Australian Government

Australian Law Reform Commission

Genes and Ingenuity

REPORT

Gene Patenting and Human Health

REPORT 99
June 2004

ISBN 0-9750600-6-6

Commission Reference: ALRC 99

The Australian Law Reform Commission was established on 1 January 1975 by the *Law Reform Commission Act 1973* (Cth) and reconstituted by the *Australian Law Reform Commission Act 1996* (Cth). The office of the ALRC is at Level 25, 135 King Street, Sydney, NSW, 2000, Australia.

Telephone:	within Australia	(02)	8238 6333
	International	+61 2	8238 6333
TTY:		(02)	8238 6379
Facsimile:	within Australia	(02)	8238 6363
	International	+61 2	8238 6363

E-mail: info@alrc.gov.au

ALRC homepage: www.alrc.gov.au

Printed by The SOS Printing Group (Australia) Pty Ltd

Australian Government

Australian Law Reform Commission

The Hon Philip Ruddock MP
Attorney-General of Australia
Suite MF 21
Parliament House
Canberra ACT 2600

29 June 2004

Dear Attorney-General,

Gene Patenting and Human Health

On 17 December 2002, the Commission formally received a reference from the then Attorney-General, the Hon Daryl Williams AM QC MP, pursuant to the *Australian Law Reform Commission Act 1996*, to undertake a review of intellectual property rights over genes and genetic and related technologies, with a particular focus on human health issues.

On behalf of the Members of the Commission who have been involved in this reference, including Justice Susan Kenny and Justice Susan Kiefel, and in accordance with section 21 of the *Australian Law Reform Commission Act 1996*, we are pleased to present to you the final report in this reference: *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC 99, 2004).

Yours sincerely

Professor David Weisbrot
President

Brian Opeskin
Commissioner

Anne Finlay
Commissioner

Contents

Part F. Licensing and Commercial Arrangements

Part G. Non-Voluntary Uses

Part H. Other Intellectual Property Issues

Terms of Reference

INTELLECTUAL PROPERTY RIGHTS OVER GENETIC MATERIALS AND GENETIC AND RELATED TECHNOLOGIES

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

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

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

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

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

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

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

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

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

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

(ii) the Australian biotechnology sector; and

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

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

(c) any other relevant matter.

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

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

Dated 17 December 2002

Daryl Williams
ATTORNEY-GENERAL

Participants

Australian Law Reform Commission

Division

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

Professor David Weisbrot (President)
Professor Anne Finlay (Commissioner in charge)
Mr Brian Opeskin (Commissioner in charge)
Mr Ian Davis (Commissioner until 12 June 2004)
Justice Susan Kenny (part-time Commissioner from May 2003)
Justice Susan Kiefel (part-time Commissioner from April 2003)

Senior Legal Officers

Bruce Alston
Miranda Biven
Lynne Thompson (until March 2003)

Legal Officers

Gabrielle Carney
Imogen Goold

Project Assistant

Tina O'Brien

Legal Interns

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

Advisory Committee Members

Associate Professor Ian Anderson, Deputy Director, Centre for the Study of Health and Society, University of Melbourne
Justice Annabelle Bennett, Federal Court of Australia
Dr Kerry Breen, Chair, Australian Health Ethics Committee of the National Health and Medical Research Council
Professor Don Chalmers, Dean of Law, University of Tasmania
Professor Andrew Christie, Intellectual Property Research Institute of Australia, University of Melbourne
Dr Trevor Davies, Partner, Allens Arthur Robinson
Dr Carina Dennis, Australasia Correspondent, *Nature*
Professor Paul Greenfield, Senior Deputy Vice-Chancellor, University of Queensland
Dr Eric Haan, Head, South Australian Clinical Genetics Service and Chair of the Human Genetics Society of Australasia
Professor Jane Hall, Director, Centre for Health Economics Research and Evaluation, University of Technology, Sydney
Ms Helen Hopkins, Executive Director, Consumers' Health Forum
Professor John Mattick, Director, Institute of Molecular Bioscience, University of Queensland
Dr Dianne Nicol, Law School, University of Tasmania
Professor Alan Pettigrew, CEO, National Health and Medical Research Council
Dr Bill Pickering, Partner, Blake Dawson Waldron
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, Australian Centre for Intellectual Property in Agriculture, Griffith University
Mr John Stonier, Davies Collison Cave
Professor Ron Trent, Head, Department of Molecular and Clinical Genetics, Royal Prince Alfred Hospital and University of Sydney
Mr Guy Wilmington, Manager–Scientific and Technical Affairs, Medicines Australia (until October 2003)

Consultant

Dr Dianne Nicol, Law School, University of Tasmania

Executive Summary

Genes and Ingenuity

Genes and Ingenuity: Gene Patenting and Human Health (ALRC 99, 2004) is the culmination of a major inquiry by the Australian Law Reform Commission (ALRC). The Report, which contains 50 recommendations for reform, is the product of an extensive research and community consultation effort over 18 months.

The Terms of Reference directed the ALRC to consider—with a particular focus on human health issues—the impact of current patenting laws and practices related to genes and genetic and related technologies on:

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

Given the diversity of interests and concerns encompassed by these three areas, the ALRC's task was a complex and delicate one. For example, reforms that might facilitate access to genetic inventions to assist healthcare providers and researchers could adversely affect the growing Australian biotechnology sector and the development and marketing of new healthcare products.

The impetus for the Inquiry came from within the ALRC and from external events. The ALRC and the Australian Health Ethics Committee (AHEC)—in their two-year inquiry into the protection of human genetic information—identified a range of related intellectual property issues of concern (see *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96, 2003). However, the Terms of Reference for that inquiry did not extend to a full examination of these complex issues; nor were the time and resources available to do them justice. The ALRC suggested instead that gene patenting would be a suitable topic for a fresh inquiry under dedicated Terms of Reference.

Around the same time, health officials in Australia and overseas were expressing growing concern about the implications of gene patents and licences for the cost of and access to healthcare. Of special concern was the behaviour of one United States company—Myriad Genetics Inc (Myriad)—which holds patents over methods and materials used to isolate and detect mutations in two genes that may indicate a predisposition to breast and ovarian cancer (BRCA1 and BRCA2). The concerns, especially in Europe and Canada, related to the breadth of the patents and to the manner of their exploitation. In particular, Myriad had proposed licence conditions that

would have required testing laboratories to send DNA samples to its laboratories in the United States for sequencing. Concerns centred on the price proposed by Myriad for the tests (up to three times those charged by laboratories in Europe and Canada); the quality of the tests; the potential loss of research expertise and data; and the separation of clinical services from research and counselling.

In Australia, Myriad licensed its BRCA1 patents to an Australian company, Genetic Technologies Limited (GTG). GTG announced during the course of the ALRC's Inquiry that it was not proposing to charge a licence fee for BRCA1 testing by public sector laboratories, nor would it require that all BRCA1 testing in Australia be conducted at its laboratories. Nevertheless, concerns remained within the health sector that other companies holding patents over genes associated with predictive and diagnostic testing would, in time, replicate the behaviour of Myriad.

Concerns also were being expressed within the research community about the possible need to obtain licences for the use of patented genetic inventions in research. In a high profile decision in the United States, *Madey v Duke University*,[1] it was held that the experimental use defence was very narrow and not available to an organisation, such as a university, conducting research as part of its legitimate business. Critics of the decision argued that it could have a 'chilling effect' on academic research.

In Australia, the *Patents Act 1990* (Cth) (*Patents Act*) does not expressly exempt experimental or research use of patented inventions from liability for infringement. However, in practice, patent holders generally do not seek licence fees from researchers using patented inventions in their research, except in those circumstances where the fees are incorporated into the cost of purchasing a research tool or other product, or where the research is for commercial purposes. During the Inquiry, GTG revealed that it was asking some research institutions to take out a licence for research using its patented method for the use of non-coding DNA.

The question of whether to recommend a statutory exemption for research or experimentation became a key issue for the Inquiry. It exemplified the complex nature of the ALRC's task. Researchers in Australia are encouraged to commercialise their research, based on a policy that this is the best way to encourage innovation. Australia's growing biotechnology sector is dominated by small and medium-sized enterprises, many of which originated in universities or other publicly funded research organisations, and whose major assets include intellectual property in genetic research tools. If there were a statutory exemption for research use, then these assets would be of little economic value and incentives to develop new products would be eroded. On the other hand, there are legitimate concerns about the time and cost needed to negotiate licences, and about the impact that this could have on further research and development.

1 *Madey v Duke University* 307 F 3d 1351 (2002).

The ALRC consulted widely in the course of the Inquiry. It released two major consultative documents: an Issues Paper (IP 27, July 2003) and a Discussion Paper (DP 68, February 2004). After the release of each, the ALRC conducted targeted consultations with key stakeholders and experts. In all, there were 73 meetings, involving hundreds of individuals from government, industry, academia, the legal profession and the health sector. A total of 119 written submissions were received.

The Inquiry was concerned with two broad areas: the patenting of genetic materials and technologies, and the exploitation of these patents. The Terms of Reference directed the ALRC to have regard to 'the objective of the protection of intellectual property rights to contribute to the promotion of technological innovation'. The Inquiry was concerned to examine whether the Australian patent system was meeting the challenges of the rapidly developing science associated with the sequencing of the human genome. In Australia and overseas, views were expressed that patent systems had not coped well with developments in genetic technologies. The Inquiry heard a broad range of concerns, which included that patents legislation fails to take sufficient account of ethical considerations; that some gene patents are too broad or too readily granted; and that insufficient usefulness or utility is required to be demonstrated to support a claim over a genetic invention.

One frequent concern was that claims over genetic sequences should not be patentable because the sequences—being naturally occurring—are 'discoveries', not inventions. Whatever the merits of that argument, the Inquiry was faced with the fact that since the 1980s—in Australia and internationally—large numbers of patents have been granted on genetic sequences, provided they have been isolated from their natural state and otherwise satisfy the statutory requirements for patentability. The Inquiry ultimately concluded that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed. Rather, it was preferable to focus on reforms that would make the system work better.

Many submissions considered the manner in which a patent holder or its licensee exploits gene patents in the marketplace. During the course of the Inquiry, it became apparent that the behaviour of a small number of patent holders or licensees generated more general concerns about the impact of gene patents and licences. Many of the concerns expressed were anecdotal or hypothetical, and evidence of problems in practice—outside a small number of well-known examples—was more difficult to find. The Inquiry faced the task of recommending reforms that would help the patent system deal with errant behaviour, without stifling future innovation and investment in genetic technologies and the development of the Australian biotechnology industry.

The Inquiry was not directed to undertake a general review of the patent system in Australia. Nevertheless, it became apparent that often it was neither possible nor appropriate to suggest reforms directed solely at the patenting of genetic materials and technologies. To the extent that gene patents highlight any deficiencies in the patenting system generally, it was preferable to direct reforms towards correcting systemic weaknesses to ensure that the system is robust enough to anticipate and respond to

future problems. Further, to propose specific laws for genetic materials and technologies may have had implications for Australia's compliance with obligations under various international trade agreements. As a result, some of the recommendations are aimed at improvements in the patent system in general, including a suite of reforms directed at patent office practice. Others are directed to the appropriate use and exploitation of gene patents and to the relationship between the patent system and the three sectors to which the ALRC is required to have regard—research, biotechnology and healthcare. A number of recommendations encourage greater utilisation of existing mechanisms within the *Patents Act* and *Trade Practices Act 1974* (Cth).

Shortly before the Inquiry concluded, the European Patent Office ruled, in opposition proceedings, that Myriad's patent on the BRCA1 gene in Europe was not valid because it lacked an inventive step. It is not always appreciated that, in granting a patent, a patent office is not making a final determination about the validity of the patent. Such a determination is for the courts, if and when a patent is challenged. One of the key recommendations of this Report is that health departments should consider more actively and strategically whether to exercise any existing legal options—including challenging patents—in order to facilitate access to particular genetic inventions where gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare.

The ALRC has adopted a nuanced approach to reform, which recognises both the generality and longevity of the patents system, on the one hand, and the new challenges generated by human genetic science and technology, on the other. There are many different points at which the patent system might be reformed to address the actual and anticipated problems posed by the patenting of genetic materials and technologies. This does not mean that reform must be sought at every point, but rather that intervention—where needed—should be directed to those areas in which it will be most effective. This Report describes the complexities of the Australian patent system and explains the ALRC's views about the desirability of reform in dealing with problems generated by developments in genetics.

The Report makes important recommendations for reform but it does not suggest any radical overhaul of the patents system. Specific reforms are directed to:

- improving patent law and practice concerning the *patenting* of genetic materials and technologies, including through amendments to the *Patents Act* and changes in the practices and procedures of IP Australia, patent examiners and the courts;
- improving patent law and practice concerning the *exploitation* of gene patents, including in relation to a new defence to claims of patent infringement, Crown use, and compulsory licensing of gene patents;

- ensuring that publicly funded research, where commercialised, results in appropriate public benefit, including through the adoption of appropriate patent practices;
- encouraging universities and other research organisations to raise the awareness of researchers about patenting issues and the commercialisation of research;
- ensuring that Australian research organisations and biotechnology companies are adequately skilled to deal with issues concerning commercialisation and the licensing of patented inventions;
- establishing mechanisms for monitoring the implications of gene patents for research and healthcare so that governments have the ability to intervene where gene patents are considered to have an adverse impact, either in specific cases or systemically;
- clarifying the application of competition law to the exploitation of intellectual property rights, including patented genetic materials and technologies; and
- clarifying the scope and practical application of exceptions to copyright infringement in relation to research.

Most of the recommendations do not require legislative change, but involve the development of new or revised guidelines, or other action by government and non-government bodies involved with various aspects of the patent system or its impact on research, biotechnology, or healthcare. For this reason, the Report contains an 'Implementation Schedule', making clear the lines of responsibility for implementing the various recommendations.

During the life of this project, the Advisory Council on Intellectual Property (ACIP) initiated two inquiries that overlapped with aspects of the ALRC's Inquiry: a review of patents and experimental use; and a review of the Crown use provisions in patents and designs legislation. The report from each ACIP inquiry is expected in late 2004. Given the ALRC's timetable for reporting, it has not been possible to take ACIP's recommendations into account in formulating the final recommendations in this Report, although the ALRC has held discussions with ACIP about common issues.

Part A. Introduction

Chapter 1 provides an introduction and background to the Report, and includes details of the Inquiry's research and public consultation efforts. The chapter outlines the scope of the Inquiry, noting those matters that were regarded as falling outside the Terms of Reference. Chapter 2 outlines the patent system—its historical origins, the function of patents, and the basic criteria for patentability. The chapter also examines the economic benefits derived from the patent system, and factors that may counteract these economic benefits in some situations. Chapter 3 describes the subject matter of gene patents. The chapter identifies four broad categories of 'genetic materials and technologies' and provides a chronology of developments in gene patenting. The

chapter summarises the social and ethical concerns about gene patenting—including concerns raised by Indigenous communities—and explains the overall approach taken by the Inquiry in recommending reform.

Part B. Patent Laws and Practices

Part B describes the system of obtaining, maintaining and challenging patent protection in Australia, and provides international comparisons where relevant.

Chapter 4 considers the international legal framework within which Australian patent law and practice operates. The chapter examines a number of international conventions that seek to harmonise procedural and substantive aspects of patent law. Provisions of a number of international agreements have been given effect in Australian domestic law and these have implications for law reform proposals. The Inquiry also needed to take account of Australia's obligations under multilateral agreements dealing with patents and other intellectual property laws—most notably the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*—and under bilateral free trade agreements with other countries—including the free trade agreement concluded with the United States in 2004.

Chapter 5 provides an overview of the domestic legal framework of the Australian patent system. It outlines the relevant legislation and institutions that comprise the system, focusing on procedural aspects of patent law and practice. The chapter considers the different types of patent protection, the procedure for obtaining a patent, the rights conferred by a patent, and the duration of patent rights. The chapter also discusses the fees charged by IP Australia and recommends that the fees should be structured to discourage patent holders from maintaining patents that lack real commercial value.

Chapters 6 and 7 address concerns that inventions involving genetic materials and technologies do not, or should not, satisfy the requirements for patentability under Australian law. Chapter 6 considers the requirements for patentability and the application of each requirement to inventions involving genetic materials and technologies.

The ALRC has concluded that inventions involving genetic materials and technologies should be assessed according to the same legislative criteria as other inventions. However, gene patents do highlight issues about the way the usefulness of an invention is assessed under Australian law. The ALRC recommends specific reforms to this requirement to increase the burden of proof on applicants and require that 'usefulness' be assessed during the examination of an application for a standard patent. Greater scrutiny of applications during examination should lead to patents that are more likely to withstand challenge. The ALRC also recommends that IP Australia develop guidelines to assist patent examiners in applying the revised usefulness requirement.

Some criticisms of patents over genetic sequences rest on ethical concerns. As discussed below, the Inquiry does not recommend that social or ethical concerns should be added as explicit grounds for excluding an invention from patentability. Arguably, the existing 'manner of manufacture' test in the *Patents Act* allows exclusion on social or ethical grounds under its requirement that an invention must not be 'generally inconvenient', but this provision has rarely been relied upon. The Inquiry considers that the 'manner of manufacture' test (which is based on the *Statute of Monopolies 1623*) is ambiguous and obscure, and recommends that it be reviewed, with a particular focus on the requirement that an invention must not be 'generally inconvenient'.

Chapter 7 discusses exclusions from patentability. It examines arguments that certain types of inventions involving genetic materials and technologies should not be patentable—even assuming that the inventions meet the requirements of patentability. The chapter considers new grounds on which genetic materials or technologies might be excluded from patentability; for example, a specific exclusion for genes and genetic sequences; for methods of medical treatment; or on social or ethical grounds. The ALRC has concluded that there are significant impediments to amending the *Patents Act* to exclude genetic materials from patentability. These include a long history of patenting such inventions, international treaty obligations, and a biotechnology industry dependent on patents and inventions. The ALRC recommends that the *Patents Act* should *not* be amended to exclude genetic materials or technologies from patentability; or to provide a new medical treatment exclusion; or to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.

Some of the criticisms of gene patents—in Australia and internationally—have centred on the capacity of patent offices to assess applications for gene patents effectively and efficiently. It has been suggested that patent offices may lack the resources or expertise to deal with the volume and nature of such applications. Chapter 8 recommends reforms to assist IP Australia in adapting its current practices to the challenges posed by inventions involving genetic materials and technologies, and to enhance mechanisms already adopted by IP Australia to address these issues. These recommendations include enhanced education and training of patent examiners; examination guidelines specific to genetic materials and technologies; and amending the *Patents Act* to require patent examiners to be satisfied on the 'balance of probabilities' when assessing those statutory requirements for patentability that must be considered at the examination stage.

Chapter 9 examines the system for challenging and enforcing patents. One of the issues highlighted by the Inquiry is the difficulty in obtaining information about gene patents, pending gene patent applications, and litigation concerning patents. IP Australia already provides substantial information about Australian patents and patent applications, including through online access to a number of databases. However, the system is complex and requires a fairly high level of understanding to use it effectively. Accordingly, the ALRC recommends that IP Australia develop and

regularly update a comprehensive searchable online database of patents and published patent applications. The ALRC further recommends that the proposed database should contain information about court proceedings concerning Australian patents.

Chapter 10 examines the role of courts and tribunals in the resolution of patent disputes, with a particular focus on the practice and procedure of the Federal Court of Australia, which hears the vast majority of Australian patent cases. The high cost of litigation, and its impact on access to justice, is a recurrent concern in civil proceedings. However, the issue has special importance in challenging or enforcing gene patents because of the significant role of universities and not-for-profit organisations in genetic research in Australia. The ALRC recommends that courts exercising jurisdiction under the *Patents Act* should continue to develop their practices and procedures for dealing with patent matters in order to promote the just, efficient and cost effective resolution of patent disputes. The ALRC also recommends that courts continue to develop procedures and arrangements to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.

Part C. Patents and Genetic Research

Part C considers a range of issues with respect to research involving genetic materials and technologies. These include how public benefit is derived from publicly funded genetic research; whether patenting has a chilling effect on research; whether a statutory exemption is needed for experimental use of patented inventions; and the impact of patenting and commercialisation on research practice.

Chapter 11 discusses how to ensure that public benefit is delivered from publicly funded research, and notes concerns about the definition of what constitutes public benefit. The chapter also discusses problems caused by lack of clarity about ownership of some intellectual property arising from research. The ALRC recommends that research funding bodies review the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles) and provide guidelines on public benefit and commercialisation of research. The Inquiry acknowledges that in most cases research organisations are well placed to make decisions about whether and how research might be commercialised, but recommends that funding bodies should be able, in exceptional cases, to place conditions on funding to encourage wide dissemination of research results. The ALRC prefers this approach to the more stringent United States approach of 'march-in' rights, which allows a federal funding body to seize any intellectual property it has funded, or to direct how it will be commercialised.

Genetic research is conducted at all stages of the continuum from basic research through to research directed toward marketable end products. Chapter 12 discusses the general impact of gene patents on research and describes the specific subject matter and claims of gene patents that are most likely to hinder research—that is, broad patents on upstream or 'foundational' inventions and patents on research tools. The

ALRC recommends that the Australian Research Council and the National Health and Medical Research Council should recognise the public benefit in ensuring the wide dissemination of research tools in their review of the National Principles.

In the light of concerns expressed by researchers about a possible chilling effect of gene patents on research, a key issue for the Inquiry was whether to recommend a statutory exemption for research or experimentation. Arguably, there is an implied exemption for experimentation in Australian law, but there is considerable doubt about its existence and scope. Chapter 13 concludes that the *Patents* Act should be amended to provide for an experimental use exemption. The ALRC recommends that the new exemption be limited to protecting study or experimentation on the subject matter of a patented invention—that is, research with a focus on discovering more about the invention and its properties. Some researchers argued for a broader exemption encompassing all use of patented inventions in research. However, the ALRC does not favour this approach because it would render patent rights over research tools illusory, penalising the Australian biotechnology industry by devaluing inventions that assist research, and removing an important incentive to innovate in this area. A broad exemption was not generally supported in submissions and consultations. The ALRC's recommended exemption is consistent with the approach in the United Kingdom and other member States of the European Union.

Chapter 14 examines the relationship between the culture of research and patenting. It considers the role of academic researchers in the patenting and commercialisation process, and the factors that may adversely affect this process. The ALRC recommends that research organisations should continue to raise the awareness of researchers about intellectual property issues to ensure that potentially valuable intellectual property is not lost. Similarly, it recommends that universities should ensure that students in health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research. The chapter also explores the relationship between the need for secrecy to protect the novelty of a new invention prior to obtaining a patent and the scientific traditions of peer review and replication of studies. The ALRC recommends a review of the operation of the provisions in the *Patents Act* that allow a period of grace if there has been inadvertent publication prior to lodgement of a patent application. It also recommends that research organisations take steps to ensure that their researchers are fully informed about the operation of the grace period provisions.

Chapter 15 focuses on stem cell technologies. Many of the concerns expressed about the patenting of stem cell technologies and the exploitation of stem cell patents are similar to those expressed about gene patents generally. However, there is particular controversy in the community about the ethical dimensions of embryonic stem cell research. Given that stem cells are an emerging and rapidly developing area of technology, the ALRC recommends that IP Australia should develop specific examination guidelines to explain how the criteria for patentability apply to inventions involving stem cells and related technologies. The ALRC further recommends that an examination of whether to establish an Australian stem cell bank should be addressed as part of the forthcoming reviews to be conducted under the *Research Involving*

Human Embryos Act 2002 (Cth) and the *Prohibition of Human Cloning Act 2002* (Cth).

Part D. Patents and Commercialisation of Biotechnology

Part D describes the biotechnology industry in Australia, the impact of patents on the industry, and issues surrounding the commercialisation of inventions arising from publicly funded research.

Chapter 16 notes that the biotechnology sector is a growing sector that is highly dependent on patents. It comprises a mix of small and medium-sized enterprises; some larger companies, including subsidiaries of multinationals; and a range of research organisations, such as universities, research institutions, health departments and other government agencies. These organisations have an important role in developing intellectual property in genetic research.

Chapter 17 examines the transfer of upstream research from research organisations to the biotechnology industry for commercial development. The industry is highly dependent on publicly funded research, but there are concerns about the capacity of some research organisations to transfer intellectual property effectively. Impediments include lack of commercial experience or institutional support; researcher attitudes; difficulty in finding industry receptors; and lack of resources. The chapter discusses the variability in transfer practices and problems with lack of clear ownership of patented technology—factors that may also hamper effective technology transfer. The ALRC recommends a number of strategies to address these issues, such as programs to assist technology transfer offices to improve commercialisation of inventions involving genetic materials and technologies, and guidelines about ownership of intellectual property resulting from collaborative or jointly funded research.

Chapter 18 examines the impact of patents on the downstream section of the biotechnology sector and considers ways in which gene patents may act as a barrier to commercial development of genetic research results. Mirroring a recommendation in Chapter 17, the ALRC recommends that Biotechnology Australia develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies.

Part E. Patents and Human Health

Part E examines the impact of gene patents and licences on the Australian healthcare system and on healthcare provision. It also discusses whether the *Patents Act* should provide a defence for the use of patented inventions in medical treatment.

Chapter 19 discusses the potential impact of gene patents on the healthcare system, how gene patents may contribute to the cost of healthcare, and the possible implications of gene patents for healthcare funding. The chapter suggests that health departments need to be more active in monitoring the impact of gene patents and

licences on the healthcare system. The chapter makes recommendations with respect to: the economic evaluation of genetic medical technologies; examination of the financial impact of gene patents on the delivery of healthcare services in Australia; the possible role of government funding and purchasing power in relation to genetic materials and technologies; and how health departments, with advice from the proposed Human Genetics Commission of Australia, may better manage legal and other issues relating to gene patents. The ALRC recommends that where particular gene patent applications, patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, health departments should consider whether to exercise any of the existing legal options to facilitate access to the inventions.

Gene patents may have an impact on the development and provision of healthcare involving medical genetic testing and novel therapies, such as gene therapy, the production of therapeutic proteins, and the use of stem cells. Chapter 20 focuses on the impact of patent laws and practices on medical genetic testing—the source of most concern in Australia and overseas about the impact of gene patents on healthcare. The chapter notes that in the United States gene patent holders are actively enforcing their rights against laboratories. However, there is little evidence that the same is true in Australia, despite growing concern about this possibility. Concerns about exclusive licensing of patents related to genetic tests include the potential impact on costs, access to testing, the quality of testing, and innovation in the development of new or improved testing techniques. The chapter discusses how recommendations elsewhere in the Report may assist in dealing with these problems.

Chapter 21 discusses the arguments for and against the introduction of a medical treatment defence in the *Patents Act.* Although there was some support for the introduction of such a defence, the ALRC makes no recommendation along these lines. A general medical treatment defence, as found in United States legislation, would seldom apply to medical treatment involving gene patents because these usually involve products and processes for use outside the human body. In relation to a defence applying specifically to the use of patented genetic materials and technologies in medical treatment, the ALRC has concluded it is premature to propose a significant diminution of patent rights where there is no demonstrated harm, particularly as such a reform has the potential to reduce innovation and investment in some areas of medical technology.

Part F. Licensing and Commercial Arrangements

Part F examines issues surrounding the exploitation of patent rights, in particular the licensing of such rights by patent holders. This Part considers how the government and industry can take steps to improve commercialisation and access to licensed technology. The Part also examines the role of competition law in relation to the anti-competitive use of intellectual property rights and mechanisms for monitoring the prices of patented genetic technologies.

Chapter 22 describes the various types of patent licences and their usual terms. The size and character of the Australian biotechnology industry mean that patent licensing is particularly important to facilitate further research and to allow the development and commercialisation of products. The chapter notes that while available evidence does not suggest restrictive licensing practices are pervasive in the Australian biotechnology industry, participants in the sector may have experienced some difficulties negotiating patent licences. The ALRC considers that an effective way to address these matters is for government, working with industry, to enhance education programs about licensing inventions that involve genetic materials and technologies. The ALRC also recommends that the peak industry body, AusBiotech Ltd, develop model licence agreements and consider whether additional industry initiatives are needed to facilitate the licensing of gene patents.

Chapter 23 discusses another option to facilitate access to patented genetic inventions, namely the creation of a statutory licensing scheme under the *Patents Act*. In the light of recommendations made in the Report to facilitate access to patented genetic inventions, and due to the lack of a demonstrated need, the ALRC does not recommend a statutory licensing scheme. However, the chapter identifies the United Kingdom's voluntary 'licence of right' for patented inventions, and the regime for licensing schemes within Part IV of the *Copyright Act 1968* (Cth) as useful models, should the need for a statutory licensing scheme arise in the future.

Chapter 24 examines the extent to which Part IV of the *Trade Practices Act 1974* (Cth) (TPA) can be used to address the anti-competitive exercise of intellectual property rights in genetic materials and technologies. The Inquiry did not hear evidence that the exploitation of intellectual property rights in such inventions has raised significant competition problems to date. Nevertheless, the ALRC notes both the potential for problems to arise and the concerns expressed in previous reviews about the lack of clarity in relation to intellectual property rights under the TPA. The ALRC recommends that the TPA be amended to clarify the relationship between Part IV of the Act and intellectual property rights. The Australian Competition and Consumer Commission (ACCC) has previously been requested to issue guidelines to clarify this relationship, and the ALRC recommends that this be done both generally and in relation to genetic materials and technologies, in particular. The ALRC also recommends that health departments and other stakeholders should make use of the existing complaint procedures under the TPA where evidence arises of anti-competitive conduct that may have an adverse impact on medical research or the cost-effective provision of healthcare.

Chapter 25 discusses the various forms of prices oversight that are available to the Australian Government and recommends that if evidence arises that the price of patented genetic inventions is having an adverse impact on access to healthcare services, the Government should use these mechanisms to investigate firm or industry pricing practices.

Part G. Non-Voluntary Uses

There are various mechanisms in the *Patents Act* to permit access to patented genetic inventions without the consent of the patent or licence holder. Part G examines the Crown use and compulsory licensing provisions.

Crown use provisions are an important mechanism through which government and its agencies may, in specific cases, address concerns that gene patents are hindering research or the provision of healthcare. Chapter 26 notes that these provisions are rarely used, but suggests that they constitute an important safeguard in helping to ensure that patent protection does not adversely affect significant public interests. The ALRC recommends that policies should be developed about the circumstances in which it is appropriate for government to invoke Crown use for the purposes of promoting human health.

Chapter 27 considers the compulsory licensing provisions of the *Patents Act*. Compulsory licences are another mechanism with potential to facilitate access to patented genetic materials and technologies for use in research and the provision of healthcare. However, few, if any, compulsory licences have been granted under Australian law. A court may grant a compulsory licence in limited circumstances if it is satisfied that the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied; and the patent holder has not given a satisfactory reason for failing to exploit the patent. The ALRC recommends reforms to add a competition-based test to the grounds for awarding a licence, and to clarify the scope of the current test.

Part H. Other Intellectual Property Issues

Although the Inquiry focused on the patentability of genetic materials and technologies, there are related intellectual property issues that have a bearing on research, commercialisation and healthcare in this field. Chapter 28 discusses the application of copyright law to the written representation of gene and protein sequences, and to databases holding genetic sequence information. It discusses the application of the fair dealing exception to copyright infringement for the purpose of research or study; and the need to achieve an appropriate balance between the rights of database owners and researchers. The Report recommends that the *Copyright Act* be amended to provide that research with a commercial purpose or objective is research in the context of fair dealing for the purpose of research or study. Further issues arise in relation to the practical exercise of fair dealing. The ALRC also makes recommendations in relation to technological protection measures and contract. As with some other recommendations in the Report, these are not directed solely at genetic databases. The Inquiry considered it preferable to correct systemic weaknesses highlighted by issues concerning genetic databases.

List of Recommendations

Part B. Patent Laws and Practices

5. Domestic Legal Framework

5–1 IP Australia should:

(a) assess the impact of patent fees on the actual term of Australian patents; and

(b) periodically review the structure and quantum of patent fees to ensure that fees are set at levels appropriate to discourage patent holders from maintaining patents that lack real commercial value.

6. Patentability of Genetic Materials and Technologies

6–1 Patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.

6–2 The responsible Minister should initiate an independent review of the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be 'generally inconvenient'.

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

(a) include 'usefulness' as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent;

(b) provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use;

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

(d) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation. (See also Recommendation 8–3.)

6–4 IP Australia should develop guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should outline factors relevant to determining whether a use disclosed in a patent application is specific, substantial and credible to a person skilled in the relevant art.

7. Exclusions from Patentability

7–1 The *Patents Act 1990* (Cth) should *not* be amended:

(a) to exclude genetic materials and technologies from patentable subject matter;

(b) to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter; or

(c) to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.

Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention.

8. Patent Office Practices

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

8–2 IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth) (*Patents Act*), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

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

9. Challenging and Enforcing Patent Rights

9–1 IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should:

(a) be accessible to the public through IP Australia's website;

(b) provide user-friendly access and search capabilities on a wide variety of bases; and

(c) as soon as practicable, provide full-text searching of all complete specifications of published Australian patent applications and granted patents.

9–2 Information about patent litigation should be readily accessible to the public. To this end:

(a) the Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to require courts exercising jurisdiction under the Act to give written notice to the Commissioner of Patents when a legal proceeding to challenge or enforce a patent is commenced, and when a decision or judgment is given in any such proceeding;

(b) the Commissioner of Patents should include information about any such notice in the file of a patent and make the information readily available, for example in the *Official Journal of Patents* and in the patents database on IP Australia's website; and

(c) courts exercising jurisdiction under the *Patents Act* should amend their Rules of Court, as necessary, to give effect to this Recommendation.

10. The Role of Courts and Tribunals in Patent Disputes

10–1 Courts exercising jurisdiction under the *Patents Act 1990* (Cth) (*Patents Act*) should continue to develop their practices and procedures for dealing with patent matters in order to promote the just, efficient and cost effective resolution of patent disputes.

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

Part C. Patents and Genetic Research

11. Publicly Funded Research and Intellectual Property

11–1 The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles) to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Recommendations 12–1 and 17–2.)

11–2 The ARC and NHMRC should develop guidelines to assist organisations receiving public funding for research in complying with the National Principles. The guidelines should, among other things:

(a) provide guidance on what is meant by 'public benefit';

(b) assist organisations in determining whether it is appropriate for particular research results to be commercialised; and

(c) identify a range of approaches to the exploitation of intellectual property and the circumstances in which they might be used.

11–3 In exceptional circumstances, where the public benefit would clearly be served by broad dissemination of the results of publicly funded research, the ARC and the NHMRC should consider attaching conditions to the grant of funding. These conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.

11–4 Research organisations should ensure that their policies on intellectual property ownership cover research undertaken by visiting researchers, students and staff—whether undertaken solely within the organisation or jointly with other bodies. (See also Recommendation 17–4.)

12. Patents and Human Genetic Research

12–1 The Australian Research Council and the National Health and Medical Research Council, in implementing Recommendations 11–1 to 11–3, should recognise the public benefit in ensuring the wide dissemination of research tools.

13. An Experimental Use Exemption

13–1 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:

(a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;

(b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and

(c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the *Patents Act*.

14. Research Culture, Patents and Commercialisation

14–1 Research organisations should continue to take steps to raise the awareness of researchers in health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required.

14–2 Universities should ensure that students undertaking degrees in health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.

14–3 The responsible Minister should initiate a review of the grace period provisions in the *Patents Regulations 1991* (Cth) (*Patents Regulations*) to examine:

(a) whether they are well understood by the research community; and

(b) how they have affected the commercialisation of Australian research in Australia or overseas.

14–4 Research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the *Patents Regulations*, particularly in relation to:

(a) the effect of publication before filing a patent application; and

(b) the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.

15. Stem Cell Technologies

15–1 IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cells and related technologies.

15–2 As part of the independent reviews to be conducted under the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning Act 2002* (Cth), the responsible Minister and the National Health and Medical Research Council should require an examination of the exploitation of intellectual property rights over stem cells when considering the establishment of a National Stem Cell Bank.

Part D. Patents and Commercialisation of Biotechnology

17. Technology Transfer

17–1 Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector:

(a) to further develop and implement programs to assist technology transfer offices in research organisations in commercialising inventions involving genetic materials and technologies; and

(b) to develop strategies to ensure widespread participation of technology transfer offices in these programs.

17–2 The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC), in implementing Recommendation 11–1, should recognise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research.

17–3 The ARC and NHMRC, in implementing Recommendation 11–2, should:

(a) provide guidance on ensuring clear ownership of intellectual property resulting from collaborative or jointly funded research; and

(b) identify a range of approaches to ensuring clarity of ownership.

17–4 Research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research. (See also Recommendation 11–4.)

17–5 Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector to develop model materials transfer agreements for use by research organisations, along the lines of the models developed by the United States Association of University Technology Managers. (See also Recommendation 22–2.)

18. Patents and the Biotechnology Industry

18–1 Biotechnology Australia, in conjunction with its member departments, and in consultation with state and territory governments and other stakeholders, should:

(a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and

(b) develop strategies to ensure widespread participation of biotechnology companies in these programs.

Part E. Patents and Human Health

19. Gene Patents and the Healthcare System

19–1 The Australian Health Ministers' Advisory Council (AHMAC) should establish processes for:

(a) economic evaluation of medical genetic testing and other new genetic medical technologies; and

(b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

19–2 AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

19–3 Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should consider whether to exercise any existing legal options to facilitate access to the inventions. These options should be exercised only with appropriate legal or patent attorney advice, and include:

(a) challenging a patent application or granted patent by initiating proceedings to oppose a patent application; requesting re-examination of a patent; or applying for revocation of a patent under the *Patents Act 1990* (Cth) (*Patents Act*) (see Chapter 9);

(b) making a complaint to the Australian Competition and Consumer Commission where evidence arises of a potential breach of Part IV of the *Trade Practices Act 1974* (Cth) (see Chapter 24);

(c) exploiting or acquiring a patent under the Crown use and acquisition provisions of the *Patents Act* (see Chapter 26); or

(d) applying for the grant of a compulsory licence under the *Patents Act* (see Chapter 27).

19–4 The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. The HGCA should liaise with and provide advice to AHMAC, health departments, and other stakeholders about ways to facilitate access to inventions, in accordance with Recommendation 19–3. Pending the establishment of the HGCA, AHMAC should establish a mechanism to perform these functions.

Part F. Licensing and Commercial Arrangements

22. Licensing of Patent Rights

22–1 Biotechnology Australia, in conjunction with its member departments, should develop and implement programs to assist research organisations and biotechnology companies in licensing and commercialising inventions involving

genetic materials and technologies. The programs should be developed in collaboration with state and territory governments, peak national bodies with an interest in licensing and commercialisation of intellectual property, and other relevant stakeholders. (See also Recommendations 17–1 and 18–1.)

22–2 AusBiotech Ltd, as the peak industry body in the biotechnology sector, should develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. The model agreements should be developed in collaboration with Biotechnology Australia, state and territory governments, and other relevant stakeholders as a non-binding model of desirable licensing practices. (See also Recommendation 17–5.)

22–3 AusBiotech Ltd should consider whether additional industry initiatives are necessary or desirable to facilitate the licensing of patent rights over genetic materials and technologies.

24. Competition Law and Intellectual Property

24–1 The Commonwealth should amend s 51(3) of the *Trade Practices Act 1974* (Cth) (*Trade Practices Act*) to clarify the relationship between Part IV of the Act and intellectual property rights.

24–2 The Australian Competition and Consumer Commission (ACCC) should develop guidelines to clarify the relationship between Part IV of the *Trade Practices Act* and intellectual property rights. The guidelines should address:

(a) when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV; and

(b) when conduct that would otherwise breach Part IV might be authorised under Part VII of the *Trade Practices Act*.

The guidelines should extend to the exploitation of intellectual property rights in genetic materials and technologies, including patent pools and cross-licensing.

24–3 As the need arises, the ACCC should review the conduct of firms dealing with genetic materials and technologies protected by intellectual property rights, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act.*

24–4 Commonwealth, state and territory health departments, and other stakeholders, should make use of existing complaint procedures under the *Trade Practices Act* where evidence arises of conduct that may breach Part IV and have an adverse impact on medical research or the cost-effective provision of healthcare.

25. Prices Oversight

25–1 If evidence arises that the prices of patented genetic materials and technologies have adversely affected access to healthcare services in Australia, the responsible Minister should consider whether to:

(a) refer the matter to the Productivity Commission for a study or inquiry pursuant to the *Productivity Commission Act 1998* (Cth); or

(b) direct the Australian Competition and Consumer Commission, or another body, to conduct an inquiry pursuant to Part VIIA of the *Trade Practices Act 1974* (Cth).

Part G. Non–Voluntary Uses

26. Crown Use and Acquisition

26–1 The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the *Patents Act 1990* (Cth) (*Patents Act*) for the purposes of promoting human health. Similarly, the Department of Health and Ageing should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health. Decisions about Crown use in specific cases must be made on their individual merits.

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

26–3 The Commonwealth should amend the *Patents Act* to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the use. Similarly, the Act should be amended to provide that, when a patent is acquired under the Crown acquisition provisions, compensation must be paid promptly and must be just and reasonable having regard to the economic value of the patent.

27. Compulsory Licensing

27–1 The Commonwealth should amend the provisions of the *Patents Act 1990* (Cth) relating to compulsory licences by:

(a) inserting the competition-based test recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence; and

(b) clarifying the scope of the 'reasonable requirements of the public test'.

Part H. Other Intellectual Property Issues

28. Copyright and Databases

28–1 The Commonwealth should amend the *Copyright Act 1968* (Cth) (*Copyright Act*) to provide that research with a commercial purpose or objective is 'research' in the context of fair dealing for the purpose of research or study.

28–2 The Commonwealth should amend the *Copyright Act* to provide that, in relation to databases protected by copyright, the operation of the provisions relating to fair dealing for the purpose of research or study cannot be excluded or modified by contract.

28–3 Prior to the implementation of art 17.4.7 of the Australia–United States Free Trade Agreement—which includes a prohibition on the circumvention of access control measures—the Australian Government should assess the need for an exception for researchers engaging in fair dealing for the purpose of research or study in relation to databases protected by copyright. Once the prohibition has been implemented, the Australian Government should periodically review the impact of the anti-circumvention provisions on the practical exercise of fair dealing for the purpose of research or study in copyright works.

Implementation Schedule

This schedule lists the action required of different bodies to implement the recommendations in ALRC 99. The required action is identified in summary form; full details may be found in the List of Recommendations and in the corresponding chapter. The schedule does not list bodies whose role in relation to a proposal is only to be consulted by another body that has primary responsibility for implementing the proposal.

AusBiotech Ltd

22–2 Develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies.

22–3 Consider whether additional industry initiatives are necessary or desirable to facilitate the licensing of patent rights over genetic materials and technologies.

Australian Competition and Consumer Commission

24–2 Develop guidelines to clarify the relationship between Part IV of the *Trade Practices Act 1974* (Cth) and intellectual property rights.

24–3 As the need arises, review the conduct of firms dealing with genetic materials and technologies protected by intellectual property rights to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act*.

Australian Government

6–3 Amend the *Patents Act 1990* (Cth) to: (a) include 'usefulness' as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent; (b) provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use; (c) require the Commissioner of Patents to be satisfied on the balance of probabilities that the criterion of usefulness is made out; and (d) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed.

8–3 Amend the *Patents Act* to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination.

9–2 Amend the *Patents Act* to require courts to give written notice to the Commissioner of Patents when a legal proceeding to challenge or enforce a patent is commenced, and when a decision or judgment is given in any such proceeding.

13–1 Amend the *Patents Act* to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention.

24–1 Amend s 51(3) of the *Trade Practices Act* to clarify the relationship between Part IV of the Act and intellectual property rights.

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

26–3 Amend the *Patents Act* to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the use; and that when a patent is acquired under the Crown acquisition provisions, compensation must be paid promptly and must be just and reasonable having regard to the economic value of the patent.

27–1 Amend the provisions of the *Patents Act* relating to compulsory licences by (a) inserting the competition-based test recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence; and (b) clarifying the scope of the 'reasonable requirements of the public' test.

28–1 Amend the *Copyright Act 1968* (Cth) to provide that research with a commercial purpose or objective is 'research' in the context of fair dealing for the purpose of research or study.

28–2 Amend the *Copyright Act* to provide that, in relation to databases protected by copyright, the operation of the provisions relating to fair dealing for the purpose of research or study cannot be excluded or modified by contract.

28–3 Prior to implementing art 17.4.7 of the Australia–United States Free Trade Agreement, assess the need for an exception to the prohibition on the circumvention of access control measures for researchers engaging in fair dealing for the purpose of research or study in relation to databases protected by copyright; and once the prohibition has been implemented, periodically review the impact of the anti-circumvention provisions on the practical exercise of fair dealing for the purpose of research or study in copyright works.

Australian Health Ministers' Advisory Council

19–1 Establish processes for: (a) economic evaluation of medical genetic testing and other new genetic medical technologies; and (b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

19–2 Examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

19–4 Pending the establishment of the Human Genetics Commission of Australia, monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases.

26–1 Develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the *Patents Act* for the purposes of promoting human health.

Australian Research Council

11–1 Review the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles) to ensure that publicly funded research, where commercialised, results in appropriate public benefit.

11–2 Develop guidelines to assist organisations receiving public funding for research in complying with the National Principles.

11–3 Consider, in exceptional circumstances, attaching conditions to the grant of funding where the public benefit would clearly be served by broad dissemination of the results of publicly funded research.

12–1 In implementing Recommendations 11–1 to 11–3, recognise the public benefit in ensuring the wide dissemination of research tools.

17–2 In implementing Recommendation 11–1, recognise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research.

17–3 In implementing Recommendation 11–2, provide guidance on ensuring clear ownership of intellectual property resulting from collaborative or jointly funded research; and identify a range of approaches to ensuring clarity of ownership.

Biotechnology Australia

17–1 Further develop and implement programs to assist technology transfer offices in research organisations in commercialising inventions involving genetic materials and technologies; and develop strategies to ensure widespread participation of technology transfer offices in these programs.

17–5 Develop model materials transfer agreements for use by research organisations.

18–1 Develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and develop strategies to ensure widespread participation of biotechnology companies in these programs.

22–1 Develop and implement programs to assist research organisations and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies.

Commonwealth, state and territory health departments

19–3 Consider whether to exercise any existing legal options to facilitate access to genetic inventions, where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare.

24–4 Make use of existing complaint procedures under the *Trade Practices Act* where evidence arises of conduct that may breach Part IV and have an adverse impact on medical research or the cost-effective provision of healthcare.

Courts exercising jurisdiction under the Patents Act

9–2 Amend Rules of Court, as necessary, to require notification to be given to the Commissioner of Patents of legal proceedings to challenge or enforce a patent.

10–1 Continue to develop practices and procedures for dealing with patent matters in order to promote the just, efficient and cost effective resolution of patent disputes.

10–2 Continue to develop procedures and arrangements to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.

Department of Health and Ageing

See also under 'Commonwealth, state and territory health departments'.

26–1 Develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health.

Human Genetics Commission of Australia

19–4 Monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases.

IP Australia

5–1 Assess the impact of patent fees on the actual term of Australian patents; and periodically review the structure and quantum of patent fees to ensure that fees are set at levels appropriate to discourage patent holders from maintaining patents that lack real commercial value.

6–4 Develop guidelines to assist patent examiners in applying the 'usefulness' requirement.

8–1 Enhance efforts to provide patent examiners with education and training in areas of technology relevant to their particular specialty; and review and update these programs regularly.

8–2 Develop examination guidelines to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

9–1 Develop and regularly update a searchable online database comprising patents and published patent applications.

9–2 Include information about legal proceeding to challenge or enforce a patent in the file of a patent and make this information readily available, when notified by a court.

15–1 Develop examination guidelines to explain how the criteria for patentability apply to inventions involving stem cells and related technologies.

Minister for Health and Ageing

15–2 Require the forthcoming review of the *Prohibition of Human Cloning Act 2002* (Cth) to examine the exploitation of intellectual property rights over stem cells when considering the establishment of a National Stem Cell Bank.

Minister for Industry, Tourism and Resources

6–2 Initiate an independent review of the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be 'generally inconvenient'.

14–3 Initiate a review of the grace period provisions in the *Patents Regulations* to examine: (a) whether they are well understood by the research community; and (b) how they have affected the commercialisation of Australian research in Australia or overseas.

National Health and Medical Research Council

11–1 Review the National Principles to ensure that publicly funded research, where commercialised, results in appropriate public benefit.

11–2 Develop guidelines to assist organisations receiving public funding for research in complying with the National Principles.

11–3 Consider, in exceptional circumstances, attaching conditions to the grant of funding where the public benefit would clearly be served by broad dissemination of the results of publicly funded research.

12–1 In implementing Recommendations 11–1 to 11–3, recognise the public benefit in ensuring the wide dissemination of research tools.

15–2 Require the forthcoming review of the *Research Involving Human Embryos Act 2002* (Cth) to examine the exploitation of intellectual property rights over stem cells when considering the establishment of a National Stem Cell Bank.

17–2 In implementing Recommendation 11–1, recognise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research.

17–3 In implementing Recommendation 11–2, provide guidance on ensuring clear ownership of intellectual property resulting from collaborative or jointly funded research; and identify a range of approaches to ensuring clarity of ownership.

Research organisations

11–4 Ensure that policies on intellectual property ownership cover research undertaken by visiting researchers, students and staff—whether undertaken solely within the organisation or jointly with other bodies.

14–1 Continue to take steps to raise the awareness of researchers in health sciences and biotechnology about intellectual property issues and the commercialisation of research.

14–4 Ensure that researchers are fully informed about the operation of the grace period provisions in the *Patents Regulations 1991* (Cth), particularly in relation to: (a) the effect of publication before filing a patent application; and (b) the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.

17–4 Ensure that policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research.

Treasurer

25–1 If evidence arises that the prices of patented genetic materials and technologies have adversely affected access to healthcare services in Australia, consider whether to: (a) refer the matter to the Productivity Commission for a study or inquiry pursuant to the *Productivity Commission Act*; or (b) direct the Australian Competition and Consumer Commission, or another body, to conduct an inquiry pursuant to Part VIIA of the *Trade Practices Act*.

Universities

14–2 Ensure that students undertaking degrees in health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.

PART A

Introduction

1. Introduction to the Inquiry

Contents

Background to the Inquiry

1.1 On 4 December 2002 the Australian Government announced that it would ask the Australian Law Reform Commission (ALRC) to conduct an inquiry into intellectual property issues raised by genetic information.[1] Soon afterwards, the Government released the Terms of Reference,[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 genetic research and genetic and related technologies.

1.2 The ALRC and the Australian Health Ethics Committee (AHEC) had previously identified the need for such an inquiry 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. It was not possible to examine gene patenting issues in that inquiry because of differences in subject matter and the additional time and resources that would have been necessary to do justice to the complexity of gene patenting.[3] Accordingly, in October 2001 the ALRC and AHEC wrote to the Attorney-General

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.

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

and the Minister for Health and Aged Care to suggest that the intellectual property issues raised by genetics become the subject of a fresh inquiry with its own Terms of Reference. This Report is the outcome of that request.

1.3 The gene patenting Inquiry was conducted independently of the earlier reference on the protection of human genetic information, but the relationship between the projects is nevertheless important. The final Report of the joint inquiry by the ALRC and AHEC, *Essentially Yours: The Protection of Human Genetic Information in Australia*, was tabled in Parliament on 29 May 2003.[4] It contained 144 recommendations, addressed to over 30 bodies, in relation to areas as diverse as medical research, health services, employment, insurance, immigration, sport, parentage and law enforcement. The Report made recommendations about how to close emerging gaps in the legal protection of human genetic information so that Australia may harness the benefits of human genetic science and technology, while avoiding the dangers, as we enter a new genetics era. *Essentially Yours* is referred to, as the need arises, in this Report.

Defining the scope of the Inquiry

Terms of Reference

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

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

1.5 The ALRC was also asked to report on what changes 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'. Thus, although the focus of the Inquiry was on patent laws and practices, other intellectual property issues (such as copyright in genetic databases) were relevant to the final recommendations. This was all to be done 'with a particular focus on human health issues'.

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

---

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

- 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.

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

Related matters not under investigation

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

- The Inquiry was 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. It was not a general review of Australian law in relation to patents or other intellectual property rights. However, some proposals for reform have a wider application because of the practical or legal difficulty of confining reform to gene patents.
- The Inquiry did not generally consider the impact of gene patents associated with plants and animals. However, where an animal's genetic material is used to develop a therapeutic product or process to be used in human medical treatment, the patent issues may be relevant to human health and thus fall within the scope of the Inquiry.

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

- Finally, the Inquiry did not extend to genetic research on humans for purposes unrelated to human health. For example, patents over genetic tests used to determine biological kinship, or used in DNA profiling for law enforcement purposes, were regarded as falling outside the scope of the Inquiry.

Process of reform

1.9 The ALRC adopts similar methods across its law reform projects, although these may be tailored to the circumstances of a particular inquiry. The process is essentially one of intensive research on the part of members and staff of the Commission, which is informed by the guidance of an Advisory Committee, targeted consultations with stakeholders, and written submissions received in response to the publication of community consultation papers. Each of these elements is described further below.

Advisory Committee

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

1.11 The Advisory Committee met on 23 May 2003, 27 November 2003 and 14 May 2004 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 remains with the ALRC's Commissioners. An Advisory Committee does not determine the ALRC's views on any issue addressed by an Inquiry.

Community consultation

1.12 Under the terms of its constituting Act, the ALRC 'may inform itself in any way it thinks fit' for the purposes of reviewing or considering anything that is the subject of an Inquiry.[7] One of the most important features of ALRC inquiries is the commitment to widespread community consultation.[8]

---

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

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

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

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

1.14 For this purpose, the Inquiry arranged a large number of targeted meetings with key stakeholders, to gain expertise, perspectives and to hear their experiences. These meetings were valuable in informing the Inquiry and in helping to develop sound policies that would both meet existing concerns and work effectively in practice. At the completion of the Inquiry, 73 such meetings had taken place around Australia, involving several hundred individuals. These included meetings with:

- federal, state and territory departments responsible for health, industry and technology;
- advisory bodies to government in the areas of intellectual property, health, biotechnology and innovation;
- the regulatory agency in the field of competition policy;
- bodies involved in the provision of public funding for genetic research;
- organisations concerned with health consumer education and advocacy;
- leading genetic researchers, genetic research laboratories, and public research institutions with an interest in commercialising biotechnology;
- companies involved in the commercialisation of genetic research or in the delivery of medical genetic services;
- peak industry bodies in the areas of biotechnology and pharmaceuticals;
- professional and academic associations dealing with intellectual property; and
- academics in intellectual property, competition law and health economics.

---

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

Written submissions

1.15 The Inquiry strongly encouraged interested persons and organisations to make written submissions to help advance the policy making process. The first round of submissions was received in response to the Issues Paper (IP 27),[10] and a second round was received in response to the Discussion Paper (DP 68).[11]

1.16 IP 27 was released in July 2003 and sought to identify the main issues relevant to the Inquiry, provide background information, and encourage informed public participation through 62 targeted questions. DP 68 was released in February 2004. It differed from the Issues Paper in that it contained a more detailed treatment of the subject matter, as well as identifying 49 proposals for reform. It also included a small number of additional questions on matters that either were not raised in IP 27 or received insufficient response to enable the ALRC to form a view.

1.17 The Inquiry received a total of 119 written submissions. These varied substantially in size and style, ranging from short notes written by individuals providing personal views, to large, well-researched documents prepared by government departments and agencies, research centres, industry bodies, professional associations and individual researchers. From the outset, the Inquiry was aware that some of the information in submissions might have commercial sensitivity, and the ALRC left open the possibility of receiving submissions in confidence. Of the submissions received, only three have been designated as confidential.

Final Report

1.18 The organisation of this Report largely follows that of DP 68, with the material divided into eight substantial Parts, each of which contains a number of chapters. It is hoped that the use of small, targeted chapters will allow readers to identify and focus upon those parts of the Report that most concern them.

1.19 As usual, the preliminary material contains both an Executive Summary and a list of the 50 final recommendations. The ALRC has also included an 'Implementation Schedule', in order to highlight the body responsible for implementing each recommendation, with the ultimate aim of facilitating the adoption of the Inquiry's recommendations.

1.20 Under s 23 of the *Australian Law Reform Commission Act 1996* (Cth), reports presented to the Attorney-General must be tabled in Parliament within 15 sitting days, after which they become public documents. All ALRC reports are available on the Commission's website, at <www.alrc.gov.au>, and may be downloaded without charge. Participants in the Inquiry, including those who have made submissions, will be provided with a copy of this Report; other interested parties may purchase the Report in hard copy or CD-Rom format from the ALRC.

---

10 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003).
11 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004).

1.21 In an earlier era, the centrepiece of any significant law reform effort was the recommendation of a major new piece of legislation. However, in a more complex environment in which authority is more diffused, modern law reform efforts usually involve a mix of strategies, including legislation, guidelines, principles, education programs, and changed practices. This is the approach taken in this Report, which directs its varied recommendations for reform to government, independent agencies, industry and other non-government groups.

1.22 Finally, as is evident from the list of recommendations, this Report is not a self-executing document. The Inquiry provides advice and recommendations about the best way to proceed, but implementation is a matter for others.[12]

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. The Patent System

Contents

Introduction

> The patent system … secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things.[1]

2.1 A patent is an intellectual property right granted by the State to the inventor of a new, inventive and useful product or process. This chapter provides an outline of the patent system by reference to its historical origins, the goals of patent law, the nature of patent rights, and the criteria for patentability.

2.2 As noted in Chapter 1, the ALRC has not been asked to undertake a wholesale review of the patent system, or its goals, but to examine ways in which the patent system can be changed to 'further the health and economic benefits of genetic research and genetic and related technologies'.[2]

2.3 The goals of the patent system are fundamentally economic—to encourage the provision of new and useful goods and services and reward inventiveness, including in the biotechnology sector and other areas of economic activity involving gene patents. The economic benefits derived from the patent system as a whole are examined in this chapter—together with other factors that may counteract the economic benefits of patents in some situations.

---

1 A Lincoln, 'Second Lecture on Discoveries and Inventions, delivered to the Phi Alpha Society of Illinois College at Jacksonville, Illinois, February 11, 1859' in R Basler (ed) *The Collected Works of Abraham Lincoln* (1953), 357.

