland Government considered that it is unclear whether a *sui generis* database right would in fact give higher protection than Australian copyright law as it presently stands. In addition, it noted that:

> The universities consulted seem to be satisfied with the use of copyright law to protect databases, however industry puts a lot more emphasis on patent protection over genetic material rather than protecting databases containing genetic information.[77]

30.62 The South Australian Government submitted that unless there is an identified practical problem with copyright law, there would not seem to be a case for introducing special database rights just for genetic databases:

> Even if the *Copyright Act* was amended to introduce a special database right in similar or the same terms as the EU's Directive on the Legal Protection of Databases, this does not justify any specific considerations in relation to gene patents. If necessary the Crown Use provisions in the *Copyright Act* could be invoked to enable reasonable access for State Government laboratories conducting genetic testing.[78]

30.63 The Australian Centre for Intellectual Property in Agriculture (ACIPA) submitted that there would be less incentive for private companies to monopolise essential scientific information if scientific databases did not attract copyright protection. ACIPA suggested that the *Copyright Act* should be amended so that scientific databases are recognised as global public goods that are not subject to copyright protection. Alternatively, the fair dealing provisions should be amended to include the sharing of scientific information within their scope.[79]

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74 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
75 A McBratney and others, *Submission P47*, 22 October 2003.
76 Ibid.
77 Queensland Government, *Submission P57*, 5 January 2004.
78 South Australian Government, *Submission P51*, 30 October 2003.
79 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

30.64 IP 27 also asked whether publicly or privately funded research is being impeded because of lack of access to data about human genetic material and, if so, whether the NHMRC's Celera subscription provides an appropriate model for seeking to increase Australian researchers' access to information about the human genome.[80]

30.65 Several organisations submitted that they do not consider that research has been impeded by a lack of access to data.[81] The Queensland Government submitted that:

> Queensland Health advises that the NHMRC's Celera subscription has improved access for researchers to data about human genetic material. Researchers and industry may benefit from education on how to use the subscription and the information obtained under the subscription.[82]

30.66 AusBiotech Ltd submitted that:

> There is little evidence that research is being impeded because of lack of access to data about human genetic material. The public databases are comprehensive, and are constantly being updated with further annotations. Although commercial databases such as Derwent's Gene Patent Database are available by subscription, access is also available on a fee per use basis. It is possible that there is some restriction on access to more specialised databases.[83]

30.67 McBratney and others submitted that:

> In our experience, patents of human genes have not impeded access to data of any part of the human genome with regard to sequences … It is important to note that the Human Genome Consortium's human genome sequence was publicly available at this time, so it would be incorrect to imply there was a lack of access to human genetic data. However, due to the database design, the information on the Celera 'Discovery System' was better organised, annotated, and easier to search. Moreover, Celera's sequence of the human genome involved fewer gaps in the data, and was also complementary to publicly available data. In addition, the Discovery System included extensive databases of human SNPs and ESTs—which combined public data with data generated by Celera. Several other organisms' genomes were available as part of the package, some of which were not publicly available at the time.
>
> Although a significant portion of the information on the database was publicly available elsewhere, the Celera package was more comprehensive, and therefore advantageous to Australian Researchers.[84]

30.68 The Department of Industry, Tourism and Resources submitted that most of the results of the Human Genome Project are publicly available, and there are several examples of genetic databases being licensed for a fee.[85]

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80 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 11–6.

81 GlaxoSmithKline, *Submission P33*, 10 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; A McBratney and others, *Submission P47*, 22 October 2003.

82 Queensland Government, *Submission P57*, 5 January 2004.

83 AusBiotech Ltd, *Submission P58*, 7 November 2003.

84 A McBratney and others, *Submission P47*, 22 October 2003.

85 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

30.69 By contrast, several submissions suggested that research has been impeded by a lack of access to data about human genetic material.[86] The New South Wales Health Department submitted that:

> NSW Health is concerned that private companies have been able, by using the patent process, to hold their findings from public access and make them available only to those who are prepared to pay. Industry licence fees are reportedly up to several millions internationally.[87]

30.70 The Walter and Eliza Hall Institute of Medical Research (WEHI) submitted that publicly and privately funded research is being impeded. WEHI commented that public databases usually catch up quite quickly, but

> where the database is in private hands the only options are to not use it or attempt to negotiate the best possible deal for public researchers.[88]

