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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

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

President
Professor David Weisbrot

Members
Professor Anne Finlay (Commissioner in charge)
Associate Professor 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
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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

List of questions

Chapter 4: Ethical, Social and Economic Dimensions

4–1 What are the principal ethical and social concerns in Australia about patents on genetic materials and technologies?

4–2 Should ethical and social concerns about patents on genetic materials and technologies be addressed through the patent system? Are there other or better approaches for dealing with these issues?

4–3 Is there 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? Are there any separate or special considerations that apply in this context in relation to indigenous people?

Chapter 5: Funding for Research and Development

5–1 What are the implications of the grant of gene patents to institutions or companies whose research was publicly funded for: (a) encouraging further research into human health; or (b) maintaining cost-effective health care in Australia?

5–2 Should holders of gene patents that have implications for human health pay a levy on any royalties with such royalties to be used for future genetic research or for health care infrastructure? If so, should it make any difference whether or not the research leading to the patent was publicly funded?

5–3 In the United States, the government retains certain residual rights to intellectual property developed from publicly funded research. These include 'march-in' rights, the right to a government-use licence and the right to limit exclusive licences. Is there any need in Australia for these or similar rights to be a condition of public funding of genetic research with implications for human health?

5–4 What are the implications of the government retaining intellectual property in any contracted genetic research with implications for human health?

Chapter 7: Gene Patents and the Healthcare System

7–1 Do gene patents pose any distinct problems of cost for the Australian healthcare system beyond those applicable to new technologies generally?

7–2 What specific problems do gene patents and future developments in genetic technologies pose for the cost and funding of genetics services?

7–3 What steps, if any, should be taken to facilitate the economic evaluation of the impact of gene patents on the cost of genetics services and other healthcare in Australia?

Chapter 8: Overview of Legal Framework

8–1 Do applications for gene patents raise special issues that are not raised by patent applications relating to other types of technology? If so, what are those issues and how should they be addressed?

8–2 Under Australian law, two types of patent protection are available—a 20-year term for a standard patent and an eight-year term for an innovation patent. Should the duration of gene patents be limited to a term less than 20 years? Would this conflict with Australia's obligations under the TRIPS Agreement? (See also Question 9–1.)

8–3 Under the *Patents Act 1990* (Cth) (*Patents Act*), in order to accept a standard patent application (or certify an innovation patent), an Australian patent examiner must be 'satisfied' that an invention is novel and inventive (or innovative) and must 'consider' that no lawful ground for objection exists. Should the threshold for acceptance of an application for a gene patent be raised? If so, what should the threshold be?

8–4 Are the mechanisms available under the *Patents Act* to challenge an accepted patent application or a granted patent (ie, opposition, re-examination and revocation) adequate in relation to gene patents and applications? What additional or alternative mechanisms might be required?

8–5 Does IP Australia have the capacity to scrutinise applications for gene patents effectively? Is there a need for IP Australia to develop new procedures or guidelines in this area?

8–6 Would the administration and enforcement of gene patents benefit from concentrating jurisdiction for patent matters in a single court? If so, how might concerns about the cost and complexity of enforcing gene patents be addressed?

Chapter 9: Patentability of Genetic Materials and Technologies

9–1 Would changes to the requirements for patentability under Australian law for inventions involving genetic materials and technologies, or to the application

of those requirements to such inventions, conflict with Australia's obligations under the TRIPS Agreement?

9–2 How should the novelty requirement apply to applications for patents over isolated genetic materials or genetic products? Are special considerations relevant in assessing the novelty of such inventions?

9–3 In light of the DNA sequencing technology now available, does the identification and isolation of genetic material involve an 'inventive step' or an 'innovative step' under current Australian law? Are the current tests for 'inventiveness' and 'innovation' appropriate for assessing the patentability of genetic materials and technologies? What alternative or additional considerations might be relevant in assessing the 'inventiveness' or 'innovation' of such inventions?

9–4 In applying the 'usefulness' requirement for patentability under Australian law to inventions involving genetic materials and technologies:

- Do patent applications claiming such inventions raise specific issues that are not raised by other technologies? If so, what are those issues?
- What alternative or additional considerations might be relevant in assessing the 'usefulness' of such inventions? Would it be appropriate to require that inventions demonstrate 'specific, substantial and credible' utility to be patentable?
- Should 'usefulness' be considered as part of the examination of a patent application? Should lack of utility also be a ground upon which a patent application might be opposed or re-examined?

9–5 In applying the 'sufficiency' and 'fair basis' criteria to applications for gene patents:

- Do claims in applications for gene patents raise specific issues that that are not raised by other technologies? If so, what are those issues?
- Are any additional or alternative considerations relevant to assessing the appropriate scope of patent claims involving genetic materials or technologies?

9–6 Should ethical considerations be relevant in assessing applications for gene patents? If so, should a specific provision to that effect be introduced into the *Patents Act 1990* (Cth), or is the current 'manner of manufacture' test sufficient to accommodate such considerations?

9–7 If ethical considerations became relevant in assessing applications for gene patents, who should be responsible for developing guidelines, providing advice, and ultimately making determinations about such issues?

9–8 Should isolated genetic materials and genetic products be regarded as 'discoveries' rather than 'inventions' for the purposes of Australian patent law, and thus excluded from patentability?

9–9 Should methods of diagnostic, therapeutic and surgical treatment of humans involving genetic materials or technologies continue to be patentable under Australian law? If not, how should the exclusion of such inventions from patentability be justified, and what should be the scope of the exclusion?

Chapter 10: Licensing and Enforcement of Patent Rights

10–1 Is sufficient information available to holders of Australian gene patents to allow them to protect their patent rights? If not, what alternative or additional information or facilities might be required?

10–2 To what type of gene patents are Australian companies, researchers, healthcare providers or other organisations seeking or granting licences? What uses are being made of such licensed gene patents?

10–3 Are requests for licences to Australian gene patents being refused by patent holders? If so, why? If not, are the terms of such licences fair and reasonable?

10–4 Are gene patents being enforced against Australian companies, researchers, healthcare providers or other organisations? If so, what types of gene patents are being enforced and by what means (for example, with cease and desist letters, offers to license, or the threat of infringement proceedings)?

10–5 Are the potential costs involved in litigating patent infringement actions preventing the enforcement of Australian gene patents? Are there any other factors influencing the decisions of holders of Australian gene patents about whether or how to enforce such patent rights?

Chapter 11: Patents and Human Genetic Research

11–1 Is there any evidence about whether gene patents or licences are encouraging or inhibiting research in biotechnology in Australia?

11–2 Do any of the following affect biotechnology research into human health in Australia: (a) broad patents over isolated genetic materials; (b) patents over expressed sequence tags (ESTs) of unknown utility; (c) patents over single

nucleotide polymorphisms (SNPs); or (d) a multiplicity of patents (sometimes known as 'patent thickets')?

11–3 Is there any evidence that licences granted to researchers in relation to patents over genetic materials or technologies encourage or hinder research into human health? Is there any evidence that materials transfer agreements encourage or hinder research into human health?

11–4 Does the recent amendment to the *Patents Act 1990* (Cth), which permits a 12 month grace period before filing, encourage the publication of scientific results? Does the grace period overcome the problem of secrecy or delay in publication?

11–5 Is there any need for Australian guidelines similar to those published by the United States National Institutes of Health to ensure that research is not being withheld from the public domain?

11–6 Is publicly or privately funded research being impeded because of lack of access to data about human genetic material? If so, does the National Health and Medical Research Council's Celera Subscription provide an appropriate model for seeking to increase Australian researchers' access to information about the human genome?

Chapter 12: Gene Patents and Healthcare Provision

12–1 Do existing patent laws and practices favour the development of genetic testing monopolies in Australia? If so, are reforms needed and what should they be?

12–2 What are the implications of current patent laws and practices for the cost and public funding of, and equitable access to, medical genetic testing and to related healthcare services such as genetic counselling?

12–3 Is medical practice 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? If so, in what ways, and with what possible consequences?

12–4 What potential do patent laws and practices have to encourage the inappropriate marketing and supply of genetic testing services and products?

12–5 Are gene patents necessary to encourage investment in research that leads to the development of new, clinically useful, medical genetic tests?

12–6 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?

12–7 Should government funding and purchasing power be used to control the cost of medical genetic testing that is subject to gene patents? If so, how might this best be achieved?

12–8 Should there be new regulation of medical genetic testing to address concerns about the possible adverse consequences of patent laws and practices on healthcare provision? If so, how might this best be achieved?

12–9 Should patent pools or clearinghouses be created to make it easier for laboratories to obtain licences for patented genetic inventions? If so, how might this best be achieved?

Chapter 13: Patents and the Biotechnology Sector

13–1 What effects do Australia's patent laws and licensing practices have on the development of Australia's biotechnology industry as it relates to human health?

13–2 Is there 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?

Chapter 14: New Defences

14–1 Should the *Patents Act 1990* (Cth) (*Patents Act*) be amended to include a defence for research use? If so, should the defence be limited to activities involving research on an invention claimed in a gene patent? Should the scope of the defence also encompass research use of a gene patent directed to: (a) improving upon the claimed invention; (b) finding a new use for the claimed invention; or (c) creating a new product or process using the claimed invention?

14–2 Should the *Patents Act* be amended to include a defence for private, non-commercial use of a patented invention? If so, what would be the relationship between a 'private use' defence and a 'research use' defence of the type identified in Question 14–1?

14–3 Should the *Patents Act* 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? If so, who should qualify as a

medical practitioner for the purposes of such a defence and what types of activities should be exempt? Should any activities be expressly excluded from the scope of such a defence?

14–4 Would amendment of the *Patents Act* to include new defences, such as those identified in Questions 14–1, 14–2 and 14–3, be consistent with Australia's obligations under the TRIPS Agreement?

Chapter 15: Crown Use and Compulsory Licensing

15–1 Are the Crown use provisions in the *Patents Act 1990* (Cth) (*Patents Act*) capable of applying to the provision of healthcare services using patented genetic materials and technologies? If not, should these provisions be amended to apply to such use?

15–2 In relation to the provisions in the *Patents Act* relating to the grant of compulsory licences:

- Do the provisions encourage patent holders to exploit or license gene patents?
- Is the grant of a compulsory licence 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? If not, should the current provisions be amended to make specific reference to such matters?
- Should compulsory licences be available only by order of a court (as the Patents Act currently provides), or should the Act be amended to allow the Commissioner of Patents, or another tribunal or agency, to grant compulsory licences?
- If compulsory licences were to be granted more frequently, should the Patents Act be amended to provide increased protections for patent holders, such as mechanisms for determining the compensation due, or certain mandatory terms to be included in such licenses?

15–3 What latitude is there for amending the Crown use or compulsory licensing provisions of the *Patents Act* consistently with Australia's obligations under the TRIPS Agreement?

Chapter 16: Copyright, Trade Secrets and Designs

16–1 What role should copyright law play in dealing with genetic materials and technologies in relation to human health?

16–2 Does Australian copyright law provide adequate protection of databases that hold factual compilations of genetic sequences and other genetic data? What would be the implications of introducing into Australian law a special database right—as distinct from copyright—in relation to such databases?

16–3 Does trade secrets law have any significant application to the conduct of genetic research and its commercialisation? If so, does the law require reform?

16–4 Do the existing or proposed design laws have any significant application to the conduct of genetic research and its commercialisation? If so, do the laws require reform?

Chapter 17: Patents and Competition Law

17–1 Following the report of the Intellectual Property and Competition Review Committee in 2000, and the Federal Government's response, are there any competition issues specifically relevant to gene patents that need to be dealt with in the course of this Inquiry?

17–2 How should competition law and policy deal with 'patent pools' relating to gene patents?

17–3 Is there a role for the Australian Competition and Consumer Commission (ACCC) in monitoring prices that are charged for medical genetic tests or any other products or services arising from the grant of gene patents or licences?

17–4 Is there a role for the ACCC in monitoring the impact on competition of gene patents and licences?

Part A

Introduction and Background

1. Introduction to the Inquiry

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Why review gene patenting and human health?

1.1 On 4 December 2002 the Federal 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.

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 then 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 contains 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 makes 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>. These documents are referred to frequently in this Issues Paper.

Defining the scope of the Inquiry

Terms of Reference

1.5 The Terms of Reference, which define the scope of the Inquiry, are reproduced at the beginning of this Issues 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.

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3 Australian Law Reform Commission and Australian Health Ethics Committee, *Protection of Human Genetic Information*, IP 26 (2001), ALRC, Sydney, see <www.alrc.gov.au>, [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), ALRC, Sydney, see <www.alrc.gov.au>.

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 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 genetic technologies may be relevant. One dimension of the Inquiry is the effect of gene patents on human health; another dimension 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.

General review of patents and intellectual property rights

1.10 The ALRC has not been asked to undertake a general review of Australian law in relation to patents or other intellectual property rights. The scope of 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 identified. As a result, while the Inquiry might identify certain problems that are common to the application of intellectual property laws in a number of contexts, the focus of the Inquiry must remain on reforms that are appropriate to 'genes and genetic and related technologies', as identified in the Terms of Reference. The ALRC's research efforts and consultation program will reflect this focus.

Genetic research on plants and animals

1.11 The ALRC has not been asked specifically to consider the impact of patents over the genes or genetic technologies associated with plants and animals. While the Terms of Reference ask the ALRC to have regard to 'the need to utilise modern genetic technologies to further Australia's national interest, including such areas as agriculture and industry', the operative part of the Terms of Reference emphasise that the Inquiry's focus is on human health issues.

1.12 The *Gene Technology Act 2000* (Cth) applies to all dealings with genetically modified organisms (GMOs), including experimentation, production, breeding, and importation of a GMO, or using a GMO in the manufacture of another thing. The Office of the Gene Technology Regulator has the primary role in regulating dealings with GMOs. In addition, a body known as Food Standards Australia New Zealand maintains a list of genetically modified foods that are approved for use in Australia and New Zealand.[5]

1.13 Given that GMOs have no direct connection with genes or genetic technologies relating to human health, they generally fall outside the scope of the Inquiry. However, there might be limited circumstances in which the patenting of products or processes involved in genetic research on plants or animals might fall within the Terms of Reference.

1.14 Humans share a significant proportion of their genetic material with other animal species. For example, as discussed in Chapter 2, the human genome is more than 98% identical to that of chimpanzees, and 97% identical to that of gorillas. 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, arguably, fall within the scope of the Inquiry.

1.15 For example, the 'Harvard oncomouse' was genetically engineered to be susceptible to cancer so that it might be used in human cancer research. Research is also being conducted into the process of xenotransplantation, which involves the transplantation of cells, tissues or organs from one species to another, such as from

5 See *Australia New Zealand Food Authority Act 1991* (Cth).

pigs to humans. This could involve the insertion of human genes into donor pigs to reduce the possibility that the pig's tissue will be rejected by the human recipient.[6]

1.16 The patent issues arising in relation to a product or process associated with genetic research on plants or animals could, therefore, indirectly fall within the scope of the Inquiry due to the potential impact on human health issues.

Genetic research on humans for purposes unrelated to human health

1.17 Patents may be sought, and granted, over products and processes developed through genetic research but which are unrelated to human health. Examples are genetic tests used to determine biological kinship, or used in DNA profiling for law enforcement purposes. As the ALRC has been asked to focus on human health issues, the patent issues arising in relation to these products or processes generally fall outside the scope of the Inquiry.

Organisation of this paper

Part A: Introduction and background

1.18 Part A contains introductory and background material relating to genetics, patent law and gene patents. Chapter 2 provides a basic scientific primer on genetics and human health. The chapter also describes the types of genetic material and technologies over which patent rights may be asserted. Chapter 3 introduces patent law and briefly explains the nature of patent rights and the criteria for patentability. Chapter 4 outlines the ethical and social dimensions of gene patents, and the sometimes competing values that are relevant to the application of patent law to genetics.

Part B: Research, biotechnology and healthcare

1.19 Part B contains introductory and background material relating to the Australian research, biotechnology and healthcare sectors. Chapter 5 outlines the structure of public research and development funding in Australia, particularly in relation to medical research and human genetics. The chapter also discusses the implications of policies that encourage the commercialisation of publicly funded biomedical research. Chapter 6 describes the structure and characteristics of the biotechnology sector and the pharmaceutical industry in Australia. Chapter 7 gives background information on the structure and funding of the Australian healthcare system and describes, in general terms, how gene patents may have an impact on the provision of healthcare.

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6 The National Health and Medical Research Council (NHMRC) is preparing guidelines to help animal and human ethics committees assess proposals for this form of research, in particular where it is used as a human therapy: National Health and Medical Research Council, *Xenotransplantation Fact Sheet*, Commonwealth of Australia, <www.health.gov.au/nhmrc/media/2002rel/xenofact.htm>, 25 June 2003.

Part C: Patent laws and practices

1.20 Part C is concerned with the application of patent laws and practices to genetic materials and technologies, and identifies the core legal issues raised in this Inquiry. Chapter 8 provides an overview of the international and domestic legal framework that shapes Australian patent laws and practices, including the *Patents Act 1990* (Cth) and relevant international conventions. Chapter 9 considers the criteria for patentability under Australian law and the application of each criterion in the context of gene patents. Chapter 10 examines the rights granted to a patent holder and the means by which a patent holder may exploit and enforce such rights.

Part D: Impact on genetic research, human health and commercialisation

1.21 Part D examines the potential impact of gene patents on genetic research, human health and commercialisation. Chapter 11 considers whether gene patents may hinder the conduct of genetic research and discusses reform options, which are intended to promote research and encourage dissemination of research findings. Chapter 12 examines the ways in which gene patents may have an impact on the development and provision of healthcare in Australia, including the use of medical genetic testing and novel therapies, such as gene therapy, the production of therapeutic proteins and the use of stem cells. The chapter discusses several options for reform. Chapter 13 considers the impact of patent laws and practices on the application and commercialisation of research and on the biotechnology sector.

Part E: New defences, Crown use and compulsory licensing

1.22 Part E examines options for addressing the adverse impact, if any, of gene patents on genetic research and human health. Chapter 14 discusses new defences to claims of infringement of gene patents, such as where patents are used for research, for private non-commercial purposes, or for medical treatment. Chapter 15 considers the circumstances in which the Crown use, Commonwealth acquisition, or compulsory licensing provisions may be invoked. The chapter asks whether these provisions are adequate to encourage the exploitation of inventions and, if not, how patent laws and practices might be reformed.

Part F: Other intellectual property issues

1.23 Part F examines the impact of other laws on gene patents and their exploitation. Chapter 16 discusses the potential application of intellectual property laws other than patents, including copyright, trade secrets and design law. Chapter 17 then considers the relationship between intellectual property law, particularly patent law, and competition law.

Process of reform

Advisory Committee

1.24 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 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.[7] As always, attention has been paid to achieving a measure of gender, geographical, and interest group balance.

1.25 The Advisory Committee met for the first time on 23 May 2003, and will meet again several times 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.

Community consultation

1.26 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 an Inquiry.[8] One of the most important features of ALRC inquiries is the commitment to widespread community consultation.[9]

1.27 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. Recent reviews of the *Marine Insurance Act 1909* (Cth) and the *Judiciary Act 1903* (Cth) fall into this category. Other ALRC references—such as those relating to children and the law, Aboriginal customary law, multiculturalism and the law, and the protection of human genetic information—have involved a much greater level of interest and involvement from the general public and the media.

1.28 The present Inquiry into gene patenting falls into the latter category. In releasing the Terms of Reference for the Inquiry, the Federal Government specifically asked the ALRC to 'undertake widespread public consultation and consult with key stakeholders'.[10] Thus, while it is essential that the ALRC familiarises itself with the

7 The members of the Advisory Committee are listed in the front of this Issues Paper.
8 *Australian Law Reform Commission Act 1996* (Cth) s 38.
9 See B Opeskin, 'Engaging the Public: Community Participation in the Genetic Information Inquiry' (2002) 80 *Reform* 53.
10 Attorney-General and Minister for Health and Ageing, 'Inquiry into Human Genetic Property Issues', *News Release,* 17 December 2002.

latest developments in Australia and overseas, it is equally important that it consult widely and provide the community with an opportunity to have its say.

1.29 There are several ways in which members of the public may participate in the Inquiry. First, individuals and organisations may indicate their **expression of interest** in the Inquiry by contacting the ALRC or applying online at <www.alrc.gov.au.>. Those who wish to be added to the ALRC's mailing list will receive press releases and a copy of each consultation document produced during the Inquiry.

1.30 Second, individuals and organisations may **make submissions** to the Inquiry, both after the release of the Issues Paper and again after the release of the Discussion Paper. 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. In recognition of the nature of the issues under investigation, including matters of commercial sensitivity, the ALRC also receives confidential submissions. Details about making a submission may be found at the front of this Issues Paper.

1.31 The ALRC strongly urges interested parties, and especially key stakeholders, to make submissions *prior* to the publication of the Discussion Paper. Once the basic pattern of proposals is established it is hard for the Inquiry to alter course radically. Although it is possible for the Inquiry to abandon or substantially modify proposals for which there is little support, it is more difficult to publicise, and gauge support for, novel approaches suggested to us late in the consultation process.

1.32 Third, the ALRC maintains an active program of **direct consultation** with stakeholders and other interested parties. The ALRC is based in Sydney, but in recognition of the national character of the Commission, consultations will be conducted around Australia during the Inquiry. Any individual or organisation with an interest in meeting with the Inquiry in relation to gene patenting issues is encouraged to contact the ALRC.

Timeframe for the Inquiry

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

1.34 This **Issues Paper** is the first document produced in the course of this Inquiry, and is intended to identify the main issues relevant to the Inquiry, provide some background information, and encourage informed public participation. If there are passages that appear to imply tentative conclusions about the likely direction of work, this is unintended and not meant to inhibit full and open discussion of issues and policy choices. At this early stage, the Inquiry is genuinely open to all approaches.

In order to be considered for use in the Discussion Paper, submissions addressing the questions in this Issues Paper must reach the ALRC by **Tuesday, 30 September 2003**. Details about how to make a submission are set out at the front of this publication.

1.35 The Issues Paper will be followed by the publication of a **Discussion Paper** early in 2004. The Discussion Paper will contain a more detailed treatment of the issues, and will indicate the Inquiry's current thinking in the form of specific reform proposals. The ALRC will then seek further submissions and undertake a further round of national consultations in relation to these proposals. Both the Issues Paper and 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.

1.36 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.[11] 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.[12]

1.37 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.

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

12 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.

2. Genetic Science, Human Health and Gene Patents

Contents

Introduction

2.1 This chapter serves as a basic primer on genetics and human health, with the purpose of providing sufficient scientific background to inform the discussion about intellectual property rights over genetic materials and technologies in this Issues Paper. The chapter draws from material published previously, as part of the ALRC and Australian Health Ethics Committee (AHEC) inquiry into the protection of human genetic information.[13]

2.2 The chapter describes the basics of modern genetic science, including the nature of DNA, RNA, genes and chromosomes, and then considers some of the implications of the 'new genetics' for human health.[14] The chapter then describes the types of genetic materials and technologies over which intellectual property rights

13 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, Ch 2.

14 Ibid. See also R Hawley and C Mori, *The Human Genome: A User's Guide* (1999) Harcourt Academic Press, Burlington; M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London; R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone; The Cooperative Research Centre for Discovery of Genes for Common Human Diseases, *GeneCRC*, <www.genecrc.org/>, 18 February 2003.

potentially may be asserted[15] and explains some of the terminology used throughout the Issues Paper.

Genetic science

DNA, RNA, genes and chromosomes

2.3 Every cell in the human body contains a nucleus, with the exception of red blood cells, which lose this structure as they mature. Within the nucleus are tightly coiled threadlike structures known as chromosomes. Humans normally have 23 pairs of chromosomes, one member of each pair derived from the mother and one from the father. One of those pairs consists of the sex chromosomes—with two X chromosomes determining femaleness, and one X and one Y determining maleness. The other 22 chromosomes are known as autosomes.

2.4 Each chromosome has within it, arranged end-to-end, hundreds or thousands of genes, each with a specific location, consisting of the inherited genetic material known as deoxyribonucleic acid (DNA). Some chromosomes are significantly larger than others, and some are more densely packed with genes. Under the standard system of identification, scientists have numbered these autosomes from 1–22 in size order, with chromosome 1 being the largest (containing nearly 3,000 genes).[16]

2.5 DNA contains a code that directs the 'expression' or production of proteins, which form much of the structure of the cell and control the chemical reactions within them. The DNA of each gene is characterised by a unique sequence of bases that form the 'genetic code'.[17] These bases are arranged in groups of three, known as codons or phrases.

2.6 There are four basic building blocks (referred to as bases or nucleotides) for DNA: adenine (A) and guanine (G), which are known as purines; and thymine (T) and cytosine (C), which are known as pyrimidines. These nucleotides link together to form long polynucleotide chains, having a defined sequence of nucleotides. A DNA molecule consists of two of these chains, linked together by hydrogen bonds, running in opposite directions. The two chains link together in a ladder-like shape, twisted into

15 The discussion is drawn in part from the Human Genome Project Information website pages on 'Genetics and Patenting': see Human Genome Project, *Patenting Genes, Gene Fragments, SNPS, Gene Tests, Proteins, and Stem Cells*, US Department of Energy, <www.ornl.gov/TechResources/Human_Genome/elsi/patents.html#2>, 17 June 2003.

16 See the US Department of Energy's 'Gene Gateway' website: US Department of Energy Human Genome Program, *Chromosome FAQs*, <www.ornl.gov/TechResources/Human_Genome/posters/chromosome/faqs.html>, 17 June 2003.

17 For an excellent popular account of modern genetics, see M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London.

the now famous double helix first described by James Watson and Francis Crick in 1953.[18]

2.7 Linkage of the chains follows a strict rule, known as complementary base pairing, so that the base A can only pair with the base T, and vice versa; and the base G can only pair with the base C, and vice versa. The human genome is comprised of about 3.2 billion of these base pairs.

2.8 There are many different definitions of a gene, but one of the most commonly accepted is that a gene contains all of the information required to determine the expression of a specific protein or chain of amino acids (a polypeptide). Sometimes a polypeptide can form a complete protein on its own (as in the case of insulin), but in most cases a number of polypeptides combine to create a single protein (as in the case of collagen and globin).

2.9 Proteins are critical components of all cells, determining colour, shape and function. Proteins can have a structural role (such as keratin, from which hair is made), or a functional role in regulating the chemical reactions that occur within each cell (such as the enzymes involved in producing energy for the cell). Proteins are themselves made up of a chain of amino acids. Within the DNA there is a code that determines which amino acids will come together to form that particular protein. The genetic code for each amino acid, consisting of three bases, is virtually identical across all living organisms.[19]

2.10 Different genes are switched on and off in different cells, leading to different proteins being made or expressed with varying structures, appearances and functions—leading to the production of brain cells, nerve cells, blood cells, and so on. Contemporary stem cell research is based on the idea that it should be possible to learn how to use gene switches to coax stem cells into developing into the specialised cells or tissue needed for therapeutic purposes.

2.11 Research has also begun to focus on 'epigenetic' changes to the human genome—subtle modifications that do not alter the DNA sequence, but may play a role in modulating gene expression. Apart from environmental influences, this may explain, for example, why many diseases appear only later in life and why one twin may develop a genetic-linked disease while the other does not.[20]

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18 Building upon work by Linus Pauling and Robert Corey, and 'stimulated by a knowledge of the general nature of the unpublished experimental results and ideas of Dr Maurice Wilkins, Dr Rosalind Franklin and their co-workers at King's College, London': See J Watson and F Crick, 'A Structure for Deoxyribose Nucleic Acid' (1953) 171 *Nature* 737. In 1962, Watson and Crick were awarded the Nobel Prize for this work.

19 There are 64 different possible codons (given the four letters in the building blocks), and no codon can code for more than one amino acid. As there are only 20 amino acids, some codons must encode the same amino acid. See R Hawley and C Mori, *The Human Genome: A User's Guide* (1999) Harcourt Academic Press, Burlington, 32.

20 See C Dennis, 'Altered States' (2003) 421 *Nature* 686 for a summary of recent research into epigenetics.

2.12 When the instructions in a gene are to be read, the DNA comprising that gene unwinds and the two strands of the double helix separate. An enzyme called RNA polymerase allows a complementary copy of one strand of the DNA to be made. This copy is made from RNA nucleotides, and is called messenger RNA (or mRNA) because it carries the coded genetic information to the protein-producing units in the cell, called ribosomes.[21]

2.13 This process of reading the message in the DNA is called transcription. In the ribosomes, the amino acids are assembled in the precise order coded for in the mRNA.[22] The process of converting the message encoded in the RNA (mRNA) to protein using the ribosome is called translation. When the whole message has been translated, the long chain of amino acids folds itself up into a distinctive shape that depends upon its sequence—and is then known as a protein.[23]

2.14 In humans, genes comprise only a small proportion of the DNA in a cell. Up to 98% of DNA consists of 'non-coding' regions—popularly, but incorrectly, referred to as 'junk DNA'—which are full of repeat sequences (micro-satellites), pseudogenes and retroviruses. By way of contrast, there are no non-coding portions of DNA in bacteria—there are only genes, each one expressing a specific protein.

2.15 In recent years, genetic scientists increasingly have come to believe that non-coding DNA may be the basis for the complexity and sophistication of the human genome, which permits only 30,000 or so genes to produce about 200,000 proteins. A leader in this field, Professor John Mattick, Director of the Institute for Molecular Biology at the University of Queensland, has surmised that non-coding DNA forms

> a massive parallel processing system producing secondary signals that integrate and regulate the activity of genes and proteins. In effect, they co-ordinate complex programs involved in the development of complex organisms.[24]

Genetic difference: genotype and phenotype

2.16 All humans have the same basic set of about 30,000–35,000 genes, according to the latest estimates.[25] This is far lower than the early estimates of 200,000 (based on the number of proteins), and even the relatively recent estimates of 100,000 used at the start of the Human Genome Project. This figure is similar for the mouse—and, at least for some people, uncomfortably close to the figures for the round worm (19,000), the fruit fly (13,000) and mustard cress (25,000). As has been widely reported, the human

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21 RNA also carries the linear code and employs the same building block letters as DNA, except that it uses U (for uracil) in place of T (for thymine).

22 Transfer RNA molecules (tRNA) also play a key role in carrying specific amino acids to the ribosome to be linked to the growing polypeptide or protein.

23 See M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 9.

24 G O'Neill, 'Ghost in the Machine', *The Bulletin*, 11 March 2003, 55.

25 E Lander, 'Genomic Information: Driving a Revolution in Bio-Medicine' (Paper presented at Seventh International Conference of the Human Genome Organisation, Shanghai, 14 April 2002).

genome is more than 98% identical to that of chimpanzees, and 97% identical to that of gorillas.[26]

2.17 Genes may come in different versions, known as alleles. These alleles arise when there is a change in the ordering of the bases described above—in effect, a 'typographical error' in the code, involving the change of a single letter, the inversion of two letters, the deletion or insertion of a codon, or the repetition of a codon. This change in the sequence (a mutation) may cause no harm, merely resulting in a polymorphism, or it may make the gene faulty in the way it directs (expresses) the production of protein. In a very few cases the mutation is beneficial.

2.18 Although any two human beings are at least 99.9% genetically identical, the precise DNA sequence of about 3.2 billion base pairs will differ slightly in each person's genetic code. The 0.1% of difference is thought to comprise more than 10 million common single-letter genetic variations (single nucleotide polymorphisms, or SNPs) as well as a larger number of rare variants. The rate of variation is very low in humans (one SNP per 1,300 bases) compared with other species, including other primates—suggesting a population that has descended from a small 'starter population'. This explains both the striking similarities among all people, which are the result of our common inheritance, and the many individual differences found even within a nuclear family.

2.19 Some genetic variations make little or no difference to health, for example hair colour. However, some mutations do affect basic functioning:

> Mutations are permanent and inheritable changes in the ability of a gene to encode its protein. Much like typographical errors, which can change the meaning of a word, or even render a sentence as gibberish, such changes in gene structure can have severe effects on the ability of a gene to encode its protein. Some mutations prevent any protein from being produced, some produce a non-functional or only partially functional protein, and some produce a faulty or poisonous version of the protein.[27]

2.20 For example, Huntington's disease (HD) is caused by a mutation to a gene that lies on chromosome 4, in which the triplet CAG repeats an abnormally large number of times. Most people have 10–35 repeats; 40 or more repeats mean that the person will develop HD at some time, with a larger number of repeats leading to earlier and more severe onset. The complete lack of this triplet, together with other mutations, will cause another rare but serious disease, Wolf-Hirschhorn syndrome.[28]

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26 The principal genetic difference is that the other primates have 24 pairs of chromosomes, rather than the 23 pairs that characterise human beings. This appears to be the result of the fusion of two medium-sized ape chromosomes to become human chromosome 2, the second largest of the human chromosomes. Human chromosome 2 is not only the same size as the two ape chromosomes put together, but it also contains the same pattern of bands: M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 24.

27 R Hawley and C Mori, *The Human Genome: A User's Guide* (1999) Harcourt Academic Press, Burlington, 6.

28 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 55.

2.21 The unique combination of alleles found in a particular individual's genetic make-up is said to constitute that person's genotype. The observable physical characteristics of this genotype, as determined by the interaction of both genetic makeup and environmental factors, is said to constitute that person's phenotype. This includes such features as eye and hair colour, determined genetically,[29] as well as height and weight—determined by genetic factors as well as by diet, access to good healthcare and other environmental influences.

Patterns of inheritance

2.22 Because mutations can affect the functioning and expression of the alleles of genes, resulting in particular traits or characteristics, it is possible to follow the pattern of inheritance of the different alleles of a gene in a family. For most genes, two copies are found in the one individual. If the two copies are the same allele, the individual is said to be homozygous. If two different alleles for that gene are present, the individual is referred to as heterozygous for that gene—except for those traits coded for by genes that are found on the X chromosome.

2.23 As noted above, autosomes are the chromosomes that do not determine sex—in humans, this means all of the chromosomes except for the X and Y. Everyone has two copies of the autosomes and therefore two copies of the genes carried on these chromosomes.

2.24 A recessive trait is one that is expressed only if an individual is homozygous for a mutated copy of that gene—that is, he or she must have two copies of the mutated allele coding for it, one inherited from the mother and one from the father. Two parents who themselves do not express a particular trait nevertheless may have a child with the trait if each parent is a heterozygous carrier for the mutated allele—that is, if each parent has one copy of the recessive mutated allele and one copy of a normally functioning allele. Where both parents are carriers, there is a one-in-four chance of a child inheriting both abnormal alleles and so developing a disorder.

2.25 A dominant trait is one that is manifested when a person has only one mutated allele in a particular gene pair. An affected person may have inherited the mutated allele from either parent or, as the result of a new mutation, may be the first person in the family to have it. There is a one-in-two chance that a child will inherit a genetic trait if one parent has a dominant mutated allele. Examples of autosomal dominant traits include HD, myotonic dystrophy, hereditary non-polyposis colorectal cancer, Marfan syndrome, familial adenomatous polyposis, and early onset familial Alzheimer's disease.

2.26 X-linked traits are determined by genes found on the X chromosome. Males have an X and a Y chromosome, so they have only one copy of each gene found on the

29 At least initially—hair and eye colour now can be modified cosmetically and, of course, hair colour can change naturally over time.

X chromosome and will always express a mutated copy of one of these genes. Because a woman has two X chromosomes, having a recessive mutated allele on one X chromosome may not cause the trait to be expressed because she will have a normally functioning allele on the other X chromosome. X-linked conditions caused by recessive genes include haemophilia, fragile X mental retardation and Duchenne muscular dystrophy.

The importance of penetrance

2.27 Penetrance is the term used to describe the degree of likelihood (based on clinical studies) that an individual carrying a particular genetic trait that *could* cause a disorder *will* actually develop it.[30] This can vary from very low to very high. For instance, it is possible to speak of the penetrance of each particular mutation (or combination of mutations) causing cystic fibrosis. For the mutation known as DF508, the penetrance is high—about 99%. For other alleles, the penetrance is lower—but this calculation is also dependent upon the definition of the disease.[31]

2.28 Mutation in the so-called 'breast cancer gene', BRCA1, which is found in up to 1% of women in certain populations, is another example. Its presence is said to increase the risk of developing breast cancer by a factor of five. However, only 60–85% of women with a BRCA1 mutation will develop breast cancer during their lifetimes (that is, 60–85% penetrance). In other words, 15–40% will not do so. HD is an example of a condition with a very high penetrance, approaching 100%. Those who test positive for the HD mutation will almost always develop the disease if they live long enough.[32] However, even for HD, some people may develop the disease very late in life, or die of something else before they manifest symptoms.

Genetics and human health

2.29 It is now common in reporting about health issues for the terms 'BRCA1' and 'BRCA2' to be used as a form of shorthand for 'breast cancer'. This is highly misleading: *everyone* has the BRCA1 and BRCA2 genes, which in their correct form have a role in suppressing the growth of tumours in breast and ovarian tissue. Increased risk of breast cancer is due to inheriting the mutated alleles of these genes, which remove their protective capacity.

2.30 Matt Ridley has pointed out that the tendency to identify a specific gene as the cause of disease obscures the vital role of genes in human health:

30 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 47.

31 In the case of cystic fibrosis, for example, clinicians must consider whether male infertility in the absence of any other clinical signs is a 'condition', a 'disease', or nothing of significance.

32 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 58. See M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 55–66.

> Open any catalogue of the human genome and you will be confronted not with a list of human potentialities, but a list of diseases, mostly named after pairs of obscure central-European doctors. … The impression given is that genes are there to cause diseases. …
>
> Yet to define genes by the diseases they cause is about as absurd as defining organs of the body by the diseases they get: livers are there to cause cirrhosis, hearts to cause heart attacks and brains to cause strokes. It is a measure, not of our knowledge but of our ignorance, that this is the way the genome catalogues read. It is literally true that the only thing we know about some genes is that their malfunction causes a particular disease. This is a pitifully small thing to know about a gene, and a terribly misleading one. … The sufferers have the mutation, not the gene.[33]

2.31 It should be noted that the labelling of many genetic variations as 'diseases' or 'disorders' is itself problematic—historically, some of these mutations served to *enhance* the prospects of survival in certain environmental contexts. For example, the (autosomal recessive) genetic variations that produce such conditions as β-thalassaemia, Tay-Sachs disease, cystic fibrosis, and sickle cell anaemia all conferred certain advantages on people with carrier status in relation to common health problems (such as malaria, in the case of β-thalassaemia and sickle cell anaemia).[34]

2.32 Medical conditions or diseases linked to genes can be classified in a number of ways,[35] including: monogenic (or single gene) disorders; polygenic (or multi-gene) disorders; and multifactorial disorders.[36]

2.33 A monogenic disorder is one in which a mutation in one or both alleles of a single gene is the main factor in causing a genetic disease. Much of our early understanding about genetic influences on health is derived from the observation and study of monogenic disorders such as HD—although such diseases are relatively rare.

2.34 The vast majority of medical conditions with some genetic link involve either the complex interaction of a number of genes (polygenic) or the complex interaction between genes and the environment (multifactorial disorders).[37]

2.35 In the case of multifactorial disorders, inheriting a mutated allele for a particular condition means that the person is susceptible or predisposed to develop the condition. Other factors such as diet or exposure to certain environmental factors are necessary to bring about the expression of the trait or condition. Most of the important and common medical problems in humans are multifactorial, including heart disease,

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33 M Ridley, *Genome: The Autobiography of a Species in 23 Chapters* (1999) Fourth Estate, London, 54–55.

34 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, [2.47].

35 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 37.

36 In addition, there are chromosomal disorders (such as Down syndrome) and somatic cell disorders (such as cancer), in which the genetic abnormality was not present at conception but is acquired during life and is found only in specific cells rather than in all cells in the body: Ibid, 210–211.

37 Ibid, 55, 211.

hypertension, psychiatric illness (such as schizophrenia), dementia, diabetes, and cancers.

2.36 According to the Human Genome Database,[38] as at 29 December 2002, 14,014 genes had been mapped to individual chromosomes, of which 1,639 had been identified as being involved in a genetic disorder. It may be that most of the simple linkages have already been made, since the rate of discovery has slowed dramatically despite better technology: of the last 3,783 genes to have been mapped, only 17 have been identified with a genetic disorder.

2.37 In order to study more complex human diseases, researchers are developing powerful statistical approaches, including haplotype mapping. Haplotypes (or haplotype blocks) are identified by patterns of SNPs closely-linked along a region of a chromosome, which tend to be inherited together.[39]

2.38 In theory, there could be large numbers of haplotypes in a chromosome region; however, recent research suggests that there are a smaller number of common haplotypes—perhaps as few as four or five common patterns across all populations—which would permit researchers to shortcut their work dramatically by testing for genetic predispositions for such complex diseases as cancer, diabetes, hypertension, and Alzheimer's block-by-block, rather than letter-by-letter.[40]

2.39 Such research may enable individuals' genetic patterns to be compared with known patterns to determine if the individual is at risk for particular diseases; enable researchers to examine drug efficacy in specific diseases with individuals' genetic patterns; and reveal the role of variation in individual responses to environmental factors.[41]

The subject matter of gene patents

2.40 Genetic science and related technologies are important in medical research and in the development and provision of healthcare. The significance of genetic science and technologies for human health is likely to increase as more becomes known about the biological function of genes and the proteins they produce.

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38 An international collaboration in support of the Human Genome Project. See the excellent website hosted by the Hospital for Sick Children in Toronto, Canada, which contains regularly updated tables containing details of 'Genetic Disorders by Chromosome', as well as a 'Display Map' to view genetic disorders mapped to a chromosome. See Hospital for Sick Children, *Reports and Statistics*, <www.gdb.org/gdb/report.html>, 18 February 2003.

39 See the National Human Genome Research Institute website: National Human Genome Research Institute, *Developing a Haplotype Map of the Human Genome for Finding Genes Related to Health and Disease*, <www.genome.gov/page.cfm?pageID=10001665>, 20 February 2003.

40 See S Gabriel and others, 'The Structure of Haplotype Blocks in the Human Genome' (2002) 296 *Science* 2225; discussed in C Morton, *The Next Big Thing in Mining the Genome: A Simpler Tool for Finding Disease Genes and Spotting Genetic Variation*, Harvard University Focus, <www.focus.hms.harvard.edu/2002/June7_2002/genomics.html>, 21 July 2002.

41 See the National Human Genome Research Institute website: National Human Genome Research Institute, *National Human Genome Research Institute*, <www.genome.com>, 24 June 2003.

2.41 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.[42] 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.

2.42 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 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*. In fact, a wide range of potential subject matter falls within the ambit of the Inquiry.

2.43 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. The Inquiry has decided that, for the purposes of this Issues Paper, the most convenient course is to group the potential subject matter of gene patents into the following four broad categories:[43]

- 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.

2.44 These categories of subject matter are discussed in more detail below. For the sake of brevity, elsewhere in this paper the term 'genetic materials and technologies' is sometimes used to encompass all four categories.

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42 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999), Commonwealth of Australia, Canberra, Ch 16.

43 These categories do not have a precise scientific or legal meaning, nor are they entirely mutually exclusive.

Genetic technologies

2.45 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.[44]

- 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 history.[45] Genetic testing for clinical (medical) purposes normally involves mutation analysis—the identification of variations in DNA sequences that are associated with disease or dysfunction.[46] Many genetic tests are patented by their developers, with medical testing conducted under licence and royalties payable to the patent holder.

- 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.[47]

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

2.46 These and other 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',

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

45 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, Ch 2, 3, 10.

46 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 28. Point mutations and deletions may be detected by PCR. However, where the genes are too large to make sequencing a practical diagnostic approach, other methods are used: See R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 28–29.

47 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 155.

'novelty', and 'usefulness' are clearer than they are in the case of patents over genetic materials.[48]

2.47 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 16, 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

2.48 The term 'natural genetic materials' is used in this Issues Paper to refer to forms of genetic material in their natural state, including DNA, RNA, genes and chromosomes.[49]

2.49 As discussed in Chapter 9, 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:

> 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.[50]

2.50 While 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 clearly distinguish what is claimed from the naturally occurring molecule.

2.51 'Natural genetic materials' include genetic material in living cells, such as stem cells. While naturally occurring (for example, as embryonic stem cells), stem cells may be patentable when isolated and propagated to produce a 'cell line'.[51] Genetic materials include living cells that have been modified by genetic manipulation—such as in gene therapy.

2.52 The Human Genome Project has noted that:

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48 See Ch 9.

49 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 (see Ch 1).