2 See Terms of Reference, reproduced at the front of this Report.

An outline of the patent system

Historical origins

2.4 Patents are the oldest form of intellectual property, but their historical origins are obscure.[3] In England, in the fifteenth century, the monarch began to grant monopoly rights as a means of attracting new industries from continental Europe, but these were more in the nature of a royal licence to avoid the effects of guild regulations than a true grant of exclusive rights to carry on an activity.[4] It was only in the following century that patents began to be granted in respect of inventions, and the patent system was put on a statutory basis for the first time in the seventeenth century with the passage of the *Statute of Monopolies 1623* (*Statute of Monopolies*). Despite its age, this English statute continues to have relevance to Australian patent law today.[5]

2.5 As it first developed, the English patent was a slow, costly and cumbersome procedure for encouraging and protecting inventions. The procedure was described in derisory terms by Charles Dickens in a short story published in 1850, 'A Poor Man's Tale of a Patent'.[6] Over the years there were many piecemeal reforms to the system, but it was the *Patents Act 1883* (UK) that provided the basis of modern patent law.

2.6 Patent legislation in Australia has always been closely modelled on that of the United Kingdom. Prior to Federation, each of the Australian colonies had its own legislation based on the *Patents Act 1883* (UK). In 1901, the *Australian Constitution* gave the newly established Commonwealth Parliament power to make laws with respect to 'copyrights, patents of invention and designs, and trade marks'.[7] In 1903, this power was exercised with the enactment of the *Patents Act 1903* (Cth).

2.7 As in the United Kingdom, there have been many amendments to Australian patent legislation in response to formal commissions of inquiry. The 1903 Act was re-enacted with substantial changes in 1952 and again in 1990. The *Patents Act 1990* (Cth) (*Patents Act*) provides the current legislative framework governing the grant and administration of patents in Australia.

Functions of patents

2.8 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.[8] 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.

---

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

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

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

6 C Dickens, 'A Poor Man's Tale of a Patent' (1850) II(70) *Household Words* 1.

7 *Australian Constitution* s 51(xviii).

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

2.9 These goals are achieved by providing incentives for innovation and knowledge sharing by granting monopoly rights, for a limited period, to exploit a new product or process.[9] Monopoly rights encourage investment by providing an opportunity to recoup the financial outlays involved in developing an invention. They also reward the inventor by allowing a return to be made on the time and resources expended on research and development.[10]

2.10 The limited duration of the monopoly means, however, that the patented invention eventually will be available for free and unrestricted use when the patent term expires: the compromise is thus 'a way of securing future benefits for the common good'.[11] In addition, patents promote knowledge sharing during the term of the patent by requiring the patent holder to place the details of the invention in the public domain. As one United States judge has stated:

> The purpose of the patent system is not only to provide a financial incentive to create new knowledge and bring it to public benefit through new products; it also serves to add to the body of published scientific/technological knowledge. The requirement of disclosure of the details of patented inventions facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance.[12]

Exploitation of patents

2.11 A patent gives the inventor the right to stop others from exploiting the invention for a limited period.[13] However, a patent does not grant an absolute right to exploit an invention in any way the inventor may choose. A patent holder may have to satisfy regulatory requirements in order to exploit the patented product or process; for example, a patented pharmaceutical compound may need approval under the *Therapeutic Goods Act 1989* (Cth) before it can be marketed lawfully and sold as a treatment for a particular condition. Similarly, the use of a patented invention is subject to the general law; for example, the components required to manufacture a car may be the subject of many patents, but the car must still be used in accordance with motor traffic laws.

2.12 A patent holder is not obliged to exploit a patented invention, but the failure to do so may have implications for the patent holder's rights. For example, the patent could be subjected to compulsory licensing, or it could be used or acquired by the Crown under relevant provisions of the *Patents Act*. A patent holder may authorise others to exploit the patent by granting a licence on agreed terms. This may be on an

---

9 The *Patents Act 1990* (Cth) s 13(1), sch 1 defines 'exploit' to include make, hire, sell or otherwise dispose of the product, use or import it, or keep it for the purpose of doing any of those things.

10 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 136.

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

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

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

exclusive, sole or non-exclusive basis, and almost certainly will require the licensee to pay royalties or other fees to the patent holder.[14]

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

Criteria for patentability

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

2.15 Chapter 6 of this Report provides a detailed discussion of the criteria for patentability under Australian law. Briefly, the *Patents Act* provides that an invention will be patentable if it is a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*; is novel; involves an inventive or innovative step; is useful; and has not been used secretly within Australia prior to filing the patent application.[15]

2.16 Certain inventions are expressly excluded from patentability. Australia has relatively few express exclusions, 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.[16] Other jurisdictions recognise a broader range of exceptions, including inventions involving diagnostic, therapeutic and surgical methods of treatment of humans and animals; and inventions whose commercial exploitation would be contrary to morality or public order.[17] Exclusions from patentability are discussed in Chapter 7.

Economic benefits of the patent system

2.17 The economic benefits of the patent system are derived from its roles in promoting innovation, and encouraging investment, economic growth, knowledge sharing and the efficient use of resources. These aspects of the patent system are briefly discussed below.

---

14 Common terms in patent licences are described further in Ch 22.

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

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

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

Promoting innovation

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

2.19 Patents promote innovation through the grant of limited monopolies, as a reward to inventors for the time, effort and ingenuity invested in creating new products and processes. The potential for financial returns adds an incentive to the traditional rewards of scientific innovation, such as academic recognition and promotion within research institutions. Without the incentive provided by patents, private investors may be reluctant to invest, resulting in greater calls on government funding or a failure to develop and exploit new technology.

2.20 The role of patents as an incentive for innovation and investment in research was widely acknowledged in submissions, including by research and healthcare organisations. For example, the Children's Cancer Institute Australia for Medical Research stated that the patent system is:

> a cornerstone in driving innovation in medical research by enabling researchers to have protection of their intellectual property and the possibility of capitalizing on their inventions. The involvement of industry in this process is also well-established and important … Intellectual property protection has been, and will continue to be, an essential component of the innovation process that drives medical research.[18]

2.21 Similarly, the Department of Human Services Victoria acknowledged that the patent system has served Australia well and 'is essential to foster and encourage continuing innovation and research, which will lead to further enhancements in human health, including in the field of genetics'.[19]

2.22 However, patents do not always reward innovation and research investment equitably. In most jurisdictions, including Australia, where two researchers independently create the same invention, only the first to apply for patent protection will be awarded a patent over the invention.[20] This may discourage some researchers from embarking on a course of research that is already being pursued elsewhere, despite the possibility that they may do better or more efficient work.

Investment and economic growth

2.23 Possessing a patent may help a company to grow by capitalising on the market potential of its inventions. Small companies may use patents to attract financial backing.[21] In addition, patents stimulate the growth of national industry because local

---

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

19 Department of Human Services Victoria, *Submission P111*, 30 April 2004. See also Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

20 In contrast, in the United States, patents are granted to the first inventor rather than the first to file for a patent.

21 See Ch 16.

companies that hold patents can attract overseas investment and develop products for export.[22] Profits generated by patent exploitation can be invested in further research and development, which may stimulate commercial and industrial growth.

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

2.25 However, patents may have adverse economic effects. Licence fees may drive up the price of goods and services that utilise the patented invention. There are also transaction costs associated with seeking the grant of a patent and enforcing patent rights. Fees must be paid before a patent application will be examined or granted, and to maintain patent rights once granted.[23] Asserting patent rights, or challenging those of a competitor, may be costly and difficult for small and medium-sized enterprises because claims of infringement may need to be pursued through the courts.[24]

2.26 Patents may also have adverse effects on the balance of payments, especially for countries like Australia, which are net importers of intellectual property. This is because expenditure on licence fees or royalties for the use of patents owned by foreign entities may exceed the income earned from the use, by foreign entities, of local inventions. Most Australian biotechnology patents are owned by foreign entities and Australian researchers generally pay licence fees to overseas companies to use these patented inventions in research.[25] Chapters 16 and 18 discuss the Australian biotechnology industry and international patent ownership.

Resource use and knowledge sharing

2.27 Patents promote knowledge sharing by requiring the details of the patented invention to be placed in the public domain in return for the exclusive right to exploit the invention. In the absence of this exchange, inventors might protect the details of new inventions through secrecy. The disclosure requirements of the patent system are based on the idea that 'scientific and technical openness benefits the progress of society more than do confidentiality and secrecy'.[26]

---

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

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

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

25 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.

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

2.28 By encouraging knowledge sharing, patents reduce the duplication of research effort and encourage researchers to build on existing inventions. Researchers may study a patented product and find ways to improve upon it. Access to patented inventions may also facilitate research that would not otherwise be possible. For example, access to a patented research tool may enable vital research into the causes of a genetic disorder and lead to the creation of a genetic test or treatment. This research may not have occurred if the tool had remained secret. Due to the cumulative nature of much genetic research, knowledge sharing may be particularly important in this context.[27]

2.29 However, patents may also inhibit research by discouraging knowledge sharing prior to filing for patent protection. The results of new research may be withheld until an inventor is in a position to apply for a patent and the invention is sufficiently well developed to ensure that the patent will be granted.[28]

Social and ethical considerations

2.30 The patent system also has social and ethical dimensions, which differ according to the type of invention. In considering reform of the patent system as it applies to genetic materials and technologies, the economic dimensions of the patent system cannot be divorced from their social or ethical impact. Rather, the economic, social and ethical dimensions of gene patenting must be taken into account in developing reforms that will serve the public interest.

2.31 There are differing views on the extent to which patent law itself should recognise social and ethical considerations, for example, through new criteria for patentability. One view is that social and ethical considerations are better addressed through direct regulation of the use or exploitation of patented inventions, rather than through the patent system directly. In contrast, it has been suggested that we should change the way we think of the patent system, so that patent law is seen 'as a regulatory mechanism for a number of economic and social ends—including investment in innovation, access to medicine, protection of the environment, and the acknowledgment of indigenous knowledge'.[29]

2.32 Aspects of how the patent system should deal with the social and ethical dimensions of gene patents are discussed in Chapters 3 and 7. However, as explained in Chapter 1, it is beyond the scope of the Terms of Reference to attempt any fundamental 're-invention' of the patent system.

---

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

28 D Dickson, 'UK Clinical Geneticists Ask for Ban on the Patenting of Human Genes' (1993) 366 *Nature* 391, 391. The disclosure of an invention may render patent protection unavailable: see Ch 5 and 6. Ch 14 considers issues relating to secrecy, publication and gene patenting.

29 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. See also B Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' (2003) 25 *European Intellectual Property Review* 301.

3. Gene Patents

Contents

Introduction

3.1 This chapter begins by describing the subject matter of gene patents, which comprises genetic technologies, natural and isolated genetic materials, and genetic products (such as proteins). Genetic materials and technologies are important in medical research and in the provision of healthcare. They are likely to become increasingly significant as more becomes known about the biological function of genes and the proteins they produce.[1]

3.2 The patent system must constantly accommodate new technologies. In the past 20 years, inventions in the field of biotechnology have become a new focus of the patent system, particularly in relation to genetic materials and technologies. This chapter provides a brief chronology of the patenting of genetic materials and technologies, as a background to the issues examined throughout this Report.

---

1 An introductory 'primer' on the relevant genetic science was included in Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Ch 2.

3.3 Gene patenting raises many social and ethical concerns. These include concerns about the social impact of gene patents on the conduct of research and the provision of healthcare; and ethical concerns about sharing the benefits of genetic research, consent to the use of genetic material in research that leads to commercial outcomes, and indigenous issues. This chapter summarises these concerns and explains the approach taken by the Inquiry in assessing possible problems with the patenting of genetic materials and technologies and in recommending reforms.

The subject matter of gene patents

3.4 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.[2] Human genetic research may lead to 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.

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

3.6 The potential subject matter of gene patents may be grouped into four broad categories: genetic technologies; natural genetic materials; isolated genetic materials; and genetic products.[3] These categories of gene patents are explained below.[4] For the sake of brevity, the term 'genetic materials and technologies' is sometimes used to encompass all four categories of subject matter.

3.7 *Genetic technologies* are 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. For example, 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.[5] Genetic technologies involve the use of many different

---

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

3 These categories do not have a precise scientific or legal meaning, and are not mutually exclusive.

4 For more detail, see Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [1.25]–[1.41].

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

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

3.8 *Natural genetic materials* are forms of genetic material in their natural state, including DNA, RNA, genes and chromosomes. 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 one that has been extracted from the body by a process of isolation and purification. Although isolated genetic materials may be patentable, genetic materials in their natural state usually are not. For example, patent claims that encompass DNA must be formulated so as to distinguish clearly what is claimed from the naturally occurring molecule.[6] However, some natural genetic materials may include genetic material in living cells, such as stem cells, which may be patentable when isolated and propagated to produce a cell line.[7]

3.9 *Isolated genetic materials* are forms of genetic material isolated from nature, for example, in the form of DNA copies known as complementary DNA (cDNA), and the genetic sequences in this material.[8] Isolated genetic material may relate to coding or non-coding sequences, or both.[9] When gene patents extend to isolated genetic materials, the genetic sequences of that material form part of the description of the patented invention.[10] 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 in other ways. Gene fragments include a wide range of different types of isolated genetic materials, including single nucleotide polymorphisms (SNPs), expressed sequence tags (ESTs), and other gene fragments encoding important regions of proteins. The patenting of gene fragments may be controversial in the absence of any disclosure of the function of the gene to which they relate.

3.10 *Genetic products* are 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. Patentable genetic products include proteins or important functional regions of proteins. As with genetic materials, proteins are naturally occurring but may

---

6 See Ch 6.

7 See Ch 15.

8 The literature often refers to the patenting of 'genetic sequences' or 'DNA sequences'. These terms are also used in this Report, although it is more accurate to say that isolated genetic materials are the subject matter of gene patents.

9 Coding genetic sequences code for particular proteins. The role of non-coding DNA is yet to be fully established, but it is thought that it may produce secondary signals that integrate and regulate the activity of genes and proteins: 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.

10 Human Genome Project, *Patenting Genes, Gene Fragments, SNPs, Gene Tests, Proteins, and Stem Cells*, United States Department of Energy, <www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml> at 16 June 2004.

be patentable when isolated or synthesised. Proteomics is widely seen as the next phase in the development of genetic science, following on from the successful sequencing of the human genome, and may form the basis of new medicines or therapies.

A brief history of gene patents

Accommodating new technologies

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

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

A chronology of genetic technologies and patents

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

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

3.15 Commercialisation of genetic technology followed soon after when, in 1976, Boyer and Swanson established the first known biotechnology company, Genentech Inc, in Berkeley, California. In 1977, Genentech reported the production of the first human protein manufactured in a bacterium.[11] The technology demonstrated that

11 The protein produced was somatostatin, a hormone that inhibits the secretion of human growth hormone.

molecules could be produced in large quantities in bacterial vectors and then administered to patients, raising hopes that recombinant technology could aid the treatment of human disease.

3.16 A second crucial breakthrough in genetic science occurred in 1977 when Sanger identified a method for reading DNA sequences.[12] Scientists could now read the genetic code, and so gain an understanding of genetic mutations that cause human disease as well as the functional and evolutionary relationships between genes. The Sanger methodology remains the basis of modern gene sequencing.

3.17 A third major innovation in genetics was the development of PCR. Developed in the 1980s by Mullis and others at Cetus Corporation, PCR provided a quick and easy method for selective amplification of DNA fragments, removing the need for cloning in micro-organisms.[13] Amplifications that previously took weeks could now be done in a matter of hours. After patenting the process, Cetus sold the patent to Hoffman-La Roche Inc (Roche). Roche now holds more than 130 patents in the United States related to the PCR process.[14] The process has become the foundation for almost all genetic laboratory work, making access to the patented technology crucial.

3.18 While genetic technology was progressing apace, legislatures, courts and regulators were also forced to address issues arising from the commercialisation of genetic inventions. The controversial decision in *Diamond v Chakrabarty*,[15] handed down by the United States Supreme Court in 1980, allowed a patent to be granted for a recombinant bacterium, thus determining that life forms are patentable subject matter under United States law. In the same year, the United States Congress passed the *Bayh-Dole Act*, providing that intellectual property rights arising from publicly funded research vest in the organisations that carry out the research.[16] The underlying policy of the legislation was to encourage innovation and exploitation by allowing universities to patent inventions flowing from their research.[17] In 1982, the United States Food and Drug Administration (FDA) approved the first recombinant DNA drug for market,[18] demonstrating that government agencies had accepted some genetically manipulated products as safe for medical use.

---

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

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

14 Roche Molecular Diagnostics, *PCR Information for Journalists*, <www.roche-diagnostics.com/ba_rmd/pcr_jounalists.html> at 16 June 2004.

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

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

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

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

3.19 The biotechnology industry expanded rapidly during the 1980s. In 1985, the FDA gave approval for the first drug to be both manufactured and marketed by a biotechnology company.[19] Sequencing methods improved with the introduction in 1986 of the automated DNA fluorescence sequencer developed by the Californian Institute of Technology and Applied Biosystems Inc. In 1988, the United States Patent and Trademark Office granted the first United States patent over an entire animal, the 'Harvard Mouse'.[20] This move provoked widespread concern about the ethics of patenting higher life forms.[21] Genetically altered mice (and other animals) are valuable research tools for both industry and academic researchers, principally because they serve as animal models of human disease.[22]

3.20 The role of patent law in facilitating innovation in the field of genetics continued to excite controversy in the 1990s. One issue of contention was the level of usefulness or utility that needed to be demonstrated to support a claim over a genetic invention. In 1991, the United States National Institutes of Health (NIH) filed patent applications on approximately 2,700 ESTs. The applications included not only claims over the ESTs, but also over their full-length gene sequences and derivative proteins.[23] These claims were controversial because the functions of these sequences were unknown at the time of filing. The NIH eventually abandoned the applications.

3.21 Another issue for patent law has been the breadth of claims made in applications for patents over genetic inventions. An example is the patent issued in 1993 to Australian scientist Dr Malcolm Simons, over 'the use of non-coding DNA for genetic analysis',[24] and the grant five years later of a further patent to cover the use of non-coding DNA for the purposes of gene mapping.[25] An Australian company, Genetic Technologies Limited, now holds these patents.[26]

3.22 The commencement of the Human Genome Project in 1990 was an indication of the thriving state of genetic research.[27] A new era of genomics was entered in February 2001, with the publication by the Human Genome Project and the Celera Genomics Group of the working draft of the human genome sequence.[28] Final sequencing of the

---

19 This was Genentech's protropin, a treatment for child growth hormone deficiency.

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

21 See, eg, Greenpeace, *Supreme Court of Canada Rejects Patent for Mouse, 5 December 2002*, <www.greenpeace.ca/e/campaign/gmo/depth/highlights> at 16 June 2004.

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

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

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

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

26 Patents have also been granted in Australia in relation to non-coding DNA: see, eg, Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes AU67519; Genomic Mapping by Direct Haplotyping Using Intron Sequence Analysis AU647806; Intron Sequence Analysis Method for Detection of Adjacent and Remote Locus Alleles as Haplotypes AU654111.

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

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

human genome was completed in April 2003.[29] The vast amount of information released during the course of the Project will be a spur to further research and innovation, and may bring with it a new array of problems for gene patenting.[30]

Concerns about gene patenting

3.23 During the course of the Inquiry, the ALRC received 119 submissions in relation to gene patenting and conducted 73 targeted consultations with stakeholders, involving many hundreds of individuals. The submissions came from individuals, organisations and government departments spanning a wide range of interests.

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

3.25 At the other end of the spectrum were those who considered the patent system to be fundamentally flawed in its application to *all* technologies, with a consequent degradation in the quality and economic value of patents throughout the industrialised world. These concerns extended well beyond the Terms of Reference. Their principal criticism was the 'functional redundancy' of patents, which was said to arise because many granted patents plagiarise earlier ones, or because the only innovation is the use of alternative linguistic expressions to describe a previously patented invention.[31] The problem was said to stem from the inadequacies in the examination process, combined with the incentive for patent offices to be overly generous in their grant of patents because their revenues depend on receipt of patent fees.

3.26 Between these extremes were the far more numerous submissions and consultations in which concerns were expressed about the patenting of genetic materials and technologies—ranging from mild dissatisfaction with particular arrangements, to strenuous objection to the way in which the patent system deals with genetic materials and technologies. These concerns are described and analysed in detail in later chapters of this Report. For present purposes it is sufficient to distinguish between two classes of criticism: those relating to the law or practice of patenting genetic materials and technologies; and those relating to the manner in which gene patents are exploited in the marketplace.

---

29 National Human Genome Research Institute, *Home Page*, <www.nhgri.nih.gov> at 16 June 2004.

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

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

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

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

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

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

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

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

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

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

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

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

Social and ethical dimensions

3.29 The goals of the patent system, whether applied to genetic materials and technologies or other patentable subject matter, are fundamentally economic. However, as noted in Chapter 2, the social or ethical impact of gene patents cannot be ignored when considering reform of the patent system. This section examines some of the social and ethical dimensions of gene patenting, including the concerns of Indigenous peoples.

The conduct of research

3.30 Gene patents may promote genetic research by providing an incentive for investment in research and development. At the same time, it has been argued that gene patents may have a 'chilling effect' on research and innovation, rather than promoting them. For example, research may be hindered by researchers' concerns about infringing patents or by difficulties in obtaining licences to use patented inventions on reasonable terms. Researchers may be reluctant to put information about research outcomes into the public domain because of concerns that this might undermine the potential to commercialise their own research.

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

3.32 The economic rewards of patenting may channel investment into the more profitable areas of research and away from other important goods and services, such as medical treatments for rare diseases.[32] Concerns have been raised that an increasing emphasis on the commercialisation of public sector research may skew basic research priorities.[33] Chapter 12 discusses the general impact of gene patents on research and describes the specific subject matter and claims of gene patents that are most likely to hinder research.

Access to healthcare

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

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

---

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

33 See House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), [7.91]–[7.96], rejecting the suggestion that patenting would distort research priorities.

3.35 Chapter 19 discusses both the use of patented genetic materials and technologies in healthcare and the implications of this for the cost and funding of healthcare. It contains several proposals for reform to address concerns about cost and access. Chapter 20 discusses the impact of gene patenting on medical genetic testing and other healthcare services.

Ethics and the grant of gene patents

3.36 Ethical concerns about gene patenting can be divided into two broad categories—ethical objections to granting patents over genetic materials, and ethical concerns about the exploitation of gene patents. This section outlines a range of ethical concerns that have been expressed about granting gene patents.[34]

3.37 When gene patents were a relatively new phenomenon, ethical concerns focused mainly on whether it was acceptable to patent human genetic materials—although the distinction between natural and isolated genetic materials was seldom made. Concerns about whether it is ethical to patent genetic materials are no longer as prominent as they once were. In part, this may be because existing gene patents are unlikely to be revoked. Many such patents have been issued in numerous countries, including Australia, and the practice of patenting isolated human genetic materials appears to be more widely accepted.[35]

3.38 A variety of ethical objections have been made to granting patents on human genetic materials. Although the 'genetics horse' may have bolted,[36] there remain those in the community who are not persuaded that the patent system adequately takes account of ethical concerns.[37] Many submissions to the Inquiry raised ethical objections to granting gene patents.

3.39 Critics of gene patents have asserted that these patents are morally wrong because they are incompatible with: the view that the human genome is the common heritage of humanity; respect for human dignity; self-determination and self-ownership; and certain religious beliefs.

3.40 The human genome is often described as the common heritage of humanity, a view that has been supported by the Human Genome Organisation's (HUGO) Ethics Committee and by the United Nations Educational, Scientific and Cultural Organization (UNESCO).[38] Patents on human genetic materials are sometimes criticised because they are thought to grant exclusive rights over this common heritage

---

34 For a discussion of what is meant by 'ethics', see Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [3.37]–[3.42].

35 Cancer Council New South Wales, *Submission P1*, 5 June 2003; South Australian Government, *Submission P51*, 30 October 2003. Some submissions disputed community acceptance of gene patenting: G Suthers, *Submission P30*, 2 October 2003.

36 Cancer Council New South Wales, *Submission P1*, 5 June 2003.

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

38 HUGO Ethics Committee, *Statement on the Principled Conduct of Genetics Research* (1996); *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, UNESCO, art 12(a).

to a limited number of entities.[39] This objection rests in part on concern for fair distribution of the benefits of genetic research. This view was expressed in a number of submissions.[40]

3.41 Another objection to patents on genetic materials is that they may engender a lack of respect for human life and dignity.[41] On this view, to grant a proprietary right over something suggests that it is an appropriate 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. Others suggest that genetic materials have a unique significance, which requires them to be treated with special respect.[42]

3.42 These objections rest on the principle of respect for persons and promotion of individual autonomy. Commodification of parts of human beings is ethically problematic because it might affect how we value people.[43] It is said to be incompatible with respect for human dignity because it reduces human beings to things to which no respect is owed,[44] and is ethically unacceptable because it precludes respect for individual autonomy. Concern about the potential commodification of the human genome was expressed in many submissions.[45] Others emphasised the need for the human genome to be treated with particular respect. For example, Dr Graeme Suthers stated that 'our genetic code is our heritage. It deserves this degree of respect. It is not merely a commercial resource'.[46]

3.43 Commodification arguments have been criticised on the basis that treating parts of humans (such as natural genetic materials) as objects does not necessarily equate with treating whole persons as objects or commodifying individuals.[47] Critics further suggest that it is not apparent that the widespread grant of patents on isolated human genetic materials has led to a change in how human beings are perceived and treated.

---

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

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

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

42 For example, it has been suggested that 'body parts, including genes, are not like other materials to be owned and traded in the market place as common commodities': Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 June 1996, 2332 (N Stott Despoja), 2333. See also *Howard Florey/Relaxin* [1995] EPOR 541, [6.4].

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

44 T Claes, 'Cultural Background of the Ethical and Social Debate about Biotechnology' in S Sterckx (ed) *Biotechnology, Patents and Morality* (2nd ed, 2000), 179, 182.

45 G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003; D McFetridge, *Submission P23*, 30 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003; B Fenelon, *Submission P68*, 10 March 2004.

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

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

3.44 It has also been argued that patents over genetic materials are incompatible with respect for an individual's self-determination because they grant ownership rights over genetic material, and consequently over parts of human beings, to someone other than the person from whom the genetic material was taken.[48] On this view, self-determination—the right to make one's own choices about how to live—is fundamentally linked to self-ownership—the right to choose how one's body is used. A number of submissions objected to gene patenting on the ground that it shifted ownership of genetic material away from the person from whom it was obtained.[49]

3.45 Critics suggest that these arguments confuse intangible intellectual property rights with physical property rights. Stephen Crespi points out that 'intellectual property provides a quite different type of ownership and lack of clarity about this can easily skew the whole debate' about gene patents.[50] 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.

3.46 Patents on genetic materials are sometimes criticised on religious grounds.[51] 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.[52] In 1998, Bruce Lehman, then United States Patent Commissioner, responded to religious objections to patents by stating: 'We are not patenting life. God, I suppose, has a patent on life. We are patenting technology'.[53]

Ethics and the exploitation of gene patents

3.47 Increasingly, ethical concerns have focused on the exploitation of gene patents, rather than on the grant of patents. It has been suggested that individuals or groups who provide tissue samples for use in genetic research have an ethical right to control the use of those samples, or to control or share in the ownership of any patented genetic

---

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

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

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

51 For example, in 1995 a group of religious leaders in the United States issued a public statement asserting 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.

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

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

inventions resulting from the research. It has also been suggested that tissue donors have an ethical right to share in the benefits of research and development using their genetic material.[54] This view may be based on the ethical principles of respect for the person, justice and beneficence.

Benefit sharing

3.48 The HUGO Ethics Committee has recommended that all humanity should share in, and have access to, the benefits of genetic research. It also recommended that, at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation; and that profit-making entities should dedicate a percentage (for example, 1–3%) of their annual net profit to healthcare infrastructure or to humanitarian efforts.[55]

3.49 There are several barriers to a research participant asserting a legal right to control or share in the benefits of genetic research in Australia. These include the fact that the law is uncertain about the nature of property rights in human tissue[56] and prohibitions on the sale of human tissue in the *Human Tissue Acts*, which may make it unlawful to provide financial benefits in exchange for tissue donation.[57]

3.50 The *Patents Act 1990* (Cth) provides that a patent may be granted only to a limited category of persons,[58] which does not specifically include research participants. It is possible, however, for research participants to enter into contractual arrangements with researchers that provide some form of control or benefit, in exchange for participation in a research program.

3.51 Gene patenting has led to significant concerns about research participants' rights to control and share in the benefits of research results, as evidenced by litigation in the United States.[59] In IP 27, the ALRC asked whether there was any need to make special provision for individuals or groups, whose genetic samples are used to make a patented invention, to benefit from any profits from the patent.[60]

---

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

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

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

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

58 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).

59 See, eg, *Moore v Regents of the University of California* 51 Cal 3d 120 (1990); *Greenberg v Miami Children's Hospital Research Institute* (Unreported, District Court for the Southern District of Florida, Moreno J, 29 May 2003), discussed in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [3.65]–[3.67].

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

3.52 Some submissions responded that the patent system is not the appropriate vehicle to address issues of benefit sharing and control.[61] The reasons for this view included that there are mechanisms other than the patent system to ensure that the rights of tissue donors are paramount,[62] and because inventions generally result from researchers' expertise, skill, time and expense.[63]

3.53 However, some submissions stated that benefit sharing should be addressed by the patents system, for example, by introducing additional requirements for the grant of a patent.[64] Other submissions supported some form of benefit sharing for research participants, but considered that these arrangements should be negotiated between the researcher and participant directly.[65]

3.54 Leaving aside concerns about indigenous genetic resources (which are discussed below), the ALRC recognises that individuals and organisations who participate in genetic research may consider they have an ethical right to control or own the results of that research, or share in the benefits of the research in some way. Approaches to allowing for such control, ownership and benefit sharing could take several forms, including legal recognition as joint inventors of the patented invention, social recognition of their contribution to research and development, or some form of financial or other benefit in exchange for participation.

3.55 However, the ALRC considers that issues of control and benefit sharing are better addressed outside the patent system, for example through the established system of ethical review of medical research, and through contractual arrangements between researchers and research participants.

Indigenous issues

3.56 Indigenous peoples have expressed particular 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.[66]

---

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

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

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

64 M Rimmer, *Submission P73*, 15 April 2004; B Hocking, *Submission P113*, 3 May 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. ACIPA recommended that the *Patents Act* be amended to 'provide the mandatory requirement a patent can only be granted if there was evidence of informed consent and benefit sharing'.

65 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; A Johnston, *Submission P72*, 14 April 2004.

66 See generally, M Davis, *Indigenous Peoples and Intellectual Property Rights* (1996-7), 4. The Human Genome Diversity Project (HGDP) has been widely criticised by Indigenous peoples: M Dodson, 'Human Genetics: Control of Research and Sharing of Benefits' (2000) 1 *Australian Aboriginal Studies*

3.57 In Australia, an existing mechanism for ethical review of research involving Indigenous communities—including genetic research—involves the use of indigenous subcommittees working in conjunction with Human Research Ethics Committees.[67] These subcommittees review proposed research projects to ensure that the subject group has given informed consent to the proposed project. In 2003, the National Health and Medical Research Council (NHMRC) released a new set of guidelines for ethical conduct in indigenous health research.[68] The NHMRC has stated that, in addition to the *National Statement on Ethical Conduct in Research Involving Humans*,[69] these guidelines are the authoritative statement on health research involving Aboriginal and Torres Strait Islander people.[70]

3.58 Submissions referred to the importance of taking into account the cultural values and wishes of Indigenous people in the conduct of genetic research.[71] Aboriginal and Torres Strait Islander Services (ATSIS) stated that Indigenous people have 'a unique attachment to their genetic resources since they are a vital part of their spiritual and cultural existence (cosmology)', and submitted that '*sui generis* (specific or stand alone) legislation is required to protect Indigenous peoples' rights' with respect to gene patenting.[72] ATSIS suggested two fundamental principles in relation to Indigenous peoples' participation in genetic research: (a) Indigenous people whose resources are used must be properly consulted, and their genetic material may only be used with their informed consent;[73] and (b) Indigenous people should have a legal right to own, control the use of, and benefit fairly from, their genetic resources (including DNA extracted from skeletal remains), and any person seeking to use their resources in any way must enter into a benefit sharing agreement to do so.[74]

3.59 Similarly, the Research Unit of the Jumbunna Indigenous House of Learning at the University of Technology, Sydney (Jumbunna) submitted that the particular relationship Indigenous people have to their genetic materials through cultural and spiritual beliefs should be acknowledged in the ALRC's recommendations:

56, 56. See also T Janke, *Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights* (1998), 29.

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

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

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

70 The guidelines assist researchers in the conception, design and conduct of research. The guidelines are based on six values: spirit and integrity; reciprocity; respect; equality; survival and protection; and responsibility.

71 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Aboriginal and Torres Strait Islander Services, *Submission P55*, 4 November 2003; B Hocking, *Submission P113*, 3 May 2004; Research Unit of Jumbunna Indigenous House of Learning, *Submission P100*, 20 April 2004.

72 Aboriginal and Torres Strait Islander Services, *Submission P55*, 4 November 2003.

73 Informed consent was said to be particularly important in relation to genetic databases: Research Unit of Jumbunna Indigenous House of Learning, *Submission P100*, 20 April 2004.

74 Aboriginal and Torres Strait Islander Services, *Submission P55*, 4 November 2003.

> We hope that the rights inherent in the status as first peoples with an entitlement to self determination can be recognized within the patent system by respecting Indigenous people's wishes in relation to past present and future collection use of their human genetic material and traditional knowledge.[75]

3.60 Jumbunna suggested reforms to patent law that would 'anticipate implementation of *sui generis* systems for the protection of Indigenous genetic materials and traditional knowledge'. It was suggested that these reforms should include: (a) an exclusion from patentability for indigenous human genetic materials,[76] pending the development of mechanisms for protecting customary practices and indigenous rights; and (b) the incorporation of Indigenous peoples' concerns into models for the operation of genetic databases. Jumbunna referred to the progress of indigenous working groups and committees of the *Convention on Biological Diversity*,[77] the World Intellectual Property Organization (WIPO) and the World Trade Organization. It also noted Australia's obligations under the *Convention on Biological Diversity* to protect indigenous genetic materials and encourage equitable benefit sharing.[78]

3.61 The ALRC acknowledges that the preservation and management of indigenous genetic resources—and benefit sharing with respect to its exploitation—are issues of critical and growing importance, in Australia and internationally. These issues are of great breadth and extend beyond human genetic materials to plant genetics and the protection of associated traditional knowledge. Policy making in this area involves consideration of benefit sharing through contractual agreements, administrative policies, legislative measures, and multilateral instruments.[79]

3.62 Importantly, these issues are currently being considered in international fora. An international regime to promote the fair and equitable sharing of benefits arising out of the utilisation of genetic resources is being negotiated within the framework of the *Convention on Biological Diversity*,[80] to which Australia is a party. One of the objectives of the *Convention on Biological Diversity* is the:

> fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.[81]

---

75 Research Unit of Jumbunna Indigenous House of Learning, *Submission P100*, 20 April 2004.

76 As discussed in Ch 7, the ALRC has concluded that the *Patents Act* should not be amended to exclude any category of genetic materials or technologies from patentable subject matter.

77 *Convention on Biological Diversity*, [1993] ATS 32, (entered into force on 29 December 1993).

78 Research Unit of Jumbunna Indigenous House of Learning, *Submission P100*, 20 April 2004.

79 Intergovernmental Committee on Intellectual Property and Genetic Resources Traditional Knowledge and Folklore, *Initial Report on the Technical Study on Disclosure Requirement Related to Genetic Resources and Traditional Knowledge (2002)*, World Intellectual Property Organization, <www.wipo.int/documents/en/meetings/2002> at 18 June 2004.

80 Secretariat of the Convention on Biological Diversity, *Access to Genetic Resources and Benefit-Sharing: International Regime on Access and Benefit-Sharing*, <www.biodiv.org/programmes/socio-eco/benefit/regime.asp> at 16 June 2004.

81 *Convention on Biological Diversity*, [1993] ATS 32, (entered into force on 29 December 1993), art 1.

3.63 In October 2000, WIPO established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore as an international forum for debate and dialogue concerning the interplay between intellectual property and traditional knowledge, genetic resources, and traditional cultural expressions (folklore). The Committee's work is intended to complement that of other bodies, including the Secretariat of the *Convention on Biological Diversity*.[82] In February 2004, a conference of the parties to the Convention directed a Working Group to 'elaborate and negotiate an international regime on access to genetic resources and benefit-sharing'.[83]

3.64 The issues being dealt with by these international bodies cut across conventional areas of intellectual property law and involve a much wider range of subject matter than human genetic material. It is not clear that intervening in the patents system to deal with indigenous concerns—for example, by excluding indigenous human genetic material from patentability—would usefully or coherently advance this agenda.

3.65 The ALRC has not been in a position to conduct the kind of extensive consultation and research that would have been necessary to support recommendations about gene patents and indigenous genetic resources specifically. However, the ALRC believes that social and ethical concerns can be addressed most effectively through direct regulation of the use and exploitation of patented inventions, or through regulation of research activities that lead to the development of inventions, rather than through excluding particular subject matter from patentability (see Chapter 7).

Approach to reform

3.66 In later chapters of this Report, the ALRC examines reforms that are designed to address possible problems with the patenting of genetic materials and technologies. This section explains the overall approach taken by the Inquiry in assessing these problems and in recommending reforms.

Working with the patents system

3.67 The ALRC's approach is predicated on acceptance of the fundamental objective of the patent system in seeking to encourage innovation by granting limited monopoly rights. In this context, there should be realistic expectations of the patent system and what it can achieve. For example, as discussed in this chapter and in Chapter 7, the patent system may be ill suited to addressing all the social and ethical concerns that are raised by the use or exploitation of patented inventions. Those issues are better addressed by laws and practices that exist outside the patent system. Some of the reforms needed were considered by the ALRC and the Australian Health Ethics

82 See, eg, World Intellectual Property Organization, *Intergovernmental Committee (IGC)*, World Intellectual Property Organization, <www.wipo.int/tk/en/igc/index.html> at 16 June 2004.

83 Secretariat of the Convention on Biological Diversity, *Access to Genetic Resources and Benefit-Sharing: International Regime on Access and Benefit-Sharing*, <www.biodiv.org/programmes/socio-eco/benefit/regime.asp> at 16 June 2004.

Committee in their 2003 report, *Essentially Yours: The Protection of Human Genetic Information in Australia*,[84] where recommendations were made, for example, to improve the ethical oversight of human genetic research.

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

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

> If one does not know whether a system 'as a whole' (in contrast to certain features of it) is good or bad, the safest 'policy conclusion' is to 'muddle through'—either with it, if one has long lived with it, or without it, if one has lived without it. If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.[85]

3.70 As Machlup implies, the patent system can be improved if particular features can be identified as good or bad. This Inquiry was directed to that task.

Evidence of the impact of gene patents

3.71 The previous sections have identified some of the concerns that have been raised about the patenting of genetic materials and technologies. One difficulty in assessing these concerns is that there have been very few empirical studies in Australia addressing gene patents and their impact on research, biotechnology or healthcare.[86] Overseas studies are also few, and their conclusions may not be capable of being generalised to Australian conditions.[87] Where studies have been conducted, the conclusions are often equivocal.

---

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

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

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

87 See J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285; Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property*

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

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

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

Need for flexibility

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

3.76 For example, patent holders may become more active in enforcing certain patent rights, perhaps in response to the success of new business models. New medical, scientific and technological developments in the field of human genetics may provide new opportunities to exploit genetic inventions. Some isolated genetic materials (and related gene patents) may come to have an importance that was unanticipated, while other much-heralded patents may end up as technological backwaters, rather than being at the forefront of developments.

Rights and Licensing Practices: Evidence and Policies (2002); M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

3.77 The nature and extent of the potential problems—and whether existing legal mechanisms provide appropriate and effective remedies—are difficult to assess. The appropriate response to this challenge is to ensure that patent laws and practices are sufficiently flexible and robust to anticipate and respond to future problems. This approach has influenced the recommendations made in this Report, which are more often directed to influencing patent practices than to recommending substantive changes to patent law. The need for flexible regulation has been described by the ALRC elsewhere as one mechanism for ensuring that today's law reform is relevant to the scientific developments of tomorrow.[88]

Constraints on reform

3.78 There are other factors that constrain the extent to which it would be appropriate for the ALRC to recommend sweeping changes to the patent system. These include: the need to balance the interests of researchers, healthcare providers and consumers, and the biotechnology industry; the desirability of maintaining the technology-neutral nature of the *Patents Act*; and the international legal framework relating to patents.

Balancing of interests

3.79 The Terms of Reference direct the ALRC to consider the impact of gene patents on: (a) research and its subsequent application and commercialisation; (b) the biotechnology sector; and (c) the cost-effective provision of healthcare. The interests of each of these sectors are different and sometimes conflict—at least on the surface—and must be balanced in recommending reform. For example, when making recommendations directed to promoting access to patented inventions for healthcare purposes, the ALRC has been mindful of the impact of reforms on the biotechnology sector and on the potential for commercialisation of research. Not surprisingly, perhaps, the views expressed in submissions from health departments often differed markedly from those expressed in submissions from departments responsible for industry and innovation.

Technological neutrality

3.80 While the Inquiry's Terms of Reference instruct the ALRC to report on the impact of patenting laws and practices related to 'genes and genetic and related technologies', in general, the ALRC does not believe that concerns about the patenting of inventions involving genetic materials and technologies should be addressed by provisions in the *Patents Act* dedicated only to these types of inventions.

3.81 While there is some scope for technology-specific regulation through guidelines issued by the Patent Office (that is, IP Australia) and other relevant institutions, there are cogent reasons for maintaining, so far as possible, the technology-neutral nature of the *Patents Act*.[89] The introduction of legislative provisions that are specific to

---

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

89 See Ch 6 in relation to patentability requirements.

inventions involving genetic materials and technologies may suggest that specific provisions should also be implemented for future technologies—an approach that would unnecessarily fragment and complicate Australian patent law in the long term.

3.82 Many reforms considered by the Inquiry do not lend themselves to being formulated in a manner that is specific to genetic materials and technologies. Some recommendations, therefore, have been framed so as to apply to all patented inventions. These include, for example, recommendations made in relation to a new experimental use exemption,[90] Crown use and acquisition,[91] and compulsory licensing.[92] In some cases, the decision to recommend reforms applicable to all patentable inventions was bolstered by submissions that identified similar problems with respect to other patentable subject matter.[93] In other cases, the uncertain implications of reform on other patentable subject matter constituted one reason not to recommend change.[94]

3.83 Legislative reform that is specific to genetic materials and technologies would represent a departure from attempts to harmonise the patent laws of various jurisdictions and lead to divergence between Australian patent law and that in major industrialised countries—with implications for investment in the Australian biotechnology sector. Further, the adoption of specific laws for genetic materials and technologies may have implications for Australia's international obligations. For example, the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*[95] imposes constraints on the extent to which the national laws of member States may discriminate by 'field of technology'.[96] This provides an important reason why it is appropriate to make some recommendations applicable to all patentable inventions.

International legal framework

3.84 As discussed in Chapter 4, the international legal framework has an important influence on the reform of Australian patent law. In particular, reform may have implications for Australia's obligations under multilateral agreements dealing with patents and other intellectual property laws, and under bilateral free trade agreements with other states.[97]

---

90 See Ch 13.
91 See Ch 26.
92 See Ch 27.
93 See, eg, Ch 13 in relation to a new experimental use exemption.
94 See, eg, Ch 21 in relation to medical treatment defences.
95 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).
96 Ibid, art 27.1.
97 Under the Australia-United States Free Trade Agreement, the parties agree to reduce differences between their patent systems and to participate in international patent harmonisation: Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.14.

3.85 Although it is possible to amend domestic laws so that they are inconsistent with Australia's international treaty obligations, Australia may be held responsible on the international plane for breaches of such obligations. The ALRC would have needed compelling reasons to recommend any reform of patent law or practice that would raise doubts about Australia's compliance with its existing international obligations.[98]

Summary of recommendations

3.86 The ALRC has not identified fundamental flaws in patent law or practice as applied to genetic materials and technologies that justify recommending radical change. However, there are means by which patent law and practice should be fine-tuned to address existing problems and provide greater flexibility in addressing future problems as they arise. This Report makes 50 recommendations for reform. These recommendations are directed to:

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

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

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

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

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

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

- clarifying the application of competition law to the exploitation of intellectual property rights, including patented genetic materials and technologies; and

---

98 The ALRC, in performing its functions, 'must have regard to all of Australia's international obligations that are relevant to the matter': *Australian Law Reform Commission Act 1996* (Cth) s 24(2).

- clarifying the scope and practical application of exceptions to copyright infringement in relation to genetic research.

3.87 The mechanisms for implementing these recommendations vary. A number of recommendations are directed to legislative change, generally involving amendment of the *Patents Act*. A small number of these recommendations would make substantive changes to patent law; for example, through the enactment of a new requirement that the Patent Office be satisfied during examination that the criterion of 'usefulness' is met;[99] a new experimental use exemption;[100] and a new competition-based test as an additional ground for the grant of a compulsory licence.[101] Other recommendations for legislative reform are of a more minor nature, or are directed to clarifying existing law. These include recommendations to elucidate the ambit of the Crown use provisions,[102] and the extent to which the 'fair dealing' provisions of the *Copyright Act 1968* (Cth) apply to commercial research.[103]

3.88 However, most recommendations do not require legislative change but involve the development of new or revised guidelines, or other action by government and non-government bodies involved with various aspects of the patent system or its impact on research, biotechnology or healthcare. These bodies include: IP Australia; the Australian Competition and Consumer Commission (ACCC); the Australian Research Council (ARC); the NHMRC; Biotechnology Australia; AusBiotech Ltd; and the Australian Health Ministers' Advisory Council.

3.89 Some of these non-legislative recommendations are intended to improve the operation of the patent system and the practices and procedures of IP Australia, patent examiners and the courts. For example, the ALRC recommends that IP Australia develop examination guidelines to assist patent examiners in applying the 'usefulness' requirement of patentability,[104] and to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.[105] The ALRC also recommends that courts should continue to develop procedures to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving gene patents. This is a matter of particular importance to the Federal Court, which hears and determines most patent litigation in Australia.[106]

3.90 Other non-legislative recommendations are directed to the relationship between the patent system and the three sectors to which the ALRC is required to have regard—namely, research, biotechnology and healthcare. For example, the ALRC recommends that the ARC and the NHMRC review their principles and guidelines to ensure that

---

99 See Ch 6.
100 See Ch 13.
101 See Ch 27.
102 See Ch 26.
103 See Ch 28.
104 See Ch 6.
105 See Ch 8.
106 See Ch 10.

publicly funded research, where commercialised, results in appropriate public benefit,[107] and that universities continue to take steps to raise the awareness of researchers about intellectual property issues and the commercialisation of research.[108] It also recommends that Biotechnology Australia take steps to assist universities and biotechnology companies in commercialising inventions involving genetic materials and technologies.[109] Commonwealth, state and territory health departments are encouraged to consider actively whether to intervene in patent proceedings where particular gene patents are thought to have an adverse impact on healthcare provision or medical research.[110]

3.91 Another category of recommendations comprises those directed to monitoring the ongoing impact of gene patents. These reforms are intended to ensure that problems are identified at an early stage; for example, through monitoring of anti-competitive conduct by the ACCC.[111] The ALRC also recommends processes for examining the economic and financial impact of gene patents on healthcare services and the monitoring of gene patents by the proposed Human Genetics Commission of Australia.[112]

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

107 See Ch 11.
108 See Ch 14.
109 See Ch 17, 18, 22.
110 See Ch 19.
111 See Ch 24.
112 See Ch 19.

PART B

Patent Laws and Practices

4. International Legal Framework

Contents

Introduction

4.1 This chapter provides an overview of the international legal framework within which Australian patent law and practice operates, with reference to a number of international conventions that seek to harmonise procedural and substantive aspects of patent law.[1] The Terms of Reference specifically require the ALRC to have regard to Australia's existing or proposed international obligations in relation to patent law and practice. In addition, the ALRC has a general legislative obligation to have regard to Australia's international obligations in performing its functions.[2]

4.2 Elements of the international legal framework have an important influence on the reform of Australian patent law. Although it is possible for domestic laws to be amended so that they do not conform to Australia's international treaty obligations, Australia may be held responsible on the international plane for breaches of such obligations. The ALRC would need the most compelling reasons to recommend any reform of patent law or practice that would raise doubts about Australia's compliance with its international obligations.

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

---

1 Aspects of the international legal framework relating to copyright are discussed in Ch 28.

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

International legal instruments

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

- *Paris Convention for the Protection of Industrial Property 1883* (Paris Convention);[3]
- *Patent Cooperation Treaty 1970* (PCT);[4]
- *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977* (Budapest Treaty);[5] and
- *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[6]

4.5 Australian domestic law has given effect to significant provisions of each of these instruments. The instruments are outlined below, with a particular focus on the TRIPS Agreement.

Paris Convention

4.6 The Paris Convention is the principal international agreement in the field of 'industrial property', including patents, trademarks, utility models and industrial designs.[7] In relation to patents, the Paris Convention requires a contracting State to provide the same rights to the nationals of other contracting States as are provided to its own nationals.[8] It also 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 specified period of time (12 months in the case of patents) may have all applications treated as if they were filed on the date of the first application.[9] It also provides that eligibility for patent protection is independently assessed by each contracting State.[10]

---

3 *Paris Convention for the Protection of Industrial Property 1883*, [1972] ATS 12, (entered into force on 27 September 1975). Australia has been party to the Paris Convention since October 1925, and party to the Stockholm revisions since 27 September 1975.

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

5 *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).

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

7 *Paris Convention for the Protection of Industrial Property 1883*, [1972] ATS 12, (entered into force on 27 September 1975), art 1(2).

8 Ibid, art 2(1).

9 Ibid, art 4.

10 Ibid, art 4bis.

Patent Cooperation Treaty

4.7 The PCT establishes administrative procedures to facilitate the simultaneous filing of patent applications on a single invention in multiple jurisdictions.[11] 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 subsequently selecting the jurisdictions in which it may wish to obtain a patent.[12] The grant or refusal of a patent based on a PCT application is, however, determined by each of the national or regional patent offices with which the PCT application is filed.[13]

Budapest Treaty

4.8 The Budapest Treaty provides an international system for the deposit of micro-organisms as a means of satisfying the disclosure requirement for the grant of a patent by a national or regional patent office.[14] The Budapest Treaty establishes that the deposit of a micro-organism[15] 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.[16]

TRIPS Agreement

4.9 The TRIPS Agreement establishes the minimum standard of patent (and other intellectual property) protection that each member of the World Trade Organization (WTO), including Australia, must provide under its national laws. More extensive patent protection may be provided under domestic law so long as it would not affect the operation of other provisions of the TRIPS Agreement. Significant provisions of the TRIPS Agreement relating to patents include:

- a requirement that member States make patent protection available for any inventions, whether products or processes, in all fields of technology;[17]
- optional exclusions from patentability that may be adopted by member States;[18]

---

11 The PCT was incorporated into Australian law by the *Patents Amendment (Patent Cooperation Treaty) Act 1979* (Cth).

12 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978), art 3, 4, 11.

13 Ibid, art 27.

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

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

16 *Patents Act 1990* (Cth) ss 6, 41–42 address requirements for the deposit of a micro-organism and implement the provisions of the Budapest Treaty.

17 TRIPS Agreement, art 27(1).

18 TRIPS Agreement, arts 27(2), (3).

- a right for member States to provide limited exceptions to patent rights (including public policy exceptions) so long as such exceptions do not unreasonably conflict with the normal exploitation of a patent, nor unreasonably prejudice a patent holder's rights;[19]

- limitations on compulsory licensing and government use of patents, including a requirement that adequate compensation be paid for such use;[20] and

- a minimum patent term of 20 years.[21]

4.10 Amendments to the *Patents Act 1990* (Cth) (*Patents Act*) were necessary to bring Australian law into conformity with the TRIPS Agreement, and were enacted in the *Patents (World Trade Organization Amendments) Act 1994* (Cth). The amendments included extension of the standard patent term from 16 years to 20 years, and changes to the compulsory licensing and Crown use provisions.

4.11 The implications of the TRIPS Agreement for patent reform are discussed below in general terms and are given further consideration in the context of specific reform options considered elsewhere in this Report.

4.12 Only one WTO case provides guidance on relevant provisions of the TRIPS Agreement.[22] The WTO panel report in the *Canada–Patent Protection* case involved a complaint by the European Communities and their member States against Canada. It provides significant commentary on the application of TRIPS provisions relating to discrimination by field of technology and permissible exceptions to patent protection.[23]

Discrimination as to field of technology

4.13 The TRIPS Agreement provides that patents shall be available for any inventions and that patent rights shall be enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.[24] It has been suggested that the main aim of the non-discrimination clause was to 'restrain the use of compulsory licences for lack of local exploitation'.[25]

---

19 TRIPS Agreement, art 30.
20 TRIPS Agreement, art 31.
21 TRIPS Agreement, art 33.
22 Department of Foreign Affairs and Trade, *Submission P29*, 2 October 2003.
23 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R.
24 TRIPS Agreement, art 27(1).
25 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 15.

4.14 The *Canada–Patent Protection* case sets out some of the parameters for assessing prohibited discrimination by field of technology. The WTO panel drew a distinction between 'differentiation' and 'discrimination' and explained that the latter, but not the former, is prohibited by art 27(1). The panel stated that the ordinary meaning of the word 'discriminate':

> certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment.[26]

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

Exclusions from patentability

4.16 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'.[27]

4.17 The TRIPS Agreement also provides that member States may exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' and 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals'.[28] These exclusions from patentability are discussed further in Chapter 7.

Exceptions to patent rights

4.18 The TRIPS Agreement provides that a patent shall confer on its owner exclusive rights to make, use, offer for sale, sell or import the patented product or process.[29] However, the Agreement allows member States to provide limited exceptions to this level of patent protection. Article 30 states:

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

4.19 Article 30 establishes three conditions for a permissible exception. The exception must be 'limited', must not 'unreasonably conflict with the normal exploitation of the patent' and must not 'unreasonably prejudice the legitimate interests

---

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

27 TRIPS Agreement, art 27(2).

28 TRIPS Agreement, art 28(3).

29 TRIPS Agreement, art 28(1).

of the patent owner, taking into account the legitimate interests of third parties'. These conditions are cumulative, so that failure to comply with any one of them may result in an exception being inconsistent with the TRIPS Agreement.[30]

4.20 The relationship between art 30 and art 27(1), which prohibits discrimination as to field of technology, has been the subject of some debate.[31] The *Canada–Patent Protection* case confirmed that art 27 does not 'prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.[32]

4.21 In the ALRC's view, it may be possible to craft defences to claims of infringement of patent rights, or other exceptions to patent rights, that are specific to gene patents. Such a provision would differentiate between certain product areas but would not 'discriminate' by field of technology within the meaning of the TRIPS Agreement. Nevertheless, there would need to be strong arguments to justify differentiating gene patents, or a category of gene patents, from patents in other fields of technology.

4.22 The extent of permissible exceptions to patent protection under the TRIPS Agreement, including through new defences to claims of infringement, are discussed in Chapters 6, 13 and 21.

Compulsory licensing and Crown use

4.23 The TRIPS Agreement contains detailed provisions dealing with the use of patented inventions 'without the authorization of the right holder, including use by the government or third parties authorized by the government'.[33] In the context of Australian patent law and practice, these provisions apply to Crown use and compulsory licensing of patented inventions.

4.24 Under the TRIPS Agreement, the basic obligation of member States is to ensure that any use permitted without the authorisation of the patent holder is considered on its individual merits.[34] Use may be permitted only if the proposed user has made unsuccessful efforts to obtain authorisation from the patent holder on reasonable commercial terms, except in cases of national emergency or other extreme urgency, or for public non-commercial use.[35] There are detailed provisions in relation to the permissible duration and scope of authorised use, remuneration of the patent holder, and judicial or other independent review of Crown use or compulsory licensing

30 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 152.
31 Ibid, 170–171; compare M Matsushita, T Schoenbaum and P Mavroidis, *The World Trade Organization: Law, Practice, and Policy* (2002), 428.
32 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 170–171.
33 TRIPS Agreement, art 31.
34 TRIPS Agreement, art 31(a).
35 TRIPS Agreement, art 31(b).

decisions.[36] The provisions of the TRIPS Agreement dealing with Crown use and compulsory licensing are discussed further in Chapters 26 and 27.

Patent term

4.25 The TRIPS Agreement provides that the term of protection shall not end before the expiration of a period of 20 years.[37] Therefore, any system for standard patents that does not provide protection to the patent holder for 20 years would be inconsistent with the TRIPS Agreement.

4.26 In addition to the standard 20-year patent, Australian law also recognises a 'second tier' of protection called an 'innovation patent'. These patents have a term of eight years, provide protection for inventions that represent a lesser level of inventiveness over the prior art, and are subject to less scrutiny by the Patent Office prior to grant.

Other international legal instruments

4.27 Activity in the international community to further the global harmonisation of patent laws may affect Australian patent laws and practices in the future. For example, the *Patent Law Treaty 2000*[38]—which primarily addresses administrative issues relating to the patent system—was opened for signature on 1 June 2000 at a Diplomatic Conference of the World Intellectual Property Organization (WIPO).[39] 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.[40] In addition, other international legal instruments that are not primarily concerned with patent law or practice may nevertheless have an impact on Australian patent laws and practices, such as the *Convention on Biological Diversity*.[41]

Bilateral free trade agreements

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

---

36 TRIPS Agreement, art 31(c)–(l).

37 TRIPS Agreement, art 33.

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

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

40 World Intellectual Property Organization, *Draft Substantive Patent Law Treaty* (2003); World Intellectual Property Organization, 'Member States Discuss Ways to Further Harmonize Patent Law', *Public Information Update No 225/2004* (Geneva), 18 May 2004, <www.wipo.int/pressroom/en/index.jsp>.

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

4.29 Most importantly, given the dominant position of the United States in the field of biotechnology, on 18 May 2004, the Australian Trade Minister (the Hon Mark Vaile), and the United States Trade Representative (Robert Zoellick) signed the Australia–United States Free Trade Agreement (AUSFTA). Before the AUSFTA can enter into force and become binding under international law, Australia and the United States must complete their 'necessary internal requirements' and exchange written notification that this has been done.[42] In the case of Australia, the internal requirements include passage of any legislation necessary to give effect to the agreement; in the case of the United States, they include ratification of the agreement by two-thirds of the Senate.[43] The target date for the agreement to enter into force is 1 January 2005.[44]

4.30 The AUSFTA contains a number of provisions relevant to patent law and practice. These include provisions with respect to: exclusions from patentability; revocation of patents; Crown use and compulsory licensing of patents; non-prejudicial disclosures; and the 'usefulness' requirement for patentability.[45] More generally, Australia and the United States agree to endeavour to reduce differences in law and practice between their respective patent systems and to participate in international patent harmonisation efforts.[46]

4.31 The provisions of the AUSFTA have implications for reform of Australian patent law. Amendments to the *Patents Act* are necessary to give effect to some provisions of the AUSFTA, for example, to preserve the criterion of a 'patentable invention' as a ground for revocation of a patent.[47] In other cases, where the AUSFTA reflects existing Australian law or practice, the agreement may act as a constraint on future change.[48] The implications of the AUSFTA for patent law reform are given further consideration in the context of specific reform options discussed elsewhere in this Report.