30.71 The Caroline Chisholm Centre for Health Ethics submitted that Celera Genomics has laid down conditions that are being followed by other companies publishing genome databases which do not ensure unrestricted access to the genetic information. The Centre commented that:

> These access issues to important information are of grave concern to many leading scientists in the field … With such important information the issue of access is paramount: who controls its release, and where it is stored becomes pivotal to progress in this emerging field. Perhaps legislation could help ensure equitable access to important information. That such databases could be restricted solely for financial motives, when doing so compromises basic human needs such as health, is questionable. This begs several important questions: which databases in particular, under what circumstances and what compensation should be made to the company(ies) that developed or generated the genetic data.[89]

Options for reform

30.72 The ALRC considers that it is important to strike an appropriate balance between the need to encourage investment in technology by protecting databases created through private funds, and the need to facilitate legitimate third party use of such databases for research. The various options for reform are discussed below.

Amend the level of copyright protection

30.73 As a result of the Federal Court's decision in *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd*,[90] Australia currently offers a high level of copyright protection for genetic and other databases. Copyright will subsist in a database of

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86 New South Wales Health Department, *Submission P37*, 17 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

87 New South Wales Health Department, *Submission P37*, 17 October 2003.

88 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

89 Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003.

90 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433.

factual information if the database owner has expended sufficient labour and expense in collecting, verifying, recording and assembling the information.

30.74 One possible reform option is to raise the level of protection of genetic databases in Australia, by adopting a *sui generis* database right similar to that existing in the EU. The ALRC considers that the primary reason to propose this option would be so that Australia could enter into an agreement with the EU for the reciprocal protection of non-original databases. The Commonwealth Attorney-General's Department submitted that:

> It is certainly arguable that the common law 'sweat of the brow' test provides, in substance, the same level of protection as the sui generis Directive. However, the form of that protection is sufficiently different as to leave some doubt as to whether protection would be granted in the absence of express legislation or agreement dealing with the issue.[91]

30.75 However, the Department noted that any proposal to adopt a *sui generis* protection in Australia would be likely to meet a significant degree of opposition from scientific and academic communities:

> While there are few parties who would deny the importance of protecting investments in information, there are many who are concerned about the 'privatisation' of information, and the effect it could have on the scientific community. Specifically, it is feared that additional protections may mean that databases that were previously available openly, and free of charge will be restricted and that the complexity and cost of research will rise as a result. Opponents also argue that current protections are sufficient, if not excessive, and additional protection is potentially risky and simply unnecessary.[92]

30.76 The ALRC considers that the level of protection of genetic databases under Australian copyright law is already high, and is arguably close to the level of protection granted by the EU's Database Directive. In the light of the submissions and consultations conducted to date, the ALRC does not consider it necessary to propose the introduction of a *sui generis* database right.

30.77 An alternative would be to amend the *Copyright Act* to lower the level of copyright protection of genetic databases to facilitate greater access for third party researchers. For example, Australia could adopt the United States' standard of originality for copyright, which requires independent creation and a minimum degree of creativity. Those databases that do not fulfil these minimum requirements would not be protected by copyright.

30.78 When IP 27 asked whether Australian copyright law provides adequate protection of databases that hold factual compilations of genetic sequences and other

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91 Attorney-General's Department, *Submission P61*, 11 November 2003.

92 Ibid.

genetic data, most of the submissions addressing this question considered that the existing level of copyright protection was adequate.

30.79 In addition, if non-original genetic databases were not protected by copyright, database owners might seek other means to protect their investment, such as the introduction of a *sui generis* database right, or the use of contract and technological prevention methods. While researchers generally would have fair dealing rights in relation to databases protected by copyright, these may be lost where databases are protected by other means. Accordingly, the lowering of copyright protection could in practice lead to more limited access to information for scientific researchers.

30.80 Further, given that the selection and arrangement and/or the contents of many genetic databases do exhibit a degree of creativity, this amendment would not have any impact on these 'original' databases.

Fair dealing for research or study

30.81 Another possible reform option would be to amend the fair dealing provisions in the *Copyright Act* to clarify to what extent 'fair dealing for the purpose of research or study' applies to commercial research using genetic databases protected by copyright. This would remove existing uncertainty for researchers who wish to rely on the fair dealing provisions but are uncertain as to their scope.