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

51 See Ch 9.

> Therapeutic cloning, also called 'embryo cloning' or 'cloning for biomedical research,' is the production of human embryos for use in research. The goal of this process is not to create cloned human beings but rather to harvest stem cells that can be used to study human development and treat disease. Stem cells are important to biomedical researchers because they can be used to generate virtually any type of specialized cell in the human body. …
>
> Cell lines and genetically modified single-cell organisms are considered patentable material. One of the earliest cases involving the patentability of single-cell organisms was *Diamond v Chakrabarty* in 1980, in which the [US] Supreme Court ruled that genetically modified bacteria were patentable.
>
> Patents for stem cells from monkeys and other organisms already have been issued. Therefore, based on past court rulings, human embryonic stem cells are technically patentable. A lot of social and legal controversy has developed in response to the potential patentability of human stem cells. A major concern is that patents for human stem cells and human cloning techniques violate the principle against the ownership of human beings. In the U.S. patent system, patents are granted based on existing technical patent criteria. Ethical concerns have not influenced this process in the past, but the stem cell debate may change this. It will be interesting to see how patent law regarding stem cell research will play out.[52]

Isolated genetic materials

2.53 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.[53] As noted above, isolated genetic material may relate to whole genomes, single genes or gene fragments. According to the Human Genome Project, over three million genome-related patent applications have been filed.[54]

2.54 Most practical applications of genetic science and technology depend upon 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.[55]

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52 Human Genome Project, *Patenting Genes, Gene Fragments, SNPS, Gene Tests, Proteins, and Stem Cells*, US Department of Energy, <www.ornl.gov/TechResources/Human_Genome/elsi/patents.html#2>, 17 June 2003, citing T Caufield, 'From Human Genes to Stem Cells: New Changes for Patent Law' (2003) 21 *Trends in Biotechnology* 101. See *Diamond v Chakrabarty* 447 US 303 (1980).

53 When gene patents extend to isolated genetic materials, the genetic sequences of that material form part of the description of the patented invention. The literature in this area often refers to the patenting of 'genetic sequences' and, where convenient, this usage is also sometimes adopted in this Issues Paper, notwithstanding that it is more accurate to say that isolated genetic materials are the subject matter.

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

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

2.55 While there is no single patent over the whole human genome, the whole genetic sequences 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.[56]

2.56 As a practical matter, sequencing generally requires natural DNA 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.[57] PCR technology was developed in 1985 (and then patented) by Dr Kary Mullis and others at Cetus Corporation in California.[58] 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).

2.57 As noted above, a gene contains all the information required to determine the expression of a specific protein (or 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.

2.58 Gene fragments include a wide range of different types of isolated genetic materials[59] including SNPs, expressed sequence tags (ESTs), and other gene fragments encoding important regions of proteins.[60]

2.59 The Human Genome Project has identified the value of SNPs for research relating to human health:

> 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.

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56 United States patent 5,350,671.

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

58 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.

59 In this Issues Paper, the term 'gene fragment' may refer to genetic material that is, technically, not part of a gene.

60 For example, extracellular domains of receptors or antigens.

> In April 1999, ten large pharmaceutical companies and the UK Wellcome Trust philanthropically announced the establishment of a non-profit foundation to find and map 300,000 common SNPs (they found 1.8 million). Their goal was to generate a widely accepted, high-quality, extensive, publicly available map using SNPs as markers evenly distributed throughout the human genome. The consortium plans to patent all the SNPs found but will enforce the patents only to prevent others from patenting the same information. Information found by the consortium is being made freely available.[61]

2.60 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.[62]

2.61 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.[63]

2.62 Professor Ron Trent also has described the way in which gene patenting can attract controversy:

> Initially, the patenting of genes or DNA sequences raised concern that there would be a reduction in dissemination of information throughout the scientific community. To date, this has not occurred to any significant extent. However, a research group at the US National Institutes of Health (NIH) surprised the scientific community by filing patents for over 6000 anonymous human brain-derived DNA sequences in 1991. These 'genes' were isolated from a brain cDNA library and their uniqueness demonstrated by sequencing a segment of the cDNA and showing on DNA database searches that the sequences were not present in the databases. Thus, they represented unique DNA segments (called ESTs—expressed sequence tags) which, since they

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

62 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>, 8 January 2003.

63 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), Intellectual Property Research Institute of Australia, Melbourne.

> came from a cDNA library, were likely to be segments of genes with, as yet, unknown function. … Since the above cDNA clones have no known function their utility is difficult to assess. … Groups on both sides of the Atlantic were drawn into the NIH controversy, which was eventually defused when the patent applications were withdrawn in 1994.[64]

2.63 Isolated genetic material may relate to coding or non-coding sequences, or both. Coding genetic sequences, such as in ESTs, code for particular proteins. As noted above, the role of non-coding DNA (including SNPs and microsatellites) is yet to be fully established. However, non-coding DNA may produce secondary signals that integrate and regulate the activity of genes and proteins.[65] Australian company Genetic Technologies Corporation Pty Ltd holds four US patents covering the use of non-coding DNA for genetic analysis[66] and for gene mapping, including the location of 'genes of interest'.[67]

Genetic products

2.64 Genetic materials may be used to produce a range of items, which can be referred to as 'genetic products'. Genetic products include:

- Proteins.[68] 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'.[69] Proteomics is widely seen 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.[70]

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64 R Trent, *Molecular Medicine: An Introductory Text* (2nd ed, 1997) Churchill Livingstone, 198–199.

65 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.

66 United States patents 5,192, 659; 5,612,179; 5,789,568. See Genetic Technologies Limited, *Slide Presentation*, GTG, <www.gtg.com.au/Presentation0503/SlidePresentation06.html#btn>, 18 June 2003.

67 United States patent 5,851,762; see Ibid.

68 Or important functional regions of proteins, such as immunoglobulin binding sites for antigens.

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

70 Human Genome Project, *Genome Glossary*, US Department of Energy, <www.ornl.gov/TechResources/Human_Genome/glossary/>, 5 June 2003.

- Anti-sense DNA. This is DNA that has been ~~modified~~ synthesised to ~~express~~ 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.[71]

71 M Jones, *Benitec Gets First US Patent for ddRNAi, Plans to Enter US Market*, Genome Web, <www.genomeweb.com/articles/view.asp?Article=200366143938>, 17 June 2003.

3. An Introduction to Patents

Contents

Introduction

3.1 The Terms of Reference require the ALRC to examine the impact of current patent laws and practices on the conduct of research, the biotechnology sector and the cost-effective provision of healthcare in Australia. This chapter provides a brief introduction to patents and, in particular, to the nature and purpose of patent rights. Greater detail may be found in subsequent chapters of this Issues Paper.

Nature of patents

3.2 A patent is an intellectual property right that is 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.[72] The government grants this monopoly right in exchange for the inventor placing the details of the invention in the public domain.

3.3 A patent does not grant an *absolute* right to exploit an invention. In practice, the patent holder may have to satisfy other legal requirements in order to exploit the patented product or process. For example, a patented pharmaceutical compound may need to be approved under the *Therapeutic Goods Act 1989* (Cth) before it can lawfully be marketed and sold as a treatment for a particular condition.

3.4 A patent holder is not obliged to exploit a patented invention, but the failure to do so may have further implications. For example, the patent could be subjected to compulsory licensing under the *Patents Act 1990* (Cth) (*Patents Act*). Chapter 15 discusses the law and practice in relation to Crown use of patents, Crown acquisition of patents, and compulsory licensing.

72 A standard patent generally has a term of 20 years; an innovation patent has a term of eight years.

3.5 Patents are a form of intellectual property right; they do not confer ownership in the physical material described in a patented product or process. For example, a patent describing a genetic sequence does not amount to ownership of the sequence itself.

Purpose of patents

3.6 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.[73] 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. Governments may use patents to foster developing research sectors and fledgling industries, and consequently to encourage economic growth and development.

3.7 These goals are achieved by providing incentives for innovation and knowledge sharing in the form of limited monopoly rights to make, hire, sell or otherwise dispose of, use, import or keep the new product or process.[74] These 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.[75]

3.8 The limited monopoly period means, however, that the patented invention will eventually be available for free and unrestricted public access when the patent term expires. As Patricia Baird has commented, the basic principles of patent law

> achieve a compromise between the broader social desirability of increasing useful technology developments, and the social undesirability of ongoing market monopolies for critical processes or products. The compromise is a way of securing future benefits for the common good.[76]

3.9 Patents promote knowledge sharing by requiring the patent holder to disclose the details of the invention in the public domain, in return for exploitation rights. Patents also provide a system for trading knowledge between countries, by enabling the transfer of technology through licensing.

Criteria for patentability

3.10 Most countries apply similar tests for patentability: an invention must be 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 adequate to allow a skilled person to create the invention independently.

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73 L Kass, 'Patenting Life' (1981) 63 *Journal of the Patent Office Society* 570, 580.

74 *Patents Act 1990* (Cth) s 13(1), sch 1.

75 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 136.

76 P Baird, 'Patenting and Human Genes' (1998) 41 *Perspectives in Biology and Medicine* 391, 391.

3.11 In Australia, the *Patents Act* provides that an invention will be 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.[77]

3.12 Certain inventions are expressly excluded from patentability. Australia has relatively few express exceptions to 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.[78] 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 social policy.[79] Chapter 9 provides a detailed discussion of the criteria for patentability under Australian law.

Other inquiries and reports

3.13 The patenting of genetic materials and technologies has raised significant concerns in other jurisdictions. During 2002–03, several overseas organisations released reports discussing the ethical, legal, social and policy implications arising from gene patents. These reports include:

- the Organisation for Economic Cooperation and Development's report, *Genetic Inventions Intellectual Property Rights and Licensing Practices: Evidence and Policies*;[80]
- the Nuffield Council on Bioethics' report, *The Ethics of Patenting DNA*;[81]

77 *Patents Act 1990* (Cth) s 18.
78 Ibid ss 18(2), 50(1)(a), 101B(2)(d).
79 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 15 April 1994) art 27(2).
80 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris.
81 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>.

- the Royal Society's report, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science*;[82]

- the Canadian Biotechnology Advisory Committee's report, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*;[83]

- the Ontario Ministry of Health and Long-Term Care's report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare—Report to the Provinces and Territories*;[84] and

- the New Zealand Ministry of Economic Development's discussion paper, *A Review of the Patents Act 1953: Boundaries to Patentability.*[85]

3.14 These reports are discussed in greater detail in subsequent chapters of this Issues Paper.

82 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003) The Royal Society, London.

83 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>.

84 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>.

85 New Zealand Ministry of Economic Development, *A Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002), New Zealand, see <www.med.govt.nz/buslt/int_prop/patentsreview/index.html>.

4. Ethical, Social and Economic Dimensions

Contents

Introduction

4.1 The Terms of Reference ask the ALRC to have regard to economic, ethical, and access and equity issues relating to gene patents. This chapter outlines the ethical, social and economic dimensions of gene patents and provides background to issues considered in later chapters.

4.2 As discussed in Chapter 2, for the purposes of this Issues Paper the potential subject matter of gene patents has been grouped into four broad categories—genetic technologies, natural genetic materials, isolated genetic materials and genetic products. When gene patents were a relatively new issue, ethical and social concerns focused mainly on whether it was acceptable to patent human genetic materials—although the distinction was seldom made between natural and isolated genetic materials.

4.3 At that time, the ethical, legal and social implications of such patents were not well understood and the application of patent law to genetic materials and technologies was not well-established. It appears that concerns about whether it is ethical to patent isolated human genetic materials are no longer as prominent as they once were. Many such patents have already been issued in numerous countries, including Australia, and the practice of patenting isolated human genetic materials appears to be more widely accepted.

4.4 However, there remains a range of broad ethical and social concerns relevant to gene patents. These concerns include the effect of gene patents on research, innovation and the cost of, and access to, health care; commercial and economic

implications; and issues about benefit sharing, consent and control in research leading to patentable inventions.

4.5 This chapter examines both the early ethical objections to patents on human genetic materials and recent concerns about the ethical, social and economic implications of gene patents generally. These implications are relevant to potential reforms to the patent system because the fundamental purpose of patents is to promote the public interest. The chapter concludes with a discussion of whether ethical and social concerns should be dealt with through the patent system or by other means.

Ethics and patents on genetic materials

4.6 Ethical concerns about patents in the context of genetic research have, in the past, centred on whether it is acceptable to issue patents on human genetic materials. Critics of this practice often assert 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.

Common heritage of humanity

4.7 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.[86] 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.[87]

Respect for human dignity

4.8 Another objection to patents on genetic materials is that they may engender a lack of respect for human life and dignity.[88] On this view, to grant a patent—a

86 HUGO Ethics Committee, *Statement on the Principled Conduct of Genetics Research* (1996), Human Genome Organisation, see <www.hugo-international.org>; *Universal Declaration on the Human Genome and Human Rights*, UNESCO, <www.unesco.org/ibc/en/genome/projet/>, 19 February 2003, art 12(a). See also *Recommendation No. 1425 on Biotechnology and Intellectual Property*, Council of Europe, (entered into force on 23 September 1999), rec 10; *Recommendation No. 1468 on Biotechnologies*, Council of Europe, (entered into force on 29 June 2000), rec 10.

87 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 22–23.

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

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.[89] Commercialisation of parts of human beings is ethically problematic because it might affect how we value people.[90]

4.9 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, including genes, are not like other materials to be owned and traded in the market place as common commodities'.[91] Objectification is said to be incompatible with respect for human dignity because it reduces human beings to things to which no respect is owed.[92] Objectification is also ethically unacceptable because it precludes respect for individual autonomy.

4.10 These 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: in other words, commodifying genetic materials does not commodify individuals.[93] Critics further suggest it is not apparent that the widespread issuing of patents on human genetic materials has led to a change in how human beings are perceived and treated.

Self-determination and self-ownership

4.11 It has also been argued that patents on 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.[94] On this view, self-determination—the right to make choices about how to live—is fundamentally linked to self-ownership—the right to choose how one's body is used. Supporters of this view argue that granting a patent over genetic material is akin to allowing parts of

89 The House of Representatives Standing Committee on Industry, Science and Technology noted similar objections in the broader context of patenting genetically modified (non-human) animals. The Committee 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), Commonwealth Parliament, Canberra, [7.37]–[7.42].

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

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

92 T Claes, 'Cultural Background of the Ethical and Social Debate about Biotechnology' in S Sterckx (ed), *Biotechnology, Patents and Morality* (2000) Ashgate, Aldershot, 179, 182. See also T Schrecker and others, *Ethical Issues Associated with the Patenting of Higher Life Forms* (1997), Westminster Institute for Ethics and Human Values McGill Centre for Medicine Ethics and Law, Montreal, see <www.strategis.ic.gc.ca/pics/ip/schrecef.pdf>, x.

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

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

people to be owned by others,[95] and some have likened it to 'a form of modern slavery'.[96]

4.12 Critics of this view argue that it is based on confusion between intangible intellectual property rights and physical property rights. 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.[97]

Religious objections

4.13 Patents on genetic materials are sometimes criticised on religious grounds.[98] 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.[99] 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'.[100]

Ethical, social and economic implications of gene patents

4.14 More current concerns focus on the variety of ethical, social and economic implications of gene patents, such as those relating to:

- the promotion of innovation;
- commercial and economic aspects of patenting;
- resource use and knowledge sharing;
- benefit sharing and research outcomes; and
- equitable access to healthcare.

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95 Ibid, 69.

96 This argument was raised as an objection to patenting a human DNA fragment involved in the production of H2 Relaxin but was rejected by the European Patent Office: *Howard Florey/Relaxin* [1995] EPOR 541, [6.1]–[6.3]. See also D Nicol, *Tissue Donations and Patents: Occasional Paper No 3* (2001), Centre for Law and Genetics, University of Tasmania, Hobart, 43, 51–52.

97 See R Crespi, *Patenting and Ethics: A Dubious Connection*, Pharmalicensing, <www.pharmalicensing.com/features/legal>, 4 June 2003.

98 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.

99 Danish Council of Ethics, *Patenting Human Genes: A Report* (1994) Danish Council of Ethics, Copenhagen, 32.

100 D Slater, 'huMouse', *Legal Affairs*, Nov-Dec 2002, 21, 26.

4.15 Some are positive implications, while others may be seen as negative. For example, the exclusive exploitation rights conferred by a patent are socially beneficial because they encourage innovation and, consequently, the development of new and useful products. However, these rights may also enable a patent holder to charge higher prices for products. This might have ethical implications, such as where the high price of a genetic test prevents some people from being tested.

4.16 As patent systems aim to promote public welfare, it is important that the negative implications of patents do not outweigh the beneficial aspects of the system. This section outlines some of the implications that need to be balanced against each other in considering possible reform of the patent system.

Promoting innovation

4.17 As discussed in Chapter 3, patents promote innovation through the provision of limited monopolies for the exploitation of new products and processes. Innovation benefits the community by creating new and improved goods that meet social needs. For example, innovations in medical research may produce new genetic tests and treatments, which will improve community health.

4.18 The knowledge sharing requirement of patents is based on the idea that 'scientific and technical openness benefits the progress of society more than do confidentiality and secrecy'.[101] By encouraging knowledge sharing, patents reduce the duplication of research efforts and encourage researchers to build on existing inventions. Researchers may study a patented product and find ways to improve it. For example, a patented genetic sequence might be vital to research into the causes of a genetic disorder, which leads to the creation of a genetic test or treatment.

4.19 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 patented inventions may provide direct returns to inventors and access to foreign markets. The grant of licences to Australian companies to manufacture inventions developed overseas can also improve the skills and know-how within the domestic community.

4.20 However, patents may have adverse implications for innovation and research. Patents may 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 an invention is sufficiently well-developed to ensure the patent will be granted.[102]

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

102 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 8.

4.21 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 a patent over the invention is awarded one.[103] This may discourage some researchers from embarking on a course of research that is already being pursued elsewhere, despite the possibility that they will do better or more efficient work.

4.22 Patents may also be a barrier to 'downstream' research. Downstream research is applied research directed at the development of a product or process with a potential commercial application. This type of research may be inhibited if patent licences are difficult to obtain or are too costly. For example, patents may hinder research by imposing charges on the use of basic tools or methods that are necessary to undertake other research.[104] Laboratories, small companies and universities may choose not to pursue research using patented research tools because of the cost and difficulty of navigating the complex set of patents that may be held by a number of different entities. The potential 'chilling effect' of gene patents on research is discussed in Chapter 11.

4.23 The economic rewards of patenting may direct investment away from producing goods with social utility, such as medical treatments for rare diseases, into more profitable areas.[105] Linked with this is the increasing emphasis on commercialisation of research within the public sector, and concerns that basic research may be skewed towards potentially profitable areas.[106] Patents may also discourage investment in research that will be made publicly available and for which patents will not be sought, because rational investors will provide financial backing only where financial returns can reasonably be expected.

4.24 In research areas where incentives to innovate are not required, patents may have more undesirable implications than benefits. For example, medical research is rarely conducted solely to reap the commercial rewards of patenting and marketing new treatments. Rather, it is often 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.

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

104 D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 76.

105 See also Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 137.

106 Similar concerns were discussed 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), Commonwealth Parliament, Canberra, [7.91]–[7.96].

Commercial and economic dimensions

4.25 Patents have a variety of commercial and economic benefits. Possessing a patent may help companies to grow by capitalising on the market potential of their inventions. Small companies may use patents to attract financial backing, and in their negotiations for funding and support from venture capital and manufacturers.

4.26 In addition, patents may stimulate the growth of national industry because local companies that hold patents can attract overseas investment and develop products for export.[107] Profits generated by patent exploitation can also be invested in further research and development, which may stimulate commercial and industrial growth.

4.27 However, patents may 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. Licence fees may also drive up prices.[108] These implications of gene patents are discussed in more detail in the context of medical genetic tests in Chapters 12 and 17.

4.28 There are considerable transactional costs associated with seeking the grant of a patent and enforcing the rights it provides. Fees must be paid before a patent application will be examined or granted, as well as to maintain patent rights that have been granted.[109] Also, claims of infringement must be pursued privately through the courts: asserting patent rights or challenging those of a competitor may be costly and difficult, particularly for small to medium enterprises.[110]

4.29 From a global perspective, patent systems may have unwanted consequences for countries that are net importers of intellectual property, where the expenditure on royalties for the use of patents owned by foreign entities might exceed the income earned from research using the patented invention. The majority of Australian biotechnology patents are owned by foreign entities (see Figure 4–1) and Australian researchers generally pay licence fees to overseas companies to utilise these patented technologies in research.[111] The Australian biotechnology industry and patent ownership are discussed in Chapter 6.

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107 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) *EIPR* 441, 445.

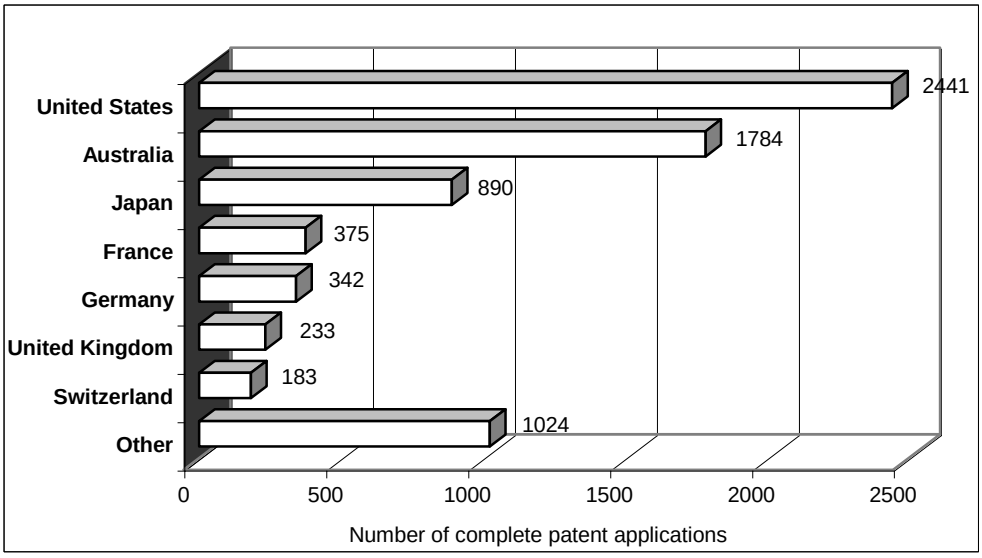
108 D Nicol, 'Gene Patents and Access to Genetic Tests' (2003) 11 *Australian Health Law Bulletin* 73, 75.

109 A patent holder is required to pay an annual fee to maintain a patent: see Ch 8.

110 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003) The Royal Society, London, 13; L Andrews, 'Genes and Patent Policy: Rethinking Intellectual Property Rights' (2002) 3 *Nature Reviews Genetics* 803, 806. See Ch 10.

111 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.

Figure 4–1 Country of residence of applicants for Australian patents 1999–2000



Source: IP Australia, *Industrial Property Statistics 1999–2000,* Table 9.

Resource use and knowledge sharing

4.30 The patent system is premised on the idea that if a resource is held in common and there is no incentive to conserve it, the resource may not be put to its optimal use. This is known as the 'tragedy of the commons'. On this view, the resource will be used more efficiently if it is owned and exploited privately. In the context of patents, this suggests that technology may be wasted if it is published without the right to prevent others from exploiting it.[112]

4.31 By contrast, Professors Michael Heller and Rebecca Eisenberg have suggested that the grant of numerous patents for biomedical inventions has produced 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.[113] In the context of gene patents, this occurs when multiple blocking patents are granted over pre-market or 'upstream' research products, particularly isolated genetic materials. The cost and inconvenience of obtaining multiple licences to use these upstream products in marketable or 'downstream' research may stifle research and innovation.[114] This is discussed further in Chapter 11.

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

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

114 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.

4.32 Gene patents also raise issues about access to, and ownership of, research results. Granting patents to private organisations or individuals is said to encourage innovation by creating a financial incentive for investment in research, and hence to stimulate research as researchers race to be the first to patent a new technology. However, private control of research results might have unwanted ethical and social implications for healthcare because private organisations may limit access to tests, therapies and drugs.

4.33 It has been suggested that it may be more appropriate for government agencies to hold patents over research results that have significant social and ethical implications, such as research tools and genetic sequences. Alternately, it might be appropriate to preclude patenting of some research results by making them available without charge. This would 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.[115]

Benefit sharing and control

4.34 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 materials or technologies should have any rights, entitlements or expectations to exercise control over, or benefit from, the research results.[116] This issue arises both in relation to individuals and groups. Benefit sharing could take many forms, including a financial benefit (such as a share in any profits or royalties made from the patent) or access to free medical care, treatment or therapy.

4.35 The HUGO Ethics Committee has recommended that all humanity should share in, and have access to, the benefits of genetic research. At a minimum, all research participants should receive information about general research outcomes and an indication of appreciation. Profit-making entities should dedicate a percentage (for example, 1–3%) of their annual net profit to healthcare infrastructure or to humanitarian efforts.[117]

4.36 Under Australian law, there are two barriers to a research participant asserting a legal right to share in any benefits of genetic research. First, the law is currently uncertain about the nature of property rights in human tissue,[118] and second,

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

116 The ALRC and the Australian Health Ethics Committee 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), ALRC, Sydney, see <www.alrc.gov.au>, Ch 15, 16, 18, 19.

117 HUGO Ethics Committee, *Statement on Benefit Sharing* (2000), Human Genome Organisation, see <www.hugo-international.org/>.

118 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, Ch 20 for more detail.

the *Patents Act 1990* (Cth) provides that a patent may only be granted to a limited category of persons, which does not include research participants.[119] However, at least in theory, a research participant could enter into a contractual arrangement with the researcher that provides some form of benefit in exchange for participation in the program.

United States case studies

4.37 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.

4.38 In *Moore v Regents of the University of California*, 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.[120]

4.39 In *Greenberg v Miami Children's Hospital Research Institute*, the Greenberg family (joined by other families and patient groups) 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 are currently seeking a permanent injunction restraining the hospital and scientist from enforcing the patent rights.[121]

4.40 A third example reflects a different approach to control and benefit sharing. An American family had two children with a rare genetic disease.[122] The parents established a foundation, found 2000 people with the disease to donate tissue for

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119 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).

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

121 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* (District Court for the Southern District of Florida, Moreno J, 29 May 2003). The plaintiffs have filed a motion for reconsideration of the order in relation to the count based on the lack of informed consent.

122 Pseudoxanthoma elasticum (PXE), which causes mineralisation of elastic tissue.

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, that any profits or revenue from the discoveries would be shared with the foundation, and that any genetic test must be made readily available to the foundation.[123]

Indigenous populations

4.41 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.[124]

4.42 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.[125] The HGDP has been widely criticised by indigenous peoples.[126]

4.43 An existing mechanism for ethical review of research on indigenous communities—including genetic research—involves the use of indigenous subcommittees working in conjunction with Human Research Ethics Committees (HRECs).[127] The subcommittee reviews proposed research projects and, among other things, ensures that the subject group has given informed consent to the proposed project. The ALRC is aware of one indigenous subcommittee that has the right of veto over HREC approval for a research project.[128]

Equitable access to healthcare

4.44 Gene patents may encourage the development of new products and processes with important healthcare applications. The prospect of obtaining a patent over a new diagnostic test or therapeutic product could be a sufficient incentive for an organisation to invest the time and resources necessary to develop the new invention. This could be

123 G Kolata, 'Sharing of Profits Is Debated As the Value of Tissue Rises', *The New York Times*, 15 May 2000.

124 See generally, M Davis, *Indigenous Peoples and Intellectual Property Rights* (1996-7), Department of the Parliamentary Library, Canberra, 4.

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

126 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), Michael Frankel & Company, Sydney, 29.

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

128 See J Condon and L Stubbs, *Top End Human Research Ethics Committee: Policy and Procedures Manual* (2000), Territory Health Services and Menzies School of Health Research, 9.

of benefit where the new product or process improves on existing methods of identifying or treating a particular genetic condition.

4.45 However, as described above, it is also possible that gene patenting might 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 a restrictive licensing scheme, this may limit access to the particular test, therapy or drug. These issues are discussed in more detail in Chapter 12.

Addressing ethical and social concerns through the patenting process

4.46 In some jurisdictions, patent laws explicitly require decision makers to consider ethical and social issues as part of the patent granting process. For example, under Article 53(a) of the *European Patent Convention* 'inventions the publication or exploitation of which would be contrary to *ordre public* or morality' are specifically excluded from patentability.

4.47 In Australia, the *Patents Act* may allow social and ethical considerations to be addressed to some extent through exclusions to patentable subject matter. Human beings and the biological processes for their generation are specifically excluded from patentability under the Act.[129] Moreover, s 50(1)(a) grants the Commissioner of Patents discretion to refuse to grant a patent for an invention the use of which would be contrary to law. It has also been suggested that the 'manner of manufacture' requirement in s 18 of the *Patents Act* may provide limited scope for ethical and social concerns to be considered in the patent process.[130]

4.48 However, the patent process under Australian law is essentially concerned with assessing whether the technology embodied in an invention meets the technical requirements for patentability. The *Patents Act* generally leaves the ethical and social implications of granting patent rights, and exploiting them, to other areas of the law. For example, a new type of engine in a car might meet the requirements for patentability, but restrictions on how and where such a car may be driven are left to traffic laws.[131]

4.49 Those who support excluding ethical and social considerations from the patent process argue that patents form part of an economic system for encouraging investment in research and they are concerned primarily with assessing the

129 *Patents Act 1990* (Cth) s 18(2).

130 See Ch 9.

131 It has been suggested that this is an appropriate approach where the use of an invention is ethically or socially objectionable: B Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement' (1994) 231 *Law & Policy in International Business* 101, 121.

inventiveness and utility of new inventions.[132] Ethical and social concerns are separate issues to be dealt with by other means.[133] Further, the patent system may be an ineffective mechanism for dealing with these considerations because it was not designed to address such issues.[134]

4.50 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 ethically or socially neutral.[135] A number of general arguments have been made for dealing with ethical and social 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, ethical considerations are implicitly and unavoidably part of the patent granting process.[136]

- The patent system exists to serve the public interest: considerations of public purpose should be fundamental to the patent granting process.[137]

- 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.[138]

- The incentives patents create may provide a mechanism for dealing with the ethical and social problems raised by the grant of patents. 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.[139]

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132 R Crespi, *Patenting and Ethics: A Dubious Connection*, Pharmalicensing, <www.pharmalicensing.com/features/legal>, 4 June 2003.

133 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) 231 *Law & Policy in International Business* 101, 121.

134 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) *EIPR* 39, 40.

135 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) *EIPR* 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), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>, 36.

136 B Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement' (1994) 231 *Law & Policy in International Business* 101, 121.

137 M Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *Australian Intellectual Property Journal* 202, 209.

138 Ibid, 211.

139 Ibid, 211.

4.51 If the patent system is to address ethical and social concerns, there is a variety of ways in which this might be achieved. These include exclusions to patentable subject matter, or a requirement that a patent application include a statement demonstrating the potential for the claimed invention to promote the public good.

4.52 It may be that some ethical and social concerns can be addressed through reforms that are designed to solve other problems raised by gene patents. It is not always necessary to separate reforms that deal with ethical and social issues from other reforms, and these will generally be considered in conjunction throughout this Issues Paper.

Question 4–1. What are the principal ethical and social concerns in Australia about patents on genetic materials and technologies?

Question 4–2. Should ethical and social concerns about patents on genetic materials and technologies be addressed through the patent system? Are there other or better approaches for dealing with these issues?

Question 4-3. Is there 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? Are there any separate or special considerations that apply in this context in relation to indigenous people?

Part B

Research, Biotechnology and Healthcare

5. Funding for Research and Development

Contents

Introduction

5.1 The Terms of Reference require the ALRC to consider the impact of patent laws and practices related to genes and genetic and related technologies on the conduct of research and its subsequent application and commercialisation. As Chapter 4 indicated, one of the issues raised by gene patents is ownership of research results and the benefits derived from patents and licences. The issue arises because much of the basic biotechnology research is undertaken either by public sector organisations or by private sector companies with the assistance of public funding or in conjunction with public sector organisations. Accordingly, it is sometimes asked whether there should be more direct public benefit derived from patents and licences, such as government retention of intellectual property rights.

5.2 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 two broad categories of funding: support for basic research largely at public institutions; and support for the commercialisation of that research by public sector spin-off companies and private sector biotechnology companies. This chapter then discusses the implications of policies encouraging the commercialisation of publicly funded biomedical research.

5.3 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).[140] In 2001, approximately $300 million was spent on publicly funded research in biotechnology.[141]

5.4 Commonwealth Government policy encourages publicly funded researchers and research organisations to work with private industry to develop Australia's intellectual capital. This policy has been stated in a number of discussion papers and reports including:

- the National Health and Medical Research Strategic Review (the Wills Report);[142]
- *Knowledge and Innovation: A Policy Statement on Research and Research Training* (the White Paper);[143]
- the Science Capability Review;[144]
- the Innovation Summit Implementation Committee's final report;[145] and
- *Backing Australia's Ability: An Innovation Action Plan for the Future* (the Innovation Statement).[146]

5.5 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.[147]

5.6 The 1999 White Paper stated that:

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140 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), Commonwealth of Australia, Canberra, see <www.pc.gov.au> [1.2].

141 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 9.

142 Health and Medical Research Strategic Review, *The Virtuous Cycle: Working Together for Health and Medical Research* (1999), Commonwealth of Australia, Canberra, see <www.health.gov.au>.

143 Minister for Education Training and Youth Affairs, *Knowledge and Innovation: A Policy Statement on Research and Research Training* (1999), Commonwealth of Australia, Canberra, see <www.latrobe.edu.au/rgso/dvcr/info/white-paper-report.pdf>.

144 Australian Science Capability Review, *The Chance to Change* (2000), Commonwealth of Australia, Canberra.

145 Innovation Summit Implementation Group, *Innovation: Unlocking the Future* (2000), Commonwealth of Australia, Canberra, see <www.industry.gov.au>.

146 Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001), Canberra, see <http://backingaus.innovation.gov.au/docs/statement/backing_Aust_ability.pdf>.

147 Health and Medical Research Strategic Review, *Enabling the Virtuous Cycle: Implementation Committee Report* (2000), Commonwealth of Australia, Canberra, see <www.health.gov.au>, 1.

> 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.[148]

5.7 The 1999 Wills Report, 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.[149]

5.8 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.[150]

5.9 The 2001 Innovation Statement announced a five-year program to develop research and innovation. Three broad themes were identified: generating ideas through research; commercialisation of those ideas; and developing and retaining a highly

148 Minister for Education Training and Youth Affairs, *Knowledge and Innovation: A Policy Statement on Research and Research Training* (1999), Commonwealth of Australia, Canberra, see <www.latrobe.edu.au/rgso/dvcr/info/white-paper-report.pdf>, 5.

149 Health and Medical Research Strategic Review, *The Virtuous Cycle: Working Together for Health and Medical Research* (1999), Commonwealth of Australia, Canberra, see <www.health.gov.au>, 125–126.

150 Ibid, 126.

skilled workforce.[151] Intellectual property 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.[152]

5.10 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[153] and the ARC jointly fund the Biotechnology Centre of Excellence, which is the National Stem Cell Centre. There are also a number of programs, administered through AusIndustry,[154] to support R&D funding in industry and to assist with the commercialisation of research.

5.11 The *Australian Biotechnology Report 2001* states that the biotechnology industry is supported by 'effective public investment in R&D'[155] 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.[156]

Principal research funding bodies

National Health and Medical Research Council

5.12 The NHMRC is an independent statutory body governed 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.

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151 Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001), Canberra, see <http://backingaus.innovation.gov.au/docs/statement/backing_Aust_ability.pdf>.

152 Ibid.

153 Biotechnology Australia is a agency of the Commonwealth Government which is responsible for co-ordinating non-regulatory biotechnology issues across departments.

154 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.

155 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 8.

156 Ibid, 9.

5.13 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.[157]

5.14 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.

5.15 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'.[158] 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.[159]

Australian Research Council

5.16 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 have been identified as priority areas for

157 National Health and Medical Research Council, *Description of Types of Research Grants for Funding Commencing in 2004* (2003), Commonwealth of Australia, Canberra, see <www.nhmrc.gov.au>, 6.

158 National Health and Medical Research Council, *Strategic Plan 2000-2003* (2000), Commonwealth of Australia, Canberra, 14.

159 Ibid, 21.

ARC funding in 2003, with one third of all funding to be directed towards these areas.[160] One of these is research exploring the connection between an organism's genes (genome) and its physical appearance or behaviour (phenotype).

5.17 Linkage program grants are designed to encourage links between public institutions and researchers and the private sector. In 2002, 470 linkage program grants, involving 736 industry partners, were awarded.[161] Of these, 98 were in the health and community sector, but it is not possible from the figures to determine the number in relation to genetics.

Public-private research linkages

5.18 As discussed above, it is government policy for public sector organisations to work with the private sector in carrying out or commercialising research. A key strategy in this policy has been the establishment of CRCs.

Cooperative Research Centres

5.19 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 July 2002, there were 62 CRCs, nine in the field of medical science and technology,[162] and one specifically in the human genome field. DEST funds and administers the CRC program.

5.20 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.[163] 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.

5.21 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

160 Australian Research Council, *Annual Report 2001–02* (2002), Commonwealth of Australia, Canberra, 60.
161 Ibid, 36.
162 Department of Education Science & Training, *Frequently Asked Questions about CRCs*, Commonwealth of Australia, <www.crc.gov.au/faq.htm>, 14 April 2003.
163 Ibid.

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 $40.6 million.[164]

5.22 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'.[165]

Incentives for industry research

5.23 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'[166] and that it 'has continued to provide high levels of support for small and medium sized businesses'.[167] In 2001–2002, small and medium enterprises (SMEs) received about $422 million in assistance through the Board's programs.[168] Those programs most relevant to the human genetics sector are described below.

Biotechnology Innovation Fund

5.24 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.[169]

Innovation Investment Fund

5.25 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

164 Department of Education Science & Training, *CRC for Discovery of Genes for Common Human Diseases*, <www.crc.gov.au/centres/medical/genes.htm>, 26 March 2003.

165 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 9.

166 AusIndustry, *Industry Research and Development Board Annual Report 2001-2002* (2003), Commonwealth of Australia, Canberra, see <www.ausindustry.gov.au/index.cfm>, 16.

167 Ibid, 17.

168 Ibid, 17.

169 AusIndustry, *Fact Sheet: Biotechnology Innovation Fund*, <www.ausindustry.gov.au>, 26 March 2003.

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.[170]

R&D Start program

5.26 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 and sciences projects but the majority of the funds go to the information technology, applied sciences and general engineering sectors.

Pooled Development Fund program

5.27 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. Kelvin Hopper and Lyndal Thorburn suggest that 'the scheme is clearly only providing a very small amount of early stage funding for biotechnology firms'.[171]

R&D tax concession

5.28 Tax concessions are available for eligible R&D expenditure. Tax concessions are the principal means by which the Commonwealth Government encourages R&D expenditure. Under the program, there is a 175% 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.[172]

State government support

5.29 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

170 AusIndustry, *Industry Research and Development Board Annual Report 2001-2002* (2003), Commonwealth of Australia, Canberra, see <www.ausindustry.gov.au/index.cfm>, 36.

171 K Hopper and L Thorburn, *2002 Bioindustry Review – Australia & New Zealand* (2002) Aoris Nova and Advance Consulting & Evaluation, Canberra, 40.

172 AusIndustry, *Industry Research and Development Board Annual Report 2001-2002* (2003), Commonwealth of Australia, Canberra, see <www.ausindustry.gov.au/index.cfm>.

researchers to universities within the various States; R&D funding to businesses operating within the States; and grants to set up biotechnology incubator facilities.[173]

The pharmaceutical industry

5.30 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).

5.31 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.

5.32 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'.[174] 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 'are much higher than have been found for other R&D incentives in Australia and internationally'.[175] 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'.[176]

5.33 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.[177]

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173 See K Hopper and L Thorburn, *2002 Bioindustry Review – Australia & New Zealand* (2002) Aoris Nova and Advance Consulting & Evaluation, Canberra, 56–59.

174 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), Commonwealth of Australia, Canberra, see <www.pc.gov.au>, XXII.

175 Ibid, XXIX.

176 Ibid, XXIII.

177 Treasurer of the Commonwealth of Australia and Minister for Finance and Administration, *2003-04 Budget Paper No. 2: Budget Measures 2003-04* (2003), Commonwealth of Australia, Canberra, see <www.budget.gov.au/>.

Intellectual property and publicly funded research

5.34 As indicated above, it is government policy to promote the commercialisation of publicly funded research. Where that 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 research. 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 have rights to any resulting intellectual property.

5.35 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*. The 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. At this time, neither the NHMRC nor the ARC assert rights to the ownership of intellectual property arising out of their funding.[178]

5.36 The principles also state that institutions and, where appropriate, individual researchers,[179] 'are expected to consider the most appropriate way of exploiting the IP generated from publicly funded research'.[180] The paper indicates 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.

5.37 The NHMRC published interim guidelines for researchers on intellectual property management.[181] The NHMRC indicated that the requirements outlined in the guidelines would be included within its future grant application and approval process and noted that 'commercial development, including patent registration [would] be considered along with other measures for grant report and review.'[182] 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'.[183]

178 Australian Research Council, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), Commonwealth of Australia, Canberra, see <www.arc.gov.au>, 5.

179 In some organisations, individual researchers can claim full or part ownership to rights arising from their research.

180 Australian Research Council, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), Commonwealth of Australia, Canberra, see <www.arc.gov.au>, 6.

181 National Health and Medical Research Council, *Interim Guidelines Intellectual Property Management for Health and Medical Research* (2001), Commonwealth of Australia, Canberra, see <www.health.gov.au/>.

182 Ibid, 3.

183 Ibid, 2.

5.38 The position in Australia on the relationship between publicly funded research and ownership of the intellectual property rights arising from the research is similar to that of the United States where, since the 1980s, there has been a strong government policy, supported by legislation, for the commercialisation of publicly funded research. However, the United States government retains some important residual rights over intellectual property. One issue for this Inquiry is whether the United States model, or something similar, ought to be adopted in Australia in relation to gene patents derived from publicly funded research.

Publicly funded research in the United States

5.39 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.

5.40 More than 60% of gene patents in the United States are based on publicly funded research.[184] One researcher has suggested that 'the close links between universities and industry are a principal reason why US firms now dominate the biotechnology market'.[185]

5.41 However, the United States government retains certain residual rights to inventions developed from publicly funded research including 'march-in' rights, the right to a government-use licence, and the right to limit exclusive licences. March-in rights allow the government to take title to any inventions where practical application has been slow or not forthcoming or where action is needed alleviate health or safety needs, or to meet the requirements for public use or where an exclusive licence has been granted. The government-use licence allows the government to use the technology for its purposes without payment.

5.42 The National Institutes of Health (NIH) has published guidelines and principles 'to promote utilization, commercialization, and public availability' of inventions developed with NIH funding.[186] The guidelines note that

184 L Andrews, M Mehlman and M Rothstein, *Genetics: Ethics, Law and Policy* (2002) West Group, St. Paul, 200.

185 See E Press and J Washburn, *Secrecy and Science*, The Atlantic Online, <www.theatlantic.com/issues /2000/03/press2.htm>, 10 April 2003, quoting the findings of Walter Powell.

186 National Institutes of Health, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*, 64 FR 72090 (1999), Department of Health and Human Services, see <http://ott.od.nih.gov/>.

> the Bayh-Dole Act encourages Recipients to patent and license subject inventions …[but] restrictive licensing of such an invention … is antithetical to the goals of the Bayh-Dole Act'.[187]

5.43 The NIH guidelines are discussed further in Chapter 11.

Intellectual property and government-contracted research

5.44 While it is Commonwealth 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 government that the government retains the intellectual property rights. It is not clear whether or how these intellectual property rights are being exploited.

Question 5–1. What are the implications of the grant of gene patents to institutions or companies whose research was publicly funded for: (a) encouraging further research into human health or (b) maintaining cost-effective health care in Australia?

Question 5–2. Should holders of gene patents that have implications for human health pay a levy on any royalties with such royalties to be used for future genetic research or for health care infrastructure? If so, should it make any difference whether or not the research leading to the patent was publicly funded?

Question 5–3. In the United States, the government retains certain residual rights to intellectual property developed from publicly funded research. These include 'march-in' rights, the right to a government-use licence and the right to limit exclusive licences. Is there any need in Australia for these or similar rights to be a condition of public funding of genetic research with implications for human health?

Question 5–4. What are the implications of the government retaining intellectual property in any contracted genetic research with implications for human health?

187 Ibid.

6. Overview of the Biotechnology Sector

Contents

Introduction

6.1 The Terms of Reference require the ALRC to consider the impact of current patent 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.

6.2 This chapter describes the structure and features of the biotechnology sector in Australia. It also describes the pharmaceutical industry in Australia. 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 on the biotechnology sector. The biotechnology sector also encompasses areas outside the scope of this Inquiry, including agriculture, food processing, manufacturing and environmental management. Much of the description in this chapter is of the sector as a whole. It is not always possible to find statistics that differentiate between industries within the sector.

6.3 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.[188]

188 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 3.

6.4 As the Terms of Reference ask 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.

Global context

6.5 Biotechnology is one of the world's fastest growing industrial sectors[189] and is worth an estimated US$296 billion.[190] The United States Department of Commerce describes biotechnology as 'the most research-intensive industry in civilian manufacturing'.[191] Ernst & Young estimates that well over US$16 billion was spent on global research and development in biotechnology from October 2000 to September 2001.[192] 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.[193]

6.6 Most companies in the global biotechnology sector are privately owned. According to Ernst & Young, from October 2000 to September 2001, there were 3,662 private companies, compared with only 622 public companies operating worldwide in the biotechnology sector.[194]

6.7 The United States dominates the sector. It generates 72% of global revenue in biotechnology and spends around three and half times more on biotechnology than Europe and 25 times more than the Asia-Pacific region.[195] The United States biotechnology sector invested US$11 billion in research and development (R&D) in 1999 and US$15.6 billion in 2001.[196]

6.8 The United States Department of Commerce reports that 'a total of 1,308 companies in the United States were founded primarily to commercialize biotechnology'[197] and states that intellectual property rights are fundamental to the competitiveness of the biotechnology sector.[198]

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189 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), Ernst & Young, Cleveland, see <www.ey.com/>, 1.