---

42 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 23.4.1.

43 *United States Constitution*, art II, sec 2; L Henkin, *Foreign Affairs and the US Constitution* (2nd ed, 1996), Ch 7.

44 Department of Foreign Affairs and Trade, *Submission P93*, 16 April 2004. See also Department of Foreign Affairs and Trade, *Australia–United States Free Trade Agreement: Frequently Asked Questions*, <www.dfat.gov.au/trade/negotiations/us_fta/faqs.html> at 16 June 2004.

45 See Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.

46 Ibid, art 17.9.14.

47 Ibid, art 17.9.5. See Ch 9. The US Free Trade Agreement Implementation Bill 2004 (Cth) was introduced into the House of Representatives on 23 June 2004.

48 Examples include the transfer of 'know-how' in association with Crown use of a patent (see art 17.9.7(b)(iii) and Ch 26); and the grace period for public disclosures of information relating to an invention (see art 17.9.9 and Ch 14).

5. Domestic Legal Framework

Contents

Introduction

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

5.2 Other chapters in this Report address substantive aspects of Australian patent law and the application of these principles to inventions involving genetic materials and technologies. The requirements that must be satisfied to obtain a patent, and the limitations on the availability of patent protection for certain types of inventions, are considered in Chapters 6 and 7. Chapters 9, 10 and 22 outline the law relating to challenging, enforcing and licensing patent rights. Later chapters examine other

Commonwealth legislation that may impact on patent practices, in particular the *Trade Practices Act 1974* (Cth).[1]

Domestic legal framework

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

5.4 Australia has enacted legislation that regulates patenting practices within the Australian 'patent area'[2] with respect to inventions involving any type of technology. The procedures for obtaining a gene patent in Australia are, broadly speaking, the same as those that apply to patents claiming any other type of technology. The discussion of patent law and practice in this chapter is therefore cast in general terms.

Legislation

5.5 Section 51(xviii) of the *Australian Constitution* grants the Commonwealth Parliament power to make laws with respect to 'copyrights, patents of inventions and designs, and trade marks'. Pursuant to this power, the Parliament has enacted the *Patents Act 1990* (Cth) (*Patents Act*) and the *Patents Regulations 1991* (Cth) (*Patents Regulations*).[3]

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

- is a 'manner of manufacture'—that is, the invention is appropriate subject matter for patent protection;
- is novel;
- involves an inventive or innovative step;
- is useful; and
- has not been used secretly within Australia before the priority date of the patent application.[4]

---

1 See Ch 24.

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

3 Chapter 2 outlines the history of Australian patent legislation.

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

Administration

5.7 The Australian patent system is administered by the Patent Office of IP Australia.[5] IP Australia is a division of the Department of Industry, Tourism and Resources, but operates independently and reports directly to the Minister.[6]

5.8 Under the *Patents Act*, the Commissioner of Patents has the power to grant a patent upon an application being filed with and examined by the Patent Office. IP Australia has developed the *Patent Manual of Practice and Procedure* (the *Manual*) to assist Australian patent examiners in applying the *Patents Act* and *Patents Regulations*.[7] IP Australia's examination practices are discussed in this chapter and in Chapter 8.

5.9 State and federal courts and the Administrative Appeals Tribunal (AAT) also have a role in administering the patent system. Decisions of the Commissioner of Patents may be subject to review by the AAT or the Federal Court of Australia.[8] The AAT may undertake merits review of the Commissioner's decisions with respect to certain procedural matters prescribed by the *Patents Act*.[9] A direct application may be made to the Federal Court for judicial review in relation to other decisions of the Commissioner; essentially those related to the grant of patents or matters closely allied to the grant (for example, amendments to patent specifications and revocations).[10]

5.10 The Federal Court and state and territory Supreme Courts share original (first instance) jurisdiction over matters relating to the exploitation and enforcement of patent rights, including challenges to patent rights, infringement proceedings and compulsory licences.[11] The AAT has no jurisdiction in relation to such issues. Jurisdictional matters are considered further in Chapter 10.

---

5 IP Australia also administers trademark and design rights in Australia.

6 IP Australia, *What is IP Australia?*, <www.ipaustralia.gov.au/about/whatis.html> at 16 June 2004.

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

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

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

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

11 *Patents Act 1990* (Cth) s 155.

Types of patents

5.11 Australian patent law recognises two principal types of patents: standard patents and innovation patents. An applicant for a patent may elect to obtain protection for an invention under either system. Figure 5–1 outlines the key features of, and the difference in the scope of protection conferred by, standard and innovation patents.

Standard patents

5.12 A standard patent is the basic form of patent protection for inventions under Australian law and is consistent with the minimum requirements for patent protection under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[12] Unless otherwise indicated, references to an Australian patent and discussions of patent rights in this Report relate only to the standard patent system.

Innovation patents

5.13 The innovation patent is a 'second tier' of protection, which was introduced in 2001 to replace the petty patent system.[13] Innovation patents are intended to provide protection for 'lower level' inventions for which standard patent protection is not available and which are not covered by the designs legislation.[14] DP 68 contained a detailed discussion of the innovation patent system.[15]

5.14 The ALRC received a small number of submissions that suggested it would be preferable for an invention involving genetic materials and technologies to be protected only by the innovation patent system. In general, these submissions were critical of genetic sequences being treated as inventions for the purposes of patent law and therefore considered the shorter term of patent protection provided by an innovation patent to be more appropriate.[16]

---

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

13 See: Advisory Council on Industrial Property, *Review of the Petty Patent System* (1995); Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 157. Other jurisdictions also provide a 'second tier' of patent protection: Advisory Council on Industrial Property, *Review of the Petty Patent System* (1995), Ch 3; D Ryan, 'Innovation Patents: What is their Likely Impact?' (2002) 48 *Intellectual Property Forum* 30, 31.

14 G McGowan, 'The New Innovation Patent System: Will It Work?' (2002) 76 *Law Institute Journal* 64; Advisory Council on Industrial Property, *Review of the Petty Patent System* (1995), rec 2. For judicial consideration of the innovation patent system, see *Datadot Technology Ltd v Alpha Microtech Pty Ltd* [2003] FCA 962.

15 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Ch 5.

16 For example, A Bankier, *Submission P19*, 30 September 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

Figure 5–1 Features of standard patents and innovation patents

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

Notes

I See Chapter 7 for a discussion of the exclusions from patentable subject matter.

II See ss 18(2), 101(b)(2)(d) and 101B(4) of the *Patents Act*.

III See Chapter 6 for a discussion of the requirements for patentability. The requirements to obtain an innovation patent are the same as those for a standard patent, except as noted.

5.15 However, as DP 68 indicated, the features of the innovation patent system—in particular, the lack of substantive pre-grant examination of an application—make it unsuitable as the sole form of patent protection available for genetic materials and technologies.[17] Several submissions to the Inquiry supported this conclusion.[18] In

17 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [5.64]–[5.68], [5.72]–[5.78].

18 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; IP Australia, *Submission P56*, 4 November 2003; Queensland Government, *Submission P57*, 5 January 2004; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

addition, a few submissions considered that the shorter term of protection conferred by an innovation patent would be undesirable because the development and commercialisation of genetic products may not be complete until many years after patent protection is first granted.[19] Limiting patent protection for genetic inventions to the innovation patent system may also be inconsistent with Australia's obligations under the TRIPS Agreement.[20] In light of this, this Report does not contain any substantive discussion of the innovation patent system.

Patents of addition

5.16 The *Patents Act* also provides for the grant of a 'patent of addition' for an improvement in, or modification to, an invention claimed in a standard patent that has already been granted.[21] A patent of addition may be obtained only by the owner of the earlier patent, or a person authorised by the owner.[22] The term of a patent of addition expires at the same time as that of the patent on the main invention.[23]

Procedure for grant of a patent

5.17 Patent rights do not arise automatically. A patent can be obtained only by following the procedure set out in the *Patents Act* and *Patents Regulations*. An understanding of the procedure for obtaining a patent is important to understanding Australian patent law generally. The steps in obtaining an Australian patent are described below. A flow chart outlining the stages in the patent application process is included in s 4 of the *Patents Act* and was reprinted in DP 68.[24]

Filing an application

5.18 For a patent to be granted, an eligible person must file an application in the form prescribed by the Patent Office. Eligible persons are the inventor of the invention claimed in the application, or a person to whom the inventor has assigned his or her rights in the invention.[25] A patent application must include a specification of the invention, which contains instructions adequate to enable a skilled person in the

---

19 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

20 Department of Foreign Affairs and Trade, *Submission P29*, 2 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; IP Australia, *Submission P56*, 4 November 2003; Queensland Government, *Submission P57*, 5 January 2004; Department of Health Western Australia, *Submission P53*, 3 November 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

21 *Patents Act 1990* (Cth) s 81. Under s 80, a patent of addition is not available in relation to an innovation patent.

22 Ibid s 81(1)(b).

23 Ibid s 83.

24 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Fig 5–2.

25 If an inventor or his or her assignee is deceased, that person's legal representative may file for patent protection: *Patents Act 1990* (Cth) s 15, sch 1.

relevant area of technology to produce or perform the invention. The specification must also indicate the 'claims' that define the invention; that is, the scope of protection that the applicant is seeking.

5.19 Australian patent law recognises two types of patent applications—provisional and complete.[26] Provisional and complete applications may be filed to obtain either a standard patent or an innovation patent.

5.20 A provisional application need only contain a description of the invention.[27] Often, an inventor files a provisional application before all the details of an invention are known. The applicant then has 12 months to file a complete application.

5.21 A complete application must contain a full description of the invention, together with claims, and an abstract summarising the invention being disclosed.[28] A complete application may be based on one or more provisional applications, and only those claims that are 'fairly based'[29] on the relevant provisional application will be entitled to the priority date of the provisional application.

5.22 The 'priority date' of a patent claim is important in determining whether the requirements for patentability of an invention have been met. As discussed in Chapter 6, the requirements of novelty and inventive step are assessed against the prior art as it existed before the priority date.[30] The priority date is typically the date on which a provisional application is filed in Australia, or the date on which an application is filed in another participating jurisdiction.[31]

5.23 An applicant may also elect to file a complete application with the Patent Office under the *Patent Cooperation Treaty* (PCT).[32] As discussed in Chapter 4, a PCT application designates all the jurisdictions that are parties to the PCT (including Australia), and secures an international priority date.

5.24 PCT applications that have entered the national phase (and will be processed as a complete application) are the main type of applications received by IP Australia.[33] In 2002–03, 16,278 PCT applications selected Australia as one of the jurisdictions in which an applicant wished to obtain patent protection and entered the national phase in

26 Ibid s 29.
27 Ibid s 40(1).
28 *Patents Regulations 1991* (Cth) rr 3.1, 3.2A, 3.3.
29 The 'fair basis' requirement is discussed in Ch 6.
30 *Patents Act 1990* (Cth) s 18(1)(b).
31 Ibid s 43; *Patents Regulations 1991* (Cth) rr 3.12–3.14.
32 *Patent Cooperation Treaty*, [1980] ATS 6, (entered into force on 24 January 1978); *Patents Act 1990* (Cth) ss 88–93.
33 IP Australia, *Annual Report* (2003).

Australia.[34] During the same period, 5,694 non-PCT applications for standard patents were filed with IP Australia.[35]

Divisional applications

5.25 Each patent application may claim protection only for a single invention.[36] If, following assessment of a patent application, a patent examiner finds that an applicant has claimed more than one invention in the application, the applicant may elect to file a 'divisional application'—that is, a new application divided from the original or parent application. A divisional application allows an applicant to continue to benefit from the priority date of the original application. [37]

5.26 Divisional applications may claim subject matter not contained in the original application so long as all the features of at least one of the claims were disclosed in the original application. There are no statutory limits on the number of divisional applications that may arise from a single complete application.

5.27 The *Patents Act* restricts the subject matter that may be claimed in a divisional application, depending on the time at which it is filed.[38] However, a divisional application, once filed, is subject to the same procedural requirements, including examination, as any other complete patent application.

5.28 In its submissions to the Inquiry, IP Australia indicated that divisional applications are currently 'open to abuse'.[39] In practice, such abuse may occur only in a small number of cases. However, IP Australia suggested that patent applicants are able to make strategic use of divisional applications in order to delay determinations by the Patent Office as to the proper scope of patent claims, or as to whether a patent should be granted.[40] IP Australia commented that the *Patents Act* allows an applicant to use a divisional application to obtain a *de facto* monopoly by extending the period within which to respond to an examiner's adverse report. While this use of divisional applications may be legitimate in some circumstances, IP Australia suggested that it might be used tactically by an applicant in 'newly developing areas of technology, such as genetics, where there is a question of [the] patentability of the subject matter'. Further, an applicant might avoid a decision in an opposition proceeding by withdrawing the opposed application and refiling it as a divisional application. To

---

34 Ibid. IP Australia may not, however, have undertaken substantive examination of all of these applications: IP Australia, *Submission P56*, 4 November 2003.

35 IP Australia, *Annual Report* (2003).

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

37 The *Patents Act* does not provide for a divisional application based on a provisional application: Ibid s 79B; IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [9.8]. The requirements for filing divisional applications based on an innovation patent are set out separately: see *Patents Act 1990* (Cth) s 79C; *Patents Regulations 1991* (Cth) r 6A.2.

38 *Patents Act 1990* (Cth) s 79B(1); *Patents Regulations 1991* (Cth) rr 3.11(2), 6A.1. See also Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [5.34].

39 IP Australia, *Submission P56*, 4 November 2003; IP Australia, *Submission P86*, 16 April 2004.

40 Commentators have made similar observations: see J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8025].

address these issues, IP Australia suggested that limitations could be imposed on the circumstances in which divisional applications are available.[41]

5.29 However, the majority of submissions and consultations on this issue did not support imposing additional limitations either on the period within which a divisional application may be filed or on the subject matter that may be claimed in a divisional application.[42] Submissions and consultations questioned whether divisional applications are being misused,[43] and commented on the lack of evidence that divisional applications claiming genetic inventions present a special case.[44]

5.30 The ALRC does not consider that reform of the *Patents Act* relating to divisional applications is required to address particular issues raised by patents over genetic materials and technologies. The concerns expressed by IP Australia about divisional applications are not limited to genetic inventions. Further, the weight of submissions considered that the current provisions are operating well and should not be amended without firm evidence of a problem.

Examination

5.31 Once an application has been filed with the Patent Office, a number of additional steps must be followed before a patent may be issued. An applicant must file a request that the Patent Office examine the application.[45] Examination is not automatic and a request for examination must generally be filed within five years of the date of filing a complete specification.[46] However, IP Australia's standard practice is to direct applicants to file a request for examination, if no request has been received, at approximately 32 months from the priority date, although this period may vary according to IP Australia's workload.[47] An abbreviated examination may be requested if an Australian patent application is related to a patent that has already been granted by the patent office in a prescribed foreign jurisdiction.[48]

---

41 IP Australia, *Submission P56*, 4 November 2003; IP Australia, *Submission P86*, 16 April 2004. See also Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 5–1.

42 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 31 March 2004.

43 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004. See also F B Rice & Co, *Submission P84*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

44 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

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

46 *Patents Regulations 1991* (Cth) r 3.15. The Commissioner of Patents may also direct an applicant to file a request for examination within a shorter period and the applicant must comply with any such request within six months or the application will lapse: *Patents Act 1990* (Cth) ss 44(2)–(4), 142(2)(a); *Patents Regulations 1991* (Cth) r 3.16.

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

48 *Patents Act 1990* (Cth) s 47; *Patents Regulations 1991* (Cth) r 3.20. The prescribed jurisdictions are Canada, New Zealand, the United States, and signatory countries to the *European Patent Convention*: *Patents Regulations 1991* (Cth) r 3.21.

5.32 The purpose of examination is to determine whether the invention meets the statutory requirements for patentability set out in the *Patents Act*.[49] The Patent Office carries out searches of previously published documents—including scientific and patent literature ('prior art information')—to determine the prior art material relevant to the claimed invention.[50] In addition, an applicant must disclose to the Patent Office the results of searches carried out by or on behalf of foreign patent offices in respect of the invention claimed in an Australian application, or in a corresponding patent application filed overseas.[51] An examiner with expertise in the relevant area of technology then examines the application, taking into account the information contained in the results of these searches and any other prior art information.

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

5.34 Following receipt of a request for examination, an examiner will make an initial assessment of an application for a standard patent and either accept the application as filed or issue a 'first report' detailing the procedural and substantive grounds for objecting to the application.[52] An applicant then has a period of 21 months to address the objections raised by the examiner. The examiner may issue further reports for each response by the applicant that does not satisfy the objections raised. An application for a standard patent will generally lapse if it is not in order for acceptance within 21 months after the date of the first report.[53]

Acceptance, publication and sealing

5.35 The Commissioner of Patents must notify an applicant of the decision to accept or refuse a patent application, and must publish notice of the decision in the *Official Journal of Patents* (*Official Journal*).[54] Formal refusal of an application is rare.[55] More commonly, applications for standard patents lapse for failure to obtain acceptance within the prescribed 21 month period following a first report. The *Official Journal* also publishes notices of lapsed applications.[56]

---

49 Currently, a patent examiner is not required to consider all the criteria for patentability specified in s 18: see Ch 6 for more detail.

50 'Prior art information' and 'prior art base' are defined in the *Patents Act 1990* (Cth) s 7, sch 1. See Ch 6.

51 Ibid s 45(3); *Patents Regulations 1991* (Cth) r 3.17A.

52 *Patents Act 1990* (Cth) s 45(1); *Patents Regulations 1991* (Cth) r 3.18.

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

54 *Patents Act 1990* (Cth) s 49(5), (7).

55 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8180]. There have been only four or five such refusals between 1991 and 2003: IP Australia, *Submission P56*, 4 November 2003.

56 *Patents Regulations 1991* (Cth) r 13.5.

5.36 Publication of a notice of acceptance in the *Official Journal* should be distinguished from the publication of a complete specification for a standard patent. This typically occurs 18 months after the earliest priority date for the application,[57] and is also advertised in the *Official Journal*.[58] An application is confidential prior to publication of the complete specification, and only bibliographic details—such as the applicant's name and title of the invention—are made available by the Patent Office.[59]

5.37 A patent is granted when the Commissioner of Patents causes the patent to be sealed with the seal of the Patent Office. For a standard patent, this will occur within six months of the date of publication in the *Official Journal* of the notice of acceptance of the application, unless the application is opposed.[60]

Rights of a patent holder

5.38 The *Patents Act* provides that the grant of a patent confers upon a patent holder the exclusive right to exploit, or to authorise another person to exploit, an invention during the patent term.[61] 'Exploit' is defined in the Act to include:

> (a) where the invention is a product—make, hire, sell or otherwise dispose of the product, offer to make, sell, hire, or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things; or
>
> (b) where the invention is a method or process—use the method or process or do any act mentioned in (a) in respect of a product resulting from such use.[62]

5.39 A patent does not, however, grant an absolute right to exploit an invention. A 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. In addition, a patent holder's ability to exploit the invention may be subject to earlier patents not owned by the patent holder.

5.40 A patent holder may assign or license its 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).[63] A licence of a patent does not transfer

---

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

58 *Patents Act 1990* (Cth) s 54(1). Certain information may be prohibited from being disclosed to the public under the *Patents Act*, even after examination and acceptance of a patent application: *Patents Act 1990* (Cth) ss 147, 152, 173, 174.

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

60 *Patents Act 1990* (Cth) s 61; *Patents Regulations 1991* (Cth) r 6.2. As a matter of practice, a standard patent is typically sealed approximately four months after acceptance of the application has been advertised in the *Official Journal*, unless the application is opposed: IP Australia, *Submission P56*, 4 November 2003.

61 *Patents Act 1990* (Cth) s 13(1).

62 Ibid sch 1.

63 The assignment of a patent must be in writing and signed by both the assignor and the assignee: Ibid s 14(1).

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.[64] Licensing practices with respect to patented genetic and biotechnological inventions are discussed in Chapter 22.

5.41 A patent holder is not obliged to exploit an invention claimed in a patent at any time during the patent term, nor to license or assign its patent rights. However, the failure to exploit the invention may encourage others to invoke the Crown use or compulsory licensing provisions in the *Patents Act*.[65]

5.42 Patent rights remain subject to challenge even after the Commissioner of Patents accepts a patent application and after the patent is sealed. Section 20 of the *Patents Act* expressly states that nothing in the Act or in the PCT[66] guarantees that a patent is valid. Challenges to patent rights are discussed in Chapter 9.

Duration of patent protection

5.43 A standard patent generally has a term of 20 years, commencing on the date of the patent; an innovation patent has a term of 8 years (see Figure 5–1).[67] The term of a standard patent relating to 'pharmaceutical substances' may be extended in certain circumstances.[68]

5.44 As discussed in Chapter 4, art 33 of the TRIPS Agreement requires member States to provide patent protection for a term of not less than 20 years from the filing date.[69] Article 27(1) requires member States to make patent protection available for all inventions, without discrimination as to the field of technology to which an invention relates.[70] The *Patents Act* was amended in 1994 to extend the term of protection for a standard patent from 16 years to 20 years in order to bring Australian patent law into conformity with the TRIPS Agreement.[71]

---

64 The grant of an exclusive licence may carry with it some of the indicia of ownership; for example, an exclusive licensee has the right to enforce the licensed patent rights and a patent holder must seek a licensee's consent to amend a patent specification (unless this requirement is waived by the Commissioner of Patents): see Ibid ss 120(1), 187, 103.

65 See Ch 26 and 27.

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

67 *Patents Act 1990* (Cth) ss 67–68. The 'date of the patent' is the date on which the complete specification was filed or, if applicable, a different date determined by the *Patents Regulations*: *Patents Act 1990* (Cth) s 65; *Patents Regulations 1991* (Cth) r 6.3.

68 *Patents Act 1990* (Cth) ss 70–79A. The provisions for pharmaceutical patent term extension are currently under review: Department of Industry Tourism and Resources, *Discussion Paper on Patent Extensions and Springboarding, and the Effect on Generic Pharmaceuticals Manufacturers in Australia* (2002).

69 TRIPS Agreement, art 33.

70 TRIPS Agreement, art 27(1).

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

5.45 While the TRIPS Agreement provides some flexibility to member States in developing their own patent laws, the minimum term of patent protection is not subject to exceptions or qualifications. The TRIPS Agreement does, however, permit member States to require compliance with reasonable procedures and formalities as a condition of the acquisition or maintenance of intellectual property rights.[72] Such procedures and formalities include the payment of fees for the filing and processing of a patent application, and for maintaining existing patent rights.

5.46 In addition, the Australia–United States Free Trade Agreement contains a provision that might affect the term of patent.[73] Article 17.9.8 provides that, if there are unreasonable delays in a Party's issuance of patents, that Party shall provide a means to adjust the term of the patent to compensate for the delay.[74] If, in the future, there is evidence of unreasonable delay in the grant of Australian patents it may be necessary to amend the *Patents Act* to provide an extension of the patent term.

Maintaining patent rights

5.47 A patent holder must pay the prescribed maintenance fees to keep a patent in force.[75] Fees are due annually, commencing on the fifth anniversary of the filing of the complete application for a standard patent.[76]

5.48 For a standard patent, maintenance fees increase incrementally from $180 (payable on the fifth anniversary) to $1,000 (payable on the nineteenth anniversary).[77] A standard patent will cease if the prescribed fees are not paid.[78]

5.49 The actual term of a patent is the period during which a patent remains in force; that is, the period during which the patent holder continues to pay renewal fees. According to IP Australia, the average actual term of standard biotechnology patents in Australia is approximately 12 years.[79] This is higher than the average actual term for standard patents generally, which is approximately eight and a half years.[80] This difference does not appear to create problems. IP Australia informed the ALRC that:

---

72 TRIPS Agreement, art 62(1).

73 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004.

74 An unreasonable delay is deemed to include a delay in the issuance of a patent of more than four years from the date of filing an application, or two years after the request for an examination has been made, whichever is later. However, delays that are attributable to the actions of a patent applicant, or any opposing third party, need not be covered: Ibid, art 17.9.8.

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

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

77 Ibid sch 7 Pt 2. See also IP Australia, *Patent Fees*, <www.ipaustralia.gov.au/patents> at 16 June 2004; IP Australia, *Submission P56*, 4 November 2003. Maintenance fees for pharmaceutical patents during any extended term are $1,200 per year.

78 *Patents Act 1990* (Cth) s 143(a).

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

80 Ibid.

> IP Australia is not aware of evidence that the maintenance of gene patents for above average periods has a detrimental effect. In their early stage, other technologies have also experienced rapid advancement, and broad claims have been maintained for up to twenty years.[81]

5.50 The report of the Intellectual Property and Competition Review Committee (IPCRC Report) suggested that the use of more steeply rising renewal fees might reduce 'the effective length of the patent term' under Australian law.[82] The IPCRC Report recommended that 'the scope for, and impact of, implementing more steeply rising renewal fees should be considered by IP Australia'.[83] In 2002, IP Australia increased the annual maintenance fees in 2002, for the first time in nine years.[84]

Patent fees and cost recovery

5.51 Other government policies may affect IP Australia's patent fee structure.[85] In particular, the guidelines for implementing cost recovery for government agencies (Cost Recovery Guidelines)[86]—which were accepted by the Australian Government in 2002 in response to a Productivity Commission review of this issue[87]—may affect patent fees in the future.

5.52 The Productivity Commission recommended that government charges should be linked as closely as possible to the costs of activities and products provided by government agencies.[88] However, the Commission considered that cost recovery should not be implemented where it would be inconsistent with policy objectives or would unduly stifle competition or industry innovation.[89]

5.53 As discussed in Chapter 8, IP Australia already operates on a cost-recovery basis and funds its activities primarily from revenue raised through charges for its intellectual property services.[90] Nonetheless, a review of IP Australia's cost recovery arrangements is scheduled to occur in 2004–05 as part of the Australian Government's implementation of the Cost Recovery Guidelines.[91]

5.54 IP Australia informed the ALRC that patent maintenance fees are currently set at a level that exceeds the cost of collecting them, but that maintenance fees subsidise the cost of examining patent applications.[92] This fee structure is designed 'to encourage

---

81 Ibid.
82 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 144.
83 Ibid, 157.
84 Maintenance fees had previously ranged from $165 (fifth anniversary) to $790 (nineteenth anniversary).
85 IP Australia, *Submission P86*, 16 April 2004.
86 Department of Finance and Administration, *Cost Recovery Guidelines for Regulatory Agencies* (2002).
87 Productivity Commission, *Cost Recovery by Government Agencies (Report No 15)* (2001).
88 Ibid, rec 7.10.
89 Ibid, rec 7.7, 7.9
90 Department of Industry Tourism and Resources, *Annual Report* (2003).
91 Department of Finance and Administration, 'Cost Recovery by Government Agencies', *Finance Circular No 2002/02*, <www.finance.gov.au/finframework/fc_2002_02.html>, attachment A.
92 IP Australia, *Submission P86*, 16 April 2004.

entry into the system at a time when applicant finances are typically low, and discourages patent holders from maintaining rights that lack commercial value'.[93]

5.55 A 2004 study of the economics of patent fees confirms that 'a social welfare maximising [patent office] will set renewal fees as high as possible and initial patent application fees as low as possible subject to encouraging invention'.[94] However, the study also concluded that if a patent office were subject to a revenue constraint that it be self-funding, there would be a trend towards decreasing maintenance fees over time in order to encourage more patent renewals.[95] Imposing a self-funding (or cost-recovery) requirement may, therefore, result in a distortion of the structure and quantum of patent fees 'in a way that lowers social welfare'.[96]

Submissions and consultations

5.56 DP 68 suggested that IP Australia should regularly review the schedule of patent fees to assess the impact of fees on the actual term of Australian patents and to ensure that fees are set at a level appropriate to discourage patent holders from maintaining patents that lack commercial value.[97] Such an approach relies on the legislative requirement that a patent holder pay annual maintenance fees to address concerns about patents persisting when a patent holder is no longer gaining a commercial advantage from the patented invention.[98]

5.57 A number of submissions supported the proposal that IP Australia review its fees on a regular basis.[99] Submissions observed that increases in patent maintenance fees might have an impact on patent holders' decisions to continue to maintain patents.[100]

5.58 However, submissions and consultations also expressed concerns about the proposal.[101] Some indicated that this approach could have a disproportionate impact on smaller entities within the biotechnology sector.[102] Others suggested that increased

---

93 Ibid.

94 J Gans, S King and R Lampe, *Patent Renewal Fees and Self-Funding Patent Offices (Working Paper No 01/04)* (2004) Intellectual Property Research Institute of Australia, 8.

95 Ibid, 9–12.

96 Ibid, 13. Other studies of the socially optimal structure for patent renewal fees have reached similar conclusions.

97 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 5–1.

98 Department of Foreign Affairs and Trade, *Submission P29*, 2 October 2003; IP Australia, *Submission P56*, 4 November 2003.

99 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

100 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

101 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004.

102 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004. See also Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

patent fees would favour inventions with clear commercial potential.[103] Submissions indicated, therefore, that 'care should be exercised by IP Australia in setting patent fees'.[104]

5.59 A number of submissions and consultations considered that the structure and quantum of maintenance fees might have only a small impact on patent holders' decisions to keep an Australian patent in force—particularly in the case of large overseas entities.[105] Commercial considerations—not related to patent fees—were likely to be the determining factor in deciding whether to abandon an Australian patent that is part of a worldwide portfolio of inter-related patents.[106]

5.60 The Institute of Patent and Trade Mark Attorneys of Australia also questioned whether review of, and potential increases in, the amount of patent maintenance fees is necessary. In their view, there was 'no evidence that there are excessive number[s] of patents remaining in force in Australia, or that the existence of any such patents is stifling commercial development'.[107]

5.61 IP Australia indicated that it regularly reviews the schedule of patent fees and that its current fee structure supports the policy objectives of the ALRC's proposal.[108] However, IP Australia also stated that in order to maintain such an approach and comply with the Cost Recovery Guidelines, a patent must be treated as a single product over its complete term, rather than seeking to recover full costs at each and every stage in the life cycle of a patent.

ALRC's views

5.62 The term of protection for gene patents should not be more limited than the term of patent protection available for any other type of invention. The ALRC considers that inventions involving genetic materials and technologies should be eligible for protection by a standard patent or an innovation patent, at an applicant's election, subject to satisfying the substantive requirements for patentability in the *Patents Act*.

---

103 AusBiotech Ltd, *Submission P94*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

104 Queensland Government, *Submission P103*, 22 April 2004. See also Centre for Law and Genetics, *Submission P104*, 22 April 2004.

105 IP Australia, *Submission P86*, 16 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 31 March 2004.

106 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 31 March 2004.

107 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

108 IP Australia, *Submission P86*, 16 April 2004.

5.63 However, the ALRC also considers that the Register of Patents generally should not contain patents that are not in use by a patent holder.[109] Users of the patent system may incur substantial costs in conducting prior art searches and in evaluating the relevance of particular patents. These costs, and the cost of patent challenges, may be unnecessarily inflated if patents with no commercial use to a patent holder remain in force. The ALRC supports the approach recommended in the IPCRC Report that, if patent fees are set at an appropriate level, a patent holder will be more inclined to evaluate whether the investment it makes to maintain patent protection over a particular invention is worthwhile.

5.64 The ALRC recognises that the quantum of Australian patent fees is not the only factor relevant to a patent holder's decision about whether to maintain patent rights. Other considerations, such as the commercial value of a patent or a worldwide patent portfolio, may have a greater impact in some circumstances.

5.65 Government policies may also have an impact on the structure and quantum of patent fees imposed by IP Australia. In particular, the Cost Recovery Guidelines would need to be taken into account when implementing the ALRC's recommendation. However, those Guidelines are not inconsistent with the ALRC's recommended approach since they allow for other policy considerations to prevail in appropriate circumstances. The policy goals that underpin both IP Australia's current practice with respect to patent fees and the ALRC's recommendation—namely, that patent fees should be structured to encourage innovation—are significant and would justify cost recovery over the entire term of a patent, rather than at each stage in a patent's lifecycle. Finally, in determining the appropriate structure and quantum of fees, IP Australia should also have regard to the effect of patent fees on small and medium sized enterprises.

Recommendation 5–1 IP Australia should:

(a) assess the impact of patent fees on the actual term of Australian patents; and

(b) periodically review the structure and quantum of patent fees to ensure that fees are set at levels appropriate to discourage patent holders from maintaining patents that lack real commercial value.

109 Use of a patent may be 'active'—that is, provide a source of revenue for a patent holder—or 'passive'—that is, although not earning revenue, a patent may operate defensively to stake a claim to an area of technology and protect a patent holder from third party allegations of infringement.

6. Patentability of Genetic Materials and Technologies

Contents

Introduction

6.1 Concerns about gene patents may be divided into two broad categories. The first involves objections to gene patents on the basis that inventions involving genetic materials and technologies do not satisfy the requirements for patentability under Australian law. The second relates to concerns about the way in which gene patents are exploited, and the way in which inventions covered by such patents are commercialised.

6.2 This chapter and Chapter 7 address issues in the first category. This chapter considers the requirements for patentability and the application of each requirement to inventions involving genetic materials and technologies. Chapter 7 considers whether existing exclusions from patentable subject matter are applicable to any types of inventions involving genetic materials and technologies and whether the *Patents Act 1990* (Cth) (*Patents Act*) should provide additional exclusions from patentability. Later chapters of this Report address concerns about the exploitation of gene patents.

6.3 To provide a context for the discussion in this chapter, it is instructive to understand the types of inventions claimed in gene patents. The following is a selected list of inventions involving genetic materials and technologies for which IP Australia has granted patent protection:

- synthetic genetic or DNA sequences;
- mutant forms and fragments of genetic sequences (including polymorphisms);
- isolated or recombinant DNA coding for a sequence of a gene;
- proteins expressed by a gene;
- vectors containing a gene;
- probes for a gene;
- methods of transformation using a gene;
- host cells, higher plants or animals carrying a gene; and
- recombinant DNA methods—such as polymerase chain reaction (PCR) and novel expression systems.[1]

---

1 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 16 June 2004.

Requirements for patentability

6.4 For an invention to be protected by an Australian patent, it must satisfy the requirements for a 'patentable invention' in s 18 of the *Patents Act*.[2] Section 18 provides that a patentable invention is one which:

- is a manner of manufacture within the meaning of s 6 of the *Statute of Monopolies 1623* (*Statute of Monopolies*);
- is novel when compared to the prior art;
- involves an inventive (or innovative) step when compared to the prior art;
- is useful; and
- has not been secretly used in Australia before the priority date by or with the authority of the patent holder.[3]

6.5 The *Patents Act* 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. Chapter 7 discusses these exclusions.

6.6 For reasons outlined later in this chapter, the ALRC does not consider that inventions involving genetic materials and technologies raise issues that warrant major changes to the legislative requirements for patentability. Moreover, as a general proposition, the ALRC does not consider that the patentability requirements should apply to genetic inventions differently to the way in which they apply to inventions involving any other type of technology. Inventions involving gene patents do, however, highlight issues about the way in which the usefulness of an invention is assessed. The ALRC, therefore, recommends specific reforms to clarify the application of the usefulness requirement to all types of inventions.

Overview of submissions

6.7 Submissions and consultations expressed a range of concerns about the patentability of genetic materials and technologies, including:

- general ethical objections;
- the identification of a gene or other genetic material (such as a protein) is a 'discovery' not an 'invention';

---

2 'Invention' and 'patentable invention' are defined in sch 1 of the *Patents Act 1990* (Cth).

3 The application of this requirement (commonly referred to as 'secret use') in the context of gene patents is not materially different to any other type of technology and thus will not be considered in any detail in this chapter. For judicial consideration, see *Azuko Pty Ltd v Old Digger Pty Ltd* (2001) 52 IPR 75.

- genetic sequences and other genetic materials are not novel and should not be patentable;
- the identification of a genetic sequence or other genetic material does not involve an inventive step;
- gene patents may be granted over inventions even if the use of the invention is not yet known; and
- gene patents contain broad claims and the disclosure in such patents does not justify the scope of the claims.

6.8 Chapters 3 and 7 discuss the objections to gene patents on the basis of ethical and social considerations. The other objections outlined above are considered in this chapter in the context of the relevant requirement for patentability.

6.9 Many submissions suggested that patent offices have not applied the requirements for patentability sufficiently stringently to inventions involving genetic materials and technologies.[4] In some cases, criticisms were directed to the patentability requirements generally. Other comments addressed specific options for reform proposed by the ALRC, but nevertheless raised issues that were relevant to other patentability requirements or to additional issues addressed in this chapter. The ALRC has cited these submissions in the context of the patentability requirement or issue to which they appear most related.

6.10 A number of submissions also expressed opinions about the specific types of inventions involving genetic materials and technologies that should be patentable, and those for which patent protection should not be available. For example, it was said that genetic sequences and proteins should not be patentable, but combinations of genes, recombinant proteins and processes for identifying such materials should be. These comments appear to be based on assumptions about the type of inventions that will *prima facie* fail to satisfy the criteria for patentability. Such an approach is contrary to the basic principle of patent law that each patent application (and the invention claimed in it) should be assessed independently to determine whether it satisfies the statutory requirements. However, to the extent possible, the ALRC has considered these comments in relation to particular patentability requirements.

---

4 See, eg, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Nuffield Council on Bioethics, *Submission P102*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

Should gene patents be treated differently?

6.11 The criteria that must be satisfied to obtain a gene patent are the same as those that apply to patents over inventions involving any other type of technology. An initial question arises as to whether genetic materials and technologies are so different as to justify specific legislative criteria for patentability, which would apply only to this type of technology.

Submissions and consultations

6.12 DP 68 proposed that IP Australia should assess patent applications relating to genetic materials and technologies according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.[5]

6.13 The weight of submissions supported this proposal and did not favour creating requirements for patentability that would apply only to genetic materials and technologies.[6] Submissions generally considered that the establishment of special rules for gene patents was neither necessary nor desirable.[7]

6.14 Some submissions suggested that implementing specific requirements for gene patents might add complexity to the Australian patent system, both in relation to inventions involving genetic materials and technologies and for other new technologies that may arise in the future.[8] IP Australia commented that technology-specific provisions 'invariably lead to uncertainty over the bounds of the subject matter, involved debate in individual cases, and increased cost and uncertainty for users of the

---

5 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 6–1.

6 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

7 See, eg, Medicines Australia, *Submission P21*, 30 September 2003; L Palombi, *Submission P28*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; IP Australia, *Submission P56*, 4 November 2003.

8 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Department of Health Western Australia, *Submission P89*, 16 April 2004.

system'.[9] IP Australia also observed that 'such measures may eventually prove at least partially ineffective, as it may be possible to draft claims to avoid the intent of [any] exclusion'.[10]

6.15 Other submissions considered that imposing particular requirements for gene patents would lead to inconsistency between the way in which genetic materials and technologies are treated under Australian patent law and the patent laws of other jurisdictions. Submissions suggested that such a divergence would create unnecessary difficulties for Australian entities seeking to obtain patent protection in foreign jurisdictions[11] and might have adverse implications for the place of the Australian biotechnology sector in the global economy.[12] A number of submissions commented that special rules for genetic materials and technologies might conflict with the requirement in art 27 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement)[13] that patent protection shall be available for inventions without discrimination as to the field of technology.[14]

6.16 However, some submissions considered that 'the uniqueness of human genes' might result in patents that are inappropriately broad and suggested that patent examiners should take this into account when granting patents over genetic materials and technologies.[15] The Department of Health and Ageing submitted:

> A patent on a particular gene or gene sequence has the practical effect of monopolising the knowledge and exploitation of the gene. In effect, it patents the particular condition or characteristic. In doing so it prevents work on alternative ways of dealing with the condition or characteristic and may limit the capacity to invent around the patent.[16]

---

9 IP Australia, *Submission P56*, 4 November 2003. See also G Suthers, *Submission P30*, 2 October 2003; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

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

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

12 Genetic Technologies Limited, *Submission P45*, 20 October 2003; South Australian Department of Human Services, *Submission P74*, 15 April 2004.

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

14 See, eg, GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Queensland Government, *Submission P57*, 5 January 2004; Queensland Government, *Submission P103*, 22 April 2004. However, a small number of submissions suggested that the TRIPS Agreement is equivocal on the issue of technology neutrality: Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; M Rimmer, *Submission P73*, 15 April 2004.

15 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; E Milward and others, *Submission P46*, 20 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

16 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

6.17 IP Australia did not consider that this issue warranted the application of special requirements for patentability.[17] Issues surrounding the appropriate scope of gene patent claims are addressed at the end of this chapter.

ALRC's views

6.18 In the ALRC's view, concerns about the patenting of inventions involving genetic materials and technologies should not be addressed by the introduction of legislative requirements that would relate only to the patentability of this type of invention. Such an approach may set an undesirable precedent for the way in which the patent system should accommodate new technologies in the future. The current requirements for patentability are technology-neutral and are able to adapt to new technologies as they arise. Introducing specific rules for inventions involving genetic materials and technologies may suggest that special requirements for patentability should be implemented for future technologies that raise a different set of issues. Such an approach would unnecessarily fragment and complicate Australian patent law.

6.19 Requirements that would apply only to genetic materials and technologies are also undesirable from an international perspective. Special rules would represent a departure from attempts to harmonise the patent laws of various jurisdictions.[18] Further, they would result in a marked divergence from approaches to inventions involving genetic materials and technologies adopted by other major economies, such as the United States, Europe and Japan. This approach is likely to have significant implications for the willingness of foreign entities to participate in the Australian biotechnology sector, and for the ability of Australian entities to commercialise genetic inventions overseas. In addition, as discussed in Chapter 4, the adoption of patentability requirements that would apply solely to inventions involving genetic materials and technologies may be inconsistent with Australia's obligations under the TRIPS Agreement.[19]

Recommendation 6–1 Patent applications relating to genetic materials and technologies should be assessed according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.

17 IP Australia, *Submission P56*, 4 November 2003. See also Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

18 See Ch 4.

19 In particular, TRIPS Agreement, art 27.

Patentable subject matter

The 'manner of manufacture' test

6.20 Currently, genetic materials and technologies are treated as inventions for which patent protection is available, provided the legislative requirements are satisfied.[20] 'Invention' is defined in the *Patents Act* as 'any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the *Statute of Monopolies*, and includes an alleged invention'.[21]

6.21 The *Statute of Monopolies* was enacted in England in 1623, but is not reproduced in the *Patents Act*. Section 6 of the Statute provides as follows:

> Provided also and be it declared and enacted that any declaration before mentioned shall not extend to any letters patent and grants of privilege, for the term of 14 years or under hereafter to be made of the sole working or making of any *manner of new manufacture* within this realm to the true and first inventor and inventors of such manufactures which others, at the time of making such letters or grant, shall not use, so as also they be not contrary to the law, nor mischievous to the state, by raising prices of commodities at home or hurt of trade or generally inconvenient.[22]

6.22 The concept of invention has not, to date, been limited to the literal meaning of the term 'manner of new manufacture' in the *Statute of Monopolies*.[23] In the leading Australian decision, *National Research Development Corporation v Commissioner of Patents* (*NRDC*),[24] the High Court indicated that a policy-oriented approach should be adopted to the meaning of the term:

> The word 'manufacture' finds a place in the present Act, not as a word intended to reduce the question of patentability to a question of verbal interpretation, but simply as the general title found in the *Statute of Monopolies* for the whole category under which all grants of patents which may be made in accordance with the developed principles of patent law are to be subsumed …
>
> The right question is: 'Is this a proper subject of the letters patent according to the principles which have been developed for the application of s 6 of the *Statute of Monopolies*?'[25]

6.23 For an invention to be a 'manner of manufacture', as interpreted in *NRDC*, it must belong to the 'useful arts' rather than the 'fine arts'; it must provide a material advantage; and its value to the country must be in the field of economic endeavour.[26]

---

20 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 16 June 2004.

21 *Patents Act 1990* (Cth) sch 1.

22 21 Jac 1 c 1 (1623) (emphasis added).

23 J Pila, 'Inherent Patentability in Anglo-Australian Law: A History' (2003) 14 *Australian Intellectual Property Journal* 109, 110.

24 *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252. The patent at issue claimed a novel treatment for killing weeds in crops. The question before the High Court was whether agricultural and horticultural inventions were patentable under Australian law.

25 Ibid, 269.

26 Ibid, 275.

However, judicial interpretation has also recognised a number of categories of subject matter that will fail to satisfy the test. These include mere discoveries, ideas, scientific theories and laws of nature.[27]

6.24 The categories of inventions that may satisfy the manner of manufacture test have gradually expanded over time. The report of the Intellectual Property Competition Review Committee (the IPCRC) in 2000 outlined the expansion of the categories of patentable subject matter from a method for extracting lead from humans, to agricultural processes, new plant varieties, micro-organisms, methods of cosmetic and therapeutic treatment of humans, and mathematical applications (in computer programs).[28] This expansion mirrors developments in other jurisdictions.[29]

6.25 The manner of manufacture test is expressed in terms that appear obscure in a modern context.[30] However, reviews of Australian patent law have recommended that the requirement be preserved as the threshold test for patentability. A 1984 report of the Industrial Property Advisory Committee (IPAC Report) considered that the concept 'operates quite satisfactorily' and 'has, in the past, exhibited a capacity to respond to new developments'.[31] The IPAC Report recommended that 'the present threshold test for patentability by reference to s 6 of the *Statute of Monopolies* and to the expression "manner of new manufacture" be retained, without specific legislative inclusions or exclusions'.[32] Similarly, the IPCRC considered that the 'open-textured standard' represented by the manner of manufacture test should be retained. It concluded that: 'Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the "manner of manufacture" test'.[33]

6.26 In reaching the conclusion that the manner of manufacture test should be retained, both the IPAC Report and the IPCRC considered that codification of a concept of invention in the *Patents Act* would be likely to result in greater uncertainty (with the attendant costs) than the current test.[34]

---

27 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.5]–[8.2.6].

28 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 147.

29 See, eg, W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 21–25. However, the Canadian Supreme Court has held that patent protection is not available for higher life forms—in that case a genetically modified mouse predisposed to cancer: *Harvard College v Canada (Commissioner of Patents)* [2002] SCC 76.

30 See, eg, New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), [22]–[31].

31 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 41.

32 Ibid, rec 12. The Australian Government accepted this recommendation when drafting the Patents Bill 1990 (Cth): Explanatory Memorandum, Patents Bill 1990 (Cth), [31].

33 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 149.

34 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 41; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 148–149.

Patentable subject matter in other jurisdictions

6.27 Other jurisdictions frame the test for patentable subject matter differently.[35] United States patent law provides that to be patentable subject matter 'the claimed invention must be a process, machine, manufacture, or composition of matter that has a practical utility'.[36] Patent legislation in the United Kingdom defines patentable subject matter by exclusion: an invention is patentable if it satisfies the other requirements for patentability and is not, among other things, a 'discovery, scientific theory or mathematical method' or 'a scheme, rule or method for performing a mental act'.[37]

6.28 Associate Professor Ann Monotti and Professor Sam Ricketson have commented that the choice of (seemingly outdated) statutory language relating to the test for patentable subject matter in patent statutes in Australia, the United States and the United Kingdom 'seems to reflect a general understanding, by both courts and legislatures, that it is impossible to find a form of language that will adequately cover, at any one time, the multifarious and diverse forms in which human inventiveness may manifest itself'.[38]

6.29 Monotti and Ricketson also suggested that the issue of what is an invention for the purposes of patent law may only become contentious at the margins, as new developments in science and technology occur. Historically, courts have been able to address patentable subject matter by a process of progressive interpretation.[39] Even where legislatures have expressly stated exceptions to patentable subject matter, these provisions have generally been limited in their effect.[40]

Application to genetic materials and technologies

6.30 There has been limited consideration in Australia of the application of the manner of manufacture test to genetic materials and technologies.[41] The requirement does not appear to have limited the types of inventions involving genetic materials and technologies that will be patentable.[42] Dr Dianne Nicol has suggested that inventions

---

35 However, a review of New Zealand patent law recommended that the definition of patentable invention be amended to mirror the definition in Australian law, including the requirement that the invention be a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*: New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), pt 1, rec 2(i).

36 35 USC s 101.

37 *Patents Act 1977* (UK) s 1(1), (2). Until 1977, United Kingdom law also relied on the 'manner of manufacture' test.

38 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [3.21].

39 Ibid, [3.22]. See also R Eisenberg, 'Re-examining the Role of Patents in Appropriating the Value of DNA Sequences' (2000) 49 *Emory Law Journal* 783, 791–792.

40 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [3.22].

41 However, see, IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 16 June 2004.

42 See the list of patented inventions at the beginning of this chapter.

involving genetic materials and technologies appear to satisfy the *NRDC* requirements because genetic research and treatments are commercial in nature and have value in an economic sense, both directly through the activities of the Australian biotechnology industry and indirectly through the ability of such technology to alleviate disease.[43]

Discoveries

6.31 It has been suggested that genetic materials are 'discoveries' and do not, therefore, constitute patentable subject matter. Traditionally, discoveries have been regarded as outside the scope of patentable subject matter because no knowledge or ingenuity has been applied to produce a new and useful thing.[44] However, distinguishing between discoveries and inventions for the purposes of patent law is difficult. The High Court in *NRDC* suggested that drawing such a distinction might be misleading and be true often only in a formal sense.[45] IP Australia's *Patent Manual of Practice and Procedure* (*Manual*) also notes that 'no general definition can be given as to what constitutes a discovery as opposed to an invention'.[46]

6.32 Consideration of the distinction between a discovery and an invention in the context of biotechnology patents first arose in relation to patent claims over micro-organisms. In Australia and elsewhere, 'man-made' micro-organisms have been accepted as constituting patentable subject matter;[47] 'isolated and purified' cultures of micro-organisms may also be patentable. However, micro-organisms in their naturally occurring state are regarded as discoveries and, as a consequence, patent protection will not be available. More recently, the difference between a discovery and an invention has arisen in relation to patent applications claiming genetic sequences. The decisions that have addressed this issue in Australia and overseas have drawn a distinction between genetic materials in their natural state and those that have been isolated and purified.

Australia

6.33 *Kiren-Amgen Inc v Board of Regents of the University of Washington* involved an opposition to a patent application for the purified or isolated DNA sequence encoding the human protein erythropoietin, which plays a major role in the formation of red blood cells.[48] The Deputy Commissioner of Patents stated: 'In my view, a claim

---

43 D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 237. See also K Ludlow, 'Genetically Modified Organisms and their Products as Patentable Subject Matter' (1999) 21 *European Intellectual Property Review* 298.

44 *Lane Fox v Kensington and Knightsbridge Electric Lighting Co* (1892) 9 RPC 413, 416, cited with approval in *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252, 263. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 22–24.

45 *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252, 264.

46 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.5.2].

47 See, eg, *Ranks Hovis McDougall's Application* [1976] 46 AOJP 3915 (Australia); *Diamond v Chakrabarty* 447 US 303 (1980) (United States).

48 'Manner of manufacture' was not a ground of opposition in the case but arose in relation to the Deputy Commissioner's consideration of whether the claimed invention was a mere discovery: *Kiren-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557.

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'.[49] He 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'.[50]

6.34 Applying this principle more generally, IP Australia has indicated that the following subject matter will not be deemed to be a discovery under Australian law:

> The building blocks of living matter, such as DNA and genes (including human DNA and genes) which have for the first time been identified and copied from their natural source and then manufactured synthetically as unique materials with a definite industrial use.[51]

6.35 In addition, IP Australia's *Manual* provides specific guidance on the difference between a discovery and an invention in the context of gene patents:

> The discovery of a micro-organism, protein, enantiomer or antibiotic in nature can be claimed in its isolated form or as substantially free of (perhaps, specified) impurities. Also, a gene can be claimed as the gene *per se* (as long as the claim does not include within its scope the native chromosome of which the gene forms part) or as the recombinant or isolated or purified gene.[52]

Other jurisdictions

6.36 In 1988, the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), and the Japanese Patent Office (JPO) issued a joint statement explaining the distinction between natural and man-made substances for the purposes of patent law in those jurisdictions:

> Purified natural products are not regarded as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.[53]

6.37 Article 52(2) of the *European Patent Convention* (EPC) provides that, among other subject matter, 'discoveries' shall not be regarded as inventions for the purposes of the European patent law.[54] The EPO considered the application of this provision in

---

49 Ibid, 569 (emphasis added).

50 Ibid, 569. The decision was appealed to the Federal Court on other grounds: *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106.

51 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 16 June 2004.

52 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.5.3].

53 'Trilateral Co-operation of the US, European and Japanese Patent Offices' (1988) 7 *Biotechnology Law Review* 159, 163 cited in R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71.

54 *European Patent Convention*, (entered into force on 7 October 1977).

the case of *Howard Florey/Relaxin*.[55] The case involved an opposition to a patent for a DNA fragment coding for a human H2-preprorelaxin—a synthetic genetic sequence that had the same operative function as natural H2-relaxin, but lacked certain introns found in the naturally occurring sequence. The Opposition Division of the EPO held that:

> a substance freely occurring in nature is a mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if this substance can properly be characterised by its structure and it is new in the absolute sense of having no previously recognised existence, then the substance *per se* may be patentable.[56]

6.38 Following the implementation of the *Directive on the Legal Protection of Biotechnology Inventions* (EU Biotechnology Directive) in 1998, the patentability of isolated genetic sequences is now expressly recognised under European law.[57] 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:

> An 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.[58]

6.39 In the United States, biological material was first recognised as patentable subject matter by the United States Supreme Court in *Diamond v Chakrabarty*.[59] The issue before the Supreme Court was whether a genetically engineered bacterium capable of breaking down crude oil constituted patentable subject matter. Upholding the patent at issue, the Supreme Court stated:

> The patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter.[60]

---

55 *Howard Florey/Relaxin* [1995] EPOR 541. The decision was upheld on appeal: *Relaxin/Howard Florey Institute* (Unreported, Boards of Appeal, European Patent Office, T0272/95, 23 October 2002).

56 *Howard Florey/Relaxin* [1995] EPOR 541, 548.

57 *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).

58 Ibid art 5(2). Certain provisions of the EU Biotechnology Directive were adopted by the EPO as supplementary interpretation of the EPC: see Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001). Rule 23(e) of the implementing regulations of the EPC contains a provision equivalent to art 5 of EU Biotechnology Directive.

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

60 Ibid, 309–310.

6.40 The Supreme Court indicated that the concept of patentable subject matter under United States law included 'anything under the sun that is made by man'.[61] Dr Dianne Nicol and Jane Nielsen have commented that this decision 'laid the foundation for a growing body of case law and patent office decisions' in the United States supporting the patentability of a range of biological material, including whole organisms, genes, proteins, and cell lines.[62]

Criticisms of the discovery/invention distinction

6.41 Various criticisms have been made of the distinction between naturally occurring genetic materials and those that have been purified and isolated.

- Isolated and purified genetic materials are structurally similar or identical to the form that exists in nature.

- Even if genetic materials are isolated and purified, the characteristics of such materials—which are the 'useful' properties or information—are naturally occurring, not created by the person who isolates and purifies the material.

- Isolation and purification of genetic materials may not, in fact, occur because genetic materials (particularly genetic sequences) may be identified by computational techniques.[63]

Submissions and consultations

The manner of manufacture test

6.42 DP 68 proposed that the responsible Minister should request the Advisory Council on Intellectual Property (ACIP) to review the appropriateness and adequacy of the manner of manufacture test as the threshold requirement for patentable subject matter under Australian law.[64]

6.43 A number of submissions supported this proposal.[65] Submissions commented that the manner of manufacture test provides only vague criteria,[66] and that its

---

61 Ibid, 308. The Supreme Court noted that there were limitations on patenting 'laws of nature, physical phenomena and abstract ideas': *Diamond v Chakrabarty* 447 US 303 (1980), 308.

62 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 23. See, eg, *Ex parte Allen* (1998) 2 USPQ 2d 1425 affirmed on appeal 846 F 2d 77 (1998) (polypoid oyster); *Moore v Regents of the University of California* 51 Cal 3d 120 (1990) (human cell line); *Amgen Inc v Chugai Pharmaceutical Co Ltd* (1991) 927 F 2d 1200 (genetic sequence).

63 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 27–28; D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 76.

64 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 6–2.

65 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Bio21 Australia Ltd, *Submission P80*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; G Suthers, *Submission P116*, 4 May 2004.

appropriateness and adequacy is questionable.[67] Some submissions suggested that the manner of manufacture test does not seem to have placed any limits on the patentability of inventions involving genetic materials to date.[68] Others considered that the manner of manufacture test should be reviewed to clarify the significance of the usefulness of an invention in determining whether a patent should be granted.[69] These latter submissions are considered later in this chapter.

6.44 Submissions commented on the nature of the proposed review and the most appropriate body to undertake it. Some submissions indicated that any such review should involve extensive consultation with stakeholders.[70] Submissions also considered that 'the focus of the review and outcomes to be achieved' should be clearly defined.[71] The Department of Health and Ageing expressed concern that issues associated with genetic materials might be given insufficient attention in a general review of the manner of manufacture test.[72] The Department encouraged the ALRC to 'address interim solutions' to these issues—in particular, the invention/discovery distinction and the circumstances in which an invention could be excluded from patentability on the grounds that it is 'generally inconvenient'.[73]

6.45 IP Australia indicated that the manner of manufacture test might be unclear to those who do not interact with the intellectual property system on a regular basis. However, it questioned whether a review of the test is warranted and observed that it would be a significant task.[74] Other submissions expressed similar objections to a review of the manner of manufacture test. They considered that the test has proven to be 'flexible and able to take account of developing technologies and developing inventive concepts'.[75] Submissions also commented that a substantial body of case law

66 South Australian Department of Human Services, *Submission P74*, 15 April 2004. See also D Jackson, *Submission P43*, 20 October 2003.

67 Medicines Australia, *Submission P75*, 15 April 2004.

68 Cancer Council Australia, *Submission P25*, 30 September 2003; L Palombi, *Submission P28*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

69 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004.