30.82 Proposal 29–1 provides that the Commonwealth should amend the *Copyright Act* to clarify the extent to which 'fair dealing for the purpose of research or study' applies to commercial genetic research. That proposal already addresses this concern.

30.83 As noted above, another issue relevant to fair dealing for the purpose of research or study is whether, in practice, an individual is able to access the contents of a genetic database in order to reproduce the copyright works for fair dealing purposes. Question 30–1 asks whether the Commonwealth should amend the *Copyright Act* to provide that, in relation to genetic databases protected by copyright, the operation of the fair dealing for the purpose of research or study provisions must not be excluded or modified by contract or technological protection measures.

Statutory licensing regime

30.84 Another option is to introduce a new statutory licensing scheme into the *Copyright Act* to facilitate third party access to, and use of, genetic databases in exchange for a reasonable royalty. An important difference between statutory licensing and fair dealing is that a statutory licence requires the payment of reasonable remuneration to use the copyright material.

30.85 As noted above, the *Copyright Act* already contains a number of statutory licensing regimes, including for Crown use of copyright works. This permits the Commonwealth or a State (or an authorised representative) to do an act comprised in the copyright in a work or other subject matter without infringing copyright, if it is

done 'for the services of the Commonwealth or State'. While this term is not defined in the legislation, it has been suggested that it should be interpreted widely in order to cover any activity related to the purpose of government.[93] If this is the case, it is possible that Commonwealth, state and territory health departments could rely on these provisions to access, and use, genetic databases protected by copyright for public health purposes.

30.86 Sackville J of the Federal Court raised the option of statutory licensing for factual compilations in *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd*:

> There may be powerful reasons … for requiring the owner of copyright in the compilation to submit to a compulsory licensing regime. Such schemes are established by statute in other areas: see, for example, *Copyright Act*, s 108, providing that copyright in a recording is not infringed by a public performance if equitable remuneration is paid. A compulsory licensing regime might appropriately reward the monopolist's labour and expense, yet leave room for innovative competitors who cannot gain access to the basic information required to establish databases of potential commercial value.
>
> A court is ill-equipped to undertake the inquiries and make the policy assessments necessary to resolve these issues. The questions are for parliament to consider.[94]

30.87 Sharon Givoni has also raised the possibility of a statutory licensing scheme for databases of factual information that are protected by copyright. She argues that this could meet the objectives of copyright law by ensuring that socially significant databases are easily accessible to the general public, and by providing a mechanism for overcoming 'free-riding'.[95]

30.88 In its submission, the Commonwealth Attorney-General's Department discussed existing statutory licensing schemes in relation to educational copyright and Crown use, and commented that:

> The statutory licensing schemes provide an effective means for institutions that have access to required materials, with minimal financial disadvantage to the owners. A similar model could potentially be used to provide access to information stored in databases. However, more analysis is necessary to determine whether any advantages would be offset by the administrative burden on the parties involved.[96]

30.89 The ALRC considers that there may be merit in introducing a statutory licensing regime for genetic databases. This would provide third parties the right to access and use such databases for public healthcare purposes, in exchange for a reasonable royalty

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93 Copyright Law Review Committee, *Copyright and Contract* (2002) [3.157], citing S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999) [12.275].

94 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 538.

95 S Givoni, 'Pushing the Boundaries of Copyright: Protection of Databases' (2003) 15 *Intellectual Property Law Bulletin* 8, 17. See also, G Stals, 'Copyright and Competition Policy in the Post-Hilmer Environment' (1997) 2 *Media and Arts Law Review* 77, 88.

96 Attorney-General's Department, *Submission P61*, 11 November 2003.

to be agreed with the copyright owner, or otherwise determined by the Copyright Tribunal. This regime would have broader application than the Crown use provisions because it would apply also to non-government organisations and individuals involved in public health research or healthcare provision.

30.90 However, any such statutory licensing scheme must comply with the Berne Convention's 'three step test' for exceptions to the exclusive rights of copyright owners.[97] In addition, it would be necessary to consider the administrative mechanism for enforcing such schemes.

30.91 The ALRC does not consider that it has sufficient information at this time to make a reform proposal regarding a statutory licensing scheme for genetic databases, but believes there is merit in further consideration of the issue. In order to obtain more information and feedback about this issue, the ALRC asks whether the Commonwealth should amend the *Copyright Act* to establish a statutory licensing scheme that would allow access to genetic databases for research in exchange for a reasonable royalty.