190 Access Economics Australia, *Pharmaceuticals and Australia's Knowledge Economy* (1998), Australian Pharmaceutical Manufacturers Association, Sydney.

191 Office of Technology Policy, *The US Biotechnology Industry* (1997), US Department of Commerce, Washington DC, see <www.ta.doc.gov/>, 30.

192 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), Ernst & Young, Cleveland, see <www.ey.com/>, 10.

193 Ibid, 10.

194 Ibid, 10.

195 Ibid, 10.

196 B Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, <http://genethics.ca/personal/History%20of%20a%20Gene%20Patent.pdf>, 17 April 2003, 3.

197 Office of Technology Policy, *The US Biotechnology Industry* (1997), US Department of Commerce, Washington DC, see <www.ta.doc.gov/>, 27.

198 Ibid, 97.

6.9 Globally, the sector has been characterised by a high attrition rate especially among the start up firms whose only assets may be patents or applications for patents. 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.[199]

Australian biotechnology sector

6.10 There are four types of companies or organisations within the Australian biotechnology sector:

- core biotechnology companies;[200]
- pharmaceutical companies;
- genomic companies; and
- public research institutions.[201]

6.11 The sector comprises a mix of small to medium enterprises (SMEs) together with larger companies, including subsidiaries of multinationals. Most major international pharmaceutical companies have Australian subsidiaries. There were at least 190 dedicated biotechnology companies as at June 2001.[202] Of these, 13% were engaged in the field of genomics/proteomics and bio-informatics and 47% were involved in human health, including diagnostics and therapeutics.[203] The sector employed about 5,700 full-time equivalent employees.[204]

6.12 As at June 2001, there were 35 core and 25 related biotechnology companies listed on the Australian Stock Exchange and 155 privately held core companies. However, one company, CSL Ltd, had more than 70% of the market capitalisation of those listed on the Australian Stock Exchange.[205]

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199 B Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, <http://genethics.ca/personal/History%20of%20a%20Gene%20Patent.pdf>, 17 April 2003, 6.

200 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* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 4.

201 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.

202 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 8. In all, it reported about 650 core and related Australian biotechnology companies. Ernst & Young, Committee for Melbourne and BioMelbourne Network, *Growing Our Knowledge Economy: Proposals for Further Reform* (2002), Ernst & Young, Victoria reported 224 dedicated biotechnology firms for the same time.

203 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 13. The balance was in other biotechnology fields.

204 Ibid, 16.

205 Ibid, 7.

6.13 In 2001, total revenue of the 35 listed core biotechnology companies was $897 million and total revenue generated by the whole sector was estimated to be almost $1 billion. Human health was one of the three areas with the greatest number of products under development.[206] The biggest contributors to revenue growth in 2001 were royalties, licensing and milestone fees.[207] The *Australian Biotechnology Report 2001* suggests that 'one of the challenges for most Australian biotechnology companies is generating sufficient funds to achieve their product development objectives'.[208] It describes the sector as growing, but small in global terms.[209]

6.14 In 2002, a survey by Kelvin Hopper and Lyndal Thorburn on the state of the sector, found that the number of new companies had declined sharply. About 30 new biotechnology companies had been formed in 2001–2002—half the number that had been formed the previous year—and half the new firms were spin-off companies from research institutions. Government grants were the largest source of capital for the new companies, followed by funds from parent organisations and venture capital.[210] Hopper and Thorburn reported that human health and therapeutics dominated among the new firms, with a significant increase in the number of companies established to supply to the sector in areas such as protein and gene sequencing.[211] The survey found that 50% of core biotechnology firms aim to develop new therapeutic or diagnostic products directed at human diseases.[212]

6.15 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. Revenue as a proportion of the labour force is well below the United States but ahead of the European Union; however R&D expenditure is well below the United States and the European Union.[213]

6.16 The *Australian Biotechnology Report 2001* describes the Australian biotechnology sector as being numerically 'dominated by small to medium players',[214] lacking geographic proximity to a large market, and therefore also lacking the 'wealth of information' provided through conferences, workshops, networking and industry associations.[215] Financially, the sector is dominated by four large companies which together account for about 60% of the products known to be under development.[216] The larger companies are frequently involved with the smaller ones through strategic

206 Ibid, 7.
207 Ibid, 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.
208 Ibid, 20.
209 Ibid, 8.
210 K Hopper and L Thorburn, *2002 Bioindustry Review – Australia & New Zealand* (2002) Aoris Nova and Advance Consulting & Evaluation, Canberra, 3.
211 Ibid, 11.
212 Ibid, 29.
213 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 22.
214 Ibid, 8.
215 Ibid, 8.
216 Ibid, 13.

alliances, in particular license agreements.[217] The report notes 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.[218]

6.17 Dr Dianne Nicol and Jane Nielson 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 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.[219]

6.18 Around $500 million a year is spent on R&D in the biotechnology sector in Australia, with about half these funds coming from the private sector.[220] 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.[221] The *Australian Biotechnology Report 2001* describes funding for R&D as 'an ongoing challenge'[222] for SMEs, although it suggests government programs have caused a 'sharp increase' in expenditure.[223] It suggests that a problem for the sector is the capacity to generate sufficient funds to achieve their objectives, whether in licensing or manufacture.[224]

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217 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) Commonwealth of Australia, Canberra, 354.

218 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 46.

219 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.

220 Ernst & Young, Committee for Melbourne and BioMelbourne Network, *Growing Our Knowledge Economy: Proposals for Further Reform* (2002), Ernst & Young, Victoria, 1.

221 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 10.

222 Ibid, 11.

223 These programs are described below.

224 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 20.

6.19 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.[225] This is particularly likely to be the case for drug discovery companies.

6.20 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.

Pharmaceutical industry

6.21 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).[226]

6.22 Globally, the pharmaceutical industry is dominated by horizontally and vertically integrated multinational entities.[227] Some of these are engaged in joint ventures with universities, other research institutions, or smaller biotechnology firms.

6.23 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 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.[228]

6.24 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.[229] Pharmaceutical research and development involves drug discovery, pre-clinical testing and clinical trials to test new drugs for their effectiveness and

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225 Ibid, 46.

226 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), Commonwealth of Australia, Canberra, see <www.pc.gov.au>, [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'.

227 Department of Industry Tourism and Resources, *Pharmaceuticals Industry Profile*, Commonwealth of Australia, <www.industry.gov.au/content/controlfiles/display_details.cfm?objectID=8B4157C0-C0F3-47EE-B3C3994EECB2A4CB>, 4 June 2003.

228 Ibid.

229 Government programs to support R&D in the pharmaceutical industry are discussed in Ch 5.

safety. Total R&D spending by pharmaceutical companies in Australia is around $300 million annually.[230]

6.25 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.[231]

Biotechnology patents

6.26 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 50% of those issued by the European Patent Office (EPO).[232] The Organisation for Economic Co-operation and Development 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.[233]

6.27 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 discussed in Chapter 2, this Issues 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) system, and because of the limited amount of published patent information.

6.28 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.

6.29 It appears reasonably clear 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, [234] examined the source of patent

230 Department of Industry Tourism and Resources, *Pharmaceuticals Industry Profile*, Commonwealth of Australia, <www.industry.gov.au/content/controlfiles/display_details.cfm?objectID=8B4157C0-C0F3-47EE-B3C3994EECB2A4CB>, 4 June 2003. Clinical trials comprise the largest component of such spending.

231 Ibid.

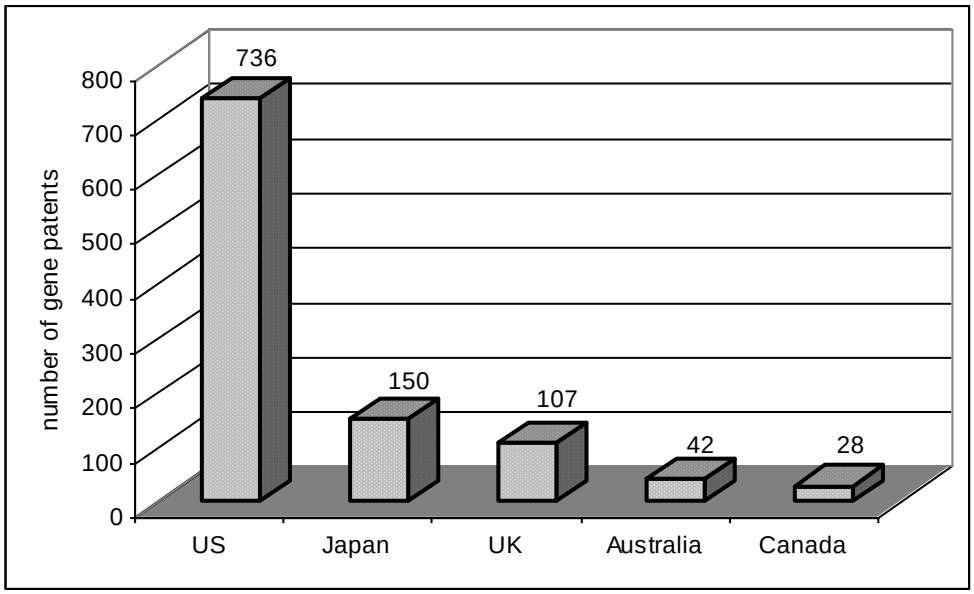
232 Organisation for Economic Co-operation and Development, *Biotechnology Statistics in OECD Member Countries: Compendium of Existing National Statistics* (2001), OECD, Paris, 12.

233 Ibid, 11.

234 L Rausch, *International Patenting of Human DNA Sequences* (2002) National Science Foundation.

applications in relation to 'international patent families' covering human DNA sequences.[235] 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 6–1).[236]

Figure 6–1 Country of origin of patent applications on human DNA sequences 1995–1999



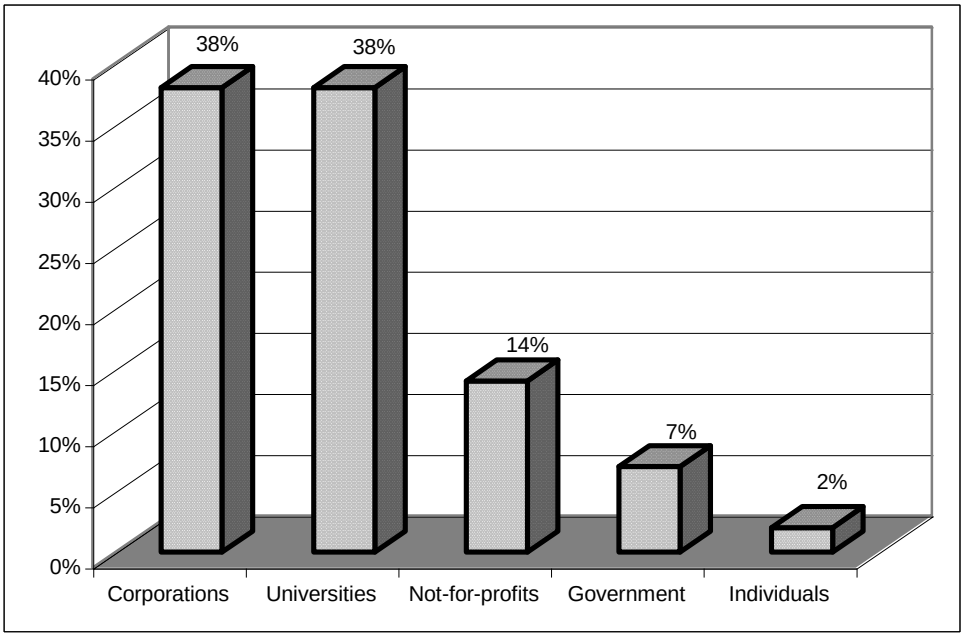
6.30 Of the 42 applications filed in Australia, 16 were filed by corporations, 16 by universities, six by other not-for-profit entities, three by government agencies and one by an individual (see Figure 6–2).[237]

235 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.

236 Ibid Table 2.

237 Ibid Table 2.

Figure 6–2 Organisations filing Australian patent applications on human DNA sequences 1995–1999



6.31 Studies relating to biotechnology patents also indicate that most such patents are foreign owned. Jane Nielsen reports that only about 2% of biotechnology applications filed in Australia originate from Australian inventors.[238] 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'.[239]

6.32 Nielsen also notes that of the biotechnology patent applications in the United States, around 2% originate from Australia.[240] 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 suggests 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'.[241]

6.33 Hopper and Thorburn report that 50 US 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 sector is the number of US

238 J Nielsen, *Biotechnology Patent Licensing Agreements and Anti-Competitive Conduct*, University of Tasmania, <www.lawgenecentre.org/fsrv/symposium2001/nielsen.pdf>, 26 March 2003, 3.
239 Ibid, 39.
240 Ibid, 39.
241 CHI Research Inc., *Inventing Our Future: The Link between Australian Patenting and Basic Science* (2000), Commonwealth of Australia, Canberra, 29.

patents granted because merely holding an Australian patent or having an Australian patent application is usually not sufficient for entry into international markets.[242] They also note, however, that many established Australian biotechnology firms hold no US patents and conclude that 'many Australian firms may not be serious about intellectual property protection in what may be their major market'.[243]

Licences

6.34 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 utilised, and is discussed in Chapter 10. 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 research or product development. It is difficult to obtain comprehensive information in Australia about the licensing of gene patents since such licences are not often registered. However, some information can be obtained from IP Australia[244] and from company reports or stock exchange announcements.

6.35 Nicol and Nielson report prolific licensing activity by companies in the biotechnology sector, noting that in 1999, 219 licences were issued and 181 were acquired.[245] Of those acquired, 45% were from overseas companies, and of those issued, 78% went to international firms. Nicol and Nielsen suggest the figures on international involvement indicate that 'Australian companies are compelled to seek alliances and financing arrangements with overseas companies'.[246] But they also suggest:

> There is evidence that an inability to obtain licences is a problem for the industry. For example, about 21 per cent of the companies surveyed by Ernst & Young had, at some time abandoned at least one project because further work or commercialisation was blocked by another company's IPRs [intellectual property rights].[247]

242 K Hopper and L Thorburn, *2002 Bioindustry Review – Australia & New Zealand* (2002) Aoris Nova and Advance Consulting & Evaluation, Canberra, 30.

243 Ibid, 30. However, there may be many more applications than grants of US patents. There is a large backlog in the USPTO (see Ch 8). Patents granted reflect previous applications not current activity.

244 IP Australia is the Commonwealth organisation that administers patent, trademark and design rights. See IP Australia, *Annual Report* (2001), Commonwealth of Australia, Canberra, see <www.ipaustralia.gov.au>.

245 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), Australian Government Publishing Service, Canberra, 35.

246 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.

247 Ibid, 363.

7. Gene Patents and the Healthcare System

Contents

page

Introduction

7.1 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.

7.2 This chapter discusses how gene patents may have an impact on the provision and cost of healthcare in Australia. The chapter presents background information on the characteristics of the Australian healthcare system and how it is funded and asks about the possible impact of gene patents on healthcare costs and funding.

Gene patents and healthcare

7.3 Gene patents may have an impact on the development and provision of healthcare in two broad categories:

- medical genetic testing, including for pharmacogenetics; and
- novel therapies, including gene therapy, the production of therapeutic proteins, and the use of stem cells.

7.4 There are numerous reasons for seeking a genetic test for healthcare purposes. Medical genetic testing can be categorised in various ways.[248] Relevant types of testing include diagnostic testing, predictive or presymptomatic testing, genetic carrier testing, screening testing and pre-implantation or prenatal testing.[249]

7.5 The uses of genetic testing in healthcare will 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.

7.6 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.[250] Currently, gene therapy is an experimental procedure.[251] However, in the future it may be used to treat ailments such as heart disease, inherited diseases or cancers.[252]

7.7 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 may be used to produce therapeutic proteins—drugs based on proteins produced by the body. These drugs include beta interferon and Epo (erythropoietin).[253] 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

248 In this Issues 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.

249 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), ALRC, Sydney, see <www.alrc.gov.au> [10.7]–[10.8].

250 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)*, Commonwealth of Australia, <www.health.gov.au/nhmrc>, 9 May 2003.

251 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*, Commonwealth of Australia, <www.health.gov.au/nhmrc>, 9 May 2003.

252 See Biotechnology Australia, *Gene Therapy*, Commonwealth of Australia, <www.biotechnology.gov.au>, 9 May 2003.

253 Beta interferon is used to treat multiple sclerosis. Epo is used as a treatment for persons with certain types of anaemia.

and umbilical cord blood.[254] Stem cells may be useful in the therapy of degenerative diseases or injuries, as well as for toxicological testing and drug design.[255]

Patents and healthcare costs

7.8 The existence of patent rights relating to genetic materials and technologies may make the provision of healthcare more expensive, where it is dependent on such inventions.

7.9 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.[256]

7.10 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 Medicare, or about the funding of public sector genetics laboratories and the testing services they provide. Demand may also be influenced by the marketing and other activities of suppliers of healthcare products and services.

7.11 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 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 indirect healthcare costs are incurred.

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254 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), Ontario Government, see <www.gov.on.ca>, 38.

255 European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (2002), European Commission, see <http://europa.eu.int/comm/european_group_ethics/docs/avis16_en_complet.pdf>, 4.

256 See Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 138.

Australian healthcare system

7.12 The healthcare system in Australia is complex, involving many funders and healthcare providers.[257] Responsibilities are split between different levels of government, and between the government and non-government sectors.

7.13 As a generalisation, the Commonwealth 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.[258]

7.14 The Commonwealth operates universal benefits schemes for private medical services (the Medicare Benefits Scheme or 'MBS') and for pharmaceuticals (the Pharmaceutical Benefits Scheme or 'PBS'). It also contributes to the funding of public hospitals through the Australian Health Care Agreements.

7.15 Public hospital services, including outpatient clinics such as those that are part of clinical genetics units, 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

7.16 The Australian Institute of Health and Welfare has reported that total expenditure on healthcare services in 1999–2000 was $53.7 billion. This represented 8.5% of gross domestic product (GDP).[259]

7.17 The healthcare system is largely government-funded. In 1999–2000, an estimated 71.2% of the total amount spent on health services was funded by governments. The Commonwealth government met 48%, and state, territory and local governments met 23.2% of total funding.[260]

7.18 Most of the Commonwealth's healthcare funding was applied to medical services (Medicare) (30.9% of Commonwealth funding) and public hospitals (27.8%).[261] Most of the state government healthcare funding was applied to public hospitals (55% of state government funding).[262]

257 See Australian Institute of Health and Welfare, *Australia's Health 2002* (2002), Australian Institute of Health and Welfare, Canberra, 238–243.
258 See G Palmer and S Short, *Health Care and Public Policy in Australia: An Australian Analysis* (3rd ed, 2000) Macmillan, Melbourne, 10.
259 Australian Institute of Health and Welfare, *Australia's Health 2002* (2002), Australian Institute of Health and Welfare, Canberra, 243.
260 Ibid, 243–244.
261 Ibid, 246.
262 Ibid, 246.

Gene patents and healthcare funding

7.19 The primary context in which concerns about the implications of gene patents for public healthcare funding have arisen is in relation to medical genetic testing (see Chapter 12). Most medical genetic tests are ordered as part of healthcare services provided by state and territory public clinical genetics services. Testing itself is most often carried out by public sector laboratories, often attached to public hospitals or significantly funded by state or territory governments.[263]

7.20 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.[264]

7.21 The extent to which private health insurance covers the cost of medical genetic testing will depend on the terms of particular insurance policies. However, in general, private patients are charged for tests scheduled on the MBS, with private insurance covering the gap between the MBS rebate and the cost of the service. Private insurance does not generally pay for genetic tests that are not scheduled on the MBS.

The challenge of new medical technology

7.22 Most experts believe that new technology is a driving force behind the long-term rise of healthcare spending.[265] However, costs attributable to recognition of patent rights are only one component of the costs that may be involved when new medical technologies are introduced.

7.23 For example, while it is sometimes claimed that patents are the sole or 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.[266] One estimate is that the value added by patent protection for pharmaceuticals is in the order of 5–10%.[267]

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263 In turn, half of all public hospital funding comes from the Commonwealth through the Australian Health Care Agreements.

264 Department of Health and Ageing, *Medicare Benefits Schedule (MBS)*, Department of Health and Ageing, <www.health.gov.au/pubs/mbs/index.htm>, 3 February 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.

265 Other factors include population growth, demographic changes, developments in new medical technologies, 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*, Department of Health and Ageing, <www.health.gov.au/pubs/hfsocc/ocpahfsv5.pdf>, 14 May 2003.

266 Biotechnology Australia, *Consultation*, Sydney, 22 May 2003.

267 M Schankerman, 'How Valuable is Patent Protection? Estimates by Technology Field' (1998) 29(1) *RAND Journal of Economics* 77: compare 15% for mechanical and electronic goods.

7.24 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.[268]

7.25 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.

7.26 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. However, such cost pressures need to be evaluated in the light of community expectations about access to the most modern and effective healthcare and the economic benefits associated with better health outcomes.

7.27 In response to this challenge it has been said that

> the policy requirement is for improved and more extensive evaluation of medical technology of all kinds using a variety of techniques, including cost-effectiveness and cost-utility analysis.[269]

7.28 These issues have been examined overseas in the context of genetic technologies specifically.[270] The Ontario government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, 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.[271]

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268 M Fett, *Technology, Health and Health Care*, Department of Health and Ageing, <www.health.gov.au/pubs/hfsocc/ocpahfsv5.pdf>, 14 May 2003.

269 G Palmer and S Short, *Health Care and Public Policy in Australia: An Australian Analysis* (3rd ed, 2000) Macmillan, Melbourne, 348.

270 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), Ontario Government, see <www.gov.on.ca>; R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), Nuffield Trust, London. In relation to pharmacogenetics, see Nuffield Council on Bioethics, *Pharmacogenetics: Ethical Issues* (2002) Nuffield Council on Bioethics; P Lipton, 'Pharmacogenetics: the ethical issues' (2003) 3 *The Pharmacogenomics Journal* 14, 14–15.

271 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, 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.

7.29 The Ontario report suggested that the Canadian Health Ministers should establish a plan for better economic evaluation of genetic technology and testing.[272] Similarly, a report by the Nuffield Trust recommended that the use of health economics in assessing the impact of genetic science on health services should be encouraged.[273] The Australian healthcare system is generally regarded as a world leader in carrying out detailed economic evaluation of the benefits of pharmaceuticals and other medical technologies prior to inclusion in the MBS and PBS.[274]

MBS and PBS evaluation

7.30 Decisions about Commonwealth funding under the MBS and PBS apply clinical and economic criteria to determine whether, and in what circumstances, the cost of new medical services or pharmaceuticals should be subsidised.[275]

7.31 These evaluation processes apply, for example, if Commonwealth funding is sought under the MBS or PBS for the provision of medical genetic tests or novel therapies, such as drugs based on therapeutic proteins.

7.32 The Medical Services Advisory Committee 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.

7.33 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.

7.34 Where items are recommended 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

272 See Ibid, 84.

273 R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), Nuffield Trust, London, 76.

274 Biotechnology Australia, *Consultation*, Sydney, 22 May 2003.

275 See Medicare Services Advisory Committee, *Funding for New Medical Technologies and Procedures: Application and Assessment Guidelines*, Commonwealth of Australia, <www.health.gov.au/msac/pdfs/guidelines.pdf>, 1 April 2000; Department of Health and Ageing, *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee*, Department of Health and Ageing, <www.health.gov.au/pbs/pubs>, 20 May 2003.

economies of scale.[276] The pricing methodology does not provide any mechanism for the recognition of patent rights by way of a price premium.

Summary

7.35 It has been asserted that genetic technologies will come to affect every sector of healthcare provision.[277] If so, health expenditure attributable to genetic technology may increase.[278] However, the extent of any increase in expenditure, or compensating savings, in other areas is uncertain.

> Whether these developments, diagnostic or therapeutic, 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 if patients will necessarily demand new genetic tests and new medicines that give only marginal benefit.[279]

7.36 The impact of new genetic technologies on healthcare services and funding may need to be monitored closely by health policy makers. Increased government expenditure on medical genetic testing and novel therapies may have an impact on the availability of resources for other areas of healthcare.

7.37 Governments have considerable control over healthcare expenditure in Australia. Spending on healthcare can be controlled through budget appropriations,[280] fixing health benefit levels, and through tax and private insurance arrangements. Where governments do not fund genetics-based healthcare, access to such services will depend on an individual's ability to pay for the services or for private health insurance that covers the cost.

7.38 Gene patents have the potential to create 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

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276 Pharmaceutical Benefits Pricing Authority, *Pharmaceutical Benefits Pricing Authority: Procedures and Methods*, Department of Health and Ageing, <www.health.gov.au/pbs/pricing/pbpamethods.pdf>, 20 June 2003.

277 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, 61.

278 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), Nuffield Trust, London, 3–4.

279 R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), Nuffield Trust, London, 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) Nuffield Council on Bioethics, 11.

280 In the case of the Commonwealth Government, appropriations include grants to the States and Territories, which 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.

these circumstances, services will either have to reduce service provision, increase user charges or obtain increases in their budget allocations.

7.39 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 the contribution that recognition of gene patents may make to this increased expenditure.

7.40 The ALRC is interested in information and comment on the ways in which gene patents and future developments in genetic technology may have an impact on the cost and funding of healthcare in Australia.

Question 7–1. Do gene patents pose any distinct problems of cost for the Australian healthcare system beyond those applicable to new technologies generally?

Question 7–2. What specific problems do gene patents and future developments in genetic technologies pose for the cost and funding of genetics services?

Question 7–3. What steps, if any, should be taken to facilitate the economic evaluation of the impact of gene patents on the cost of genetics services and other healthcare in Australia?

Part C

Patent Laws and Practice

8. Overview of Legal Framework

Contents

Introduction

8.1 This chapter provides an overview of the international and domestic legal framework that regulates Australian patent laws and practices. It considers relevant international conventions that seek to harmonise certain procedural and substantive aspects of patent law, as well as the Commonwealth legislation that regulates the procedure for granting and challenging Australian patents. Later chapters of this Issues Paper separately address other Commonwealth legislation that may impact on patent practices in Australia, in particular the *Trade Practices Act 1974* (Cth).

International legal framework

8.2 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);[281]
- *Patent Cooperation Treaty 1970* (PCT);[282]
- *The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977* (Budapest Treaty);[283] and
- *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[284]

8.3 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

8.4 The Paris Convention is the principal international agreement in the field of 'industrial property,' including patents, trademarks, utility models and industrial designs.[285]

8.5 Relevantly, 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.[286] 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

281 *Paris Convention for the Protection of Industrial Property*, [1972] ATS 12, (entered into force on 20 March 1883). 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.

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

283 *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).

284 *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 15 April 1994).

285 *Paris Convention for the Protection of Industrial Property*, [1972] ATS 12, (entered into force on 20 March 1883) art 1(2).

286 Ibid art 2(1).

filed on the date of the first application.[287] Third, the Paris Convention provides that eligibility for patent protection is independently assessed by each contracting State.[288]

Patent Cooperation Treaty

8.6 The PCT establishes administrative procedures to facilitate the simultaneous filing of patent applications on a single invention in multiple jurisdictions.[289]

8.7 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.[290] 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.[291]

8.8 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.[292]

Budapest Treaty

8.9 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.[293] 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.[294]

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287 Ibid art 4.

288 Ibid art 4bis.

289 *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).

290 Ibid arts 3, 4, 11.

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

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

293 Usually, an invention is 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 9.

294 *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). Sections 6, 41 and 42 of the *Patents Act 1990* (Cth) 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: IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [6.1.5].

Agreement on Trade-Related Aspects of Intellectual Property Rights

8.10 The TRIPS Agreement establishes the minimum standard of patent (and other intellectual property) protection that each member of the World Trade Organization must provide under its national laws.[295] 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.

8.11 Significant provisions of the TRIPS Agreement relating to patents include:

- a minimum patent term of 20 years;[296]
- a requirement that contracting States make patent protection available for any inventions, whether products or processes, in all fields of technology;[297]
- optional exceptions to patentability may be adopted by contracting States if the commercial exploitation of an invention would be contrary to public order or morality; for diagnostic, therapeutic and surgical methods of the treatment of humans and animals; and for plants and animals (other than micro-organisms) and essentially biological processes for the production of plants and animals;[298]
- a right for contracting States to provide limited exceptions to patent rights so long as such exceptions do not unreasonably conflict with exploitation of a patent, nor unreasonably prejudice a patent holder's rights;[299] and
- limitations on compulsory licensing and government use of patents, including a requirement that adequate compensation be given for such use.[300]

Other international legal instruments

8.12 Other international legal instruments may also impact Australian patent laws and practices, for example the *Convention on Biological Diversity*.[301] In addition, activity in the international community to further the global harmonisation of patent

295 *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 15 April 1994). Australia incorporated relevant aspects of the TRIPS Agreement into domestic patent law by the enactment of the *Patents (World Trade Organization Amendments) Act 1994* (Cth), which amended provisions of the *Patents Act* not already in compliance with the patent provisions of the TRIPS Agreement.

296 Ibid art 33.

297 Ibid art 27(1).

298 Ibid arts 27(2), 27(3).

299 Ibid art 30.

300 Ibid art 31.

301 *Convention on Biological Diversity*, [1993] ATS 32, (entered into force on 5 June 1992). 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 Secretariat of the Convention on Biological Diversity, *Convention on Biological Diversity*, United Nations Educational, Scientific and Cultural Organisation, <www.biodiv.org/>, 11 June 2003.

laws may affect Australian patent laws and practices in the future. For example, the *Patent Law Treaty 2000*[302]—which primarily addresses administrative issues relating to the patent system—has been adopted by a Diplomatic Conference of the World Intellectual Property Organization (WIPO) at which Australia was represented, but has not yet entered into force.[303] 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.[304]

Domestic legal framework

Legislation

8.13 Section 51(xviii) of the Australian Constitution grants the 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. Details of this legislative framework are described further below and in Chapters 9 and 10.

Administration

8.14 The Australian patent system is administered by the Patent Office of IP Australia.[305] The Commissioner of Patents may grant a patent upon an application being filed with, and examined by, the Patent Office. IP Australia has developed the *Manual of Practice and Procedure* to assist Australian patent examiners in applying the *Patents Act* and *Patents Regulations*.[306]

Should gene patents be treated differently?

8.15 The procedures for obtaining and challenging a gene patent in Australia are, broadly speaking, the same as those that apply to patents on any other type of technology. The majority of the discussion of Australian patent laws and practices in this chapter is, therefore, cast in general terms.

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302 *Patent Law Treaty* (1 June 2000), WIPO, Geneva, see <www.wipo.int/clea/docs/en/wo/wo038en.htm>.

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

304 World Intellectual Property Organization, *Draft Substantive Patent Law Treaty* (2003), see <www.wipo.int/scp/en/documents/session_9/doc/scp9_2.doc>; World Intellectual Property Organization, *Member States Review Provisions on Patent Law Harmonization (Update 194/2003)*, WIPO, 22 May 2003.

305 IP Australia is the Commonwealth organisation that also administers trade mark and design rights. See website at <www.ipaustralia.gov.au>.

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

8.16 One aspect of the ALRC's inquiry, however, is to determine what, if any, characteristics of gene patents might warrant the grant of, or challenge to, a gene patent being treated differently to patents on any other type of technology. Questions directed to specific aspects of the procedures for granting and challenging patents are raised in the following sections. To the extent that additional matters are relevant, the ALRC invites comments and further information on such issues.

Question 8–1. Do applications for gene patents raise special issues that are not raised by patent applications relating to other types of technology? If so, what are those issues and how should they be addressed?

Types of patents and their duration

8.17 Australian patent law recognises two types of patents: standard patents and innovation patents. A standard patent generally has a term of 20 years, commencing on the 'date of the patent'.[307] An extension of the patent term of up to five years is available for certain patents relating to 'pharmaceutical substances' for which marketing approval is sought from the Therapeutic Goods Administration.[308] In addition to the other criteria for patentability (that is, manner of manufacture, novelty and no secret use of the invention), an applicant for a standard patent must show that the claimed invention represents an *inventive step* over the prior art.[309]

8.18 Australian patent law recognises a 'second tier' of protection called an innovation patent. Innovation patents are a recent development in Australian patent law, introduced in 2001 to replace the petty patent system.[310] Innovation patents have a term of eight years and provide protection for inventions that represent a lesser inventive level over the prior art, namely an *innovative step* rather than the 'inventive step' required to obtain a standard patent.[311] Innovation patents are also subject to less scrutiny by the Patent Office prior to grant.[312]

307 *Patents Act 1990* (Cth) s 67. 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. 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.

308 *Patents Act 1990* (Cth) ss 70–79A.

309 See Ch 9 for a discussion of the criteria for patentability under Australian law, including the 'inventive step' requirement.

310 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), Commonwealth of Australia, 157.

311 The difference between an 'inventive step' and an 'innovative step' is discussed in Ch 9.

312 See the discussion of the procedures for grant of a patent in the following sections.

8.19 The *Patents Act* also provides for the grant of a 'patent of addition' for a single improvement in, or modification to, an invention claimed in a standard patent that has already been granted.[313] A patent of addition may only be obtained by the owner of the earlier patent, or a person authorised by the owner.[314] The term of a patent of addition is generally the same as that of the patent on the main invention.[315]

8.20 Maintenance fees must be paid to keep a standard or innovation patent in force.[316] Maintenance 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.[317]

8.21 It has been suggested that rapid advances in biotechnology and genomics mean that inventions in these fields may become outmoded before the expiration of a patent covering the particular invention. In light of this, and the potential adverse impacts of gene patents that are discussed elsewhere in this Issues Paper, it has been suggested that the duration of patent rights on genetic materials and technologies should persist only for as long as patent holders would gain a commercial advantage from such patents. Such an approach may, however, conflict with the TRIPS Agreement, which requires patent protection to be afforded to all inventions without regard to the technology involved.[318] It would also require further investigation of the relationship between the duration of patent rights and the actual monopoly benefit conferred by such rights.

8.22 In addition, the duration of a particular gene patent may be limited to eight years if the invention claimed in the patent represents only an 'innovative step' over the prior art, and not an 'inventive step'. This issue is considered further in Chapter 9. It is sufficient for current purposes to note that Australia's obligations under the TRIPS Agreement would also have to be considered if it were found that many or all inventions involving genetic materials or technologies involve only an 'innovative step', or do not satisfy the inventiveness requirement for patentability at all.

313 *Patents Act 1990* (Cth) s 81. A patent of addition is not available in relation to an innovation patent: s 80.
314 Ibid s 81(1)(b).
315 Ibid s 83.
316 Ibid ss 142–143A, 227.
317 *Patents Regulations 1991* (Cth) sch 7 Pt 2.
318 TRIPS Agreement art 27(1). For example, a recent proposal by Mexico to limit the term of pharmaceutical patents to ten years, with the right to renew protection for a further ten years, has been criticised as conflicting with the provisions of the TRIPS Agreement: L Schmidt, *Threat to Mexican Patent Holders*, Legal Media Group, <www.legalmediagroup.com>, 3 June 2003.

Question 8–2. Under Australian law, two types of patent protection are available—a 20-year term for a standard patent and an eight-year term for an innovation patent. Should the duration of gene patents be limited to a term less than 20 years? Would this conflict with Australia's obligations under the TRIPS Agreement? (See also Question 9–1.)

Procedure for grant of a patent

8.23 Patent rights do not arise automatically. A patent may only be obtained by following the procedures set forth in the *Patents Act* and *Patents Regulations*. An understanding of the procedure for obtaining a patent is important to understanding Australian patent law and practices generally. The various steps in obtaining an Australian patent are described below.[319]

Filing an application

8.24 In order for a patent to be granted in Australia, an eligible person must file an application in the form prescribed by the Patent Office.[320] 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, and the scope of protection that the applicant is seeking.

Types of patent applications

8.25 Applications may be provisional or complete[321] and may be prepared only by a patent attorney.[322]

8.26 A provisional application need only contain a preliminary description of the invention.[323] Often, a provisional application is filed by an inventor before all of the details of an invention are known. An applicant then has 12 months from the date of filing a provisional application to file a complete application, containing claims 'fairly based' on the provisional application.

8.27 A complete application must contain a specification of the invention, together with claims, and an abstract summarising the invention being disclosed.[324]

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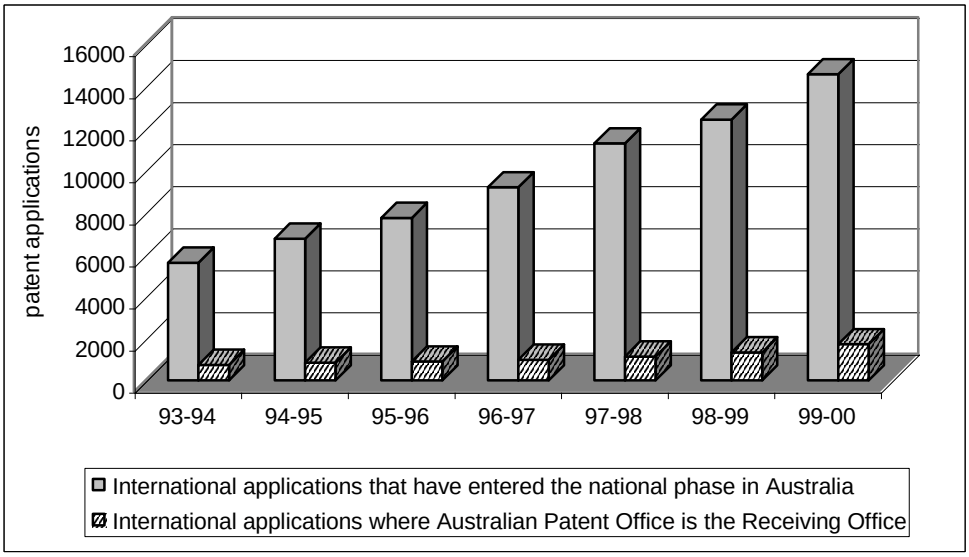
319 A flow chart describing the stages in the patent application process is also included in s 4 of the *Patents Act 1990* (Cth).
320 Ibid s 15, sch 1.
321 Ibid s 29(2).
322 Ibid ss 200(1), 201(1), 201(7).
323 Ibid s 40(1).
324 *Patents Regulations 1991* (Cth) rr 3.1, 3.2A, 3.3.

8.28 An applicant may also elect to file a PCT application with the Patent Office.[325] As discussed above, a PCT application allows an applicant to designate all of the jurisdictions, including Australia, in which patent protection is desired, and to secure an international priority date.[326]

8.29 PCT applications are the main type of applications received by IP Australia,[327] which acts as a Receiving Office under the PCT for the purposes of accepting and processing PCT applications. Figure 8–1 shows the growth in the number of PCT applications from 1993–94 to 1999–2000. '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 other jurisdictions during this period, which designated Australia as one of the jurisdictions in which the inventor wished to obtain patent protection and in relation to which substantive examination of the application was commenced.

Figure 8–1 Patent applications under the Patent Cooperation Treaty (PCT)



Source: IP Australia, *Industrial Property Statistics 1999–00*, Table 3.

325 *Patents Act 1990* (Cth) Ch 8 Pt 1.

326 The 'priority date' of a patent claim is important in determining the novelty and inventiveness of an invention claimed in an application. As discussed further in Ch 9, novelty and inventiveness are assessed against the prior art as it existed before the 'priority date.' For Australian patent applications, the priority date is typically the date on which a provisional application is filed or the date on which a PCT application is filed, whether in Australia or another jurisdiction.

327 IP Australia, *Annual Report* (2002), Depart of Industry, Tourism and Resources, see <www.industry.gov.au>.

Time for filing a patent application

8.30 Until recently, public disclosure or use of an invention prior to filing a patent application would generally prevent patent protection being obtained in Australia. Certain exceptions to this general rule existed, including disclosure of the invention at a recognised exhibition or to a learned society.[328]

8.31 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—often referred to as a 'grace period'.[329] These more lenient requirements apply only to disclosures made on or after 1 April 2002.[330] While these provisions may save patent applications filed in Australia, prior disclosure of an invention may still prevent a patent application being filed in some other countries or regions.[331]

Examination

8.32 Once an application has been filed with the Patent Office, a number of additional steps must be followed before a patent may issue. First, an applicant must file a request that the Patent Office examine the application.[332] Examination is not automatic and typically a request for examination must be filed within five years of the date of filing a complete specification.[333] Under certain circumstances, the Commissioner of Patents may direct an applicant to file a request for examination within a shorter period.[334] 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.[335]

8.33 The purpose of examination is to determine whether the invention meets the statutory requirements for patentability set out in the *Patents Act*.[336] The Patent Office carries out searches of previously published documents—including scientific and patent literature—to determine the prior art relevant to the claimed invention.[337] An

328 *Patents Act 1990* (Cth) s 24; *Patents Regulations 1991* (Cth) rr 2.2, 2.3.

329 On the effects of the amendment, see W Condon and R Hoad, 'Amazing Grace: New Grace Period for Patents in Australia' (2002) 15 *Australian Intellectual Property Law Bulletin* 73.

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

331 For example, Europe adopts an 'absolute novelty' requirement.

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

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

334 *Patents Act 1990* (Cth) s 44(2)–(4).

335 Ibid s 47; *Patents Regulations 1991* (Cth) rr 3.20, 3.21.

336 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 9.

337 As a result of the *Patents Amendment Act 2001* (Cth), an applicant must also disclose to the Patent Office the results of documentary searches carried out prior to the grant of a patent by or on his or her behalf, whether in Australia or elsewhere: *Patents Act 1990* (Cth) s 45(3); *Patents Regulations 1991* (Cth) r 3.17A. Equivalent disclosure requirements exist with respect to documentary searches relating to an innovation patent: *Patents Act 1990* (Cth) s 101D; *Patents Regulations 1991* (Cth) r 9A.2A.

examiner with expertise in the area of technology to which the claimed invention relates then examines the application in light of these search results.

8.34 Examination of a patent application typically involves an exchange between the patent examiner and the applicant about the appropriate scope of the specification and the patent claims in light of the prior art. This process is known as 'prosecution' of a patent application, and once it is complete, an examiner will prepare a report recommending either acceptance or refusal of the application. Prosecution of an application may last for months, or even years.

8.35 No substantive examination is required in connection with an application for an innovation patent. The Patent Office is only required to determine that the application is complete and passes a 'formalities check'.[338] Substantive examination of an innovation patent is required, however, before it can be enforced.[339]

Acceptance, publication and sealing

8.36 The Commissioner of Patents must notify an applicant of the decision to accept or refuse a patent application, and must publish notice of such decision in the *Official Journal of Patents* (*Official Journal*).[340]

8.37 Publication of a notice of acceptance in the *Official Journal* is to 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,[341] and is also advertised in the *Official Journal*.[342] Prior to publication of the complete specification, an application is confidential and details will not generally be disclosed by the Patent Office.

8.38 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*.[343] An innovation patent will be sealed provided that there is no order in place preventing publication of information about the claimed invention.[344]

338 *Patents Act 1990* (Cth) s 52; *Patents Regulations 1991* (Cth) r 3.2B.
339 *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.
340 *Patents Act 1990* (Cth) ss 49(5), 49(7) (standard patents) and s 62(2) (innovation patents).
341 Ibid ss 54, 55; *Patents Regulations 1991* (Cth) r 4.2.
342 *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.
343 *Patents Act 1990* (Cth) s 61; *Patents Regulations 1991* (Cth) r 6.2.
344 *Patents Act 1990* (Cth) s 62(1).

Role of the Patent Office

8.39 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.[345]

8.40 The test of 'satisfaction' was introduced into the *Patents Act* in 2001 by the *Patents Amendment Act 2001* (Cth).[346] Prior to this amendment, it was sufficient if the Commissioner only 'considered' that there was no lawful ground of objection to a patent.[347] The report of the Intellectual Property and Competition Review Committee (IPCRC Report) noted that, as interpreted by the courts, the earlier position was that 'the Commissioner [could] only refuse to grant a patent where it [was] clear that a valid patent [could not] be granted.'[348]

8.41 IP Australia's *Manual of Practice and Procedure* explains the effect of the differing threshold tests in the following terms:

> In practice, this means the threshold test for assessing novelty, inventive step and innovative step is the standard based on 'balance of probabilities'. For all other objections, the applicant should be given 'the benefit of the doubt'.[349]

8.42 The *Manual* further explains that:

> [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).[350]

8.43 These amendments create a higher threshold for the grant of Australian patents. In the context of gene patents, this change may be particularly desirable because a higher threshold test for acceptance makes it more likely that granted gene patents are valid.[351] Indeed, it has been suggested that even higher threshold tests should apply to gene patents, perhaps requiring the Commissioner to be 'satisfied' that

345 Ibid 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.

346 The amendment largely implemented recommendations made by the ACIP Report and the IPCRC Report: Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 2; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 167.

347 *Patents Act 1990* (Cth) s 49 (as in force at 30 September 2001).