70 South Australian Department of Human Services, *Submission P74*, 15 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

71 South Australian Department of Human Services, *Submission P74*, 15 April 2004. See also Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

72 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

73 Ibid. See also South Australian Department of Human Services, *Submission P74*, 15 April 2004; G Suthers, *Submission P116*, 4 May 2004. The 'generally inconvenient' proviso is discussed in Ch 7.

74 IP Australia, *Submission P86*, 16 April 2004.

75 F B Rice & Co, *Submission P84*, 16 April 2004. See also Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P94*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

exists on the scope of the manner of manufacture test[76] and that there is the potential for a new test to create a new raft of problems.[77] A few submissions suggested that such problems would be particularly significant if Australia were to adopt the European system of defining patentable subject matter through exceptions.[78]

Discoveries

6.46 Many submissions asserted that genetic materials, and in particular genetic sequences, are discoveries and should not be patentable.[79] These concerns were expressed primarily by participants in the research and healthcare sectors. Some submissions considered that genetic materials should not be patentable subject matter because an 'improved' version of naturally occurring genetic material cannot be developed (except, perhaps, by natural selection).[80] For example, Dr Graeme Suthers submitted:

> If a patent is granted on a process … a better process can conceivably be patented in the future. A patented process may be the only means of achieving some task today, but it need not be the exclusive means in the future. Conversely, a patent on a naturally occurring item or concept represents a very different sort of right. A naturally occurring entity cannot be improved, and there is no prospect of another person patenting a better version in the future.[81]

6.47 Other submissions were critical of the basis upon which the patentability of genetic materials and technologies is justified—namely, that isolated and purified genetic material is an invention, not a discovery.[82] Luigi Palombi suggested that this concept is a 'legal and scientific fiction': regardless of the process of isolation and purification, the fundamental characteristics of isolated genetic material remain the same as those found in nature.[83] Palombi suggested that the comparison between

---

76 F B Rice & Co, *Submission P84*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; AusBiotech Ltd, *Consultation*, Melbourne, 2 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

77 IP Australia, *Submission P86*, 16 April 2004. See also Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; J McKeough, *Consultation*, Sydney, 23 March 2004.

78 IP Australia, *Submission P86*, 16 April 2004. See also Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

79 See, eg, A Morley, *Submission P18*, 30 September 2003; A Bankier, *Submission P19*, 30 September 2003; D McFetridge, *Submission P23*, 30 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Medicines Australia, *Submission P75*, 15 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; G Suthers, *Submission P116*, 4 May 2004.

80 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; D McAndrew, *Submission P14*, 30 September 2003; A Bankier, *Submission P19*, 30 September 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

81 G Suthers, *Submission P30*, 2 October 2003. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

82 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; M Betta, *Submission P20*, 30 September 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Medicines Australia, *Submission P75*, 15 April 2004.

83 L Palombi, *Submission P28*, 1 October 2003. See also E Milward and others, *Submission P46*, 20 October 2003; S Brown, *Submission P78*, 16 April 2004.

inventions involving genetic materials and those involving chemical compounds is 'not helpful and is misleading' in determining whether genetic materials should constitute patentable subject matter and that the useful and commercially valuable characteristic of a genetic sequence is information—namely, instructions that code for a protein.[84]

6.48 Similarly, Sonya Brown submitted that, 'due to the information storage role of DNA, purified gene sequences are unique chemical compounds', and the patent system was not designed to deal with materials that are hybrid compositions of chemicals and information.[85] Suthers agreed that patent offices need to recognise the dual nature of genes. He considered that a distinction should be drawn between a 'gene-as-a-chemical' (which may be patentable) and a 'gene-as-information' (which should not be).[86]

6.49 However, submissions from a range of organisations regarded the patentability of isolated and purified forms of naturally occurring material—including genetic material—as a well-established principle.[87] Others thought that the practice of patenting isolated genetic materials could not be revisited at this point, even if it was flawed in principle.[88] Davies Collison Cave, a firm of patent attorneys, commented that claims that genetic materials are non-patentable discoveries may be based on a misunderstanding of the nature of patents:

> It is a common … misconception that a claim to such an 'isolated' material product somehow seeks to claim the material or product that exists in nature; such misconceptions reflect a general misunderstanding of the nature of patents and particularly of the role of the claims of a granted patent in defining the rights of the patent holder under the patent.[89]

6.50 Some submissions suggested that the argument that inventions involving genetic materials are discoveries does not adequately take into account the requirements for patentability.[90] For example, the procedures required to isolate and purify particular genetic materials are relevant to an assessment of whether or not there has been an inventive step. Further, mere isolation and purification of genetic material may not satisfy the manner of manufacture test or the disclosure requirements, unless some

---

84 L Palombi, *Submission P28*, 1 October 2003.
85 S Brown, *Submission P78*, 16 April 2004.
86 G Suthers, *Submission P116*, 4 May 2004.
87 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003.
88 See, eg, A Morley, *Submission P18*, 30 September 2003; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.
89 Davies Collison Cave, *Submission P48*, 24 October 2003.
90 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

corresponding commercial application has been identified for the material. These requirements are considered further below.

ALRC's views

6.51 It is clear that the *processes* for identifying, isolating and purifying naturally occurring materials, including biological material such as genetic sequences, should be patentable when those processes satisfy the other requirements of patentability—namely, when they are novel, inventive, useful and fully disclosed. However, legitimate concerns have been raised about the patenting of biological *materials* that occur in nature, but have been isolated and purified by humans. Isolated biological materials may, in some cases, replicate exactly the composition and characteristics of material that occurs in nature. Although one cannot deny the legitimacy of patenting processes for isolating and purifying naturally occurring materials, or the legitimacy of patenting new chemical substances that are the product of human ingenuity, there are attractive arguments for the view that such materials should not have been treated as patentable subject matter.

6.52 However, the time for taking this approach to the patenting of products and materials has long since passed. For decades, naturally occurring chemicals have been regarded by patent offices in many jurisdictions as patentable subject matter, when they are isolated and purified. This principle has been applied by analogy to biological materials, including genetic sequences, on the basis that they are 'merely' complex organic compounds. This development was certainly not foreseen when the modern patent system was established, and a different approach might have been available when the issue first arose for consideration.

6.53 Nonetheless, the ALRC considers that a new approach to the patentability of genetic materials is not warranted at this stage in the development of the patent system, for the following reasons:

- It would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions, and may adversely affect investment in the Australian biotechnology industry.

- It may fail to deliver the anticipated benefits because many pure and isolated genetic sequences do not exist in exactly the same form in nature—for example, patented sequences may not contain the introns that are found in the naturally occurring material.

- Claims to genetic materials in their natural form (that is, *in situ*) do not constitute patentable subject matter.

- Arguments that genetic materials are not patentable inventions do not always take adequate account of the fact that—in addition to the threshold requirement of 'patentable subject matter'—a number of statutory requirements must be

satisfied for patent protection to be obtained. In particular, patent protection cannot be conferred over genetic materials unless a use for such materials has been identified and fully disclosed.

- It would be difficult, on any rational basis, to confine reform to genetic materials and technologies, yet the extension of the reform to other fields—where the patenting of pure and isolated chemicals that occur in nature is uncontroversial—may have unknown consequences.

6.54 The test for patentable subject matter may nevertheless warrant reform. The manner of manufacture test was considered in 1984 by the IPAC Report and in 2000 by the IPCRC, and was endorsed on both occasions. Yet it has become apparent during the course of this Inquiry that there are problems with the test.

6.55 The ALRC is a law reform body whose statutory functions are to bring the law into line with current conditions, remove defects in the law, simplify the law, adopt more effective methods for administering the law, and provide improved access to justice.[91] From this perspective, it is indeed odd that the key concept of 'manner of manufacture' depends on a provision in a 380 year old English statute that has long since been repealed in the jurisdiction in which it was enacted; and that the relevant section of the statute is not reproduced in Australian patent legislation.

6.56 The ALRC recognises the value of maintaining a threshold test for patentable subject matter that is flexible and capable of adapting to developments in technology as they arise. However, it is apparent that the terms of s 6 of the *Statute of Monopolies 1623* are ambiguous and obscure. In some circumstances, the case law that has evolved around the meaning of this provision offers no further clarification. For example, the grant of letters patent under s 6 does not extend to any manner of new manufacture that is 'generally inconvenient'. As discussed in Chapter 7, Australian courts and IP Australia have been reluctant to rely on this proviso to deny patent protection to particular inventions. However, it has been suggested that the generally inconvenient proviso could provide a basis for excluding inventions from patentability on ethical or social grounds. The circumstances in which this might be justified are, however, unknown. In addition, the discussion of the usefulness requirement later in this chapter indicates that, while the usefulness of an invention is an aspect of the manner of manufacture test and relevant to the disclosure requirements, the way in which the requirements interact in practice is unclear.

6.57 In the light of the ALRC's Terms of Reference, any general reform of the way in which Australian patent law should approach the concept of patentable subject matter is beyond the scope of the current Inquiry. It would involve an in-depth analysis of the way in which the manner of manufacture test has been applied to a broad range of inventions—not merely those involving genetic materials and technologies—and require consultations with a more diverse group of stakeholders.

---

91 *Australian Law Reform Commission Act 1996* (Cth) s 21.

6.58 The ALRC believes that an independent review of the manner of manufacture test is desirable and could be undertaken by a body such as the Intellectual Property Research Institute of Australia (IPRIA), or ACIP. Such a review should focus particularly on the generally inconvenient requirement, including the extent to which this requirement has been invoked by patent examiners and in challenges to patent rights, and whether there are alternative and preferable ways to formulate a threshold requirement for patentable subject matter. Any reform of the manner of manufacture test should take into account the recommendations of this Inquiry, including those relating to the requirement of usefulness (see Recommendations 6–3 and 6–4).

Recommendation 6–2 The responsible Minister should initiate an independent review of the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law, with a particular focus on the requirement that an invention must not be 'generally inconvenient'.

Novelty

6.59 An Australian patent will only be granted for an invention that is 'novel'. In other words, the invention must be new.[92] The novelty of each claim in a patent application is assessed against the 'prior art base' that comprises publicly available 'prior art information' as it existed at the 'priority date' of the relevant patent claim.[93]

6.60 The prior art base includes information that is made publicly available in a document or a related series of documents, or through doing an act or a related series of acts, as well as information contained in a published patent application that has an earlier priority date than the application under examination.[94] Separate disclosures of an invention in more than one document, or by more than one act, will only be considered together if the relationship between the documents or the acts is such that a person skilled in the relevant art would treat them as a single source of information.[95]

6.61 The test applied to determine whether an invention is novel is known as the 'reverse infringement' test.[96] The prior art information must disclose all of the features

92 *Patents Act 1990* (Cth) ss 18(1)(b)(i), 18(1A)(b)(i).

93 Ibid ss 18(1)(b)(i), 18(1A)(b)(i); sch 1. The significance of the priority date is discussed in Ch 5.

94 Ibid s 7(1), sch 1. The *Patents Amendment Act 2001* (Cth) expanded the definition of prior art base to include documentary publications worldwide, as well as oral disclosures and acts done anywhere in the world. For existing patents, and patent applications filed prior to 1 April 2002, only acts occurring within the patent area (ie Australia) are relevant to an assessment of novelty.

95 *Patents Act 1990* (Cth) s 7(1). Seeking to connect disclosures made in more than one document (or act) to support a claim that an invention is not novel—often referred to as 'making a mosaic'—is not permitted under Australian law: see *Nicaro Holdings Pty Ltd v Martin Engineering Co* (1989) 91 ALR 513; *Minnesota Mining & Manufacturing Co v Beiersdorf (Australia) Ltd* (1980) 144 CLR 253, 292–293.

96 *Meyers Taylor Pty Ltd v Vicarr Industries Ltd* (1977) 137 CLR 228; IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [3.2.1].

of an invention—or all of the essential features—in clear, unequivocal and unmistakable terms in order for the invention at issue to lack novelty.

6.62 Whether or not a disclosure relating to an invention is 'publicly available' has been the subject of much judicial consideration.[97] Public availability may exist even if the disclosure was limited to a small number of people;[98] or was contained in a foreign language document that could be understood only by an expert in the field;[99] or if a limited number of embodiments of the invention were distributed to members of the public on a non-confidential basis.[100]

6.63 IP Australia has indicated that the novelty requirement will be satisfied in relation to inventions covering biological materials—including genes, genetic sequences and DNA—if the claimed invention is 'new in the sense of not being previously publicly available'.[101]

6.64 Patent laws in other jurisdictions express the novelty requirement in similar terms to the *Patents Act*.[102] The assessment of the novelty of inventions involving genetic materials and technologies in these jurisdictions does not appear to have raised issues that are materially different from those that arise under Australian patent law.

Submissions and consultations

6.65 The ALRC received a range of submissions from participants in the research and healthcare sectors suggesting that isolated genetic materials, and genetic sequences in particular, are not novel.[103] For example, the Royal College of Pathologists of Australasia (RCPA) submitted that:

> Natural materials are only novel in the sense that they have not previously been discovered by humans. Natural DNA sequences are the result of over a billion years of evolution and exist independent of inventors.[104]

6.66 However, other submissions considered that isolated genetic materials are capable of satisfying the novelty requirement for patentability, in the same manner as other naturally occurring products that have been isolated and purified, and do not raise any particular issues that might not be raised by inventions over other types of

---

97 A small number of public disclosures do not preclude an invention satisfying the novelty requirement: *Patents Regulations 1991* (Cth) rr 2.2, 2.3. See Ch 14.

98 *Sunbeam Corp v Morphy-Richards (Aust) Pty Ltd* (1961) 180 CLR 98.

99 *Dennison Manufacturing Co v Monarch Marking Systems Inc* (1983) 66 ALR 265.

100 *Fomento Industrial SA v Mentmore Manufacturing Co Ltd* [1956] RPC 87.

101 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 16 June 2004.

102 See, eg, 35 USC s 102; *Patents Act 1977* (UK) s 2.

103 See, eg, Medicines Australia, *Submission P21*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003.

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

technologies.[105] These submissions noted that genetic materials do not exist in nature in an isolated or purified form; and human intervention is required to achieve this. For example, GlaxoSmithKline submitted that:

> Genetic material, or DNA, is simply a chemical compound. To the extent that it can be regarded as a natural product, obtained by isolating it from nature, there is ample precedent for patenting natural products … Furthermore, DNA which is the subject of patent claims is frequently claimed as cDNA (complementary DNA) which is a copy of the genomic DNA but lacking the interspersed intron sequences. cDNA does not occur naturally (except in rare cases where a gene is not interrupted by introns) and is novel for that reason alone.[106]

6.67 Similarly, IP Australia submitted that:

> In order to be acceptable, patent claims must not include within their scope anything which occurs already, either artificially or naturally. As a consequence, patents are not granted for genetic materials which already exist in the body of any living thing. The same principle applies to all chemical compounds which have been newly isolated from nature.[107]

6.68 A few submissions specifically stated that the current test for novelty does not require reform.[108] Dr Amanda McBratney and others commented that, as a result of amendments to the definition of prior art information in the *Patents Act* in 2001, Australia's novelty requirements are comparable to those in the United States and Europe.[109] They, therefore, considered that 'no further upward adjustment to accommodate gene-related inventions is necessary'.[110] McBratney and others also submitted that changes to IP Australia's current approach in assessing the novelty of genetic materials and technologies are undesirable because they would represent a 'departure from the internationally accepted approach'.[111]

6.69 However, the Australian Centre for Intellectual Property in Agriculture (ACIPA) submitted that the *Patents Act* should be amended to raise the standard for novelty, but did not propose specific reforms in this regard.[112]

---

105 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; IP Australia, *Submission P56*, 4 November 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

106 GlaxoSmithKline, *Submission P33*, 10 October 2003. However, a few submissions took issue with the distinction that has been drawn by patent offices worldwide between cDNA and genomic DNA: see Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; G Suthers, *Submission P116*, 4 May 2004.

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

108 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

109 See *Patents Amendment Act 2001* (Cth).

110 A McBratney and others, *Submission P47*, 22 October 2003. See also Centre for Law and Genetics, *Submission P104*, 22 April 2004.

111 A McBratney and others, *Submission P47*, 22 October 2003.

112 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

ALRC's views

6.70 Inventions involving genetic materials and technologies do not appear to raise any special issues regarding the application of the novelty requirement. Many submissions suggested that genetic materials in a pure and isolated form are not new because they are discoveries of pre-existing material. For the reasons considered earlier in this chapter, the ALRC is not persuaded that this approach should be adopted. The fact that genetic materials exist in nature in combination with other biological material does not mean that genetic materials are 'previously available', and therefore not novel, for the purposes of patent law.[113]

6.71 However, if an invention involving genetic material has been previously disclosed or described in prior art information—for example through one of the available databases of gene sequence information—then the novelty requirement might not be satisfied. The novelty of genetic inventions can only be determined for each patent application on a case-by-case basis in light of the prior art and should not be based on *a priori* assumptions relating to the field of technology.

Inventive step

6.72 It has been suggested that inventions involving certain types of genetic materials and technologies, particularly genetic sequences, may not satisfy the requirement that claims in a patent must involve an inventive step.

6.73 A 2003 report produced by Professor William Cornish, Dr Margaret Llewelyn and Dr Michael Adcock for the United Kingdom Department of Health (UK Report) commented on the significance of the inventive step requirement in the context of inventions involving genetic materials and technologies:

> Patent Offices now lay emphasis on the standard requirement of inventive step (non-obviousness) as the requirement which will do most to retain genetic patenting within acceptable bounds … With the growth of bioinformatics techniques to achieve automated comparison of gene functions between different species, it becomes increasingly difficult to characterise the work as anything other than routine.[114]

Inventiveness requirement under Australian law

6.74 Patent protection will be granted in Australia only for novel inventions that involve an 'inventive step' (in the case of an application for a standard patent),[115] or an 'innovative step' (in the case of an application for an innovation patent).[116] The discussion below focuses on what is required to satisfy the inventive step requirement to obtain a standard patent.[117]

---

113 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 29.
114 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 32.
115 *Patents Act 1990* (Cth) ss 7(3), 18(1)(b)(ii).
116 Ibid ss 7(4)–(6), 18(1A)(b)(ii).
117 The 'innovative step' requirement was discussed in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [6.106]–[6.108]. See also Ch 5.

6.75 Inventive step is defined in s 7 of the *Patents Act* and requires a determination of whether an invention would have been obvious to 'a person skilled in the relevant art'. This assessment is made in light of the 'common general knowledge', as it existed in Australia before the priority date of the claim. It may also take into consideration prior art information before the priority date that a person skilled in the art could reasonably be expected to have ascertained, understood and regarded as relevant.[118]

6.76 In 2002, the High Court considered the inventive step requirement in *Aktiebolaget Hässel v Alphapharm Pty Ltd* (*Alphapharm*).[119] The majority of the Court held that, in assessing whether or not the inventive step requirement has been satisfied, the issue is whether a notional research group in the field 'would have been led directly as a matter of course to pursue one avenue in the expectation that it might well produce the [claimed compound]'.[120] The majority found that the results of a 'routine literature search' that have not entered into the common general knowledge are not relevant to an assessment of inventiveness.[121] Further, the majority 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.[122]

6.77 The *Patents Amendment Act 2001* (Cth) introduced changes to the assessment of the inventive step requirement by allowing 'mosaicing' of prior art information during patent examination.[123] Mosaicing allows a patent examiner to assess the inventive step in light of two or more pieces of prior art information in combination, provided that a person skilled in the relevant art could reasonably have been expected to combine such information.[124] Prior to the amendment, patent examiners were only permitted to assess the inventive step in light of a single piece of prior art information, alone or combined with common general knowledge in the relevant art in Australia.

Application to genetic materials and technologies

6.78 In 1992, a report of the House of Representatives Standing Committee on Industry, Science and Technology suggested that it was 'unlikely … that [genetic sequence] patents would pass the test of "non-obviousness" [that is, inventive step]'.[125]

---

118 *Patents Act 1990* (Cth) s 7(2), (3).
119 *Aktiebolaget Hassel v Alphapharm Pty Ltd* (2002) 194 ALR 485.
120 Ibid, 499.
121 Ibid, 500.
122 Ibid, 501.
123 *Patents Amendment Act 2001* (Cth). The amendments apply to complete patent applications filed on or after 1 April 2002 (s 13).
124 *Patents Act 1990* (Cth) s 7(3). See also IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [4.1.4.2].
125 House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), 240–241.

6.79 Some academic consideration of the inventive step requirement has expressed a similar view. 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.[126]

6.80 To date, however, consideration of how the inventive step requirement applies to gene patent applications has primarily occurred at the Patent Office level, and the courts have had little opportunity to provide guidance on this issue.[127]

6.81 The *Manual* indicates that patent examiners should adopt a 'problem–solution' approach to the requirement of inventive step.[128] It instructs patent examiners to consider whether a claimed invention would fail to satisfy the test because 'the solution would have been obvious to any person of ordinary skill in the art who set out to solve the problem'.[129] Professor Andrew Christie and Melanie Howlett have stated that under this approach a patent claim will not be regarded as involving an inventive step if, 'although the essential features of a claim have not been previously disclosed, the claimed features would be obvious to a person skilled in the particular art who set out to solve the problem and those features could be achieved as a matter of routine'.[130]

6.82 A study by Christie and Howlett comparing the approaches of the Trilateral Patent Offices[131] and IP Australia in assessing patent applications claiming partial DNA sequences, such as expressed sequence tags (ESTs), concluded that IP Australia's approach to inventive step exhibited similarities with the approaches of the EPO and JPO.[132] Christie and Howlett concluded that Australian patent examiners do not, as a general matter, consider that the 'application of standard techniques and practice in the art to isolate and sequence a gene from the tissue of interest' constitutes an inventive step, unless 'the isolated sequence possesses an unexpected property that provides an advantageous effect'.[133]

---

126 C Lawson, 'Patenting Genetic Materials: Old Rules May be Restricting the Exploitation of New Technology' (1999) 6 *Journal of Law and Medicine* 373, 379. See also D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 79.

127 For a discussion of relevant opposition proceedings, see C Lawson and C Pickering, 'Patenting Genetic Material: Failing to Reflect the Value of Variation in DNA, RNA and Amino Acids' (2000) 11 *Australian Intellectual Property Journal* 69.

128 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [4.1.6].

129 Ibid, [4.1.6.1], citing *HPM Industries Pty Ltd v Gerard Industries Ltd* (1957) 98 CLR 424, 437.

130 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 13.

131 The Trilateral Project (also referred to as the Trilateral Offices) is a cooperative venture of the USPTO, the EPO and the JPO. It has been in operation since 1983, primarily to facilitate the exchange of information regarding patent examination practices: United States Patent and Trademark Office, European Patent Office and Japanese Patent Office, *About Trilateral Cooperation*, <www.jpo.go.jp/saikine/tws/gen.htm> at 16 June 2004.

132 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 16.

133 Ibid, 15–16.

Inventiveness requirement in other jurisdictions

6.83 A report of the United Kingdom's Nuffield Council on Bioethics (Nuffield Council) in 2002 considered that the technological advances in DNA sequencing may mean that isolating a genetic sequence can no longer be regarded as inventive, as it is a routine and industrialised process.[134] In the Nuffield Council's view, once a gene associated with a disease is identified, the use of the genetic sequence in gene therapy is obvious—particularly when such use is claimed on a purely speculative basis—and should seldom be protected by gene patents.[135]

6.84 Under European patent law, the inventiveness requirement will not be satisfied by an invention involving isolated genetic sequences that have a structure closely related to existing sequences with a known function.[136] The EPO has stated that 'sequences as well as all other chemical compounds should solve a technical problem in a non-obvious manner to be recognised as inventive'.[137] The EPO will regard a genetic invention as involving an inventive step only 'if the applicant can demonstrate that obtaining the sequence was in fact a technical achievement or that they have discovered a new or unexpected property associated with the gene'.[138]

6.85 In the United States, the requirement of inventive step (known there as 'non-obviousness') has been applied in a different manner to inventions involving genetic sequences. Under United States law, a claimed genetic sequence may not be obvious even if the prior art discloses both the structure of the protein for which the gene codes and the general methods for isolating a gene encoding a known protein.[139]

6.86 In adopting this approach, the United States Court of Appeals for the Federal Circuit has stated that 'the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein'.[140] The Court considered that, in the absence of prior art information suggesting a particular DNA

---

134 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 29.

135 Ibid, 62.

136 European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Trilateral Project B3b: Mutual Understanding in Search and Examination: Report on Comparative Study on Biotechnology Patent Practices* (2001), Annex 2, 43. The Nuffield Council has agreed with this approach: Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 30, 50.

137 European Patent Office, Japan Patent Office and United States Patent and Trademark Office, *Trilateral Project B3b: Mutual Understanding in Search and Examination: Report on Comparative Study on Biotechnology Patent Practices* (2001), Annex 2, 43.

138 United States National Research Council, *A Patent System for the 21st Century (Prepublication Copy)* (2004), 76. In April 2004, the EPO upheld a challenge to Myriad Genetics Inc's patent on the BRCA1 on the basis that, among other matters, it did not involve an inventive step: European Patent Office, '"Myriad/Breast Cancer" Patent Revoked after Public Hearing', *Press Release* (Munich), 18 May 2004.

139 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 365. See also D Keays, 'Patenting DNA and Amino Acid Sequences: An Australian Perspective' (1999) 7 *Health Law Journal* 69, 83; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 30.

140 *Re Dueul* 51 F 3d 1552 (Fed Cir, 1995), 1558. See also *Re Bell* 991 F 2d 781 (Fed Cir, 1993), 784; P Ducor, 'In re Deuel: Biotechnology Industry v Patent Law?' (1996) 18 *European Intellectual Property Review* 35.

sequence encoded the relevant protein, a person skilled in the relevant art could not know the structure of that sequence without conducting appropriate experiments.[141] Further, the Court indicated that the existence of a general method of isolating genetic sequences is 'essentially irrelevant'.[142]

6.87 This approach means that the non-obviousness requirement under United States law may be easier to satisfy for inventions involving genetic sequences than in Europe. The Nuffield Council has criticised the United States approach as setting the threshold for inventiveness in relation to genetic inventions too low: 'the outcome of any complex procedure which could not have been predicted in advance, however familiar the procedure, will be judged inventive'.[143] Similarly, the United States National Research Council has criticised the Court of Appeals for the Federal Circuit for creating 'a per se rule that the obviousness of obtaining the gene could *never* be relevant to patentability'.[144] The National Research Council has encouraged the USPTO to assess the obviousness of such inventions according to the general test of whether the invention was obtained by a route that was obvious to try, coupled with a reasonable expectation of success.[145]

Submissions and consultations

6.88 A number of submissions from healthcare and research sector organisations argued that the identification of genetic sequences or the linking of identified genetic sequences to a particular disease do not involve an inventive step.[146] These submissions considered that the only inventiveness involved in an isolated genetic sequence, or its association with a particular biological function or dysfunction, is the *method* by which this information is derived. Given that sequencing techniques, linkage disequilibrium analysis, and gene mapping—among other techniques—are now well known in the genetics field, these submissions considered that the method by which the information is derived could not be inventive. A few submissions suggested that, although identification of genetic sequences may have had the required inventiveness in the past, this is no longer true.[147]

---

141 *Re Dueul* 51 F 3d 1552 (Fed Cir, 1995), 1558–1559; *Re Bell* 991 F 2d 781 (Fed Cir, 1993), 784–785.

142 *Re Dueul* 51 F 3d 1552 (Fed Cir, 1995), 1559, citing *Re Bell* 991 F 2d 781 (Fed Cir, 1993).

143 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 30.

144 United States National Research Council, *A Patent System for the 21st Century (Prepublication Copy)* (2004), 76.

145 Ibid, 77–78. See also United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), rec 3.

146 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Queensland Government, *Submission P57*, 5 January 2004; G Suthers, *Submission P116*, 4 May 2004.

147 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Nuffield Council on Bioethics, *Submission P102*, 22 April 2004.

6.89 The Department of Health and Ageing and ACIPA submitted that the standard for inventiveness under Australian law should be raised.[148] The Department of Health and Ageing commented that the current test for inventiveness 'places too much emphasis on the diligence and determination of the inventor'.[149] ACIPA supported an approach to the inventive step requirement in line with that proposed by the United States Federal Trade Commission, namely, that the standard of a hypothetical person skilled in the relevant art should take greater account of the creativity and problem solving skills characteristic of such people.[150]

6.90 Some submissions were also critical of the way IP Australia appears to apply the inventive step requirement to inventions involving genetic materials and technologies and, in particular, genetic sequences. The RCPA submitted:

> The test for inventiveness … now rests entirely on whether the sequence of a particular gene was not obvious. The test will apply in most instances because the sequence of bases of an unknown gene cannot be known before it was isolated.[151]

6.91 However, McBratney and others stated:

> in light of High Court authority [in *Alphapharm*], it is not valid to judge the obviousness of an invention by the fact that the avenue of research was obvious to try. *A fortiori*, whether those methods were complicated or required little work will be irrelevant; it is the invention as claimed that matters. The ease with which sequences are generated with today's technology should therefore not be seen as *ipso facto* depriving a new molecule of patentability.[152]

6.92 The Centre for Law and Genetics commented that the amendments to the *Patents Act* in 2001 'significantly increased the stringency' of the inventive step requirements' and that further amendments are currently inappropriate.[153]

6.93 Some submissions emphasised that whether a genetic invention represents an inventive step over the prior art can only be determined on a case-by-case basis. These submissions commented that determinations as to inventiveness should not be based on assumptions about the current state of the art in the field of technology to which the invention relates. For example, GlaxoSmithKline submitted:

> Certainly, the issue of whether identification or isolation of genetic material today is inventive/innovative will be affected by advances in sequencing technology and may perhaps mean that it is more difficult to meet the relevant test. However, each case

148 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

149 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

150 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. See also United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), rec 3; Ch 1, 15–19.

151 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; L Palombi, *Submission P28*, 1 October 2003; A Hughes, *Submission P42*, 20 October 2003; E Milward and others, *Submission P46*, 20 October 2003.

152 A McBratney and others, *Submission P47*, 22 October 2003.

153 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

> must be assessed on its merits and while the way in which an invention was made is a relevant consideration for the assessment of inventive step, it is not the only or the determinative one: what is important is what the patent contributes over the prior art, not how the invention was made.[154]

6.94 IP Australia indicated that, as a matter of practice, few gene patents are associated with processes for isolating genetic material and identifying genetic sequences, and that only a small number of gene patents are now granted on the basis that the means of identifying and isolating genetic material was inventive. IP Australia submitted:

> the inventive or innovative step of most granted patents is now associated with what can be achieved by using the isolated and identified genetic material. There continues to be innovation in the purpose for which a given polynucleotide can be put. The employment of a standard process of isolating genetic material does not automatically render unpatentable an application directed to a use of the genetic material. Similarly, isolating and identifying any type of chemical compound through standard techniques does necessarily render unpatentable an application directed to the use of the compound. Hence, patents continue to be granted by IP Australia and the major IP offices for genes and parts thereof, on the basis that the applicant has inventively or innovatively determined a useful property associated with the gene or part thereof.[155]

ALRC's views

6.95 Some submissions to the Inquiry revealed a concern that the inventive step requirement is not sufficiently stringent, at least with respect to genetic materials and technologies.[156] However, the ALRC does not consider that any changes are currently required to the inventive step or innovative step requirement in the *Patents Act*, nor to how those requirements are applied by IP Australia to inventions involving genetic materials and technologies.

6.96 The ALRC agrees with those submissions that emphasised the importance of an inventive step analysis being conducted on a case-by-case basis, and of not relying on *a priori* assumptions about inventiveness based on the field of technology to which the claimed invention relates. It appears that IP Australia typically requires more than the identification and isolation of a genetic sequence to grant a gene patent, in line with the current state of the art in the genetics field. Recent changes to the definition of prior art information in the *Patents Act* will also allow patent examiners greater access to prior art material in assessing the inventiveness of a particular genetic invention claimed in a patent application. The evolution of searching and cross-referencing systems in electronic databases is likely to result in links between documents being more readily

---

154 GlaxoSmithKline, *Submission P33*, 10 October 2003. See also Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71.

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

156 See also K O'Connell and J Cooke, 'Australia: A Patentee's Paradise' (2003) 25 *European Intellectual Property Review* 481.

established and may, therefore, lead to a more expansive interpretation of the information that is relevant in assessing the inventiveness of a patent application.[157]

6.97 To the extent that the concerns expressed in submissions relate to the stringency with which IP Australia applies the inventive step requirement to gene patent applications, the ALRC recommends reforms in other chapters of this Report. In particular, in Chapter 8 the ALRC recommends procedures to assist patent examiners in assessing gene patent applications, including enhancing the education and training of patent examiners in areas of technology relevant to their particular specialty, and developing examination guidelines relating to biotechnological inventions.[158]

Usefulness

6.98 There has been considerable debate about whether isolated genetic materials of various types fulfil the requirement that an invention be 'useful'. For example, the Nuffield Council has noted that:

> Since the development of large-scale DNA sequencing techniques over the past ten years, more DNA sequences have become available without a concomitant understanding of their function. As a result, many patent applications have been filed on genes or parts of genes without the demonstration of a 'credible utility'.[159]

6.99 In particular, concerns have been expressed that inventions involving ESTs and single nucleotide polymorphisms (SNPs) may not display the requisite usefulness for patentability.[160] ESTs and SNPs may be used to identify previously unknown genetic sequences or as templates for expressing and characterising proteins for the purposes of further research. Questions have been raised about whether such uses should be sufficient to satisfy the concept of usefulness.[161]

---

157 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.

158 See rec 8–1 to 8–3.

159 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 31.

160 C Baldock and others, 'Report Q 150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes' (2000) 22 *European Intellectual Property Review* 39; M Howlett and A Christie, 'An Analysis of the Approach of the European, Japanese and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)' (2003) 34 *International Review of Industrial Property and Copyright Law* 581; S Chambers, 'Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *American Intellectual Property Law Association Quarterly Journal* 53; R Eisenberg and R Merges, 'Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *American Intellectual Property Law Association Quarterly Journal* 1; R Eisenberg and R Merges, 'Reply to Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences' (1995) 23 *American Intellectual Property Law Association Quarterly Journal* 61; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 32–34.

161 For example, the United States National Institutes of Health filed patent applications claiming ESTs in the early 1990s, which were rejected by the USPTO for lack of utility. The applications were later abandoned: see P Ginsburg, 'Patentability and Technology Transfer Issues Relating to the NIH Patent

6.100 Gene patents have also been criticised on the basis that they capture for a patent holder 'any number of possible applications even though those uses may be unattainable and unproven'.[162] In relation to this requirement under United States law, it has been proposed that 'claim scope should be limited to uses that are disclosed in the patent application and that allowing claims to DNA itself would enable the inventor to assert claims to "speculative" uses of the DNA that were not foreseen at the time the patent application was filed'.[163]

Usefulness requirement in Australia

6.101 Australian patent law requires that an invention be 'useful', both as an express requirement in s 18 of the *Patents Act* and as an implicit requirement that an invention be a manner of manufacture. The usefulness of an invention may also be considered in determining whether the disclosure requirements in s 40 have been satisfied.

6.102 As interpreted by Australian courts, the express requirement of usefulness in s 18 has a limited meaning. It requires only that the patent must produce the results that are promised upon a fair reading of the specification, and that the end in itself is useful.[164] Nicol and Nielsen have commented that the usefulness criterion does not require that an invention be useful in the sense that it is worthwhile or commercially practical; only that if a particular result is claimed, it must be achievable.[165]

6.103 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 stated 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'.[166]

6.104 IP Australia's *Manual* indicates that an invention claimed in a patent application may not satisfy the manner of manufacture test if it fails to indicate a specific use or practical function:

> 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.[167]

Applications' (1994) 382 *Practising Law Institute Patents, Copyrights, Trademarks and Literary Property Course Handbook Series* 441.

162 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092, [1095].

163 Ibid, [1095].

164 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 277. See also *Martin Engineering Co v Trison Holdings Pty Ltd* (1989) 14 IPR 330.

165 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 32. See also *Rehm Pty Ltd v Websters Security Systems (International) Pty Ltd* (1988) 81 ALR 79, 96–98; *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 111 ALR 205.

166 *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252, 275.

167 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.4.1]. See also IP Australia, *Submission P56*, 4 November 2003.

6.105 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.[168]

6.106 The usefulness of an invention may also be considered indirectly pursuant to the requirement in s 40 of the *Patents Act* that a complete specification fully describe the use of the invention and how it can be achieved. If the invention cannot be achieved on the basis of the description in the specification and requires unreasonable experimentation to make it work, it might fail to satisfy this sufficiency requirement.[169] Further, if a use for the invention described in the claims is not reasonably supported by the description, the claims in the patent application may not be fairly based.[170]

6.107 Currently, the usefulness of an invention is not an express requirement for examination of an Australian patent application. Usefulness is addressed at the examination stage only as an aspect of the manner of manufacture test and through the disclosure requirements. The Commissioner of Patents does not have to be satisfied that an invention is useful under s 18(1)(c) before accepting a patent application.[171] 'Lack of utility' (as the objection is phrased) can be raised as an express objection only in revocation proceedings.[172] It is not a separate basis upon which a patent may be opposed or re-examined.[173] There may, however, be scope to raise the usefulness of an invention claimed in an accepted application in opposition proceedings on the basis of failure to satisfy the manner of manufacture or disclosure requirements.[174]

Approach to usefulness in other jurisdictions

6.108 In other jurisdictions, the requirement that an invention be useful is more clearly expressed and is relevant in the examination of a patent application.

United States

6.109 Under United States law, the requirement is known as 'utility'.[175] United States courts have held that in order to satisfy the utility requirement, a patent application must disclose an invention that is 'practically useful'. In *Brenner v Manson*, the United States Supreme Court held that '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

168 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.4.2].
169 IP Australia, *Submission P56*, 4 November 2003. See also M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 18.
170 IP Australia, *Submission P56*, 4 November 2003.
171 *Patents Act 1990* (Cth) ss 49(1); 101B(2).
172 Ibid s 138(3)(b).
173 Opposition, re-examination and revocation proceedings are discussed in Ch 9.
174 A McBratney and others, *Submission P47*, 22 October 2003; IP Australia, *Submission P56*, 4 November 2003.
175 35 USC s 101.

may prove to be a broad field'. The Supreme Court also stated that an invention that 'either has no known use or is useful only in the sense that it may be an object of scientific research' is not patentable.[176]

6.110 In 2001, the USPTO issued revised examination guidelines setting out the way in which the utility requirement should be applied by United States patent examiners (US Revised Utility Guidelines).[177] The guidelines have now been incorporated into the USPTO's *Manual of Patent Examining Procedure* (MPEP).[178] The US Revised Utility Guidelines require a patent applicant to demonstrate a utility for an invention that is 'specific, substantial and credible'.[179] A patent applicant will demonstrate a 'specific and substantial' utility where 'any particular practical purpose' for the claimed invention is stated in the application, so long as such purpose is not 'throw-away', 'insubstantial' or 'non-specific'.[180] The utility of the invention must be 'specific' to the subject matter claimed, not a 'general utility that would be applicable to the broad class of the invention'.[181] A 'substantial' utility is one that defines a 'real world' use; that is, no further research is required to identify an immediate benefit.[182] The requirement that the utility claimed for an invention is 'credible' will be satisfied if it is believable to a person of ordinary skill in the art, based on the totality of evidence and reasoning provided.[183]

6.111 The USPTO has indicated that an 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'.[184]

Europe

6.112 Under European law, the criterion of usefulness takes the form of a requirement that an invention must be 'capable of industrial application'.[185] The EPC further provides that an invention shall be considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.[186] Additional requirements apply with respect to the industrial applicability of inventions relating to the sequence or partial sequence of a gene, following the implementation of the EU

176 *Brenner v Manson* 383 US 519 (1966), 534–535.
177 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092.
178 United States Patent and Trademark Office, *Manual of Patent Examining Procedure (8th Edition)* (2003), [2107].
179 Ibid, [2107] cl II(A).
180 Ibid, [2107] cl II(B)(1)(i).
181 Ibid, [2107.01] cl I.
182 Ibid, [2107.01] cl I.
183 Ibid [2107] cl II(B)(1)(ii). See also United States Patent and Trademark Office, *Revised Interim Utility Guidelines Training Materials*, <www.uspto.gov/web/offices/pac/utility/utilityguide.pdf> at 16 June 2004, 6.
184 United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092, 1094.
185 *European Patent Convention*, (entered into force on 7 October 1977), art 52(1).
186 Ibid, art 57.

Biotechnology Directive.[187] Article 5(3) of the Directive requires a patent applicant to disclose the industrial application of a sequence or partial sequence of a gene.[188]

6.113 In December 2003, the EPO issued revised examination guidelines that address the 'industrial applicability' requirement for inventions involving genetic sequences:

> A mere nucleic acid sequence without an indication of a function is not a patentable invention … In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could [for example] be that the sequence exhibits a certain transcription promoter activity.[189]

Adoption of specific, substantial and credible utility in other jurisdictions

6.114 Several jurisdictions have endorsed the approach adopted by the US Revised Utility Guidelines, and interpret the requirement of utility (or industrial application) as requiring an applicant to disclose a 'specific, substantial, and credible' use for a claimed invention. For example, guidelines issued by the United Kingdom Patent Office relating specifically to biotechnological inventions (UK Biotechnology Examination Guidelines) state that 'a "specific, substantial, and credible" utility, is arguably the sort of disclosure, relating to industrial application that we would expect to appear in a UK application'.[190] The UK Biotechnology Examination Guidelines also indicate that this approach has been followed in the EPO to date.[191] Further, a 2003 report of the New Zealand Ministry of Economic Development recommended that usefulness should be a specific criterion that must be satisfied before a patent is granted under New Zealand law, and that the usefulness must be credible, specific, and substantial.[192]

---

187 *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).

188 The implementing regulations of the EPC were amended in 1999 to ensure consistency between the EPC and the EU Biotechnology Directive: Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001). Rule 23e of the implementing regulations of the EPC contains provisions equivalent to art 5 of the EU Biotechnology Directive.

189 European Patent Office, *Guidelines for Examination in the European Patent Office* (2003), Pt C, IV.4.5.

190 United Kingdom Patent Office, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office (November 2003)*, <www.patent.gov.uk/patent/reference/index> at 16 June 2004, [35]. The Guidelines note, however, that this approach has not yet been considered by courts in the United Kingdom, or by the EPO, and may not be upheld if challenged by a patent applicant.

191 Ibid, [36]. The December 2003 version of the EPO's Examination Guidelines do not, however, refer expressly to the requirement of 'industrial applicability' being satisfied if the disclosed use of an invention is 'specific, substantial and credible': see European Patent Office, *Guidelines for Examination in the European Patent Office* (2003) Pt C, IV.

192 See, eg, New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003) Pt 2, [50].

Criticism of the specific, substantial and credible utility standard

6.115 Some criticisms have been levelled at the standard adopted in the US Revised Utility Guidelines. The Nuffield Council considered that the standard of utility established by the Guidelines is too low,[193] and suggested that a 'credible' utility merely required an applicant to claim a 'theoretically possible' purpose.[194] Given the state of genetic science and the ability to hypothesise the function of genetic material on the basis of homology with other species, the Nuffield Council considered that a theoretical purpose should not be a sufficient basis on which to award a patent.[195]

6.116 The US Revised Utility Guidelines have also been criticised for failing to address adequately whether a patent should be granted if the application discloses only a single useful function for a gene. However, the MPEP expressly states that 'an applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement';[196] that is, the applicant is not required to demonstrate that all possible uses of the invention claimed in a patent application satisfy the standard of 'specific, substantial and credible' utility. The UK Biotechnology Examination Guidelines have been said to adopt a similar approach.[197]

Reform of the usefulness requirement under Australian law

6.117 In 2000, the IPCRC stated that the manner of manufacture and 'utility' criteria 'have taken on greater importance in some new areas of technology, particularly biotechnology, where the dividing line between mere discovery and invention has become more difficult to define'. The IPCRC concluded that references to 'use' or 'utility' in current Australian law might conflict. The IPCRC considered that 'it has not always been clear how this requirement [to demonstrate a defined use for an invention] has been imposed'. It stated that the extent to which s 40 requires a patent application to contain a 'clear statement' of use or utility is not currently evident.[198]

6.118 Seeking to address these concerns, the IPCRC endorsed the approach adopted by the USPTO in the US Revised Utility Guidelines and recommended that IP Australia should ensure that 'the use described in the specification is specific, substantial and credible to a person skilled in the art'.[199] The IPCRC did not, however, recommend specific changes to the *Patents Act* or the *Patents Regulations 1991* (Cth) (*Patents Regulations*).

---

193 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 31. See also Nuffield Council on Bioethics, *Submission P102*, 22 April 2004.

194 Similar comments have been made by W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 31.

195 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 31.

196 United States Patent and Trademark Office, *Manual of Patent Examining Procedure (8th Edition)* (2003), [2017] cl II(B)(1)(ii).

197 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 31, 62.

198 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 152.

199 Ibid, 154.

6.119 In response to the IPCRC's recommendations, the Australian Government indicated that it would ask IP Australia to ensure that examinations of patent applications address all aspects of the use of an invention being specific, substantial and credible.[200] However, the Government noted that the 'specific, substantial and credible' test is already broadly included within current examination practice under the manner of manufacture and 'fair basis' requirements.[201]

6.120 As noted above, IP Australia's *Manual* does not explain how the standard of 'specific, substantial and credible' use is incorporated into the requirements for patentability under Australian law. However, IP Australia informed the ALRC that it is in the process of amending the *Manual* to address this issue.[202]

6.121 Nicol and Nielsen have suggested that a 'specific, substantial and credible requirement marks a radical change from the previous interpretations of the usefulness criterion by the Federal Court'.[203] Nicol and Nielsen stated that amendments to the *Patents Act* and *Patents Regulations* may be required to implement the recommendation of the IPCRC effectively.[204] They also suggested that s 45 of the *Patents Act* may need to be amended to allow patent examiners to consider the usefulness of an invention in examining an application.[205] Alternatively, they proposed that the *Patents Regulations* could be amended to require utility to be considered at the examination stage.[206]

6.122 Amendments to the current approach to usefulness under Australian law may also be required to implement the provisions of the Australia–United States Free Trade Agreement (AUSFTA).[207] The AUSFTA provides that 'a patent may only be revoked on grounds that would have justified a refusal to grant a patent'.[208] In order for lack of utility to be retained as a ground upon which a patent may be revoked, the *Patents Act* may need to be amended to make usefulness under s 18(1)(c) a ground of examination or opposition. In addition, the AUSFTA provides that 'each Party shall provide that a claimed invention is useful if it has a specific, substantial, and credible utility'.[209] While this provision does not require 'specific, substantial and credible utility' to be

200 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 16 June 2004.
201 Ibid.
202 IP Australia, *Submission P56*, 4 November 2003.
203 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.
204 Ibid, 367; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 234–235.
205 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.
206 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 234.
207 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004.
208 Ibid, art 17.9.5.
209 Ibid, art 17.9.13.

the sole basis on which a patent may satisfy the requirement of usefulness,[210] the implementation of the AUSFTA provides an opportunity to clarify the operation of the usefulness requirement in Australian law.

Submissions and consultations

6.123 Many submissions expressed concern about the grant of patents over genetic inventions, where the use of such inventions is unknown or speculative.[211] For example, the RCPA stated that: 'One of the major problems relating to the utility of genes is that we do not know the varied roles of most genes and claims about their actual or potential utility are largely grounded in ignorance'.[212]

6.124 To address this issue, DP 68 proposed that the *Patents Act* should be amended to: (a) include usefulness as a specific requirement that must be satisfied before a patent is granted; (b) require the Commissioner of Patents to be satisfied on the balance of probabilities that the usefulness criterion is made out; and (c) include lack of usefulness as a basis upon which a patent application may be opposed, in addition to its current role as a ground for revocation.[213]

---

210 Submissions disagreed as to the effect of the provision. For example, ACIPA considered that the AUSFTA obliged Australia to adopt the US Revised Utility Guidelines: Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. Others interpreted the provision to be inclusive, allowing other means of satisfying the usefulness requirement: Intellectual Property Research Institute of Australia, *Consultation*, Melbourne, 1 April 2004.

211 Cancer Council New South Wales, *Submission P1*, 5 June 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003. Luigi Palombi expressed a similar concern but considered that the issue should be addressed by excluding patent claims to 'isolated or purified polyproteins and nucleotides' from the category of patentable subject matter, rather than by reforming the 'usefulness' requirement: L Palombi, *Submission P28*, 1 October 2003. See also G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

212 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. See also G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

213 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 6–3.

Examination of the usefulness requirement

6.125 A wide range of submissions and consultations supported including usefulness as a separate ground upon which a patent application should be examined.[214] Submissions suggested that usefulness is an important issue, but there is confusion about the significance of this requirement and how it currently operates.[215] The South Australian Department of Human Services considered that the usefulness requirement should 'stand apart from the "manner of manufacture" test so that it is given clear and specific focus'.[216]

6.126 Submissions indicated that requiring usefulness to be considered at the examination stage could address concerns about patent applicants claiming theoretical or speculative uses for an invention without substantiating such assertions.[217] Others suggested that it could also assist in addressing concerns about inappropriately broad patent claims.[218] The weight of opinion considered that any change should apply to inventions involving all types of technology, not only genetic materials and technologies.[219]

---

214 See, eg, Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; G Suthers, *Submission P116*, 4 May 2004; Queensland Law Society, *Submission P118*, 7 May 2004; J McKeough, *Consultation*, Sydney, 23 March 2004; AusBiotech Ltd, *Consultation*, Melbourne, 2 April 2004. IPRIA supported making usefulness an additional requirement for examination, but considered that the requirement should be renamed the 'utility' criterion 'to differentiate it, and avoid importation of the jurisprudence associated with the old concept of usefulness': Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

215 See, eg, Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004.

216 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

217 South Australian Government, *Submission P51*, 30 October 2003; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004.

218 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

219 See, eg, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A Hughes, *Submission P42*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

6.127 In its submission, IP Australia indicated that it could 'foresee no particular difficulties' with the ALRC's proposals. It also noted that, in responding to the report of the IPCRC, the Australian Government 'asked IP Australia to ensure that examination covers all aspect of use being specific, substantial and credible'.[220]

6.128 However, some submissions considered that the usefulness of a claimed invention is already adequately addressed in Australian patent law.[221] The Centre for Law and Genetics, while agreeing that the requirement of usefulness should be relevant at the examination stage, perceived difficulties with the reforms proposed by the ALRC. The Centre considered that, given the existing body of case law interpreting s 18(1)(c) of the *Patents Act*, extending the requirement of usefulness in the manner contemplated by the ALRC could cause confusion. The Centre proposed that the standard of specific, substantial and credible utility could be considered as part of the manner of manufacture requirement, or by amending the *Patents Regulations* to include 'specific, substantial and credible utility' as a prescribed matter to be addressed by a patent examiner.

6.129 Other submissions identified concerns about the usefulness requirement being considered at the examination stage. For example, a firm of patent attorneys, F B Rice & Co submitted that requiring usefulness to be addressed at the examination stage would mean that an examiner 'will need to be educated … as to the background, development, object and outcome potential of an invention'. F B Rice & Co also suggested that the costs of examination could increase as a result of applicants having to provide 'substantial evidence from experts or the like in the industry'.[222] Other submissions considered that examination of the usefulness requirement might delay the publication of an invention,[223] or deter inventors from using the patent system.[224]

6.130 Some submissions considered that the scope of the monopoly conferred by a gene patent should be limited to the uses for a genetic invention that are disclosed in a patent specification.[225] Associate Professor Ross Barnard submitted that 'applicants should not be allowed to claim all possible (including unknown) future uses of a particular nucleic acid (or derived protein) sequence'.[226] The Queensland Government stated that 'all patents should demonstrate a commercial or industrial use, and a

---

220 IP Australia, *Submission P86*, 16 April 2004. The IPCRC's recommendation and the Australian Government's response are outlined above.

221 F B Rice & Co, *Submission P84*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

222 F B Rice & Co, *Submission P84*, 16 April 2004. See also IP Australia, *Submission P56*, 4 November 2003.

223 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

224 F B Rice & Co, *Submission P84*, 16 April 2004.

225 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004.

226 R Barnard, *Submission P32*, 7 October 2003.

monopoly granted only in relation to the use(s) disclosed in the patent application'.[227] The Walter and Eliza Hall Institute of Medical Research considered that it might also be acceptable to include 'credibly predicted uses that would be an obvious extrapolation from the examples in the patent'.[228]

6.131 However, F B Rice & Co submitted that 'whilst a patent application with masses of experimental data to support each and every claim would be optimal, this is not a realistic scenario'.[229] They suggested that such a requirement may be particularly problematic in relation to claims relating to 'methods of treating diseases' in humans because obtaining such data involves the time and effort of substantial experimentation in cellular or animal models before human trials are able to be conducted.

Balance of probabilities standard

6.132 DP 68 proposed that a single 'balance of probabilities' standard of proof should apply to all the requirements for patentability relevant at the examination stage.[230] Submissions that commented on this issue are addressed in Chapter 8, which makes a recommendation on similar terms to those proposed in DP 68.[231] In addition, a number of submissions specifically commented that patent examiners should be satisfied on the balance of probabilities that the requirement of usefulness has been made out in order to accept a patent application.[232] For example, the Department of Health and Ageing indicated that the adoption of a balance of probabilities standard will 'assist in restricting speculative use claims in gene patent applications'.[233] In contrast, the Institute of Patent and Trademark Attorneys (IPTA) submitted that 'it is unlikely that an Examiner will necessarily be in a position to make a final determination on the issue of usefulness and the establishment of a high standard in this regard … may provide an impediment to the grant of patent protection'.[234]

---

227 Queensland Government, *Submission P103*, 22 April 2004. See also Queensland Government, *Submission P57*, 5 January 2004.

228 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

229 F B Rice & Co, *Submission P84*, 16 April 2004.

230 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 8–5.

231 See rec 8–3.

232 See, eg, Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004.

233 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

234 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004. See also Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

Grounds for challenge

6.133 A range of submissions supported amending the *Patents Act* to permit patent applications to be opposed on the basis of lack of usefulness.[235] A number of submissions considered that usefulness should also be grounds for re-examination of a patent.[236] However, IP Australia submitted that usefulness should, at most, be a basis upon which a patent may be opposed:

> Assessment of use may be conducted as part of the opposition process without any obvious difficulty, as the process is designed to deal with higher evidentiary burdens. [However,] re-examination is similar to the examination process, in that it is conducted *ex parte* and is not designed to consider evidence to the extent that would be required for a thorough assessment of use.[237]

6.134 Other submissions suggested that adding usefulness as a basis upon which a patent may be opposed (or re-examined) would have limited effect.[238] The South Australian Government commented that, as most genetic material is already protected by patents, amendments to the grounds for opposition of a patent may not have a significant impact.[239] Others noted that it was unlikely that a challenge would be initiated against a patent that was not useful.[240] In addition, McBratney and others suggested that usefulness did not need to be added as a specific ground upon which a patent may be opposed because such an objection may already be raised as part of the manner of manufacture test.[241]

Examination Guidelines

6.135 DP 68 also proposed that IP Australia develop examination guidelines to assist patent examiners in applying the usefulness requirement and that the guidelines should require that the usefulness must be 'specific, substantial and credible' to a person skilled in the relevant art.[242]

---

235 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; A Hughes, *Submission P42*, 20 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

236 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; A Hughes, *Submission P42*, 20 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Queensland Government, *Submission P57*, 5 January 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004.

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

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

239 South Australian Government, *Submission P51*, 30 October 2003.

240 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

241 A McBratney and others, *Submission P47*, 22 October 2003. See also F B Rice & Co, *Submission P84*, 16 April 2004.

242 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 6–4.

6.136 The development of guidelines relating to the usefulness requirement was supported in a large number of submissions and consultations.[243] For example, the South Australian Department of Human Services commented that guidelines 'would assist patent examiners to adopt a common and uniform basis for assessment'.[244] Many submissions endorsed the proposition that patent applications should disclose a utility for the claimed invention that is 'specific, substantial and credible'.[245]

6.137 A few submissions suggested that the content of the usefulness requirement should be made clear in legislation.[246] In particular, IPRIA commented that requiring the usefulness of an invention to be 'specific, substantial and credible' to a person skilled in the relevant art is a significant change from the Federal Court's interpretation of the usefulness requirement in s 18(1)(c) of the *Patents Act* and that amendments to the Act would, therefore, be required to implement such a change.[247] IPRIA considered that guidelines would be insufficient to effect this reform because they are merely suggestive of the application of patent law principles, and do not bind the courts in interpreting the *Patents Act*. However, IPRIA considered that examination guidelines could also be developed to explain the criterion of usefulness further and to give practical examples of how it would be applied. IPTA submitted that any guidelines developed by IP Australia should be confined to procedures for examination.[248]

---

243 Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Medicines Australia, *Submission P75*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004; G Suthers, *Submission P116*, 4 May 2004; Queensland Law Society, *Submission P118*, 7 May 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004. A McBratney and others, *Submission P47*, 22 October 2003 also supported the development of a set of technology-neutral guidelines relating to the usefulness requirement, but did not consider that changes were required to the Patents Act.

244 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

245 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004. Two submissions supported the implementation of a 'specific, substantial and credible' standard but nonetheless expressed concern that a credible use would only require that the use was 'theoretically possible' and this may not be sufficiently stringent: Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004.

246 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

247 Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

248 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

ALRC's views

6.138 The ALRC considers that reform is needed to the way in which the usefulness of an invention is addressed in the requirements for patentability. It was evident from submissions and consultations early in the Inquiry that there is considerable confusion about the application of the usefulness requirement. These misunderstandings relate to the extent to which an invention claimed in a patent application must be useful; how such a requirement is imposed; the standard for satisfying this requirement; and the extent to which usefulness can or should limit the scope of patent claims.

6.139 While usefulness is an important consideration in awarding patent protection for inventions involving all types of technologies, the ALRC endorses the view expressed by the IPCRC that the criteria of manner of manufacture and 'utility' have taken on a greater importance in new areas, such as biotechnology, where the dividing line between mere discovery and invention has become difficult to define.[249]

6.140 Reform of the usefulness requirement would clarify IP Australia's assessment of the function and use of genetic material claimed in a patent application. However, adopting specific provisions in relation to genetic materials and technologies is generally undesirable. The present approach of the *Patents Act* is essentially technology-neutral and is capable of accommodating inventions in new technological fields as they arise. Implementing specific patentability requirements for genetic materials and technologies would diverge from the approach adopted in most other jurisdictions and may conflict with Australia's obligations under the TRIPS Agreement. The ALRC's recommendations in relation to the usefulness requirement are not, therefore, limited to inventions involving genetic materials and technologies.