Question 30–2 Should the Commonwealth amend the *Copyright Act* to establish a statutory licensing scheme in relation to genetic databases protected by copyright?

Genetic database subscriptions

30.92 The final potential reform option is to expand the scope of genetic database subscriptions for use by Australian researchers and research institutions.

30.93 As noted above, the NHMRC initially negotiated a three-year agreement with Celera Genomics providing publicly funded institutions with access to five of Celera's databases. The NHMRC paid a base subscription to Celera, and each institution paid an additional licence fee depending on the number of users, and the databases used. When that agreement expired in June 2003, the NHMRC negotiated a new three-year academic subscription agreement. The NHMRC is no longer involved in the administration of the subscription. Fees under the new agreement have increased to US$2,000 per person per database, and all users requiring access must register individually.[98]

30.94 IP 27 asked whether the NHMRC's Celera subscription provides an appropriate model for seeking to increase Australian researchers' access to information about the human genome.[99] While few submissions addressed this issue, the ALRC heard

97 *Berne Convention for the Protection of Literary and Artistic Works* (1886) art 9(2).

98 National Health and Medical Research Council, *About Celera and NHMRC Celera Subscription*, <www.nhmrc.gov.au/research/special/celdesc.htm> at 10 December 2003.

99 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 11–6.

general satisfaction with the NHMRC's subscription in consultation meetings. AusBiotech Ltd submitted that:

> The current model of the National Health and Medical Research Council's Celera Subscription is certainly an avenue of providing access to increase Australian researchers' access to information about the human genome. However, there is limited data on how effective this has been and whether the increasing volume and quality of information with the publicly available databases offer a suitable alternative to such initiatives.[100]

30.95 The ALRC has not heard any substantial concerns with the operation of the Celera subscription. However, as the new agreement commenced operation only recently, it is difficult to determine whether this apparent satisfaction applied only to the previous agreement, or extends also to the new access arrangement.

30.96 The ALRC would like further information regarding the practical operation of the new Celera agreement, and other database subscriptions. In particular, the ALRC is interested in views as to whether it would be desirable for the NHMRC—or another Commonwealth body—to have responsibility for monitoring the negotiation and practical operation of these agreements in the future.

Question 30–3 Does the new Celera subscription agreement cause any significant concerns for public research institutions or researchers engaging in publicly funded research? If so, what are these concerns?

Question 30–4 Should the National Health and Medical Research Council, or another Commonwealth body, have responsibility for monitoring the operation of agreements between genetic database owners and publicly funded research institutions within Australia?

100 AusBiotech Ltd, *Submission P58*, 7 November 2003.

Appendix 1. List of Submissions

Name	*Submission no*	*Date*
Aboriginal and Torres Strait Islander Services	P55	4 Nov 03
Attorney General's Department	P61	11 Nov 03
AusBiotech Ltd	P58	7 Nov 03
Australian Association of Pathology Practices Inc	P10	24 Sep 03
Australian Centre for Intellectual Property in Agriculture	P12	29 Sep 03
Australian Competition and Consumer Commission	P64	12 Dec 03
Australian Health Ministers' Advisory Council	P49	23 Oct 03
Australian Huntington's Disease Association (NSW) Inc	P27	1 Oct 03
Associate Professor Agnes Bankier	P19	30 Sep 03
Associate Professor Ross Barnard	P32	7 Oct 03
Dr Michela Betta	P20	30 Sep 03
Breast Cancer Action Group NSW Inc	P08	19 Sep 03
Breast Cancer Network Australia	P22	30 Sep 03
Cancer Council Australia	P25	30 Sep 03
Cancer Council New South Wales	P01	5 June 03
Cancer Council South Australia	P41	9 Oct 03
Cancer Council Tasmania	P40	29 Sep 03
Cancer Council Victoria	P16	30 Sep 03
Cancer Foundation of Western Australia Inc	P34	10 Oct 03
Cancer Voices NSW Inc	P07	16 Sep 03
Caroline Chisholm Centre for Health Ethics Inc	P38	17 Oct 03