348 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 167. See for example, *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232.

349 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [12.5.2.1].

350 Ibid, [12.5.2.2].

351 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), Commonwealth of Australia, 167.

all of the criteria for patentability have been met, not merely the criteria of novelty and inventive (or innovative) step.[352]

Question 8–3. Under the *Patents Act 1990* (Cth) (*Patents Act*), in order to accept a standard patent application (or certify an innovation patent), an Australian patent examiner must be 'satisfied' that an invention is novel and inventive (or innovative) and must 'consider' that no lawful ground for objection exists. Should the threshold for acceptance of an application for a gene patent be raised? If so, what should the threshold be?

Challenges to patent rights

8.44 After a patent application has been accepted by the Commissioner, or after a patent has been sealed, the validity of the patent rights may still be challenged. The three mechanisms for challenging patent rights under Australian law are opposition, re-examination and revocation.

Opposition

8.45 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.[353] Opposition to a standard patent therefore occurs before the patent is sealed.[354]

8.46 The grounds upon which an application for a standard patent may be opposed are limited to the following:[355]

- 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*;[356] or

352 See further Ch 9.
353 *Patents Act 1990* (Cth) s 59; *Patents Regulations 1991* (Cth) r 5.3(1).
354 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.
355 *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.
356 Sections 40(2) and (3) of the *Patents Act* require that the patent specification describes the invention fully including the best known method to the applicant to make the invention; that it ends with claims

- the invention relates to human beings or biological processes for their generation.

8.47 The objections 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. Opposition hearings are the responsibility of the Commissioner of Patents and are typically heard and determined by senior examination staff within the Patent Office.[357]

8.48 There are several possible outcomes of opposition proceedings. The Commissioner may dismiss them on procedural grounds, either in whole or in part.[358] They may result in the amendment of one or more of the patent claims in order to rectify deficiencies in the opposed application; or they may be successful, in which case the Commissioner may refuse to grant a patent.[359] Decisions of the Commissioner may be appealed to the Federal Court by both the patent holder and the opponent (see below).[360]

8.49 In practice, only a very small proportion of accepted applications are opposed. For example, in the five years from 1997–98 to 2001–02, only 1.3% (or one in 77) accepted patent applications were opposed. Statistics on the number of oppositions filed in relation to gene patents are not readily available,[361] but data for the broader category of biotechnology patents suggest that the number of oppositions is very small. According to data provided to the ALRC by IP Australia, in the same five year period, there were only 14 substantive decisions made on biotechnology oppositions (an average of less than three per year), although 86% of these were successful.

8.50 Figure 8–2 indicates the total number of oppositions filed each year from 1997–98 to 2001–02. The graph also indicates the success rate of oppositions that were the subject of a decision by IP Australia.

8.51 The IPCRC Report examined the current system for opposing patents as part of its review of the *Patents Act*. The IPCRC Report recommended that:

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describing the invention; and that the claims are clear and succinct and fairly based on the subject matter described in the invention in the specification. See further Ch 9.

357 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), Commonwealth of Australia, 173.

358 *Patents Regulations 1991* (Cth) r 5.5.

359 *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.

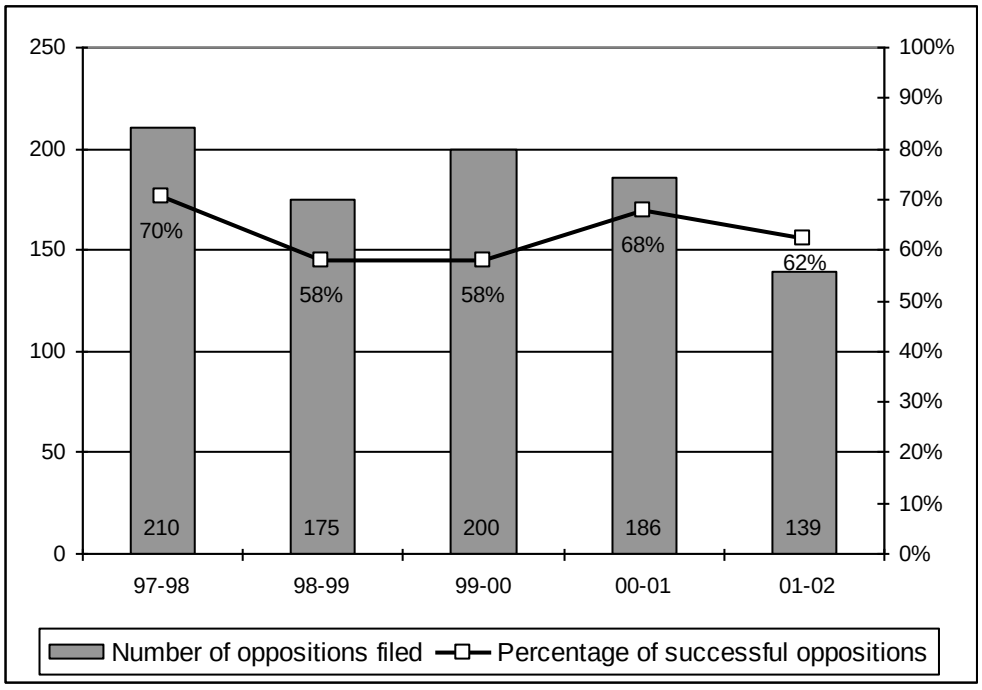
360 *Patents Act 1990* (Cth) s 60(4) (standard patents), s 101N(7) (innovation patents).

361 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.

> 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.[362]

8.52 In addition, the IPCRC Report indicated that hearings officers in opposition matters should continue to comprise senior examination officers at the Patent Office and that a specialist hearing section (comparable to those in the United States Patent & Trademark Office (USPTO) and the Europe Patent Office) did not need to be established.[363]

Figure 8–2 Total oppositions filed and their success rate



Source: Statistics provided by IP Australia.[364]

362 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 175. In its response, the Government indicated that it would ask IP Australia to appoint a senior officer 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: IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/general/response1.pdf>, 2 May 2003.

363 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 175.

364 The number of oppositions filed includes oppositions to the grant of a patent, as well as oppositions to amendments, extensions of term, and so on. The success rate is based on the number of substantive decisions in a given year: there is often a 2–3 year lag between filing an opposition and a substantive decision.

8.53 Other jurisdictions have recently considered improvements to the mechanisms for challenging gene patents. Amendments to Canadian patent law have been proposed to introduce an opposition procedure.[365] The Ontario government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Ontario Report), noted the importance of challenges to patents at an early stage as such mechanisms entail less cost and complication than court proceedings.[366] The Ontario Report also stated that, in the context of gene patents, challenges provide a means of increasing public confidence that the grant of such patents is transparent.[367]

Re-examination

8.54 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.[368]

8.55 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.[369] 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.[370]

8.56 Re-examination proceedings are conducted *ex parte* and are typically undertaken by senior examination staff within the Patent Office who also have responsibility for opposition matters.[371]

8.57 As a result of re-examination, one or more claims in a patent application or an issued patent may be amended as directed by the Commissioner.[372] 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-

365 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>, 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), Ontario Government, see <www.gov.on.ca>, rec 13(g).

366 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, 51.

367 Ibid, 52.

368 *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), Canberra, rec 31. Re-examination is only available for patent applications filed after 30 April 1991: *Patents Act 1990* (Cth) ss 233(3), 234(4).

369 *Patents Act 1990* (Cth) s 98(1) (standard patents), s 101(G)(3) (innovation patents).

370 Ibid s 97 (standard patents), s 101G(1) (innovation patents).

371 P Spann, 'Re-examination in Australia: 10 Years On' (2002) 13 *Australian Intellectual Property Journal* 97, 98.

372 *Patents Act 1990* (Cth) ss 100A(2)(b), 101(2)(b) (standard patents); s 101J(3)(c) (innovation patents).

examination report.[373] A patent holder may appeal decisions of the Commissioner on re-examination to the Federal Court.[374]

8.58 To date, the re-examination provisions of the *Patents Act* have been invoked only on a limited number of occasions.[375] 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.[376]

Revocation

8.59 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.[377] However, revocation of a patent may be sought by any person independently of infringement proceedings.[378]

8.60 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:[379]

- 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

373 Ibid ss 100A(1), 101(1) (standard patents), s 101J(1) (innovation patents).

374 Ibid ss 100A(3), 101(4) (standard patents), s 101J(5) (innovation patents). Third parties 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: IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [21.9.4].

375 P Spann, 'Re-examination in Australia: 10 Years On' (2002) 13 *Australian Intellectual Property Journal* 97, 98.

376 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 attached: Ibid, 98–99.

377 *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). See Ch 10 for a discussion of patent infringement.

378 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).

379 *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.

- the patent specification does not comply with s 40(2) or s 40(3) of the *Patents Act*.

8.61 The *Patents Act* prescribes 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;[380] by the Commissioner in response to a patent holder's offer to surrender his or her patent rights;[381] and, in the case of innovation patents, following an adverse report upon re-examination.[382]

8.62 Revocation of a patent is effective upon either issuance of an appropriate court order or receipt of notice in writing from the Commissioner.

Question 8–4. Are the mechanisms available under the *Patents Act* to challenge an accepted patent application or a granted patent (ie, opposition, re-examination and revocation) adequate in relation to gene patents and applications? What additional or alternative mechanisms might be required?

Patent Office practice

8.63 Internationally, questions have been raised about the capacity of patent offices to assess applications for gene patents effectively and to process such applications efficiently.[383] 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 extent to which these are issues currently faced by the Australian Patent Office is relevant to this Inquiry.

8.64 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 and may not have complete access to the relevant prior art in order to examine patent applications effectively.[384] The Royal Society recommended that searches of the prior art by patent examiners should be as broad as possible (including journals and trade literature) and that examiners should consult experts to ensure that their understanding of the relevant area of science is extremely high.[385] In the Royal

380 *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 15.
381 *Patents Act 1990* (Cth) s 137(3).
382 Ibid s 101J. See further the discussion of re-examination above.
383 B Lehman, *Making the World Safe for Biotech Patents*, International Intellectual Property Institute, <www.iipi.org/newsroom/speeches/Boston%20022602.pdf>, 7 May 2003.
384 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003) The Royal Society, London, [3.27].
385 Ibid, [3.28].

Society's view, patent examiners should be able to apply the same demanding standards in both developing and established areas of science.[386]

8.65 Concerns have also been expressed about the USPTO's examination of patent applications.[387] It has been estimated that the USPTO currently has a backlog of 300,000 patent applications; [388] including 40,000 applications relating to biotechnology.[389] Changes to address the issues currently facing the USPTO have been proposed, including: 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 use more of the funds that it raises in patent fees for its own purposes); and implementing an electronic filing and processing system for patent applications.[390]

8.66 There do not appear to be widespread concerns about the capacity of IP Australia to conduct adequate prior art searches and assess applications for gene patents effectively. A report on the Australian biotechnology industry produced in 2001 indicated that IP Australia has adapted its processes to accommodate particular features of biotechnology inventions.[391] The report 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.[392] The report also cited specific procedural accommodations that IP Australia has made to facilitate the processing of applications for gene patents, including that IP Australia will accept genetic and protein sequences on computer disks or CD for searching purposes.[393]

8.67 In addition, as Figure 8–3 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 8–3 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 applications filed with the Patent Office has, however, continued to rise (see Figure 8–4).

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386 Ibid.

387 United States Patent and Trademark Office, *Performance and Accountability Report for Fiscal Year 2002* (2002), USPTO, Alexandria, see <www.uspto.gov>, 22. In response to concerns about the capacity of the USPTO to process pending patent applications efficiently and accurately, the USPTO introduced the United States Patent and Trademark Office, *21st Century Strategic Plan*, USPTO, <www.uspto.gov/web/offices/com/strat21/index.htm>, 2 June 2003.

388 J Kurlantzick, *Losing the Race*, Entrepreneur Magazine, <www.entrepreneur.com/magazines>, 13 May 2003.

389 T Zwillich, *Biotech Firms Want to Sway Patent Office Revamp*, Reuters Health, <www.reuters.com>, 2 May 2003.

390 See, United States Patent and Trademark Office, *21st Century Strategic Plan*, USPTO, <www.uspto.gov/web/offices/com/strat21/index.htm>, 2 June 2003. See also B Lehman, *Making the World Safe for Biotech Patents*, International Intellectual Property Institute, <www.iipi.org /newsroom/speeches/Boston%20022602.pdf>, 7 May 2003, 5–6.

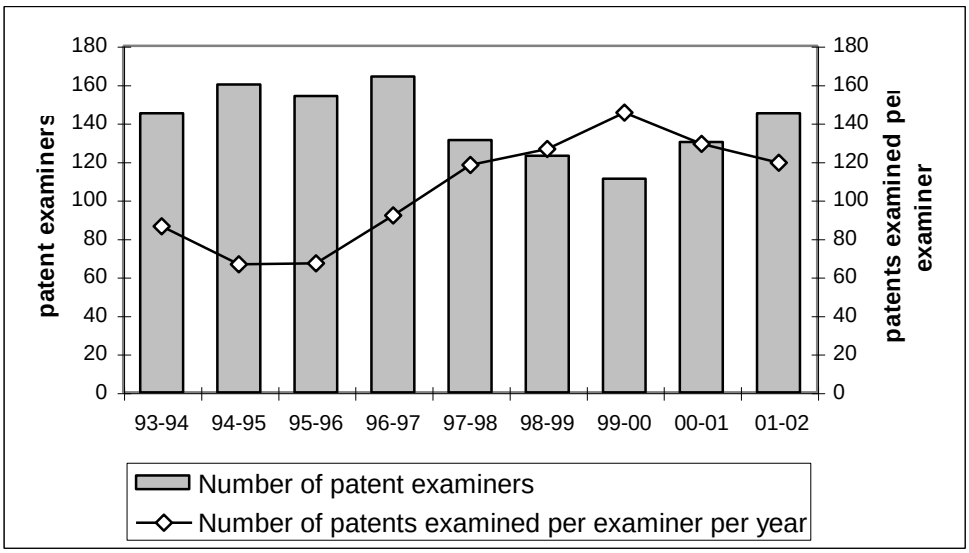
391 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 31.

392 Ibid.

393 Ibid; *Patents Regulations 1991* (Cth) sch 3, cl 12.

8.68 Nonetheless, in connection with applications for patents relating to other technologies, it has been suggested that IP Australia would benefit from additional resources. This might include recruitment of additional staff with the appropriate level of expertise and a refinement of the patent examination process (for example, to allow patent examiners access to a wider range of prior art information).[394] In the future, similar concerns may arise in relation to the Patent Office's ability to assess and process applications for gene patents.

Figure 8–3 Patent examiners and their workload

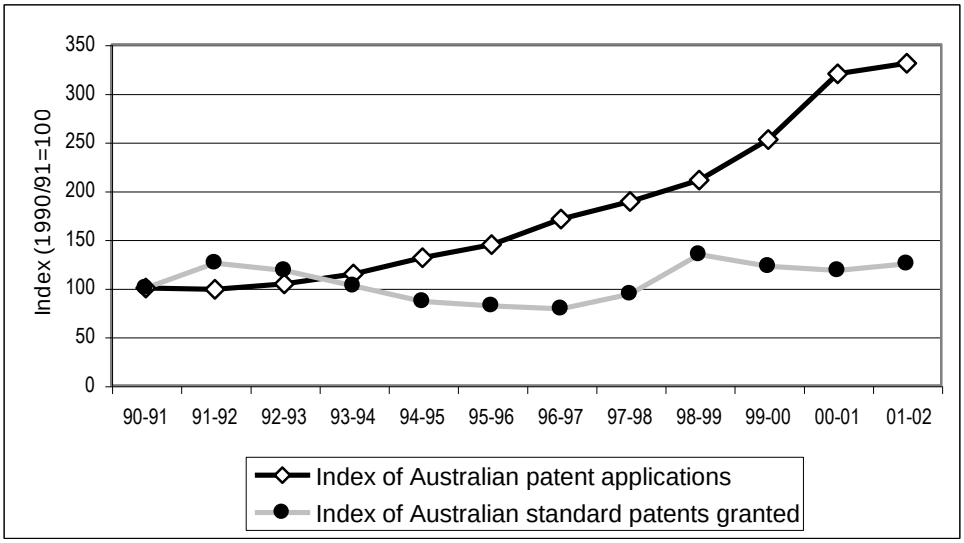


Sources: IP Australia, *Industrial Property Statistics*, Table 2, various years; Department of Industry Tourism and Resources, *Annual Report*, various years.[395]

394 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>, 4 June 2003.

395 The number of patents examined is based on data for the 'first reports issued' on patent applications filed with IP Australia.

Figure 8–4 Indices of Australian patent applications and grants



Source: IP Australia, *Industrial Property Statistics*, Tables 1 and 2, various years.

Question 8–5. Does IP Australia have the capacity to scrutinise applications for gene patents effectively? Is there a need for IP Australia to develop new procedures or guidelines in this area?

Judicial review and enforcement of patents

8.69 State and federal courts, as well as the Administrative Appeals Tribunal (AAT), have a role in the Australian patent system.

8.70 Decisions of the Commissioner of Patents may be subject to various types of review by the AAT or the Federal Court.[396] The AAT may undertake merits review of the Commissioner's decisions with respect to certain procedural matters prescribed by the *Patents Act*.[397] Decisions of the AAT on matters of law may be appealed to the Federal Court.[398] A direct appeal to the Federal Court may be made 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

396 A limited set of decisions by the Commissioner (primarily those made under the *Patents Regulations*) are not subject to review by either the AAT or the Federal Court. For a full discussion, see Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General* (1998), Commonwealth of Australia, Canberra.

397 *Patents Act 1990* (Cth) s 224; *Patents Regulations 1991* (Cth) r 22.26.

398 *Administrative Appeals Tribunal Act 1975* (Cth) s 44.

and revocations).[399] The Federal Court also has jurisdiction to review decisions of the Commissioner under the *Administrative Review (Judicial Decisions) Act 1977* (Cth) on the basis of legal or procedural error.[400]

8.71 The Federal Court and state and territory Supreme Courts share original jurisdiction over matters related to the exploitation and enforcement of patent rights,[401] including infringement proceedings, applications for relief against unjustified threats of infringement, the grant of declarations of non-infringement, and compulsory licences. Appeals on matters of law from decisions of a single judge of the Federal Court and from decisions of state and territory Supreme Courts may be heard by the Full Federal Court and then by the High Court.[402]

8.72 A series of reports in recent years have reviewed the division of jurisdiction in Australia over intellectual property matters (including patents) among various judicial or quasi-judicial bodies.[403] Broadly speaking, 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 court system to facilitate the enforcement of intellectual property rights, particularly by small and medium-sized enterprises.

8.73 A range of options and recommendations have been canvassed to address these issues, including: limiting or entirely removing the jurisdiction of state and territory Supreme Courts in relation to patent matters; expanding the jurisdiction of the Federal Magistrates Service to include patent matters; and expanding the jurisdictions of the AAT to undertake merits review of all decisions of the Commissioner.

8.74 The ALRC and the Advisory Council on Intellectual Property (ACIP) have each recommended that jurisdiction over intellectual property matters (including patents) be concentrated in the Federal Court. In *The Judicial Power of the*

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399 *Patents Act 1990* (Cth) s 154.

400 Judicial review is also available by the Federal Court under s 39B of the *Judiciary Act 1903* (Cth) and by the High Court under s 75(v) of the Australian Constitution.

401 *Patents Act 1990* (Cth) 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.

402 *Patents Act 1990* (Cth) 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). Special leave is required in relation to appeals to the High Court: *Patents Act 1990* (Cth) s 158(3).

403 See Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General* (1998), Commonwealth of Australia, Canberra; Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), ALRC, Sydney, Ch 7; Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act and Related Legislation*, ALRC 92 (2001), ALRC, Sydney, 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), Commonwealth of Australia.

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 [including the *Patents Act*] be conferred exclusively on federal courts. The original jurisdiction presently exercised by state and territory courts in these matters should be abolished.[404]

8.75 In ACIP's report, *Review of Enforcement of Industrial Property Rights* (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'.[405]

8.76 Both ALRC 92 and the ACIP Report noted that uniformity of decision-making in intellectual property decisions was highly desirable.[406] The Federal Court currently has an intellectual property panel comprised of selected judges based in Sydney and Melbourne, and judges from the panel sit on appellate intellectual property benches nationally.[407] The ACIP Report noted this practice of the Federal Court with approval, but also recommended that that the Federal Court should be encouraged to promote further specialisation of intellectual property judges.[408]

8.77 The ALRC's and ACIP's recommendations relating to increased specialisation of intellectual property judges and concentration of jurisdiction with respect to patent matters reflects trends in other jurisdictions in seeking to provide 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.[409] The creation of a specialist intellectual property court is also currently under consideration in Japan.[410]

8.78 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

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404 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act and Related Legislation*, ALRC 92 (2001), ALRC, Sydney, rec 20–1.

405 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 6.

406 Ibid, 20; Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act and Related Legislation*, ALRC 92 (2001), ALRC, Sydney, [20.23]–[20.32].

407 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act and Related Legislation*, ALRC 92 (2001), ALRC, Sydney, [20.19].

408 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 7.

409 R Posner, *The Federal Courts: Challenge and Reform* (2nd ed, 1999) Harvard University Press, Cambridge, 252–253. 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.

410 R Cunningham, *Specialist Court to Boost Profile of IP in Japan*, Legal Media Group, <www.legalmediagroup.com/news>, 3 June 2003.

was noted in the ACIP Report and in the report of the Intellectual Property and Competition Review Committee.[411] Both reports considered that the Federal Magistrates Service might have a role in this regard.[412] 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.[413]

8.79 The Federal Government deferred its response to this recommendation in the IPCRC Report and asked ACIP to consider the issue in further detail.[414] ACIP's final report on this matter has not 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.[415]

8.80 In the context of gene patents, both of the concerns underpinning arguments for reform of the existing system for enforcing patent rights 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 for consistency in decision making by the courts in this relatively new area. However, as discussed in Chapter 6, universities and non-profit organisations hold more than half of the gene patents granted in Australia to date. These institutions have limited resources to undertake patent enforcement actions. Accessible and cost-effective enforcement mechanisms for gene patents are therefore desirable.

Question 8–6. Would the administration and enforcement of gene patents benefit from concentrating jurisdiction for patent matters in a single court? If so, how might concerns about the cost and complexity of enforcing gene patents be addressed?

411 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), Commonwealth of Australia, 176–177.

412 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), Commonwealth of Australia, 177. See also Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act and Related Legislation*, ALRC 92 (2001), ALRC, Sydney, [20.32]

413 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 178. At the time the ACIP Report was released in March 1999, the establishment of the Federal Magistrates Service was still under consideration by the Federal Government. As a result, ACIP made no formal recommendations on this issue.

414 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/general/response1.pdf>, 2 May 2003.

415 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), ACIP, Canberra, see <www.acip.gov.au>, 1.

9. Patentability of Genetic Materials and Technologies

Contents

Introduction

9.1 This chapter considers the required elements of patentability under Australian law and the application of each element in the context of gene patents.

9.2 Currently, patent protection will be granted to inventions involving genetic materials and technologies provided that the requirements for patentability set out in the *Patents Act 1990* (Cth) (*Patents Act*) are satisfied. IP Australia has indicated that a patent may be obtained for inventions involving, for example, synthetic genes or DNA sequences, mutant forms and fragments of gene sequences, proteins expressed by a

gene, vectors containing a gene, probes and promoters, as well as recombinant DNA methods such as polymerase chain reaction (PCR) and novel expression systems.[416]

9.3 It has been suggested that some inventions involving genetic materials or technologies may not, or should not, meet the legal criteria for patentability. This chapter outlines the arguments that have been advanced in this regard as a basis for considering potential reforms to the current law.

Requirements for patentability

9.4 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*.[417] Section 18 provides that the patentable invention is one which:

- is a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies 1623* (UK);
- 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.[418]

9.5 The *Patents Act*, however, expressly 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.[419] These exclusions are outlined after the requirements for patentability have been discussed.

Should gene patents be treated differently?

9.6 The requirements that must be satisfied in order to obtain a gene patent are the same as those that apply to patents on inventions involving any other type of technology. The discussion in this chapter focuses on the application of these criteria to

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416 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf>, 31 March 2003.

417 *Patents Act 1990* (Cth) s 18(1) (standard patents); s 18(1A) (innovation patents). 'Invention' and 'patentable invention' are defined in *Patents Act 1990* (Cth) sch 1.

418 The application of this requirement (commonly referred to as 'secret use') in the context of gene patents does not appear to be materially different to any other type of technology and will not therefore be considered in any detail at this stage of the ALRC's inquiry. For recent judicial consideration of this requirement, see *Azuko Pty Ltd v Old Digger Pty Ltd* (2001) 52 IPR 75.

419 *Patents Act 1990* (Cth) ss 18(2), 50 (standard patents); ss 18(2), 18(3), 101B(2)(d), 101B(4) (innovation patents).

inventions involving genetic sequences in particular, as these types of inventions have been the principal subject of debate and concern surrounding gene patents to date. However, in analysing whether Australian patent law requires reform to address issues that may be raised by the grant of gene patents, a number of additional matters need to be considered.

9.7 First, patent protection is granted on a case-by-case basis. A particular application for a gene patent may not raise all or any of the issues that are canvassed in this chapter. Care must be taken in invoking general arguments or concerns (which may be based on isolated examples rather systemic problems) to justify amendments to the current law.

9.8 Second, the requirements for patentability set out in the *Patents Act* are technology-neutral and are, therefore, able to adapt to new technologies as they arise. If specific provisions are introduced to apply to inventions involving genetic materials and technologies, the impact of such an approach on the current statutory framework must be assessed. Further, the basis for introducing specific requirements in relation to the patentability of genetic materials and technologies, but not other types of inventions, will need to be justified.

9.9 Third, consideration needs to be given to Australia's obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement provides that patent protection shall be afforded to any inventions regardless of the type of technology.[420] The introduction of specific rules for the patentability of inventions involving genetic materials and technologies might be in conflict with this provision. On the other hand, a recent report of the Organisation for Economic Co-operation and Development (OECD Report) has suggested that applying the criteria for patentability in a particular manner given the nature of inventions involving genetic materials and technologies might not be so regarded.[421] The ALRC invites comments and further information on these issues.

Question 9–1. Would changes to the requirements for patentability under Australian law for inventions involving genetic materials and technologies, or to the application of those requirements to such inventions, conflict with Australia's obligations under the TRIPS Agreement?

420 *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 15 April 1994) art 27(1).

421 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 43–44.

Manner of manufacture

9.10 The initial requirement for patentability under the *Patents Act* is that an invention must be a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*. Various interpretations of the term 'manner of manufacture' have been offered in English and Australian cases.[422] The decision of the High Court in *National Research Development Corporation v Commissioner of Patents* (*NRDC*)[423] is the leading Australian authority on the meaning of the term, and adopted a broad approach:

> 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*?'[424]

9.11 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.[425]

9.12 Dr Dianne Nicol has argued that inventions involving isolated genetic materials appear to satisfy the *NRDC* requirements because genetic research and treatment is commercial in nature and has 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.[426]

9.13 The 'manner of manufacture' test is expressed in terms that appear somewhat obscure in a modern context. In essence, it imposes a requirement that an invention be appropriate subject matter for the grant of a patent, and it expresses that requirement in words of sufficient generality to allow the concept of patentable subject matter to keep pace with advances in technology—including, for example, in biotechnology.

9.14 The efficacy of maintaining an 'open-textured' approach to patentable subject matter, such as that represented by the 'manner of manufacture' test, was recently considered in a report of the Intellectual Property and Competition Review Committee (IPCRC Report). The IPCRC Report recommended that the 'manner of manufacture' test be retained and concluded that:

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422 An outline of the evolution of the 'manner of manufacture' requirement is provided in Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 147.

423 *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252.

424 Ibid, 269.

425 Ibid, 275.

426 D Nicol, 'Should Human Genes be Patentable Inventions Under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 237.

> Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the 'manner of manufacture' test.[427]

9.15 The inclusion of the 'manner of manufacture' requirement in the *Patents Act* appears, however, to have had the effect of limiting the number of express exclusions to patentable subject matter in the Act. The current exclusions, and whether any additional exclusions are warranted in light of concerns raised by gene patents, are considered below.

Novelty

9.16 An Australian patent will only be granted for an invention that is 'novel.'[428] 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.[429]

9.17 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.[430] Separate disclosures of an invention (or parts 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.[431]

9.18 As discussed in Chapter 8, recent amendments to the *Patents Regulations 1991* (Cth) (*Patents Regulations*) mean that any publication or use of an invention by or with the consent of the inventor within a period 12 months prior to the filing of a complete application is irrelevant to an assessment of novelty and inventive step.[432] The amendments apply to disclosures made on or after 1 April 2002. For disclosures made prior to that date, a more limited range of publications is excluded from being relevant to an assessment of novelty.[433]

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427 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 149.

428 *Patents Act 1990* (Cth) s 18(1)(b)(i) (standard patents); s 18(1A)(b)(i) (innovation patents).

429 Ibid s 18(1)(b)(i) (standard patents); s 18(1A)(b)(i) (innovation patents); sch 1.

430 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.

431 *Patents Act 1990* (Cth) s 7(1). Seeking to connect disclosures made in more than one document (or act) for the purpose of a claim that an invention is not novel—often referred to as 'making a mosaic'—is not permitted under Australian patent 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.

432 *Patents Regulations 1991* (Cth) rr 2.2, 2.3.

433 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.

9.19 The test applied to determine whether an invention is novel is known as the 'reverse infringement' test.[434] The prior art information must disclose all of the features of an invention in clear, unequivocal and unmistakable terms in order for the invention at issue to lack novelty. If the prior art does not disclose all of the features of an invention, but nonetheless discloses all of the essential features, the invention may also lack novelty.

9.20 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 has been limited to a small number of people,[435] was contained in a foreign language document that could be understood only by an expert in the field,[436] or if a limited number of embodiments of the invention were distributed to members of the public on a non-confidential basis.[437]

Application to isolated genetic materials

9.21 It has been suggested that the presence of genetic materials in nature might be considered sufficient to render isolated genetic materials or genetic products available to the public and, therefore, not novel for the purposes of patent law.

9.22 This proposition is contrary to the approach currently adopted under Australian law. IP Australia has indicated that the novelty requirement will be satisfied in relation to inventions covering biological materials generally, including genes, genetic sequences and DNA, if the claimed invention is 'new in the sense of not being previously publicly available'.[438] IP Australia has suggested that the only circumstances in which a patent will not be available is in the case of inventions covering 'materials in their naturally occurring state' and 'materials which have previously been made publicly available'.[439]

9.23 The Nuffield Council on Bioethics (Nuffield Council) has expressed a similar understanding of the concept of 'public availability'. It noted that individual genes and DNA sequences in their naturally occurring state are not directly accessible to the public and additional work is required to isolate such material. The Nuffield Council added that:

434 *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228.
435 *Sunbeam Corporation v Morphy-Richards (Aust) Pty Ltd* (1961) 180 CLR 98.
436 *Dennison Manufacturing Co v Monarch Marking Systems Inc* (1983) 66 ALR 265.
437 *Fomento Industrial SA v Mentmore Manufacturing Co Ltd* [1956] RPC 87.
438 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf>, 31 March 2003.
439 Ibid.

> isolation of a gene separates it from other molecules that are naturally associated with it and allows biochemical characterisation in the form of description of the sequence of the bases.[440]

Question 9–2. How should the novelty requirement apply to applications for patents over isolated genetic materials or genetic products? Are special considerations relevant in assessing the novelty of such inventions?

Inventive or innovative step

9.24 Patent protection will only be granted 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).[441]

Inventive step

9.25 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 relevant claim. It may also take into consideration prior art information before the priority date, which a person skilled in the art could reasonably be expected to have ascertained, understood and regarded as relevant.[442]

9.26 The High Court recently considered the inventive step requirement in *Aktiebolaget Hässel v Alphapharm Pty Ltd*.[443] The High 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]'.[444] The High Court found that the results of a 'routine literature search' that have not entered into the common general knowledge would not be relevant to an assessment of inventiveness.[445] 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 is not the taking of routine steps to which a hypothetical formulator was taken as a matter of course.[446]

440 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 29.
441 *Patents Act 1990* (Cth) s 18(1)(b)(ii) (standard patents); s 18(1A)(b)(ii) (innovation patents).
442 Ibid ss 7(2), 7(3).
443 *Aktiebolaget Hassel v Alphapharm Pty Ltd* (2002) 194 ALR 485.
444 Ibid, 499.
445 Ibid, 500.
446 Ibid, 501.

9.27 The *Patents Amendment Act 2001* (Cth) introduced changes to the assessment of the inventive step requirement by patent examiners by allowing 'mosaicing' of prior art information during patent examination.[447] 'Mosaicing' allows a patent examiner to assess the requirement of 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.[448] Prior to the amendment, patent examiners were only permitted to assess the inventive step requirement in light of a single piece of prior art information, alone or combined with common general knowledge in the relevant art in Australia.

9.28 The impact of this amendment to the assessment of applications for gene patents is unclear at this stage. However, the evolution of searching and cross-referencing systems in electronic databases may 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.[449]

Innovative step

9.29 '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.[450]

9.30 The term 'innovative step', and the difference between this requirement and the requirement of 'inventive step' applicable to standard patents, has not yet been the subject of judicial consideration. However, the Revised Explanatory Memorandum to a recent amendment to the *Patents Act* provides some guidance on the differences between the two requirements. It 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'.[451] The Revised Explanatory Memorandum suggests that to

447 *Patents Amendment Act 2001* (Cth). The amendments apply to complete patent applications filed on or after 1 April 2002 (s 13).

448 *Patents Act 1990* (Cth) s 7(3). See also IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [4.1.4.2].

449 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.

450 *Patents Act 1990* (Cth) ss 7(4)–(6). Prior art information is limited to that made available by a single document or act, or in two or more related documents or acts if the relationship between the documents or acts was such that a person skilled in the art would treat them as a single source of information: s 7(5). See also IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [30.4.5.4].

451 Revised Explanatory Memorandum to Patents Amendment (Innovation Patents) Bill 2000 (Cth), [6].

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'.[452]

Application to isolated genetic materials

9.31 It has been suggested that, in some circumstances, no inventive step is required to isolate genetic material. For example, the Nuffield Council has stated that 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.[453]

9.32 The Nuffield Council noted that, in the past, genes were identified by procedures such as positional cloning and the use of protein sequences to derive nucleic acid sequences.[454] However,

> now that the human genome has been sequenced, the isolation of a DNA sequence and the identification of its association with a disease are significantly more straightforward. Furthermore, inferring a possible function for a DNA sequence, by analogy with another sequence for which some information about its function is known, is relatively routine.[455]

9.33 The Nuffield Council has also stated that, 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.[456]

9.34 The Nuffield Council's understanding of the inventive step requirement has been criticised by English patent attorney, Stephen Crespi, who has emphasised that inventiveness must be judged on a case-by-case basis and by the proper legal authorities.[457] Crespi has expressed the concern that the Nuffield Council seemed to be 'ready to dismiss patent claims to the test procedure and methodology in such cases as well as the claims to the gene and its variants'.[458]

Approaches in other jurisdictions

9.35 The Europeam Patent Office (EPO) regards the isolation of genetic sequences that have a structure closely related to existing sequences for which the

452 Ibid, [6].
453 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 29.
454 Ibid, 29.
455 Ibid, 49–50.
456 Ibid, 62.
457 R Crespi, *Patenting and Ethics: A Dubious Connection*, Pharmalicensing, <www.pharmalicensing.com ///features/disp/1046280396_3e5cf8cc0fb40>, 4 June 2003.
458 Ibid.

function is known as not being sufficient to satisfy the requirement of 'inventive step'.[459] 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.[460]

9.36 For example, opposition to a Myriad patent on the BRCA1 gene[461] 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'.[462]

9.37 In the United States, the requirement of inventive step (known as 'non-obviousness' in United States law) 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.[463]

9.38 In adopting this approach, United States courts have accepted that the redundancy of the genetic code means that a number of different nucleotide sequences might code for a particular protein and that a person skilled in the relevant art could not, therefore, know the structure of a particular genetic sequence without conducting appropriate experiments.[464] United States courts have held that the existence of a general method of isolating genetic sequences is irrelevant.

9.39 This approach means that the inventive step 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,

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459 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), Trilateral Project, San Francisco, Annex 2, 43. The Nuffield Council has indicated that it agrees with this approach: Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 30, 50.

460 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), Trilateral Project, San Francisco, Annex 2, 43.

461 EP 705 902.

462 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), Institut Curie, Paris.

463 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), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 30.

464 *In re Dueul* (1995) 51 F3d 1552; *In re Bell* (1993) 991 F2d 781. See generally, P Ducor, 'In re Deuel: Biotechnology Industry v Patent Law?' (1996) *EIPR* 35.

> 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.[465]

Australian approach to 'inventive step'

9.40 It is an open question whether the application of the inventive step requirement under Australian law to inventions involving isolated genetic materials would be similar to the European or the United States approach. IP Australia has stated that, to satisfy the inventive step requirement, an invention involving biological materials (including genes and gene fragments) must involve 'the technical intervention of a technologist applying their inventive ingenuity to produce something distinguishable from natural source material'.[466] What this means in practice is unclear.

9.41 The issue has only arisen for consideration by the Patent Office in opposition proceedings.[467] The ALRC understands, however, that the 'inventive step' requirement has not presented a significant obstacle to the patenting of genetic materials and technologies to date.

9.42 By contrast, academic consideration of the 'inventive step' requirement under Australian law has expressed a similar view to that 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.[468] 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'.[469]

9.43 In 1992, a report of the House or Representatives Standing Committee on Industry, Science and Technology expressed the same view, stating that it was 'unlikely … that [genetic sequence] patents would pass the test of "non-obviousness"'.[470]

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465 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 30.

466 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf>, 31 March 2003.

467 For a discussion of these 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.

468 C Lawson, 'Patenting Genetic Materials: Old Rules May be Restricting the Exploitation of New Technology' (1999) 6 *Journal of Law and Medicine* 373, 379.

469 D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 79.

470 House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), Parliament of the Commonwealth of Australia, Canberra, 240–241.

9.44 If an invention involving isolated genetic material does not satisfy the requirement of 'inventive step' necessary for a standard patent to be granted, a question arises as to whether such an invention may nonetheless satisfy the requirement of 'innovative step' sufficient for the grant of an innovation patent. As noted above, the 'innovative step' requirement has a lower threshold, although it is not clear what will be necessary to satisfy this requirement.

Question 9–3. In light of the DNA sequencing technology now available, does the identification and isolation of genetic material involve an 'inventive step' or an 'innovative step' under current Australian law? Are the current tests for 'inventiveness' and 'innovation' appropriate for assessing the patentability of genetic materials and technologies? What alternative or additional considerations might be relevant in assessing the 'inventiveness' or 'innovation' of such inventions?

Usefulness

9.45 There has been considerable debate about whether isolated genetic materials in various forms fulfil the requirement that an invention be 'useful' in order for a patent to be granted. 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'.[471]

9.46 In particular, concerns have been expressed that inventions involving expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs)[472] may not display the requisite usefulness for patentability.[473] 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

471 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 31.

472 See Ch 2 for a discussion of ESTs and SNPs.

473 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) *EIPR* 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), Intellectual Property Research Institute of Australia, Melbourne; S Chambers, 'Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *AIPLA 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 *AIPLA 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 *AIPLA Quarterly Journal* 61; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 32–34.

as to whether such uses are, or should be, sufficient to satisfy the concept of usefulness for the purposes of patent law.[474]

Usefulness requirement in Australia

9.47 Australian patent law requires that an invention be 'useful', both as an express requirement for patent protection in s 18 of the *Patents Act* and as an implicit requirement that an invention be a 'manner of manufacture'.

9.48 The 'usefulness' requirement in s 18 has been interpreted narrowly by Australian courts. An invention need not be useful in the sense that it is worthwhile or commercially practical,[475] rather it is a requirement that the patent must produce the results that are promised upon a fair reading of the patent specification.

9.49 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'.[476]

9.50 IP Australia's *Patent Manual of Practice and Procedure* states that:

> 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.[477]

9.51 Applying this principle 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.[478]

9.52 However, Australian patent examiners are not required to consider the usefulness of an invention in assessing a patent application[479] and the Commissioner of Patents does not need to be 'satisfied' that an invention is useful before accepting a

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474 For example, the United States National Institutes of Health (NIH) filed patent applications claiming ESTs in the early 1990s, which were rejected by the United States Patent and Trademark Office (USPTO) for lack of utility. The applications were later abandoned by the NIH: see P Ginsburg, 'Patentability and Technology Transfer Issues Relating to the NIH Patent Applications' (1994) 354 *Practising Law Institute* 641.

475 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 277. See also *Martin Engineering Co v Trison Holdings Pty Ltd* (1989) 14 IPR 330.

476 *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 275.

477 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [8.4.1].

478 Ibid, [8.4.2].

479 *Patents Act 1990* (Cth) s 45(1).

patent application.[480] 'Lack of utility' (as the objection is phrased) is an issue that can be raised only in revocation proceedings.[481] It is not a basis upon which a patent may be opposed, nor is it relevant upon re-examination.[482]

Utility requirement in other jurisdictions

9.53 In other jurisdictions, such as the United States, the requirement that an invention be useful in order for patent protection to be obtained is more stringent and is relevant in the examination of a patent application.

9.54 Under United States law, this requirement is known as 'utility'.[483] 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.[484]

9.55 The Supreme Court stated further 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.[485]

9.56 In response to issues that were raised by patent applications involving genetic sequences (particularly ESTs) for which a function was not known, the United States Patent and Trademark Office (USPTO) recently revised its guidelines on the satisfaction of the utility requirement.[486] The Revised Utility Guidelines require that a patent applicant demonstrate a utility for an invention that is 'specific, substantial and credible'.[487] The USPTO's comments on the 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'.[488]

9.57 The IPCRC Report endorsed the approach adopted by the USPTO in the Revised Utility Guidelines. The IPCRC Report recommended that the Australian Patent Office should ensure that its examination practice included consideration as to whether 'the use described in the specification is specific, substantial and credible to a

480 Ibid s 49(1) (standard patents); s 101B(2) (innovation patents).
481 Ibid s 138(3)(b).
482 Opposition, re-examination and revocation proceedings are discussed in Ch 8.
483 35 USC §101.
484 *Brenner v Mason* (1966) 383 US 519, 534–535.
485 Ibid, 535.
486 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092 ('Revised Utility Guidelines').
487 Ibid, 1098.
488 Ibid, 1094.

person skilled in the art'.[489] The Government has accepted the IPCRC's recommendation and indicated that it will ask IP Australia to ensure that an examination of a patent application addresses all aspects of the use of an invention being specific, substantial and credible.[490] However, additional amendments to the *Patents Act* and *Patents Regulations* may be required to implement the IPCRC's recommendation effectively.[491]

Question 9–4. In applying the 'usefulness' requirement for patentability under Australian law to inventions involving genetic materials and technologies:

- Do patent applications claiming such inventions raise specific issues that are not raised by other technologies? If so, what are those issues?
- What alternative or additional considerations might be relevant in assessing the 'usefulness' of such inventions? Would it be appropriate to require that inventions demonstrate 'specific, substantial and credible' utility to be patentable?
- Should 'usefulness' be considered as part of the examination of a patent application? Should lack of utility also be a ground upon which a patent application might be opposed or re-examined?

Disclosure of an invention

9.58 Patent law in Australia and in other jurisdictions requires that a patent application must fully describe the invention claimed. 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. The way in which this requirement applies to gene patents is a matter of contention.[492]

489 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 154.

490 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/general/response1.pdf>, 2 May 2003. The Government noted that the 'specific, substantial and credible' tests are already broadly included within current examination practice under the grounds of manner of manufacture and fair basis.

491 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. In particular, 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. Nicol and Nielsen have commented that a 'specific, substantial and credible requirement marks a radical change from the previous interpretations of the usefulness criterion by the Federal Court'.

492 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 30.

9.59 In Australia, the requirement that a patent fully disclose an invention is set out in s 40 of the *Patents Act*. 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 that the patent claims must be 'clear and succinct and fairly based on the matter described in the specification'. This is commonly referred to as the 'fair basis' requirement.

9.60 The Federal Court considered the application of s 40 to biotechnology inventions in *Genetics Institute v Kirin Amgen Inc (No 3)*.[493] The principal claim at issue in the case was for an isolated and purified polypeptide having the primary structural conformation and one or more of the biological characteristics of naturally occurring erythropoietin (which plays a major role in regulating the formation of red blood cells). Heerey J held that the claim was permissibly wide because the genetic sequence for erythropoietin was a principle of general application and a claim in correspondingly general terms was therefore acceptable.[494]

9.61 It has been suggested, however, that broad claims of the type accepted by Heerey J may not be desirable in the context of gene patents. Such patent claims are often referred to as 'product *per se*' claims and confer 'absolute protection'; that is, such claims give the patent holder protection against all further uses of the claimed product, whether known or unknown, during the patent term.[495] The issues that may arise from the acceptance of such claims are illustrated by the CCR5 patent, described below.