6.141 The ALRC considers that Australian patent examiners should examine, and report on, the usefulness of an invention disclosed in a patent application as a separate requirement, and not merely as one of a number of considerations in determining whether an invention satisfies the manner of manufacture and disclosure requirements in ss 18 and 40 of the *Patents Act*.

6.142 The standard of usefulness disclosed in an application should satisfy the 'specific, substantial and credible' test endorsed by the IPCRC and confirmed in the AUSFTA. The ALRC agrees with submissions that suggested this test should be included in the *Patents Act* because it represents an important change to the way in which the usefulness requirement has historically been interpreted. Further, the ALRC considers that the usefulness requirement should be satisfied *only* if a 'specific, substantial and credible' use for the invention is disclosed. Such reforms would make Australian law consistent with approaches to usefulness adopted in other major jurisdictions. In addition, such a standard would preclude a patent being granted over a

249 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 152.

genetic invention when further research or investigation is required to understand whether the invention has a practical application.

6.143 In Chapter 8, the ALRC recommends that a single standard of proof should apply to all requirements for patentability assessed by patent examiners (see Recommendation 8–3). As discussed in that chapter, requiring different standards of proof for the patentability criteria—as currently provided in s 49 of the *Patents Act*—adds unnecessary complexity to the assessment of patent applications. The ALRC considers that the balance of probabilities standard should also apply to the requirement of usefulness. This reform may go some way to addressing concerns that the disclosed use of a genetic invention may be speculative.

6.144 The ALRC considers that challenges to patent rights on the basis of lack of usefulness of an invention should not be confined to post-grant proceedings by way of revocation. As discussed in Chapter 9, opposition proceedings may be initiated before a patent is sealed and may result in the narrowing or withdrawal of patent claims, or a determination not to allow an accepted application to be sealed. The ALRC recommends that the grounds for opposition set out in the *Patents Act* should be amended to include lack of usefulness. This would allow third parties to adduce evidence that may not have been available to the examiner during examination.

6.145 On the other hand, the ALRC does not believe that any significant benefit would result from including lack of usefulness as a new basis for re-examination. Re-examination is not significantly different in form to the examination of a patent application. The process is conducted *ex parte* and based largely on documentary evidence, albeit at a later stage in the life of a patent or patent application.

6.146 The ALRC considers that IP Australia should develop guidelines to assist patent examiners in applying the proposed usefulness requirement. Such guidelines could be included in IP Australia's *Manual*, which sets out relevant considerations in applying the requirements for patentability to inventions involving all types of technology. However, the ALRC considers that the examination guidelines relating to biotechnological inventions—which are recommended in Chapter 8—should specifically address the application of the usefulness requirement to biotechnological inventions. Materials developed by the USPTO in conjunction with the US Revised Utility Guidelines could serve as a helpful resource to IP Australia in formulating examination guidelines relating to the usefulness requirement.

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

(a) include 'usefulness' as a requirement in the examination of an application for a standard patent and in the certification of an innovation patent;

(b) provide that an invention will satisfy the requirement of 'usefulness' only if the patent application discloses a specific, substantial and credible use;

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

(d) include 'lack of usefulness' as a basis upon which an accepted application for a standard patent may be opposed, in addition to its current role as a ground for revocation. (See also Recommendation 8–3.)

Recommendation 6–4 IP Australia should develop guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to assist patent examiners in applying the 'usefulness' requirement. The guidelines should outline factors relevant to determining whether a use disclosed in a patent application is specific, substantial and credible to a person skilled in the relevant art. (See also Recommendation 8–2.)

Effect of reforming the usefulness requirement

6.147 A number of submissions suggested that a gene patent should confer a monopoly on the patent holder only in relation to those uses of an invention that are disclosed and demonstrated.

6.148 The law in this area is complex and there was some uncertainty in submissions about the way in which the usefulness requirement applies. As discussed above, the usefulness of an invention is a separate requirement for patentability under s 18(1)(c) of the *Patents Act*, but it is also relevant in determining whether an invention satisfies the manner of manufacture test and the disclosure requirements.[250] In addition, the 'use' of a patented invention is one of the rights conferred upon a patent holder as part of its exclusive right 'to exploit' the invention.[251]

250 *Patents Act 1990* (Cth) ss 18(1)(a), 40.
251 Ibid, s 13; sch 1.

6.149 In recommending reforms to the usefulness requirement, the ALRC has not adopted suggestions that the usefulness requirement be amended to ensure that the scope of the monopoly conferred by a gene patent is limited only to those uses for a genetic invention that are disclosed in a patent specification. The usefulness criterion recommended by the ALRC would require a patent examiner to assess whether an invention has a commercial or industrial application, but so long as an applicant discloses *a use*, the requirement will be satisfied. The ALRC does not believe that a more extensive amendment of the usefulness requirement is either necessary or desirable to address concerns about the scope of the monopoly conferred by a gene patent.

6.150 To adopt a reform that would to limit a patent holder's monopoly to those uses that are disclosed in a patent specification is unlikely, in practice, to achieve the result sought by those who advocate this approach. This is because most of the gene patents that are perceived to be problematic have already been granted, while any amendments to the *Patents Act* would only affect gene patents granted in the future. Moreover, most human genetic sequences are now in the public domain as a result of the Human Genome Project. In the future, it is likely that gene patents will be granted only over new uses for human genetic sequences, rather than over the sequences themselves.[252]

6.151 The suggestion is also premised upon confusion between the patentability requirements and the scope of rights conferred on a patent holder by the grant of the patent. The grant of a patent over a genetic *product* gives the patent holder the right to exploit the product. This entitles the patent holder to make, hire, sell, use or import the product for whatever purposes it may lawfully be used, even if the potential applications of the product are not known at the time a patent is granted.

6.152 Limiting the scope of exclusive rights conferred by a gene patent would be a radical departure from the existing patent system. It would involve treating gene patents differently to patents over other technologies because applicants for gene patents would need to satisfy more stringent patentability requirements. For the reasons set out earlier in this chapter, the ALRC does not favour this approach.

6.153 Further, the TRIPS Agreement limits the extent to which Australian patent law may restrict the rights conferred by a patent.[253] Article 28 requires that, in the case of a patented product, a patent holder shall have the right to prevent third parties from 'making, *using*, offering for sale, selling or importing' the patented product.[254] Article 30 permits member States to provide limited exceptions to the exclusive rights conferred by a patent provided such exceptions do not unreasonably conflict with the 'normal exploitation of the patent and do not unreasonably prejudice the legitimate

252 GlaxoSmithKline, *Submission P33*, 10 October 2003.
253 See Ch 4.
254 Emphasis added. Article 28 of the TRIPS Agreement also sets out the rights conferred upon the holder of a patented process.

interests' of a patent holder.[255] In the ALRC's view, limiting the scope of the monopoly conferred by gene patents to those uses of an invention that are disclosed and demonstrated by the applicant is likely to conflict with Australia's obligations under the TRIPS Agreement.

6.154 The patent system already contains mechanisms to encourage further innovation with respect to a patented invention and to reward third parties who exhibit inventiveness in this regard. A gene patent that claims an isolated genetic sequence or other genetic material per se does not necessarily give the patent holder the exclusive right to exploit all uses of the sequence or material.[256] Depending on the scope of the claims in the original patent, later patents might be granted to another party for novel and inventive applications of the isolated genetic sequence or other material. In practice, the later patent holder may require a licence from the holder of the patent on the genetic product in order to exploit its invention.[257] Conversely, the holder of the patent on the genetic product may require a licence in order to exploit the patent on the new application. However, it is difficult to generalise: much will depend on the claims of the particular patents in question.

6.155 To the extent that submissions raised concerns about the scope of the monopoly conferred by a gene patent and its effect on subsequent research and innovation, these concerns are addressed by reforms recommended in other chapters of this Report, including the introduction of an experimental use exemption.[258]

Disclosure of an invention

6.156 Patent law in Australia and in other jurisdictions requires a patent specification to disclose an invention in such a manner as to allow a person skilled in the relevant art to make or carry out the invention.[259] This requirement is intended to ensure that the scope of protection afforded by a patent is commensurate with the technical contribution made by the claimed invention.

Disclosure requirements under Australian law

6.157 Section 40 of the *Patents* Act sets out the requirement that a patent specification must fully disclose an invention. Section 40(2)(a) provides that a complete specification must 'describe the invention fully, including the best method known to the applicant for performing the invention'. This is known as the 'sufficiency'

255 TRIPS Agreement, art 30.
256 IP Australia, *Submission P56*, 4 November 2003.
257 Ibid.
258 See rec 13–1. One submission specifically noted that an experimental use exemption represents 'a principled limitation' on the rights conferred by a product patent, which could in substance achieve a similar result to limiting a patent holder's monopoly to exploit a patented invention solely to the uses disclosed in the patent specification: Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.
259 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003), 22.

requirement. Section 40(3) requires the patent claims to be 'clear and succinct and fairly based on the matter described in the specification'. This is known as the 'fair basis' requirement.

6.158 The Federal Court considered the application of s 40 to biotechnology inventions in *Genetics Institute v Kirin-Amgen Inc (No 3)*.[260] The principal claim at issue was for an isolated and purified polypeptide having the primary structural conformation, and one or more of the biological characteristics, of naturally occurring erythropoietin. The patent disclosed specific DNA sequences for human and monkey DNA, but the claims included other mammalian species. Heerey J held that the claims were permissibly wide because they disclosed the coding sequence for erythropoietin, which is a 'principle capable of general application'.[261] His Honour held that a claim in correspondingly general terms was therefore acceptable.[262]

6.159 It has been suggested that broad claims of the type accepted by Heerey J in *Kirin Amgen* may no longer satisfy the disclosure requirement given the developments in the field of genetics since that case was decided.[263] There is, however, little other guidance in Australian case law to assist patent examiners in determining how the disclosure requirements should apply to gene patents. IP Australia commented that, although the decision in *Kirin-Amgen* is consistent with decisions in other areas of technology, the gene technology at issue in the case was relatively straightforward and the case was not required to address 'many of the more complex and contentious issues that arise in gene technology'.[264]

6.160 IP Australia's *Manual* sets out its approach to one particular issue in the application of the disclosure requirements to inventions in the biotechnology field, namely, the question of 'reach-through claims'.[265] A reach-through claim is one that seeks to claim the right to a future invention on the basis of a currently disclosed invention.[266] In such cases, the *Manual* explains that:

> The specification generally discloses a new peptide or nucleic acid sequence, or a newly discovered link between a peptide or a nucleic acid and a specific disease or medical condition, and then claims compounds that interact with the peptide or nucleic acid and downstream uses of those compounds.[267]

---

260 *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30 (Heerey J). This decision was an appeal from the decision of the Deputy Commissioner of Patents in *Kiren-Amgen Inc v Board of Regents of University of Washington* (1995) 33 IPR 557 discussed above. An appeal to the Full Federal Court was dismissed: *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106.

261 *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (1998) 156 ALR 30, 46.

262 Ibid, 46.

263 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 33. See also C Lawson, *Submission P67*, 4 March 2004.

264 IP Australia, *Submission P86*, 16 April 2004.

265 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10].

266 S Kunnin and others, 'Reach-through Claims in the Age of Biotechnology' (2002) 51 *American University Law Review* 609, 618–619.

267 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10.1].

6.161 The *Manual* states that reach-through claims that seek to cover compounds that interact with a specific peptide or nucleic acid sequence may fail to satisfy the fair basis requirement because they are not claims to the product of the invention, but are merely directed to compounds inherently capable of interaction with the invention.[268] In addition, such claims may fail to satisfy the sufficiency requirement because they provide insufficient information to enable the production of the full range of compounds that potentially fall within the scope of the claims.[269] The *Manual* suggests, however, that reach-through patent claims to *methods* of using candidate compounds may not raise the same issues.[270]

Disclosure requirements in the United States

6.162 In the United States, the disclosure requirements are expressed in terms of 'enablement' and 'written description'.[271] Enablement requires a determination of whether a person skilled in the art can make and use the claimed invention without undue experimentation.[272] The written description requirement is satisfied if a patent specification describes the claimed invention in sufficient detail that a person skilled in the art can reasonably conclude that the inventor 'had possession' of the claimed invention.[273] Satisfaction of the enablement and written description requirements are closely linked to the utility requirement because the application of an invention claimed in a patent must be described such that a person skilled in the art could make and use the invention themselves on the basis of the patent claims.

6.163 Recent decisions of the Court of Appeals for the Federal Circuit have begun to elucidate principles governing the nature of the disclosure that will be required for particular types of genetic inventions.[274] In 2001, the USPTO introduced new guidelines for the application of the written description requirement by United States patent examiners.[275]

---

268 Ibid, [10.10.3].

269 Ibid, [10.10.4]. 'Reach-through' compound claims may also fail to satisfy the novelty requirement: IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10.2].

270 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [10.10.5].

271 35 USC s 112.

272 *Re Wands* 858 F 2d 731 (Fed Cir, 1988).

273 United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099. See also United States Patent and Trademark Office, *Manual of Patent Examining Procedure (8th Edition)* (2003), [2161]–[2163].

274 See, eg, *University of Rochester v G D Searle & Co Inc* (2004) 69 USPQ 2d 1886; *Regents of the University of California v Eli Lilly & Co* 119 F 3d 1559 (Fed Cir, 1997); *Enzo Biochem Inc v Gen-Probe Inc* 285 F 3d 1013 (Fed Cir, 2002). See also A Cantor, 'Using the Written Description and Enablement Requirements to Limit Biotechnology Patents' (2000) 14 *Harvard Journal of Law & Technology* 267.

275 United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099.

Submissions and consultations

6.164 Several submissions expressed concern about the scope of gene patent claims.[276] Concerns about the breadth of claims in gene patents were primarily directed to the potential adverse impact such claims may have on further research and the development, cost and accessibility of new procedures and products involving genetic materials and technologies.[277]

6.165 DP 68 asked whether the fair basis and sufficiency requirements in s 40 of the *Patents Act* adequately limit the scope of gene patent claims and, if not, what reforms are required to address deficiencies in the way these requirements are applied.[278]

6.166 A number of submissions considered that the sufficiency and fair basis requirements in s 40 are capable of adequately limiting gene patent claims.[279] Some suggested that there was no evidence of a particular problem.[280] Others commented that broad claims are characteristic of patents relating to all types of new technologies, not only gene patents.[281] A few submissions indicated that the scope of gene patent claims appears to have narrowed in recent times.[282]

6.167 IP Australia did not consider that inventions involving genetic materials and technologies require special treatment under the sufficiency and fair basis requirement. It acknowledged, however, that there may be a lack of understanding about the application of s 40 to genetic inventions. It suggested that this might be a result of the fact that 'many legal practitioners do not have a genetics or biotechnology background'; a situation which is compounded by the paucity of relevant case law in Australia and overseas.[283]

---

276 See, eg, Cancer Council Australia, *Submission P25*, 30 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; South Australian Government, *Submission P51*, 30 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

277 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

278 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 6–1.

279 F B Rice & Co, *Submission P84*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

280 J Abbot, *Submission P83*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

281 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003; Department of Health Western Australia, *Submission P89*, 16 April 2004.

282 National Health and Medical Research Council, *Submission P52*, 31 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; F B Rice & Co, *Submission P84*, 16 April 2004.

283 IP Australia, *Submission P86*, 16 April 2004. In contrast, another submission considered that patent examiners lack sufficient expertise to apply the sufficiency and fair basis requirements: Department of Health Western Australia, *Submission P89*, 16 April 2004.

6.168 However, IP Australia considered that greater certainty in the application of s 40 to gene patents will develop as case law and practice evolves.[284] It suggested that the development of specific examination guidelines relating to biotechnological inventions would 'improve technical understanding of the interaction between s 40 and gene technology'.[285] Other submissions also supported the development of guidelines in this area.[286] IPTA and AusBiotech Ltd suggested that it is possible to apply precedents developed in relation to chemical and pharmaceutical compounds to inventions involving genetic materials and technologies, by analogy.[287]

6.169 In his submission, Dr John Abbott analysed the scope of claims in a range of Australian patents and patent applications relating to gene-based diagnostic testing of human diseases.[288] The study suggested a wide range in the scope of patent claims, but concluded that existing provisions in the *Patents Act*—particularly s 40—may provide mechanisms to limit the scope of gene-based diagnostic patents. Abbott considered that the application of the sufficiency and fair basis requirements could be facilitated by accepting 'a more sophisticated and detailed level of scientific input'—including by 'changes to the levels of scientific expertise of those involved in the process, as well as [the] evidence provided for their consideration'.[289]

6.170 A small number of submissions commented on the type of information that a patent applicant should be required to adduce to satisfy the disclosure requirements. AusBiotech Ltd considered that 'the specification must disclose an actual *experimental* demonstration of at least one biological function of the nucleic acid or corresponding protein'.[290] Similarly, the Australian Health Ministers' Advisory Council considered that 'experimental evidence of biological function [should be] disclosed in the patent specification'.[291] The Department of Health Western Australia considered that a patent applicant should be required to support the claims in a patent with 'proof of concept' data, at the bare minimum.[292]

6.171 Some submissions considered that the sufficiency and fair basis requirements are not being stringently applied by Australian patent examiners and may require reform.[293] ACIPA stated that 'the evidence would suggest that patent attorneys are still

---

284 IP Australia, *Submission P86*, 16 April 2004. See also GlaxoSmithKline, *Submission P33*, 10 October 2003.

285 See rec 8–2.

286 A McBratney and others, *Submission P47*, 22 October 2003; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

287 AusBiotech Ltd, *Submission P58*, 7 November 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

288 J Abbot, *Submission P83*, 16 April 2004.

289 Ibid. Dr Abbott's comments in this regard were not limited to Australian patent examiners or judges, but included those who present the 'evidence and analysis' of a particular case to an examiner or judge (ie, legal practitioners).

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

291 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

292 Department of Health Western Australia, *Submission P53*, 3 November 2003.

293 C Lawson, *Submission P67*, 4 March 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; S Brown, *Submission P78*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

drafting broad claims in respect of genes and gene sequences, and such claims are being accepted by the Patent Office in large part'.[294] ACIPA questioned the way in which the disclosure requirements have been applied by IP Australia:

> It is submitted that genetic materials are presently being patented in a way that fails to recognise the potential additional inventiveness … by granting broad claims which include the additional potential of the sequence and other biological processes associated with that sequence.[295]

6.172 McBratney and others also considered that the fair basis requirement is 'long overdue for review and reform', but that the difficulties raised by the requirement are not restricted to inventions involving genetic materials and technologies:

> [T]here is great ambiguity as to what experimentation and disclosure is necessary to sufficiently enable Australian and US patents, especially as relating to 'gene patents' and more so with potential drug targets and 'method of treating disease' patents. The same problem may also be encountered with 'composition of matter' patents which claim broad classes of analogue compounds for inhibiting certain targets or proteins. The question is where to draw the line.[296]

6.173 McBratney and others proposed that this issue might be addressed by the development of clear guidelines on sufficiency and fair basis, similar to the USPTO's Written Description Guidelines.[297]

ALRC's views

6.174 While some submissions raised concerns about the scope of gene patent claims, no firm evidence was provided to the Inquiry that the sufficiency and fair basis requirements in s 40 of the *Patents Act* are not adequate to address them. The ALRC agrees with submissions suggesting that complexities in the way in which these requirements apply to inventions involving genetic materials and technologies are likely to be resolved by the development of further guidance in this area. Pending further judicial consideration of this issue, the ALRC believes that guidelines developed by IP Australia could assist patent examiners and users of the patent system in understanding how the s 40 requirements should apply to patents over genetic materials and technologies (see Recommendation 8–2).

6.175 In Chapter 8, the ALRC recommends that IP Australia should enhance its education and training programs for patent examiners in areas of technology relevant to their particular specialties and that the Commissioner of Patents should be satisfied on

---

294 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003. See also R Barnard, *Submission P32*, 7 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

295 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003. See also 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.

296 A McBratney and others, *Submission P47*, 22 October 2003.

297 Ibid. See also United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099.

the balance of probabilities that each requirement for patentability relevant at the examination stage is made out.[298] These reforms will assist patent examiners in understanding particular issues that may be raised by genetic technologies in the application of the sufficiency and fair basis requirements. It will also raise the standard of proof from the 'benefit of the doubt' standard that currently applies to the examination of the fair basis and sufficiency requirements.[299]

298 See rec 8–1 and 8–2.
299 See rec 8–3. See also Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

7. Exclusions from Patentability

Contents

Introduction

7.1 A 'patentable invention' under Australian law is one that satisfies the requirements set out in s 18 of the *Patents Act 1990* (Cth) (*Patents Act*).[1] The *Patents Act* requires that the invention fall within the concept of patentable subject matter under Australian law. Subject to certain express exclusions in the *Patents Act*, this requirement is primarily expressed in terms of the 'manner of manufacture' test.

1 Namely that the invention is novel and inventive when compared to the prior art, is useful, and has not been secretly used in Australia before the priority date.

7.2 Chapter 6 examined arguments that certain types of inventions involving genetic materials and technologies are not, or should not be, patentable on the grounds that such inventions do not satisfy patentability requirements, for example that the isolation of a genetic sequence and identification of its function may not involve an inventive step. It has also been suggested that certain types of inventions involving genetic materials and technologies should not be patentable on the ground that the inventions are not, or should not be, patentable subject matter. This amounts to a claim that certain genetic materials and technologies should fall within an exclusion from patentability.

7.3 This chapter begins by examining the existing exclusions from patentability contained in the *Patents Act* and their possible application to genetic materials and technologies. The chapter then outlines grounds on which some genetic materials or technologies might be excluded from patentability. These could involve new exclusions from patentability for genes and genetic sequences specifically; for methods of medical treatment; or on social or ethical grounds.

Existing exclusions from patentability

7.4 The *Patents Act* excludes certain categories of subject matter from patentability and grants the Commissioner of Patents the discretion to refuse a patent application for other types of inventions.[2] As discussed below, the existing grounds of excluded and excludable subject matter are limited and have been interpreted narrowly by IP Australia.

Human beings and the biological processes for their generation

7.5 'Human beings, and the biological processes for their generation' are excluded from patentability.[3] This provision has not been considered judicially, and its precise scope remains unclear. IP Australia's *Manual of Practice and Procedure* (the *Manual*) states that inventions that are 'clearly encompassed' by the provision include: human beings, foetuses, embryos or fertilised ova; methods of *in vitro* fertilisation or cloning methods that generate human beings; and processes—beginning with fertilisation and ending with birth—that are wholly biological and result in a human being.[4]

7.6 It seems unlikely that s 18(2) excludes many inventions involving genetic materials and technologies from patentability. In particular, the *Manual* states that 'human genes, tissues and cell lines' are outside the scope of s 18(2) and will be patentable, if the other requirements set out in the *Patents Act* are satisfied.[5] However, the application of s 18(2) to inventions involving human stem cells and stem cell technologies has been a matter of some debate. This issue is discussed in Chapter 15.

---

2 Where exclusions are discretionary, it is possible for the Commissioner to accept applications for such patents even though the invention falls within a class of excludable subject matter.

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

4 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1]–[8.5.2].

5 Ibid, [8.5.1]. See also D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 241.

Contrary to law

7.7 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 ground that its use would be 'contrary to law'.[6]

7.8 The *Manual* states that the discretionary power conferred on the Commissioner of Patents under s 50(1)(a) should be invoked only 'in the clearest of circumstances'.[7] The *Manual* also states that the provision should be relied on to exclude an invention only if an unlawful use, and no alternative or additional lawful use, has been described in the application.[8]

7.9 Section 50(1)(a) has limited application to inventions involving genetic materials and technologies because a patent applicant will generally be able to identify a lawful use for such an invention.

Food or medicine produced by mere admixture

7.10 The Commissioner of Patents may also refuse to accept an application for a standard patent that claims an invention capable of being used as a food or medicine for humans or animals and that is merely a mixture of known ingredients, or is a process to produce such substance by mere admixture.[9] It is unlikely that this exclusion would apply to genetic materials and technologies or other biotechnology inventions.[10]

Plants and animals

7.11 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.[11] This provision is currently under review by the Advisory Council on Intellectual Property (ACIP). ACIP released an Issues Paper on this subject in 2002 and is preparing a report for the Australian Government.[12]

---

6 The Commissioner may revoke an innovation patent on equivalent grounds: *Patents Act 1990* (Cth) s 101B(2)(d).

7 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.6.1].

8 Ibid, [8.6.3]–[8.6.4].

9 *Patents Act 1990* (Cth) s 50(1)(b). The Commissioner may revoke an innovation patent on equivalent grounds: *Patents Act 1990* (Cth) s 101B(4). See also IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.7].

10 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 39.

11 *Patents Act 1990* (Cth) s 18(3). This exclusion does not apply if the invention is a microbiological process or a product of such a process: *Patents Act 1990* (Cth) s 18(4).

12 Advisory Council on Intellectual Property, *Innovation Patent: Exclusion of Plant and Animal Subject Matter* (2002).

Exclusion of genetic materials and technologies

7.12 The existing exclusions from patentability do not place any significant constraints on the patenting of genetic materials or technologies. It has been suggested that some types of inventions involving genetic materials and technologies should not be patentable subject matter. This section discusses possible new exclusions from patentability relevant to genetic materials and technologies.

Reform proposals in Australia

7.13 One way to exclude genetic materials and technologies, or a subset of them, from patentability would be through an exclusion directed specifically to genetic inventions. Such an exclusion was proposed in 1990 during consideration of the Patents Bill 1990 (Cth).[13] The amendment, which was rejected by the Senate Standing Committee on Industry, Science and Technology, would have presumptively excluded genes, genetic material and genetically modified organisms from patentability.[14]

7.14 A similar amendment to the *Patents Act* was proposed in 1996.[15] The proposed amendment provided that naturally occurring genes, gene sequences, or descriptions of the base sequence of a naturally occurring gene or gene sequence would not be regarded as novel or inventive for the purposes of s 18 of the *Patents Act*.[16]

Reform proposals in other jurisdictions

7.15 There have been suggestions in other countries that some genetic materials should not be patentable. In 2001, the Canadian House of Commons Standing Committee on Health (the Canadian Standing Committee) expressed concern that the *Patent Act 1985* (Canada) did not specifically disallow patenting of human genes, DNA sequences and cell lines. The Canadian Standing Committee recommended that the patenting of 'human materials' should be prohibited.[17]

---

13 By Senator Coulter (Australian Democrats).

14 Senate Standing Committee on Industry Science and Technology, *Report on the Consideration of the Patents Bill 1990* (1990), 2; Commonwealth of Australia, *Parliamentary Debates*, Senate, 20 September 1990, 2653 (J Coulter). The Senate Standing Committee adopted an alternate provision proposed by Senator Brian Harradine, which is now embodied in s 18(2) of the *Patents Act*. See further Ch 15.

15 By Senator Stott Despoja (Australian Democrats): Patents Amendment Bill 1996 (Cth); Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 June 1996, 2332 (N Stott Despoja). Senator Stott Despoja put forward the proposal again in 2001, as a proposed amendment to the Patents Amendment Bill 2001 (Cth): Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 September 2001, 28195 (N Stott Despoja). The proposed amendments were re-tabled in 2002. There has been no further parliamentary consideration of them: Parliament of Australia, *Senate Daily Bills Update, 15 June 2004*, <www.aph.gov.au/parlinfo/billsnet/billsupd.pdf> at 16 June 2004.

16 The terms were not defined, but the amendment was apparently intended to apply to both human and non-human genetic material.

17 House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families* (2001), rec 34.

7.16 However, in general, such a sweeping approach to reform has been rejected. For example, the Ontario Government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Ontario Report) rejected the Canadian Standing Committee's call for a complete ban on gene patents and instead suggested a range of proposals to achieve an 'appropriate balance between the public interest in accessing the health benefits offered by genetic technologies and maintaining the economic and commercial incentives that fuel this research'.[18]

7.17 There have also been international statements suggesting that genes and genetic sequences should be excluded from patentability. The United Nations Educational, Scientific and Cultural Organisation (UNESCO) *Universal Declaration on the Human Genome and Human Rights* states that 'the human genome in its natural state shall not give rise to financial gains'.[19] Similarly, the International Bioethics Committee of UNESCO has stated 'there are strong ethical grounds for excluding the human genome from patentability'.[20]

7.18 In March 2000, the European Parliament called on the European Patent Office (EPO) to ensure that patent applications in the European Union do not violate the principle of non-patentability of human genes or cells 'in their natural environment'.[21] This resolution, originally made in the context of concerns about human cloning, was subsequently reiterated in connection with the patenting of the BRCA1 and BRCA2 genes associated with predisposition to breast and ovarian cancer.[22] However, as discussed in Chapter 6, genetic materials are generally considered to be patentable if they have been isolated from nature.

Submissions and consultations

7.19 In DP 68, the ALRC indicated that it did not support amending the *Patents Act* specifically to exclude genetic materials and technologies from patentable subject matter.[23] Many submissions and consultations supported this position.[24] Some

---

18 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), iii, 31–32.

19 *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, UNESCO, art 4.

20 International Bioethics Committee of UNESCO, *Advice of the IBC on the Patentability of the Human Genome* (2001).

21 European Parliament, *Bulletin EU 3-2000 Human Rights (5/11): Parliament Resolution on the Decision by the European Patent Office (EPO) with Regard to Patent No EP 695 351 Granted on 8 December 1999*, <http://europa.eu.int/abc/doc/off/bull/en/200003/p102005.htm> at 16 June 2004.

22 European Parliament, *Bulletin EU 10-2001 Human Rights (3/9): Parliament Resolution on the Patenting of BRCA1 and BRCA2 Genes*, <http://europa.eu.int/abc/doc/off/bull/en/200110/p102003.htm> at 16 June 2004.

23 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 7–1.

24 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Cancer Council Victoria, *Submission P101*,

submissions indicated that technology-specific exclusions from patentability are undesirable because such an approach limits the ability of patent law to adapt flexibly to new technologies as they arise.[25] It was said that such an approach might ultimately increase the complexity and cost of obtaining patent protection.[26] Further, a few submissions commented that technology-specific exclusions might not be effective. IP Australia submitted:

> Such measures invariably lead to uncertainty over the bounds of the subject matter, involved debate over individual cases, and increased cost and uncertainty for users of the system. Such measures may eventually prove at least partially ineffective, as it may be possible to draft claims to avoid the intent of the exclusion. Defining the bounds of a technology is a non-trivial issue.[27]

7.20 Submissions also commented on the potential negative effects of excluding genetic materials and technologies from patentability.[28] Some submissions were concerned about the potential for detrimental effects on the biotechnology industry and the development of new genetic products and technologies, if genetic materials were not patentable.[29] Others indicated that it would be undesirable to adopt a position that differed greatly from the approach to patenting genetic inventions in other countries.[30]

7.21 However, a small number of submissions to the Inquiry considered that genetic materials—particularly genetic sequences—should not be patentable.[31] In general, these submissions did not specifically endorse an amendment to exclude genetic materials from the scope of patentable subject matter. Rather, they encouraged the

---

20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; G Suthers, *Submission P116*, 4 May 2004; Department of Industry Tourism and Resources, *Consultation*, Canberra, 25 March 2004; Walter and Eliza Hall Institute of Medical Research, *Consultation*, Melbourne, 1 April 2004.

25 A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

26 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

27 IP Australia, *Submission P56*, 4 November 2003. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

28 Cancer Council Victoria, *Submission P16*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003.

29 R Barnard, *Submission P32*, 7 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

30 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

31 D McAndrew, *Submission P14*, 30 September 2003; G De Ruyter, *Submission P3*, 14 August 2003; J Graham, *Submission P5*, 26 August 2003; L Palombi, *Submission P28*, 1 October 2003; Research Unit of Jumbunna Indigenous House of Learning, *Submission P100*, 20 April 2004. Luigi Palombi submitted that isolated genetic material should be excluded as patentable subject matter under the *Patents Act*, and that a new *sui generis* intellectual property right should be created (to be known as a 'genetic sequence right'). Another submission advocated an exclusion from patentability for 'indigenous human genetic materials', pending the development of mechanisms for protecting customary practices and indigenous rights: Research Unit of Jumbunna Indigenous House of Learning, *Submission P100*, 20 April 2004.

ALRC to review whether genetic materials should be patentable,[32] or focused on the application of the existing patentability requirements to genetic materials and technologies—including the question whether the subject matter of some gene patents constitutes a 'discovery' or an invention.[33]

ALRC's views

7.22 In the ALRC's view, there are significant impediments to amending the *Patents Act* to exclude genetic materials from patentability. In Canada, it has been said of such an exclusion that 'the momentum of the biotech industry, the long history of patentability of gene sequences and the impact and complexity of existing international trade agreements make this, at present, an impractical and unrealistic option'.[34]

7.23 Similar considerations apply in the Australian context. Importantly, excluding genetic materials from patentability could have detrimental effects on the Australian biotechnology industry. Jurisdictions that have substantial biotechnology research and commercialisation programs appear to agree that patents on inventions involving gene sequences should generally be permitted.[35] While the fact that other jurisdictions generally accept patents on genetic sequences is not conclusive of the approach that should be adopted in Australia, it is reason to question whether amending the *Patents Act* to implement such an exclusion from patentability is desirable.

7.24 Submissions encouraged the ALRC to consider the global nature of the biotechnology industry and patent rights.[36] The Australian biotechnology industry relies on foreign investment and partnerships with overseas entities to commercialise the results of research involving genetic materials and technologies. Australia's adoption of a position that diverges from the general international consensus would likely have adverse implications for Australia's participation in the global biotechnology market. For example, it might affect adversely the extent to which foreign entities participate in, and provide capital investment for, research and commercialisation of genetic materials and technologies in Australia.

---

32 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Nuffield Council on Bioethics, *Submission P102*, 22 April 2004.

33 These submissions are discussed in detail in Ch 6.

34 T Caulfield and others, 'Genetic Technologies, Health Care Policy and the Patent Bargain' (2003) 63 *Clinical Genetics* 15, 16.

35 D Nicol, 'Gene Patents: The Ultimate Snatch' (Paper presented at Hatching, Matching, Snatching and Dispatching, AIHLE 7th Annual Conference, Newcastle, 27–30 June 2002), 9; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 232.

36 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; S Karpeles, *Submission P44*, 20 October; A McBratney and others, *Submission P47*, 22 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003; D Weston, *Submission P62*, 12 November 2003; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

7.25 Further, excluding genetic materials from patentability may conflict with Australia's international obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[37] As discussed in Chapter 4, the TRIPS Agreement provides that patents shall be available for any inventions, and that patent rights shall be enjoyable without discrimination as to 'the field of technology'.[38] Excluding genetic materials from patentability may be inconsistent with these provisions.

7.26 Even assuming that the express exclusion of genetic materials from patentability is consistent with Australia's international obligations, it may be argued that such an exclusion would not provide a complete, or even a satisfactory, solution to the problems said to be associated with the grant of some gene patents.[39] There would be considerable difficulty involved in defining the scope of any exclusion relating to genetic materials—for example, would proteins produced by genetic materials be covered? Excluding inventions involving gene sequences from patentability may only 'invite patent attorneys to engage in creative drafting'.[40]

7.27 The ALRC does not consider that the *Patents Act* should be amended to exclude genetic materials or technologies from patentability. Such a reform would pose a significant risk to Australia's biotechnology industry, raise problems for Australia's compliance with the TRIPS Agreement, and be difficult to implement effectively.

Methods of medical treatment

Australian law

7.28 The *Patents Act* does not expressly exclude methods of medical treatment from patentability. Before 1972, Australian law recognised surgical or medical treatment of the human body, as well as non-medical procedures (such as cosmetic treatment), as an exclusion from patentability.[41] The reason for the exception was that such treatment was considered 'essentially non-economic' and 'generally inconvenient' within the terms of s 6 of the *Statute of Monopolies 1623* (*Statute of Monopolies*).[42]

---

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

38 TRIPS Agreement, art 27(1). A similar provision is included in Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.1.

39 D Nicol, 'Gene Patents: The Ultimate Snatch' (Paper presented at Hatching, Matching, Snatching and Dispatching, AIHLE 7th Annual Conference, Newcastle, 27–30 June 2002), 9; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 161.

40 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 232. See also IP Australia, *Submission P56*, 4 November 2003.

41 *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.

42 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.13.1].

7.29 Based on case law,[43] IP Australia considers that it is now 'firmly established that methods of medical treatment are patentable subject matter'.[44] IP Australia's practice is that no objection to a patent application may be made to 'methods or processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the human body is involved'.[45]

7.30 In *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (*Rescare*),[46] a 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*.[47] 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.[48] Wilcox J agreed that methods of medical treatment should be patentable, noting that the Parliament had an opportunity to include an exception in the *Patents Act* when it was re-enacted in 1990, and had chosen not to. Courts should, therefore, be hesitant to introduce the exclusion by reference to 'the very general principles' contained in s 6 of the *Statute of Monopolies*.[49]

7.31 The approach to the patentability of methods of medical treatment taken in *Rescare* was affirmed by a Full Court of the Federal Court in *Bristol-Myers Squibb Company v FH Faulding & Co Ltd*.[50] 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'.[51]

Other jurisdictions

7.32 In the United Kingdom, methods of medical treatment of the human body are expressly excluded from patentability, on the basis that such inventions are not to be taken to be capable of 'industrial application'[52]—the equivalent of the criterion of usefulness in Australian law (see Chapter 6).

---

43 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1; *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439.

44 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.2.13.3].

45 Ibid, [8.2.13.1].

46 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1. The case concerned the patentability of a method and device for the prevention of sleep apnoea.

47 The 'generally inconvenient' proviso in the *Statute of Monopolies* is discussed below.

48 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 19.

49 Ibid, 42–43.

50 *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.

51 Ibid, 444.

52 See *Patents Act 1977* (UK) s 4(2). The European Patent Convention contains a similar provision: *European Patent Convention*, (entered into force on 7 October 1977), art 52(4).

7.33 In other jurisdictions, including Canada and New Zealand, methods of medical treatment are excluded by reference to the patentability requirements of their legislation. In Canada, methods of medical treatment are not patentable inventions because they are generally considered not to meet the Canadian utility (usefulness) criterion.[53] In New Zealand, case law has held that methods of medical treatment are not patentable on the basis that they do not constitute a 'manner of manufacture' under the *Patents Act 1953* (NZ).[54] Following a decision of the New Zealand Court of Appeal which cast doubt on this approach,[55] the New Zealand Ministry of Economic Development has recommended that the Act be amended to provide a specific exclusion from patentability for 'inventions concerning diagnostic, therapeutic and surgical methods of treatment of humans'.[56]

Scope of a method of medical treatment exclusion

7.34 The medical treatment exclusion from patentability, as applied in the United Kingdom, Canada and New Zealand, relates only to treatment or diagnosis on the human body—and not to procedures carried out *in vitro*, or exclusively outside the body.[57] In particular, methods of diagnosis performed on tissues or fluids that have been permanently removed from the body are not excluded.[58]

7.35 Article 27(3)(a) of the TRIPS Agreement permits members to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability. This exclusion has not been definitively interpreted but its scope may not be as broad as may appear at first glance.

7.36 It is not clear whether the TRIPS Agreement permits exceptions for *in vitro* procedures. While the language may be broad enough on its face to encompass *in vitro* procedures (for example, as a 'diagnostic method') these words may need to be interpreted in the light of the national laws existing at the time the treaty was negotiated.[59] As discussed above, the medical treatment exclusion in many jurisdictions relates only to treatment or diagnosis on the human body.

---

53 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 31.

54 *Wellcome Foundation Ltd v Commissioner of Patents* [1983] 2 NZLR 385.

55 *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.

56 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 1, rec 2(ii). To date, amendments to the *Patents Act 1953* (NZ) to implement this recommendation have not been introduced into the New Zealand Parliament.

57 Canada: Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 51. United Kingdom: United Kingdom Patent Office, *Manual of Patent Practice* (5th ed, 2003).

58 United Kingdom Patent Office, *Manual of Patent Practice* (5th ed, 2003).

59 The general rules of treaty interpretation permit recourse to supplementary means of interpretation, including the preparatory work of the treaty (travaux préparatoires) and the circumstances of its conclusion: *Vienna Convention on the Law of Treaties*, [1974] ATS 2, (entered into force on 27 January 1980), art 31–32.

7.37 This limitation is significant when considering the possible application of a new exclusion for methods of medical treatment in the context of gene patents. Gene patents most often relate to products and processes for use outside the human body, notably in connection with genetic sequencing and diagnostic genetic testing. Even in the case of gene therapy, patents are likely to relate to processes carried out *in vitro*—such as inserting genes into a gene carrier (or 'vector') and using the vector to carry the genes into somatic cells. Procedures for introducing vectors, modified cells or stem cells into the human body (for example, by injection) could be excluded as methods of medical treatment. However, such an exclusion may have limited practical benefit if related *in vitro* processes remained patentable.

Submissions and consultations

7.38 In DP 68, the ALRC proposed that the *Patents Act* should not be amended to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter.[60] This proposal received broad support.[61] Some submissions suggested that excluding methods of medical treatment from patentability might have an adverse effect on innovation in healthcare.[62] Others indicated that such an exclusion might not be as effective as might be hoped.[63] In support of this view, submissions noted that, although the *European Patent Convention* provides that methods of treating humans are not patentable subject matter, the EPO has interpreted this provision restrictively.[64]

7.39 While supporting the ALRC's conclusion, the Department of Industry, Tourism and Resources (DITR) noted that the patenting of surgical methods 'has given rise to controversy'.[65] The Australian Centre for Intellectual Property in Agriculture (ACIPA) considered that, if protection continued to be available for methods of medical

60 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 7–2.

61 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; G Suthers, *Submission P116*, 4 May 2004; Department of Industry Tourism and Resources, *Consultation*, Canberra, 25 March 2004.

62 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; IP Australia, *Submission P56*, 4 November 2003; Sydney IVF Limited, *Submission P98*, 19 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

63 For example, Centre for Law and Genetics, *Submission P104*, 22 April 2004. In contrast, the Department of Health Western Australia commented that a narrow interpretation of such an exclusion was not inevitable: Department of Health Western Australia, *Submission P89*, 16 April 2004.

64 A McBratney and others, *Submission P47*, 22 October 2003; IP Australia, *Submission P56*, 4 November 2003.

65 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004. DITR commented that inventions involving surgical methods might not satisfy a requirement of commercial application. Even if such patents are granted, DITR noted that monitoring compliance with such patents is difficult.

treatment, an appropriately crafted defence should be enacted to address the potential adverse consequences of patents on these types of inventions.[66]

7.40 A small number of submissions supported the introduction of an exclusion from patentability for methods of medical treatment, primarily on the grounds that patents over such inventions are 'incompatible with the optimal provision of healthcare'.[67]

ALRC's views

7.41 The ALRC does not recommend that a new exclusion from patentability for methods of medical treatment be introduced in Australia to address concerns about patents on genetic materials and technologies. The ALRC is concerned that such an exclusion would have adverse effects on investment in biotechnology, medical research and innovation in healthcare and may not be consistent with Australia's obligations under the TRIPS Agreement.

7.42 This leaves open the possibility of introducing some form of medical treatment defence, which is discussed in Chapter 21. The introduction of a new defence—as opposed to an exclusion from patentability—may have some advantages because a defence could apply to both *in vivo* and *in vitro* procedures, and could be more targeted in its application to patented inventions. However, for the reasons discussed in Chapter 21, the ALRC has also rejected this approach.

Exclusions from patentability on social or ethical grounds

7.43 Gene patenting raises many social and ethical concerns, including concerns about the social impact of gene patents on the conduct of research and the provision of healthcare; and ethical concerns, including those about sharing the benefits of genetic research; consent to the use of genetic material in research that leads to commercial outcomes; and indigenous issues.[68]

7.44 It has been suggested that the patent system should provide avenues for addressing these concerns, for example, by including social and ethical considerations in the assessment of gene patent applications.

7.45 The following material examines the extent to which social and ethical considerations may be taken into account under existing Australian patent law and the law of other countries, and discusses whether the patent system is an appropriate vehicle through which to address these concerns.

---

66 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. Medical treatment defences are discussed in Ch 21.

67 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004. See also Breast Cancer Network Australia, *Submission P22*, 30 September 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Department of Health Western Australia, *Submission P89*, 16 April 2004.

68 See Ch 3.

Australian law

7.46 The *Patents Act* does not contain an explicit mechanism to allow social and ethical considerations to be taken into account by patent examiners in assessing the patentability of a particular invention. The Act may, however, include an indirect means for this to occur.

7.47 As discussed in Chapter 6, s 18 of the *Patents Act* states that a patent may be granted for a 'manner of manufacture' within the meaning of s 6 of the *Statute of Monopolies*.[69] Section 6 of that Statute provides that an invention should 'be not contrary to the law, nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient'.

7.48 It is arguable that the term 'generally inconvenient' includes social and ethical considerations within its scope.[70] 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.[71] However, Australian courts have generally declined to rely solely upon matters of public policy or ethics under this 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.[72]

7.49 Further, as a matter of practice, it appears unlikely that ethical considerations are considered by Australian patent examiners in their assessment of whether an invention constitutes a 'manner of manufacture'. IP Australia's *Manual* specifically notes that:

> 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.[73]

Other jurisdictions

7.50 In contrast to the Australian position, a number of overseas jurisdictions expressly permit an invention to be excluded from patentability on social or ethical grounds.[74] Article 27(2) of the TRIPS Agreement provides that member States may

---

69 *Patents Act 1990* (Cth) s 18(1)(a) (standard patents); s 18(1A)(a) (innovation patents).

70 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441, 441. See also D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 241–242; M Forsyth, 'Biotechnology, Patents and Public Policy: A Proposal for Reform in Australia' (2000) 11 *Australian Intellectual Property Journal* 202, 215–218.

71 *Joos v Commissioner of Patents* (1972) 126 CLR 611, 623; *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; *Bristol-Myers Squibb Company v FH Faulding & Co Ltd* (1998) 41 IRP 467, 479–481, on appeal to the Full Federal Court; *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439, 444–445.

72 See, eg, *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994) 50 FCR 1, 45.

73 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.1.2].

74 While United States legislation does not expressly recognise ethical considerations as a ground for excluding patents, its courts have interpreted the utility requirement as preventing the patenting of

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'.[75]

7.51 European law provides an exclusion from patentability on the basis of '*ordre public* or morality' in similar terms to the TRIPS Agreement. The exclusion is set out in art 53(a) of the *European Patent Convention* (EPC)[76] and is replicated in art 6(1) of the European Parliament's *Directive on the Legal Protection of Biological Inventions* (EU Biotechnology Directive).[77]

7.52 In addition, the EU Biotechnology Directive provides that certain inventions presumptively fall within the ambit of the exclusion from patentability on the grounds of *ordre public* or morality.[78] Those inventions are: (a) processes for cloning human beings or for modifying the germ line identity of human beings; (b) uses of embryos for industrial or commercial purposes; and (c) processes for modifying the germ line identity of animals that are likely to cause them suffering without substantial medical benefit to humans or animals, and also the animals resulting from such processes.[79] This list of inventions is not, however, intended to be exhaustive.[80]

7.53 The terms '*ordre public*' and 'morality' are not defined in either the EPC or the EU Biotechnology Directive. An EPO Board of Appeal has indicated that the concept of '*ordre public*' covers 'the protection of public security and the physical integrity of individuals as part of society', as well as 'the protection of the environment'.[81] Further, the concept of morality is said to be 'related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of accepted norms which are deeply rooted in a particular culture'.[82]

---

inventions that are 'injurious to the well-being, good policy, or sound morals of society': *Lowell v Lewis*, (1817) 15 Fed Cas 1018, quoted in *Tol-O-Matic Inc v Promo Produkt-und Marketing Gesellschaft MbH* 945 F 2d 1546 (Fed Cir, 1991), 1553.

75 A similar provision is included in Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.2(a).

76 *European Patent Convention*, (entered into force on 7 October 1977), art 53(a).

77 *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).

78 In 1999, the implementing regulations of the EPC were amended following the introduction of the EU Biotechnology Directive to ensure consistency between the EPC and the Directive in relation to these provisions: see Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001) rr 23(b)–23(e).

79 *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998), art 6(2).

80 *Relaxin/Howard Florey Institute* (Unreported, Boards of Appeal, European Patent Office, T0272/95, 23 October 2002), [7].

81 *Plant Genetic Systems/Glutamine Synthetase Inhibitors* (Unreported, Boards of Appeal, European Patent Office, T0356/93, 21 February 1995), [5].

82 Ibid, [6].

7.54 Despite the seemingly broad scope given to the concepts of *ordre public* and morality under European patent law, the exception has been very narrowly applied.[83] The Examination Guidelines for the EPO indicate that the art 53(a) exclusion is likely to be invoked only in 'rare and extreme cases' in order to exclude from protection inventions 'likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour' such as letter-bombs and anti-personnel mines: 'A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable'.[84]

7.55 In *Howard Florey/Relaxin*,[85] the Opposition Division of the EPO specifically rejected the relevance of the exception to a patent claiming a genetic sequence encoding human H2-preprorelaxin. The decision was affirmed by an EPO Board of Appeal, which further held that materials isolated from the human body were outside the scope of the *ordre public* or morality provision as a matter of interpretation.[86]

7.56 The EPO has indicated that determining whether a patent is contrary to *ordre public* or morality requires 'a careful weighing up' of competing interests.[87] A recent report on the impact and management of intellectual property rights in the United Kingdom healthcare sector commented that such a 'utilitarian (benefit/detriment) approach' means that it is unlikely a challenge on *ordre public* or morality grounds would succeed.[88] Indeed, the *ordre public* or morality exclusion has been raised successfully in only two known cases—one involving a hairless mouse used to test hair growth products, the other involving the cloning of a fused human and pig cell.[89]

7.57 Provisions permitting the exclusion of inventions from patent protection on ethical or social policy grounds also exist in patent statutes enacted by the United Kingdom (implementing the EPC and EU Biotechnology Directive),[90] Japan[91] and

---

83 See, eg, *Lubrizol/Hybrid Plants* [1990] EPOR 173; *Harvard/Oncomouse* [1990] EPOR 501; *Howard Florey/Relaxin* [1995] EPOR 541; *Plant Genetic Systems/Glutamine Synthetase Inhibitors* (Unreported, Boards of Appeal, European Patent Office, T0356/93, 21 February 1995).

84 European Patent Office, *Guidelines for Examination in the European Patent Office* (2003) Pt C, IV.3.1.

85 *Howard Florey/Relaxin* [1995] EPOR 541. The patent at issue was opposed on the grounds that the invention involved the patenting of human life, an abuse of women, a return to slavery and the piecemeal sale of women to industry. The Opposition Division rejected these arguments as being unfounded in principle and in the circumstances of the case. The opponents also asserted that patent on human genes in general were immoral. The Opposition Division concluded that, in 1994, there was no general consensus that patenting human genes was immoral and that art 53(a) of the EPC did not, therefore, apply.

86 Rule 23(e)(2) of the Implementing Regulations to the EPC, which provides that 'an element isolated from the human body' may be a patentable invention, is considered to qualify the *ordre public*/morality exclusion in art 53(a) of the EPC: *Relaxin/Howard Florey Institute* (Unreported, Boards of Appeal, European Patent Office, T0272/95, 23 October 2002), [4], [6]–[7].

87 *Harvard/Oncomouse* [1990] EPOR 501, 513.

88 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 82.

89 See Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 39 fn 35.

90 *Patents Act 1977* (UK) s 1(3)(a).

91 *Patent Law* (Law No 121 of 1959) (Japan) s 32.

New Zealand.[92] To date, consideration of the scope of these exclusions by courts and patent offices or in academic commentary has been very limited. Such provisions have rarely been invoked with any success.[93]

7.58 Nonetheless, in Canada, the Ontario Report recommended that the Canadian Government consider amending the *Patent Act 1985* (Canada) to include an *ordre public* or morality clause.[94] The Ontario Report suggested that 'such a mechanism appropriately modified from the European experience would grant the Commissioner of Patents the ability to reject patents on processes, products and techniques which are deemed to violate Canadian morals and ethics'.[95] In New Zealand, a review of the *Patents Act 1953* (NZ) by the Ministry for Economic Development recommended that the Act be amended to include a provision in similar terms to the European *ordre public* or morality exception.[96]

Ethics and the patent system

7.59 There are widely differing views about the relevance of social and ethical considerations in the assessment of patents. One view is that patents form part of an economic system for encouraging investment in research and that the patent system should be concerned primarily with assessing the inventiveness and utility of new inventions.[97] Social and ethical concerns are separate issues to be dealt with by other means.[98]

7.60 Further, it has been argued that the patent system may not be an effective mechanism for dealing with social and ethical considerations because it was not designed to address such issues.[99] In a 2002 report, the Organisation for Economic Co-operation and Development Working Party on Biotechnology Report (OECD Report) stated that it was generally agreed that 'in cases where fundamental ethical decisions are at stake, the debate needs to take place in society at large rather than in the patent offices, which have no special authority in moral matters' and that intellectual property

92 *Patents Act 1953* (NZ) s 17(1).

93 See, eg, New Zealand Ministry of Economic Development, *Review of the Patents Act 1953: Boundaries to Patentability: A Discussion Paper* (2002), 17.

94 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(f).

95 Ibid, xx. The modifications to the European model proposed by the Ontario report are discussed further below.

96 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 2, rec 2(i).

97 R Crespi, 'Patenting and Ethics: A Dubious Connection' (2001/2002) 5 *Bio-Science Law Review* 71.

98 C Ho, 'Building a Better Mousetrap: Patenting Biotechnology in the European Community' (1992) 3 *Duke Journal of Comparative and International Law* 173, 195 cited in B Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement' (1994) 26 *Law and Policy in International Business* 101, 121.

99 C Baldock and others, 'Report Q 150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes' (2000) 22 *European Intellectual Property Review* 39, 40.

law is 'fashioned primarily to promote inventiveness and the disclosure of advances in technology' and cannot be easily reformed to operate as an ethico-legal instrument of public policy.[100]

7.61 These views have been challenged on the basis that any system that affects the interests of individuals or groups—as the patent system does—cannot be socially or ethically neutral.[101] A number of general arguments have been made for dealing with social and ethical concerns through patent laws, which may be applicable in the context of gene patents. These include the following:

- Decisions made by patent examiners are affected by the values and social interests of the community of which they are a part. Therefore, social and ethical considerations are implicitly and unavoidably part of the patent process.[102]

- The patent system exists to serve the public interest: considerations of public purpose should be fundamental to the patent granting process.[103]

- 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.[104]

- The incentives that patents create may provide a useful mechanism for dealing with any social and ethical problems raised by the use of patented inventions. Thus, it may be effective to regulate the adverse consequences of patents through the laws that create these incentives, rather than by creating a separate set of rules.[105] Alternatively, the patent system might be used to bolster existing regulation of conduct in other areas.[106]

7.62 If the patent system is to address social and ethical considerations, there is a variety of ways in which this might be achieved. Some mechanisms may be more suitable than others, depending upon the nature of the social or ethical concerns at issue and, in particular, whether they relate to the grant of a patent covering a genetic invention or to the way in which such patents are exploited.

---

100 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 75.

101 P Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 *European Intellectual Property Review* 441, 441. See also Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 36.

102 B Looney, 'Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement' (1994) 26 *Law and Policy in International Business* 101, 121.

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

104 Ibid, 211.

105 Ibid, 211.

106 See, eg, B Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' (2003) 25 *European Intellectual Property Review* 301, 305–308.

7.63 The *Patents Act* contains mechanisms that might be used indirectly to address social or ethical concerns about the manner in which patent rights are exploited. For example, the compulsory licensing provisions may be invoked where the reasonable requirements of the public with respect to a patented invention are not being satisfied.[107] This might include circumstances in which access to a patented medical genetic technology is not being provided equitably.

7.64 However, the material below focuses on reforms intended to allow social and ethical considerations to be assessed as part of the process for *granting* patents—that is, to allow inventions to be excluded from patentability on social or ethical grounds.

Options for exclusion on social or ethical grounds

7.65 One option would be to introduce an *ordre public* or morality exclusion similar to provisions in European patent law discussed above. Such exclusions are generally applicable to inventions involving all types of technologies.

7.66 Another approach would be to introduce mechanisms to address specific social or ethical concerns raised by genetic inventions. In particular, it has been suggested that patent applicants should be required to demonstrate that prior informed consent to the use of genetic materials has been obtained before a patent for an invention involving such genetic material will be granted.

7.67 This requirement was initially proposed in connection with inventions based on natural genetic resources to bolster the operation of national laws implementing the *Convention on Biological Diversity*[108]—in particular, its provisions relating to consent and benefit sharing arrangements. The application of a consent requirement for the patenting of inventions involving biological material of human origin has also been considered as a means of ensuring compliance with established ethical standards for research involving humans.[109]

The role of patent examiners

7.68 Suggestions that the patent system should deal with social and ethical concerns raise questions about how such decisions should be made, and by whom. Some approaches would require patent examiners to consider whether a patent application should be rejected on ethical or social grounds as part of the examination process.

---

107 *Patents Act 1990* (Cth) s 133. See Ch 27.

108 *Convention on Biological Diversity*, [1993] ATS 32, (entered into force on 29 December 1993), particularly the provisions in art 15 relating to consent and benefit sharing arrangements. See, eg, N Pires de Carvalho, 'Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: The Problem and the Solution' (2000) 2 *Washington University Journal of Law and Policy* 371; B Sherman, 'Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery' (2003) 25 *European Intellectual Property Review* 301.

109 See, eg, G van Overwalle, *Study on the Patenting of Inventions Related to Human Stem Cell Research* (2002) Paper prepared for European Group on Ethics in Science and New Technologies to the European Commission, 82–85.

7.69 However, it has been suggested that patent examiners lack the training and expertise to make decisions of this kind.[110] For example, the OECD Report concluded that:

> In the absence of commonly agreed criteria for making moral judgments as to the application of new technology, therefore, it is difficult to apply morality provisions … In addition, the patent system is meant primarily to regulate competition, and patent examiners are not in a position to define or even interpret the basic values of society.[111]

7.70 Patent examiners could be assisted in assessing the social and ethical considerations involved in patent applications by guidelines developed by an authoritative body. However, there are no international precedents for the development of guidelines by which to assess the social and ethical implications of gene patents, or patents generally. This may indicate that, given the breadth of potential social and ethical considerations of relevance to inventions in different technological fields, the drafting of guidelines in this area may be impracticable.