Children's Cancer Institute Australia for Medical Research	P13	30 Sep 03
Mr Justin Cole and Mr Somerset Barnard	P63	12 Nov 03
Commonwealth Department of Health and Ageing	P65	28 Jan 04
Confidential Submission	P17	30 Sep 03
Confidential Submission	P54	31 Oct 03
Davies Collison Cave	P48	24 Oct 03
Department of Foreign Affairs and Trade	P29	2 Oct 03
Department of Health Western Australia	P53	31 Oct 03
Department of Industry, Tourism and Resources	P36	13 Oct 03
Mr Gerard De Ruyter	P03	14 Aug 03
Mrs Rae Edson	P09	23 Sep 03
Mr Dimitrios Eliades	P24	30 Sep 03
Genetic Support Council WA (Inc)	P59	7 Nov 03
Genetic Technologies Limited	P45	20 Oct 03
GlaxoSmithKline	P33	10 Oct 03
Dr John Graham	P05	26 Aug 03
Mr Anton Hughes	P42	20 Oct 03
Human Genetics Society of Australasia	P31	3 Oct 03
IP Australia	P56	31 Oct 03
Professor David Isaacs	P06	12 Sep 03
Mr David Jackson	P43	20 Oct 03
Mr Adam Johnston	P15	30 Sep 03
Mr Stephen Karpeles	P44	20 Oct 03
Professor John Mattick	P35	13 Oct 03
Mr David McAndrew	P14	30 Sep 03
Dr Amanda McBratney and others	P47	22 Oct 03
Dr Duncan McFetridge	P23	30 Sep 03

Medicines Australia	P21	30 Sep 03
Dr E Milward and others	P46	20 Oct 03
Professor Alec Morley	P18	30 Sep 03
National Health and Medical Research Council	P52	31 Oct 03
Dr Warwick Neville	P50	29 Oct 03
New South Wales Health Department	P37	17 Oct 03
Ms Carol O'Donnell	P02	13 Aug 03
Mr Luigi Palombi	P28	1 Oct 03
Mr Malcolm Pryor	P60	6 Nov 03
Queensland Government	P57	5 Nov 03
Royal College of Pathologists of Australasia	P26	1 Oct 03
South Australian Government	P51	29 Oct 03
Dr Graeme Suthers	P30	2 Oct 02
Dr Ian Turnbull	P11	25 Sep 03
Walter & Eliza Hall Institute of Medical Research	P39	17 Oct 03
Del Weston	P62	12 Nov 03
Wondu Business & Technology Services Pty Ltd	P04	20 Aug 03

Appendix 2. Abbreviations

AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
ACIP	Advisory Council on Intellectual Property
ACIPA	Australian Centre for Intellectual Property in Agriculture
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
ALRC	Australian Law Reform Commission
ALRC 74	Australian Law Reform Commission, *Designs* (1995)
ALRC 89	Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System* (2000)
ALRC 92	Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation* (2001)
ALRC 96	Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia* (2003)
ANGIS	Australian National Genomic Information Service
APAs	Australian Postgraduate Awards
APPS	AU Published Patent Data Searching
ARC	Australian Research Council
ART	Assisted reproductive technology
ASEAN	Association of South-East Asian Nations
ATSIS	Aboriginal and Torres Strait Islander Services
AUSFTA	Australia–United States Free Trade Agreement
AUTM	Association of University Technology Managers (US)
BIF	Biotechnology Innovation Fund
CAL	Copyright Agency Limited
CAT	Computerised Axial Tomography
cDNA	Complementary DNA
CBAC	Canadian Biotechnology Advisory Committee
CLRC	Copyright Law Review Committee
CIPO	Canadian Intellectual Property Office
CPC	Community Patent Convention
CRCs	Cooperative Research Centres
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Cth	Commonwealth of Australia
DEST	Department of Education, Science and Training
DITR	Department of Industry, Tourism and Resources