CCR5 Gene Patent. The United States company, Human Genome Sciences Inc (HGS), was granted a United States patent which contained claims covering the isolated CCR5 gene and all medical applications thereof. Research conducted by other scientists, not affiliated with HGS, later found that the CCR5 gene makes a receptor protein that the HIV virus uses to gain access to an immune cell. At the time, HGS filed for a patent application, it understood the utility of the CCR5 protein product would be as a cell-surface receptor and it was unaware that the receptor was one of the entry points for the HIV virus into human cells. HGS' patent claims were, however, broad enough to allow HGS to assert rights over any use of the gene, including use as a viral receptor. HGS has agreed to license the use of the CCR5 receptor gene for research into new drugs, including for the

493 *Genetics Institute Inc v Kirin-Amgen Inc* (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 below in the section 'Discoveries'. The case involved s 40 of the *Patents Act 1952* (Cth), which is not relevantly different from s 40 of the *Patents Act 1990* (Cth). An appeal to the Full Federal Court was dismissed: *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1999) 92 FCR 106.

494 *Genetics Institute Inc v Kirin-Amgen Inc* (1998) 156 ALR 30, 46.

495 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 28–30.

development of AIDS therapies. The patent granted to HGS provides an example of the potential impact of broad patent claims and patent protection being granted for inventions involving genetic sequences where the applicant has an incomplete knowledge of the function of the gene.

9.62 The Royal Society has indicated that thought should be given to whether 'a wide ranging scope should be given to claims on chemical and biological entities or whether such claims should be allowed at all.'[496] In addition, the Royal Society indicated that limiting claims to the field of application to which a patent is directed should be considered.[497]

9.63 In the United States, recent decisions of the Court of Appeals for the Federal Circuit interpreting the 'written description' and 'enablement' requirements under United States law have begun to elucidate certain disclosure requirements for particular types of inventions.[498] In addition, the USPTO introduced new guidelines for the application of the written description requirement by United States patent examiners in 2001.[499]

9.64 Although it has been suggested that the scope of early gene patent claims was unduly broad,[500] broad claims are often a feature of patents granted in the early stages of a new technology. Initial developments in a field often underpin a range of subsequent work and as such represent significant contributions that have multiple applications in the area.[501] The ALRC understands that claims of such broad scope are less frequently found in gene patents that are now being granted by Australian Patent Office. The ALRC is interested in obtaining further information about the current scope of claims in gene patents and the extent to which the grant of broad patent claims remains an issue.

496 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003) The Royal Society, London, [3.35].

497 Ibid.

498 35 USC §112. See for example, *Regents of the University of California v Eli Lilly & Co* (1997) 119 F3d 1559.

499 United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications Under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099.

500 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, 78–79.

501 T Moore, 'IP Australia's Experience with Biotech Inventions' (Paper presented at Legal Protection of Australian Biotechnology, Sydney, 30 May 2002); 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.

Question 9–5. In applying the 'sufficiency' and 'fair basis' criteria to applications for gene patents:

- Do claims in applications for gene patents raise specific issues that that are not raised by other technologies? If so, what are those issues?
- Are any additional or alternative considerations relevant to assessing the appropriate scope of patent claims involving genetic materials or technologies?

Exceptions to patentable subject matter

9.65 The *Patents Act* does not currently contain an express exclusion from patentability with respect to inventions involving genetic materials or technologies. The express exclusion of patents on genes and genetic sequences has, however, been proposed. In 1990, Senator Coulter proposed amendments to the Patents Bill 1990 (Cth), which would have presumptively excluded genes, genetic material and genetically modified organisms from patentability.[502] In 1996, Senator Stott Despoja proposed a similar amendment to the *Patents Act*, which provided that naturally occurring genes, gene sequences, or descriptions of the base sequence of a naturally occurring gene or gene sequence, would not to be regarded as either novel or inventive for the purposes of s 18 of the *Patents Act*.[503] To date, such proposals have been unsuccessful.[504]

Current exceptions in Australia

9.66 Currently, the *Patents Act* provides only limited exceptions to patentable subject matter. 'Human beings, and the biological processes for their generation' are excluded from patentability under s 18(2) of the *Patents Act*. This provision has been interpreted narrowly. The Patent Office's *Manual of Practice and Procedure* states that 'human genes, tissues and cell lines' are outside the scope of s 18(2) and will be patentable if the requirements set out in the *Patents Act* are satisfied.[505] The application of this provision to inventions involving human stem cells is less clear[506] and may warrant further consideration by the ALRC in the context of this Inquiry.

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502 Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, 2478 (J Coulter).

503 Patents Amendment Bill 1996 (Cth); Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 June 1996, 2332 (Natasha Stott Despoja).

504 The Patents Amendment Bill 1996 (Cth) has been re-tabled and is pending consideration: Parliament of Australia, *Senate Daily Bills Update*, Commonwealth of Australia, 16 June 2003.

505 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [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.

506 See Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Commonwealth of Australia,

9.67 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 it would be 'contrary to law'.[507] The *Manual of Practice and Procedure* indicates that s 50(1)(a) 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.[508] It appears that this section 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.

9.68 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 is merely a mixture of known ingredients, or is a process to produce such substance by mere admixture.[509] It is unlikely that this exclusion would apply to inventions relating to biotechnology.[510]

9.69 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.[511]

Canberra, [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. Patentability of inventions involving human stems is also a matter of debate in other jurisdictions. See L Nielsen and P Whittaker, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (2000), European Commission, see <http://europa.eu.int/comm/european_group_ethics/docs/avis16_en.pdf>; European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (2002), European Commission, see <http://europa.eu.int/comm/european_group_ethics/docs/avis16_en_complet.pdf>. The United Kingdom Patent Office has recently sought to clarify the issue in a Practice Note, which states that inventions involving processes for obtaining stem cells from human embryos or involving 'human totipotent cells' are not patentable, but inventions involving 'human embryonic pluripotent stems cells' that satisfy the normal requirements for patentability will be patentable: UK Patent Office, *Practice Notice: Inventions Involving Human Embryonic Stem Cells*, <www.patent.gov.uk/patent/notices/practice/stemcells.htm>, 18 June 2003.

507 The Commissioner may also revoke an innovation patent on equivalent grounds: *Patents Act 1990* (Cth) s 101B(2)(d). For a discussion of examination and revocation of innovation patents, see Ch 8.

508 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [8.6.3]–[8.6.4].

509 *Patents Act 1990* (Cth) s 50(1)(b). The Commissioner may also revoke an innovation patent on equivalent grounds: *Patents Act 1990* (Cth) s 101B(4).

510 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Commonwealth of Australia, Canberra, 39.

511 *Patents Act 1990* (Cth) ss 18(3), (4). 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: Advisory Council on Intellectual Property, *Innovation Patent — Exclusion of Plant and Animal Subject Matter* (2002), Commonwealth of Australia, Canberra, see <www.acip.gov.au>.

9.70 In addition to the express statutory exclusions, judicial interpretation of Australian patent legislation[512] has considered a number of other grounds upon which an invention may be regarded as unsuitable subject matter for patent protection. Critics of gene patents have relied on these judicial exclusions in asserting that isolated genetic materials and, sometimes genetic products and technologies, may be excluded from patentability, as discussed further below.

Unethical inventions

9.71 The specific ethical concerns that are raised by patents, and in particular by gene patents, have been outlined in Chapter 4. It has been suggested that the patent system should provide avenues for addressing these concerns. One mechanism for doing so would be to allow patent applications to be refused on ethical grounds.

Ethical considerations under Australian law

9.72 The *Patents Act* does not contain an explicit mechanism to allow ethical issues to be considered by patent examiners in assessing the patentability of an invention. It may, however, include an indirect requirement that ethical and social policy issues be considered in granting a patent. Section 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*.[513] This section 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'.

9.73 It is arguable that the term 'generally inconvenient' includes ethical considerations within its scope.[514] 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.[515] 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.[516]

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512 Judicial interpretation of United Kingdom patent legislation, on which the Patents Act 1990 (Cth) and the Patents Act 1952 (Cth) were closely based, are also relevant.

513 *Patents Act 1990* (Cth) s 18(1)(a) (standard patents); s 18(1A)(a) (innovation patents).

514 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) *EIPR* 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.

515 *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).

516 See, for example, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45 (Wilcox J).

9.74 Further, as a matter of practice, it appears unlikely that ethical considerations are considered by 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.[517]

Ethical considerations in other jurisdictions

9.75 In contrast to the Australian position, a number of overseas jurisdictions expressly permit an invention to be excluded from patentability on ethical or social policy grounds.[518]

9.76 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.' The European Patent Convention and European Parliament's Directive on the Legal Protection of Biological Inventions (EU Biotechnology Directive) contain provisions in similar terms.[519] Provisions permitting the exclusion of inventions from patent protection on ethical or social policy grounds also exist in the patent statutes enacted by the United Kingdom (implementing the EU Biotechnology Directive),[520] New Zealand[521] and Japan.[522]

9.77 To date, these ethical exceptions have rarely been invoked with any degree of success. A recent discussion paper on the New Zealand *Patents Act 1953* noted that the 'morality exception' under New Zealand patent law had rarely, if ever, been

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517 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [8.1.2]

518 United States patent law does not contain an express provision permitting patent applications to be rejected on ethical grounds, but United States courts have interpreted the 'utility' requirement as preventing the patenting of inventions that are 'injurious to the well-being, good policy, or sound morals of society': *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 & Trademark Office, *Media Advisory: Facts on Patenting Life Forms Having a Relationship to Humans*, USPTO, <www.uspto.gov/web/offices/com/speeches/98-06.htm>, 19 May 2003.

519 European Patent Office, *European Patent Convention*, EPO, <www.european-patent-office.org /legal/epc/index.html>, 13 March 2003 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).

520 *Patents Act 1977* (UK) s 1(3)(a).

521 *Patents Act 1953* (NZ) s 17(1).

522 *Patent Law 1999* (Japan) s 32.

applied.[523] Similarly, decisions of the EPO have indicated that the *ordre public*/morality exception contained in the European Patent Convention will be narrowly construed.[524] The Examination Guidelines for the EPO state that the exception 'is likely to be invoked in only rare and extreme cases'.[525] In 1994, the Opposition Division of the EPO specifically rejected the relevance of the exception to a patent claiming a genetic sequence.[526]

9.78 Dealing with ethical concerns through the patent system also raises the issue of how, and by whom, decisions about ethics are to be made. It has been suggested that patent examiners lack the training and expertise to make decisions of this kind.[527] Patent applications that raise ethical considerations might be referred to a specialised body that could either provide advice on such issues or make determinations itself.[528] Alternatively, ethical questions arising in connection with patent applications could be left to patent examiners to determine in accordance with clear guidelines. Responsibility for formulating and administering any such guidelines may also be an issue.

Question 9–6. Should ethical considerations be relevant in assessing applications for gene patents? If so, should a specific provision to that effect be introduced into the *Patents Act 1990* (Cth), or is the current 'manner of manufacture' test sufficient to accommodate such considerations?

523 New Zealand Ministry of Economic Development, *A Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002), New Zealand, see <www.med.govt.nz/buslt/int_prop /patentsreview/index.html>, 17.

524 See *Lubrizol/Hybrid Plants* [1990] EOPR 173; *Harvard/Onco-mouse* [1990] EOPR 501; *Howard Florey/Relaxin* [1995] EPOR 541; *Plant Genetic Systems/Glutamine Synthetase Inhibitors* [1995] EOPR 357. It appears that 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. See Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>, 39 fn 35.

525 European Patent Office, *Guidelines for Examination in the European Patent Office* (2003), EPO, Munich, see <www.european-patent-office.org/legal/gui_lines/e/>, Pt C–IV, [3.1]

526 *Howard Florey/Relaxin* [1995] EPOR 541.

527 See, for example, Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>, 40; R Ford, 'The Morality of Biotech Patents: Differing Legal Obligations in Europe?' (1997) *EIPR* 315, 317; D Slater, 'huMouse', *Legal Affairs*, Nov-Dec 2002, 21, 24.

528 European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (2002), European Commission, see <http://europa.eu.int/comm/european_group_ethics/docs/avis16_en_complet.pdf>, [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), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>, 40.

Question 9–7. If ethical considerations became relevant in assessing applications for gene patents, who should be responsible for developing guidelines, providing advice, and ultimately making determinations about such issues?

Discoveries

9.79 It has been suggested that isolated genetic materials are merely 'discoveries', not inventions, and are not therefore appropriate subject matter for patent protection.

9.80 A 'discovery' does not constitute a 'manner of manufacture' under Australian patent law.[529] Exactly what will be regarded as a discovery for the purposes of patent law is unclear. The *Manual of Practice and Procedure* notes that 'no general definition can be given as to what constitutes a discovery as opposed to an invention'.[530] In addition, the High Court in *NRDC* suggested that drawing a distinction between a discovery and an invention may be misleading and is often only true in a formal sense.[531]

9.81 Consideration of the distinction between a discovery and an invention in the context of biotechnology patents first arose in relation to patent claims to micro-organisms. In Australia and in other jurisdictions, 'man-made' micro-organisms have been accepted as constituting patentable subject matter.[532] Naturally-occurring micro-organisms will, however, be treated as discoveries and, as a consequence, patent protection will not be available.

9.82 The difference between a discovery and an invention in relation to patent applications claiming genetic sequences has also arisen for consideration. In applying the principle that a discovery is not patentable subject matter, these decisions have drawn a distinction between genetic materials in their natural state and those that have been 'isolated and purified'.

9.83 In *Kiren-Amgen Inc v Board of Regents of the University of Washington*, a patent application for the purified or isolated DNA sequence encoding the human protein erythropoietin was opposed.[533] The Deputy Commissioner of Patents stated:

529 *Lane Fox v Kensington and Knightsbridge Electric Lighting Co* (1892) 9 RPC 413, 416 cited with approval in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 263.

530 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [8.2.5.2].

531 *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252, 264.

532 See, for example, *Ranks Hovis McDougall's Application* [1976] 46 AOJP 3915 (Australia); *Diamond v Chakrabarty* 447 US 303 (1980) (United States).

533 Whether the claimed invention was a 'manner of new manufacture' was not a ground of opposition in the case but arose in relation to the Deputy Commissioner's consideration as to whether the invention related

> 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.[534]

9.84 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'.[535]

9.85 Considering the difference between a discovery and an invention in the context of gene patents, the *Manual of Practice and Procedure* states that:

> 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.[536]

9.86 This issue has also arisen for consideration in Europe. Article 52(2)(a) of the European Patent Convention provides that 'discoveries, scientific theories and mathematical methods' shall not be regarded as inventions for the purposes of the European patent law.[537] The EPO was required to consider the application of this provision in the case of *Howard Florey/Relaxin*,[538] which 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:

> to find 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.[539]

9.87 The EU Biotechnology Directive contains an express provision recognising the patentability of isolated genetic sequences.[540] 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,

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to a mere discovery: *Kiren-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557.

534 Ibid, 569 (emphasis added).

535 Ibid, 569. The Deputy Commissioner's decision in this case was appealed to the Federal Court on other grounds: *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1999) 92 FCR 106.

536 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra [8.2.5.3].

537 European Patent Office, *European Patent Convention*, EPO, <www.european-patent-office.org /legal/epc/index.html>, 13 March 2003.

538 *Howard Florey/Relaxin* [1995] EPOR 541.

539 Ibid, 548.

540 *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).

> [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.[541]

9.88 The Nuffield Council has questioned reliance on the distinction between naturally occurring genetic materials and those that have been purified and isolated. The Nuffield Council has suggested that, in drawing such a distinction, patent offices have assumed that knowledge of the structure of a genetic sequence (and its uses) can only be obtained by creating an artificial, purified form of the sequence.[542] The Nuffield Council noted, however, that even if this was once true, identification of genes sequences is now achieved by computational techniques and may no longer involve actual isolation and purification of a gene.[543]

9.89 David Keays has argued that genetic sequences might properly be regarded as discoveries rather than inventions because characterisation of a genetic sequence may be 'discovered' by applying an established method to an existing state of affairs.[544]

Question 9–8. Should isolated genetic materials and genetic products be regarded as 'discoveries' rather than 'inventions' for the purposes of Australian patent law, and thus excluded from patentability?

Methods of medical treatment

9.90 The *Patents Act* does not expressly exclude methods of medical treatment from patentability. However, before 1972, Australian law recognised non-medical (including cosmetic), as well as surgical or medical treatment of the human body as an exception to patentability.[545] 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*.[546]

541 Ibid art 5(2).

542 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 27–28.

543 Ibid, 28.

544 D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 76.

545 *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.

546 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [8.2.13.1].

9.91 Based on recent case law,[547] the Patent Office considers it is now 'firmly established that methods of medical treatment are patentable subject matter'.[548] Patent Office 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'.[549]

9.92 In *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (*Rescare*),[550] the Full Court of the Federal Court considered whether methods of medical treatment could constitute a '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:[551]

> 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.[552]

9.93 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* 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*.[553]

9.94 The approach to the patentability of methods of medical treatment taken by Lockhart and Wilcox JJ in *Rescare* was affirmed by the Full Court of the Federal Court in *Bristol-Myers Squibb Company v F H Faulding & Co Ltd*.[554] 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.[555]

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547 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439.

548 IP Australia, *Patent Manual of Practice and Procedure Volume 2 – National* (2002), Commonwealth of Australia, Canberra, [8.2.13.3].

549 Ibid, [8.2.13.1].

550 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (*Rescare*) (1994) 50 FCR 1. The case concerned the patentability of a method and device for the prevention of sleep apnoea.

551 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 19.

552 Ibid, 16.

553 Ibid, 42–43.

554 *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.

555 Ibid, 444.

Medical treatment exception in other jurisdictions

9.95 In the United Kingdom, methods of medical treatment of the human body are expressly excluded from patentability.[556] 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.

9.96 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.

9.97 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).[557] Methods of medical treatment are not patentable inventions because they are generally considered not to meet the Canadian utility criteria.[558]

9.98 The *Patents Act 1953* (NZ) does not expressly exclude methods of medical treatment from patentability, 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'.[559] More recently, the New Zealand Court of Appeal appears to have departed from this view in concluding that 'it can no longer can be said that a method of treating humans cannot be an invention'.[560] The issue is now under consideration as part of the New Zealand Ministry of Economic Development's review of the *Patents Act 1953* (NZ).[561]

A new medical treatment exclusion

9.99 As discussed in more detail elsewhere in this Issues Paper,[562] concerns have been expressed about the possible adverse impact of gene patents on the cost-effective provision of healthcare. Following the United Kingdom model, methods of medical treatment of the human body could be expressly excluded from patentability.

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556 See *Patents Act 1977* (UK) s 4(2).

557 Canadian Patent Office, *Manual of Patent Office Practice* (1998), Government of Canada, Ottawa, see <http://patents1.ic.gc.ca/>, [16.04(b)].

558 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>, 31.

559 See *Wellcome Foundation Ltd v Commissioner of Patents* [1983] 2 NZLR 385.

560 *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.

561 See New Zealand Ministry of Economic Development, *A Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002), New Zealand, see <www.med.govt.nz/buslt/int_prop/patentsreview/index.html>, 53–60.

562 See Ch 4, 7, 12.

9.100 The medical treatment exception to 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.[563] In particular, methods of diagnosis performed on tissues or fluids which have been permanently removed from the body are not excluded.[564]

9.101 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. While not explicit, it seems most likely that the permissible exclusion is limited to methods performed on or inside the body, consistent with existing exclusions in the United Kingdom and Canada.

9.102 This limitation is significant when considering the possible application of any new methods of medical treatment exclusion to gene patents. Gene patents will 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.

9.103 For this reason, if legislative reform is considered desirable, the introduction of a new medical treatment defence (discussed in Chapter 14), as opposed to an exclusion from patentability, may be preferable.[565] Such a defence could apply to both *in vivo* and *in vitro* procedures.[566]

Question 9–9. Should methods of diagnostic, therapeutic and surgical treatment of humans involving genetic materials or technologies continue to be patentable under Australian law? If not, how should the exclusion of such inventions from patentability be justified, and what should be the scope of the exclusion?

563 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), Ontario Government, see <www.gov.on.ca>, 51. United Kingdom: United Kingdom Patent Office, *Manual of Patent Practice*, UK Patents Office, <www.patent.gov.uk/patent/reference/mpp/>, 11 February 2003.

564 United Kingdom Patent Office, *Manual of Patent Practice*, UK Patents Office, <www.patent.gov.uk /patent/reference/mpp/>, 11 February 2003.

565 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, 51.

566 It has been suggested that the distinction between in vivo and in vitro procedures is a theoretical one, which is difficult to maintain in practice: Ibid, 51.

10. Licensing and Enforcement of Patent Rights

Contents

Introduction

10.1 This chapter considers the rights granted to a patent holder and the means by which a patent holder may exploit and enforce these rights. It outlines patent licensing practices, the enforcement of patent rights and existing defences to patent infringement claims under Australian law. This provides the context for the discussion in later chapters of the impact of gene patents on research, the commercialisation of genetic materials and technologies, and the provision of healthcare.

Rights of a patent holder

10.2 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.[567] '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

567 *Patents Act 1990* (Cth) s 13(1). Note that the right to exploit an invention is, however, subject to earlier patents not owned by the patent holder, as well as any necessary government approvals.

> (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.[568]

10.3 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').[569] 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.[570]

10.4 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.[571] However, any licence or assignment of a co-owned patent requires the consent of all of the patent holders.[572]

10.5 Subject to a limited number of safeguards,[573] 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.

Licensing patent rights

10.6 A patent licence is an agreement by a patent holder to allow a third party to conduct certain activities involving a patented invention, which would otherwise amount to an infringement of the patent holder's rights. 'Licence' is defined in the *Patents Act* as 'a licence to exploit, or to authorise the exploitation of, a patented invention'.[574]

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568 Ibid sch 1.

569 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 (ed) *Patents, Trade Marks & Related Rights: Looseleaf service* (2001) Butterworths, Sydney, [22,008].

570 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 and to oppose a proposed amendment to a patent specification: *Patents Act 1990* (Cth) ss 120(1), 187, 103.

571 Ibid s 16(1)(b).

572 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 all 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, <http:// www.genomeweb.com/>, 9 May 2003.

573 In particular, the Crown use and compulsory licensing provisions in the *Patents Act 1990* (Cth) and relevant provisions under the *Trade Practices Act 1974* (Cth). See Ch 15 and 17.

574 *Patents Act 1990* (Cth) sch 1.

10.7 A licence to one or more gene patents may be a stand-alone transaction or part of a larger commercial arrangement, such as a joint venture or strategic alliance, or a collaboration, sponsored research, consortium or manufacture and supply agreement.

10.8 The decision to license gene patents may be based on a number of factors.[575] 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 and 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. Strategic patent licensing by a company may also result in the establishment of profitable, long-term alliances leading to future research collaborations. Finally, patent licences, especially cross-licences of patent rights among competitors, may be a means of avoiding or settling patent litigation.

Types of patent licences

10.9 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 such rights to a different entity (perhaps also on an exclusive basis).

10.10 A sole licence permits both the patent holder and a licensee to exploit a patented invention, but prevents the patent holder from licensing the rights to any other entity.

10.11 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.

Common terms in patent licences

10.12 The *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.

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575 For a general discussion of the factors relevant to a decision to license patent rights, see Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Commonwealth of Australia, Canberra, Ch 8; Department of Foreign Affairs and Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001), Commonwealth of Australia, Canberra, see <www.dfat.gov.au/>, Module 9.

10.13 Patent licences usually address the following matters:[576]

- 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;
- duration of the licence;
- financial terms—such as licence fees,[577] payment terms and liability for taxes;
- 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;
- 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;
- 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.

Licensing of gene patents

10.14 To date, much of the concern about the potential adverse impact of gene patents has entailed criticism of restrictive licensing practices in relation to two

576 This list is not comprehensive and is intended only as a guide to issues that a patent holder may wish to regulate in their relationship with a licensee. It has been suggested that 'standard terms' in patent licences relating to biotechnology inventions are a myth because rapid developments in this field have resulted in agreements with relatively novel structures: T Davies, D Blanke and T Corder, *United States: Strategic Business Alliances in Biotech Industry*, Mondaq, <http://www.mondaq.com/>, 16 May 2003.

577 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.

particular types of gene patents: patents on genetic 'research tools'[578] and patents on diagnostic genetic tests.

Research tools

10.15 Ready access to 'research tools' in the genetics field is said to be essential to the conduct of further research and development in this area. It has been suggested that the proliferation of patents on genetic research tools may impede research if such patents are not widely licensed.[579]

10.16 Examples of exclusive licences being granted in relation to patents on targets with specific therapeutic and diagnostic functions do exist; for example, the CCR5 receptor referred to in Chapter 9.[580] However, the non-exclusive licensing of the Cohen-Boyer gene-splicing patent and of polymerase chain reaction (PCR) technology are evidence that an alternative approach to exploiting patents on genetic research tools has also been adopted.[581]

10.17 In a recent report, the Nuffield Council on Bioethics (Nuffield Council) considered the concerns that have been voiced about the exclusive licensing of gene patents. The Nuffield Council suggested that particular concerns may arise with respect to the licensing of patented research tools because many such patents have been granted to universities and biotechnology companies that have a greater tendency to enter into exclusive licence arrangements.[582] It indicated that exclusive licensing practices in this area may not be in the public interest and recommended that licensing such patents exclusively, or to a limited number of licensees, should be discouraged.[583]

Diagnostic genetic tests

10.18 Exclusive licensing of patents relating to diagnostic genetic tests has also given rise to concern.[584] In particular, Myriad Genetics' approach to the commercialisation of its patents on the BRCA genes—entailing both the grant of

578 Various definitions of 'research tools' have been offered: see Ch 11.

579 Research tools may also be found to have therapeutic or diagnostic qualities that make such material useful outside a laboratory and marketable to consumers directly: Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools*, NIH, <www.nih.gov/news/researchtools/index.htm>, 10 April 2003.

580 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 50.

581 M Young, *The Legacy of Cohen-Boyer*, Signals Magazine, 28 May 2003.

582 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 60. 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 strategies than private companies: M Henry and others, 'DNA Patenting and Licensing' (2002) 297 *Science* 1279.

583 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 60.

584 For research on the impact of patents on diagnostic genetic testing in the United States, see M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3; A Schissel, J Merz and M Cho, 'Survey Confirms Fears About Licensing of Genetic Tests' (1997) 402 *Nature* 118.

exclusive territorial licences and the imposition of additional restrictions as to how and where certain aspects of these diagnostic tests may be conducted—has generated criticism.[585] Myriad Genetics' licensing practices, and concerns about patents on diagnostic genetic tests generally, are discussed in Chapter 12.

10.19 In Australia, both the Australian Health Minister's Advisory Council (AHMAC) and the Human Genetics Society of Australasia (HGSA) have voiced objections to licensing practices in relation to diagnostic genetic tests. An AHMAC Working Group has recommended that gene patents relating to the provision of healthcare should be broadly licensed, and licensing agreements should not limit access through excessive cost.[586] Similarly, the HGSA has stated that patent holders should not grant exclusive licences for genetic tests.[587]

Licensing of gene patents in Australia

10.20 The size and character of the Australian biotechnology industry (which is discussed in Chapter 6) 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.[588] In addition, the primary expertise of 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.[589]

10.21 It is 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.[590] Information about patent licence agreements may be gleaned from the following sources:

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585 See, for example, 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), Institut Curie, Paris.

586 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 26, rec 5.

587 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html> [3.6].

588 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Commonwealth of Australia, Canberra, 115.

589 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*, University of Tasmania, <www.lawgenecentre.org/fsrv/symposium2001/nielsen.pdf>, 26 March 2003, 39, 43. See further Ch 6.

590 Limitations on the availability of patent licensing information have also been noted by the OECD: Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 45. Research is currently being conducted by an Australia academic, Dr Dianne Nicol, on the licensing practices of the Australian biotechnology industry to obtain data about the impact of biotechnology patents on the public and private sectors, as well as diagnostic facilities in Australia: D Nicol, 'Gene Patents and Access to Genetic Tests' (2003) 11 *Australian Health Law Bulletin* 73.

- the records of IP Australia—including, patent licences that may be filed with the Patent Office;[591]

- certain disclosures made by publicly-traded Australian companies pursuant to the Australian Stock Exchange listing rules [592] (and equivalent disclosure requirements imposed by securities exchanges in other jurisdictions);[593] and

- an individual company's press releases.

10.22 Such sources will, however, only reveal a proportion of the transactions that have actually been concluded. For example, Figure 10–1 indicates the number of patent licences and mortgages registered with IP Australia between 1993–94 and 1999–2000—less than 0.5 % of the number of standard patents sealed in each year during the period. In addition, public sources of information about patent licences generally exclude details of the commercial terms of such agreements to preserve confidentiality.

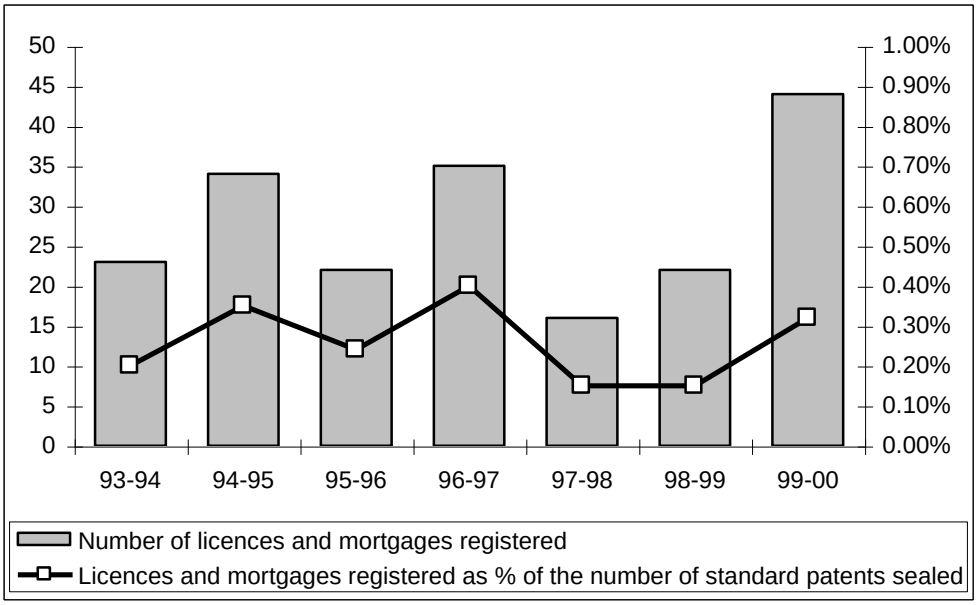
10.23 Because publicly available information about licensing practices with respect to gene patents in Australia is very limited, it is unclear whether restrictive licensing practices are prevalent and need to be addressed.

591 *Patents Act 1990* (Cth) ss 187, 193; *Patents Regulations 1991* (Cth) r 19.1. It is not mandatory to file patent licences with IP Australia: see J Lahore (ed) *Patents, Trade Marks & Related Rights: Looseleaf service* (2001) Butterworths, Sydney, [22,008].

592 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.

593 For example, the Melbourne-based company, Genetic Technologies Ltd, filed a number of announcements with the Australian Stock Exchange in 2002 and 2003 relating to the execution of licences for use of its patents covering non-coding DNA: see Genetic Technologies Ltd, *Announcements 2003*, <www.gtg.com.au/Announcements.html>, 3 June 2003.

Figure 10–1 Australian registered patent licences and mortgages



Source: IP Australia, *Industrial Property Statistics 1999–00*, Table 2.[594]

Enforcement of patent rights

10.24 Patent protection is generally sought in order to protect and preserve the competitive advantage that may result from an invention, as well as to recoup the cost incurred in development of an invention. Patent rights are, however, of limited value unless they are enforced to deter patent infringers and to provide a remedy for a person or entity whose rights have been infringed.

Monitoring compliance with patent rights

10.25 Investigation and monitoring to detect potentially infringing activities may be undertaken in a number of ways. Such efforts will generally focus both on third parties who have been authorised to use a patented genetic invention pursuant to a licence agreement and on others who may have no contractual or other commercial relationship with the patent holder.

10.26 Mechanisms for monitoring a licensee's compliance with the terms of a licence are typically stipulated in the licence agreement. A patent licence may include a requirement that a licensee submit periodic reports detailing product sales or, if

594 The graph shows the number of licences *and* mortgages registered with IP Australia during the period; statistics about the number of licences only are not available. The licences recorded may relate to patents granted prior to the period represented in the graph.

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.

10.27 A patent holder's ability to monitor the activities of third parties with whom it has no commercial relationship is more limited. Information and resources within a patent holder's organisation are one means by which potential patent infringers may be detected. Familiarity with the relevant area of technology, the identity of competitors and competitors' activities may mean that employees of a patent holder are in the best position to identify potential infringement by third parties.

10.28 '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 genetic 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.[595]

Commercial responses to infringement

10.29 If a patent holder determines that his or her patent is being infringed, a variety of means may be employed to enforce patent rights, including commercial actions and legal proceedings. For example, a patent holder may notify a potential infringer of the existence of a patent and indicate that their activities involving such 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 his or her patent rights.

595 Most patent applications are published 18 months after the date on which the application was first filed: see Ch 8.

Legal responses to patent infringement

10.30 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.596 Patent infringement may be either direct or contributory. The infringement is direct if a person, without authorisation, exercises any of the exclusive rights conferred upon the patent holder.[597] Contributory infringement exists in cases of supply of a product by one person to another where the use of such product would constitute an infringement of a patent.[598]

10.31 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.[599] 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. In addition, Australian courts have found that omitting an inessential part of a patent claim or replacing it with an equivalent will not necessarily prevent a finding of infringement.[600] 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.[601]

10.32 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, has been certified.[602]

Remedies

10.33 If a patent holder successfully proves that his or her patent rights have 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

596 An exclusive licensee who initiates infringement proceedings must join the patent owner 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 owner, 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).

597 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) Federation Press, Sydney, 318.

598 *Patents Act 1990* (Cth) s 117.

599 *Populin v HB Nominees Pty Ltd* (1982) 41 ALR 471, 475.

600 *Fisher & Paykel Healthcare Pty Ltd v Avion Engineering Pty Ltd* (1991) 103 ALR 239.

601 *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 (Finklestein J).

602 *Patents Act 1990* (Cth) ss 57, 120(1A).

account of profits, at the patent holder's option.[603] A court may also make orders for the inspection[604] and delivery up of infringing materials.[605]

10.34 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.[606]

Defences to patent infringement

Defences available under the Patents Act

10.35 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;[607]
- 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);[608]
- use of a patented invention that is subject to a contractual condition prohibited under s 144 of the *Patents Act*;[609] 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.[610]

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603 Ibid s 122(1).

604 Ibid s 122(2).

605 See, for example, *Roussel Uclaf v Pan Laboratories Pty Ltd* (1994) 51 FCR 316.

606 Interlocutory relief may also be available under common law principles by means of an Anton Piller Order: *Anton Piller KG v Manufacturing Processes Ltd* [1976] Ch 55. See, for example, B Fitzmaurice, 'Protecting Intellectual Property with Anton Piller Orders' (2002) 15 *Australian Intellectual Property Law Bulletin* 103.

607 *Patents Act 1990* (Cth) s 118.

608 Ibid s 119.

609 For example, subject to certain exceptions, a contractual condition relating to the sale, lease or licence of a patented invention is void under s 144(1) of the *Patents Act* if the effect of the condition would be either (a) to prohibit or restrict the other party to the contract from using a product or process supplied or owned by a person other than the patent holder, or (b) to require the other party to the contract to acquire from the patent holder a product not protected by the patent. These contractual conditions are commonly known as 'tie-in' arrangements. See Ch 17.

610 *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 only be obtained 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).

10.36 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.[611] 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.

Defences available under general law

10.37 In addition to the defences specifically provided under the *Patents Act*, general equitable defences are available against a claim of patent infringement.[612]

10.38 An alleged infringer may claim that the patent holder is estopped from enforcing their rights if, by their 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.[613]

10.39 An alleged infringer may assert delay or acquiescence on the part of the patent holder in the enforcement of his or her rights. Such a defence is unlikely to avoid an injunction restraining future infringement, but may substantially reduce the damages that may be awarded if the patent holder successfully demonstrates that the patent has been infringed.[614]

10.40 However, Australian patent law does not contain defences that specifically address concerns that have been raised about the adverse impact of gene patents. Chapter 14 discusses possible amendments to the *Patents Act* to enact new defences based on research uses of gene patents, or uses of gene patents for the purposes of medical treatment.

Enforcement of gene patents

10.41 Little information is available about the enforcement of gene patents in Australia to date. It may be that enforcement actions have not been necessary because there has been a high degree of compliance with those patents that have been granted. Alternatively, actions for infringement of gene patents, although warranted, may not be being instigated. There may be several explanations for this.

611 *Patents Act 1990* (Cth) s 78.

612 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Commonwealth of Australia, Canberra, 155.

613 See for example, *Woodbridge Foam Corporation v AFCO Automotive Foam Components Pty Ltd* [2002] FCA 883.

614 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Commonwealth of Australia, Canberra, 155.

10.42 First, infringement of gene patents may be difficult to detect. A recent report of the Organisation for Economic Cooperation and Development (OECD Report) noted that the use of 'research tools' occurs behind laboratory doors, making infringement particularly difficult to monitor.[615] Further, many biotechnology companies do not yet have commercial products that could lead a patent holder to suspect that such products had been developed using patented research tools.[616]

10.43 Second, enforcement of patent rights 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.[617]

10.44 A patent holder is, therefore, typically required to make strategic decisions about the best use of resources in enforcing his or her rights. Patent protection for an invention is frequently obtained in more than one jurisdiction and an Australian patent holder may elect to enforce his or her rights in the jurisdictions that represent the largest markets for a patented product. Alternatively, a patent holder may select certain defendants for tactical reasons.[618] 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.

10.45 Third, infringement proceedings expose the validity of the patent rights to attack. As discussed in Chapter 8, a defendant may file a counter-claim for revocation[619] 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 such rights 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 clear authority delineating the scope of rights conferred by a gene patent, patent holders may regard infringement proceedings as entailing too great a risk.

Are changes to patent laws and practices needed?

10.46 Proposals to change current law and practices relating to the licensing and enforcement of gene patents have been criticised on the basis that there has been no demonstrated adverse impact on research, commercialisation or healthcare. The officers of one American genomics company have written:

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615 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 47.

616 Ibid, 48.

617 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Commonwealth of Australia, Canberra, 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: Ibid.

618 J Berkowitz, *United States: Trends in Enforcing and Licensing Patents*, <www.mondaq.com/default2.asp>, 23 May 2003.

619 *Patents Act 1990* (Cth) s 121. The grounds upon which revocation may be sought are set out in s 138(3).

> Debate on concerns that gene patents inhibit either basic research or the provision of health care in a timely and affordable manner is itself very healthy. However, it is of some very real concern that unsubstantiated assertions about what 'might' happen if patentees act in a manner that seems both unlikely from an economic point of view as well as destructive from a societal perspective seem to be fuelling not only debate but ill-conceived legislative 'fixes' for ills that do not actually exist.[620]

10.47 The OECD Report reached a similar conclusion:

> The available evidence does not suggest a systematic breakdown in the licensing of genetic inventions. The few examples used to illustrate theoretical economic and legal concerns … appear anecdotal and are not supported by economic studies.[621]

10.48 The OECD Report, however, also concluded that continued monitoring of the patenting and licensing of genetic inventions is necessary if policy makers are to embark upon significant reform of the patent system.[622]

10.49 In Australia, there is currently no clear evidence that the exploitation and enforcement of gene patents has significantly affected the conduct of research, the commercialisation of genetic materials and technologies, or the provision of healthcare.[623] An important role of this Inquiry is to obtain more information about the likely future impact of gene patents on Australian industry and the healthcare system, for the purpose of assessing the need for changes to patent laws and practices.

620 L Bendekgey and D Hamlet-Cox, 'Gene Patents and Innovation' (2002) 77 *Academic Medicine* 1373, 1378, referring to the Genomic Research and Diagnostic Accessibility Bill 2002 (US).

621 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 77.

622 Ibid, 78.

623 The preliminary results of surveys of gene patent licensing to date has evidenced the existence of fears about the adverse impacts of gene sequence and research tool patents, but no actual detrimental effect in Australia to date: D Nicol, 'Gene Patents and Access to Genetic Tests' (2003) 11 *Australian Health Law Bulletin* 73, 74–75.

In order to assess the impact of Australian patent laws and practices on the licensing and enforcement of gene patents, the ALRC seeks further information about current commercial practices in Australia in this area. The information required to answer these questions might be considered to be commercial-in-confidence. However, the ALRC undertakes to take all reasonable steps to safeguard the confidentiality of any such information provided. The ALRC will use commercial-in-confidence information only with prior consent and according to the terms on which it is provided, to the extent permitted by law.

Question 10–1. Is sufficient information available to holders of Australian gene patents to allow them to protect their patent rights? If not, what alternative or additional information or facilities might be required?

Question 10–2. To what type of gene patents are Australian companies, researchers, healthcare providers or other organisations seeking or granting licences? What uses are being made of such licensed gene patents?

Question 10–3. Are requests for licences to Australian gene patents being refused by patent holders? If so, why? If not, are the terms of such licences fair and reasonable?

Question 10–4. Are gene patents being enforced against Australian companies, researchers, healthcare providers or other organisations? If so, what types of gene patents are being enforced and by what means (for example, with cease and desist letters, offers to license, or the threat of infringement proceedings)?

Question 10–5. Are the potential costs involved in litigating patent infringement actions preventing the enforcement of Australian gene patents? Are there any other factors influencing the decisions of holders of Australian gene patents about whether or how to enforce such patent rights?

Part D

Impact on Genetic Research, Human Health and Commercialisation

11. Patents and Human Genetic Research

Contents

Introduction

11.1 The Terms of Reference require 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 some patents may have a 'chilling effect' on research; the granting of broad patents; patents over gene fragments and research tools; 'reach-through' claims; and secrecy. The chapter also discusses potential means of assisting research, including 'research only' exemptions under patent law; public databases of genomic information and guidelines to encourage dissemination of research findings.

11.2 Whether patent laws are the best means to encourage research and innovation in knowledge-based areas such as medical research is a matter of debate. The United Kingdom Commission on Intellectual Property Rights argued that:

> The patent system fits best a model of progress where the patented product, which can be developed for sale to consumers, is the discrete outcome of a linear research process. The safety razor and the ballpoint pen are examples, and new drugs also share some of these characteristics.

> By contrast 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.[624]

11.3 It is noteworthy that the United States Patents and Trademarks Office (USPTO) acknowledged that:

> One of the biggest public concerns voiced against the granting of patents by the United States Patent Office (USPTO) to inventions in biotechnology, specifically inventions based on genetic information, is the potential lack of reasonable access to the technology for the research and development of commercial products and for further basic biological research.[625]

Is there a chilling effect on research?

11.4 One of the major debates in this area is whether gene patents and licences have a chilling effect on research and innovation, rather than promoting them. There are two principal reasons advanced for this: fear (whether misplaced or real) of infringing patents; and reluctance to put information in the public domain in the light of the possibility of commercialising research. Other concerns include the cost and complexity of dealing with patents and licences.

11.5 There have been conflicting results in overseas studies about the impact on research of gene patents and licences. Dr Mildred Cho found that 25% of United States university and commercial laboratories are refraining from providing genetic tests or continuing with some of their research for fear of breaching patents or because they lack the funds to pay licence fees or royalties.[626]

11.6 A study by the United States National Institutes of Health (NIH) found that American universities are themselves hindering the free exchange of basic research tools such as genetic sequences and reagents, despite making similar complaints about industry. The study found that universities impose conditions on the use of their research tools, such as the insistence on vetting manuscripts before publication and

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624 Commission of Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, <www.iprcommission.org/graphic/documents/final_report.htm>, 26 March 2003, 124.

625 United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000), United States Patents and Trademarks Office, Washington, see <www.uspto.gov>, 2.

626 M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

claims to future discoveries derived from the use of their research tools.[627] Research tools are discussed further below.

11.7 However, another United States study by John Walsh, Ashish Arora and Wesley Cohen (the Walsh study) noted that, while patenting of 'upstream' discoveries[628] had increased, almost no-one reported that worthwhile projects had stopped because of restrictions on access to intellectual property rights for research tools.[629] Instead, the Walsh study found that most researchers, both in universities and industry, had adopted 'working solutions' such as

> licensing, 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).[630]

11.8 The Walsh study also considered the issue from the perspective of industrial holders of intellectual property. The study found that industrial holders tolerated academic research infringements, except for infringement of patents on diagnostic tests used in clinical research. They reported a variety of reasons for allowing academic research to proceed unchallenged, including:

- 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
- a reluctance 'to upset the norms of open access … for fear of losing the goodwill of … peers and the associated access to materials and information'.[631]

11.9 The Organisation for Economic Co-operation and Development in a recent report (OECD Report) found that

> contrary to fears that the recent growth in the number and complexity of biotechnology patents would cause a breakdown in the patent system and so prevent access to inventions by researchers and health service providers, in fact patents and

627 E Press and J Washburn, *Secrecy and Science*, The Atlantic Online, <www.theatlantic.com/issues /2000/03/press2.htm>, 10 April 2003.

628 These are patents over genetic material which might be used to develop further inventions, for example diagnostic tests or pharmaceutical products ('downstream products'). They are discussed further below.