An ethical advisory body

7.71 Another option would be to refer patent applications that raise social or ethical considerations to a specialised body that could provide guidelines or advice on these issues, or make determinations itself.[112]

7.72 Reviews of the patent legislation in New Zealand and Canada recommended that specialised bodies, outside the patent office, could assist patent examiners in assessing patent applications for compliance with applicable moral standards.[113] In relation to the ethical aspects of patenting inventions involving human stem cells, the European

---

110 See, eg, Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 40; Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 50; R Ford, 'The Morality of Biotech Patents: Differing Legal Obligations in Europe?' (1997) 19 *European Intellectual Property Review* 315, 317; D Slater, 'HuMouse', *Legal Affairs*, Nov-Dec 2002, 21, 24; P Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (3rd ed, 1999), 258.

111 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 45.

112 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), [2.10]; Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 40.

113 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003) Pt 2, rec 2(ii) (suggesting advice might be obtained from the Maori Consultative Group and the Bioethics Council); Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 50 (proposing the establishment of a specialised body with expertise in science, ethics and competition law). See also R Gold and T Caulfield, 'The Moral Tollbooth: A Method that Makes Use of the Patent System to Address Ethical Concerns in Biotechnology' (2002) 359 *The Lancet* 2268.

Group on Ethics in Science and Technologies proposed that ethics review of patent applications by an independent advisory body should be incorporated into the patent examination process.[114]

7.73 In Australia, the review of patent applications involving genes, genetic material and genetically modified organisms by a committee with bioethical expertise was proposed in 1990.[115] This proposal, for an additional layer of review of patent applications, was criticised in Parliament on the basis that it would increase uncertainty[116] and further complicate the operation of the patent system.[117]

7.74 There are Australian precedents for the establishment of ethics advisory bodies in other regulatory regimes. For example, the Gene Technology Ethics Committee, provides advice to the Gene Technology Regulator and the Gene Technology Ministerial Council on ethical issues associated with gene technology.[118]

Submissions and consultations

7.75 In DP 68, the ALRC stated that it did not support amending the *Patents Act* to expand the circumstances in which social and ethical considerations may be taken into account in decisions about granting patents. Rather, the ALRC suggested that social and ethical concerns should be addressed primarily though direct regulation of the use or exploitation of a patented invention.[119]

7.76 A range of submissions and consultations expressed support for the approach proposed by the ALRC.[120] In particular, submissions commented that social and ethical considerations would be better addressed through direct regulation of the use or exploitation of genetic inventions.[121] Submissions highlighted the difficulties involved in incorporating social or ethical considerations into the Australia patent system and

---

114 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), [2.10].

115 In association with a proposed exclusion from patentability of inventions involving genetic materials: Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, 2478 (J Coulter).

116 Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, 2481 (R Collins).

117 Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, 2482 (B Archer).

118 *Gene Technology Act 2000* (Cth) s 112.

119 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 7–3.

120 Davies Collison Cave, *Submission P48*, 24 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; G Suthers, *Submission P116*, 4 May 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; Department of Industry Tourism and Resources, *Consultation*, Canberra, 25 March 2004; Walter and Eliza Hall Institute of Medical Research, *Consultation*, Melbourne, 1 April 2004.

121 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Medicines Australia, *Submission P75*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

questioned the appropriateness of the Patent Office making determinations that were better left to the legislature.[122] Others commented on the practical difficulties inherent in requiring patent examiners—who are specialists in scientific and technical fields—to assess social or ethical considerations.[123]

7.77 In contrast, other submissions suggested that social and ethical considerations should be taken into account in assessing gene patent applications[124] and criticised the ALRC's reluctance to address ethical and public policy considerations within the framework of the patent system.[125] Many of these submissions recognised that if social and ethical considerations were to be taken into account in assessing patent applications, Australian patent law and practice would need to change to facilitate this.

7.78 The possibility of amending the *Patents Act* to include an *ordre public* or morality exclusion from patentability was raised in some submissions.[126] Others suggested that the *Patents Act* should be amended to include 'public interest and social impact criteria' in the assessment of patent applications.[127] A number of submissions supported the establishment of an expert committee to assess and advise on ethical considerations arising from patent applications.[128] Some submissions suggested that patent examiners should be provided with training on ethical and social matters,[129] or advocated the development of guidelines to assist examiners in the assessment of social and ethical issues.[130]

---

122 See, eg, IP Australia, *Submission P56*, 4 November 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.

123 GlaxoSmithKline, *Submission P33*, 10 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

124 See, eg, Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Breast Cancer Network Australia, *Submission P22*, 30 September 2003; D McFetridge, *Submission P23*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Foundation of Western Australia Inc, *Submission P34*, 10 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; D Jackson, *Submission P43*, 20 October 2003.

125 South Australian Government, *Submission P51*, 30 October 2003; M Rimmer, *Submission P73*, 15 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

126 D McFetridge, *Submission P23*, 30 September 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; South Australian Department of Human Services, *Submission P74*, 15 April 2004.

127 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004.

128 D Jackson, *Submission P43*, 20 October 2003; S Karpeles, *Submission P44*, 20 October; M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Research Unit of Jumbunna Indigenous House of Learning, *Submission P100*, 20 April 2004.

129 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

130 Cancer Council Australia, *Submission P25*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; D Jackson, *Submission P43*, 20 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

7.79 Three submissions proposed that the *Patents Act* be amended to include a requirement for patent applications to 'disclose evidence of consent from the source where an invention is based on biological material of human origin or where the invention uses such material'.[131] The Centre for Law and Genetics commented that imposing such a requirement would serve to reinforce the value placed on compliance with ethical standards in research involving humans,[132] and would be consistent with proposals that have been advanced in connection with patenting natural genetic resources.[133] These submissions acknowledged that such a requirement might be controversial and present some administrative difficulties for the Patent Office, but did not consider these issues to be insurmountable.[134]

ALRC's views

7.80 It is arguable that the 'generally inconvenient' proviso included in the 'manner of manufacture' requirement in s 18 of the *Patents Act* already provides some limited basis upon which social and ethical considerations may be relevant to the patentability of a genetic invention under Australian law.[135] However, the ALRC does not believe that the *Patents Act* should be amended to expand the circumstances in which such considerations are taken into account in decisions about granting patents.

7.81 In the ALRC's view, there is no compelling case for amending the *Patents Act* to allow expressly for the exclusion of particular subject matter from patentability on social or ethical grounds. If such a provision were to be included in the Act, an obvious model would be an exclusion from patentability on the grounds of *ordre public* or morality, as found in some European countries and as permitted by the TRIPS Agreement. Yet, adopting such a provision in Australia would not address the particular concerns expressed about the patentability of genetic materials or technologies. In Europe, the difficulties in applying the exclusion have led to a very narrow interpretation of the provision, and it has had no discernible impact on the granting of gene patents in those jurisdictions.

7.82 Patent offices and examiners have no special authority in philosophical or moral matters. Examiners are chosen for their expertise in particular scientific and technical fields. For example, examiners who assess patent applications for genetic materials and

---

131 Centre for Law and Genetics, *Submission P104*, 22 April 2004. See also M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. ACIPA considered that proof of a 'benefit sharing' arrangement with the source (or sources) of biological material should also be a pre-condition to the grant of a patent: Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

132 In particular, the National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999) and the *Privacy Act 1988* (Cth): Centre for Law and Genetics, *Submission P104*, 22 April 2004.

133 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

134 M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

135 *Patents Act 1990* (Cth) s 18. See also Rec 6–2, which recommends an independent review of the 'manner of manufacture' test in the *Patents Act*.

technologies must have qualifications in the field of biochemistry.[136] It may be possible to provide examiners with training in social and ethical matters but they will not necessarily be the individuals best suited to making assessments on such grounds. Further, given the breadth of potential social and ethical considerations of relevance to inventions in different technological fields, it may not be possible to provide them with the training or guidelines necessary to assess the social and ethical implications of all new inventions. Where the use or exploitation of new inventions gives rise to social or ethical concerns, it may be argued that decisions belong in the political arena and should not be taken by individuals whose training and experience is primarily scientific and technical in nature.

7.83 The establishment of a new ethics advisory body may be a better mechanism for addressing social and ethical concerns than leaving them to individual patent examiners. However, such a mechanism would inevitably add to the cost and complexity of the patent system. Any determination about the possible social and ethical implications of a particular invention is likely to be contested and new review or appeal mechanisms may be needed.[137] Given that only a small proportion of patent applications can be expected to have contentious social or ethical implications, ethics assessment of all patent applications seems unlikely to be the most efficient or effective form of regulation. Reform to permit inventions to be excluded from patentability based on the views of patent examiners or some new ethics advisory body would thus have uncertain consequences for the efficiency of the patent system.

7.84 The ALRC's view is that social and ethical concerns can be addressed most effectively through direct regulation of the use and exploitation of patented inventions (or through regulation of research activities that lead to the development of inventions), rather than by excluding a particular subject matter from patentability, or imposing additional conditions on the grant of a patent. There are, for example, many more direct ways to encourage the ethical conduct of human genetic research than requiring proof of informed consent as part of the patent application process.[138] Attempting to adapt the patent system to address issues of research ethics, consent or benefit-sharing would be likely to create undesirable complexity. Further, any new exclusion from patentability that is not covered by internationally accepted *ordre public* or morality grounds may conflict with Australia's international obligations, including those under the TRIPS Agreement.

---

136 See Ch 8.

137 For similar reasons, the ALRC has considered, and rejected, the creation of an expert panel to advise patent examiners on technical scientific issues that may arise in the assessment of gene patent applications: see Ch 8.

138 The ALRC and the Australian Health Ethics Committee (AHEC) have recommended reforms to encourage ethical human genetic research—including in relation to consent, ethics review and disclosure to research participants of actual or anticipated commercial arrangements: Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 13–17.

7.85 Arguments about the relevance of social and ethical considerations tend to be directed towards two quite different outcomes: either that particular subject matter should not be patentable because the invention is objectionable and its use should be curtailed or prohibited; or that particular subject matter should not be patentable because the invention is beneficial and its use should be promoted.

7.86 In the ALRC's view, it is better in the former case to regulate the use of the invention directly than to address the ethical or social concerns by excluding the subject matter from patentability. To exclude such an invention from patentability does not prevent the inventor from using the 'objectionable' technology, although it might have the incidental effect of encouraging secret use and limiting the dissemination of the technology. Thus, intervening at the point of patentability does not address the mischief that is said to arise from the invention. An example is human embryonic stem cells—these can generally be patented but their derivation and use in research is carefully controlled by federal, state and territory legislation, as well as guidelines and standards issued by the National Health and Medical Research Council.[139]

7.87 In the latter case—where an invention is seen as beneficial and access is to be encouraged—somewhat different considerations apply, but the ALRC here too has come to the view that it is generally better to regulate use of the patented invention than to exclude the subject matter from patentability. Those who argue for an exclusion from patentability in order to promote broad access to the invention generally do so because the granting of a patent over the invention, with its concomitant monopoly rights, enables the patent holder to limit use of the invention through restrictive licensing practices or charging excessive prices. But this is to take a short term view. In the longer term, the inability to patent a particular type of technology (for example, research tools or diagnostic genetic tests) may have negative implications for research and development in that field. The net outcome might be to reduce access to that technology in the longer term.

7.88 Social and ethical considerations relating to access can be better addressed by specific measures to facilitate the use of particular patented inventions, both through the patent system and by other means. For example, research on a patented invention can be promoted by a new experimental use exemption (see Chapter 13); and exploitation of a patent can be promoted by better utilisation of the Crown use (Chapter 26) and compulsory licensing provisions (Chapter 27) of the *Patents Act*. Solutions such as these allow for a targeted response to existing and emerging problems in the field of genetic materials and technologies. This is unlikely to be achieved by the categorical exclusion of such inventions from patentability.

139 See Ch 15.

Recommendation 7–1 The *Patents Act 1990* (Cth) should *not* be amended:

(a) to exclude genetic materials and technologies from patentable subject matter;

(b) to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter; or

(c) to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.

Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention.

8. Patent Office Practices

Contents

Introduction

8.1 The Australian patent system is administered by the Patent Office of IP Australia. This chapter provides an overview of certain aspects of IP Australia's practices and addresses concerns about the examination of applications for gene patents. It considers the resources available to IP Australia; the expertise of, and training provided to, Australian patent examiners; and the assistance available to patent examiners in applying Australian patent law to gene patent applications.

8.2 DP 68 outlined the general concerns voiced in submissions and consultations about IP Australia's capacity to scrutinise gene patent applications.[1] The ALRC believes that these concerns do not warrant fundamental changes to the functions performed by IP Australia. Rather, these concerns may be addressed by specific recommendations with respect to: (a) the training of patent examiners; (b) the development of examination guidelines for genetic inventions; and (c) the standard of proof to be applied by patent examiners when assessing whether the requirements for patentability have been satisfied at the examination stage.

8.3 Benchmarking activities conducted by IP Australia and recent academic studies indicate that IP Australia's practices are comparable to those of other major patent offices. IP Australia noted that a comparison with the United Kingdom Patent Office suggests that similar patentability outcomes were reached by the two patent offices when examining the same patent applications.[2] A 2003 study by Professor Andrew Christie and Melanie Howlett compared the approaches adopted by the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO), the Japanese Patent Office (JPO) and IP Australia in examining a series of hypothetical claims for partial DNA sequences (or expressed sequence tags).[3] They found that while each patent office adopted its own approach to interpreting and applying the requirements for patentability, the end result of the examination of such claims was the same for all the offices.[4]

8.4 The issues raised about IP Australia's practices are not unique to Australia. Internationally, questions have been raised about the capacity of patent offices to assess applications for gene patents effectively and to process such applications efficiently.[5] It has been suggested that patent offices may lack the resources or expertise to deal with the volume and nature of patent applications filed in this area. The reforms recommended in this chapter are intended to assist IP Australia in adapting its current practices to the challenges posed by inventions involving genetic materials and technologies, and to enhance mechanisms already adopted by IP Australia to address these issues.

---

1 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [8.8]–[8.17].

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

3 M Howlett and A Christie, *An Analysis of the Approaches of the Trilateral and Australian Patent Offices to Patenting Partial DNA Sequences (ESTs)* (2003). The hypothetical claims were taken from a similar comparative study conducted by the Trilateral Offices—that is, the USPTO, EPO and JPO.

4 Ibid, 25–28.

5 See, eg, United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), Ch 5; United States National Research Council, *A Patent System for the 21st Century (Prepublication Copy)* (2004), 84–87. The USPTO has introduced a Strategic Plan in response to concerns about its capacity to process pending applications efficiently and accurately: United States Patent and Trademark Office, *21st Century Strategic Plan*, <www.uspto.gov/web/offices/com/strat21/index.htm> at 16 June 2004. See also B Lehman, *Making the World Safe for Biotech Patents* (2002) International Intellectual Property Institute Discussion Paper, 26 June 2002; T Hsieh, J Hack and L Galvin, *United States: Thinking Small: The Patent Office Grapples with Nanotechnology*, Mondaq, <www.mondaq.com> at 16 June 2004.

Overview of IP Australia's examination practices

8.5 IP Australia receives patent applications from applicants in Australia and overseas. Patent applications may be filed in person at one of IP Australia's state offices, by mail or electronically. The Patent Office is divided into various groups, which have responsibility for different aspects of processing a patent application, including groups responsible for patent administration and patent examination.

8.6 The patent administration branch initially processes patent applications. Applications are categorised and assigned to a particular examination section according to the International Patent Classification (IPC) system at the subclass level.[6] The IPC system is a hierarchical classification system created by international convention and administered by the World Intellectual Property Organization.[7] It comprises sections, classes, subclasses and groups (main groups and subgroups). In the seventh edition of the IPC, there are 628 subclasses but no single category of the IPC encompasses all inventions involving genetic materials and technologies.

8.7 The patent examination branch handles examination of patent applications and challenges to patent rights determined by the Commissioner of Patents.[8] Currently, the examination branch includes two Deputy Commissioners of Patents and eleven examination sections. Each examination section comprises one supervising examiner, three to four senior examiners and approximately 16 patent examiners. A third Deputy Commissioner is responsible for dealing with challenges to patent rights. This section comprises one supervising examiner, one senior examiner and two clerical staff.

8.8 Examination of a patent application is generally undertaken by a single patent examiner, although a team of three examiners is used when prior art searches are conducted. The work within each examination section, and of each patent examiner, is prioritised to ensure that statutory time limits are met and IP Australia's targets and standards are also fulfilled to the extent possible.

8.9 The supervising examiner and senior examiners within each examination section perform a variety of functions, including training and evaluation of newly recruited examiners; managing any issues referred by examiners assigned to a particular application; and reviewing examiners' work for quality control purposes.

Resources

8.10 The capacity of IP Australia to examine gene patent applications efficiently and effectively depends, in part, on the financial and human resources available to the organisation.

---

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

7 World Intellectual Property Organization, *General Information on the Seventh Edition of the International Patent Classification System (IPC)*, <www.wipo.org/classifications> at 16 June 2004.

8 Challenges to patent rights are discussed in Ch 9.

Funding for IP Australia

8.11 IP Australia operates on a full cost-recovery basis and funds its activities from revenue raised through charges for its intellectual property services.[9] Unlike some other government agencies, therefore, IP Australia is not dependent on appropriations from Parliament to carry out its normal activities.[10] For the fiscal year ending 30 June 2003, IP Australia's annual revenue from its ordinary activities amounted to approximately $85.5 million. Of that amount, $50.6 million represented amounts collected in patent fees.[11]

Australian patent examiners

8.12 IP Australia currently has up to 200 people involved in the process of examination—as patent examiners, senior examiners or supervising examiners. This is a relatively small number compared with the USPTO, which has approximately 3,500 examiners.[12] As Figure 8–1 indicates, the number of patent examiners employed by IP Australia increased between 1999–2000 and 2001–02, after a period of significant decline, but the number has stabilised in the last two years. Figure 8–1 also shows that, following a steady increase in the number of patents examined annually per examiner in the 1990s, that number has declined in recent years. The total number of patent applications filed each year with IP Australia has risen most years since 1990–91.[13] If this trend continues, the number of applications that Australian patent examiners will have to assess each year will also continue to increase, unless there is a corresponding increase in the number of examiners.[14]

8.13 In addition to the examination of patent applications addressed in Figure 8–1, Australian patent examiners conduct prior art searches relating to applications filed under the *Patent Cooperation Treaty* (PCT)[15] and on behalf of overseas patent offices. These are discussed further below.

---

9 Department of Industry Tourism and Resources, *Annual Report* (2003). See also Ch 5.

10 Ibid.

11 The balance of IP Australia's annual revenue from its ordinary activities includes trademark and design fees, revenue gained from sale of assets, and accrued interest: Ibid.

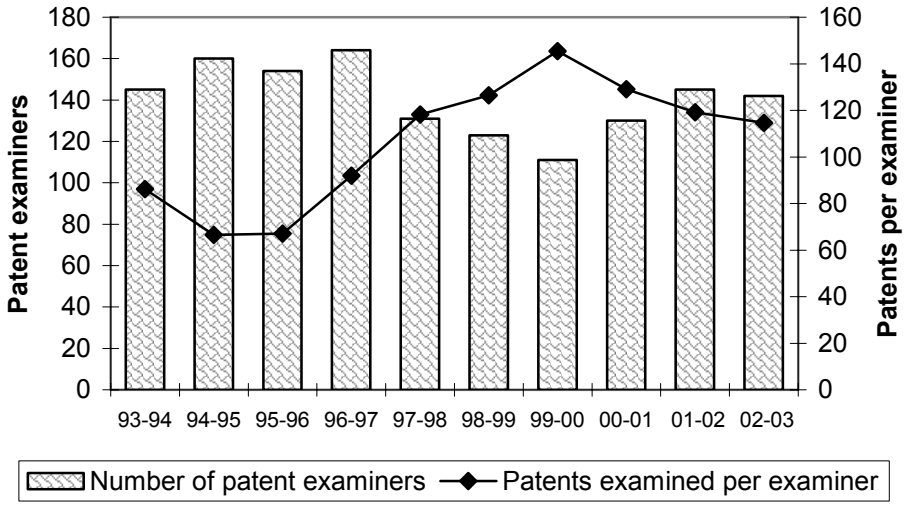
12 IP Australia, *Submission P56*, 4 November 2003.

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

14 However, the rate of increase in annual filings appears to have stabilised more recently. Similar trends are evident in Europe and the United States: European Patent Office, *Annual Report* (2003), 2; United States Patent and Trademark Office, *Performance and Accountability Report for Fiscal Year 2003* (2003), Pt 6.4.2.

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

Figure 8–1 Patent examiners and their workload



Sources: IP Australia, *Industrial Property Statistics*, Table 2, various years; Department of Industry Tourism and Resources, *Annual Report*, various years.[16]

Submissions and consultations

Funding

8.14 While the Inquiry received some general comments on the need to ensure that IP Australia has sufficient resources,[17] only two organisations specifically addressed the issue of funding. The Australian Centre for Intellectual Property in Agriculture (ACIPA) was critical of the current funding arrangements for IP Australia, which are based on a cost-recovery model.[18] ACIPA considered that IP Australia should receive independent public funding, rather than being reliant upon application and maintenance fees to fund its activities. In its view, the fact that IP Australia's funding (like that of the USPTO) is dependent upon patent fees may lead it to adopt a more service-oriented approach to the patent application process, and may provide incentives to IP Australia to issue patents in order to maintain funding levels.

16 The number of patents examined is based on data for the 'first reports issued' on patent applications filed with IP Australia. The number of patent examiners does not include supervising and senior examiners because they do not generally have responsibility for examining applications in the first instance.

17 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003.

18 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

8.15 The Centre for Law and Genetics suggested that increases in the funding available to IP Australia would allow more examiners to be employed and the development of further training opportunities for examiners.[19] The Centre submitted that increases in IP Australia's revenue might be achieved by increasing the maintenance fees for patents in the later years of a patent term.[20]

Patent examiners

8.16 Concerns were also expressed about whether IP Australia has access to a sufficient number of experienced examiners to assess applications for gene patents in an adequate and timely manner. For example, the Walter and Eliza Hall Institute of Medical Research suggested that 'the rapidly increasing volume of gene patents raises questions of access to sufficiently experienced examiners'.[21]

8.17 GlaxoSmithKline and ACIPA supported additional examiners being made available to IP Australia in all areas of technology.[22] However, GlaxoSmithKline also suggested that 'the efficiency and quality of examination by IP Australia has noticeably improved' since the employment of significant numbers of new examiners in recent years.[23] GlaxoSmithKline contrasted current practices of IP Australia with the general decrease in the number of Australian patent examiners in the late 1990s which, combined with an increase in patent filing activity, was said to have adversely affected the timeliness and quality of examinations.

ALRC's views

8.18 The ALRC acknowledges the concerns expressed in submissions and consultations about the number of Australian patent examiners and the resources available to IP Australia. The services provided by IP Australia, like any other government body, could no doubt be improved with additional funding. However, no evidence was presented to the Inquiry demonstrating that lack of funding is currently hampering IP Australia's examination of gene patent applications, or applications claiming any other type of technology. On the contrary, some submissions suggested that there have been significant improvements in IP Australia's examination practices in recent years. Furthermore, concerns about Australian patent examiners did not focus on the number of patent examiners per se but on the experience of examiners. This issue is addressed below.

---

19 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

20 Ch 5 discusses patent maintenance fees.

21 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; UniQuest, *Consultation*, Brisbane, 3 October 2003.

22 GlaxoSmithKline, *Submission P33*, 10 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

23 GlaxoSmithKline, *Submission P33*, 10 October 2003. See also BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

Qualifications, training and assistance

8.19 IP Australia has a number of examination sections, each of which specialises in different areas of technology.[24] A report on the Australian biotechnology industry published in 2001 noted that biotechnology inventions are assessed by examiners with particular expertise and training in the field, in accordance with the practices of patent offices in other jurisdictions.[25] However, IP Australia informed the ALRC that 'while there is a degree of specialisation within each field, IP Australia examiners are expected to assess a greater range of technologies than may be the case in the larger offices such as the USPTO and EPO'.[26] IP Australia has provided the ALRC with further information about qualification requirements and training programs for Australian patent examiners.[27]

Qualifications

8.20 To be eligible for a position as a patent examiner, an applicant must hold a university degree in science or engineering. Examiners who assess applications for genetic materials and technologies must have qualifications in the field of biochemistry. Although experience in a relevant industrial field is not mandatory, it is now common for newly recruited examiners to have considerable industrial experience, as well as graduate or postgraduate qualifications. IP Australia also uses its recruitment process strategically and 'particularly seeks to recruit staff with demonstrated expertise in emerging technologies'.[28]

8.21 IP Australia trains new recruits to allow them to perform the various functions required of a patent examiner. Supervising and senior examiners conduct this training, which covers Australian patent law and practice. It includes a formal assessment regime, as well as practical training and supervision. The purpose of this training is to enable new examiners to reach the required competency standard to exercise the 'acceptance delegation'.[29] Acceptance delegation refers to the Commissioner of Patents' ability under the *Patents Act* to delegate his or her power to examine and, if appropriate, accept patent applications.[30] Examiners must demonstrate an 'appropriate level and quality of work output and have the experience, knowledge and judgement to be able to reliably exercise the delegation'.[31] Typically, examiners reach this level of competence after approximately 30 months of service with IP Australia.

---

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

25 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001).

26 IP Australia, *Submission P56*, 4 November 2003. See also Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003; Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

27 IP Australia, *Submission P56*, 4 November 2003; IP Australia, *Submission P86*, 16 April 2004.

28 IP Australia, *Submission P86*, 16 April 2004.

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

30 Subject to certain formalities, the Commissioner may delegate powers and functions conferred upon him or her under the *Patents Act* or any other Act: *Patents Act 1990* (Cth) s 209. Other powers of the Commissioner of Patents may also be delegated to more senior examiners, for example, the power to hear and determine oppositions and re-examinations.

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

Training

8.22 IP Australia has a continuing professional development program for patent examiners. The program aims to develop examiners' skills in patent law, examination and searching practices, and knowledge in relevant technological fields. The majority of resources allocated to IP Australia's professional development program are directed to improving examiners' understanding in relevant technological fields.[32] The program includes: supporting examiners in postgraduate studies; internal and external training programs conducted by industry specialists or tertiary institutions; participation in conferences and seminars; visits to relevant industries; and placements in patent attorney firms.

8.23 Each examination section within IP Australia also has access to relevant on-line resources, text books and key scientific journals—such as *Nature* and *Science*—to allow examiners 'to keep abreast of the latest scientific developments and for researching issues for particular examination cases'.[33]

Assistance

8.24 Currently, patent examiners may refer any issues or problems to senior or supervising examiners within their section. IP Australia's *Patent Manual of Practice and Procedure* (the *Manual*) indicates that an examiner should raise any concerns he or she may have about mastering the technical and legal aspects of an application with a senior examiner.[34] IP Australia has adopted policies that require patent applications for certain types of technologies to be referred to a supervising examiner automatically; for example, patent applications that may claim human beings or the biological processes for their generation.[35] In addition, examiners faced with new issues may consult other examiners with relevant expertise to obtain assistance on an informal basis.[36]

8.25 A more formalised system for review of particular types of patent applications has been adopted by the USPTO. The USPTO has announced that it will expand its practice of 'second-pair-of-eyes' review to cover fields such as biotechnology, semiconductors and software.[37] A report of the United States Federal Trade Commission in 2003 endorsed such initiatives[38] and commented that they 'can significantly help improve the quality of patent application review'.[39]

---

32 IP Australia, *Submission P86*, 16 April 2004.
33 Ibid.
34 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [12.1(f)].
35 Ibid, [8.5]. The exclusion from patentability of inventions claiming human beings or the biological processes for their generation is discussed in Ch 7 and 15.
36 IP Australia, *Submission P86*, 16 April 2004.
37 United States Patent and Trademark Office, *21st Century Strategic Plan*, <www.uspto.gov/web/offices/com/strat21/index.htm> at 16 June 2004; United States Patent and Trademark Office, *Patent Quality Improvement: Expansion of the Second-Pair-of-Eyes Review*, <www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm> at 16 June 2004.
38 United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), rec 5(c).
39 Ibid, Ch 6, 20.

8.26 To date, there is limited precedent for providing patent examiners with access to outside scientific or technical expertise.[40] A recent report of the Royal Society recommended that patent examiners in the United Kingdom should consult experts to ensure that their understanding of relevant areas of science is extremely high,[41] so that examiners are able to apply the same demanding standards in both developing and established areas of science.[42] The USPTO has engaged an in-house business practice specialist to act as a resource on industry practices, terminology and standards for patent examiners assessing applications for business systems. However, IP Australia indicated in its submission that an equivalent position 'would not be feasible … due to the much smaller scale of operations' in Australia.[43]

Submissions and consultations

Qualifications and training

8.27 During the Inquiry, concerns were raised about patent examiners' expertise and the need for continuing training to allow patent examiners to keep abreast of technological developments in relevant fields. Some submissions considered that the expertise of patent examiners in any rapidly developing area of science might be an issue because the quality of patent examination is limited by the level of technical skill of an examiner.[44] Other submissions commented that this might be a particular issue for patent applications relating to genetic materials and technologies, and stem cell technologies, because the assessment of such applications might require a greater understanding of the relevant scientific background than in other areas of technology.[45] Variations in the level of skill of Australian patent examiners were noted in consultations.[46] A small number of submissions indicated that the expertise of patent examiners is not currently a concern, but is a matter that warrants further review.[47]

---

40 For example, in Singapore, legislation grants the Registrar of Patents the discretion to appoint a scientific adviser from a panel of advisers established under the Act to assist the court and the Registrar of Patents: *Patents Act 1995* Chapter 221 (Singapore) s 90. Creation of an independent ethical advisory body as part of the Australian patent system is considered in Ch 7.

41 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), [3.28].

42 Ibid.

43 IP Australia, *Submission P86*, 16 April 2004.

44 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003.

45 South Australian Government, *Submission P51*, 30 October 2003; BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

46 National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003; BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.

47 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003. See also New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003.

8.28 To ensure the ongoing competence of Australian patent examiners in assessing patent applications, DP 68 proposed that IP Australia should continue to enhance its efforts to provide examiners with continuing education in areas of technology relevant to their particular specialty.[48]

8.29 A majority of submissions supported this proposal.[49] Some submissions indicated that providing continuing education to patent examiners is vital 'given the rapid growth in the scope and complexity of gene technology'[50] and the concomitant difficulties for examiners in finding and managing all relevant information.[51] Others considered that enhancing IP Australia's current education programs would help to ensure that, when determining whether to grant a patent, examiners strike an appropriate balance between 'providing an incentive to innovate and ensuring that the results of such innovation are readily … available'.[52] Dr Amanda McBratney and others suggested that there should be regular 'auditing and updating of examiner skills'.

> Examiners should be involved in a process of ongoing education so that they are as up to date in the relevant technological areas as possible. Continuing education should be mandatory—not only course work, but attendance at conferences (as this is where the most up to date information is discussed).[53]

Expert assistance

8.30 At an early stage of the Inquiry, a number submissions and consultations indicated that expert advice should be available to patent examiners in assessing patent applications, whether involving genetic materials and technologies or new technologies generally.[54] However, differing views were expressed about the composition of any

---

48 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 8–1.

49 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Medicines Australia, *Submission P75*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; G Suthers, *Submission P116*, 4 May 2004.

50 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004. See also Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004.

51 Department of Health Western Australia, *Submission P89*, 16 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

52 Ministry for Science and Medical Research New South Wales, *Submission P109*, 28 April 2004. See also Medicines Australia, *Submission P75*, 15 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004.

53 A McBratney and others, *Submission P47*, 22 October 2003.

54 Ibid; Department of Health Western Australia, *Submission P53*, 3 November 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; Consumers' Health Forum of Australia, *Consultation*, Canberra, 23 September 2003.

expert panel, the types of issues on which expert advice should be provided, and the function of an expert advisory panel.[55]

8.31 DP 68 proposed that the *Patents Act* be amended to authorise IP Australia to establish panels of legal and scientific experts to advise patent examiners in assessing patent applications, as circumstances may require.[56] A number of submissions supported this proposal as a means of improving patent examination practices.[57] For example, the Department of Health and Ageing submitted:

> The provision of expert advice through panels of experts would enable the consideration of complex issues beyond that which is realistically achievable by individual examiners.[58]

8.32 However, other submissions expressed a range of concerns about the establishment of an expert panel. Comments suggested that the use of expert panels would increase the costs of examining patent applications and delay the grant of patents.[59] A few submissions observed that a panel of experts would introduce additional decisions in respect of which a patent applicant may seek administrative or judicial review.[60] Those decisions include: an examiner's decision as to whether an application should be referred to the panel; the advice provided by the panel in relation to a particular application; and the decision of an examiner about whether or not to adopt the panel's advice. Further, an obligation to accord procedural fairness may require that an applicant be notified of, and be given the opportunity to make submissions in relation to, each of these decisions.[61] Submissions also indicated that procedural fairness would require that an applicant be provided with copies of relevant information relied upon by the patent examiner, as well as any written advice of the panel.[62]

---

55 Chapter 7 considers the potential role of ethicists in advising patent examiners.

56 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposals 8–2 and 8–3.

57 Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004; G Suthers, *Submission P116*, 4 May 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

58 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

59 IP Australia, *Submission P86*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; South Australian Government, *Submission P51*, 30 October 2003.

60 IP Australia, *Submission P86*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004; A Bennett, *Consultation*, Sydney, 15 March 2004.

61 IP Australia, *Submission P86*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004; Unisearch, *Consultation*, Sydney, 15 March 2004.

62 IP Australia, *Submission P86*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

8.33 Submissions also raised concerns about the operation of the panel.[63] Some questioned whether patent examiners are equipped to decide whether to rely on advice provided by an expert panel.[64] Others indicated that members of the panel might be too highly skilled to be capable of assessing applications according to the relevant legal standard—that is, from the perspective of 'a person skilled in the relevant art'.[65]

8.34 The composition of an expert panel was also seen as problematic, particularly if the pool from which experts are selected is limited to those within Australia.[66] Submissions considered that actual and potential conflicts of interest might be a significant issue.[67] Further, IP Australia commented that, given the breadth of issues that may arise, it might be difficult to maintain a panel with sufficient breadth of expertise to allow useful advice to be obtained relatively quickly.[68]

8.35 In its submission to the Inquiry, IP Australia considered alternative means of addressing concerns about the level of expertise of patent examiners, based on models provided by the USPTO. IP Australia indicated that it could provide a 'second level of review in genetic technologies by increasing the role of senior and supervising examiners in checking the work of examiners'—similar to the 'second-pair-of-eyes' review instituted by the USPTO. However, as discussed above, IP Australia considered that introducing an industry expert to act as a resource for Australian patent examiners assessing gene patent applications was not feasible.[69]

ALRC's views

8.36 New developments in human genetics require an increasingly detailed grasp of the scientific context to distinguish potentially novel developments from what has come before. It is important that IP Australia has in place mechanisms to ensure that patent examiners have sufficient expertise in the areas of technology in which they may be required to assess applications.

---

63 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; J McKeough, *Consultation*, Sydney, 23 March 2004; A Bennett, *Consultation*, Sydney, 15 March 2004.

64 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; A Bennett, *Consultation*, Sydney, 15 March 2004.

65 IP Australia, *Submission P86*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004. See *Patents Act 1990* (Cth) s 7(2). A person skilled in the relevant art is a 'skilled but non-inventive worker in the relevant field of technology': IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [4.2.4.2].

66 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; J McKeough, *Consultation*, Sydney, 23 March 2004.

67 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; IP Australia, *Consultation*, Canberra, 24 September 2003; Unisearch, *Consultation*, Sydney, 15 March 2004; J McKeough, *Consultation*, Sydney, 23 March 2004; Walter and Eliza Hall Institute of Medical Research, *Consultation*, Melbourne, 1 April 2004.

68 IP Australia, *Submission P86*, 16 April 2004. See also Sydney IVF Limited, *Submission P98*, 19 April 2004.

69 IP Australia, *Submission P86*, 16 April 2004.

8.37 DP 68 proposed that one way to achieve this is by introducing a panel of scientific and technical experts to assist examiners in assessing patent applications in appropriate circumstances. However, submissions and consultations raised a number of concerns about the effectiveness of this approach. In particular, the introduction of an expert panel may provide a number of additional decisions in respect of which a patent applicant may seek administrative or judicial review during the examination process. This could increase both the time and cost of examination, which the ALRC considers to be undesirable.[70]

8.38 It is particularly important that patent examiners have access to training and professional education to allow them to continue to develop knowledge and skills in relevant areas of technology. IP Australia employs a comparatively small number of patent examiners, and these examiners assess patent applications in a broad range of technological fields. To maintain high quality in the examination of patent applications, particularly in the genetics field, examiners should participate regularly in education and training programs that highlight new directions in genetic research and assist examiners in understanding the practical implications of these developments.

8.39 IP Australia currently operates a professional development program for patent examiners, and has implemented mechanisms to assess the suitability of such programs in light of technological developments. Submissions and consultations did not identify specific inadequacies in the current training of Australian patent examiners. However, the ALRC believes that IP Australia should review the subject matter and structure of its education and training programs regularly to so that examiners remain up to date with new developments. Regular reviews will also highlight areas in which additional education or training programs, or strategic recruitment by IP Australia, may be required.

8.40 IP Australia has some mechanisms in place to resolve difficult issues that may arise during the assessment of a particular patent application—for example, referral of particular matters to supervising or senior examiners. Regular audits of IP Australia's education and training programs, and the organisation's needs, will allow IP Australia to identify whether additional mechanisms are required—such as systematic review by senior examiners of patent examiners' work in particular areas of technology.

8.41 The need for appropriate education and training is not unique to inventions involving genetic materials and technologies.[71] It will also be an important issue in connection with new technologies that emerge in the future.

---

70 A similar conclusion was reached by the United States National Research Council: United States National Research Council, *A Patent System for the 21st Century (Prepublication Copy)* (2004), 74.

71 A 2003 report of the Advisory Council on Intellectual Property (ACIP) on patenting business systems noted similar concerns about the expertise of examiners. ACIP recommended that IP Australia enhance its business training for patent examiners: Advisory Council on Intellectual Property, *Report on a Review of the Patenting of Business Systems* (2003), rec 4.

Recommendation 8–1 To ensure the ongoing competence of Australian patent examiners in examining patent applications, IP Australia should enhance its efforts to provide examiners with education and training in areas of technology relevant to their particular specialty. IP Australia should review and update its education and training programs regularly so that new developments can be incorporated as required.

Examination guidelines for biotechnology patents

Australia

8.42 As discussed in Chapter 16, the Australian biotechnology industry is still in the early stages of development. One consequence of this is that there has been limited judicial consideration of how patent law applies to biotechnological inventions.[72] Little specific guidance is available to patent examiners in assessing whether a particular biotechnological or genetic invention satisfies the requirements for patentability. Dr Dianne Nicol and Jane Nielsen have suggested that 'the absence of judicial guidance in this area is problematic'.[73]

8.43 IP Australia has developed the *Manual* to assist Australian patent examiners in applying the *Patents Act* and *Patents Regulations 1991* (Cth) (*Patents Regulations*).[74] The *Manual* is intended as a reference guide for examiners on all aspects of patent practice, including: search and examination procedures; interpretation and application of the requirements of patentability under Australia law and relevant procedural provisions of the *Patents Act*; and practice and procedures in connection with patent applications filed under the PCT. The *Manual* does not, however, contain a section that specifically considers issues that may arise in applying each of the requirements of patentability to inventions involving genetic materials and technologies.[75]

8.44 To date, the only specific guidance that IP Australia has developed on the patentability of biological inventions is the user guide entitled *Australian Patents for: Microoganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; and Genetically Manipulated Organisms.*[76] However, this guide is directed primarily to

---

72 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 20.

73 Ibid, 20.

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

75 There are isolated references to genetic materials in the *Manual*, as well as a chapter setting out the principles and procedures relevant to the deposit of micro-organisms and other life forms: IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.4.2], Ch 6.

76 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 16 June 2004.

potential patent applicants, rather than patent examiners, and focuses on the way in which the disclosure requirements might be satisfied in relation to biological inventions.[77]

Other jurisdictions

8.45 Other jurisdictions, particularly the United States and Europe, have more highly-developed case law on patents over biotechnological inventions generally, and inventions involving genetic materials and technologies in particular. In addition, patent offices in some jurisdictions have released specific guidelines outlining the way in which patent law might apply to biotechnological or genetic inventions.

United Kingdom

8.46 In September 2002, the United Kingdom Patent Office released its *Examination Guidelines for Patent Applications Relating to Biotechnology Inventions in the UK Patent Office* (UK Biotech Examination Guidelines),[78] which supplement the *Manual of Patent Practice* developed by the United Kingdom Patent Office for general use by patent examiners. The introduction to the UK Biotech Examination Guidelines states that applying the basic patentability requirements to biotechnological inventions can 'place considerable demands on the judgment of the examiner'.[79] To assist United Kingdom patent examiners in assessing such applications, the Guidelines set out relevant case law in this area, and also indicate how patentability requirements should be applied to biotechnological inventions, subject to further guidance from the courts and the Boards of Appeal of the EPO.[80]

United States

8.47 The United States has not issued specific guidelines for examiners about the application of United States patent law to biotechnological or genetic inventions. United States case law in this area is, however, considerably more developed than in other jurisdictions.[81] In addition, the USPTO has provided guidance about its approach to gene patent applications in connection with its implementation of new guidelines for examination of patent applications under the utility and written description requirements for patentability in United States law.[82] While these guidelines apply to

---

77 The fair basis and sufficiency requirements for patentability under Australian law are discussed in Ch 6.

78 United Kingdom Patent Office, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office (November 2003)*, <www.patent.gov.uk/patent/reference/index> at 16 June 2004.

79 Ibid, [6].

80 Ibid, [6].

81 See, eg, *University of Rochester v G D Searle & Co Inc* (2004) 69 USPQ 2d 1886; *Enzo Biochem Inc v Gen-Probe Inc* 285 F 3d 1013 (Fed Cir, 2002); *Regents of the University of California v Eli Lilly & Co* 119 F 3d 1559 (Fed Cir, 1997); *Re Dueul* 51 F 3d 1552 (Fed Cir, 1995); *Re Bell* 991 F 2d 781 (Fed Cir, 1993).

82 United States Patent and Trademark Office, 'Guidelines for Examination of Patent Applications under the 35 USC 112, "Written Description" Requirement' (2001) 66 *FR* 1099; United States Patent and Trademark Office, 'Utility Examination Guidelines' (2001) 66 *FR* 1092. These guidelines have now been incorporated into the United States Patent and Trademark Office, *Manual of Patent Examining Procedure (8th Edition)* (2003), [2107], [2161]–[2171].

all relevant technologies, the USPTO has indicated that the impetus for their adoption was to assist patent examiners in reviewing 'biological patent applications'.[83]

Japan

8.48 In Japan, the JPO has published implementing guidelines for inventions in specific fields, including genetic engineering,[84] as well as model examination reports for certain types of genetic inventions, including applications claiming DNA fragments (or expressed sequence tags) and single nucleotide polymorphisms.[85]

Canada

8.49 In Canada, reports by both the Ontario Government and the Canadian Biotechnology Advisory Committee (CBAC) have proposed that the Canadian Intellectual Property Office develop new patent office guidelines, procedures and training manuals relating to gene patents.[86] In addition to assisting patent examiners, CBAC considered that such guidelines would be useful for smaller biotechnology companies who are inexperienced in the patent process.[87]

Submissions and consultations

8.50 DP 68 proposed that IP Australia should develop examination guidelines, consistent with the *Patents Act*, *Patents Regulations* and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.[88] A wide range of submissions and consultations supported this proposal.[89]

---

83 United States Patent and Trademark Office, 'Request for Comments on Interim Examination Guidelines for Examination of Patent Applications under the 35 USC 112 para 1 "Written Description" Requirement' (1998) 63 *FR* 32639. As a result of certain comments that the USPTO received on the interim written description guidelines, the agency determined that a review of the utility examination guidelines was also required: United States Patent and Trademark Office, 'Revised Utility Examination Guidelines: Request for Comments' (1999) 64 *FR* 71440.

84 Japan Patent Office, *Implementing Guidelines for Inventions in Specific Fields: Biological Inventions*, <www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/txt/bio-e-m.txt> at 16 June 2004.

85 Japan Patent Office, *Examples of Examinations on the Inventions Related to Genes (DNA Fragments, Full-length cDNAs, and Single Nucleotide Polymorphisms) (Abridged Translation)*, <www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/dnas.htm> at 16 June 2004.

86 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(b); Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), rec 10.

87 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 21. An update of the Canadian *Manual of Patent Office Practice* is scheduled for completion by September 2004: Canadian Intellectual Property Office, *Information about the Manual of Patent Office Practice*, <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop/mopop-e.html> at 16 June 2004.

88 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 8–4.

89 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; National Health and Medical

8.51 Some submissions considered that the adoption of examination guidelines for genetic inventions would assist in improving IP Australia's examination practices and ensuring that the criteria for patentability are correctly applied—particularly in determining the permissible scope of patent claims.[90] Other submissions indicated that guidelines would help potential patent applicants understand the process by which applications are considered and examined by the Patent Office.[91]

8.52 A few submissions commented on the processes for developing the examination guidelines. The National Health and Medical Research Council suggested that there should be 'extensive consultation' in the formulation of the guidelines.[92] The Genetic Support Council WA (Inc) considered that the guidelines needed to 'include consumer input'.[93] The Caroline Chisholm Centre for Health Ethics suggested that IP Australia should review the guidelines regularly—'every three years or so'—to keep them 'current, appropriate and identify any unanticipated areas needing reform'.[94]

8.53 A few concerns were expressed about the effect of adopting examination guidelines for biotechnological inventions alone. The Garvan Institute of Medical Research suggested that, while the proposed guidelines may increase the predictability and transparency of the Patent Office's decisions in relation to gene patent applications, they may also discourage overseas companies from applying for Australian patents.[95] Similarly, Unisearch Ltd suggested that patent examiners' reliance on the guidelines might, over time, result in a more rigid application of the patentability criteria.[96] ACIPA submitted that administrative guidelines should be supported by legislative reform of the patentability criteria.[97]

ALRC's views

8.54 IP Australia has published general guidelines to assist patent examiners in applying Australian patent law to particular inventions and a users' guide on patent applications for biological material. However, the ALRC considers that additional guidelines would be desirable to assist patent examiners in applying general patent law

---

Research Council, *Submission P107*, 19 April 2004; G Suthers, *Submission P116*, 4 May 2004; J McKeough, *Consultation*, Sydney, 23 March 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

90 Medicines Australia, *Submission P75*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

91 Queensland Government, *Submission P103*, 22 April 2004. See also A McBratney and others, *Submission P47*, 22 October 2003; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004.

92 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

93 Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

94 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004. See also J McKeough, *Consultation*, Sydney, 23 March 2004.

95 Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

96 Unisearch, *Consultation*, Sydney, 15 March 2004.

97 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

principles to biotechnological inventions.[98] Currently, Australian patent examiners have little relevant case law to assist them in determining how the general requirements for patentability in s 18 of the *Patents Act* apply to a specific genetic invention.

8.55 The examination guidelines should outline IP Australia's general approach to genetic inventions, and the considerations it regards as relevant in applying the requirements for patentability to gene patent applications, particularly where analogies must be drawn with other technologies on the basis of established case law. The guidelines must be consistent with the *Patents Act*, the *Patents Regulations* and existing case law. While the final interpretation of the Act and the Regulations lies with the courts—which may ultimately reject an interpretation of patent law that has been adopted by IP Australia—the ALRC considers that a clear explanation of IP Australia's approach in assessing gene patent applications would be useful. This approach is consistent with the practices of other Australian regulatory agencies, which have developed guidelines to assist in understanding the application of relevant legislation to specific circumstances.[99]

8.56 The proposed examination guidelines will make IP Australia's assessment of applications for gene patents more transparent. It will also assist applicants and their legal advisers in assessing the likely availability of patent protection for a particular genetic invention, and in drafting patent claims appropriately. To this end, the guidelines should be in a form that is comprehensible to both patent examiners and patent applicants. The UK Biotech Examination Guidelines are a worthwhile model. However, the ALRC agrees with IP Australia's suggestion that the proposed guidelines could be included as a separate section in the *Manual* in order to maintain all instructions on patent examination practices in a single source.[100]

8.57 IP Australia is clearly the most appropriate body to formulate specific guidelines relating to the assessment of patent applications for biotechnological inventions. It should, however, engage relevant stakeholders and other interested parties in consultations before adopting any guidelines in final form. In addition, IP Australia should review the guidelines periodically to ensure that case law and other relevant matters are incorporated.

Recommendation 8–2 IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth) (*Patents Act*), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

98 Nicol and Nielsen have also proposed biotechnology-specific guidelines for assessing the 'description criteria' (that is, the sufficiency and fair basis requirements for patentability): D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 258.

Prior art searches

8.58 DP 68 discussed IP Australia's practices in relation to prior art searches and the resources available to Australian patent examiners in this regard.[101] In addition to performing prior art searches for Australian patent applications, IP Australia conducts searches for patent offices in other jurisdictions—as one of the twelve International Searching Authorities under the PCT[102] and pursuant to bilateral arrangements with the patent offices of certain countries in the Asia–Pacific region.[103] In 2003, IP Australia conducted over 3,500 such prior art searches.[104]

8.59 Conflicting views were expressed about IP Australia's capacity to conduct prior art searches for patent applications claiming genetic materials and technologies. Concerns were voiced about the capacity of IP Australia to identify all relevant prior art against which the novelty and inventiveness of a claimed genetic invention should be tested.[105] However, others noted that IP Australia's searching practices are comparable to other major patent offices and subject to on-going internal review.[106]

8.60 Two recent reports have considered IP Australia's practices relating to prior art searches and have recommended limited reforms. The 2000 report of the Intellectual Property and Competition Review Committee (IPCRC Report) recommended that IP Australia should 'devote additional resources to improving the quality of examination, particularly to prior art processes including through enhanced use of technology'.[107] Similarly, a 2003 report on patenting business systems by the Advisory Council on Intellectual Property (ACIP Business Systems Report) encouraged IP Australia to 'make further use of non-patent literature during the examination process'.[108] Both reports also considered that increased co-operation between

---

99 See, eg, Australian Competition and Consumer Commission, *Telecommunications Competition Notice Guidelines* (2004), developed pursuant to s 151AP of the *Trade Practices Act 1974* (Cth).

100 IP Australia, *Submission P86*, 16 April 2004.

101 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [8.77]–[8.91].

102 See Ch 4 and 5 for a discussion of the PCT and IP Australia's responsibility for processing applications filed under the Treaty. See also IP Australia, *International Patent Application Kit*, <www.ipaustralia.gov.au/pdfs/patents/internationalpatentapplicationkit.pdf> at 16 June 2004.

103 IP Australia, *Annual Report* (2003); Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 168. See also Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003.

104 IP Australia, *Annual Report* (2003), Fig 4.

105 R Barnard, *Submission P32*, 7 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Benitec Ltd, *Consultation*, Brisbane, 3 October 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.

106 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; IP Australia, *Submission P56*, 4 November 2003; IP Australia, *Consultation*, Canberra, 24 September 2003.

107 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 168.

108 Advisory Council on Intellectual Property, *Report on a Review of the Patenting of Business Systems* (2003), rec 3.

IP Australia and other patent offices in relation to prior art searches would be beneficial.[109]

8.61 On the basis of the limited evidence presented to the Inquiry, it does not appear that IP Australia's practices relating to prior art searches raise particular issues in the context of gene patent applications. If implemented by IP Australia, the recommendations made in the IPCRC Report and the ACIP Business Systems Report may benefit examiners conducting prior art searches in the genetics field. In addition, as discussed in Chapter 6, the disclosure obligations and the definition of prior art in the *Patents Act* have recently been amended.[110] The impact of these changes is yet to be seen,[111] but such provisions may well result in a wider range of prior art information being made available to IP Australia in relation to all types of technologies. The ALRC does not, therefore, consider that additional reforms to the practices of IP Australia in conducting prior art searches are required at this stage.

Standard of proof

Australia

8.62 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.[112]

8.63 The satisfaction test was introduced into the *Patents Act* in 2001 by the *Patents Amendment Act 2001* (Cth), following recommendations in a 1999 report of the Advisory Council on Industrial Property (ACIP IP Enforcement Report) and in the IPCRC Report in 2000.[113]

8.64 Prior to the 2001 amendment, it was sufficient if the Commissioner 'considered' that there was no lawful ground of objection to a patent.[114] The IPCRC Report noted that, as interpreted by the courts, the earlier position gave the benefit of the doubt to a

---

109 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 168; Advisory Council on Intellectual Property, *Report on a Review of the Patenting of Business Systems* (2003), rec 3. In response to the IPCRC Report, the Australian Government indicated that IP Australia will continue to co-operate with relevant patent offices to pursue issues of harmonisation, mutual recognition and other means of simplifying the patent system: IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 16 June 2004.

110 See further Ch 6.

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

112 *Patents Act 1990* (Cth) s 49(1). 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 5.

113 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 15; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 167. See Explanatory Memorandum, Patents Amendment Bill 2001 (Cth).

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

patent applicant and the Commissioner could only refuse to grant a patent where it was clear that a valid patent could not be granted.[115]

8.65 Both the ACIP IP Enforcement Report and the IPCRC Report recommended increasing the threshold for acceptance of patent applications 'so that granted patents would be more likely to be valid'.[116] The ACIP IP Enforcement Report specifically recommended that 'the rule giving the benefit of the doubt to the applicant should be abrogated in so far as it relates to novelty and obviousness'.[117] The IPCRC Report endorsed the views expressed in the ACIP IP Enforcement Report, but cast its recommendation in more general terms:

> The Committee recommends changing the *Patents Act* to require a 'balance of probabilities' approach to be used during examination, rather than conferring the 'benefit of the doubt' to the applicant as at present.[118]

8.66 As now amended, s 49 requires a patent examiner to apply two different standards of proof in assessing the requirements for patentability relevant to examination of a patent application.[119] The requirement that the Commissioner be 'satisfied' that an invention is novel and involves an inventive (or innovative) step is a 'balance of probabilities' standard. With respect to other requirements for patentability relevant at the examination stage—including that the patent claims comply with s 40 of the *Patents Act*; that the claimed invention is a 'manner of manufacture'; and that the invention is not a human being or a biological process for the generation of a human being[120]—the Commissioner need only 'consider' that such grounds are met. As noted above, this has been interpreted as giving the applicant the 'benefit of the doubt'.[121]

8.67 The *Manual* explains the considerations relevant in assessing whether each of the standards of proof has been met:

> [The 'balance of probabilities'] test requires an examiner to weigh up all the material before them and decide, on balance, whether a claimed invention is 'more likely than not' to be novel and inventive (or innovative).[122]
>
> In the case of objections other than novelty, inventive step, and innovative step, the benefit of the doubt is given to the applicant, and objections are maintained if there is

---

115 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 167. See, eg, *Commissioner of Patents v Microcell Ltd* (1959) 102 CLR 232.

116 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 15.

117 Ibid, rec 2.

118 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 167.

119 The situation is the same for the examination of an innovation patent: *Patents Act 1990* (Cth) s 101E.

120 Ibid s 45(1). Under the *Patents Regulations*, examiners are also required to consider certain other matters, which are primarily of a procedural nature: *Patents Regulations 1991* (Cth) r 3.18.

121 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [0.2.4], [12.5.2.1] (standard patent); [30.4.3.3] (innovation patent). See also Explanatory Memorandum, Patents Amendment Bill 2001 (Cth), [18], [23].

122 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [12.5.2.2].

little uncertainty as to whether the objection still applies (having regard to the response from the applicant).[123]

Other jurisdictions

8.68 Other jurisdictions formulate the standard of proof for acceptance of a patent application in a number of different ways. In general, however, the standard of proof is a 'balance of probabilities' standard, or equivalent. A 'balance of probabilities' standard is applied, for example, by the United Kingdom Patent Office.[124] The USPTO applies a 'preponderance of the evidence' test, which is the civil standard of proof under United States law and, broadly speaking, equates with the 'balance of probabilities' standard applied in other jurisdictions.[125] In addition, unlike Australia, patent offices in other jurisdictions appear to apply a single standard of proof to all the elements of patentability relevant to examination.

8.69 A 2003 report of the New Zealand Ministry for Economic Development (NZ Report) recommended changes to the standard of proof for acceptance of patent applications.[126] Currently, a New Zealand patent examiner may reject a patent application only if he or she is 'practically certain' that any patent granted would be invalid. However, the NZ Report recommended amending the *Patents Act 1953* (NZ) to 'provide that patents can only be granted if, on the balance of probabilities, the requirements for patentability are met'.[127]

Submissions and consultations

8.70 DP 68 proposed that the *Patents Act* be amended to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination.[128] A range of submissions supported this proposal, including those from government, the healthcare sector and legal academics.[129] Submissions considered that a single standard of proof could

---

123 Ibid, [12.5.2.3].

124 United Kingdom Patent Office, *Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the UK Patent Office (November 2003)*, <www.patent.gov.uk/patent/reference/index> at 16 June 2004. See also New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 1, [55].

125 United States Patent and Trademark Office, *Manual of Patent Examining Procedure (8th Edition)* (2003), [706]. 'Preponderance of evidence' requires that the greater weight of evidence, or evidence which is more credible and convincing, is in favour of a particular conclusion: H Black, *Black's Law Dictionary* (4th ed, 1968); B Garner, *A Dictionary of Modern Legal Usage* (2nd ed, 1995).

126 New Zealand Ministry of Economic Development, *Review of the Patents Act 1953 Stage 3: Boundaries to Patentability* (2003), Pt 1.

127 Ibid, Pt 1, rec 2(iii).

128 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 8–5.

129 Medicines Australia, *Submission P75*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; G Suthers, *Submission P116*, 4 May 2004; Queensland Law Society, *Submission P118*, 7 May 2004.

simplify the examination process and improve examination practices. In addition, some submissions specifically addressed the appropriate standard of proof to apply to the usefulness requirement, which is discussed in Chapter 6.