DFAT	Department of Foreign Affairs and Trade
DNA	Deoxyribonucleic acid
DOJ	Department of Justice (US)
ECJ	European Court of Justice
EC Treaty	*European Community Treaty*
EPC	*European Patent Convention*
EPO	European Patent Office
EST	Expressed sequence tag
EU	European Union
FDA	Food and Drug Administration (US)
FTC	Federal Trade Commission (US)
GDP	Gross Domestic Product
Gene CRC	Cooperative Research Centre for Discovery of Genes for Common Human Diseases
GTEC	Gene Technology Ethics Committee
GTG	Genetic Technologies Limited
GTTAC	Gene Technology Technical Advisory Committee
HGDP	Human Genome Diversity Project
HGCA	Human Genetics Commission of Australia
HGSA	Human Genetics Society of Australasia
HREC	Human Research Ethics Committee
HUGO	Human Genome Organisation
ICSTD	International Centre for Trade and Sustainable Development
IIF	Innovation Investment Fund
IP	Intellectual property
IP 27	Australian Law Reform Commission, *Gene Patenting and Human Health* (2003)
IPAC	Industrial Property Advisory Committee
IPC	International Patent Classification
IPCRC	Intellectual Property and Competition Review Committee
IPRs	Intellectual property rights
IR&D Board	Industry Research and Development Board
KCA	Knowledge Commercialisation Australasia
JPO	Japanese Patent Office
MBS	Medicare Benefits Scheme
MRI	Magnetic resonance imaging
MSAC	Medical Services Advisory Committee
MTA	Materials transfer agreement
NCC	National Competition Council
NHGRI	National Human Genome Research Institute (US)
NHMRC	National Health and Medical Research Council
NIH	United States National Institutes of Health
NPS	New Patent Solution system
NSCC	National Stem Cell Centre
OECD	Organisation for Economic Co-operation and Development
PatAdmin	Patent Administration System

PatIndex	Patent Indexing System
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PCR	Polymerase chain reaction
PCT	*Patent Cooperation Treaty 1970*
PDF	Pooled development funds
PDF Program	Pooled Development Fund Program
PIIP	Pharmaceuticals Industry Investment Program
PMSEIC	Prime Minster's Science Engineering and Innovation Council
PSA	*Prices Surveillance Act 1983* (Cth)
R&D	Research and development
RCPA	Royal College of Pathologists of Australasia
RNAi	Ribonucleic acid interference
SMEs	Small and medium-sized enterprises
SNP	Single nucleotide polymorphism
TGA	Therapeutic Goods Administration
TPA	*Trade Practices Act 1974* (Cth)
TRIPS Agreement	*Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*
TSC	The SNP Consortium
UNCTAD	United Nations Conference on Trade and Development
UNESCO	United Nations Educational Scientific and Cultural Organization
USPTO	United States Patent and Trademark Office
WARF	Wisconsin Alumni Research Foundation
WEHI	Walter and Eliza Hall Institute of Medical Research
WiCell	WiCell Research Institute Inc
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Appendix 3. Glossary

Adult stem cells
Undifferentiated cells found in differentiated tissue (in a foetus or a fully developed organism). Adult stem cells can self-renew and are multipotent—that is, they can give rise to specialised cell types within the tissue from which they originated. (See also **multipotent stem cells**.)

Allele
A version of a gene. Different alleles produce variation in inherited characteristics, for example eye colour.

Assignment
The transfer of intellectual property rights to a third party.

Bioinformatics
The application of computational tools and methods to managing and analysing biological data.

Biotechnology
The technological application and manipulation of living organisms, for example in the development of pharmaceutical drugs, therapeutics and research tools, or in environmental management and industry.

Blastocyst
An early embryo comprising about 120 to 150 cells. A blastocyst is a sphere made up of an outer layer of cells (which later forms the placenta), a fluid-filled cavity and a cluster of cells on the interior (called the inner cell mass).

Broad patent
A patent asserting broad rights to an invention, for example to all future uses of the claimed product or process, whether known or unknown.

Complementary DNA (cDNA)
Strong, amplified copies of otherwise fragile mRNA.

Compulsory licence
A licence granted pursuant to a court order requiring a patent holder to allow a third party to use a patented product or process, where the patent holder has failed to exploit it, or has exploited it on overly restrictive terms.

Copyright
An intellectual property right subsisting in an original literary, dramatic, musical or artistic work (or other subject matter), and which protects against the unauthorised reproduction or other acts in relation to the whole, or a substantial part of, the work.

Deoxyribonucleic acid (DNA)
A large molecule comprising a chain of sugar groups that are missing an oxygen molecule. It is mainly found in the nucleus of a cell.

Design
An intellectual property right protecting the distinctive appearance of an article.

Downstream product
A product or process resulting from downstream research, for example a pharmaceutical drug, genetic test, therapy or therapeutic device.

Downstream research
Applied research usually directed at the development of a product or process with a potential commercial application.