629 J Walsh, A Arora and W Cohen, 'Working Through the Patent Problem' (2003) 299 *Science* 1021.

630 Ibid.

631 Ibid.

> licenses for genetic inventions seem to stimulate research, knowledge flows, and the entry of new technology into markets.[632]

11.10 The OECD Report suggested that patents have the effect of making 'knowledge a tradeable commodity which both encourages the circulation of new information and promotes a division of labour'.[633] The OECD Report identified a number of issues concerning gene patents and research, which are discussed in subsequent sections of this chapter. These issues included:

- broad or blocking patents;
- increased secrecy;
- increased research and transaction costs; and
- increased litigation involving public research organisations.[634]

11.11 As noted above, overseas studies present varying results about the impact of gene patents and licences on research. There have been no comprehensive studies in Australia about whether gene patents and licences are having an impact on research. The ALRC is interested to hear from researchers on this issue.

Question 11–1. Is there any evidence about whether gene patents or licences are encouraging or inhibiting research in biotechnology in Australia?

Broad patents

11.12 Broad patents are patents that grant broad rights to the patent holder. For example, a patent application over isolated genetic material might nominate only one specific use of that genetic material but nevertheless claim rights in relation to other unspecified uses of it. If granted, this would include applications discovered later by someone else. Broad patents may be a feature of foundational or 'upstream' discoveries. Some of the issues raised by broad upstream patents concern the interpretation of the legislative requirements of novelty, inventive step, utility, sufficiency, and fair basing, which are addressed in Chapter 9.

632 Organisation for Economic Co-operation and Development and Federal Ministry of Education and Research, *Short Summary of the Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), OECD, Paris, see <www.oecd.org>, 2.

633 Ibid, 3.

634 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 12–15.

11.13 It has been argued 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 royalties to those whose patents were granted first (a 'reach-through effect'). There are also concerns about the impact of broad patents on the development and improvement of clinical tests. This is discussed in Chapter 12.

11.14 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.[635]

11.15 By contrast, a narrowly expressed patent may encourage others to 'work around' the patent, thereby having less impact on related research.

11.16 Linked with the issue of broadly expressed patents is that of whether a proliferation of upstream patents may impede downstream research and innovation by adding to the cost and time of biomedical invention. Professors Michael Heller and Rebecca 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'.[636] However, they also argue that this can 'go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research'.[637] Heller and Eisenberg suggest that such barriers could be 'transitional phenomena'[638] and the costs may be worth incurring if 'fragmented privatisation allows upstream research to pay its own way and helps ensure its long term viability'.[639] However, they also express concern that 'a patent anticommons could prove more intractable in biomedical research than in other settings'.[640]

11.17 Although there are widespread concerns about broad patents and their impact on both research and healthcare, in practice researchers appear to be gaining access to some broad patents. The Nuffield Council on Bioethics (the Nuffield Council) cited the example of the patent over the CCR5 receptor, which was discussed in Chapter 9.[641]

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635 National Human Genome Research Institute, *NHGRI Policy Regarding Intellectual Property of Human Genomic Sequence* (1996), NHGRI, Rockville, see <www.genome.gov/>.

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

637 Ibid, 698.

638 Ibid, 700.

639 Ibid, 700.

640 Ibid, 700. See discussion of the anti-commons in research in Ch 4.

641 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, [4.9]–[4.10].

The Nuffield Council indicated that the patent holder, Human Genome Sciences Inc, had issued several licences for research into HIV/AIDS drugs but did not plan to prevent academics from undertaking unlicensed research into CCR5. However, as discussed below, there can be disputes about what constitutes non-commercial research.

11.18 The ALRC is interested to hear from researchers about whether their work has been adversely affected by broad gene patents.

Research tools

11.19 As discussed above, one of the concerns of genetic researchers is that patents have been granted over basic research tools. Research tools are the range of resources that scientists use in their laboratories that have no immediate therapeutic or diagnostic value. 'Research tools' have been variously defined. For example, the NIH Working Group on Research Tools has adopted the following definition:

> 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.[642]

11.20 Genetic research is somewhat unusual in that patents are commonly held not only over the end-products of research but also over the basic information and tools needed for further research. As 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.[643]

11.21 Similarly, the NIH Working group noted:

> One institution's research tool may be another institution's end product … Institutions that seek to retain a competitive advantage from their proprietary research tools are generally unwilling to make them freely available. In order to minimize risks of competitive harm, they may seek to limit who has access to the tools, restrict how they are used, and restrict or delay disclosure of research results.[644]

11.22 The Nuffield Council has stated that:

642 Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools*, NIH, <www.nih.gov/news/researchtools/index.htm>, 10 April 2003.

643 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 & Policy* 229, 233.

644 Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools*, NIH, <www.nih.gov/news/researchtools/index.htm>, 10 April 2003.

> biotechnology companies which specialise in genomics appear to have been the most active in filing patent applications [over DNA sequences as research tools], and many of these have been granted.[645]

11.23 Patents over research tools raise concerns about access, delay caused by the need to negotiate licence agreements, and cost. As the USPTO said:

> 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. 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 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.[646]

11.24 The Nuffield Council suggested a number of ways in which patents covering genetic sequences, whose primary function is as research tools, might inhibit innovation:

- 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').[647]

11.25 However, the Nuffield Council also indicated that there is

> 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.[648]

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645 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, [5.32].

646 United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000), United States Patents and Trademarks Office, Washington, see <www.uspto.gov>, 3.

647 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, [5.39].

648 Ibid, [5.40].

11.26 The Nuffield Council recommended 'that in general the granting of patents which assert rights over DNA sequences as research tools should be discouraged'.[649]

11.27 Accompanying those concerns is the fear that licences over those tools often allow for a 'reach-through' claim so that the owner of the research tool gains rights over any subsequent invention. Heller and Eisenberg suggest that:

> in principle, RTLAs [research tool licence agreements] offer advantages to both patent holders and researchers. They permit researchers with limited funds to use patented research tools right away and defer payment until the research yields valuable results … In practice, RTLAs may lead to an anticommons as upstream owners stack overlapping and inconsistent claims on potential downstream products.[650]

11.28 Heller and Eisenberg give several examples of universities and other non-profit research institutions baulking at terms in licence agreements for the use of research tools.[651] It is unclear whether there are problems in Australia in relation to research tools and licence agreements and the ALRC is interested in hearing from researchers about the extent of the problem, if any.

11.29 Dr Dianne Nicol and Jane Nielsen suggest that little work has been done to determine whether the research efforts of Australian biotechnology companies are being hampered by restricted access to essential research tools and technologies.[652] However, they raise the spectre of adverse impact on healthcare through lack of development of products if broad patents are used to impede research.

> Unless a proper legal framework is in place, the great promises offered by medical technology may never be achievable, or may be so expensive that they are only available to a small and exclusive sector of the Australian population.[653]

11.30 Two research tools that raise particular concerns are expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs).

Expressed sequence tags

11.31 EST patents are patents over gene fragments with unknown function.[654] 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. However, the Human Genome Organisation (HUGO) has raised concerns that while it is not particularly difficult to generate an EST, it is much

649 Ibid, [5.41].
650 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.
651 Ibid, 699.
652 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, 348–349.
653 Ibid, 349.
654 See more detailed discussion in Ch 2.

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.[655]

11.32 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'.[656]

11.33 In Australia, Melanie Howlett and Professor Andrew Christie note that 'the subject of patent protection for ESTs has continued to be contentious'.[657] They identify a range of concerns about patents over ESTs, noting claims that such patents

- will impede further research;
- will allow 'reach-through' claims;[658]
- 'may give disproportionate rewards for routine effort that constitutes a minor step on the road to developing a routine product';[659] and
- may lead to a race to patent ESTs 'thus impeding cooperation between laboratories and limiting the availability of data and materials necessary for the successful completion of the Human Genome Project'.[660]

11.34 Howlett and Christie note that:

> The scientific community, as well as national and international organisations, has expressed concern regarding the patenting of ESTs and the need to ensure a fair allocation of intellectual property rights. The patenting of ESTs is a controversial area of patent law and clarification of the Trilateral Offices the European Patent Office (EPO), the Japanese Patent Office (JPO), and the United States Patent and Trademark Office (USPTO) would be of considerable benefit.[661]

11.35 However, Howlett and Christie conclude from a study of the practices of the United States, European and Japanese Patent Offices that

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655 HUGO Ethics Committee, *Patenting of DNA Sequences* (1995), Human Genome Organisation, see <www.hugo-international.org>.

656 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, [5.38].

657 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), Intellectual Property Research Institute of Australia, Melbourne, 8.

658 There would be a 'reach-through' effect if a patent over an EST or partial gene sequence allowed the patent holder to claim rights to the full sequence even if the full sequence had been isolated by someone else and that person did not use the EST.

659 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), Intellectual Property Research Institute of Australia, Melbourne, 8.

660 Ibid, 8–9.

661 Ibid, 1.

> 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. Accordingly, it seems that the fear of numerous EST patents inhibiting later research is also unfounded.[662]

11.36 The patentability of ESTs is discussed in Chapter 9. The ALRC is interested to hear from researchers about whether patented ESTs are having any impact on their work.

Single nucleotide polymorphisms

11.37 In theory, the patenting of SNPs raises similar concerns to those about ESTs. SNPs are valuable in determining the genetics of a disease or in 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.

11.38 It is unclear whether there is a problem in relation to the patenting of SNPs and access for research in Australia. The ALRC is interested to hear from researchers as to the extent of any problem.

Question 11–2. Do any of the following affect biotechnology research into human health in Australia: (a) broad patents over isolated genetic materials; (b) patents over expressed sequence tags (ESTs) of unknown utility; (c) patents over single nucleotide polymorphisms (SNPs); or (d) a multiplicity of patents (sometimes known as 'patent thickets')?

Impact of licences

11.39 The need to obtain a licence in order to have access to a patented invention can affect research by increasing costs or inhibiting collaboration. The OECD Report expressed concern that previous informal exemptions to allow academic research to proceed without a licence were being jeopardised[663] and 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.[664]

662 Ibid, 39.

663 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 14–15.

664 Ibid, 14.

11.40 The OECD Report cited the DuPont Cre-lox gene-splicing tool as an example of concerns about increased research and transaction costs.[665] The 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. Although some public sector institutions agreed to the terms, the NIH objected and the issue was resolved with a memorandum of understanding in 1998 that simplified access for public sector researchers in the United States.[666]

11.41 The OECD Report linked research costs with increased transaction costs, suggesting that the need to negotiate access to tools and technologies may cause delays and impose administrative burdens, which might stifle research. It noted the development in the United States of 'simple, standard "materials transfer agreements" that could reduce paperwork and maximise the exchange of technologies'.[667]

11.42 The use of materials transfer agreements (MTAs) is a relatively new phenomenon in research. MTAs require researchers to sign agreements to obtain access to materials. A concern about MTAs is that they may include reach-through claims, which are discussed in Chapter 13.

Non-exclusive licensing for research

11.43 As discussed in Chapter 10, 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 innovator to a researcher who wishes to make use of the innovation, or to a party wishing to commercialise the innovation.

11.44 Licences can be granted for different purposes. Licences granted exclusively for research may entail fees well below those granted for commercial purposes, including therapeutic or diagnostic use. Widespread licensing at reasonable rates has the potential to encourage further research. Examples include Stanford University's Cohen-Boyer licensing of basic recombinant DNA technology[668] and Genentech licences of its Itakura/Riggs gene expression patents.

11.45 In Australia, Genetic Technologies Corporation Pty Ltd (GTG), which holds patents for non-coding DNA, is reported to have said that academic institutions could obtain a licence to use its technology purely for research at a 'token cost', but that

665 Ibid, 14.
666 Ibid, 14.
667 Ibid, 14.
668 During the life of the patent, this licence earned about $200 million for the universities that owned it: A Williamson, 'Gene Patents: Socially Acceptable Monopolies or an Unnecessary Hindrance to Research?' (2001) 17 *Trends in Genetics* 671.

universities providing commercial services, such as testing that utilised GTG's patents, would be required to negotiate a commercial licence.[669] GTG announced its first research licence to the University of Utah on 8 May 2003, noting that this licence did not grant commercial rights and that any commercial applications arising would need to be covered by a separate commercial licence.[670]

11.46 Non-exclusive licensing of research tools has the potential to overcome some of the problems identified by the OECD Report, provided the licence fees are set at reasonable levels.

Question 11–3. Is there any evidence that licences granted to researchers in relation to patents over genetic materials or technologies encourage or hinder research into human health? Is there any evidence that materials transfer agreements encourage or hinder research into human health?

Research use defence

11.47 A legislative 'research use' defence might overcome some of the problems discussed above, provided there was clarity about its breadth. A research use defence expressly exempts the use of patented inventions in research from liability for patent infringement. There is an argument that s 13 of the *Patents Act 1990* (Cth) contains an implied research use exemption but there has been no judicial consideration of the section.[671]

11.48 Even where legislation contains a research use defence, there may still be uncertainty about its scope. The OECD Report found that the definition of non-infringement for research was a source of commercial uncertainty, which needed to be clarified.[672] In the United States, the decision of the Court of Appeals for the Federal Circuit in *Madey v Duke University*[673] illustrated the very limited nature of the exemption for research use, at least in that country. The fact that Duke University was a private university whose research furthered the institution's business objectives was held to be sufficient to take it outside the exemption. The Court held that the research use defence 'is very narrow and strictly limited'.[674] Research use defences are discussed further in Chapter 14.

669 M Trudinger, 'GTG Sues "Major US Companies" for Patent Infringements', *Australian Biotechnology News*, 2 April 2003, <www.biotechnews.com.au>.

670 Genetic Technologies Limited, *GTG Grants License to University of Utah, Salt Lake City, USA*, <www.gtg.com.au/8may>, 3 June 2003.

671 See discussion in Ch 14.

672 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 59.

673 *Madey v Duke University* (2002) 307 F 3d 1351.

674 Ibid.

Secrecy

11.49 Scientific research and publication is built on a tradition of peer review and replication of studies. Commercialisation of research has the potential to alter this tradition. Since patent law depends on novelty, publication before a patent application has been filed may prevent a patent being granted (see Chapter 8). Accordingly, there are concerns that previously open research has become secret. The OECD Report suggested that

> there is some evidence in the biomedical sciences that research delays … are increasing, although it is unclear why this is occurring.[675]

11.50 It is not uncommon for scientists who perform research with private funding to sign secrecy agreements. A United States study published in 2003 found that 58% of 210 life science companies that sponsor research require delays of more than six months before publication.[676] Similarly, a 1997 American study of 2,167 university scientists revealed that nearly 20% had delayed publication for more than six months to protect proprietary information.[677]

11.51 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.[678] The Bill's sponsor cited the example of research 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.[679]

11.52 A contrary view to the argument that patents hinder publication is that they aid research because, without patent protection, many results would 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*.[680] This can be a valuable source of technical information for use in further research and development.

Grace periods

11.53 Grace periods are a mechanism for overcoming the impediment to research caused when information is withheld from peer review and discussion prior to the lodging of a patent application. A period of grace prevents invalidation by prior, even

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675 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 13.

676 E Press and J Washburn, *Secrecy and Science*, The Atlantic Online, <www.theatlantic.com/issues/2000/03/press2.htm>, 10 April 2003.

677 Ibid.

678 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.

679 United States, *Congressional Debates, House of Representatives*, 14 March 2002, E353 (L Rivers).

680 *Patents Act 1990* (Cth) s 49 (standard patents), s 62(2) (innovation patents).

inadvertent, disclosure and has the potential to minimise delays in scientific publication. As discussed in Chapter 8, grace periods are provided for in the patent laws of several countries, notably the United States, Canada, Japan and (since 1 April 2002) Australia. Australia amended the *Patents Act* to allow 12 months publication before the filing of an application, but the question remains whether the period of grace adequately meets the objection.

Question 11–4. Does the recent amendment to the *Patents Act 1990* (Cth), which permits a 12 month grace period before filing, encourage the publication of scientific results? Does the grace period overcome the problem of secrecy or delay in publication?

Research practice

11.54 A number of international initiatives have sought to overcome some of the concerns about lack of access to information about the human genome.

The Bermuda principles

11.55 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 at an International Strategy Meeting on Human Genome Sequencing[681] in 1996 and endorsed in Bermuda the following year. The Bermuda Principles state:

- primary genomic sequence should be in the public domain;
- primary genomic sequence should be rapidly released; and
- HUGO should be advised of large-scale sequencing of particular regions of the genome.[682]

681 Those taking part in the meeting included the Wellcome Trust, the UK 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 Human Genome Organisation (HUGO) and the Human Genome Project of Japan: Wellcome Trust, *Genome Data Release*, <www.wellcome.ac.uk/en/1/awtvispoldat.html>, 10 April 2003.

682 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>, 10 April 2003.

HUGO Statement on Genomic Databases

11.56 In December 2002, HUGO's Ethics Committee released a *Statement on Human Genomic Databases*, which declared there was a need to rapidly place primary genomic sequences in the public domain.[683]

United States guidelines

11.57 In the United States, the NIH has taken steps to help researchers gain access to information for research. The NIH has published principles and guidelines for recipients of NIH research grants and contracts to promote access to research tools.[684] The principles include the following.

- 'Ensure academic freedom and publication.' This principle states that 'recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish' and that '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.'[685] This principle states that 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'.

- '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 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.'[686]

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683 HUGO Ethics Committee, *Statement on Human Genomic Databases* (2002), see <www.hugo-international.org/hugo/>. The HUGO Statement is discussed in detail in Ch 16.

684 National Institutes of Health, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*, 64 FR 72090 (1999), Department of Health and Human Services, see <http://ott.od.nih.gov/>.

685 See the discussion in Ch 5.

686 National Institutes of Health, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*, 64 FR 72090 (1999), Department of Health and Human Services, see <http://ott.od.nih.gov/>.

Question 11–5. Is there any need for Australian guidelines similar to those published by the United States National Institutes of Health to ensure that research is not being withheld from the public domain?

Public databases

11.58 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 developed from products derived from such public genomic information. The Bermuda Principles were a statement of support from those involved in the public sequencing consortium for basic genetic sequencing information to be kept in the public domain and released rapidly.

11.59 Internationally, publicly available databases include the International Human Genome Sequencing Consortium; the Mammalian Gene Collection (MGC); the International Nucleotide Sequence Database Collaboration (a joint European, Japanese and European initiative); and the SNP Consortium. 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 UK.

11.60 GenBank is the NIH genetic sequence database providing access to all publicly available genetic sequences. It is a member of the International Nucleotide Sequence Database Collaboration. However, the database does not guarantee that all information it provides is free from patent, copyright or other intellectual property claims. Similarly, the NIH has a program to develop a library of clones of all human genes.[687]

11.61 The SNP Consortium Ltd was established in 1999 to produce a public resource of SNPs in the human genome. The aim was to avoid, as much as possible, the patenting of research tools and techniques that might affect further research. The SNP Consortium comprises a mix of academic institutions as well as biomedical, pharmaceutical and biotechnology companies together with the Wellcome Trust. The SNP Consortium has indicated 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.[688]

687 However, one writer has argued that the United States government and those who use some of the clones will be infringing patents: J Merz, *A Note from the Editor*, University of Pennsylvania Center for Bioethics, <www.med.upenn.edu/bioethic/newsletter/pdf/PennBioethicsNL_v10n3.pdf>, 10 April 2003.

688 SNP Consortium, *The SNP Consortium: Frequently Asked Questions*, TSC, <http://snp.cshl.org/about/faq.shtml>, 10 April 2003.

11.62 The OECD has suggested that collective actions such as the SNP Consortium are a means of overcoming transaction costs associated with the complex patent environment.[689]

Private databases

11.63 In addition to public genomic databases, private databases have 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: annotations have been added to the sequence information.

The Celera subscription

11.64 In June 2000, the National Health and Medical Research Council (NHMRC) entered into an agreement with the United States based company, Celera Genomics (Celera) to allow Australian researchers to access Celera's human genome database.[690] Under the arrangement, subscribers through the NHMRC have access to five of Celera's databases that integrate proprietary information with publicly available data. The databases include Celera's Human Genome Database, the Celera Human Gene Index and Celera's Human SNP Reference Database. The technology is available to researchers who are funded through Australian Research Council (ARC) funding together with other publicly funded bodies such as the Commonwealth Scientific and Industrial Research Organisation (CSIRO). Each participating institution pays an annual licence fee of approximately $6,000. This compares with private industry licence fees—reportedly up to $15 million, internationally.[691]

Question 11–6. Is publicly or privately funded research being impeded because of lack of access to data about human genetic material? If so, does the National Health and Medical Research Council's Celera subscription provide an appropriate model for seeking to increase Australian researchers' access to information about the human genome?

689 Organisation for Economic Co-operation and Development and Federal Ministry of Education and Research, *Short Summary of the Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), OECD, Paris, see <www.oecd.org>, 3.

690 The subscription also includes Celera's mouse and Drosophila databases.

691 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.

12. Gene Patents and Healthcare Provision

Contents

Introduction

12.1 Gene patents may have an impact on the development and provision of healthcare involving medical genetic testing and novel therapies, including gene therapy, the production of therapeutic proteins and the use of stem cells.

12.2 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.[692] The chapter 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.

12.3 There is a range of possible adverse consequences of existing patent laws and practices. These relate to monopoly control and the cost of testing, access to testing and related healthcare services, the quality of testing and medical practice, and

692 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.

innovation in the development of new or improved testing techniques. The chapter asks a number of questions about the impact of gene patents on various aspects of healthcare provision and presents options for reform.

Medical genetic testing

12.4 The following 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

12.5 Medical genetic tests are generally ordered by medical practitioners. Some genetic testing may involve referral of the patient to a clinical geneticist and 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.

12.6 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[693] and individuals must be referred by a medical practitioner. However, the range of genetic testing available to the public is likely to expand in the future.[694]

12.7 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.[695] 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.

12.8 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

693 81% of laboratories offering diagnosis of genetic disorders listed on the HGSA's website in November 2002 were located in public hospitals: D Nicol, *The Impact of Patents on the Delivery of Genetic Tests in Australia* (2003), Unpublished Manuscript.

694 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, [11.50]–[11.63].

695 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html>, 19 February 2003. Not all tests are available from all laboratories. The register does not include newborn screening laboratories.

and accreditation, and regulation of testing provided direct to the public (rather than through a medical practitioner).[696]

12.9 The availability of genetic testing in Australia may be dependent on decisions about which tests are ethically acceptable,[697] 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[698] may soon make it technically possible and financially practicable to test for numerous genetic mutations simultaneously in a single procedure.

12.10 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 DNA diagnostic service for that disease.

Cost of medical genetic testing

12.11 As with other health services, access to medical genetic testing may depend on the cost to consumers of testing procedures and on the rebates provided by public and private health insurers.

12.12 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.[699]

12.13 Depending on the test and the laboratory, testing may be free to the patient or fees may be charged.[700] 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 7).

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696 In ALRC 96, the ALRC and the Australian Health Ethics Committee 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), ALRC, Sydney, see <www.alrc.gov.au>, rec 11–1, 11–5, 23–3.

697 For example, predictive testing of minors for late onset disorders (such as Huntington's disease) may be considered unethical.

698 Also known as 'gene chips', 'biochips' and 'DNA microarrays'.

699 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, [10.20]–[10.21].

700 See D Nicol, *The Impact of Patents on the Delivery of Genetic Tests in Australia* (2003), Unpublished Manuscript, Table 4.

Patents and medical genetic testing

12.14 Patents may be granted in Australia over isolated genetic material which has been separated from the human body and manufactured synthetically, provided the patent application satisfies the threshold tests for patentability.[701] 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.

12.15 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, 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[702] and products and processes involved in its breast cancer predisposition test, which is called 'BRACAnalysis'.

12.16 A patent that asserts rights to isolated genetic material may also 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 ovarian cancer.[703] In other words, any technique for BRCA1 testing is likely to require use of Myriad's patents.

12.17 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 amounts for testing, were granted to Cetus Corporation in 1989, and assigned in 1991 to Roche Diagnostics.[704]

12.18 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

701 See Ch 9.

702 See M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20, 21–23.

703 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 33.

704 A division of F Hoffmann-La Roche Ltd: Roche Diagnostics, *Roche Molecular Diagnostics Patents Portfolio*, Roche Diagnostics, <www.roche-diagnostics.com>, 11 June 2003.

> 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.[705]

12.19 There are about 220 medical genetic tests available in Australia.[706] Many of these medical genetic tests, and particularly common ones, are likely to be subject to patents on isolated genetic materials.[707]

12.20 Recent research conducted in the United States confirms that 12 common genetic tests are subject to United States patents.[708] Research conducted by the Centre for Law and Genetics confirms that most of these United States patents have equivalent Australian registered patents or patent applications.[709]

12.21 The ALRC understands that these patents generally include claims over isolated genetic materials containing sequences that code for proteins. However, patents over so called 'junk' or non-coding genetic sequences are also relevant to medical genetic testing. The use of non-coding genetic sequences is integral to medical genetic testing because they are a source of genetic markers.

Enforcement of patent rights

12.22 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.[710] Myriad has sought to enforce its patent rights against Canadian

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705 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 48.

706 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html>, 19 February 2003.

707 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 gene patent applications filed with the Australian Patent Office: D Nicol, *The Impact of Patents on the Delivery of Genetic Tests in Australia* (2003), Unpublished Manuscript.

708 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 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.

709 D Nicol, *The Impact of Patents on the Delivery of Genetic Tests in Australia* (2003), Unpublished Manuscript.

710 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.

provincial government health authorities.[711] Myriad's patents are being opposed in Europe[712] and have led to calls for patent law reform in France and Canada.[713]

12.23 In the United States, research indicates that gene patent holders are actively enforcing their rights against laboratories.[714] 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.[715] 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.[716]

12.24 In contrast, a recent survey of Australian laboratories that perform medical genetic testing found 'little or no indication to date that holders of patents related to disease genes are actively enforcing their patents against Australian genetic test laboratories'.[717]

12.25 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 Corporation Pty Ltd (GTG).[718] GTG has stated publicly that the rights it has obtained from Myriad for breast cancer susceptibility testing will not be enforced against other service providers in Australia and New Zealand.[719]

12.26 However, in March 2003, GTG advised public sector laboratories in Australia and New Zealand that they would need to negotiate licences in relation to its gene patents on non-coding DNA polymorphisms.[720] GTG has claimed that these 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).

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711 As of mid-2002, all but one Canadian province had decided to continue to provide genetic testing that may infringe on patents granted to Myriad: E Gold, 'Gene Patents and Medical Access' (2000) 49 *Intellectual Property Forum* 20, 23.

712 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), Institut Curie, Paris.

713 See E Gold, 'Gene Patents and Medical Access' (2000) 49 *Intellectual Property Forum* 20, 23.

714 M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

715 Ibid, 5.

716 Ibid, 5.

717 D Nicol, *The Impact of Patents on the Delivery of Genetic Tests in Australia* (2003), Unpublished Manuscript.

718 Genetic Technologies Limited, *Genetic Technologies and Myriad Genetics Announce Strategic Licensing Agreement*, Genetic Technologies Limited, <www.gtg.com.au/Announcements2002.html#28oct>, 28 May 2003.

719 Genetic Technologies Limited, *Genetic Susceptibility Testing — A Third Progress Report*, Genetic Technologies Limited, <www.gtg.com.au/Announcements.html#22may>, 28 May 2003. See Ch 10 for a discussion of the effect of such a declaration in creating an estoppel.

720 See also Genetic Technologies Limited, *Licensing the 'Non-Coding' Patents — A Third Report to the ASX*, Genetic Technologies Limited, <www.gtg.com.au/Announcements.html#2apr.>, 28 May 2003.

Impact of gene patents on medical genetic testing

12.27 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 Working Group on Human Gene Patents (AHMAC Working Group).

12.28 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 and research.[721] Similar concerns have been expressed in position statements on gene patents prepared by the HGSA and the Royal College of Pathologists of Australasia (RCPA).[722]

12.29 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.

Monopoly control and competition

12.30 Many concerns about the impact of patent laws and practices on medical genetic testing are traceable to concerns about monopoly control of genetic testing. 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.

721 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 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.

722 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>; Royal College of Pathologists of Australia, *Position Statement: Patenting of Human Genes* (2001), RCPA, see <www.rcpa.edu.au/docs/nonMembers/home/home.cfm>.

12.31 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 described as including the following.

- 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 more 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.[723]

12.32 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. These new strategies and business models threaten the optimal provision of genetic health care and the integrated clinical service structures through which they are currently provided.[724]

Question 12–1. Do existing patent laws and practices favour the development of genetic testing monopolies in Australia? If so, are reforms needed and what should they be?

Cost of medical genetic testing

12.33 If access to medical genetic testing is restricted by patent laws and practices, the implications for healthcare can be serious. People may die if they are not diagnosed for serious but preventable genetic diseases, such as some breast, ovarian or colon

723 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'.

724 P Dawkins and others, *Human Gene Patents: The Possible Impacts on Genetic Services Health Care* (2003), Unpublished Manuscript.

cancers. Children may be born with incurable inherited diseases.[725] 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.

12.34 The cost of medical genetic testing is clearly 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. In particular, concerns have been expressed about exclusive licensing of gene patents relating to genetic testing.[726]

12.35 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 terms of the licence 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 is common, particularly for medical genetic testing.[727]

12.36 In 2001, the AHMAC Working Group estimated that, if testing for the BRCA1 gene in Australia were to be performed by Myriad rather than by 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.[728] This estimate assumed that the cost of each test would rise from A$1200–2000 to US$2400, if performed by Myriad.[729] The AHMAC Working Group concluded that, if BRCA1 testing in Australia were to be subject to an exclusive licensing arrangement, significant increases in health system funding would be required to maintain the existing level of service.[730]

12.37 In 2001, the Canadian province of British Columbia discontinued paying for genetic breast cancer testing because the health care system could not afford the fees charged by Myriad.[731] However, the province has subsequently resumed testing.[732]

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725 For example, in relation to US 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. See also Ch 4.

726 See the discussion of patent licensing in Ch 10.

727 J Merz and others, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577, 578.

728 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 11.

729 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 €2744 compared with an estimated cost of €914 for testing in other laboratories, and that testing French patients through Myriad could generate 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), Institut Curie, Paris, 6.

730 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 19.

731 L Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 91.

732 British Columbia Ministry of Health Services, 'Federal Leadership Urged as Genetic Testing Resumes', *Press Release*, 14 February 2003.

12.38 Concerns about the cost to patients and to public health systems have been an important element of broader concerns about the possible adverse impact of monopoly control of genetic testing. One American commentator has stated:

> It seems evident that monopoly rents, or excess profits attributable to the patent, will be extracted from those able to pay, to the detriment of those patients effectively priced out of testing by the monopolist.[733]

12.39 In Australia, the HGSA has stated that patent holders should not issue exclusive licences for genetic tests because a monopoly

> is likely to reduce access to genetic testing because of higher cost—government will be less able to fund testing and, if this occurs, access to clinically indicated genetic tests will be determined, for many people, by capacity to pay…[734]

12.40 Similarly, the RCPA has stated that the consequences of gene patents are likely to include: reduced patient access to testing, increased costs of testing and division between those who can afford tests and those who cannot.[735] In practice, gene patents and exclusive licensing of genetic testing do not appear to have had a significant impact on healthcare costs in Australia, but this may change in future.

Access to testing and related healthcare services

12.41 Leaving aside issues of cost, concerns have also been expressed about the implications of patent laws and practices for access to testing and related healthcare services, such as clinical advice and genetic counselling.

12.42 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.

12.43 The AHMAC Working Group noted 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.[736] This may have consequences in relation to access to pre- and post-test genetic counselling. Concerns

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733 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 326.

734 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>; Royal College of Pathologists of Australia, *Position Statement: Patenting of Human Genes* (2001), RCPA, see <www.rcpa.edu.au/docs/nonMembers/home/home.cfm>.

735 Royal College of Pathologists of Australia, *Position Statement: Patenting of Human Genes* (2001), RCPA, see <www.rcpa.edu.au/docs/nonMembers/home/home.cfm>.

736 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 11.

have been expressed that 'commercial testing might disassociate genetic testing from proper screening and genetic counselling'.[737]

12.44 It has also been suggested 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. The AHMAC Working Group stated:

> 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.[738]

12.45 The HGSA has 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 molecular genetics expertise.[739] 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.[740]

Question 12–2. What are the implications of current patent laws and practices for the cost and public funding of, and equitable access to, medical genetic testing and to related healthcare services such as genetic counselling?

Quality of testing and medical practice

12.46 Concerns have been raised about the possible impact of patent laws and practices on the quality of genetic testing and associated medical practice:

> Disease gene patents have spawned a new phenomenon in clinical laboratory medicine: monopolization of testing services. Such monopoly is at fundamental odds with good medical practice, and patents should not be used to limit the practice of medicine in any way.[741]

12.47 It has been suggested that testing monopolies may adversely affect the technical quality of testing. For example, 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

737 See M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20, 26.

738 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 6.

739 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>, 4.

740 Ibid, 4.

741 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 329.

to detect 10–20% of all expected mutations in the BRCA1 gene (which were detected by an alternative testing technique).[742] 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 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.[743]

12.48 More generally, the HGSA has stated that testing monopolies 'militate against independent assessment of quality assurance'.[744] 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.[745] Such programs may be difficult to establish where only one or a small number of laboratories perform genetic testing.

12.49 Leaving aside issues relating to quality assurance, there is a concern that patent laws or practices may prevent the use of more appropriate tests for the same genetic condition and thereby prejudice medical practice. It has been stated that:

> disease 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 (eg, sequencing instead of less sensitive but substantially less costly methods … or limiting the conditions for which testing may be done (such as refusing to perform pre-natal testing for late-onset disease).[746]

12.50 The AHMAC Working Group has 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'.[747]

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742 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), Institut Curie, Paris, 5.

743 See B Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, <http://genethics.ca/personal/History%20of%20a%20Gene%20Patent.pdf>, 17 April 2003, 23.

744 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>.

745 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), Therapeutic Goods Administration, Canberra, 42.

746 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 327.

747 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 19–20.

12.51 It has been claimed that monopoly control of genetic testing may have adverse effects on medical practice by changing the interface between medical practitioners and laboratory scientists. 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 whose expertise covers both areas and, by doing so, reduce the quality of medical services.[748]

12.52 Communication and information transfer between practitioners and scientists is said to develop mutual expertise, particularly in interpreting scientific information[749] and is important in providing best practice medical care.[750] The interpretation of results may 'suffer from lack of discussion regarding abnormalities in testing the accuracy of the test results'.[751] On the other hand, there may be no reason why good communication cannot be developed between medical practitioners and laboratories operating under an exclusive licence to use a particular genetic testing technology.

12.53 Where there are existing patents that contain claims to all conceivable diagnostic tests related to a particular gene, there may be less incentive to develop new or improved tests.[752] Medical genetic testing is routinely subject to incremental improvement as more is learned about the genetics of a disease.[753] Concerns have been expressed that gene patents may hinder innovation in medical genetic testing at the clinical and laboratory level.[754]

12.54 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 associated with disease. Medical practitioners with access to family pedigrees discover many such mutations over time. It has been suggested that 'limiting the number of laboratories permitted to do the testing could slow this incremental process of discovery'.[755]

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748 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>.

749 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 19.

750 For example, clinicans 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: Ibid, 19.

751 Ibid, 20.

752 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 4.

753 R Eisenberg, 'Why the Gene Patenting Controversy Persists' (2002) 77(12) *Academic Medicine* 1382, 1382–1383.

754 The ways in which gene patents may restrict the conduct of research more generally are discussed further in Ch 11.

755 R Eisenberg, 'Why the Gene Patenting Controversy Persists' (2002) 77(12) *Academic Medicine* 1382, 1383.

12.55 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.[756]

Question 12–3. Is medical practice 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? If so, in what ways, and with what possible consequences?

Commercialisation of medical genetic testing

12.56 A related concern is that the commercialisation of genetic testing, which is facilitated by gene patents, may encourage the inappropriate marketing and supply of genetic testing services and products.

12.57 The Ontario government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, stated that, without appropriate safeguards, there is some risk that

> the commercial considerations of genetic patenting could also result in genetic tests being offered commercially too early, before the results of testing can be properly interpreted, evaluated and used.[757]

12.58 In Australia, concerns have also been expressed about attempts to 'create markets' for genetic tests of doubtful clinical utility,[758] and in particular about the provision of medical genetic testing direct to the public, rather than through medical practitioners.[759]

12.59 Regulation of the quality, availability and advertising of genetic test products and services was discussed in ALRC 96.[760] The report recommended, among other things, that the *Therapeutic Goods Act 1989* (Cth) be amended to enable the

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756 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.

757 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, 44.

758 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>.

759 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, Ch 11; Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>.

760 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney, see <www.alrc.gov.au>, Ch 11.

Therapeutic Goods Administration to regulate more effectively medical devices used in genetic testing provided directly to the public.[761]

Question 12–4. What potential do patent laws and practices have to encourage the inappropriate marketing and supply of genetic testing services and products?

The need for patents on medical genetic testing

12.60 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.

12.61 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.

Patents as an incentive to genetic test development

12.62 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 Nuffield Council on Bioethics (Nuffield Council) has stated that an incentive, in the form of the patents, may be required for the development of some medical genetic tests.[762]

12.63 However, 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. 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:[763]

> 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

761 Ibid, rec 11–5, 11–7.

762 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 51.

763 L Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 77–79.

> cases, a disease gene has been identified one day and testing begun almost immediately.[764]

12.64 Andrews 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'.[765]

12.65 A recent study of clinical laboratories in the United States found that laboratories are quickly able to translate published data into clinical tests, without the incentive provided by patents.[766] 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.[767]

12.66 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.[768]

12.67 One laboratory director in the United States has noted:

> We do not check whether a patent has been filed before deciding to develop a diagnostic test based on the published literature, nor do we have the negotiating skills or financial resources for cross-licensing of the patented information required for the diagnostic test.[769]

12.68 He stated that such laboratory-developed testing should be able to continue freely because 'diagnostic tests can be introduced in individual laboratories more quickly than commercial test kits can be developed and brought to market'.[770] However, commercial companies, relying on the same published medical or scientific literature, may

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764 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.

765 L Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 78–79.

766 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.

767 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.

768 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 325.

769 D Leonard, 'Medical Practice and Gene Patents: A Personal Perspective' (2002) 77 *Academic Medicine* 1388, 1389.

770 Ibid, 1389.

> identify patents needed for specific diagnostic tests before the patent even issues and negotiate an exclusive license for diagnostic testing based on that patent. Once the patent issues, the laboratories that have developed the medical need and use for the test and are already performing it are prevented from continuing to perform the test.[771]

Question 12–5. Are gene patents necessary to encourage investment in research that leads to the development of new, clinically useful, medical genetic tests?

Impact on other healthcare provision

12.69 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.

12.70 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 evidence from research to show that they have made experimental progress towards realising this theoretically obvious possibility.[772]

12.71 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.[773]

12.72 Gene patents may also relevant to the use of stem cells in medical treatment. By 2002, there had been over 2000 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.[774]

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771 Ibid, 1389.

772 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 61. See the discussion of 'usefulness' in Ch 9.

773 Ibid, 63.

774 European Group on Ethics in Science and New Technologies to the European Commission, *Opinion on the Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (2002), European Commission, see <http://europa.eu.int/comm/european_group_ethics/docs/avis16_en_complet.pdf>, 10.

12.73 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.[775]

Question 12–6. 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?

Reform options

12.74 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.

12.75 As discussed in Chapter 9, these changes could include legislative reform relating to the patentability of genetic materials and technologies. Patent law could be amended in other ways to address concerns about the impact on healthcare provision—for example by enacting new defences to infringement actions or new compulsory licensing provisions (see Chapters 14 and 15).

12.76 The options for reform include changes to government funding policies and administrative or regulatory measures, which would not necessarily require amendment to patent laws. Some of these options are discussed below.

Control through government funding and purchasing power

12.77 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. Government decisions about healthcare funding can indirectly influence patent holders' decisions about licensing and the level of licence fees.

12.78 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

775 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, 39.

national funding program that is limited to tests of proven clinical utility and cost effectiveness', with the price to be negotiated by government.[776]

12.79 The AHMAC Working Group recommended 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 budgets.[777] 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'.[778]

12.80 The Pharmaceutical Benefits Scheme (PBS) has been cited as an example of how government purchasing power may assist in controlling the cost of healthcare.[779] There is some evidence that the PBS allows relatively low prices for drugs to be maintained through the government being the single buyer in a market with a number of pharmaceutical sellers.[780] 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.[781]

Question 12–7. Should government funding and purchasing power be used to control the cost of medical genetic testing that is subject to gene patents? If so, how might this best be achieved?

Regulating medical genetic testing

12.81 In relation to the impact of gene patents on medical genetic testing, one view is that the problem does not lie in the patenting of genetic material, but in the way in which such patents are commercially exploited.

776 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), HGSA, see <www.hgsa.com.au/policy/patgen.html>.

777 Australian Health Minister's Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), AHMAC, 27, rec 7.

778 P Dawkins and others, *Human Gene Patents: The Possible Impacts on Genetic Services Health Care* (2003), Unpublished Manuscript.

779 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), Australian Institute of Health and Welfare, Canberra, 255.

780 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>, 6 April 2003; Productivity Commission, *International Pharmaceutical Price Differences: Research Report* (2001), Productivity Commission, Canberra, see <www.pc.gov.au>.

781 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), Commonwealth of Australia, Canberra, see <www.pc.gov.au>, [3.12].

12.82 Therefore, solutions may lie in the regulation of medical genetic testing services directly, rather than in changes to patent laws. For example, an expert body could be given the role of approving the supply of medical genetic testing services to the public, subject to appropriate conditions. Where medical genetic testing is subject to gene patents, these might include conditions relating to licensing arrangements, for example, that there be a minimum number of service providers.

Question 12–8. Should there be new regulation of medical genetic testing to address concerns about the possible adverse consequences of patent laws and practices on healthcare provision? If so, how might this best be achieved?

Patent pooling

12.83 One problem identified by an expert workshop convened by the Organisation for Economic Co-operation and Development is that it can be difficult for laboratories to obtain licences related to genetic tests, even where the patent holders may be willing to grant them.[782] This is especially the case where there are several mutations associated with the same disease, subject to patents held by multiple patent holders.[783]

12.84 The Nuffield Council has identified a particular problem with gene patents relating to DNA microarrays, which allow simultaneous analysis of thousands of genetic sequences.

> As things stand, the application of these technologies could be obstructed by the grant of many patents claiming human DNA sequences, many of which will overlap, or relate to different mutations of the same genes. With the grant of such patents, the negotiation of licensing to allow simultaneous testing for more than one disorder is likely to be complex, uncertain and expensive.[784]

12.85 Approaches to patent practices could focus on making it easier for laboratories to obtain licences to perform medical genetic testing, including through patent pooling. As discussed in Chapter 17, patent pools are agreements between several patent owners to license or assign their collective patents at a single price. The creation of patent pools or clearinghouses might make it easier for laboratories to obtain licences for patented genetic inventions and reduce transaction costs.

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782 Organisation for Economic Co-operation and Development and Federal Ministry of Education and Research, *Short Summary of the Workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices* (2002), OECD, Paris, see <www.oecd.org>, 4. The summary report of the workshop stated that 'Clinical laboratories often fall shy of concluding licensing agreements with the holders of such patents, though the defining reasons remain to be clarified'.

783 For example, the US patents to tests for spinocerebellar ataxia (SCA1, SCA2, SCA3, SCA6) are held by four different patent holders. See 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, Table 2.

784 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 53.

Question 12–9. Should patent pools or clearinghouses be created to make it easier for laboratories to obtain licences for patented genetic inventions? If so, how might this best be achieved?

13. Patents and the Biotechnology Sector

Contents

Introduction

13.1 The Terms of Reference require the ALRC to consider the impact of current patent laws and practices related to genes and genetic and related technologies on the application and commercialisation of research and on the biotechnology industry.

13.2 Chapter 6 described the structure and features of the biotechnology industry in Australia. As noted in that chapter, the biotechnology sector (including pharmaceuticals) is heavily dependent on patents; and for some firms, intellectual property is their only or main asset.

13.3 Chapter 11 considered the impact of patent laws and practices on research generally. This chapter considers their impact on the commercialisation of research. Many of the issues discussed in Chapter 11, such as patents over research tools and broad patents, could present problems for commercialisation. Indeed, while pure academic research may be able to proceed in the absence of a licence, the same is unlikely to be true for commercial research. While there are many reports and considerable academic writing about the problems that some gene patents could pose for research, it is more difficult to find information about actual problems being experienced by industry. The ALRC is interested to hear from the sector in relation to any difficulties being encountered.

Impediments to commercialisation

13.4 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'.[785]

13.5 Dr Dianne Nicol and Jane Nielsen suggest 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.[786]

13.6 Nicol and Nielsen argue that 'the regimes protecting IPRs [intellectual property rights] may prove to be a significant barrier for the development of the Australian industry'.[787] They note 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.[788]

13.7 As has been discussed elsewhere in this Issues 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.

13.8 However, as discussed in Chapter 11, patents can 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 suggest that biotechnology companies 'face unique challenges'. They cite 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.[789]

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785 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report 2001* (2001), Ernst & Young, Canberra, see <www.ey.com/>, 49. The others were access to capital, the availability of skilled human resources, and the relatively small size of the domestic market.