8.71 However, submissions from some patent attorneys expressed concern about imposing a balance of probabilities standard for all the patentability criteria relevant at the examination stage. F B Rice & Co submitted that a benefit of the doubt standard should continue to apply in relation to the issues of fair basis, best method, succinctness and the meaning of specific terms in a patent specification.[130] Similarly, the Institute of Patent and Trademark Attorneys of Australia (IPTA) indicated that the requirements of usefulness, fair basis and sufficiency should be assessed according to a benefit of the doubt standard because these issues cannot be thoroughly or objectively considered at the examination stage.[131]

8.72 IPTA was particularly concerned about the effect of applying a balance of probabilities standard to the manner of manufacture requirement. It suggested that the ability of Australian patent law to adapt to changes in technology 'has only been possible through the applicant being given the benefit of the doubt when considering whether new "unpatented" subject matter qualified for protection'.[132]

8.73 However, IP Australia commented that applying a balance of probabilities standard to the manner of manufacture requirement 'would not make a significant difference to the standard that currently applies':

> An objection based on manner of manufacture is unlikely to involve evidence, in contrast to objections based on novelty, fair basis and sufficiency. Rather, it is whether, in the Commissioner's opinion, the application is for patentable subject matter according to precedent, and the flexible notion of 'is this a proper subject of letters patent according to the principles which have been developed for the application of s 6 of the Statute of Monopolies?'[133]

8.74 IP Australia expressed support for the proposal that a balance of probabilities standard should apply to all criteria for patentability relevant at the examination stage. For simplicity, it said that no criterion should be excluded from the higher threshold.[134]

8.75 A small number of submissions cautioned that raising the standard of proof may have adverse consequences for perceptions of Australian patent law and for Australian companies in the global biotechnology market and that these factors should be

---

130 F B Rice & Co, *Submission P84*, 16 April 2004.

131 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004. IPTA stated that the issue of the appropriate standard of proof to apply at the examination stage was thoroughly canvassed in consultations for the ACIP IP Enforcement Report in 1999 and that the recommendation made by ACIP—outlined above—'still reflects the consensus of opinion on this issue'.

132 Ibid.

133 IP Australia, *Submission P86*, 16 April 2004 (citing *National Research Development Corp v Commissioner of Patents* (1959) 102 CLR 252).

134 IP Australia, *Submission P86*, 16 April 2004.

carefully considered before any amendments were proposed.[135] Other submissions noted that, if the standard of proof were raised, the change should apply to applications claiming all types of technologies, not merely to gene patent applications.[136]

ALRC's views

8.76 Submissions to the Inquiry did not support the adoption of a standard of proof that would apply only to gene patent applications. The ALRC agrees that gene patent applications should be subject to the same standard of proof as applications for patents over any other type of technology. To draw a distinction would require difficult, and sometimes arbitrary, boundaries to be drawn between applications for patents over different types of technology. In addition, requirements that would apply only to gene patents may be inconsistent with Australia's obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* to provide patent protection to all inventions without discrimination as to field of technology.[137]

8.77 The ALRC considers that the *Patents Act* should be amended to provide a single standard of proof for all patent applications examined by IP Australia and that the applicable standard of proof should be on the balance of probabilities (see Recommendation 8–3). As discussed in Chapter 6, this standard should also apply to the question whether an invention claimed in a patent application is 'useful' (see Recommendation 6–3). Recommendation 8–3 would not change the standard of proof applicable to the requirements of novelty and inventive (or innovative) step because a balance of probabilities standard already applies to these requirements. However, it would raise the bar in relation to other requirements for patentability that are relevant at the examination stage.

8.78 In the ALRC's view, the rationale for maintaining two different standards of proof in relation to different requirements for patentability at the examination stage is unclear. Applying different standards of proof adds unnecessary complexity to the examination of patent applications and might generate confusion on the part of patent applicants and patent examiners. There are practical difficulties for examiners in applying different levels of proof to different criteria for patentability, and the effect of this might be that examiners apply a single standard of proof in practice.

8.79 The ALRC is not persuaded by arguments in submissions that certain requirements for patentability should be excluded from the application of a higher standard of proof. In particular, IP Australia has suggested that the manner of

---

135 Genetic Technologies Limited, *Submission P45*, 20 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

136 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

137 *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995), art 27. See Ch 4.

manufacture requirement is not primarily a factual matter in relation to which evidence can be adduced. A change in the standard of proof is therefore unlikely to have a significant effect on the Patent Office's decisions in this area.

8.80 Applying a balance of probabilities standard might increase the burden placed on an applicant and require additional evidence to be adduced at the examination stage. However, the ALRC agrees with the views expressed in the ACIP IP Enforcement Report and the IPCRC Report that requiring a balance of probabilities standard to be met before a patent application is accepted will increase the likelihood that a granted patent will be held to be valid. This is particularly important in relation to patents over genetic materials and technologies. The advantages of this approach include the potential to reduce enforcement costs by increasing a patent's prospects of validity. It is also worth noting that the patent law in many other jurisdictions requires patent examiners to apply a balance of probabilities standard, or an equivalent, with no apparent ill effects.

8.81 Imposing a balance of probabilities standard may not address all the concerns that have been raised about the examination of gene patent applications because there are inherent—and justifiable—limitations to the examination process.[138] In particular, the prosecution of a patent application is analogous to an *ex parte* procedure in that a patent examiner does not generally have the benefit of arguments and supporting evidence on both sides of any issue. The limitations of the examination process must also be seen in the light of other mechanisms in the patent system that allow the validity of patents to be tested. Other recommendations in this Report are directed to improving mechanisms for challenging patent rights and the way in which patents are exploited.[139]

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

138 See further, M Lemley, 'Rational Ignorance at the Patent Office' (2001) 95 *Northwestern University Law Review* 1.

139 See Ch 9, 10 and 19.

9. Challenging and Enforcing Patent Rights

Contents

Introduction

9.1 This chapter addresses issues relating to the law and practice of challenging and enforcing gene patents in Australia. The chapter first outlines the procedures available to challenge Australian gene patents, both prior to the grant of a patent and after a patent has been sealed. The chapter then addresses the variety of ways in which gene

patents may be enforced—from commercial negotiations to license a patent, to legal proceedings. The chapter also considers the factors that affect a patent holder's decision as to which enforcement strategies it will pursue. An important issue is the ability of Australian patent holders to detect infringing activities. The chapter addresses mechanisms for monitoring compliance with patent rights, including through information made available by IP Australia. The chapter concludes with a discussion of insurance policies that provide coverage for the costs of patent litigation.

Challenges to patent rights

9.2 Opportunities to object to the grant of patent rights exist at each stage of the patenting process—prior to acceptance of a standard patent application, after the Commissioner of Patents has accepted an application, and after a patent has been sealed. The mechanisms for challenging patent rights are discussed below.[1]

Intervention in the examination process

9.3 Under s 27 of the *Patents Act 1990* (Cth) (*Patents Act*), any person may intervene in the examination of a standard patent application. A person may file a notice (commonly referred to as a 's 27 notice') with the Patent Office asserting that the invention claimed in the patent application is not novel or does not involve an inventive step. The notice may be filed any time after publication, but before acceptance, of a complete application.[2] It must contain reasons for the assertion that the claimed invention is not patentable and attach any documentary evidence on which the assertion is based.[3]

9.4 Upon receipt of such a notice, the Commissioner of Patents must notify the applicant and make available copies of documents provided in support of the notice. In practice, documents provided to the Patent Office pursuant to a s 27 notice are included in the prior art information used by the examiner assessing the application, and are also open to public inspection.[4]

9.5 A patent examiner is not, however, required to raise an objection to an application based on information provided under a s 27 notice. Once the s 27 notice has been filed, the notifier does not take any further part in the prosecution of the patent application and will not be aware of the impact of the notice unless and until the application has been accepted.[5]

---

1 The mechanisms for challenging innovation patents were considered in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Ch 9.

2 *Patents Regulations 1991* (Cth) r 2.5.

3 *Patents Act 1990* (Cth) s 27(1); *Patents Regulations 1991* (Cth) r 2.7.

4 *Patents Act 1990* (Cth) s 27(3).

5 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8225].

9.6 A report by the Advisory Council on Intellectual Property (ACIP)[6] on the patenting of business systems (ACIP Business Systems Report) commented on the 'potentially great benefit' of the general public and industry experts providing prior art to patent examiners under a s 27 notice.[7] ACIP recommended that IP Australia should raise public awareness of the ability to submit relevant citations for specific patent applications pursuant to s 27.[8] Similarly, Professor James Lahore has commented that a s 27 notice 'has the advantage of cheapness and potential anonymity, and best suits circumstances of clear prior publication'.[9] He notes, however, that '[t]here is the disadvantage of telegraphed intentions without an opportunity to stay involved'.[10]

Opposition

9.7 The three primary mechanisms for challenging a patent after acceptance of the patent application are opposition, re-examination and revocation.

9.8 Any person may initiate proceedings to oppose the grant of a standard patent within three months of publication of a notice of its acceptance by the Commissioner of Patents.[11] Opposition to a standard patent thus occurs before the patent is sealed.

9.9 Currently, the grounds upon which an application for a standard patent may be opposed are limited to the following:[12]

- the applicant is not the person who is entitled to the grant of a patent, or is only entitled in conjunction with some other person;[13]
- 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* relating to sufficiency and fair basis; or
- the invention relates to human beings or to biological processes for their generation.

---

6 This body was formerly known as the Advisory Council on Industrial Property. ACIP is used in this Report to refer to both bodies.

7 Advisory Council on Intellectual Property, *Report on a Review of the Patenting of Business Systems* (2003), [10.3].

8 Ibid, rec 7.

9 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8225].

10 Ibid, [8225].

11 *Patents Act 1990* (Cth) s 59; *Patents Regulations 1991* (Cth) r 5.3(1).

12 *Patents Act 1990* (Cth) s 59.

13 The applicant is entitled to the grant of a patent only if it is either the inventor of the claimed invention or has a legal right to the claimed invention by operation of law or pursuant to an assignment by the inventor: Ibid s 15. See Ch 5.

9.10 An objection raised by an opponent, and the prior art cited in support of an objection, may be similar or in addition to that already overcome by an applicant during examination of the patent application by the Patent Office.[14] Opposition hearings are the responsibility of the Commissioner of Patents and are heard and determined by senior patent examiners within the Patent Office.

9.11 There are several possible outcomes of opposition proceedings. The Commissioner may dismiss an opposition on procedural grounds, either in whole or part;[15] the proceedings may result in the amendment of one or more of the patent claims in order to rectify deficiencies in the application; or the opposition may be successful, in which case the Commissioner may refuse to grant a patent.[16] The most common outcome of opposition proceedings is that the scope of the opposed patent claims is restricted. The patent holder or the opponent may appeal decisions of the Commissioner to the Federal Court.[17]

9.12 In practice, only a very small proportion of accepted applications—approximately 1.5%—are opposed.[18] Statistics on the number of oppositions filed in relation to gene patents are not readily available, but data for the broader category of biotechnology patents suggest that the number of oppositions is also very small.[19] According to data provided by IP Australia, in the five years from 1997–98 to 2001–02, there were only 14 substantive decisions made on biotechnology oppositions (an average of less than three per year), although 12 of these were successful.[20]

Review of the opposition process in Australia

9.13 Two reports have reviewed the system for opposing patents under Australian law—a 1999 ACIP report on the enforcement of intellectual property rights (ACIP Report)[21] and the 2000 report of the Intellectual Property and Competition Review Committee (IPCRC Report).[22] The reports addressed two principal concerns about the

---

14 Examination of patent applications and IP Australia's practices are discussed in Ch 5 and 8, respectively.

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

16 *Patents Act 1990* (Cth) s 60.

17 Ibid s 60(4).

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

19 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. For example, in December 2003, Benitec Ltd announced the settlement of opposition proceedings filed against its patents on DNA-directed RNA interference technology (ddRNAi): GenomeWeb, *Benitec Settles ddRNAi Dispute with Australia's CSIRO and DPI*, GenomeWeb Daily News, 9 December 2003, <www.genomeweb.com> at 16 June 2004; Benitec Ltd, *Milestone Strategic Agreement to Commercialise Australian Biotech Invention*, <www.benitec.com/news/index.htm> at 16 June 2004.

20 In this context, 'successful' means that the Patent Office decided in favour of the opponent on at least some grounds. It does not mean that the opposed application was refused in all cases, because the applicant may have been given an opportunity to amend the specification to remove any deficiencies.

21 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999).

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

current opposition process: whether oppositions should be available prior to the grant of a patent (as is currently the case) or only post-grant; and who should have responsibility for hearing opposition proceedings.

9.14 ACIP considered perceived deficiencies in the current system of pre-grant opposition, and commented on the fact that third parties may use opposition proceedings to delay the grant of a patent.[23] However, consultations conducted by ACIP indicated that industry did not generally support replacing pre-grant opposition with post-grant opposition. Further, the IPCRC Report indicated that there might be concerns about adopting a post-grant opposition procedure because such a review might be regarded as an unconstitutional exercise of judicial power by a non-judicial body (that is, by IP Australia).[24]

9.15 Both reports suggested that there was scope to improve the procedures for pre-grant opposition. The ACIP Report did not make a specific recommendation on this issue but encouraged IP Australia and the Institute of Patent and Trade Mark Attorneys of Australia to review the current procedures.[25] The IPCRC Report indicated that hearings officers in opposition matters should continue to comprise senior examination officers at the Patent Office. While a specialist hearing section—comparable to those in the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO)—did not need to be established, the IPCRC Report recommended that 'IP Australia take further measures to improve perceptions of the hearings process [for oppositions] being independent of, and more generally fair and equitable to, all parties'.[26] IP Australia has formed an Opposition Hearings and Legislation section in response to the issues raised in the IPCRC Report.[27]

Re-examination

9.16 Re-examination provides another mechanism for challenging the validity of a patent (or, in some cases, an accepted application for a standard patent).[28]

9.17 The only relevant issues in re-examination are whether the invention claimed in the patent or patent application is novel or involves an inventive step.[29] 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.[30]

---

23 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 24–25.

24 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 172.

25 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 24.

26 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 175.

27 The division of responsibility for patent matters within IP Australia is outlined in Ch 8.

28 *Patents Act 1990* (Cth) s 97.

29 Ibid s 98(1).

30 Ibid s 97.

9.18 Re-examination is conducted *ex parte*—that is, in the presence of one party, but not the other. The Commissioner of Patents is responsible for re-examination. However, in practice, re-examination is usually undertaken by patent examiners to whom the Commissioner has delegated the power to examine patent applications.[31]

9.19 As a result of re-examination, one or more claims in a patent may be amended as directed by the Commissioner.[32] The Commissioner also has power to refuse to grant a patent application, or to revoke an issued patent (either in whole or part) that has been the subject of an adverse re-examination report.[33]

9.20 A patent holder may appeal decisions of the Commissioner on re-examination to the Federal Court.[34] Third parties, however, have no right to 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 available course of action is to apply for revocation under s 138 of the *Patents Act*.[35]

9.21 Prior to amendments to the *Patents Act* in 2001,[36] the re-examination provisions had been invoked only on a few occasions and it had been suggested that other mechanisms for challenging patents were more attractive.[37] IP Australia informed the ALRC that re-examination is now more common as a result of amendments to s 45(3), requiring an applicant to disclose to the Patent Office the results of searches carried out by or on behalf of foreign patent offices in respect of an invention claimed in an Australian patent application, or in a corresponding patent application filed overseas. IP Australia indicated that the increase in the number of re-examinations is largely a result of this change in procedure, rather than changes in the behaviour of third parties who wish to challenge patent rights.

Revocation

9.22 A patent may be revoked after it has been granted. Typically, an application for revocation of a patent is filed as a counter-claim to a claim of infringement.[38] However, a person may seek revocation of a patent independently of infringement proceedings.[39]

---

31 This is referred to as 'acceptance delegation' and is discussed in Ch 8: Ibid s 209. See also P Spann, Re-examination in Australia: 10 Years on' (2002) 13 *Australian Intellectual Property Journal* 97, 98.

32 *Patents Act 1990* (Cth) ss 100A(2)(b), 101(2)(b).

33 Ibid ss 100A(1), 101(1).

34 Ibid ss 100A(3), 101(4).

35 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [21.9.4].

36 *Patents Amendment Act 2001* (Cth) s 14, amending s 45(3) of the *Patents Act 1990* (Cth).

37 P Spann, 'Re-examination in Australia: 10 Years on' (2002) 13 *Australian Intellectual Property Journal* 97, 98–99.

38 *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).

39 Ibid s 138(1).

9.23 The grounds upon which an application for revocation may be made are broader than those for opposition or re-examination. The grounds include that:[40]

- the patent holder is neither the inventor, nor has a legal right to the invention and is therefore not entitled to the patent;
- the invention is not a 'patentable invention' as defined in s 18;[41]
- the patent holder has contravened a condition in the patent;
- the patent was obtained by fraud, false suggestion or misrepresentation; or
- the patent specification does not comply with s 40(2) or s 40(3) relating to sufficiency and fair basis.

Other jurisdictions

9.24 Patent laws in some other jurisdictions, such as Canada and the United States, provide more limited mechanisms for challenging patent rights both before and after a patent has been granted.[42] However, recent reviews in these countries have proposed reforms, with a view to promoting mechanisms for challenging patent rights that are cheaper and less complicated than court proceedings.

9.25 In Canada, two reports published in 2002 recommended the introduction of an opposition procedure to allow challenges within a limited period following the grant of a patent.[43] Similarly, in the United States, the Federal Trade Commission and the National Research Council have recommended improvements to the procedures for post-grant review of patents, which would allow third parties to challenge the validity of a patent on broader grounds than are currently available under United States law.[44]

---

40 Ibid s 138(3). Additional grounds for revocation are set out in ss 134 and 137(3) of the *Patents Act*.

41 Amendments to the *Patents Act* may be required to preserve this ground for revocation when the Australia–United States Free Trade Agreement (AUSFTA) comes into force. The AUSFTA provides that 'a patent may only be revoked on grounds that would have justified the refusal to grant a patent', but all of the requirements for patentability set out in s 18 of the *Patents Act* are not currently assessed in examination: Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004 art 17.9.5; *Patents Act 1990* (Cth) s 45; IP Australia, *Consultation*, Canberra, 6 April 2004. See Ch 6.

42 See further Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [9.30]–[9.33].

43 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), rec 13; Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(g).

44 United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), rec 1; United States National Research Council, *A Patent System for the 21st Century (Prepublication Copy)* (2004), 78–83. Currently, patent rights may be challenged under United States law by interference proceedings, and by *ex parte* or *inter partes* re-examination: 35 USC ss 135, 301–307, 311–318.

The USPTO has also contemplated improving the available grounds for post-grant review of patents as part of its *21st Century Strategic Plan*.[45]

Submissions and consultations

9.26 The ALRC sought comments about whether existing mechanisms for challenging gene patents were adequate, or whether additional or alternative mechanisms might be required. Submissions and consultations did not support the introduction of new mechanisms to permit challenges specifically to gene patent applications or granted gene patents.[46] A number of submissions commented that the current mechanisms for challenging patents are generally satisfactory.[47] Dr Amanda McBratney and others considered that current procedures strike the right balance between giving third parties an opportunity to test the validity of a patent or patent application and not unduly delaying the grant of patent rights.[48] The peak body of the Australian biotechnology industry, AusBiotech Ltd, indicated that its members generally considered that the Australian procedures for challenging patents were better than in other jurisdictions, such as Europe or the United States.[49]

9.27 However, many submissions indicated that, while the mechanisms for challenging patent rights might be effective if invoked, the financial cost of a patent challenge is often prohibitive, particularly for smaller organisations and public sector institutions.[50]

9.28 A small number of submissions proposed specific reforms to the current mechanisms for challenging patent rights.[51] The Australian Centre for Intellectual Property in Agriculture (ACIPA) suggested that third party participation in patent challenges should be facilitated, for example by expanding the grounds on which a

---

45 United States Patent and Trademark Office, *21st Century Strategic Plan*, <www.uspto.gov/web/offices/com/strat21/index.htm> at 16 June 2004; United States Patent and Trademark Office, *Action Paper: Post-Grant Review of Patent Claims* (2003).

46 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; IP Australia, *Submission P56*, 4 November 2003; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

47 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

48 A McBratney and others, *Submission P47*, 22 October 2003.

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

50 Cancer Council Australia, *Submission P25*, 30 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

51 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

patent may be re-examined and allowing third party appeals from adverse re-examination decisions.[52] ACIPA and the Centre for Law and Genetics also encouraged the ALRC to consider whether changes recommended to the procedures for post-grant review of United States patents should be implemented in Australia.[53]

ALRC's views

9.29 The ALRC's view is that no changes are currently required to the mechanisms for challenging gene patent applications or granted gene patents. The ALRC agrees with submissions that suggested that genetic materials and technologies do not give rise to any special needs in this regard.

9.30 No evidence was provided to the Inquiry that the opposition, re-examination or revocation procedures set out in the *Patents Act* are inadequate avenues for challenging gene patent rights. While a few submissions considered that proposed changes to the mechanisms for challenging patents under United States law might be implemented in Australia, the ALRC does not support this approach. The avenues for challenging Australian patents are already more extensive than those available under United States law. Furthermore, differences between jurisdictions—both as to the substance and administration of patent law—mean that procedures for challenging patent rights are not automatically transferable from one system to the other.[54]

9.31 Third parties may intervene in each stage of the patent process and, in the ALRC's view, no additional avenues for intervention are currently required. However, in Chapter 6 the ALRC recommends that 'usefulness' should be considered by Australian patent examiners in examining patent applications and, consequently, should be a ground upon which an accepted patent application may be opposed (see Recommendation 6–3).

9.32 Some submissions expressed concern about the cost involved in challenging patent rights. The large investment of time and resources required to challenge a gene patent might result in patents of questionable validity not being challenged. In the ALRC's view, this is not necessarily a failure of the mechanisms currently available to challenge patents, but it does raise questions about who should initiate such challenges. As discussed later in this chapter, litigation insurance may provide a person with the financial resources necessary to conduct patent litigation. In addition, Chapter 19 considers ways in which health departments and other organisations may participate more actively in evaluating and, if necessary, challenging patents that may have an adverse impact on human health or genetic research. As discussed in that chapter,

---

52 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

53 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

54 For example, the Board of Patent Appeals and Interferences in the United States is a tribunal operating within the USPTO. Administrative patent judges sit on the Board and hear appeals from decisions of patent examiners in relation to patent applications and determine issues of priority and patentability in interference proceedings: 35 USC s 6. No equivalent body exists in Australia.

intervention in patent processes by public sector agencies can achieve public policy outcomes, as demonstrated by the revocation of Myriad Genetics' European patent on the BRCA1 gene as a result of opposition proceedings filed by a group of healthcare organisations.

Enforcement of patent rights

9.33 Patent protection is generally sought in order to secure and preserve the competitive and commercial advantage that may result from an invention, as well as to recoup the cost incurred in developing an invention. Patent rights are of limited value unless they are enforced to deter potential infringers and to provide a remedy for a person whose rights have been infringed. Nonetheless, a patent holder typically makes strategic decisions about the best use of its resources in enforcing its rights.

Factors affecting the decision to enforce a patent

9.34 Several factors might affect the decision of an Australian patent holder as to whether to enforce its patent rights. Enforcement of a patent is dependent on a patent holder identifying individuals or entities that are infringing its patent rights. In the case of gene patents, infringement may be difficult to detect.[55] Many biotechnology companies may not yet have commercial products that could lead a patent holder to suspect that products have been developed using patented research tools.[56] The procedures for monitoring the use of Australian patents, and the difficulties that Australian gene patent holders may face in discovering infringement, are discussed later in this chapter.

9.35 Apart from the difficulties of detection, a patent holder may decide not to instigate action to prevent infringement of its gene patents, even though such measures are warranted. Patent protection is frequently obtained in more than one jurisdiction and an Australian patent holder may choose to enforce its rights in those jurisdictions that represent the largest markets for a patented product. Even if the Australian market for a patented product is significant, a patent holder may decide that pursuing certain infringers is not financially viable, or could attract too much adverse publicity.[57]

---

55 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 47; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 215–216, 257.

56 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 48; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 147–148.

57 Such factors may be particularly relevant if the alleged infringer is an academic institution: D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 220. See also Ch 12 and 13 for a discussion of gene patents in the context of genetic research.

9.36 A patent holder may also select particular defendants for tactical reasons.[58] For example, a patent holder might pursue alleged infringers with limited financial resources, who are therefore unlikely to challenge the patent holder's rights, before seeking to enforce the patent against better-resourced entities.

9.37 Infringement proceedings also expose the validity of a patent to attack. As discussed above, a defendant may file a counter-claim for revocation so that a patent holder seeking to enforce its rights may be required to prove both that the rights are valid and that they have been infringed. There has been relatively limited consideration of the application of Australian patent law to genetic materials and technologies to date. In the absence of judicial decisions delineating the scope of rights conferred by a gene patent, infringement proceedings may be thought to entail too great a risk.[59]

9.38 Finally, patent litigation is generally a complex, time-consuming and costly process. In Australia, it has been estimated that the cost to a patent holder of litigating a patent infringement action at first instance may be $750,000 or more.[60] This figure may be conservative. In light of the fact that the Australian biotechnology sector is dominated by small and medium sized enterprises (SMEs) and publicly funded research organisations,[61] such amounts are significant.

Commercial responses to infringement

9.39 If a patent holder decides to enforce its patent, it may employ a variety of means to do so, including commercial actions and legal proceedings. A patent holder may notify a potential infringer of the existence of a patent and indicate that the use of the invention claimed in the patent should be terminated—often referred to as a 'cease and desist letter'. Alternatively, a patent holder may notify a potential infringer of the existence of a patent and request that activities covered by the patent claims be conducted only pursuant to a licence—commonly termed an 'offer to license'. If these approaches are not successful, a patent holder may need to consider initiating civil proceedings to enforce the patent.

---

58 J Berkowitz, *United States: Trends in Enforcing and Licensing Patents*, Mondaq, <www.mondaq.com> at 16 June 2004.

59 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 257.

60 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 152. The cost of patent infringement actions in Australia is relatively low compared with the United States, where it has been estimated that the average cost of patent infringement litigation (including appeals) is US$1.5 million: Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 152. Others have suggested that litigation costs in biotechnology matters have ranged from US$5 million to US$7 million: United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), Ch 3, 22.

61 See Ch 16; D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347.

Legal responses to patent infringement

9.40 A patent holder (or its exclusive licensee) may take legal action to prevent the infringement of the exclusive rights granted pursuant to a patent.[62] Patent infringement may be either direct or contributory. The infringement is direct if a person, without authorisation, exercises any of the exclusive rights conferred on the patent holder.[63] Infringement is contributory if a person who is not the patent holder or a licensee supplies a product the use of which would constitute an infringement of the patent.[64]

9.41 A patent will be infringed if the defendant has taken all of the essential features (or 'integers') of the patent holder's claim.[65] Thus, a court must determine whether or not the substantial idea of an invention disclosed in a patent specification (and subject to a definite claim) has been taken and embodied in an item alleged to infringe the patent. Australian courts have found that omitting an inessential part of a patent claim, or replacing it with an equivalent, will not necessarily prevent a finding of infringement.[66] What constitutes an 'essential integer' is a matter of construction of the patent specification. In general, it has been held that such construction must be purposive rather than purely literal.[67]

9.42 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.[68]

Defences to patent infringement

9.43 The *Patents Act* establishes a limited number of defences, which may be asserted in answer to 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;[69]

---

62 An exclusive licensee who initiates infringement proceedings must join the patent holder as a party to the suit, and the licensee's interest in the patent must be entered on the register of patents maintained by IP Australia: *Patents Act 1990* (Cth) ss 120(2), 187; *Patents Regulations 1991* (Cth) r 19.1. In infringement proceedings initiated by an exclusive licensee, the licensee stands in the shoes of the patent holder, subject to any additional terms relating to enforcement of patent rights in the licence agreement (for example, allocation of any damages awards, liability for the costs of any infringement proceedings, or the right to control proceedings).

63 Direct infringement of a patent is not defined in the *Patents Act*, but can be inferred from s 13: see R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 318.

64 *Patents Act 1990* (Cth) s 117.

65 *Populin v HB Nominees Pty Ltd* (1982) 41 ALR 471, 475.

66 *Fisher & Paykel Healthcare Pty Ltd v Avion Engineering Pty Ltd* (1991) 103 ALR 239.

67 *Populin v HB Nominees Pty Ltd* (1982) 41 ALR 471, 476. However, at least one 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.

68 *Patents Act 1990* (Cth) s 57.

69 Ibid s 118.

- prior use of an invention, provided the alleged infringer did not obtain the subject matter of the invention from the patent holder (or its predecessor in title);[70]

- use of a patented invention that is subject to a contractual condition prohibited under s 144 of the *Patents Act* (such as a 'tie-in' arrangement);[71] 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.[72]

9.44 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.[73] This defence is limited to circumstances in which the pharmaceutical substance claimed in the patent was used: (a) after the extension of the patent term has been granted, for the purpose of registering a product on the Australian Register of Therapeutic Goods (or any foreign equivalent thereof); or (b) during the extended portion of the patent term, for a non-therapeutic purpose.

9.45 In addition to these defences, it has been suggested that general equitable defences may be available against a claim of patent infringement.[74] The circumstances in which such defences may be available were outlined in DP 68,[75] but there is little case law on this issue[76] and the effect of pleading such a defence is unclear. It should also be noted that Chapter 13 of this Report recommends that the *Patents Act* be amended to enact a new exemption based on the experimental use of a patented invention.

Remedies

9.46 If a patent holder successfully proves that its patent has been infringed, remedies are available to prevent further infringement and to compensate the patent holder for any loss incurred. These remedies include an injunction and either compensation in the

---

70 Ibid s 119.

71 See further Ch 24.

72 *Patents Act 1990* (Cth) ss 124–127. A declaration of non-infringement is a court order that use of an invention does not fall within the scope of the claims of a particular patent. It may be obtained only if a person or company has previously sought an admission from the patent holder that their proposed activities are not within the scope of the relevant patent claims and the patent holder has refused, or failed to provide, such an admission. A declaration of non-infringement is not a complete defence, and may limit but not negate the award of damages.

73 Ibid s 78.

74 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155; J Bergmann and T Davies, 'Junk DNA or Junk Debate?', *Allens Arthur Robinson Biotech News*, 3 September 2003, <www.aar.com.au/pubs/bt>.

75 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [9.78]–[9.80].

76 See, eg, *Woodbridge Foam Corp v AFCO Automotive Foam Components Pty Ltd* [2002] FCA 883.

form of damages or an account of profits, at the patent holder's option.[77] A court may also make orders for the inspection[78] and delivery up of infringing materials.[79]

9.47 Provisional relief is available 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.[80]

Enforcement of gene patents in Australia

Submissions and consultations

9.48 During the Inquiry, the ALRC sought information about the enforcement of Australian gene patents, the factors affecting Australian entities' decisions to enforce gene patents, and the type of action such entities initiate in this regard.[81]

9.49 Submissions that addressed this issue reflected different views as to what amounts to 'enforcement' of a gene patent. A number of submissions used the term to refer only to infringement proceedings. Others adopted a broader view and regarded 'offers to license' a patent as also amounting to enforcement action. A few submissions considered that the term encompassed an even wider range of actions. For example, a multi-national pharmaceutical company, GlaxoSmithKline, commented that patents may be effective on a number of levels, including:

> (a) providing a deterrent against infringement, (b) giving rise to licensing or cross-licensing arrangements, (c) being the subject of letters of demand, and (d) being the subject of full scale patent infringement litigation.[82]

9.50 A number of submissions commented on the apparently low level of enforcement activity that is occurring in Australia with respect to gene patents.[83] AusBiotech Ltd indicated that 'so far there has been very little actual litigation'.[84] However, the low level of patent litigation does not take into account disputes that have been settled, or disputes that occur prior to a gene patent being granted (for

---

77 *Patents Act 1990* (Cth) s 122(1). However, a court may decline to award damages or an account of profits in the case of 'innocent' infringement; that is, if the infringer was not aware, and had no reason to believe, that a patent for the invention existed: *Patents Act 1990* (Cth) s 123.

78 *Patents Act 1990* (Cth) s 122(2).

79 See, eg, *Roussel Uclaf v Pan Laboratories Pty Ltd* (1994) 51 FCR 316.

80 Interlocutory relief may also be available by means of an Anton Piller Order: *Anton Piller KG v Manufacturing Processes Ltd* [1976] Ch 55. See also R Meagher, D Heydon and M Leeming, *Meagher, Gummow and Lehane's Equity: Doctrine and Remedies* (4th ed, 2002), [21.495]–[21.500]; B Fitzmaurice, 'Protecting Intellectual Property with Anton Piller Orders' (2002) 15 *Australian Intellectual Property Law Bulletin* 103.

81 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 10–4.

82 GlaxoSmithKline, *Submission P33*, 10 October 2003. See also Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

83 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003.

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

example, opposition proceedings).[85] Other submissions agreed that the level of enforcement of gene patents is difficult to gauge,[86] particularly because communications about such matters are generally confidential unless infringement proceedings are initiated.[87]

9.51 The factors that may influence a patent holder's decision as to how to enforce a gene patent were addressed in a number of submissions. The Department of Industry, Tourism and Resources suggested that the cost of gene patent litigation is 'a major factor influencing the capacity to enforce gene patents'.[88] Other submissions indicated that the costs of infringement litigation might act as a disincentive to pursue individuals or entities who are infringing Australian gene patents,[89] particularly in the case of research institutions.[90] Some submissions commented that the cost of infringement litigation is an issue in enforcing patents over any type of technology, not only gene patents.[91] Submissions also suggested that the cost of gene patent litigation encouraged patent holders and potential infringers to license gene patent rights or reach some other commercial solution to potential infringement.[92]

9.52 Submissions identified other factors as influencing a patent holder's decision to enforce its rights. GlaxoSmithKline and Davies Collison Cave referred to the provisions in the *Patents Act* that provide for action to be taken against a patent holder who makes 'unjustified threats of infringement'.[93] It was said that, as a result, patent holders 'will generally not make threats of initiating legal proceedings unless they are prepared to actually proceed in this manner'. Other submissions commented that the potential for adverse publicity might also affect the decision to enforce patents against particular types of entities, such as academic institutions.[94]

---

85 Ibid.

86 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

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

88 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003. See also Queensland Government, *Submission P57*, 5 January 2004.

89 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Royal College of Pathologists of Australasia, *Consultation*, Sydney, 30 March 2004.

90 A McBratney and others, *Submission P47*, 22 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 220, 257.

91 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

92 GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004.

93 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003 (referring to ss 128–132 of the *Patents Act*).

94 Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

Nicol–Nielsen Study

9.53 A recent empirical study conducted by Dr Dianne Nicol and Jane Nielsen into patenting and technology transfer practices in the Australian medical biotechnology industry (Nicol–Nielsen Study) reported responses largely consistent with the views expressed in submissions to this Inquiry. Nicol and Nielsen concluded that there has been little enforcement of gene patents in Australia to date.[95] Respondents to the Nicol–Nielsen Study indicated that potential patent infringement issues are most often resolved by negotiating a licence to use the patented invention. Nicol and Nielsen commented, however, that there is evidence that this situation may be changing in other jurisdictions, and that enforcement actions may become more likely in Australia.[96] In particular, they noted that Genetic Technologies Limited's (GTG) announcements of the steps being taken to license and enforce the company's non-coding DNA patents occurred after responses to the study had been received.[97]

Monitoring compliance with patent rights

Monitoring by Australian patent holders

9.54 A patent holder's ability to enforce its rights depends on its ability to obtain information about third parties' activities that may infringe the claims of a patent. Such information may be obtained from a variety of sources, including in-house procedures established by a patent holder, patent offices, or private information services that monitor patent compliance. The mechanisms by which Australian patent holders may monitor and investigate potentially infringing activities are considered below.

9.55 Information and resources within a patent holder's organisation are two means by which potential patent infringers may be detected. Employees of a patent holder may be in the best position to identify potential infringement by third parties because of their familiarity with the relevant area of technology, the identity of competitors, and competitors' business activities.

9.56 'Patent watch' services, which are generally provided by law firms or patent attorneys, may also be used. Patent watch services review notices in the Official Journals published by patent offices, as well as other computer databases covering patent and technical data, for information about inventions or patent filings that may infringe a patent holder's rights. Searches may be restricted by subject matter (for example, to a particular genetic sequence or technology), or by organisation name (for

---

95 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 38, 201–204, 217, 256-257.

96 Ibid, 61–63, 139–140, 199–203. Referring to studies conducted by Dr Mildred Cho and her colleagues: see, eg, M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3; J Merz and others, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577.

97 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 106, 139–140, 202, 256. Aspects of GTG's licensing practices and its non-coding patents are discussed in Ch 12 and 20.

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.[98]

9.57 It is somewhat easier for patent holders to monitor the activities of third parties who have been authorised by them to use a patented genetic invention pursuant to a licence agreement. Mechanisms for monitoring a licensee's compliance with the terms of a licence are typically stipulated in the agreement (see Chapter 22). A patent licence may include a requirement that a licensee submit periodic reports detailing product sales or—if research and development is still required in connection with licensed gene patents—describing progress during the reporting period. A patent holder may have the right to audit a licensee's records relevant to activities covered by an agreement—for example, financial accounts and 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.

Monitoring by users of Australian gene patents

9.58 Individuals, research organisations and biotechnology companies may conduct prior art searches before embarking on a particular line of research, or commercialising any genetic material or technology, to ensure that their activities will not infringe existing patent rights.

9.59 Respondents to the Nicol–Nielsen Study indicated that conducting prior art searches is an onerous and expensive exercise, and is becoming increasingly more difficult as the gene patent landscape becomes more complex.[99] The study found that prior art searches are commonly conducted by Australian biotechnology companies to ensure that research does not infringe third party patent rights. However, the research institutions and diagnostic facilities surveyed in the Nicol–Nielsen Study demonstrated less inclination to perform such searches.[100] Prior art searches by such entities might occur only when a commercial application for the relevant research becomes apparent.[101] Nicol and Nielsen concluded that 'there is some desirability for finding ways of reducing the onerous demands of patent searching and tracking infringement'.[102]

Patent information available from IP Australia

9.60 IP Australia makes information about granted patents and published patent applications available in the *Official Journal of Patents* (*Official Journal*); by way of

98 Most patent applications are published 18 months after the date on which the application was first filed: see Ch 5.

99 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 181–182.

100 Ibid, 178–179.

101 Ibid, 180.

102 Ibid, 259. For Nicol and Nielsen's suggested solutions to these problems see Ch 22 and 23.

searchable online databases on IP Australia's website; and by subscription to CD–ROMs containing copies of patent applications and specifications.

9.61 Section 222 of the *Patents Act* provides for publication of the *Official Journal* by the Commissioner on a periodic basis. The *Official Journal* contains notices and other matters prescribed in the *Patents Act* and the *Patent Regulations*. The *Official Journal* reports all significant events and actions that occur in relation to each Australian patent, as well as general information and notices about amendments to Australian patent law or the *Patent Cooperation Treaty* (PCT), or to IP Australia's practices. The *Official Journal* is available from IP Australia's offices and is distributed on CD–ROM to libraries and other reference organisations throughout Australia. A supplement to the *Official Journal*—containing only information about patents included in the New Patent Solution System—is made available by IP Australia on its website. IP Australia intends to make the entire *Official Journal* available electronically in the future.

9.62 IP Australia also provides online access to a number of databases that contain information about Australian patents and patent applications.

- Patents mainframe bibliographic databases—*Patent Administration System* (PatAdmin) and *Patent Indexing System* (PatIndex)—provide bibliographic information about patent applications that have been filed up to 4 July 2002, including patent or application number, inventor and applicant, as well as current status of the patent or application.

- *AU Published Patent Data Searching* (APPS) contains Australian patent abstracts; that is, the first page of a patent application at the time of its publication.

- *Patent Specifications Database* contains complete copies of published Australian patent applications (other than Australian patent applications filed under the PCT).[103]

- *New Patent Solution System* (now known as Patsearch) provides bibliographic information about patent applications filed from 5 July 2002, similar to the information available for patent applications filed before this date in the PatAdmin and PatIndex databases.

9.63 Currently, the databases on IP Australia's website contain overlapping information and each database is limited in the information it contains. To conduct a patent search on IP Australia's website, at least two databases (and frequently more) must be used, and the search results must be cross-referenced in order to cover all

103 A user is transferred to the EPO's online database, 'esp@cenet', for copies of Australian patent applications filed under the PCT, which are published prior to acceptance.

necessary information. The nature of a user's needs will determine which of IP Australia's databases must be accessed to obtain the relevant information. For example, if a user requires bibliographic information about a patent application, a search of both PatAdmin and Patsearch would be required to complete a search. However, if a user requires information on an invention claimed in a patent application, a search of APPS and certain of IP Australia's CD–ROM products would be appropriate.[104] This is time-consuming and may potentially produce misleading results, particularly for inexperienced users, or those with a limited understanding of the Australian patent system.

9.64 Online databases provided by patent offices in some other jurisdictions, such as the USPTO and EPO, are more user-friendly. Search functionality is concentrated in one area of their website, and searches may be conducted using a wide range of fields.[105] Search results include both bibliographic information about the patent and a copy of the complete patent specification, or a patent application (if published).

9.65 IP Australia informed the ALRC that it is in the process of upgrading its online databases and facilitating links between its various databases. Patsearch is a new patent database developed by IP Australia, and operates in parallel to the PatAdmin system. IP Australia intends to 'migrate relevant data from the PatAdmin into [Patsearch]' and provide a single search portal for these databases. IP Australia is also continuing to improve the search functions of Patsearch to provide access to additional information that users may wish to obtain.[106]

9.66 In addition, IP Australia is investigating ways to facilitate links between searches of bibliographic information about a patent or patent application with the relevant patent abstract or complete specification.[107] For example, IP Australia is considering linking the results of searches in Patsearch with relevant abstracts stored in the APPS. It is also investigating the cost-effectiveness of providing full-text searching capability for Australian patent specifications.

9.67 In 2003, the ACIP Business Systems Report commented on the benefits of users being able to conduct keyword searches of patent abstracts and specifications contained in IP Australia's online databases.[108] ACIP recommended that IP Australia make the abstracts of all Australian patent applications and grants searchable by text

---

104 IP Australia is in the process of ensuring that APPS contains abstracts from patent applications that are included in both the PatAdmin and Patsearch so that a search of the APPS system alone would be sufficient in this case.

105 For example, the USPTO database allows searches using the following fields: patent number and application serial number; type of patent application; inventor name, applicant and assignee name or location; patent title; issue date; application date; claim and specification details; patent classification; registered interested (eg, security interests, exclusive licenses and US government interests); patent examiner who assessed the application; and patent attorney of record.

106 IP Australia, *Submission P86*, 16 April 2004; IP Australia, *Consultation*, Canberra, 6 April 2004.

107 IP Australia, *Submission P86*, 16 April 2004; IP Australia, *Consultation*, Canberra, 6 April 2004.

108 Advisory Council on Intellectual Property, *Report on a Review of the Patenting of Business Systems* (2003), 39.

and International Patent Classification number[109] on the IP Australia website as soon as possible. ACIP also recommended that this should extend to full text searching of complete specifications at a later stage.[110]

Information about patent proceedings

9.68 Currently, there is no centralised public source of information about litigation involving challenges to, or the enforcement of, Australian patent rights.[111] Limited information about opposition proceedings is published in the *Official Journal* and is included in Patsearch for patent applications filed from 5 July 2002. Information about court proceedings involving a particular patent can be obtained only at the registry of the federal, state or territory court in which the proceedings were filed,[112] or by searching judicial decisions on patent matters. This can be complex, time-consuming and costly. In addition, such a search will not always reveal pending patent proceedings, or those that have settled prior to a judgment being given.

9.69 Information about patent proceedings may be relevant to potential licensees of a patent, or entities that are alleged to have infringed a patent. These entities may wish to know if the relevant patent is the subject of legal proceedings, or its validity has previously been considered. This information may inform decisions by potential licensees and alleged infringers about the strength of the patent, and in the case of a potential licensee, assist in assessing the value of the licence.

9.70 Other jurisdictions have mechanisms to make information about patent proceedings more easily accessible. In the United States, courts are required to notify the Director of Patents when legal proceedings relating to a patent are filed and upon a decision or judgment being issued in any such proceedings.[113] The notice must include the names and addresses of the parties, the name of the inventor and the number of the patents at issue in the proceedings. The information contained in the notices is included in the file of each patent held by the USPTO.

Submissions and consultations

Comprehensive database of patent information

9.71 DP 68 proposed that IP Australia develop and regularly update a searchable online database comprising patents and published patent applications. The ALRC contemplated that this database would provide user-friendly access and search

---

109 The International Patent Classification system is discussed in Ch 8.

110 Advisory Council on Intellectual Property, *Report on a Review of the Patenting of Business Systems* (2003), rec 8.

111 Information about Australian patent proceedings may be available in some patent databases compiled by commercial firms, although access to such information is fee-based.

112 Members of the public require a court file number for the proceedings to conduct such a search: Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

113 35 USC s 290. Similar obligations exist in relation to registered trademarks and registered copyrights: 15 USC s 1116(c); 17 USC s 508.

capabilities on a wide variety of bases and that, if a fee is charged for use of the database, it would be kept at a level that does not unreasonably limit access.[114]

9.72 The difficulty of obtaining information about gene patents and pending gene patent applications was identified as a problem during the course of the Inquiry.[115] A large number of submissions supported the ALRC's proposal to facilitate access to this information, including those from the healthcare, research, government and industry sectors.[116]

9.73 A number of submissions and consultations stated that access to the proposed database should be free.[117] The Centre for Law and Genetics commented that 'any requirement to pay a fee would undermine the public disclosure component of the patent system'.[118] Free access to online patent information would also be consistent with the practice of other major patent offices, such as the USPTO and the EPO.

9.74 Submissions supported the proposed database for a variety of reasons. The Caroline Chisholm Centre for Health Ethics commented that availability of patent information would 'bolster confidence in the patent system'.[119] Other submissions suggested that easy access to patent information would decrease the likelihood of third parties infringing patent rights and duplication of research effort in areas of genetic technology already protected by patent rights.[120] Another submission commented that facilitating access to information about existing patent rights would assist processes for challenging patents.[121]

9.75 However, some submissions indicated that, even if the proposed database facilitated access to information about Australian patents, appropriate professional

---

114 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 9–1.

115 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; AusBiotech Ltd, *Consultation*, Melbourne, 2 April 2004.

116 See, eg, Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; AusBiotech Ltd, *Submission P94*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

117 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; AusBiotech Ltd, *Consultation*, Melbourne, 2 April 2004.

118 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

119 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004.

120 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004.

121 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

advice should be obtained before filing for patent protection or seeking to enforce patent rights.[122] In particular, IP Australia commented:

> It is also important not to underestimate the complexity of searching and analysing IP data. No amount of user-friendliness of the database search tool can substitute for the significant skill that must be possessed by the searcher, especially in relation to infringement searches. Also, as Australian patents make up a very small proportion of patents worldwide, searches conducted to check the novelty of an invention must consider foreign databases as the primary source.[123]

Information about patent proceedings

9.76 The Intellectual Property Research Institute of Australia (IPRIA) suggested that the *Patents Act* be amended to impose an obligation on Australian courts to report patent proceedings to IP Australia, based on the model provided by United States patent law. IPRIA considered that this information should include, at a minimum, the patent number and court file number for relevant proceedings. IPRIA noted that details of the parties to proceedings and how such proceedings are terminated (whether settled, withdrawn or the subject of a judgment) would also be useful. IPRIA submitted that IP Australia should include information contained in such notices in the comprehensive online database proposed by the ALRC.[124] No other submissions addressed this issue.

ALRC's views

9.77 The ALRC considers that IP Australia should develop a comprehensive database that incorporates, and centralises in a user-friendly format, the patents information already made available by IP Australia on its website.

9.78 Submissions and consultations indicated that information about Australian gene patents is not readily accessible and that this impedes the licensing and enforcement of gene patents. The ALRC considers that a comprehensive database of patent information, developed by IP Australia, could assist inventors, biotechnology companies and research organisations in conducting preliminary searches of existing Australian patents and published patent applications, which are an important part of any prior art search. Such a database could assist in identifying whether a particular activity or area of research involves intellectual property problems, or in refining the scope of a comprehensive prior art search.

9.79 Currently, patent information is provided by IP Australia in a number of overlapping databases. Developing a comprehensive database relating to all Australian patents and published patent applications would allow searches for patents and published patent applications claiming genetic materials and technologies, as well as all other types of inventions.

---

122 GlaxoSmithKline, *Submission P33*, 10 October 2003; Queensland Government, *Submission P57*, 5 January 2004; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

123 IP Australia, *Submission P86*, 16 April 2004.

124 Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

9.80 Some of the other difficulties that a user currently encounters in searching for patent information using IP Australia's on-line databases may be addressed when improvements to Patsearch are completed. However, in its current form, Patsearch does not provide all of the information that a user might require when conducting a patent search. For example, access to full copies of patent specifications (for the purpose of obtaining information about claimed inventions) is available only from a separate database with limited search capability. Further, Patsearch only contains information about patents filed after 5 July 2002.

9.81 Much of the information that should be contained in any new patent database is already available to IP Australia, but would need to be compiled and centralised. In identifying the criteria by which such a database may be searched, the databases offered on the USPTO and EPO websites are worthwhile models. In the ALRC's view, the ability to conduct searches of the patents database based on any of the following information would be useful: patent number and application serial number; inventor name; applicant name and assignee name; patent title; issue date; application date; specification details; patent classification; and registered encumbrances (for example, security interests and exclusive licenses). Many of these search criteria are available in Patsearch, which provides a valuable starting point.

9.82 The ALRC also believes that full-text searching of Australian patents and patent applications should be made available by IP Australia[125] and encourages IP Australia to continue its investigations into how this facility may best be offered on its website.

9.83 Developing a comprehensive online database with full text search capability is likely to require considerable resources on the part of IP Australia. As noted above, submissions expressed concern about the potential effect of charging a fee for use of the database. The ALRC is of the opinion that accessibility of the information is a primary consideration and that, if IP Australia were to charge a fee to some or all users, the fee should be nominal.

9.84 The ALRC is also of the view that the proposed database should contain information about court proceedings concerning Australian patents. The *Patents Act* should be amended to require courts exercising jurisdiction under the Act to notify the Commissioner of Patents when legal proceedings to challenge or enforce a patent are commenced, and when a decision is given in any such proceeding. This information should be made readily available to the public, for example in the *Official Journal* and in the patents database on IP Australia's website. Amendments should also be made to the Rules of Court of courts exercising jurisdiction under the *Patents Act*, where necessary, to give effect to this recommendation.[126]

---

125 See, eg, AusBiotech Ltd, *Submission P94*, 16 April 2004.

126 There appears to be no need to impose a similar obligation on the Administrative Appeals Tribunal (AAT). Although the AAT has power to review certain decisions of the Commissioner of Patents, these relate primarily to procedural matters, rather than to the scope of patent claims or the exploitation of patent rights. See Ch 10.

9.85 The ALRC recognises that the role of IP Australia is not, and should not be, to provide advice to prospective patent applicants about their ability to obtain patent protection, or to users of patent rights about freedom to operate in a particular field. It is important, therefore, that individuals and corporations obtain legal advice in appropriate cases about filing for patent protection, enforcing patent rights, or defending against allegations of infringement. Patent watch services and commercial databases containing patent and other prior art information are also available to assist patent holders and others in monitoring compliance with patent rights.

Recommendation 9–1 IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should:

(a) be accessible to the public through IP Australia's website;

(b) provide user-friendly access and search capabilities on a wide variety of bases; and

(c) as soon as practicable, provide full-text searching of all complete specifications of published Australian patent applications and granted patents.

Recommendation 9–2 Information about patent litigation should be readily accessible to the public. To this end:

(a) the Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to require courts exercising jurisdiction under the Act to give written notice to the Commissioner of Patents when a legal proceeding to challenge or enforce a patent is commenced, and when a decision or judgment is given in any such proceeding;

(b) the Commissioner of Patents should include information about any such notice in the file of a patent and make the information readily available, for example in the *Official Journal of Patents* and in the patents database on IP Australia's website; and

(c) courts exercising jurisdiction under the *Patents Act* should amend their Rules of Court, as necessary, to give effect to this Recommendation.

Patent litigation insurance

9.86 Patent litigation entails substantial costs and involves a degree of risk, both to the patent holder whose patent rights may be revoked and to the defendant who may be prevented from pursuing an aspect of its business if liability is found. In light of this, companies may consider investing in patent litigation insurance.

Types of patent litigation insurance

9.87 There are several types of insurance policies covering contingencies related to patent litigation.[127]

- *Patent enforcement litigation insurance* provides coverage for the legal costs a patent holder incurs as a result of legal proceedings to protect and enforce its patent rights.[128]

- *Patent infringement liability insurance* provides coverage for the legal costs involved in defending a patent infringement claim and, in some cases, may also cover damages awards if liability is found.[129]

- *Intellectual property litigation insurance* covers the legal costs incurred in the enforcement of all intellectual property rights—for example, trademarks, copyrights and rights in computer software, as well as patents.[130]

9.88 Commercial general liability insurance may also cover the cost of defending an intellectual property infringement claim, although this depends on the wording of the policy, many of which now expressly exclude coverage for such claims.[131]

Prevalence of patent litigation insurance

9.89 Patent litigation insurance is a relatively new development. The ALRC understands that currently no Australian insurers offer such policies,[132] although Australian companies may be able to obtain from overseas underwriters patent litigation insurance that covers patent infringement proceedings in foreign jurisdictions as well as Australia.[133]

---

127 See further: Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155–156.

128 This type of insurance may also be called, 'offensive patent insurance', 'patent pursuit insurance' or 'infringement abatement insurance'.

129 This type of insurance may also be called, 'defensive patent insurance'.

130 This type of policy may also cover legal costs incurred in defending a challenge to the ownership, validity or title to covered intellectual property rights, or in enforcing the terms of intellectual property licences and non-disclosure agreements.

131 M Simensky and E Osterberg, 'The Insurance and Management of Intellectual Property Risks' (1999) 17 *Cardozo Arts and Entertainment Law Journal* 321; J Cahill and T Fitzgibbon, 'Intellectual Property Assets Raise Insurance Issues', *National Law Journal*, 25 October 1999; IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association.

132 Dexta Corporation Ltd, *Correspondence*, 10 December 2003. Until recently, patent litigation insurance was offered in Australia by Dexta Corporation Ltd.

133 J Walker, 'Patents Insurance Has Its Virtues', *Business Review Weekly*, 30 May 2002, 78.

9.90 Patent litigation insurance is more widely available in the United States and Europe. However, even in these jurisdictions the number of insurers offering patent litigation policies is small,[134] and the effectiveness of such policies is yet to be fully evaluated. A report on patent litigation insurance prepared for the European Commission in 2003 (EC Insurance Report) concluded that, to date, litigation insurance had not been particularly successful in any jurisdiction.[135]

Advantages of patent litigation insurance

9.91 Patent litigation insurance may provide a number of advantages, particularly for SMEs. Patent litigation insurance assists SMEs in enforcing their patent portfolios against, or defending allegations of patent infringement by, larger companies without having to settle or license to avoid escalating costs. Further, it may strengthen a party's bargaining power in any negotiations to settle an infringement claim. It has been suggested that, for patent holders, 'publication of the existence of insurance in company literature and on websites acts as an effective deterrent to potential infringers'.[136] For example, GTG (which has patents in many jurisdictions)[137] has indicated that patent litigation insurance is an important part of its licensing and enforcement strategy, and has allowed the company to initiate proceedings against major biotechnology companies in the United States.[138]

9.92 In licensing negotiations, litigation insurance may strengthen a patent holder's ability to license its patents to corporate entities that want to commercialise aspects of the company's patented technology.[139] Potential licensees may indeed require a patent holder to obtain patent litigation insurance to ensure that the patent holder will be able to indemnify the licensee in the event that a patent infringement claim is made by a third party.[140]

9.93 Patent litigation insurance may also provide indirect benefits to a company.[141] A substantial portion of the value of many biotechnology companies is based on their intellectual property portfolio, making protection of their intellectual property rights paramount. Patent litigation insurance facilitates a company's protection of its intellectual property. This, in turn, may attract investors. An insurance company's

---

134 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), app A; IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association, 14–18.

135 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), 1.

136 N Rawlingson Plant, 'Competitive Advantage of Patent Insurance' (2002) 15 *Australian Intellectual Property Law Bulletin* 27.

137 Genetic Technologies Limited, *Annual Report* (2003), 4–9.

138 J Walker, 'Patents Insurance Has Its Virtues', *Business Review Weekly*, 30 May 2002, 78, ABC Television, 'Patently a Problem', *Four Corners*, 11 August 2003, <www.abc.net.au/4corners/archive.htm>.

139 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 157.

140 N Rawlingson Plant, 'Competitive Advantage of Patent Insurance' (2002) 15 *Australian Intellectual Property Law Bulletin* 27, 28.

141 Ibid, 27–28; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 157.

assessment of the validity of a company's patent portfolio, which is a prerequisite to any patent litigation policy being issued, may add credibility to claims that the company's patents are both valid and valuable.[142]

Limitations and criticisms of patent litigation insurance

9.94 Patent litigation insurance does, however, have a number of limitations. The costs involved in obtaining and maintaining patent insurance are significant and, in some cases, prohibitive.[143] The EC Insurance Report concluded that, in the United States, Europe and Japan, 'high costs have meant that insurance has only been of interest to the few'.[144] Further, the report commented that 'no insurance scheme [in Europe or the United States] has shown any capacity to provide adequate cover at premiums affordable to patentees in general'.[145]

9.95 The coverage provided by a patent litigation insurance policy may be limited in a number of ways.[146] In addition to co-payment provisions,[147] the value of legal costs that an insurer will cover is generally limited to a predetermined indemnity level and may exclude coverage for certain costs. For example, in the case of patent infringement liability insurance, punitive or exemplary damages and fines are generally excluded. Territorial limitations may also apply, leaving the insured to pay all costs involved in patent litigation outside the designated countries covered by its policy. For patent enforcement litigation insurance, coverage may be limited to specific patents or may only cover a company's patent portfolio at the date the policy was issued, with payments required to update the policy to cover new patents.

9.96 Other conditions contained in patent litigation insurance policies may limit the insured's discretion in formulating a litigation strategy. Policies typically make coverage conditional on the insurer's approval of the patent holder's legal counsel and litigation budget.[148] In some cases, an insurer may also require control of the litigation.

---

142 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 156, 157.

143 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003. Information about policy premiums for various types of patent litigation insurance was outlined in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [9.129].

144 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), 1.

145 Ibid, 1.

146 J Bergmann and T Davies, 'Junk DNA or Junk Debate?', *Allens Arthur Robinson Biotech News*, 3 September 2003, <www.aar.com.au/pubs/bt>; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 157. See also Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

147 A co-payment, like an excess or deductible payment, is the amount that the insured must pay if a claim is made under a patent litigation insurance policy. Co-payments are typically calculated as a percentage of a claim and are typically between 15% and 25% in patent litigation insurance policies: IPO Insurance Committee, *Status Report of the Insurance Committee* (2002) Intellectual Property Owners Association, 15, 16; Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 156.

148 J Bergmann and T Davies, 'Junk DNA or Junk Debate?', *Allens Arthur Robinson Biotech News*, 3 September 2003, <www.aar.com.au/pubs/bt>.