Embryonic stem cells
Undifferentiated cells derived from the inner cell mass of a developing blastocyst. Embryonic stem cells are self-renewing and pluripotent—that is, they are capable of forming all the different types of cells found in the body, except the placenta and other supporting tissue necessary for foetal development.

Exon
The region of DNA within a gene that codes for a protein. A protein is usually coded by multiple exons, separated by introns.

Expressed sequence tag (EST)
A known cDNA sequence of several hundred nucleotides, which forms part of a gene and is derived from RNA. The RNA usually codes for a protein or protein fragment of unknown function.

Gene
An ordered sequence of nucleotides that contains all the information to direct the production of a specific protein or RNA.

Gene fragment
A wide range of different types of isolated genetic materials including SNPs, ESTs and other gene fragments that encode important regions of proteins. The term may refer to sequences that are not, technically, part of a gene.

Gene therapy
The transfer of DNA or RNA into human cells to treat disease using various delivery methods, including improving membrane permeability to DNA, microinjection and the use of viral vectors.

Genetic materials
All forms of DNA, RNA, genes and chromosomes, including genetic materials of whole genomes, single genes and gene fragments. In this Discussion Paper 'natural genetic material'—forms of genetic material in their natural state—are distinguished from 'isolated genetic materials'—forms of genetic material isolated from nature, such as cDNA.

Genetic products
In this Discussion Paper, items produced by the use of genetic materials, including proteins, nucleic acid probes, nucleic acid constructs (such as vectors and plasmids), and anti-sense DNA.

Genetic sequences
Any sequence of nucleotides in DNA or RNA.

Genetic technologies
In this Discussion Paper, a broad category of methods and items used in genetic research and healthcare services, including those used in sequencing DNA, medical genetic testing and gene therapy.

Genome
The complete sequence of DNA in a cell or organism.

Genomics
The study of genes and their function.

Genotype
The unique combination of alleles found in an individual's genome.

Grace period
The period between an inventor's public disclosure of a product or process and the latest date on which the inventor may file a patent application without the prior disclosure precluding a patent being granted.

Haplotype
Closely linked alleles along a region of a chromosome which tend to be inherited together. A haplotype is identified by patterns of SNPs. Haplotype maps are intended to identify complex genetic variations of importance to health and disease.

Infringement
The use or exploitation of another individual or organisation's intellectual property rights without lawful authority.

Inner cell mass
A cluster of cells inside a blastocyst from which embryonic stem cells are derived. In a developing embryo, the inner cell mass gives rise to all of the organs and tissue of the future embryo and foetus.

Intellectual property
Property rights granted in relation to the product of original creative endeavour, such as patents, copyright, designs and trade secrets.

Intron
A DNA sequence—usually with no currently identified function—that interrupts the protein-coding sequence of a gene.

Inventiveness
A requirement for patentability. An invention must not be obvious to a person skilled in the technological field of the invention at the time a patent application is filed.

Licence
An agreement between a patent holder and a third party authorising the use of a patented product or process, which would otherwise constitute infringement of the patent holder's rights.

Licence fee
A payment made to a patent holder by a licensee (or to a licensee by a sub-licensee) in return for the right to use a patented invention. Licence fees may take the form of one or more of the following: royalties; fixed fees; minimum guaranteed payments; or milestone fees.

Licence-in
To acquire a licence authorising the use of a patented product or process.

Licence-out
To grant a licence authorising the use of a patented product or process by a third party.

Manner of manufacture
A requirement for patentability under Australian law. The manner of manufacture requirement is used to determine whether an invention is appropriate subject matter for patenting.

March-in right
A right, under United States law, allowing the government to acquire title to a patented product or process developed with public funds, in certain limited circumstances.

Materials Transfer Agreement
An MTA is a written agreement defining the terms and conditions governing the transfer of biological or other research materials from the owner or authorised licensee to a third party for internal research purposes only.

Medical genetic testing
Molecular genetic testing that directly analyses DNA or RNA for clinical or medical purposes. This includes diagnostic testing, predictive or presymptomatic testing, genetic carrier testing, screening testing and pre-implantation or prenatal testing.

Messenger RNA (mRNA)
A complementary copy of DNA made up of RNA nucleotides, which carries the coded genetic information to the protein-producing units in the cell, called ribosomes.

Milestone fee
A lump sum payment made by a patent licensee upon reaching specified stages in the development or commercialisation of a product or process.