786 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.

787 Ibid, 348.

788 Ibid, 348–349.

789 Ibid, 374.

13.9 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.

13.10 The following discussion addresses the issues raised by the OECD Report together with other issues that have the potential to impede the commercialisation of research in the area of human genetics. The discussion also notes mechanisms that might assist to overcome these barriers.

Patent thickets

13.11 'Patent thickets' are a consequence of multiple upstream patents.[790] 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.[791]

13.12 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.[792] The issue is not confined to gene patents and is an issue across a number of fields. 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.

13.13 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.[793] 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.

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790 Such as patents over isolated genetic materials that might be used to develop further inventions such as diagnostic tests or pharmaceutical products (downstream products).

791 C Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting* (2001), University of California at Berkeley, see <http://faculty.haas.berkeley.edu/shapiro/thicket.pdf>.

792 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 698. See also Ch 4.

793 The majority of introns serve no currently identifiable function.

Royalty stacking

13.14 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.

13.15 The OECD Report linked concerns about patents over research tools[794] 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. The OECD Report suggested that royalties could comprise up to 20% of the net price of some products and gave the example of the development of a pharmaceutical drug that might require 'licences to access genomics technologies, targets such as receptors, assays and high-throughput technologies'.[795]

13.16 Patent pools[796] are a mechanism for overcoming some of the difficulties of access to research tools and technologies caused by a multiplicity of patents.[797] Commercial products such as therapeutic proteins or genetic diagnostic 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.

13.17 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.[798]

13.18 Patent pools may also raise competition issues, which are discussed in Chapter 17.

Reach-through claims

13.19 Reach-through claims are claims by patent holders to future intellectual property in new products that might follow the use of a patented invention. Chapter 11 discussed the problem of reach-through claims for research and cited the case of the DuPont Cre-lox gene-splicing tool and the claim by DuPont for the commercial rights to future inventions that might arise from the use of the invention.

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794 See Ch 11 for more detail.

795 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 15.

796 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.

797 See United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000), United States Patents and Trademarks Office, Washington, see <www.uspto.gov>.

798 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700.

13.20 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.[799]

13.21 The ALRC is uncertain of the extent of this problem in the Australian biotechnology sector and is interested in hearing from the sector about the impact of reach-through claims on commercialisation.

Dependency and uncertainty

13.22 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'[800] leading to uncertainty about which patent holder would be able to prevent the others from using the invention. The OECD 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.[801]

13.23 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.[802]

13.24 However, the OECD Report also indicated difficulties in assessing whether this was really an issue for industry. The ALRC is interested in hearing from the biotechnology sector on this issue in Australia (see Question 13–2).

13.25 Compulsory licences can be a solution to the problem of dependent patents. Chapter 15 discusses the provisions in the *Patents Act 1990* (Cth) for compulsory licences over dependent patents.

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799 HUGO Ethics Committee, *Statement on Patenting of DNA Sequences* (2000), Human Genome Organisation, see <www.hugo-international.org/>.

800 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 16.

801 Ibid, 16.

802 Ibid, 45.

Blocking patents

13.26 Blocking patents are patents used to stifle developments by others. Nicol and Nielsen note that

> 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 health care sector as a whole.[803]

13.27 It is difficult to determine whether blocking patents are an issue for the Australian biotechnology sector and the ALRC is interested in determining if they present a problem for the sector (see Question 13–2).

Licensing

13.28 Licensing is the means by which technology is transferred.[804] 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
- those where technology is transferred from a patent holder to allow further research or the development of a new product or the exploitation of a product (licence-out).

13.29 The development of a product may require cross-licences, and the need for cross-licences may encourage alliances and mergers.

13.30 The need to licence-in 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 high prices to be charged or because they restrict access to needed genetic materials or research tools. This is addressed in Chapter 17.

13.31 Chapter 6 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. The ALRC is interested in information that would assist in assessing the extent of this problem (see Question 13–1).

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803 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.

804 Chapter 10 discusses licences generally and Ch 12 discusses the role of licences in health care, particularly in relation to genetic tests.

Lack of commercial 'know-how' in the public sector

13.32 As discussed in Chapter 5, it is government policy for public sector institutions to work with industry to commercialise the products of their research. This is based on the belief that patenting by public sector institutions and licensing of technologies to the private sector will increase the rate of commercial application of knowledge. Examples of this policy are the development of Cooperative Research Centres (CRCs) and other linkage programs between the public and private sector; the growth in universities and other public sector institutions having their own private companies to exploit their research and the increase in the number of public institutions holding patents.

13.33 However, a potential impediment to effective commercialisation of the research occurring in the public sector is lack of experience in commercialisation. The National Health and Medical Council (NHMRC), the Australian Research Council (ARC) and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) carried out a study in 2000 into the performance of Australian public research institutions in commercialising their research. The study suggested that Australia performed better than Canada but worse than the United States in commercialising its research, measured in terms of income generated from licences relative to dollars invested in research.[805]

13.34 The study suggested that unless there was appropriate support for individual researchers, they could be disadvantaged because of:

- A lack of expertise in IP [intellectual property] management …;
- A lack of financial means to meet patents while searching for a commercial partner … the need to move to a full patent after 12 months and the need to file internationally can involve very large costs …;
- A lack of commercial and legal expertise to negotiate deals involving IP …; and
- A lack of time, information networks and travel funds to locate commercial partners.[806]

13.35 The study also expressed concern about a shortage of 'industry receptors' for Australian research, suggesting that much of the commercialisation of Australian research would go overseas.[807]

805 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), Commonwealth of Australia, Canberra.
806 Ibid, 21.
807 Ibid, 18.

Question 13–1. What effects do Australia's patent laws and licensing practices have on the development of Australia's biotechnology industry as it relates to human health?

Question 13–2. Is there 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?

Part E

New Defences, Crown Use and Compulsory Licensing

14. New Defences

Contents

Introduction

14.1 This chapter discusses potential changes to the *Patents Act 1990* (Cth) (*Patents Act*) to enact new defences to claims of infringement of gene patents where such patents are used for research, privately and without any commercial purpose, or for medical treatment.

14.2 The ALRC is interested in comments on whether these or other new defences warrant further consideration in view of the problems that patent laws and practices may present for the use of genetic materials and technologies in research and healthcare provision.

Defence for research use

14.3 Gene patents have been criticised on the basis that they may impede biotechnology research if patent holders fail to exploit inventions or adopt restrictive licensing practices.

14.4 The Director of the United States National Human Genome Research Institute, Dr Francis Collins, recently indicated that the sequencing of the human genome only lays a foundation of scientific knowledge in the genomic arena and much research and work still needs to be done to convert this information into practical applications.[808] The ability to undertake further research in relation to genetic materials

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

and technologies is necessary for the development of improved healthcare, including diagnostic genetic tests and therapies.[809]

14.5 The Nuffield Council on Bioethics (Nuffield Council) has expressed particular concerns about the grant of gene patents over inventions that constitute 'research tools', namely those involving genetic sequences that have no immediate therapeutic or diagnostic value, but which may be useful (even essential) in conducting genetic research.[810] In considering the scope of the existing research use defence in the United Kingdom and in other jurisdictions, the Nuffield Council 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.[811]

14.6 In addition, the Nuffield Council indicated that the use of genetic sequences should be exempt from claims of patent infringement when there is no obvious prospect of commercial development arising from such use.[812]

Research use defence under Australian law

14.7 The *Patents Act* does not expressly exempt research use of patented inventions from liability for infringement.[813] However, it has been suggested that an implied research use exemption exists in Australian law. This view is based on the nature of the patent rights granted by s 13 of the *Patents Act*, and a restrictive reading of the term 'exploit', which would limit the exclusivity granted by a patent to exploitation through commercial activities.

14.8 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 a patented process. Arguably, all of these activities are commercial in nature. Activities that are not commercial—including those undertaken for scientific or research purposes if the results of such research will not be commercialised—may not amount to exploitation of a patent and may, therefore, be exempt from claims of infringement.

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809 P Dawkins and others, *Human Gene Patents: The Possible Impacts on Genetic Services Health Care* (2003), Unpublished Manuscript.

810 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 47, 56–57. Various definitions of 'research tools' have been proposed. See the discussion in Ch 11.

811 Ibid, 61. See discussion of the research use defence in the United Kingdom and other jurisdictions below.

812 Ibid.

813 Nor was such a defence available under the *Patents Act 1952* (Cth).

14.9 This interpretation of the scope of patent holders' rights was articulated by Jessel MR in *Frearson v Loe*:

> 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.[814]

14.10 In *New York University v Nissin Molecular Biology Institute Inc*,[815] a delegate of the Commissioner of Patents relied upon *Frearson v Loe* in interpreting the words 'experimental purposes' in r 3.25(4) of the *Patents Regulations 1991* (Cth). This provision addresses the uses that a third party may make of a sample of a micro-organism deposited with a prescribed depository institution under the Budapest Treaty;[816] it does not provide a defence to a claim of infringement. The Commissioner's delegate indicated that the term 'experimental purposes' should be construed analogously to those experimental uses that do not give rise to infringement of a patent, thus suggesting that a research use defence has been accepted under Australian law.[817]

14.11 There has been no judicial consideration of this issue in Australia.[818] Nonetheless, the ALRC understands that Australian academic researchers often assume that their use of patented inventions is immune from claims of patent infringement.[819]

Research use defence in other jurisdictions

14.12 In some other jurisdictions, a research (or 'experimental') use defence exists either by virtue of an express statutory provision or by case law. The precise scope of the defence varies. The *Patents Act 1977* (UK) provides an example of the way in which a legislative research use defence may be framed:

> 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;[820]

814 *Frearson v Loe* (1876) 9 Ch D 48, 66–67.
815 *New York University v Nissin Molecular Biology Institute inc* (1994) 29 IPR 173.
816 *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). See Ch 8.
817 *New York University v Nissin Molecular Biology Institute inc* (1994) 29 IPR 173, 177–178.
818 To the extent that there has been any consideration of experimental use of a patent, the cases relate to patent validity rather than a defence to claims of patent infringement and they focus on the element of patentability set out in s 18(1)(d), namely 'secret use'. See, for example, *Longworth v Emerton* (1951) 83 CLR 539; *Re Application of Lake* (1992) 24 IPR 281.
819 See C Dennis, 'Geneticists Question Fees for Use of Patented 'Junk' DNA' (2003) 423 *Nature* 105.
820 *Patents Act 1977* (UK) s 60(5).

14.13 In the United States, the experimental use defence is based on common law and is limited to actions involving a patented invention that are performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry'.[821] The defence will not apply if a patented invention is used in experiments 'in the guise of scientific inquiry' which have 'definite, cognizable, and not insubstantial commercial purposes'.[822]

14.14 Amendments to the experimental use defence in the United States to address issues raised by patents claiming rights over genetic sequences were proposed as part of the Genomic Research and Diagnostic Accessibility Bill, which has now lapsed.[823] The amendments sought to add a new statutory defence to the United States patents legislation covering the use of 'genetic sequence information' for the purposes of 'research' to ensure that scientists may use patented tools, techniques and materials in performing basic research.[824]

Issues in the application of a research use defence

Scope of the research use defence

14.15 A key issue in the application of a research use defence is the need to distinguish between 'pure' or 'basic' research and research that may have (or be intended to have) some commercial application.[825] Difficulty arises because it may not be clear when research with potential application to the development of a new product or method of treatment ceases to be 'basic' in nature, and becomes directed to commercial purposes.

14.16 A further issue to be addressed is the distinction between research *on* a patented invention (which is exempt from claims of patent infringement) and research *involving* the use of a patented invention (which is not exempt).[826] This distinction, which is drawn by most jurisdictions that recognise a research use defence, may be significant in relation to patented genetic materials and technologies. For example,

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821 *Embrex Inc v Service Engineering Corp* (2000) 216 F 3d 1343, 1349. See also *Roche Products Inc v Bolar Pharmaceutical Co* (1984) 733 F2d 858, 863.

822 *Roche Products Inc v Bolar Pharmaceutical Co* (1984) 733 F2d 858, 863. See also *Embrex Inc v Service Engineering Corp* (2000) 216 F 3d 1343, 1353.

823 The Bill was referred to the House Subcommittee on the Courts, the Internet, and Intellectual Property on 5 May 2002, but it lapsed at the end of the 107th Congress.

824 The Bill proposed that 'genetic sequence information' be defined as 'any ordered listing of nucleotides comprising a portion of an organism's genetic code'; and that 'research' be defined as 'a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge'; Genomic Research and Diagnostic Accessibility Bill 2002 (US) §§ 2(2)(B), (E). See also United States, *Congressional Debates, House of Representatives*, 14 March 2002, E353 (L Rivers).

825 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 58–59; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 60–61.

826 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 60.

using a patented diagnostic genetic test to establish whether it accurately identifies particular mutations may fall within the scope of a research use defence, as it is currently formulated in most jurisdictions. However, using the same test to conduct research on a genetic mutation and its relationship to a particular disease may fall outside the scope of such a defence.

Application of the research use defence to particular entities

14.17 Courts have also struggled to determine the level of commercial purpose or commercial involvement that will disqualify an alleged infringer from relying upon a research use defence. This issue is of particular relevance to entities that may be engaged in both research and commercial activities. In particular, the application of a research use defence to universities and clinical research laboratories is of interest in the context of gene patents.

14.18 In the recent case of *Madey v Duke University* (*Madey*),[827] the United States Court of Appeals for the Federal Circuit held that use of a patented invention in the course of research activities conducted by Duke University may not fall within the scope of the experimental use defence under United States law.[828] The Court stated that universities are not immune from patent infringement claims solely because of their non-profit status and educational purposes. The Court noted that universities may have commercial interests and that research activities may further a university's 'business objectives' of recruiting and educating students and faculty, and securing research funding. In addition, the Court noted that Duke University, like most research institutions, has an aggressive and successful licensing program that generates substantial revenue.

14.19 If the view expressed in the *Madey* decision is followed in other jurisdictions, it appears that use of gene patents by university researchers would rarely fall within the scope of a research use defence. In addition, the application of such a defence may become increasingly less likely given the trend in the United States and other jurisdictions, including Australia, for universities to incorporate separate entities for the purpose of commercialising their research results.[829]

14.20 In the case of laboratories that conduct basic or clinical research and diagnostic testing in relation to the same genetic condition, there is limited guidance on how a research use defence may apply. A recent report of the Organisation for Economic Co-operation and Development (OECD Report) noted that distinguishing

827 *Madey v Duke University* (2002) 307 F 3d 1351. The case was appealed to the United States Supreme Court but certiorari was denied: United States Supreme Court, *Orders in Pending Cases, 27 June 2003*, United States Supreme Court, <http://www.supremecourtus.gov/orders/courtorders/062703pzor.pdf>, 1 July 2003.

828 *Madey v Duke University* (2002) 307 F 3d 1351, 1362. The Court of Appeals was not required to determine whether the research use defence was made out on the facts. The Court ordered the case to be remanded to the United States District Court for such a determination.

829 See further Ch 11.

clinical research use from commercial use might be difficult.[830] The OECD Report considered whether a separate 'clinical use' defence might provide a solution, but it did not address the scope of such a defence or how it would differ from a 'research use' defence.[831]

Question 14–1. Should the *Patents Act 1990* (Cth) (*Patents Act*) be amended to include a defence for research use? If so, should the defence be limited to activities involving research on an invention claimed in a gene patent? Should the scope of the defence also encompass research use of a gene patent directed to: (a) improving upon the claimed invention; (b) finding a new use for the claimed invention; or (c) creating a new product or process using the claimed invention?

Defence for private and non-commercial use

14.21 Some jurisdictions also provide a defence to claims of infringement based on the 'private and non-commercial use' of a patented invention. 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; …

14.22 An alternative statutory formulation of this defence is contained in the Canadian *Patents Act 1985*, which provides that it is not an infringement if a patented invention is used in connection with

> acts done privately and on a non-commercial scale or for a non-commercial purpose or 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.[832]

14.23 In Canada and in the United Kingdom, legislation provides a defence for 'private use' of a patented invention in addition to an 'experimental use' defence. As there has been limited judicial consideration of the 'private use' defence, the scope of

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830 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 73.

831 Ibid, 73. See also Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, rec 13(d).

832 *Patent Act 1985* (Canada) s 55.2(6). Recent reports in Canada have proposed that this defence be amended to clarify its scope: Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, rec 13(d); Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), Canadian Biotechnology Advisory Committee, Ottawa, see <www.cbac-cccb.ca/>, rec 5.

this defence and how it may differ from an 'experimental use' defence is unclear.[833] It appears, however, that a private use defence will only apply 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.[834] In the United Kingdom, even a possible commercial application of the results of activities involving a patented invention has been held to preclude the application of the defence.[835]

14.24 In Australia, a defence for private and non-commercial use of a patented invention is not expressly included in the *Patents Act*. However, the interpretation of the *Patents Act* discussed above in connection with an implied research use defence might also be used to support an implied private use defence.

Question 14–2. Should the *Patents Act* be amended to include a defence for private, non-commercial use of a patented invention? If so, what would be the relationship between a 'private use' defence and a 'research use' defence of the type identified in Question 14–1?

Defence for use in medical treatment

14.25 As discussed in Chapter 12, concerns have been expressed about the impact of gene patents on the provision of healthcare. If patents are granted covering genetic materials or technologies that have medical uses, there may be an adverse impact on the cost of, and equitable access to, healthcare services. Further, patent laws and practices may compromise medical practice, for example, if exclusive licensing arrangements effectively limit the diagnostic genetic tests that can be performed.

14.26 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. Australia has not adopted this approach to date.[836] Provided that an invention meets the requirements for patentability set out in the *Patents Act*, the Patent Office will allow patents on diagnostic, therapeutic or surgical methods of treatment.

14.27 The United States, like Australia, allows patent protection to be obtained for diagnostic, therapeutic or surgical methods of treatment. United States law has, however, sought to address some of the objections that have been raised to such patents. A limited statutory defence exists to an infringement claim asserted against a

833 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 59.

834 M Fysh, *Infringement, Experimental Use and Clinical Trials: The Experience of the United Kingdom and Ireland*, <www.les-europe.org/italy/docs/fysh.doc>, 30 April 2003.

835 *McDonald v Graham* [1994] RPC 407.

836 See further Ch 9.

'medical practitioner' or a 'related health care entity' in connection with their performance of a 'medical activity'.[837]

14.28 This 'medical treatment' defence applies to licensed medical practitioners and persons acting under their direction, as well as entities with which such medical practitioners are professionally affiliated.[838] 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.[839]

14.29 Certain activities are expressly excluded from the ambit of the 'medical treatment' defence, including 'the practice of a process in violation of a biotechnology patent'[840] and clinical laboratory services.[841] Recent amendments have been proposed that would remove these exclusions and extend the application of the defence to include 'performance of a genetic diagnostic, prognostic, or predictive test'.[842]

14.30 The United States approach to patents on methods of medical treatment has been recommended in other jurisdictions. For example, methods of medical treatment are currently excluded from patentability under Canadian law.[843] The Ontario government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, recommended that this exclusion be replaced with a provision preventing patent holders from bringing an action for infringement against a medical practitioner for providing medical services, including both treatment and diagnosis, to patients.[844] The report noted that such an approach 'while providing protection would still allow the full patenting of genetic testing technologies'.[845]

Question 14–3. Should the *Patents Act* 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? If so, who should qualify as a medical practitioner for the purposes of such a defence and what types of activities should be exempt? Should any activities be expressly excluded from the scope of such a defence?

837 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).
838 35 USC §§ 287(c)(2)(B), (C), (D).
839 35 USC §§ 287(c)(2)(A), (E), (F).
840 35 USC § 287(c)(2)(A)(iii). The term 'biotechnology patent' is not defined.
841 35 USC § 287(c)(3).
842 Genomic Research and Diagnostic Accessibility Bill 2002 (US).
843 See further Ch 9.
844 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, rec 13(e), 51.
845 Ibid, 51.

International obligations and new defences

14.31 As discussed in Chapter 8, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) establishes a minimum standard of protection that must be afforded to patent holders under the national laws of member States of the World Trade Organization. The TRIPS Agreement also specifies a number of permitted exceptions to the exclusive rights conferred on a patent holder. Whether the addition of any new defences to the *Patents Act* may conflict with Australia's obligations under the TRIPS Agreement, therefore, needs to be considered.

14.32 The TRIPS Agreement expressly allows member states to create additional exceptions to the exercise of rights by patent holders in order to achieve an appropriate balance between patent holders' interests in protecting their inventions and the legitimate interests of third parties. Specifically, art 30 of the TRIPS Agreement provides that:

> 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.[846]

14.33 The TRIPS Agreement also allows member States to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability.[847] A defence to an infringement claim based on use of a patented genetic invention for the purposes of diagnostic, therapeutic or surgical treatment of similar scope is arguable permissible under the TRIPS Agreement.

Question 14–4. Would amendment of the *Patents Act* to include new defences, such as those identified in Questions 14–1, 14–2 and 14–3, be consistent with Australia's obligations under the TRIPS Agreement?

846 *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 15 April 1994).

847 Ibid art 27(3). See further Ch 8, 9.

15. Crown Use and Compulsory Licensing

Contents

Introduction

15.1 This chapter considers the circumstances in which the Crown use, Commonwealth acquisition and compulsory licensing provisions of the *Patents Act* 1990 (Cth) (*Patents Act*) might be applied to address concerns that gene patents may impede access to genetic materials and technologies for use in research and the provision of healthcare.

15.2 The chapter considers the application of these existing provisions of the *Patents Act* where patent holders fail to exploit a gene patent for their own benefit, or enter into licensing arrangements to permit others to do so. The chapter asks whether the existing provisions are adequate to encourage the exploitation of inventions covered by gene patents and, if not, how patent laws and practices might be changed in these respects.

Crown use of patents

15.3 The Crown use provisions of the *Patents Act*[848] may provide a means for the Commonwealth and State[849] governments to facilitate access to inventions covered by gene patents in connection with the provision of healthcare.

15.4 The Commonwealth or a State, or a person authorised in writing by the Commonwealth or a State, may exploit an invention covered by a patent (or a pending patent application) 'for the services of the Commonwealth or the State'.[850] Such uses are deemed by the *Patents Act* not to constitute an infringement of the relevant patented invention.

848 *Patents Act 1990* (Cth) Ch 17, Pt 2.

849 'State' is defined to include the Australian Capital Territory, the Northern Territory and Norfolk Island for the purposes of Ch 17 of the Act: Ibid Sch 1.

850 Ibid s 163.

15.5 In order for use of a patented invention to fall within the scope of this statutory immunity, the exploitation of the invention must be 'necessary for the proper provision' of the services within Australia.[851] The right to exploit the invention under the Crown use provisions includes the right to sell products made in the exercise of the right.[852]

15.6 Certain procedural matters must be satisfied in order for the Crown use provisions of the *Patents Act* to apply. The Commonwealth or State must notify the patent holder of the exploitation.[853] The terms of the exploitation and the compensation to be paid must be agreed between the patent holder and the Commonwealth or State or, in the absence of agreement, determined by a prescribed court.[854]

15.7 The extent to which the Crown use provisions may allow the provision of healthcare services by the Commonwealth or a State using patented genetic materials or technologies without infringing patent rights is an open question.

15.8 One uncertainty involves the interpretation of the term 'for services of the Commonwealth or the State'. It is unclear whether the statutory immunity applies only to the exploitation of an invention to provide services directly to the Commonwealth or a State, or whether it extends to situations in which the Commonwealth or a State provides services, such as healthcare, to the public. For example, is there a relevant distinction between use of a genetic sequence that is subject to a gene patent in research by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and use by medical practitioners in providing diagnostic genetic testing to patients of a public hospital?

15.9 Australian courts have not considered the application of the Crown use provisions in the context of healthcare services. However, in the United Kingdom, the House of Lords has interpreted equivalent provisions in the *Patents Act 1949* (UK) and held, by majority, that supply of a patented drug to National Health Service hospitals for patients was a 'use for the services of the Crown' and, therefore, within the scope of the statutory immunity.[855] Lord Reid indicated that, in practice, it would be unworkable to distinguish between the use of patented articles for the benefit of the 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.[856]

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851 Ibid s 163(3). The Commonwealth's exploitation of a patented invention in connection with the supply of products to a foreign country for the purposes of that country's defence is also deemed to be use of a patented invention 'for the services of the Commonwealth': *Patents Act 1990* (Cth) s 168.

852 *Patents Act 1990* (Cth) s 167.

853 Ibid s 164.

854 Ibid s 165.

855 *Pfizer Corporation v Ministry of Health* [1965] AC 512. The decision has been considered in Australia, but Cooper J stated that he was not required to express a view as to whether it reflected the law in Australia: *Stack v Brisbane City Council* (1994) 131 ALR 333, 348.

856 *Pfizer Corporation v Ministry of Health* [1965] AC 512, 534.

15.10 Another issue that may arise is whether a particular healthcare provider should be regarded as 'the Commonwealth' or 'a State', or as an 'authority' of the Commonwealth or a State.[857] A polity such as the Commonwealth or a State is an abstraction—it can only carry out its activities through the agency of others. Whether a particular body is to be regarded as 'the Commonwealth' or a 'State', or an 'authority' of the Commonwealth or a State, generally depends on two factors: 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.[858] The resolution of this issue usually requires a careful assessment of the facts of the particular case.

Question 15–1. Are the Crown use provisions in the *Patents Act 1990* (Cth) (*Patents Act*) capable of applying to the provision of healthcare services using patented genetic materials and technologies? If not, should these provisions be amended to apply to such use?

Commonwealth acquisition of patents

15.11 Section 171 of the *Patents Act* provides for compulsory acquisition by the Commonwealth of an invention covered by a patent or patent application.[859] The Act does not stipulate any limitations on the circumstances in which the Commonwealth may acquire an invention.

15.12 However, the Commonwealth must compensate a patent holder for the acquisition of a patent pursuant to s 171 by an amount agreed between the Commonwealth and the patent holder or, in the absence of agreement, by an amount determined by a prescribed court.[860] In addition, the Commonwealth's acquisition of a patent will fall within the scope of s 51(xxxi) of the Australian Constitution, which requires that any acquisition of property—including intellectual property—by the Commonwealth must be on just terms.[861]

15.13 The Commonwealth could exercise some control over the cost of healthcare involving the use of patented genetic materials and technologies by acquiring patents on such inventions pursuant to s 171. It is arguable, however, that this provision should

857 References to the Commonwealth or a State in Ch 17 of the Act include references to an 'authority' of the Commonwealth or a State: *Patents Act 1990* (Cth) s 162.

858 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, DP 64 (2000), ALRC, Sydney, [29.6]–[29.17]. See also *Stack v Brisbane City Council* (1994) 131 ALR 333, 337–344 (Cooper J).

859 *Patents Act 1990* (Cth) s 171. Compulsory acquisition of a patented invention by a State or Territory is not provided for under the Act.

860 Ibid s 171(4). Compensation must also be paid to any other person recorded on the Register of Patents as having an interest in the patent: see definition of 'compensable person' *Patents Act 1990* (Cth) sch 1.

861 See, for example, *Trade Practices Commission v Tooth & Company Limited* (1979) 142 CLR 397, 434 (Murphy J); *Australian Tape Manufacturers Association Ltd v Commonwealth* (1993) 177 CLR 480, 527 (Dawson and Toohey JJ); *Smith Kline & French Laboratories (Australia) Ltd v Secretary, Department of Community Services and Health* (1990) 95 ALR 87, 134 (Gummow J).

not be relied upon too readily and should only be invoked in exceptional circumstances in order to preserve confidence in the patent system. 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 licensing of Bayer's patent on the ciprofloxacin antibiotic following bioterror attacks in the United States.[862] However, even in these circumstances, compulsory acquisition of a patent may be controversial.

Compulsory licensing

15.14 The compulsory licensing provisions in the *Patents Act* may provide another mechanism to address concerns relating to access to gene patents, including for use in research and healthcare provision.

15.15 Under s 133 of the *Patents Act*, a person may apply to a prescribed court for an order requiring a patent holder to grant the applicant a licence to use a patented invention—known as a 'compulsory licence'. A prescribed court may order the grant of a compulsory licence if:

- the reasonable requirements of the public with respect to the patented invention have not been satisfied; and
- the patent holder has given no satisfactory reason for failing to exploit the patent.[863]

15.16 The court must be satisfied that the applicant for the compulsory licence has tried, unsuccessfully, to negotiate a licence on reasonable terms and conditions for a reasonable period of time.[864] A compulsory licence must not be exclusive[865] and the patent holder is entitled to be paid for use of the patent at an agreed rate, or failing agreement, by 'such amount as is determined by a prescribed court to be just and reasonable having regard to the economic value of the licence'.[866]

15.17 Additional provisions apply where the patent in relation to which a compulsory licence is being sought is a 'dependent patent'—that is, an invention that cannot be worked without infringing another patent. In that case, to order that a patent holder must grant a licence to the applicant, the court must also be satisfied that the dependent invention involves an important technical advance of considerable economic significance on the other invention.[867] If required, the patent holder of the other

862 Consumer Project on Technology, *Ciprofloxacin: The Dispute Over Compulsory Licenses*, <www.cptech.org/ip/health/cl/cipro/>, 3 June 2003.
863 *Patents Act 1990* (Cth) s 133(2).
864 Ibid s 133(3A).
865 Ibid s 133(3)(a).
866 Ibid s 133(5).
867 Ibid s 133(3B)(a).

invention may also receive a cross-licence on reasonable terms to use the dependent patent.[868]

Reasonable requirements of the public

15.18 The grant of a compulsory licence turns upon an applicant's ability to show that the 'reasonable requirements of the public' have not been met. Section 135 of the *Patents Act* sets out the circumstances under which the 'reasonable requirements of the public' will be deemed not to have been satisfied. These circumstances include unfair prejudice to a new or existing 'trade or industry' in Australia as a result of:

- a patent holder's failure to manufacture sufficient quantities of a patented product or supply it on reasonable terms, to carry on a patented process to a reasonable extent, or to grant licences on reasonable terms; or

- conditions attached by a patent holder to the purchase, hiring or use of a patented product or to the use of a patented process.[869]

15.19 As the compulsory licensing provisions in the *Patents Act* have not been subject to judicial interpretation in the context of the biotechnology, healthcare or pharmaceutical industries, the scope of their application is uncertain. For example, whether the 'reasonable requirements of the public' test may apply if a patent holder's failure to exploit a gene patent limits access to healthcare services or the ability to pursue medical research is open to debate.

Reform of compulsory licensing provisions

15.20 Statutory provisions to allow the grant of compulsory licences are regarded as an important mechanism to ensure access to patented genetic materials and technologies. However, the ALRC understands that few, if any, compulsory licences have been granted under the *Patents Act*.[870]

15.21 Nonetheless, these provisions may promote exploitation of patents by patent holders and influence patent holders' willingness to negotiate licensing arrangements. The Intellectual Property and Competition Review Committee (IPCRC) stated that:

> compulsory access, even if limited, can affect the terms on which parties negotiate licences for the use of patents. The Committee was told that the current s 133 Patents Act provisions, though they appear ineffectual, have a continuing impact on licence

868 Ibid s 133(3B)(b)(ii).
869 Ibid s 135(1).
870 There is only one reported case dealing with compulsory licensing of patents: *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation* (1969) 119 CLR 572. A 1992 report of the House of Representatives Standing Committee on Industry, Science and Technology stated that 'no compulsory licenses have been granted since Federation': House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), Parliament of the Commonwealth of Australia, Canberra, 227.

> negotiations, notably between foreign rights owners and potential users of patents in Australia.[871]

15.22 In relation to gene patents in the United Kingdom, the Nuffield Council on Bioethics has noted that:

> extensive application of compulsory licensing provisions in relation to diagnostic tests may not be required, as experience has shown that the mere threat of compulsory licensing has been sufficient to encourage industry to devise other solutions.[872]

15.23 The ALRC is interested in comments on whether the existing compulsory licensing provisions in the *Patents Act* are adequate to address concerns about access to gene patents and, if not, how these provisions should be amended.

15.24 The IPCRC recommended that the 'reasonable requirements of the public' criterion be replaced with a competition-based test. The IPCRC proposed that such a test should balance the need for access to a patented invention to provide competition in the relevant market against the legitimate interests of a patent holder in sharing in the return on a patented invention and any successive inventions.[873]

15.25 In its response to the IPCRC's report, the Federal Government accepted the IPCRC's recommendation for a competition-based test for compulsory licensing in part. The Government stated that a competition-based test should supplement rather than replace the current 'reasonable requirements of the public' test. The Government indicated that a competition-based test might be more stringent that the existing test and, therefore, reduce the incentive to negotiate patent licences. In addition, in the Government's view, a competition-based test would

> not cover some situations where the non-working of the invention, or other effective denial of reasonable access to it, has some negative effect on the public interest which is not dependent on competition in the market.[874]

15.26 Arguably, one situation where failure to exploit a patented invention may not affect competition in the market, but may nonetheless have a negative impact, is in the context of access to gene patents, particularly in connection with the provision of healthcare—where public provision of healthcare services is dominant and competition in the market is already limited.

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871 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 162. See also H Ergas, *Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia*, Network Economics Consulting Group, <www.necg.com.au/pappub/papers-ergas-compulsory-licenses-may02.pdf >, 19 February 2003.

872 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), Nuffield Council on Bioethics, London, see <www.nuffieldbioethics.org>, 55.

873 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 162–163.

874 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/general/response1.pdf>, 2 May 2003.

Compulsory licensing in other jurisdictions

15.27 Compulsory licensing is available under the patent laws of other jurisdictions and experiences in these jurisdictions may be informative.

15.28 Statutory provisions in other jurisdictions relating to the grant of compulsory licences differ in content.[875] In the United Kingdom, compulsory licences may be granted if the demand for a patented product is not being met by the patent holder on reasonable terms, or if the refusal to grant a licence to use a patented invention is causing unfair prejudice to the efficient working of another patented invention or the establishment or development of commercial activities.[876] In Japan, compulsory licences may be granted if, among other things, such a licence is in the interests of the general public.[877] Compulsory licensing provisions are also included in the Canadian patents legislation.[878]

15.29 Dr Richard Gold, a Canadian academic, has suggested that:

> patent offices could show a greater willingness to use anti-abuse provisions existing in most patent statutes to ensure that patent holders widely license DNA sequence patents for diagnostic purposes.[879]

15.30 The Ontario government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Ontario Report), proposed that Canadian patent legislation be amended to provide for the application of compulsory licensing to patents on genetic diagnostic and screening tests.[880] The Ontario Report suggested that compulsory licences should be granted in return for a reasonable royalty established by the Commissioner of Patents after the Commissioner had engaged appropriate industry and health sector expertise.[881] The Ontario Report did not, however, believe that prior negotiation with patent holders for a licence in respect of these patents should be required.[882]

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875 There is no general requirement under United States patent law for the grant of compulsory licenses to patented technology. Compulsory licensing of particular categories of inventions may be separately provided for under other United States statutes: see, for example, the *Clean Air Act* (42 USC § 185h-6) and *Atomic Energy Act* (42 USC § 2183(g)). In addition, it has been suggested that de facto 'compulsory licenses' may be obtained under United States law as a remedy in an antitrust suit alleging refusal to deal, or in a patent infringement suit where a request for an injunction to stop further infringing activity is not granted on the basis of public interest or need.

876 *Patents Act 1977* (UK) ss 48A, 48B.

877 *Patent Law 1999* (Japan) s 93. See also, J Love, *Experimental Use and Compulsory licenses in Japan*, <http://lists.essential.org/pipermail/pharm-policy/2000-September/000352.html>, 20 March 2003.

878 *Patent Act 1985* (Canada) ss 65–71.

879 E Gold, 'Gene Patents and Medical Access' (2000) 49 *Intellectual Property Forum* 20, 25.

880 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare — Report to the Provinces and Territories* (2002), Ontario Government, see <www.gov.on.ca>, rec 13(h).

881 Ibid.

882 Ibid.

15.31 Extensions to provisions under French law akin to compulsory licensing have also been proposed to address healthcare concerns raised by gene patents. French legislation currently allows drugs to be subject to an 'automatic or *ex officio* licence' ('*licence d'office*') if the demands of a patent holder appear to be contrary to the interests of public health. French opponents of patents on the BRCA1 gene have suggested that the provisions could be broadened to apply to all patents relating to public health and, in particular, to diagnostic genetic tests.[883]

Question 15–2. In relation to the provisions in the *Patents Act* relating to the grant of compulsory licences:

- Do the provisions encourage patent holders to exploit or license gene patents?
- Is the grant of a compulsory licence 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? If not, should the current provisions be amended to make specific reference to such matters?
- Should compulsory licences be available only by order of a court (as the *Patents Act* currently provides), or should the Act be amended to allow the Commissioner of Patents, or another tribunal or agency, to grant compulsory licences?
- If compulsory licences were to be granted more frequently, should the *Patents Act* be amended to provide increased protections for patent holders, such as mechanisms for determining the compensation due, or certain mandatory terms to be included in such licenses?

International obligations

15.32 As discussed in Chapter 8, government use and compulsory licensing of patented inventions are addressed in the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement).[884] Any amendments to the *Patents Act* would, therefore, need to comply with the minimum standards for patent protection provided under the TRIPS Agreement.

883 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), Institut Curie, Paris, 8.

884 *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 15 April 1994), art 31.

Question 15–3. What latitude is there for amending the Crown use or compulsory licensing provisions of the *Patents Act* consistently with Australia's obligations under the TRIPS Agreement?

Part F

Other Intellectual Property Issues

16. Copyright, Trade Secrets and Designs

Contents

Introduction

16.1 The Terms of Reference refer to the objective of protecting intellectual property rights in order to contribute to the promotion of technological innovation in a manner conducive to social and economic welfare, and to a balance of rights and obligations. This chapter discusses the potential application of forms of intellectual property law, other than patents, to genetic materials and technologies used in genetic research in Australia.

Copyright law

16.2 Genetic researchers might seek to protect certain research tools and results through copyright law rather than through other forms of intellectual property. 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.

16.3 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 literary, dramatic, musical and artistic works, and 'subject matter other than works'.[885]

885 *Copyright Act 1968* (Cth) ss 10(1), 85–88.

16.4 Copyright is protected internationally through several international treaties, in particular the *Berne Convention for the Protection of Literary and Artistic Works 1886* and the *Agreement on Trade Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[886] These conventions define minimum periods and levels of protection for member countries, and provide 'fair dealing' provisions for specified uses.

16.5 Copyright subsists in an unpublished literary, dramatic, musical or artistic work if the author was a 'qualified person'[887] at the time the work was made or for a substantial part of this time. Copyright subsists in a published work if the work is first published in Australia;[888] 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.[889]

16.6 Copyright protects 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 recordings of the work; for computer programs, to enter into a commercial rental arrangement in respect of that program; and to authorise the doing of one of these acts.[890]

16.7 Generally, copyright subsists until 50 years after the end of the calendar year in which the author died. Where a literary work was not published before the author's death, copyright subsists until the end of 50 years after the end of the calendar year in which it was first published.[891]

16.8 Copyright might be more attractive than patent protection for several reasons. First, copyright applies automatically upon the creation of a work, and does not require formal registration. Second, copyright in a work generally lasts from the date of its creation until 50 years after the author's death, whereas patent protection lasts for 20 years for a standard patent and eight years for an innovation patent. However, while a patent grants the patent holder the right to stop third parties exploiting the particular product or process, copyright only protects the work from being copied.

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886 *Berne Convention for the Protection of Literary and Artistic Works*, [1972] ATS 13, (entered into force on 9 September 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 15 April 1994). See also *Universal Copyright Convention*, [1969] ATS 9, (entered into force on 16 September 1955).

887 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: *Copyright Act 1968* (Cth) ss 32 (4), 10(1).

888 'Publication' is the authorised supply of reproductions of a work to the public: Ibid s 29(1).

889 Ibid s 32(2). In addition, the *Copyright (International Protection) Regulations 1969* (Cth) confer a similar protection on most works that are made or published overseas.

890 *Copyright Act 1968* (Cth) s 31(1).

891 Ibid s 33. By contrast, the European Union has extended the duration of copyright in works to 70 years after the author's death: R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 69.

Subsistence of copyright

Ideas and expression

16.9 Copyright does not protect the ideas contained in a work but only the form in which they are expressed.[892] 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.[893]

16.10 It is unclear whether the 'merger doctrine' applies in Australia. Some commentators have suggested that Australian courts have accepted the principle,[894] while others suggest that the High Court has impliedly rejected it.[895] 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.[896]

Works

16.11 As noted above, copyright may subsist in literary, dramatic, musical and artistic works. Literary works include tables and compilations expressed in words, figures or symbols, computer programs and compilations of computer programs.[897] 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.[898] This requirement has been interpreted broadly, and has been held to include codes comprising foreign or invented words, and computer source codes.[899] 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'.[900]

892 S Ricketson (ed) *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999) Lawbook Co, Sydney, [4.65].

893 See J McKeough and A Stewart, *Intellectual Property in Australia* (1997) Butterworths, Sydney, 137–138.

894 See Ibid.

895 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 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 o the doctrine in Australian law: *Autodesk Inc v Dyason* (1992) 173 CLR 330.

896 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474.

897 *Copyright Act 1968* (Cth) s 10(1).

898 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 42–44, citing *Hollinrake v Truswell* [1894] 3 Ch 420 (Davey LJ).

899 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 44–45.

900 *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* (1997) Butterworths, Sydney, 142.

Originality

16.12 A work must be original in order to attract copyright.[901] The work need not be the expression of original or inventive thought, but it must originate with an author and must not be a mere copy. A work originates with an author if it is the product of the author's skill, labour and expertise or experience. The required amount of labour, skill and expertise to establish originality will depend on the facts of the case and will be a question of degree.[902] 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.[903]

Copyright infringement

16.13 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.[904] 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.[905]

16.14 In relation to a factual compilation, substantiality is determined by reference to the originality of that part of the work taken. Where originality in a factual compilation is based in whole or in part on the compiler's labour or expense in collecting the information, infringement depends on the extent to which the collected information has been appropriated.[906]

16.15 The *Copyright Act* provides both civil and criminal remedies for copyright infringement. The civil remedies include (a) an injunction; (b) an account of profits; (c) damages for infringement;[907] (d) damages for conversion; and (e) delivery up of infringing copies.[908] Criminal offences apply in relation to certain infringing conduct where the offender knew or ought reasonably to have known that the copy was an infringing copy.[909]

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901 *Copyright Act 1968* (Cth) s 32.

902 S Ricketson (ed) *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999) Lawbook Co, Sydney, [7.50], [7.60].

903 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433. See also J Lahore (ed) *Patents, Trade Marks & Related Rights: Looseleaf service* (2001) Butterworths, Sydney, [10,065], [10,115]. Desktop Marketing Systems Pty Ltd has filed an application for special leave to appeal this decision to the High Court of Australia.

904 *Copyright Act 1968* (Cth) s 36(1).

905 J McKeough and A Stewart, *Intellectual Property in Australia* (1997) Butterworths, Sydney, 191.

906 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 533 (Sackville J).

907 *Copyright Act 1968* (Cth) s 115.

908 Ibid s 116(1). See S Ricketson (ed) *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999) Lawbook Co, Sydney, Ch 13.

909 *Copyright Act 1968* (Cth) s 132. See R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 136.

Fair dealing

16.16 The *Copyright Act* provides for certain acts of 'fair dealing' with a work, which will not constitute infringement of copyright.[910] One such defence is fair dealing for the purpose of research and study.[911]

16.17 The *Copyright Act* specifies the matters that must be considered in order to determine whether the reproduction of a work constitutes a fair dealing for the purpose of 'research or study'. These matters include: the purpose and character of the dealing; the nature of the work; the possibility of obtaining the work within a reasonable time at an ordinary commercial price; the effect of the dealing on the potential market for, or the value of, the work; and, where only a part of the work is copied, the amount and substantiality of that part compared to the whole.[912]

16.18 The term 'research' has been interpreted to mean 'diligent and systematic enquiry or investigation into a subject in order to discover facts or principles'.[913] It is not clear whether or not this defence is limited to 'non-commercial' research.[914]

Copyright in genetic material

16.19 Genetic research may involve the identification of natural or isolated genetic material and the genetic sequences it contains, and the modification of this material. Such research may involve the use of computer programs.

Genetic materials

16.20 Genetic researchers might seek to assert copyright over the written representation of the genetic sequence of natural, isolated or modified genetic material, on the basis that it is an 'original literary work' within the meaning of the *Copyright Act*.[915]

16.21 As noted above, the *Copyright Act* definition of a 'literary work' includes a table or compilation, expressed in words, figures or symbols. Therefore, the written representation of a genetic sequence—in the form of a string of letters representing the four nucleotides A, T, C and G—is likely to be a 'literary work' within the meaning of the *Copyright Act*. Sue Coke has commented that:

910 *Copyright Act 1968* (Cth) ss 40–42, 43(2).
911 Ibid s 40.
912 Ibid s 40(2).
913 *De Garis v Neville Jeffress Pidler Pty Ltd* (1990) 37 FCR 99, 105 (Beaumont J), applying the definition in the *Macquarie Dictionary*.
914 See S Ricketson (ed) *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999) Lawbook Co, Sydney, [11.30].
915 Copyright might also be asserted over the written representation of genetic products, such as proteins.

> 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.[916]

16.22 Where substantial independent skill, labour and effort are involved in 'elucidating' a genetic sequence, the representation may satisfy the originality requirement for copyright.[917]

16.23 In some jurisdictions it has been suggested that copyright may not subsist in the representation of a genetic sequence because there is only one established way of representing a sequence of nucleotides. In this case, the idea and expression merge.[918] 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.[919]

16.24 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.[920] Therefore, copyright may subsist in the representation of a genetic sequence provided sufficient skill, labour and effort is involved in creating that expression.

16.25 Several commentators in other jurisdictions have suggested that copyright may subsist in a modified genetic sequence itself, in addition to its written representation.[921] However, this is unlikely under Australian law because the DNA strand, by itself, is not in writing and provides no information, instruction or entertainment to human beings, unlike its written representation.

16.26 The recognition of copyright in genetic sequences could have significant implications due to the duration and exclusive nature of copyright protection. For example, where a scientist asserts copyright over the representation of a modified

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916 S Coke, 'Copyright and Gene Technology' (2002) 10 *Journal of Law and Medicine* 97, 102.

917 See Ibid.

918 See the discussion in Ibid, 101, 108.

919 G Karnell, 'Opinion: Protection of Results of Genetic Research by Copyright or Design Rights?' (1995) 8 *European Intellectual Property Review* 355, 357.

920 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474 (Lindgren J).

921 See, for example, 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* 31, 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 Law School, <www.bc.edu/bc_org/avp/law/st_org/iptf/articles>, 1 May 2003, 2, 4.

genetic sequence, this could present an impediment to its use in scientific research of potential medical or therapeutic benefit (unless the research falls within the scope of the fair dealing exception). Of course, where another scientist independently creates the same modified sequence, and represents it in the same way, copyright would not be infringed.

Computer programs

16.27 Computers are increasingly used as tools in scientific and genetic research. Computer programs may be designed to conduct various steps in the identification or modification of genetic sequences, or in the storage of such sequences or associated information.[922] Copyright may protect computer programs developed for these purposes.

16.28 A computer program or a compilation of computer programs, may attract copyright as a 'literary work'.[923] 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'.[924] Copyright thus protects the expression of the set of instructions that constitute a computer program.[925]

Question 16–1. What role should copyright law play in dealing with genetic materials and technologies in relation to human health?

Legal protection of databases

16.29 Databases are collections of data organised in a systematic way in either hard copy or computerised form. The creation of private and public databases of genetic information has highlighted existing tensions in copyright law between the need to provide incentives for the investment involved in compiling and arranging the data, and the need to ensure researchers' access to such data, on reasonable terms, to advance scientific knowledge.[926]

922 See Ch 11 for more detail about the tools used in human genetic research.
923 *Copyright Act 1968* (Cth) s 10(1).
924 Ibid. This definition was inserted into the *Copyright Act* by the *Copyright Amendment (Digital Agenda) Act 2000* (Cth). The Attorney-General's Department is currently conducting a review of the operation of this legislation, which is due to be completed in 2004.
925 Australian Copyright Council, *Information Sheet G50: Computer Software & Copyright* (2002), ACC, Sydney, 1.
926 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003) The Royal Society, London, 23.

Copyright in databases

16.30 Copyright may subsist in a database that is an 'original literary work' in the form of a compilation. A compilation need not hold original or novel information but will be an original literary work if the compiler has exercised skill, judgment or knowledge in selecting, presenting or arranging the material.[927] In Australia, the labour or expense involved in collecting, receiving, verifying, recording or otherwise assembling the information can also be sufficient to confer copyright protection.[928]

16.31 The leading Australian case in relation to factual compilations is *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd.* In that case, the Federal Court held that Telstra's telephone directory was an original literary work because of the labour and expense involved in compiling the information. The Court noted that that the concepts of authorship and originality do not require novelty, inventiveness or 'a creative spark'.[929] Instead, a compilation of factual information will be sufficiently original to attract copyright if the compiler has undertaken substantial labour or incurred substantial expense in collecting the information.[930]

16.32 In Australia, copyright in factual compilations may therefore extend to the 'sweat of the brow' involved in obtaining and compiling information as well as the selection and arrangement of the information. The reproduction of a substantial part of the content of a database will be an infringement of copyright. In addition, copyright may subsist in the individual items contained within the database.

16.33 The United States has taken a different approach to factual compilations. 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 Court noted that copyright did not subsist in the individual telephone book entries, but could subsist in an original selection, co-ordination or arrangement of these facts provided this involved independent creation and a minimum degree of creativity. The Court rejected the 'sweat of the brow' basis for originality.[931]

927 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 532–533 (Sackville J).

928 Ibid.

929 Contrast the novelty and inventiveness requirements for patentability, as discussed in Ch 9.

930 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433. See also G Sauer, 'Copyright in Telstra Directories: the Appeal' (2002) *Blake Dawson Waldron* , 2.

931 *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.

Special database right

16.34 In 1996, the European Parliament and Council of the European Union (EU) issued a *Directive on the Legal Protection of Databases* (EU Directive).[932] The purpose of the directive was to harmonise copyright law among EU member states in relation to databases, and to increase the legal protection of databases within those member states that did not recognise copyright in factual compilations.[933]

16.35 The EU 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.[934] One part of the EU Directive provides for a uniform approach to copyright protection for databases which, by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation.[935]

16.36 The second part of the EU Directive creates a *sui generis* or special right for the protection of databases, whether or not they qualify for copyright protection. This 'database right' applies to any database for which the owner has made a substantial investment, either quantitatively or qualitatively, in obtaining, verifying or presenting the contents of a database. The EU Directive prohibits the unauthorised extraction or re-utilisation of a substantial part of the database contents.[936] The term of protection is 15 years, but this may be extended by a substantial change (in qualitative or quantitative terms) in the contents of the database.[937]

16.37 The protection provided by the database right may be higher than copyright protection in several ways. First, like copyright in factual compilations, the database right protects against the taking of a substantial part of the information contained in the database. However, the database right goes further in prohibiting the repeated and systematic extraction or re-utilisation of insubstantial parts of the database where these acts would conflict with the normal exploitation of the database, or would

932 *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). The United States Congress has considered several bills addressing the protection of databases, one of which was based on the EU Directive: E Baba, 'From Conflict to Confluence: Protection of Databases Containing Genetic Information' (2003) 30 *Syracuse Journal of International Law and Commerce* 121, 138–139. For a discussion of the United States and EU law regarding the legal protection of databases, and moves for an international agreement on the issue, see M Davison, *The Legal Protection of Databases* (2003) Cambridge University Press, Cambridge (forthcoming).

933 See M Davison, 'Sui Generis or Too Generous: Legislative Protection of Databases, Its Implications for Australia and Some Suggestions for Reform' (1998) 21 *UNSW Law Journal* 729, 734–735.

934 *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 1(2).

935 Ibid, Ch II. See M Davison, *Report on the Protection of Databases* (2002), European Bureau of Library, Information and Documentation Associations, Melbourne, 4.

936 *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) Ch III. See M Davison, *Report on the Protection of Databases* (2002), European Bureau of Library, Information and Documentation Associations, Melbourne, 4.

937 *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 10.

unreasonably prejudice the legitimate interests of the database owner.[938] Second, the exceptions to the database right are more limited than those available under general copyright law. The main exception to the database right applies to extraction for the purpose of illustration for teaching or scientific research, provided the source is indicated and extraction is limited to the extent justified by the non-commercial purpose.[939]

16.38 The database right has been criticised for the lack of certainty of several provisions. Since the implementation of the EU Directive by member states, courts have been asked to interpret several provisions including the meaning of a 'database', the 'substantiality' of the investment required to attract the right, the status of database 'maker',[940] and the test of infringement.[941] 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.[942]

16.39 The exceptions to the database right have also been criticised on the basis that: the meaning of 'illustration' for scientific research is unclear; there is no right of re-utilisation for scientific research; and the limitation of the exception to 'non-commercial' purposes may cause certain practical difficulties, for example where a publicly funded research program develops commercial implications.[943]

16.40 In 1996, the World Intellectual Property Organization (WIPO) considered a draft treaty that would create a special protection regime similar to that provided in the EU Directive. To date, the treaty has not been adopted.[944] In 2002, a WIPO-commissioned study on the impact of the protection of non-original databases in developing countries concluded that *sui generis* protection of these databases 'would

938 Ibid, art 7(5).
939 Ibid, art 9(b).
940 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.
941 M Davison, *Report on the Protection of Databases* (2002), European Bureau of Library, Information and Documentation Associations, Melbourne, 9–10.
942 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.
943 M Davison, *Report on the Protection of Databases* (2002), European Bureau of Library, Information and Documentation Associations, Melbourne, 9–10. See also The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003) The Royal Society, London, 23–24.
944 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).

have negative effects on developing countries, and on the scientific and academic communities worldwide'.[945]

Databases of genetic information

16.41 Genetic databases may hold compilations of the genetic 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). Such databases may also hold information about the biochemical pathways related to the expression of genes. These databases may be compiled by academic or government institutes, or by biotechnology or pharmaceutical companies.[946]

16.42 In recent years, there has been a proliferation of both public and private databases created for scientific research. Edward Baba has suggested three reasons why databases have become essential for research biologists:

> 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.[947]

16.43 In Australia, copyright will subsist in a database of genetic sequences or other factual information where the owner has expended substantial labour or resources in collecting the information. In addition, database owners who wish to protect the contents of a database may place financial or other conditions on third party access to it. As Australia already offers a high level of protection for database owners there may be little reason to consider the introduction of a special database right, such as that adopted in the EU Directive.

16.44 The recognition of copyright in databases that constitute factual compilations raises significant policy considerations. While it has been suggested that copyright in factual compilations could confer monopoly rights in relation to facts, there should be some incentive for a person or organisation to spend the necessary labour and

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945 Standing Committee on Copyright and Related Rights, *Study on the Protection of Unoriginal Databases* (2002), WIPO, Geneva, 2. The study expressed the concern that *sui generis* protection of databases will significantly reduce the availability of free information and data; may create perpetual monopolies by allowing database owners to extend the protection indefinitely; will be harmful to the free flow of information among scientific communities; will be harmful to the development of the Internet and software industry; and will hinder many aspects of development in the developing and under-developed world: 10.

946 E Baba, 'From Conflict to Confluence: Protection of Databases Containing Genetic Information' (2003) 30 *Syracuse Journal of International Law and Commerce* 121, 124, 127. See Ch 11 for more detail about the public and private databases used in human genetic research.

947 Ibid, 127.

resources to collect and arrange the data in database form—particularly where this data could be of value in furthering scientific knowledge.[948]

16.45 In December 2002, the Human Genome Organisation's Ethics Committee released a *Statement on Human Genomic Databases*, which recommended that: human genomic databases are global public goods; individuals, families, communities, commercial entities, institutions and governments should foster the public good; the free flow of data and the fair and equitable distribution of benefits from research using databases should be encouraged; the choices and privacy of individuals, families and communities should be respected; and researchers, institutions, and commercial entities have a right to a fair return for intellectual and financial contributions to databases.[949]

16.46 The United Kingdom's Royal Society has expressed the concern that database owners might charge for access to the database contents even if some or all of the information is in the public domain, or has resulted from publicly funded research. Alternatively, publicly funded databases could be transferred to private ownership, and access subsequently limited.[950]

16.47 The Royal Society has suggested that one way to ensure that information is kept in the public domain is to fund the public database collections adequately so that they can compete with the private sector and prevent a monopoly arising. Another option could be to introduce a compulsory licensing scheme to ensure reasonable access to a privately owned database.[951]

Question 16–2. Does Australian copyright law provide adequate protection of databases that hold factual compilations of genetic sequences and other genetic data? What would be the implications of introducing into Australian law a special database right—as distinct from copyright—in relation to such databases?

Trade secrets

16.48 The common law has developed other doctrines for the protection of intellectual property rights in addition to those that have a legislative basis (such as copyright and patents). For example, 'trade secrets' are a form of confidential

948 See generally, *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 536–537 (Sackville J).

949 HUGO Ethics Committee, *Statement on Human Genomic Databases* (2002), see <www.hugo-international.org/hugo/>. 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; the potential risk of misusing genetic data; and the need to rapidly place primary genomic sequences in the public domain.

950 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003) The Royal Society, London, 25–26.

951 Ibid, 24.

information that arises in a commercial context.[952] An individual may bring an action either in contract or in equity for breach of confidence in relation to a trade secret.

16.49 A genetic researcher may 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. In addition, trade secrets may protect the background information about a patented invention, which makes it possible to use the new product or process most effectively.[953]

16.50 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.[954] However, this protection may be lost if the information is disclosed—for example by a third person who is given limited access to the information, or by a former employee—or otherwise enters the public domain.

16.51 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 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.[955]

16.52 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'.[956] 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;

952 J Lahore (ed) *Patents, Trade Marks & Related Rights: Looseleaf service* (2001) Butterworths, Sydney, [33,080]. By contrast, 'know how' represents the confidant's (ie employee's) accumulated experience and knowledge in a 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) Federation Press, Sydney, 520–521.

953 Department of Foreign Affairs and Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001), Commonwealth of Australia, Canberra, see <www.dfat.gov.au/>, 1–16.

954 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 531.

955 J Lahore (ed) *Patents, Trade Marks & Related Rights: Looseleaf service* (2001) Butterworths, Sydney, [33,070].

956 Ibid, [33,000], citing *Moorgate Tobacco Co Ltd v Philip Morris Ltd (No 2)* (1984) 156 CLR 414, 437–438 (Deane J).

- 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
- misuse of that information must be actual or threatened, without the confider's consent.[957]

16.53 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.[958]

16.54 There are several defences to an action for breach of confidentiality, including legal compulsion, disclosures in respect of which privilege is claimed, equitable defences, and disclosures made in the public interest.[959]

16.55 A trade secret may be more attractive than patent protection because it is not limited to a specific duration and does not require the time and financial resources involved in obtaining patent protection.[960] However, unlike a patent, a trade secret cannot be enforced against third parties who independently develop the invention. While a patent results in the disclosure of the invention's details in the public domain, trade secret protection is based on the secret nature of the information. Trade secrets can therefore inhibit further research and development by other persons because the knowledge is not placed in the public domain.

Question 16–3. Does trade secrets law have any significant application to the conduct of genetic research and its commercialisation? If so, does the law require reform?

Designs

16.56 Design registration is another form of intellectual property right that may apply to genetic research. The industrial design system protects the distinctive appearance of an article. In order to be protected, a design must differ in appearance

957 J Lahore (ed) *Patents, Trade Marks & Related Rights: Looseleaf service* (2001) Butterworths, Sydney, [33,000], citing *Smith Kline & French Laboratories (Australia) Ltd v Secretary, Department of Community Services and Health* (1990) 17 IPR 545, (Gummow J). It is not clear whether the plaintiff must also show that use or disclosure of the information will be detrimental to the plaintiff.

958 J Lahore (ed) *Patents, Trade Marks & Related Rights: Looseleaf service* (2001) Butterworths, Sydney, [33,260].

959 Ibid, [39,000].

960 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.

from previous works in the area. It has been suggested that design protection may be useful in product development in the biotechnology field, for example by protecting the distinctive appearance of products such as diagnostic kits and analytical tools.[961]

16.57 The *Designs Act 1906* (Cth) (*Designs Act*) grants the owner of a registered design a monopoly in that design. The monopoly is restricted to the article or articles in relation to which the design is registered.[962] The Act defines a 'design' as

> features of shape, configuration, pattern or ornamentation applicable to an article, being features that, in the finished article, can be judged by the eye, but does not include a method or principle of construction.[963]

16.58 The *Designs Act* provides a system for registration of designs. In order to be registered, a design must be 'new or original'. A design will not be registered in respect of an article if the design differs only in immaterial details or in features commonly used in the relevant trade from a design that is already registered, published or used in Australia for the same article; or is an obvious adaptation of a design that is already registered, published or used in Australia in respect of any other article.[964]

16.59 The initial registration period is for a period of 12 months from the date of registration. The registered owner may then apply for an extension until the end of six years from the priority date of the application, followed by two further periods of five years each (16 years in total).[965]

16.60 There is no process for objecting to an application before the initial registration of a design, however a person may challenge the validity of a registered design or oppose the first extension period of registration. Alternatively, 'any person interested' may apply to the prescribed court for the grant of a compulsory licence in prescribed circumstances.[966]

16.61 A registered owner's monopoly in a design is infringed if, without authorisation, a person applies the design, or an obvious or fraudulent imitation of it to any article in respect of which the design is registered; imports an article for which the design has been registered, and for which the design or an obvious or fraudulent imitation of the design has been applied outside Australia; or sells, offers or hires etc

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961 Department of Foreign Affairs and Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001), Commonwealth of Australia, Canberra, see <www.dfat.gov.au/>, 1–20.

962 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 456.

963 *Designs Act 1906* (Cth) s 4(1). An 'article' is as any article of manufacture, including a part of such an article if made separately, but not including an integrated circuit (or part thereof), or a mask used to make such a circuit: s 4(1).

964 Ibid s 17.

965 J McKeough and A Stewart, *Intellectual Property in Australia* (1997) Butterworths, Sydney, 253. See *Designs Act 1906* (Cth) s 27A.

966 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003) Federation Press, Sydney, 474–476.

any article to which the design or obvious imitation of it has been applied whether within or outside Australia.[967]

16.62 In December 2002, the Federal Government introduced the Designs Bill 2002 (Cth) (Designs Bill) and the Designs (Consequential Amendments) Bill 2002 (Cth) into Parliament. If passed, the Designs Bill will replace the existing *Designs Act* and implement a new registration system for industrial designs. The proposed changes include a more streamlined registration system, stricter eligibility and infringement tests, better enforcement and dispute resolution procedures, and clearer definitions.[968]

Question 16–4. Do the existing or proposed design laws have any significant application to the conduct of genetic research and its commercialisation? If so, do the laws require reform?

967 Ibid, 477. See *Designs Act 1906* (Cth) s 30.

968 Explanatory Memorandum to the Designs Bill 2002 (Cth), 1. These Bills represent the Federal Government's response to the ALRC's report, Australian Law Reform Commission, *Designs*, ALRC 74 (1995), ALRC, Sydney.

17. Patents and Competition Law

Contents

Introduction

17.1 This chapter considers the relationship between patent law and competition law. The issue is addressed because of the potential for the holder of a gene patent to behave in an anti-competitive manner. Patent laws appear, at first, to be antithetical to the aims of competition law because they authorise the grant of a legal monopoly. However, the position is more complex than this.

17.2 There are two key pieces of legislation in this area. The *Trade Practices Act 1974* (Cth) (TPA) proscribes a range of anti-competitive conduct.[969] However, the Act contains important exemptions for intellectual property, which are discussed below. The *Patents Act 1990* (Cth) (*Patents Act*) also contains provisions that seek to give effect to competition principles.[970]

Competition law and policy

17.3 Competition laws seek to enhance competition and economic efficiency in the market in the belief that competition between firms drives down prices and enhances the range and quality of goods and services available to consumers. Competition is often thought to be a preferable mechanism for promoting economic growth and high living standards to other mechanisms for allocating scarce resources.

969 *Trade Practices Act 1974* (Cth) Pt IV, s 4D.
970 *Patents Act 1990* (Cth) ss 133, 144–146.

17.4 A key concept in competition policy is that of rivalry, where existing firms compete with each other. In addition, new firms, seeing an opportunity to make a profit, enter the market. Rivalry may also promote the development of new or improved goods.

17.5 Patents also seek to encourage and reward innovation. They do this by creating statutory property rights, which grant a patent holder a right to exclude others or control exploitation by others. This protection lasts for the term of the patent. Typically, the owner of a patent will license others to exploit the patent. Where goods and services created pursuant to a patent compete with other like goods and services, there is no conflict with competition laws. Where patents allow the development of new and improved products, competition may be enhanced.

17.6 However, potential conflict with competition laws occurs when the holder of a patent (or other intellectual property right) engages in anti-competitive conduct or misuses its market power. Issues might arise, for example, over the grant of an exclusive licence to exploit a patent. This could allow a licence holder to use its market power to charge more than a fair return. Additionally, patents held by 'upstream companies'[971] may inhibit further innovation unless the invention is widely licensed.

17.7 The exercise of intellectual property rights is not comprehensively excluded from the operation of Australia's competition laws, but there are important exemptions. Intellectual property is treated differently from other goods and services under competition laws because it is readily copied or replicated and because the use of intellectual property by one person does not generally prevent use of the same property by others.

Gene patents and competition

17.8 Dr Dianne Nicol and Jane Nielsen suggest that gene patents raise a number of anti-competitive concerns including:

- mergers which lead to patent 'bundling';
- refusal to license patents;
- the terms on which patents are licensed;
- obtaining patents for blocking purposes;
- patent pooling and cross licensing;
- licensing 'bundles' of patents; [and]

971 These are companies that hold patents over isolated genetic materials which might be used to develop further inventions such as diagnostic tests or pharmaceutical products ('downstream products').

- entering into licences as part of infringement proceeding settlement agreements.[972]

17.9 Nicol and Nielsen state that broad upstream patents may give rise 'to particularly acute competition law issues', and suggest that the 'ability of the government to monitor biotechnology patents is important in the light of these issues'.[973] They suggest that many biotechnology companies will be unable or unwilling to raise competition issues or instigate litigation and that there 'may be a role for the [Australian Competition and Consumer Commission] to take a more proactive stance'.[974] (See Question 17–4.)

Intellectual Property and Competition Review

17.10 The National Competition Policy (NCP)[975] requires that any legislation with the potential to restrict competition be reviewed and retained only if the benefits to the community outweigh the costs, and if the objectives of the legislation can be achieved only by restricting competition. This requirement led to a Federal Government inquiry commencing in 1999. The Intellectual Property and Competition Review Committee (IPCRC) considered the relationship of intellectual property legislation to competition policy. In 2000, the IPCRC issued its final report (IPCRC Report), which recommended changes to the TPA and to the *Patents Act.*[976] In 2001, the Federal Government issued a formal response in which it accepted most of the recommendations. In the light of the significance of this review, this chapter considers the IPCRC Report in some detail.

Trade Practices Act 1974

17.11 Broadly, the TPA does not oblige patent holders to exploit their patent, or to license others to exploit it.[977] However, there is potential for anti-competitive conduct in relation to the granting of licences. This could occur in relation to the grant of exclusive and non-exclusive licences, as well as the terms of licence agreements.

17.12 The main sections of the TPA that are aimed at anti-competitive conduct are as follows:

- Section 45 forbids provisions in agreements which substantially lessen competition (collusive conduct). Section 45A forbids contracts, arrangements or understandings in relation to price that have the effect of lessening competition (price fixing).

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972 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, 373.

973 Ibid, 373.

974 Ibid, 373.

975 The National Competition Policy is an agreement signed in 1995 between the Federal Government and all State and Territory Governments to encourage competition. See <www.nccc.gov.au>.

976 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia.

977 Failure to license or exploit an innovation may, however, lead to compulsory licensing (see Ch 15).

- Section 46 provides that a corporation with a substantial degree of power in a market shall not take advantage of that power for the purpose of eliminating or substantially damaging existing competitors, or preventing the entry of potential competitors. Section 46 is particularly relevant to the issue of patents and licences and is discussed in more detail below.

- Section 47 forbids exclusive dealing in relation to a number of vertical restraint practices. These practices include a purchaser accepting some restriction on the right to resupply goods and services.

- Section 48 forbids resale price maintenance. This would cover any provision in a licence that required a licensee to impose a condition on any subsequent purchasers that they sell a product or service at a certain price. For example, a licensee of a genetic test cannot specify the price that others are required to charge to perform that test.

17.13 As discussed below, the exemptions for patents and other intellectual property under s 51(3) of the TPA have the effect that ss 45, 45A and 47 do not apply to the extent that they impose or give effect to a condition in a licence or assignment related to the subject matter of a patent (or other intellectual property). This would exempt conditions in licences, for example, as to quality control or other technical matters.

Section 46 and licensing

17.14 Section 46 of the TPA, which targets misuse of substantial market power, has been said to provide 'a potentially powerful compulsory licensing tool'.[978] Where a corporation has substantial power within a market it must not use that power to:

- eliminate or substantially damage a competitor;

- prevent the entry of a person into that or any other market; or

- deter or prevent a person from engaging in competitive conduct in that or any other market.

17.15 While some case law suggests that the exercise of intellectual property rights within their statutory limits will not breach of s 46,[979] a decision of the High Court in 1989 suggests that when a corporation with substantial market power withholds supply it may be seen to have taken advantage of its market power.[980]

978 H Ergas, *Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia*, Network Economics Consulting Group, <www.necg.com.au/pappub/papers-ergas-compulsory-licenses-may02.pdf >, 19 February 2003, [26].

979 *Australasian Performing Rights Association Ltd v Ceridale Pty Ltd* (1991) ATPR [41–074]; *Broderbund Software Inc v Computermate Products (Australia) Pty Ltd* (1992) ATPR [41–155].

980 *Queensland Wire Industries Pty Ltd v The Broken Hill Pty Co Ltd* (1989) 167 CLR 177.

17.16 In a paper delivered in 2002, the Chairman of the IPCRC, Henry Ergas, suggested that the interaction of s 46 and treatment of informational assets under the *Copyright Act 1968* (Cth) (*Copyright Act*) is uncertain.[981] Ergas cited two settlements and a case to suggest that a corporation with significant market power may be required to provide information that they hold to others. These were:

- A settlement between the Australian Competition and Consumer Commission (ACCC) and the Commonwealth Bureau of Meteorology in 1995 required the Bureau to supply basic meteorological data to a competitor and established a general access policy and model licence agreement. The ACCC had alleged a breach of s 46.[982]

- Telstra gave legally enforceable undertakings to the ACCC that it would ensure third-party access to its business telephone directory data. Telstra noted that the price would be much lower than Telstra had initially proposed charging. The ACCC had alleged that Telstra would breach s 46 if it refused to supply the information on reasonable terms.

- The Federal Court held that the Australian Stock Exchange had breached s 46 in restricting the use of electronic information about stock market dealings, which the Exchange had supplied to Pont Data.[983]

17.17 Although these disputes arose in the context of the *Copyright Act*, they also raise issues about the implications of s 46 for patent holders who withhold licences. Ergas concluded that s 46 of the TPA was probably the 'most significant' of the possible grounds for compelling intellectual property licensing, although he noted that

> it has also been argued that the *Patents Act* provisions have considerable value as incentives to reach voluntary licensing agreements.[984]

17.18 As yet there have been no decided cases on s 46 involving gene patents. However, a situation considered by some to be potentially anti-competitive could occur if an 'upstream' patent holder declines to issue a licence to its competitors, thereby blocking further innovation. In order to demonstrate a breach of s 46, it would be necessary to show the nature of the relevant market, whether the company has substantial market power in that market and, if so, whether it had engaged in the proscribed conduct.

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981 H Ergas, *Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia*, Network Economics Consulting Group, <www.necg.com.au/pappub/papers-ergas-compulsory-licenses-may02.pdf>, 19 February 2003, [32].

982 Ibid, [32].

983 *Pont Data Australia Pty Ltd v ASX Operations Pty Ltd* (1990) 21 FCR 385.

984 H Ergas, *Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia*, Network Economics Consulting Group, <www.necg.com.au/pappub/papers-ergas-compulsory-licenses-may02.pdf>, 19 February 2003, [37]. See Ch 15 on the practical effect of the compulsory licensing provisions.

17.19 Jane Nielsen has suggested that:

> On the basis of current case law, it is only in rare circumstances that a refusal to license [intellectual property] will contravene s 46. Generally, this will only occur where a patent owner stifles competition by refusing to license its patent to a competitor in a downstream or secondary market to enable the competitor to produce a new product.[985]

Exemptions for intellectual property

17.20 The TPA contains important exemptions for intellectual property. Section 51(3) exempts intellectual property licences and assignments from the operation of certain sections of the Act. These exemptions apply to ss 45, 45A, 47, 50 and 50A, to the extent that the relevant conduct imposes or gives effect to a condition in a licence or assignment related to the subject matter of a patent (or other intellectual property). Therefore, conditions in a licence specifying technical matters about the patent would be exempt from the operation of the TPA even if they were thought to be anti-competitive in breach of s 45. This exemption does not extend to ss 46, 46A or 48 of the TPA.

17.21 The Australian Government Solicitor has indicated that there is a lack of clarity about the extent of relevant exemptions under s 51(3). One interpretation suggests that exclusive licensing, territorial restraints, and restrictions as to price and quantity in relation to intellectual property rights would be exempt. On another view, the exercise of intellectual property rights is unlikely to constitute a breach of TPA, even absent s 51(3), unless the conduct increases market power above that granted by the intellectual property right.[986]

Intellectual Property and Competition Review

17.22 In its submission to the IPCRC, the National Competition Council (NCC) argued for s 51(3) to be amended to remove protection for price and quantity restrictions and horizontal agreements.[987] The NCC also suggested that the ACCC should formulate guidelines on when licensing and assignment conditions might be exempted under s 51(3) and when the ACCC might give authorisations for conduct otherwise in breach of Part IV and not caught under s 51(3).[988]

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985 J Nielsen, *Biotechnology Patent Licensing Agreements and Anti-Competitive Conduct*, University of Tasmania, <www.lawgenecentre.org/fsrv/symposium2001/nielsen.pdf>, 26 March 2003, 45.

986 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 207.

987 Ibid, 203. Horizontal agreements are arrangements between competitors at the same level in a supply chain.

988 Section 88(1) of the TPA provides that the ACCC may grant an authorisation if satisfied that any anti-competitive aspect of the arrangement or conduct is outweighed by the public benefit arising from the arrangement or conduct.

17.23 The NCC identified two types of conduct as being potentially anti-competitive:

- horizontal arrangements, for example, cross-licences between competitors; and
- other arrangements (horizontal or vertical) that substantially lessen competition, but where there is difficulty in establishing a breach of s 46.[989]

17.24 However, the IPCRC reported that most submissions were opposed to any amendment of s 51(3) along the lines suggested by the NCC. The IPCRC identified a range of objections to the NCC's proposal, which included the following:

- s 51(3) provides certainty, thereby encouraging innovation;
- private funders might go to other jurisdictions;
- there are costs, delay and difficulties in using the ACCC's notification and authorisation processes; and
- s 51(3) obviates the need for expensive investigations into negotiated licensing positions.[990]

17.25 Some submissions to the IPCRC argued that intellectual property ought to be treated no differently from any other property.[991] However, the IPCRC report concluded that intellectual property laws must be able to be exercised to the exclusion of others, in order to encourage innovation. It stated that:

> Intellectual property rights are sufficiently different from other property rights and assets to warrant special exemptions from the general provisions of the Trade Practices Act (TPA).[992]

17.26 The IPCRC Report noted three factors about intellectual property that lead to the use of licences and assignments and which are relevant to any determinations about competition law:

- The initial owners of intellectual property rights are often not the best placed parties to exploit the products derived from their efforts. This applies in genetics where the patent holders may be small publicly funded research organisations.

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989 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 203.
990 Ibid, 208.
991 Ibid, 209.
992 Ibid, 11.

- Products may be developed using dozens of patents. This involves complex arrangements involving cross licensing and multiple owners. This is a feature of some parts of the biotechnology industry, including pharmaceuticals.

- The costs of impeding effective licensing in the intellectual property field can be high. The report noted that because the use of intellectual property by one person does not usually prevent its use by others ('non-rivalrous' usage), there can be inefficiencies in production if there is a need to invent around existing knowledge.[993]

17.27 Accordingly, the IPCRC Report stated there were strong arguments for keeping regulatory burdens to a minimum. Nevertheless, it cautioned against 'open slather' for intellectual property owners to act as they please. The IPCRC Report concluded that the existing exemptions under s 51(3) 'are seriously flawed, as the extent and breadth of the exemptions are unclear, and may well be over-broad'.[994] It did not believe that s 51(3) 'properly defines the interaction between intellectual property laws and Part IV prohibitions'.[995] However, it argued against a simple repeal of the section and recommended:

- repealing the current section 51(3) and related provisions of the TPA; and

- inserting an amended section 51(3) and related provisions in the TPA to give effect to ensuring a contravention of Part IV of the TPA, or of section 4D of that Act, shall not be taken to have been committed by reason of the imposing of conditions in a licence, or the inclusions of conditions in a contract, arrangement or understanding, that relate to the subject matter of that intellectual property statute, so long as those conditions do not result, or are not likely to result, in a substantial lessening of competition. The term 'substantial lessening of competition' is to be interpreted in a matter consistent with the case law under the TPA more generally.[996]

17.28 The IPCRC Report also recommended that the ACCC issue guidelines to assist owners of intellectual property rights to understand the type of behaviour that is likely to be regarded as resulting in a substantial lessening of competition.

Federal Government's response

17.29 In its response to the IPCRC Report, the Federal Government accepted in part the recommendation that intellectual property rights continue to be accorded distinctive treatment under the TPA. It indicated that intellectual property in relation to ss 46, 46A and 48 would continue to be treated as previously. Intellectual property licensing would be subject to the provisions of Part IV, but a contravention of the *per*

993 Ibid, 210–211.
994 Ibid, 211.
995 Ibid, 210.
996 Ibid, 215.

se prohibitions of ss 45, 45A and 47, or of s 4D, would be subject to a substantial lessening of competition test. This means that the arrangements prohibited under ss 4D, 45, 45A and 47 will not apply to intellectual property agreements unless they have the effect of lessening competition.

17.30 The Federal Government's response also indicated that the ACCC would issue guidelines about its enforcement procedures in relation to these provisions. The guidelines would outline:

- when intellectual property licensing and assignments might be exempted under s 51(3);
- when intellectual property licences and assignments might breach Part IV; and
- when conduct that is likely to breach Part IV might be authorised.

17.31 To date, the intellectual property guidelines have not been formulated. The former Chairman of the ACCC, Professor Alan Fels, stated in 2002 that the ACCC would consult with interested parties and consider overseas approaches to antitrust enforcement of intellectual property, including guidelines issued by the United States Department of Justice and Federal Trade Commission, the United Kingdom Office of Fair Trading, and the Competition Bureau of Canada. Professor Fels said that public comment would be sought before the guidelines were released.[997]

Patents Act 1990

17.32 The *Patents Act* includes provisions that seek to give effect to the principles of competition policy. Section 133 provides for compulsory licences to overcome a failure to exploit or licence a product on reasonable terms, and ss 144–146 void contracts that have 'tie-in' conditions.[998]

17.33 The IPCRC Report was critical of the formulation of the test in the *Patents Act* for the grant of a compulsory licence and recommended its replacement with a competition-based test.[999] As discussed in Chapter 15, the Federal Government has accepted the need for a competition-based test, but not to the exclusion of the existing 'reasonable requirements of the public' test that is found in s 133.

17.34 The IPCRC Report noted that 'tie-in' conditions were once considered to be automatically anti-competitive. However, it noted that economists now consider that such conditions can 'enhance efficiency and … reduce the social costs arising from a

997 A Fels, 'Intellectual Property and Competition' (Paper presented at Protecting Intellectual Property or Protecting Consumers: Is There a Trade-Off?, Melbourne, 6 December 2002), 5.

998 These are conditions that (a) require a buyer or licensee to use a product from the patent holder which is not covered by the patent, or (b) limit the sourcing of products or processes from a third party.

999 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 162–163.

patent grant'.[1000] Accordingly, the IPCRC Report recommended the repeal of ss 144–146 and suggested that such conduct should be dealt with through its suggested amendments to s 51(3) of the TPA. The Federal Government announced that it has accepted the IPCRC recommendations in relation to ss 144–146.[1001]

Question 17–1. Following the report of the Intellectual Property and Competition Review Committee in 2000, and the Federal Government's response, are there any competition issues specifically relevant to gene patents that need to be dealt with in the course of this Inquiry?

Cooperative arrangements and patent pools

17.35 Patent pools are agreements between several patent owners to license or assign their collective patents at a single price. They have also been defined as

> the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by a patentee or through some medium, such as a joint venture, set up to administer the patent pool.[1002]

17.36 Patent pools are valuable where more than one patent is required for the development of a product. They exist in fields such as electronics and chemicals. Yet they are potentially anti-competitive because they involve agreements that may impact on the price and availability of goods or services in a market. Professor Warren Pengilley has described them as having

> both useful and pernicious effects. They can be a way of either utilising or of blocking innovative technology.[1003]

17.37 Although the TPA contains certain exemptions for patents and other intellectual property, these do not extend to patent pools. Whether a patent pool is anti-competitive depends on how it operates. Pengilley has identified a number of factors that are relevant to determining whether a patent pool breaches the TPA. These include whether:

- the pool contains price fixing agreements;

1000 Ibid, 161.
1001 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, Commonwealth of Australia, <www.ipaustralia.gov.au/pdfs/general/response1.pdf>, 2 May 2003.
1002 United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000), United States Patents and Trademarks Office, Washington, see <www.uspto.gov>, 4.
1003 W Pengilley, 'Patents and Trade Practices – Competition Policies in Conflict?' (1977) 5 *Australian Business Law Review* 172, 197.

- 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 pool 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; and
- the arrangement amounts to an aggregation of substantial market power and there is a misuse of that power.[1004]

17.38 In the United States, the Justice Department and the Federal Trade Commission issued *Antitrust Guidelines for the Licensing of Intellectual Property* in 1995. These guidelines specifically address patent pool arrangements. They state that pooling is pro-competitive when it:

(1) integrates complementary technologies,

(2) reduces transaction costs,

(3) clears blocking positions,

(4) avoids costly infringement litigation, and

(5) promotes the dissemination of technology.[1005]

17.39 The guidelines state that pooling is anti-competitive if:

(1) the excluded firms cannot effectively compete in the relevant market for the good incorporating the licensed technologies,

(2) the pool participants collectively possess market power in the relevant market, and

(3) the limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies.[1006]

17.40 Patent pools are considered to be an antidote to 'patent thickets', that is, the proliferation of patents needed for further development of a product or process, requiring the negotiation of multiple licences. They may also eliminate the problems

1004 Ibid, 194–197.

1005 United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000), United States Patents and Trademarks Office, Washington, see <www.uspto.gov>, 6.

1006 Ibid, 6.

caused by 'blocking' patents, that is, patents needed for the development of products, the presence of which can prevent further innovation unless a licence is granted.

17.41 The OECD has expressed doubt about whether patent pools are applicable to genetic inventions,[1007] but others have suggested that they may encourage the cooperative efforts needed to realise the benefits of the genomic revolution.[1008]

17.42 The NCC, in its submission to the IPCRC, suggested that patent pools could enhance efficiency in some circumstances, for example, to establish a common industry standard. It suggested that patent pools be dealt with on a case-by-case basis rather than be subject to a blanket exemption.[1009] The IPCRC Report made no specific recommendations about patent pools.

Question 17–2. How should competition law and policy deal with 'patent pools' relating to gene patents?

Prices surveillance

17.43 Chapter 12 discussed the ways in which gene patents may affect the price of associated goods or services, such as medical genetic tests. If there are price effects, there is a question as to whether the federal prices surveillance process might be used if the prices charged are too high. One area of potential concern is where medical genetic tests are performed under an exclusive licence.

17.44 The *Prices Surveillance Act 1983* (Cth) (PSA) regulates the supply of goods and services within Australia for which a price is charged. 'Services' is defined to include 'the performance of work including work of a professional nature, whether with or without the supply of goods'[1010] and this would include medical genetic tests.

17.45 The ACCC exercises a monitoring role on prices charged by the private sector in those areas where competition is light.[1011] The ACCC's role includes a requirement that price increases be notified,[1012] formal monitoring,[1013] and informal

1007 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), OECD, Paris, 67.

1008 United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000), United States Patents and Trademarks Office, Washington, see <www.uspto.gov>, 8.

1009 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement* (2000), Commonwealth of Australia, 203–204.

1010 *Prices Surveillance Act 1983* (Cth) s 3(1).

1011 The role extends to surveillance of prices charged by businesses owned by the Federal Government.

1012 In the past this applied to certain 'declared' goods such as beer and cigarettes.

1013 This has applied to biscuits, compact discs and charges at certain airports.

monitoring.[1014] This power is found under s 17(3) of the PSA, which provides a general framework for price surveillance.

17.46 Under s 17(1) of the PSA, the ACCC has three statutory functions:

- vetting proposed price rises of organisations that have been placed under surveillance;
- holding public inquiries into matters related to prices for the supply of goods or services, and reporting to the Minister the results of each such inquiry; and
- monitoring prices, costs and profits in any industry or business as directed by the Minister, and reporting the findings to the Minister.

17.47 The Minister determines which goods, services or organisations are 'declared' for the purpose of notifying price rises.[1015] At this time, few goods, services or organisations are declared.

17.48 In exercising its power, the ACCC is required under s 17(3)(b) to consider 'the need to discourage a person who is in a position substantially to influence a market for goods or services from taking advantage of that power in setting prices'.

17.49 The Productivity Commission reviewed the PSA in 2001 and considered whether there was a role for prices oversight in areas not covered by the TPA's national access regime, [1016] including intellectual property. The Productivity Commission argued that there were 'severe limitations to the role that price control can play in areas where competition is not strong'. [1017] The Productivity Commission suggested there were difficulties in regulators setting an appropriate price—too high a price would disadvantage consumers, while too low a price could drive firms from an industry. The Commission concluded that 'governments and regulators should be wary of setting prices (either explicitly or indirectly)'.[1018]

17.50 However, the Productivity Commission indicated that, 'although increasingly unlikely', there could be 'pockets of substantial market power in markets of national significance in areas not covered by Part IIIA'[1019] and concluded that price control should be retained as 'a remedy of last resort'.[1020]

1014 This has included interstate airfares and pay TV.
1015 *Prices Surveillance Act 1983* (Cth) s 21(1).
1016 Under Pt IIIA of the TPA, there is an access regime to facilitate businesses obtaining access to services of certain infrastructure facilities, such as ports, power transmission and telecommunications.
1017 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), Commonwealth of Australia, Melbourne, see <www.pc.gov.au/>, XVII.
1018 Ibid, XVII.
1019 Ibid, XVIII.
1020 Ibid, Finding 2.2.

17.51 The Productivity Commission also recommended retention of the inquiry and monitoring function under the NCP but recommended that the PSA be repealed and replaced by a new Part in the TPA.[1021] The PSA has not yet been repealed.

Question 17–3. Is there a role for the Australian Competition and Consumer Commission (ACCC) in monitoring prices that are charged for medical genetic tests or any other products or services arising from the grant of gene patents or licences?

Question 17–4. Is there a role for the ACCC in monitoring the impact on competition of gene patents and licences?

1021 Ibid, rec 5.1.

Abbreviations

AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
ACIP	Advisory Council on Intellectual Property
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
ALRC	Australian Law Reform Commission
ALRC 96	Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), ALRC, Sydney
ARC	Australian Research Council
BIF	Biotechnology Innovation Fund
CAT	Computerised Axial Tomography
cDNA	Complementary DNA
CBAC	Canadian Biotechnology Advisory Committee
CRCs	Cooperative Research Centres
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Cth	Commonwealth of Australia
DEST	Department of Education, Science and Training
DNA	Deoxyribonucleic acid
EPO	European Patent Office
EST	Expressed sequence tag
EU	European Union
GDP	Gross Domestic Product
Gene CRC	Discovery of Genes for Common Human Diseases Cooperative Research Centre
GMO	Genetically modified organism
GTG	Genetic Technologies Corporation Pty Ltd
HD	Huntington's disease
HGDP	Human Genome Diversity Project
HGS	Human Genome Sciences Inc
HGSA	Human Genetics Society of Australasia
HREC	Human Research Ethics Committee
HUGO	Human Genome Organisation
IIF	Innovation Investment Fund
IPCRC	Intellectual Property and Competition Review Committee
IR&D Board	Industry Research and Development Board
JPO	Japan Patent Office
MBS	Medicare Benefits Scheme
MGC	Mammalian Gene Collection

MRI	Magnetic Resonance Imaging
mRNA	Messenger RNA
MSAC	Medical Services Advisory Committee
MTA	Materials transfer agreement
NCC	National Competition Council
NCP	National Competition Policy
NHGRI	National Human Genome Research Institute
NHMRC	National Health and Medical Research Council
NHS	National Health Service (UK)
NIH	National Institutes of Health (US)
OECD	Organisation for Economic Cooperation and Development
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PCR	Polymerase chain reaction
PCT	Patent Cooperative Treaty
PDF	Pooled development funds
PDF Program	Pooled Development Fund Program
PIIP	Pharmaceuticals Industry Investment Program
PSA	*Prices Surveillance Act 1983* (Cth)
R&D	Research and development
RCPA	Royal College of Pathologists of Australasia
RNA	Ribonucleic acid
SMEs	Small and medium enterprises
SNP	Single nucleotide polymorphism
TPA	*Trade Practices Act 1974* (Cth)
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights 1994
UNESCO	United Nations Educational Scientific and Cultural Organization
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization

Glossary

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.

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 of 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.

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.

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 Issues 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 Issues 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 Issues 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.

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.

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.

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.

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 claim
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.

Single nucleotide polymorphism (SNP)
Single nucleotide variations in the genome sequence.

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.