Multipotent stem cells
See **adult stem cells**.

Non-coding DNA
Regions of the DNA molecule that do not code for proteins—popularly, but incorrectly, referred to as 'junk DNA'.

Novelty
A requirement for patentability. An invention must not have been known or available to the public before the priority date of a patent application.

Nucleotide
The building blocks of DNA and RNA. There are four nucleotides for DNA: adenine (A) and guanine (G), which are known as 'purines'; and thymine (T) and cytosine (C), which are known as 'pyrimidines'. In RNA, thymine is replaced by uracil (U). Nucleotides are arranged in triplets, called codons.

Patent
An intellectual property right granted by a patent office to the inventor of a new, inventive and useful product or process, allowing its exclusive exploitation for a limited period of time.

Patent application
A formal application to a patent office requesting that patent protection be granted for a product or process.

Patent claims
Written statements that define a patented product or process and the scope of protection granted by the patent.

Patent holder
The individual or organisation entitled to exercise the rights granted by a patent. A patent holder may also be referred to as a 'patentee'.

Patent pool
A cooperative arrangement allowing the holders of several patents—all of which are necessary for the development of a product or process—to license or assign their rights at a single price.

Patent specification
A written description of a patented product or process, including a technical description and the patent claims, which define the scope of patent protection.

Patent thicket
The problem caused by multiple upstream patents, where overlapping rights may impede the commercialisation of a product or process.

Pharmacogenetics (or pharmacogenomics)
The study of the interaction between an individual's genetic make-up and his or her response to a particular drug.

Phenotype
An individual's physical characteristics determined by the interaction of genotype and environmental factors.

Pluripotent stem cells
Stem cells that can become all types of cells found in the body, but not the placenta and other supporting tissue necessary for foetal development.

Polymorphism
A variation in DNA sequence between individuals, which may cause no harm, or may make a gene faulty in the way it directs the production of a protein.

Priority date
A specified date—usually the date when a patent application is first filed—against which the novelty and inventiveness of an invention is assessed.

Protein
A large molecule composed of one or more chains of amino acids in a specific order. Proteins are required for the structure, function and regulation of the body's cells, tissues and organs; and each protein has unique functions.

Proteomics
The study of the full set of proteins encoded by the genome.

Reach-through
A claim made by a patent holder in a patent or a patent licence asserting rights over a future product or process that might result from the use of a patent.

Research tools
The range of resources that scientists use in their laboratories, which have no immediate therapeutic or diagnostic value. Examples include cell lines, monoclonal antibodies, reagents, laboratory equipment and machines, databases and computer software.

Ribonucleic acid (RNA)
A single stranded nucleic acid molecule that plays an important role in protein synthesis and other chemical activities of the cell. There are three types of RNA: messenger (mRNA), transfer, and ribosomal.

Royalty
A payment made by a licensee as compensation for the use of a patented invention, for example a percentage of gross sales of a patented product or process, or a fixed sum paid each time a patented product or process is used.

Royalty stacking
A problem caused by a multiplicity of patents over a single area, which requires the payment of licence fees to many patent holders.

Seed funding
An early stage investment in a start up company or project, generally used to develop an idea to proof of concept stage, to conduct market research or for initial product development.

Single nucleotide polymorphism (SNP)
Single nucleotide variations in the genome sequence.

Stem cells
Cells capable of differentiating into specialised cell types, and of renewing themselves—allowing the maintenance of stem cell populations for long periods through cell division.

Totipotent cells
The zygote and cells from fertilization to about the eight-cell stage. Totipotent cells have the capacity to form the placenta and other supporting tissue necessary for embryonic development, as well as all types of cells found in an embryo, foetus and developed organism.

Trade secret
An intellectual property right protecting confidential information that arises in a commercial context.

Transcription
The process by which the DNA sequence is copied into RNA.

Translation
The process by which RNA is used to produce a protein in the ribosomes.

Upstream patent
Foundational patents on which further knowledge and development depends.

Upstream research
Research that usually focuses on increasing fundamental knowledge, for example, research into the sequence and function of a gene.

Usefulness
A requirement for patentability. An invention claimed in an Australian patent application must produce the results that are promised upon a fair reading of the patent specification.

Venture capital
Funding provided by investors to early stage companies, generally after they have demonstrated strong growth potential and good management. Often provided in return for equity in the company.