9.97 A number of submissions to the Inquiry expressed concern that patent litigation insurance may make the cost of challenging and litigating patent rights prohibitively expensive,[149] or at least deter challenges to patent rights.[150] This view seems to assume that, if a party to a patent suit is insured, it will refuse to settle proceedings, or will engage in tactics requiring the other party to spend large amounts of time and resources to participate in the suit.

Government consideration of patent insurance schemes

9.98 Currently, patent litigation insurance is available only from private sector insurers. However, reports in Australia and Europe have addressed the possibility of a patent insurance scheme being administered by the government as part of the patent system.[151]

9.99 In 1999, ACIP considered whether a levy should be imposed on all granted patents to fund insurance coverage for infringement litigation and validity challenges.[152] ACIP concluded that such insurance should be left to the private sector and that involvement by government would be inconsistent with the government's policy that 'its primary role in the IP area is to ensure Australia has effective IP and legal systems'.[153] Nonetheless, ACIP suggested that industry associations, education institutions and IP Australia might wish to include intellectual property litigation insurance as a topic in future awareness programs.[154]

9.100 In Europe, the EC Insurance Report was commissioned to examine the feasibility of implementing a patent litigation insurance scheme for widespread use in the European Union. The report is based on a preliminary empirical and analytical study of the patent litigation insurance market in Europe, the United States and Japan. It concludes that the European Commission should continue its efforts to develop a patent litigation insurance scheme.[155] The EC Insurance Report also makes recommendations about the structure of any such scheme, including that it should be

---

149 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004.

150 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; New South Wales Health Department, *Submission P37*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

151 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999); CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003).

152 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 27–28.

153 Ibid, 27.

154 Ibid, 28. Biotechnology Australia included information about patent litigation insurance in its *Biotechnology Intellectual Property Manual*: Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 155–157.

155 CJA Consultants Ltd, *Patent Litigation Insurance: A Study for the European Commission on Possible Insurance Schemes against Patent Litigation Risks* (2003), [15.1].

compulsory and that premiums should be collected annually through the patent system and might be varied according to the size of the patent portfolio.[156] The European Commission does not appear to have taken any action on the report to date.

ALRC's views

9.101 In the ALRC's view, intervention either to encourage or further limit the availability of patent litigation insurance in Australia is not appropriate at this stage. The decision to purchase patent litigation insurance is a commercial one to be made by an inventor, research organisation, biotechnology company or other entity, having regard to its own commercial needs and business strategy. Those with limited resources may be willing to risk involvement in litigation without the cushion of insurance, and to invest the amount that would have been spent in insurance premiums in further research and development, or marketing efforts.

9.102 Patent litigation insurance may be beneficial to the operation of the patent system as a whole. As outlined earlier in this chapter, the cost of challenging or enforcing patent rights and the complexity of such matters may be prohibitive for certain entities or individuals. Patent litigation insurance may provide the financial resources necessary to participate in such suits and could encourage challenges to gene patents that are of questionable validity.

9.103 The ALRC agrees with ACIP that information about patent litigation insurance should be more readily available to Australian patent holders. As a practical matter, the availability of patent litigation insurance to Australian inventors, research organisations and biotechnology companies is limited. However, such entities would benefit from a greater understanding of the benefits and the limitations of patent litigation insurance. This would assist in decisions about whether to invest in patent litigation insurance, and how to deal with a third party who has such insurance in licence negotiations or litigation. In Chapter 22, the ALRC recommends that Biotechnology Australia, in conjunction with its member departments, develop various programs to assist research organisations and biotechnology companies.[157] Patent litigation insurance should be included as a topic in such programs.

156 Ibid, [15.2], [15.15]–[15.16].
157 See rec 22–1.

10. The Role of Courts and Tribunals in Patent Disputes

Contents

Introduction

10.1 This chapter focuses on the role of Australian courts and tribunals in resolving patent disputes. The chapter outlines the current allocation of jurisdiction with respect to matters arising under the *Patents Act 1990* (Cth) (*Patents Act*). It identifies various proposals to change the allocation of jurisdiction in order to provide greater consistency in the interpretation of patent law and to facilitate enforcement of patent rights, particularly by small and medium-sized enterprises. The chapter then considers the practices and procedures applied in patent matters in the Federal Court of Australia, which hears the great majority of Australian patent cases. The chapter concludes with a discussion of the role of assessors in providing expert advice to judges in patent proceedings.

Judicial and administrative review

Allocation of jurisdiction over patent matters

10.2 As outlined in Chapter 5, state and federal courts, as well as the Administrative Appeals Tribunal (AAT), have a role in the Australian patent system. Decisions of the Commissioner of Patents may be subject to various types of review by the AAT or the Federal Court of Australia (the Federal Court).[1] The AAT may undertake merits review

1 A limited set of decisions by the Commissioner of Patents (primarily those made under the *Patents Regulations 1991* (Cth)) are generally not subject to review by either the AAT or the Federal Court. See also Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General, Report 43* (1998).

of the Commissioner's decisions with respect to certain procedural matters prescribed by the *Patents Act*.[2] Decisions of the AAT on matters of law may be appealed to the Federal Court.[3] A direct approach may be made to the Federal Court for judicial review in relation to other decisions of the Commissioner, essentially those related to the grant of patents or matters closely allied to the grant (for example, amendments to patent specifications and revocations).[4] The Federal Court also has jurisdiction to review decisions of the Commissioner under the *Administrative Review (Judicial Decisions) Act 1977* (Cth), and under s 39B of the *Judiciary Act 1903* (Cth), on the basis of legal or procedural error.[5]

10.3 The Federal Court and state and territory Supreme Courts share original (first instance) jurisdiction over matters related to the exploitation and enforcement of patent rights,[6] including infringement proceedings, applications for relief against unjustified threats of infringement, the grant of declarations of non-infringement, and compulsory licences.

10.4 Appeals from decisions of a single judge of the Federal Court and from decisions of state and territory Supreme Courts may be heard by a Full Court of the Federal Court,[7] and then by the High Court, with special leave to appeal.[8] The Federal Court's appellate jurisdiction in appeals from first instance decisions is exclusive.

Reform of jurisdiction in patent matters

10.5 Several reports in recent years have reviewed the allocation of jurisdiction over intellectual property matters (including patents) among various judicial or quasi-judicial bodies.[9] These reports have identified two competing concerns underpinning criticisms of the current enforcement system for intellectual property rights. On the one hand there is a need for consistency in decision making; on the other hand there is a need to reduce the cost and complexity of the current system to facilitate the enforcement of intellectual property rights, particularly by small and medium-sized enterprises.

---

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

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

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

5 Judicial review by the High Court is also available under s 75(v) of the *Australian Constitution*.

6 *Patents Act 1990* (Cth) s 155, sch 1.

7 Ibid s 158. The Federal Court's leave is required to appeal a decision of a single Federal Court judge in relation to a decision or direction of the Commissioner: *Patents Act 1990* (Cth) s 158(2).

8 *Patents Act 1990* (Cth) s 158(3).

9 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984); Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General, Report 43* (1998); Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999); Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), Ch 7; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000); Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), Ch 20; Advisory Council on Intellectual Property, *Should the Jurisdiction of the Federal Magistrates Service be Extended to Include Patent, Trade Mark, and Design Matters?* (2003).

10.6 Both of these concerns are evident in the context of gene patents. Gene patents raise a range of complex legal and scientific issues, which require a high level of expertise. There is a need for consistency in decision making by the courts in this relatively new area. However, as discussed in Chapter 9, there are also concerns about the cost of challenging patents, as well as participating in patent infringement suits, whether as plaintiff or defendant. This concern is significant in the context of gene patents because of the prominent role of universities and non-profit organisations in genetic research in Australia.[10] These institutions have limited resources to undertake patent enforcement actions. Accessible and cost-effective enforcement mechanisms for gene patents are therefore desirable.

10.7 Reports on these issues have focused primarily on the appropriate allocation of jurisdiction for matters arising under the *Patents Act*, and the expertise of judges appointed to hear patent disputes. Suggestions have been made to: limit or entirely remove the jurisdiction of state and territory Supreme Courts in patent matters;[11] expand the jurisdiction of the Federal Magistrates Service (FMS) to include patent matters;[12] and expand the jurisdiction of the AAT to undertake merits review of decisions of the Commissioner.[13]

10.8 In 2003, the Advisory Council on Intellectual Property (ACIP)[14] published a report that examined whether the jurisdiction of the FMS should be extended to include patent, trademark and design matters (ACIP FMS Report).[15] ACIP considered that the jurisdiction of the FMS should be extended in this way, and made a suite of recommendations designed to give effect to this proposal.[16] However, ACIP also acknowledged that 'an extension of the jurisdiction of the FMS to IP matters alone will not resolve the current problems'.[17] The ACIP FMS Report thus made

---

10 See further Ch 16.

11 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), rec 20–1; Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 6. See also Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), rec 35(i). Specialist intellectual property courts in other countries were discussed in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [10.12]–[10.14].

12 Advisory Council on Intellectual Property, *Should the Jurisdiction of the Federal Magistrates Service be Extended to Include Patent, Trade Mark, and Design Matters?* (2003), rec 1.1, 1.2; Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 177; Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), 20. See also Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.32].

13 Administrative Review Council, *Administrative Review of Patents Decisions: Report to the Attorney General, Report 43* (1998), rec 2, 3.

14 This body was formerly known as the Advisory Council on Industrial Property. ACIP is used in this Report to refer to both bodies.

15 Advisory Council on Intellectual Property, *Should the Jurisdiction of the Federal Magistrates Service be Extended to Include Patent, Trade Mark, and Design Matters?* (2003).

16 Ibid, rec 1.1–1.6.

17 Ibid, 29.

recommendations aimed at streamlining existing court procedures and encouraging a proactive approach to case management in intellectual property matters.[18]

Practice and procedure of the Federal Court

10.9 Although the Federal Court shares jurisdiction in patent matters with the state and territory Supreme Courts, in practice the vast majority of patent cases are heard in the Federal Court. The practices and procedures of that Court are therefore central to the role of courts in the Australian patent system.

10.10 The Federal Court has provided the ALRC with information about its practices and procedures in relation to patent disputes. The Court keeps its practices and procedures in relation to these matters under regular review. It has meetings with specialist sections of the Law Council of Australia and also has intellectual property 'user group' meetings with practitioners in the field in Sydney and Melbourne (the two major patent litigation centres). These meetings deal with emerging problems, examine possible solutions, and seek to improve efficiencies and remove uncertainties in patent practice and procedure, including discovery. The outcomes of the meetings are disseminated throughout the Federal Court.

10.11 The Federal Court is currently exploring ways to make the provision of evidence in patent matters more efficient, including the use of:

- the docket system to ensure early management, enable early definition of issues in dispute, and obviate the need for unnecessary evidence;
- joint experts to narrow issues and identify the areas of agreement between the parties;
- 'hot tubbing' of experts;[19]
- independent qualified experts as assessors to advise the judge in cases involving complex technological issues (see further below);
- an agreed primer on background technology with the possibility of the primer being provided orally to reduce cost and increase its educative value; and

---

18 Ibid, rec 2.1, 2.2, 3.1, 3.2, 3.3.

19 'Hot tubbing' refers to a practice that involves the joint empanelment of experts of the same discipline, after all the lay evidence in a trial has been given. Each expert gives a brief summary of their position in light of the lay evidence and is then asked questions directly by the other empanelled experts. Following this, each expert provides a summary of their opinion and is then cross-examined and re-examined by counsel. The advantages of 'hot tubbing' of experts include the presentation of the expert evidence of all parties together and after the critical issues in the case have been refined, as well as the saving of hearing time: P Heerey, 'Expert Evidence: The Australian Experience' (Paper presented at World Intellectual Property Organization Asia–Pacific Colloquium, New Delhi, 6 February 2002); P Heerey, 'Expert Evidence: The Australian Experience' (2002) 7 *Bar Review: The Journal of the Bar of Ireland* 166.

- video-conferencing facilities for the provision of overseas or interstate evidence, reducing inconvenience and cost.

10.12 As a national court, the Federal Court also has the ability to sit anywhere in Australia to hear evidence. In patent cases that do not involve global litigation, parties are also encouraged to consider early alternative dispute resolution, in particular early mediation. If appropriate, the Court may order that mediation occur.

10.13 A patent panel has been established in the Sydney and Melbourne registries of the Federal Court. It is constituted by judges with a special interest in the area, with the aim of promoting a consistent approach to patent practice and procedure throughout the Federal Court.

10.14 The Federal Court's intellectual property panels conduct regular seminars for its judges and the Federal Court's broader program of judicial studies includes intellectual property matters. The Federal Court has an ongoing association with the United States-based Einstein Institute of Science Health and the Courts (EINSHAC) and, in 2003, conducted a well-attended three-day seminar on 'Genetics in the Courtroom', in association with EINSHAC and leading scientists and ethicists.

Submissions and consultations

10.15 DP 68 proposed that the *Patents Act* be amended to provide that original jurisdiction in matters arising under the Act be conferred exclusively on federal courts, and that the jurisdiction currently exercised by state and territory courts under the Act be abolished.[20]

10.16 A number of submissions supported this proposal.[21] Submissions commented that, given the relatively low frequency of patent cases, such an approach would assist judges to develop specialised skills, knowledge and experience in dealing with patent matters[22] and increase consistency and certainty in judicial interpretation of the *Patents Act.*[23]

---

20 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 10–1.

21 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

22 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

23 GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; South Australian Government, *Submission P51*, 30 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Attorney-General for South Australia, *Submission P115*, 3 May 2004.

10.17 Other submissions commented on the potential disadvantages of concentrating the administration and enforcement of patent matters in a single court. For example, the Attorney-General for South Australia commented that conferring exclusive jurisdiction on the Federal Court might cause additional cost, time and inconvenience to parties who wish to have all claims tried together if some of these claims do not fall within the Federal Court's jurisdiction.[24] The submission also observed that specialist courts 'tend to become narrow in focus and idiosyncratic' and may also become (or be perceived to become) 'unduly favourable to a particular category of litigants'.[25] However, as the ALRC has noted in an earlier Report, the Federal Court has jurisdiction in respect of a large number of federal statutes, and therefore has diverse civil jurisdiction in matters of federal law.[26]

10.18 Some submissions stated that the jurisdiction of state Supreme Courts over patent matters should be preserved.[27] The Queensland Government endorsed the submission of the Queensland Supreme Court to the ALRC's review of the *Judiciary Act 1903* (Cth). Among other matters, the Queensland Supreme Court's submission had suggested that uniformity of decision making could still be achieved if parallel jurisdiction were maintained in the state and federal courts and expressed concerns about the narrowing of legal principles and agency capture if jurisdiction were to be concentrated solely in the Federal Court.[28]

10.19 The Inquiry heard different views about whether the FMS should have jurisdiction over patent matters.[29] The patent attorney firm, F B Rice & Co considered that conferring jurisdiction on the FMS might enable small and medium-sized enterprises to enforce their patent rights in a more cost-effective manner.[30] Other submissions indicated that, given the complexity of legal and scientific issues in many patent cases, the FMS was not generally an appropriate forum for patent litigation.[31]

---

24 Attorney-General for South Australia, *Submission P115*, 3 May 2004. Some of these additional claims may fall within the Federal Court's accrued or associated jurisdiction, and may therefore be adjudicated by the Court as federal matters: see Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [2.17]-[2.26], [4.12]–[4.13].

25 Attorney-General for South Australia, *Submission P115*, 3 May 2004. See also A McBratney and others, *Submission P47*, 22 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004. However, the submissions of McBratney and ACIPA concluded that, despite such criticisms, the concentration of jurisdiction in the Federal Court could be beneficial.

26 See further Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), Ch 4.

27 Queensland Government, *Submission P57*, 5 January 2004; Queensland Government, *Submission P103*, 22 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004.

28 Queensland Government, *Submission P57*, 5 January 2004; Queensland Government, *Submission P103*, 22 April 2004. See Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.15]–[20.18].

29 A Bennett, *Consultation*, Sydney, 15 March 2004; J McKeough, *Consultation*, Sydney, 23 March 2004; Intellectual Property Research Institute of Australia, *Consultation*, Melbourne, 1 April 2004.

30 F B Rice & Co, *Submission P84*, 16 April 2004.

31 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Attorney-General for South Australia, *Submission P115*, 3 May 2004.

10.20 GlaxoSmithKline offered specific suggestions about ways to address concerns relating to the cost and complexity of gene patent litigation, such as: ensuring that any costs award adequately reflects the 'winner's' actual costs; penalising inefficient or oppressive litigation in costs awards; providing public funding for patent litigation; and encouraging alternative dispute resolution.[32]

ALRC's views

10.21 Disputes involving gene patents highlight more general concerns that have been raised about the current enforcement system for patent rights in Australia. Genetics is a rapidly developing and highly technical scientific field. It raises complex issues for patent law, suggesting that judges with special expertise are best equipped to handle litigation of this type. However, the biotechnology sector in Australia is dominated by small and medium-sized enterprises and publicly funded institutions, which may be deterred from enforcing their patent rights if the procedures to do so are overly complicated and costly.

10.22 DP 68 suggested that one way to address these issues is to confer original jurisdiction over matters arising under the *Patents Act* exclusively on federal courts. The ALRC proffered no opinion about how that jurisdiction should be allocated between the Federal Court and the FMS. However, given the absence of FMS jurisdiction in patent matters at the present time, the practical effect of the proposal would have been to capitalise on the substantial expertise that the Federal Court has already developed in handling and determining such cases. Nevertheless, submissions raised concerns about the effectiveness of this approach. In particular, it was suggested that the concentration of jurisdiction in the Federal Court might not address concerns about the time and cost involved in patent litigation. With the benefit of these submissions, the ALRC now believes that these concerns are best addressed directly by examining, and where necessary improving, the practices and procedures of all Australian courts with jurisdiction over patent matters.

10.23 Available statistics suggest that the Federal Court is the forum of choice in most patent matters, and that state courts are used only on an occasional basis.[33] The impact of the ALRC's recommendation will therefore fall primarily on the Federal Court. As discussed above, the Federal Court has already adopted a proactive approach in adapting its practices and procedures in patent cases, and it keeps these matters under regular review. It has an established panel of specialist intellectual property judges, as well as continuing education programs to assist judges in keeping up to date with developments in patent law. These practices were noted favourably in submissions.[34]

---

32 GlaxoSmithKline, *Submission P33*, 10 October 2003.

33 D Drummond, 'Are the Courts Down Under Properly Handling Patent Disputes?' (2000) 42 *Intellectual Property Forum* 10, 22–29; Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [20.28].

34 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004. See also Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights* (1999), rec 7.

The Federal Court is also examining ways to facilitate the provision of evidence and the expeditious resolution of patent disputes. The Federal Court's practices and procedures provide a valuable model for other courts exercising jurisdiction under the *Patents Act*. But other courts, too, may have particular practices and procedures that are worthy of consideration by courts that hear and determine patent matters. The ALRC therefore recommends that all courts exercising jurisdiction under the *Patents Act* should continue to develop their practices and procedures for dealing with patent matters with the object of promoting the just, efficient and cost effective resolution of patent disputes.

Recommendation 10–1 Courts exercising jurisdiction under the *Patents Act 1990* (Cth) (*Patents Act*) should continue to develop their practices and procedures for dealing with patent matters in order to promote the just, efficient and cost effective resolution of patent disputes.

Role of assessors in patent cases

10.24 Gene patents raise complex scientific and legal issues, whose resolution may require expert advice and assistance. This section addresses the role of experts in providing advice to judges hearing gene patent matters.

10.25 Section 217 of the *Patents Act* enables Australian judges to have access to expert assistance in patent proceedings in appropriate cases. The provision states: 'A prescribed court may, if it thinks fit, call in the aid of an assessor to assist it in the hearing and trial or determination of any proceedings under this Act'.[35]

10.26 The term 'assessor' is not defined the *Patents Act*. The role of an assessor was considered by the ALRC in its report, *Managing Justice: A Review of the Federal Civil Justice System* (ALRC 89).[36] An assessor is an expert available for a judge to consult if the judge requires assistance in understanding the effect or meaning of expert evidence.[37]

35 *Patents Act 1990* (Cth) s 217. A 'prescribed court' is defined to mean the Federal Court, the Supreme Court of a State and the Supreme Court of each of the Australian Capital Territory, the Northern Territory and Norfolk Island: *Patents Act 1990* (Cth) sch 1. State and territory Supreme Courts may also be empowered to appoint an assessor in any type of proceedings: see, eg, *Supreme Courts Act 1995* (Qld) s 255(2); *Supreme Court Act 1935* (SA) s 71; *Supreme Court Act 1935* (WA) s 56; *Supreme Court Rules 1970* (NSW) Pt 39, r 7; Queensland Government, *Submission P103*, 22 April 2004; Attorney-General for South Australia, *Submission P115*, 3 May 2004.

36 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000). See also P Heerey, 'Expert Evidence in Intellectual Property Cases' (1998) 9 *Australian Intellectual Property Journal* 92.

37 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), [7.150].

10.27 Heerey J considered the benefits of an assessor in *Genetic Institute Inc v Kirin-Amgen Inc (No 2)*.[38] That case involved complex and contested issues of molecular biology and, between them, the parties intended to call 15 scientific experts from various disciplines.[39] Heerey J held that, in such a case, a non-expert judge would be aided by expert assistance, such as that provided by an assessor, and thus perform the judicial task better.[40]

10.28 However, concerns have been expressed about assessors exercising too much influence over a judge, and about the procedural fairness of contact between judges and experts in chambers.[41] These matters may be appropriately addressed by a clear and detailed prescription of an assessor's functions.[42] Heerey J explained it in these terms:

> There is no question of an assessor giving any judgment or making any order (even by consent) or otherwise exercising any judicial functions. An assessor is to assist the judge, both in hearing and trial and/or in determination of any proceeding. The judgment in the case, the exercise of the judicial power, remains that of the judge. In exercising judicial power, a judge is routinely assisted by persons who are not judges: counsel, solicitors, witnesses, the judge's associate and secretary and other court staff.[43]

10.29 Despite the potential benefits, the appointment of assessors in Australian patent cases is rare. Although the power to appoint assessors had been included in Australian patents legislation since 1903,[44] it has been considered and invoked in a very small number of cases to date.[45]

10.30 Different regimes for the appointment and use of experts by a court exist under the *Federal Court Rules*[46] and comparable provisions in the rules of state and territory Supreme Courts.[47] For example, under the *Federal Court Rules*, 'expert assistants' may

---

38 *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247.

39 Ibid, 251.

40 Ibid, 251–252.

41 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), [7.153]–[7.155].

42 *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247, 251; *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106, 117–118; *Beecham Group Ltd v Bristol-Myers Company* [1980] 1 NZLR 185, 190.

43 *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247, 250.

44 *Patents Act 1903* (Cth) s 86(8). See also Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, ALRC 92 (2001), [7.149].

45 *Adhesives Pty Ltd v Aktieselskabet Dansk Gaerings-Industri* (1935) 55 CLR 523 (assessor appointed by consent); *Genetic Institute Inc v Kirin-Amgen Inc (No 2)* (1997) 149 ALR 247 (assessor appointed by court order, upheld on appeal: *Genetics Institute Inc v Kirin-Amgen Inc* (1999) 92 FCR 106); *F Hoffman-La Roche AG v New England Biolabs Inc* (1999) 47 IPR 105 (appointment of assessor deferred until later stage of proceedings). In addition, Branson J commented on the role of assessors in patent proceedings in a case arising under the *Evidence Act 1995* (Cth): *EI DuPont de Nemours & Co v Imperial Chemical Industries plc* (2002) 54 IPR 304.

46 *Federal Court Rules 1979* (Cth) O 34B. 'Expert' is defined in r 2(3) as a 'person who has specialised knowledge based on the person's training, study or experience'.

47 See, eg, *Supreme Court Rules 1970* (NSW) Pt 39, rr 1–6; *Rules of the Supreme Court 1987* (SA) rr 82.01–82.07; *Rules of the Supreme Court 1971* (WA) O 40. See also Queensland Government, *Submission P103*, 22 April 2004.

assist a judge of the Federal Court on 'any issue of fact or opinion' identified by the Court or a judge (other than an issue involving a question of law).[48] The appointment of an expert assistant requires the consent of both parties, and any assistance provided by the expert must be reduced to writing and made available to both parties.[49]

Submissions and consultations

10.31 DP 68 proposed that courts exercising jurisdiction under the *Patents Act* should continue to develop procedures and arrangements to allow judges to benefit from the advice of assessors or scientific advisers in litigation involving patents over genetic materials and technologies.[50]

10.32 A range of submissions supported this proposal.[51] Submissions considered that assessors could help judges in examining and determining issues in litigation involving genetic technologies. Submissions also commented that such experts could be a valuable resource for judges. For example, the Centre for Law and Genetics submitted: 'judges are more likely to be able to give a reasoned and informed judgment if properly advised on the technical matters inherent in litigation involving gene and biotechnology patents'.[52]

10.33 A few submissions voiced reservations about assessors or scientific advisers being appointed too readily, particularly given that the views of these experts may not be subject to examination by the parties.[53] GlaxoSmithKline was concerned that scientific advisers may '*de facto* … become arbiters of fact' because 'a non-technically qualified judge may find it difficult to come to a finding of fact which is inconsistent with the views expressed by the assessor or adviser'.[54] GlaxoSmithKline submitted that the role of scientific advisers should be carefully limited to assisting a judge 'to understand the issues and evidence before him'.

---

48 *Federal Court Rules 1979* (Cth) O 34B r 2(1).

49 Ibid O 34B r 3.

50 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 10–2.

51 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

52 Centre for Law and Genetics, *Submission P104*, 22 April 2004. See also Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004.

53 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004.

54 GlaxoSmithKline, *Submission P85*, 16 April 2004.

ALRC's views

10.34 In ALRC 89, the ALRC noted the value of assessors in patent cases, given the novel and technical issues frequently raised.[55] The ALRC recommended that: 'The Federal Court should continue to develop appropriate procedures and arrangements, in consultation with legal and professional user groups, to allow judges to benefit from expert assistance in understanding the effect or meaning of expert evidence'.[56] The ACIP FMS Report also encouraged the use of 'court-appointed experts to assist courts, particularly with technical aspects of patent cases'.[57]

10.35 In its response to the ALRC's recommendation, the Australian Government indicated that this was a matter for the Federal Court.[58] The Government noted that the *Federal Court Rules* had been amended to provide for the appointment of a Court expert assistant, and that the Court had advised it would continue to consult with the legal profession and user groups on issues concerning expert evidence.[59] The Government's response did not make specific reference to the use of assessors pursuant to s 217 of the *Patents Act*.

10.36 In a paper delivered in 2002 about techniques used by the Federal Court to address issues posed by expert evidence, Justice Heerey commented that:

> Today the complexity of science expands at an exponential rate … Looking back to the 1960s, a decade when many of today's judges commenced their professional careers, there are many fields of science which were not merely less complicated than today; they simply did not exist … [Further,] scientific issues about which eminent scientists themselves have doubt, fall to be decided by judges who, in common law countries at any rate, usually do not have much in the way of formal scientific education.[60]

10.37 Some Australian judges have specialist scientific training, or a familiarity with scientific matters as a result of their professional or personal interests. However, many judges could benefit, in appropriate cases, from the additional assistance that an assessor may provide in interpreting and understanding scientific evidence. The pace of scientific change is rapid, and expert evidence may be complicated and voluminous. Even those judges who have specialist training in a relevant discipline are unlikely to have the detailed knowledge of an assessor or scientific adviser in the specific field to which the case relates.

---

55 Australian Law Reform Commission, *Managing Justice: A Review of the Federal Judicial System*, ALRC 89 (2000), [7.148].

56 Ibid, rec 85.

57 Advisory Council on Intellectual Property, *Should the Jurisdiction of the Federal Magistrates Service be Extended to Include Patent, Trade Mark, and Design Matters?* (2003), rec 2.2.

58 Australian Government, *Government Response to Recommendations of Australian Law Reform Commission Report Managing Justice: A Review of the Federal Civil Justice System* (2003), 39.

59 Ibid, 39. The Australian Government has not yet published its response to the ACIP FMS Report.

60 P Heerey, 'Expert Evidence: The Australian Experience' (Paper presented at World Intellectual Property Organization Asia–Pacific Colloquium, New Delhi, 6 February 2002).

10.38 The ALRC considers that the use of an assessor may be particularly beneficial in gene patent litigation, which may involve novel issues and complex scientific and technical evidence. The ALRC recognises the concerns that have been identified about the use of assessors, including issues relating to the appropriate role of an assessor in patent proceedings, the costs involved, and potential conflicts of interest.[61] However, the ALRC considers that such issues are capable of being addressed on a case-by-case basis with appropriate cooperation between the court and the parties to the proceedings.[62] One example of such cooperation is the practice of appointing assessors from a joint list presented by the parties—which allows for greater confidence in the expertise and impartiality of the assessor.

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

61 Similar concerns were expressed at a round table conducted by ACIP in connection with the ACIP FMS Report: Advisory Council on Intellectual Property, *Should the Jurisdiction of the Federal Magistrates Service be Extended to Include Patent, Trade Mark, and Design Matters?* (2003), 26.

62 See, eg, the orders made by Emmett J in a case relating to identification of an assessor at a time when a party was still in the process of retaining expert witnesses: *F Hoffman-La Roche AG v New England Biolabs Inc* (1999) 47 IPR 105, 107.

PART C

Patents and Genetic Research

11. Publicly Funded Research and Intellectual Property

Contents

Introduction

11.1 The Terms of Reference direct the ALRC to examine the impact of current patenting laws and practices related to 'genes and genetic and related technologies' on the application and commercialisation of research. In doing so, the ALRC is to consider reforms that may encourage the creation and use of intellectual property to further the health and economic benefits of genetic research.

11.2 This chapter examines the relationship between public funding of research and intellectual property ownership. The majority of human health-related biotechnology research conducted in Australia is funded by the Australian Government and occurs in

research institutions, universities, health departments and government agencies (research organisations).

11.3 Where research is carried out in an organisation such as a university, hospital, or other government research organisation, normally the employer would be entitled to claim ownership of any intellectual property rights arising out of the research. This is a general principle of the common law and may also be found in relevant statutes, policies and employment agreements.

11.4 However, where the research has been funded from outside the organisation, a question could arise as to whether funding bodies should have rights to any resulting intellectual property. As a general rule, governments and their public funding agencies do not claim intellectual property rights over the results of the research they fund. Instead, they influence exploitation of the intellectual property through funding policy and the development of guiding principles.

11.5 This chapter considers the effectiveness of this approach in promoting research commercialisation to generate returns on public investment in research and in producing healthcare products and services for the Australian population. It discusses approaches taken in other jurisdictions and examines a number of reform options.

Public funding of research

Objectives of public funding

11.6 The Australian Government provides funding for medical and scientific research with the broad aim of promoting the national interest. Within this aim, there are a number of more defined objectives: promoting research; improving healthcare; and stimulating economic growth.

11.7 These benefits flow as a result of the 'utilisation' of publicly funded research. Utilisation occurs when results are transferred to end users, through what are sometimes referred to as 'routes to end use'. These routes include the transfer of research into the public domain where it can be used freely; and transfer to industry for development into marketable healthcare products, such as tests and treatments.[1]

11.8 In 2001, the Australian Government launched *Backing Australia's Ability,* a five-year strategy designed to promote research, development and innovation. Three broad themes were identified in the strategy: generating ideas through research; commercialisation of those ideas; and developing and retaining a highly skilled workforce. Intellectual property protection was nominated as one of the strategies for accelerating the commercialisation of ideas.[2]

---

1 Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 29.

2 Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001), 18.

11.9 This strategy is supported by the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC).[3] The NHMRC has identified a number of reasons why the protection and commercial exploitation of research provides important public benefits:

> The rapid development of science and technology, especially the emergence of modern biotechnology, provides Australia with an unprecedented opportunity to use its strong position in health and medical research to build knowledge-based industries that can compete in the global knowledge economy. Commercial exploitation of research findings benefits the economy through employment growth and national wealth generation, as well as being an essential step in the delivery of new drugs or health treatments to the community.[4]

Promoting research

11.10 The Australian Government funds research activities through various agencies, principally the ARC and the NHMRC. In 2001, approximately $300 million was spent on publicly funded research in biotechnology.[5] Such funding enables researchers to purchase equipment and resources and may provide financial support for researchers to devote time to pursuing a particular project.

11.11 Promoting research is also a means of increasing the population of skilled researchers in Australia. This may help create a critical mass of researchers in a particular area, aid Australia in becoming well recognised in a field of research, and consequently attract more overseas researchers.

Improving healthcare

11.12 Funding research into genetics and biotechnology allows researchers to investigate the causes of disease and promotes the development of new or improved treatments and tests. Such research may improve the options available to the medical profession for identifying and treating disease. Most publicly funded research is upstream research and further development may be needed to turn the outcomes of this research into downstream products. The public benefits from improved healthcare through reduced mortality and illness.

Stimulating economic growth

11.13 Government can foster the development of a strong research base needed in a knowledge-based economy by public investment in research. Developing a research base is crucial for Australia's continuing economic growth.[6] For example, it has been

---

3 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), 2.

4 National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), 1. The Interim Guidelines are no longer in effect.

5 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 9.

6 See, eg, Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 125–126; Australian Government, *Backing Australia's Ability: The Australian Government's Innovation Report 2003–04* (2003), 24.

estimated that encouraging the commercial development of research results has the potential to generate between 10,000 and 15,000 new jobs in Australia over five years.[7]

11.14 It is Australian Government policy to promote the commercialisation of publicly funded research.[8] Encouraging effective commercial development of research stimulates growth by creating products and product ideas. These might be manufactured and sold by Australian companies, creating employment and helping to develop the Australian manufacturing sector. If these products are marketed overseas, this may increase the export of Australian products. Alternatively, research results may be commercially developed to the stage where licensing agreements can be made with overseas companies to develop the product to market-ready stage. This generates income for Australian organisations holding intellectual property in the form of licensing fees and royalties. These financial returns may be put back into research and development to support the Australian biotechnology research sector and industry further.

Public benefit from research funding

11.15 Few would dispute that if public money is used to fund research, the benefits of this research should flow back to the community in some form. A major issue is how best to ensure that the benefits of publicly funded research are realised. It is not always clear whether this is best achieved by freely sharing the results of publicly funded research or by commercialisation of research results, and if commercialisation is preferable, what is the best way to maximise the gains.

11.16 It has been argued that the results of such research should be publicly available because the research has been supported with public funds. Exclusive control of new technology, such as through patent protection, may prevent others from freely using it.

11.17 However, the public benefits of such research may sometimes be realised more effectively by attracting investment for commercial development to take research through to the product stage. In its 2003 report on patenting and licensing by public research organisations, the Organisation for Economic Co-operation and Development (OECD Report) noted that governments are increasingly recognising that 'placing the outputs of publicly funded research in the public domain is not sufficient to generate

---

7 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), xvii.

8 For example, the objective of the Cooperative Research Centres program is 'to enhance Australia's industrial, commercial and economic growth through the development of sustained, user-driven, cooperative public–private research centres that achieve high levels of outcomes in adoption and commercialisation': Department of Education Science and Training, *Cooperative Research Centres Program: 2004 Selection Round Guidelines for Applicants* (2004), [1.2.1]. See also Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998); Minister for Education Training and Youth Affairs, *Knowledge and Innovation: A Policy Statement on Research and Research Training* (1999); Australian Science Capability Review, *The Chance to Change* (2000); Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001); Australian Government, *Backing Australia's Ability: Building Our Future through Science and Innovation* (2004).

social and economic benefits from research'.[9] John Grace, former chief executive of Australian biotechnology company Amrad Corporation Limited, has made a similar point:

> If a researcher is doing something really clever that might lead to a new drug, the only way that benefit will get to the community will be through the commercial activities of the company in developing it. And no company in the world will develop a drug without a patent. So … if you are a researcher that really wants to benefit mankind through a discovery, via some treatment, then a patent is not only essential, it is legitimate.[10]

11.18 This thinking was also the basis of shifts in United States policy in the early 1980s to allow organisations receiving public funding for research to patent and commercialise the results of that research. This policy is discussed later in this chapter in the context of 'march-in' rights.

Benefit to research organisations

11.19 Research organisations can benefit from holding intellectual property by exploiting it to generate financial returns that can be used for further research and to support the organisation. They are able to do this by:

- establishing spin-off companies to develop and market products created from technology patented by the organisation; and
- licensing patented technology to industry and other research organisations in return for licence and royalty payments.

11.20 The Garvan Institute of Medical Research (Garvan Institute) is an example of an organisation realising such benefits. The Garvan Institute is an autonomous, not-for-profit medical research institute with strengths in gene-based research. In 2002, the Garvan Institute's commercial relationships generated $2.5 million, which it used for its operations and growth.[11]

Intellectual property ownership

11.21 One of the issues in the commercialisation of research is where intellectual property rights should vest to ensure the public benefits from the research it helps to fund. This involves considering which organisation will most effectively exploit intellectual property to realise these benefits.

---

9 Organisation for Economic Co-operation and Development, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003), 9.

10 B Pheasant, 'The Value of a Pure Thought', *Financial Review* (Sydney), 12–13 August 2000, 26. See also M Stott and J Valentine, 'Gene Patenting and Medical Research: A View from a Pharmaceutical Company' (2004) 3 *Nature Reviews Drug Discovery* 364.

11 Garvan Institute of Medical Research, *Annual Report* (2002), 59.

11.22 Currently, a mixture of contract, common law rules and legislative mechanisms determines the ownership of intellectual property that is generated within research organisations. Ownership may also be altered by an organisation's policies.

Current law and practice

11.23 Under s 15(1) of the *Patents Act 1990* (Cth) (*Patents Act*), a research organisation may apply for a patent over an invention created by employees in the course of their employment. The section provides that:

> a patent for an invention may only be granted to a person who:
>
> (a) is the inventor; or
>
> (b) would, on the grant of a patent for the invention, be entitled to have the patent assigned to the person; or
>
> (c) derives title to the invention from the inventor or a person mentioned in paragraph (b).[12]

11.24 Although the *Patents Act* does not explicitly address an employer's right to patent an invention created by its employees, s 15(1)(b) is generally relied upon by employers to claim proprietary rights in such inventions by virtue of their employment of the inventor, or by virtue of the terms of an employment contract.[13]

11.25 The terms of the employment contract may include an explicit agreement to assign rights to an invention to the employer, allowing the employer to apply for a patent under s 15(1)(b).[14] Where there is no explicit agreement to assign, the court may imply such an agreement into a contract of employment. According to Professors Jill McKeough and Andrew Stewart:

> the courts have basically tended to favour employer ownership. Any invention will impliedly belong to the employer, so long as it is arrived at in the course of duties the employee is engaged to perform.[15]

11.26 The nature of the employment and the duties it encompasses will therefore be determinative of whether an employer may assert rights to an invention created by the employee in the absence of an explicit assignment.[16] Where the employer is an organisation receiving public research funding, and the employee is an academic staff member or researcher, the organisation's claim to ownership of inventions created by the researcher will be determined by the nature and scope of the employment and the

---

12 *Patents Act 1990* (Cth) s 15(1).

13 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [8030]. See also J McKeough and A Stewart, *Intellectual Property in Australia* (2nd ed, 1997), [13.5]. It may also be that where no common law support can be found for assigning rights to the invention to the employer, and the inventor and the research institution have executed an agreement for intellectual property assignment, the institution may be entitled to apply for a patent under s 15 (1)(c).

14 J McKeough, A Stewart and P Griffith, *Intellectual Property in Australia* (3rd ed, 2004), [13.4].

15 Ibid, [13.7]. See also *Sterling Engineering Co Ltd v Patchett* [1955] AC 534, 543–544, 547.

16 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 329.

terms of the employment contract. The employer's rights may also be altered by an organisation's statutes and policies.[17]

11.27 According to a report by the Department of Education, Science and Technology (DEST Report), universities may claim ownership of inventions created: using university resources; by academic staff in the course of their employment; and through publicly funded research received as part of an agreement with a government funding agency.[18]

11.28 In some instances, it may be difficult to determine which inventive activities fall within the scope of the researcher's employment. Associate Professor Anne Monotti and Professor Sam Ricketson suggest that the situation is complicated because:

- the duties associated with an academic position may not always be clear;
- different research positions within organisations will have different duties attached to them, including teaching, curriculum development and leadership within research groups;
- a researcher will tend to move between organisations over the course of a career, and will enter each new position possessing knowledge and, in some cases, intellectual property from previous positions;
- a researcher may spend part of his or her time working in start-up companies, in collaborative research projects and centres, public teaching hospitals and other organisations; and
- a researcher may undertake research during leave or while on exchange to another organisation.[19]

Intellectual property policies

11.29 As indicated above, research organisations generally address intellectual property ownership issues through internal statutes and policies. Organisations vary in their practices as to whether they claim ownership of intellectual property generated by staff or within the organisation. Typically, however, they will seek to claim ownership.

11.30 In addition, an organisation's policies often include provisions to encourage publication and the wide dissemination of research. However, where research leads to an invention, these policies usually provide for the organisation to delay publication

---

17 These are discussed further below. See also *Victoria University of Technology v Wilson* [2004] VSC 33 [107]–[122].

18 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), vii.

19 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.08]–[4.20].

while patenting and commercialisation are explored. Policies also normally provide that commercial development must be for the benefit of the organisation, the inventor, government and commercial or other partners.[20]

11.31 Some Australian research organisations may choose to assign intellectual property rights to the researcher, if the organisations do not wish to develop these to commercial stage. The researcher may then choose to develop the invention.

11.32 Alternatively, and more rarely, some organisations allow researchers to hold intellectual property rights in their research results. In these cases, the organisation may foster commercialisation by supporting individual researchers through the commercialisation process.[21]

Students and visitors

11.33 A research organisation's rights to inventions created by students and visitors are somewhat different to the general position. As the relationship between a student and an research organisation is not one of employment, the organisation may not imply a right to ownership of inventions created by the student during the course of their education in the same manner as for academic staff. The relationship between the organisation and a student is, in part, based in contract.[22] If the organisation is established by statute, its statutes, by-laws and regulations bind the student and may also affect the relationship. The student will not be automatically bound by non-legislative policies and resolutions. However, he or she may agree to be bound and thereby agree to assign ownership of intellectual property to the organisation.[23]

11.34 Students funded through government scholarship schemes, such as the Australian Postgraduate Awards (APAs), may also be subject to conditions on the award including that the organisation administering the scholarship controls the grant and any research results arising from it. As the organisation is required to adhere to its own intellectual property policy, which will generally direct that the research is exploited for the public benefit, the organisation will exercise a degree of control over the intellectual property that results from the student's research.[24]

11.35 Visitors to research organisations include researchers on exchange from other organisations, and honorary or salaried appointees. The research organisation's rights in relation to intellectual property created by a visitor will depend on the nature of the appointment.

---

20 See, eg, University of Adelaide, *Commercial Development of the University's Intellectual Property Policy* (1989), [1.4].

21 An example of this is the University of Melbourne, which allows academic staff who create intellectual property through research undertaken at the University to retain ownership of that intellectual property: University of Melbourne, *Statute 14.1: Intellectual Property* (1996), 14.1.3.

22 See, eg, *Bayley-Jones v University of Newcastle* (1990) 22 NSWLR 424.

23 *Ex parte Forster; Re University of Sydney* (1963) 63 SR (NSW) 723, 731. See also A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.21]–[4.22].

24 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.49].

11.36 A 1999 ARC survey of university research commercialisation in Australia found that all respondent universities had intellectual property policies in place for staff, and most also had policies for postgraduate students. However, fewer had policies covering undergraduate students and university visitors.[25]

Collaborative research

11.37 A growing feature of biotechnology research in Australia is collaborative arrangements between research organisations or between organisations and industry. These collaborations may take a broad range of forms, from informal sharing of knowledge to highly formalised collaborative arrangements. Collaboration may involve staff, students or visitors from a number of organisations, funding bodies, government agencies and commercial entities in a variety of combinations. Such collaborations raise issues around intellectual property ownership.

11.38 In the absence of clear agreement on the terms of the collaboration, the ownership of resulting intellectual property will be determined by legislation and common law principles.[26] The *Patents Act* allows for co-ownership of patents. Section 16(1) provides that:

> subject to any agreement to the contrary, where there are 2 or more patentees:
>
> (a) each of them is entitled to an equal undivided share in the patent; and
>
> (b) each of them is entitled to exercise the exclusive rights given by the patent for his or her benefit without accounting to the others; and
>
> (c) none of them can grant a licence under the patent, or assign an interest in it, without the consent of the others.[27]

11.39 Some research organisations have included provisions to address collaborative research in their intellectual property policies and statutes.[28] However, regardless of the organisation's policies, rights arising out of a particular collaboration will be determined by the contractual arrangements between the parties.

11.40 Much collaborative research in Australia occurs within Cooperative Research Centres (CRCs). The model agreement for the establishment of a CRC provides that intellectual property generated through the research, training and commercialisation activities of the CRC shall be owned by the parties to the CRC agreement 'as tenants in

---

25 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), 28.

26 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), [4.59].

27 *Patents Act 1990* (Cth) s 16(1).

28 See, eg, James Cook University, *Commercial Research and Consultancy Services: Policy and Procedures*, 6.2(a), which provides that rights to intellectual property arising from collaborative research should be negotiated on a case-by-case basis and will be determined by the contractual agreement between the parties to the arrangement.

common in proportion to their Participating Shares'.[29] Research organisation policies may also provide that such agreements will override their own internal policies for intellectual property ownership.[30]

Jointly funded research

11.41 Questions of intellectual property ownership may be similarly complex where research is funded jointly by a number of bodies, as each body may have different policies regarding the ownership of research results.[31] This may be particularly problematic where research is funded partially by overseas bodies. For example, the *National Health and Medical Research Council Act 1992* (Cth) requires that intellectual property generated through NHMRC-funded research be vested in an Australian organisation. However, this may conflict with the requirements of other bodies that also provide funding.

Issues and concerns

Effective commercialisation

11.42 One concern raised by allowing ownership of gene patents to vest in research organisations is whether they have the capacity to exploit such patents effectively. If patents are not properly exploited, the research may not be translated into public healthcare benefits.

11.43 This may occur for a number of reasons. The organisation may fail to transfer the technology to a commercial partner for development into a usable product, such as a test or therapy, if the organisation does not prioritise commercialisation or lacks the skills needed for effective commercial negotiations. The organisation may attempt to develop the technology through the creation of a spin-off company. If the company fails, the patent may pass to another organisation, such as a private company. These concerns are discussed further in Chapter 17.

Clear ownership and control

11.44 Genetic research undertaken by students or visitors may raise concerns about the ownership of resulting gene patents due to the complex relationship between the organisation and students or visitors. Issues about clear ownership may arise in the absence of policies determining which party will own any resulting intellectual property.

11.45 Difficulties in determining ownership may also arise where researchers at a number of organisations conduct research jointly. Similarly, as discussed above, disputes about ownership may occur where research has been jointly funded and each

---

29 Cooperative Research Centres Programme, *Agreement for the Establishment and Operation of a Cooperative Research Centre*, cl 23.1.

30 See Melbourne Research and Innovation Office, *Guide for Researchers and Research Administrators: An Overview of Research and Research-Related Policies and Procedures (2nd edn, September 2003)*, University of Melbourne, <www.research.unimelb.edu.au/guide/17.html> at 16 June 2004.

31 National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003.

funding body has differing policies about ownership. This may impede commercialisation because industry may be unwilling to pick up intellectual property where there is a lack of clarity in ownership. As noted in Chapter 18, joint ownership may form a barrier to commercialisation, as industry partners are generally unwilling to invest in developing intellectual property where negotiation with multiple parties will be necessary.

Options for reform

11.46 Public benefit from research is promoted when research results are exploited most effectively. If research results are not protected effectively, they may fail to attract commercial developers and products that require considerable industry development may not be created. If valuable research is not identified and utilised appropriately, its value to the public may not be realised. For these reasons, the vesting of ownership of intellectual property in publicly funded research may affect the promotion of public benefit. This section considers a number of ownership models.

11.47 Property rights could vest in one of a range of individuals or organisations involved in funding and producing research. Intellectual property rights to publicly funded research results could be vested in:

- a government;
- the body that provided funding for the research that led to the invention's creation;
- the researcher; or
- the organisation, initially, but subsequently vested in the funding body or government if the commercial potential of the invention is not developed within a reasonable time period.

11.48 The OECD Report asserted that for governments, granting research organisations rights to intellectual property generated with public funds

> can lead to better use of research results that might otherwise remain unexploited as well as to the creation of academic spin-offs or start-ups that create employment. For PROs [public research organisations] the benefits may include increased licensing and royalty revenues, more contract research and greater cross-fertilisation between entrepreneurial faculty and industry. Equally important, however, are the intangible benefits to an institution's reputation and to the quality of its research that closer interaction with the private sector can generate.[32]

32 Organisation for Economic Co-operation and Development, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003), 9.

11.49 The ARC has indicated that to date it has left commercial development to research organisations and that intervention in commercialisation has not been its practice, or that of the Australian Government.

> However, when there is a real problem requiring a real solution then a top down approach may offer the most effective approach to bring about a significant change in the culture in Australia towards the commercialisation of university research.[33]

11.50 In a 2000 report, the ARC raised the issue of granting university researchers, rather than the university, a licence to exploit the results of publicly funded research as a condition of the award of a grant. Such an approach would create financial incentives for researchers to identify and develop the commercial potential of their research.[34]

11.51 The strength of this approach lies in its potential to stimulate a more entrepreneurial attitude among researchers. This might focus early research efforts on areas of study that may lead to commercially profitable products. However, placing the onus to exploit intellectual property on researchers may be problematic where they lack the financial capacity to take their research results through to the commercialisation stage. Researchers also may not possess the business and legal expertise required for successful commercial negotiations.[35]

11.52 The ARC has suggested that these problems could be overcome if research organisations provide appropriate support to researchers.[36] This support might extend only to an advisory service, or more hands-on involvement in the commercialisation process. Research culture and commercialisation are discussed in Chapter 14.

11.53 The OECD Report supported intellectual property ownership by organisations, rather than vesting rights in individuals, because this provides:

> greater legal certainty for firms interested in exploiting research results, lowers transaction costs for partners and encourages more formal and efficient channels for knowledge and technology transfer.[37]

11.54 The DEST Report also favoured ownership by organisations[38] and suggested that the experience from Canada 'reveals many problems that may arise out of a laissez-faire approach to IP ownership'.[39] It argued against funding bodies retaining ownership. It suggested that 'the UK experience reveals problems that arise when

---

33 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 20.
34 Ibid, 20.
35 Ibid, 21.
36 Ibid, 21.
37 Organisation for Economic Co-operation and Development, *Turning Science into Business: Patenting and Licensing at Public Research Organisations* (2003), 11.
38 The report does, however, suggest that research institutions should be able to assign patent rights 'on a case-by-case basis where the institution believes such an assignment would lead to an optimal outcome with respect to commercialisation': Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), xii.
39 Ibid, x.

research funders maintain too much control over IP generated from their funds' and concluded that 'experiences therefore point to research bodies as the most desirable owners of IP'.[40]

Submissions and consultations

11.55 DP 68 proposed that universities and other publicly funded research organisations should ensure that their guidelines on intellectual property ownership cover research undertaken by visiting researchers and students, as well as staff—whether undertaken solely within the organisation or jointly with other bodies.[41]

11.56 This proposal met with widespread approval.[42] One submission also emphasised the difficulties research organisations face in developing and enforcing good intellectual guidelines that can be applied across all situations.[43]

11.57 The Queensland Government noted a number of considerations relevant when entering into an agreement for visiting researchers and students to undertake research. These included:

- whether the agreement should be made with the visiting researcher or the researcher's organisation;
- how and when the ownership of the intellectual property should be determined;
- whether the intellectual property should be shared, or owned solely by the host organisation;
- whether the visiting researcher or the organisations they represent should be entitled to a royalty stream from the commercialisation of the patent; and
- what administrative arrangements need to be in place to oversee the management of these agreements, particularly where the host organisation has a number of visiting researchers at any one time.[44]

---

40 Ibid, x.

41 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 12–4.

42 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Australian Research Council, *Submission P108*, 19 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

43 Queensland Government, *Submission P103*, 22 April 2004.

44 Ibid.

Intellectual property and public funding

11.58 As discussed above, most health-related research in Australia is publicly funded. This raises issues about the role of the funding body in decisions about the commercialisation of any resulting research.

11.59 Neither the ARC nor the NHMRC assert rights to the ownership of intellectual property arising out of their funding.[45] They have stated that they 'do not wish to hold a stake in direct ownership of IP nor do they intend to benefit directly from commercial outcomes of the research they fund through their financial support'.[46] However, each body emphasises that organisations should seek to commercialise intellectual property for the public benefit where appropriate and address issues of identification and protection of intellectual property and issues of management.

11.60 The ARC and NHMRC influence the exploitation of intellectual property resulting from research they fund through the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles). These principles were released in 2001 by the then Minister for Education, Training and Youth Affairs and the Minister for Health and Aged Care. The decision to develop the principles came as a result of the Australian Government's policy to further support research investment and commercialisation.[47]

11.61 The National Principles state that public funding bodies should have clear policies about whether they will claim ownership or associated rights for intellectual property generated from research supported by their funding. A requirement for compliance with the National Principles is often included in the ARC funding rules and agreements for particular grant programs.[48]

11.62 The National Principles require organisations receiving funding to have procedures and policies to:

- support researchers in recognising discoveries that may have commercial value and provide for a review process to identify intellectual property that can be protected and exploited;[49]

---

45 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), 5.

46 Ibid, 2.

47 The National Principles were developed by a working party comprising representatives from a number of key government organisations involved with, or with an interest in the outcomes from, publicly funded research: Ibid. The NHMRC also released its own intellectual property management guidelines in 2001, the National Health and Medical Research Council, *Interim Guidelines: Intellectual Property Management for Health and Medical Research* (2001), which largely mirror the content of the National Principles. These are no longer in effect.

48 See, eg, Australian Research Council, *Discovery Projects: Funding Rules for Applicants for Funding Commencing in 2004*, December 2003, [10.5].

49 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), Principle 2.

- clarify staff responsibilities in relation to intellectual property, including the prevention of premature public disclosure of research results prior to obtaining intellectual property protection;[50]

- outline whether they will claim any ownership or associated rights to intellectual property from publicly funded research (including research conducted by postgraduate students);[51]

- guide researchers in assessing the existing intellectual property that may affect their freedom to operate in their field of research;[52]

- review intellectual property and associated commercial activities and outcomes;[53]

- recognise the rights and needs of all stakeholders involved in the research and define the way in which benefits from the development and exploitation of the intellectual property will be allocated;[54] and

- provide guidance in relation to potential conflicts of interest concerning ownership, management, protection and exploitation of intellectual property.[55]

11.63 The National Principles state that organisations and, where appropriate, individual researchers[56] 'are expected to consider the most appropriate way of exploiting the IP generated from publicly funded research'.[57] The National Principles indicate that the options range from exclusive and non-exclusive licences, research agreements or contracts, through to joint ventures or the establishment of spin-off companies.

11.64 Research organisations are also required to be in a position to report on their intellectual property management.[58] However, the ARC does not take action to ensure that the results of ARC funded research are commercialised. It also does not require organisations receiving ARC funding to comply with any national interest policy.[59] However, it does track the research projects it funds, and conducts surveys with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and the

---

50 Ibid, Principle 3.
51 Ibid, Principle 4.
52 Ibid, Principle 5.
53 Ibid, Principle 6.
54 Ibid, Principle 7.
55 Ibid, Principle 9.
56 In some organisations, individual researchers can claim full or part ownership to rights arising from their research.
57 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), 6.
58 Ibid, Principle 7.
59 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 20.

NHMRC to see how many produce patents and commercial outcomes such as spin-off companies.[60]

Promoting the public interest

11.65 A range of issues arises from the current allocation of intellectual property rights in publicly funded research. These centre on whether this allocation promotes the major objectives of health and medical research funding, which are to generate healthcare and economic benefits for the Australian population.

11.66 A concern raised by some researchers is that shifting focus towards commercialisation of publicly funded research will direct research efforts away from some less lucrative fields. Some researchers are concerned that they must favour work areas that will yield patentable discoveries that can be commercialised because they are expected to exploit intellectual property to fund further research.[61]

11.67 There are also concerns that leaving the development and exploitation of research results to research organisations may mean they are not effectively translated into community benefits. This concern results, in part, from the absence of any requirement for organisations receiving public funding to exploit any resulting intellectual property in a way that benefits the public. As discussed above, public funding bodies in Australia generally take a 'hands-off' approach to the commercial development of research results and do not direct how results should be exploited.

11.68 Allowing research organisations to hold intellectual property in the results of publicly funded research may limit access by other researchers and developers to these results. Given that these results have been generated using public money, it may be desirable to ensure that benefits flow back to the public.

11.69 There may also be tensions between what might be perceived as organisational benefit, public benefit and national benefit. In deciding how to develop its intellectual property, an organisation may be confronted with a choice between maximising its own financial returns and maximising the benefits that may flow to the Australian community in the form of jobs, wealth and healthcare.

Defining the public benefit

11.70 A subset of concerns about the public benefit returns from public funded research is whether those benefits should flow to the Australian public in particular, or to the global public generally. This concern may also extend to whether to benefit Australia economically, for example by fostering growth of the biotechnology industry, or to benefit Australians in other ways, such as by providing access to healthcare products. These objectives are not necessarily mutually exclusive. As the NHMRC noted in its submission:

---

60 Australian Research Council, *Consultation*, Canberra, 22 September 2003.

61 B Pheasant, 'The Value of a Pure Thought', *Financial Review* (Sydney), 12–13 August 2000, 26.

> The NHMRC clearly supports the conduct of ethical research that leads to the maximum benefit for Australia. However, the NHMRC acknowledges that this does not necessarily equate to providing Australian companies with an advantage and acknowledges that benefits to Australia may flow through a number of different means.[62]

11.71 Placing restrictions on the way intellectual property in publicly funded research is exploited is one mechanism for favouring national benefit. DP 68 asked whether the National Principles should be expanded to require research organisations to:

- favour Australian industry when commercialising patented inventions created through the use of public funds; or
- include a 'no Australian disadvantage' clause in any sale, licence or partnership arrangement involving patented inventions created through the use of public funds.[63]

11.72 Many submissions expressed strong objections to introducing requirements to favour, or avoid disadvantage to, Australian industry.[64] These objections included:

- It is unclear what would constitute 'favouring', or 'avoiding disadvantage to', Australian industry.[65]
- Requirements of this kind may conflict with Australia's obligations under various World Trade Organization and bilateral free trade agreements.[66]
- The Australian biotechnology industry is small and mainly comprised of small-to-medium sized enterprises, which may not possess the resources and expertise to commercialise some technologies well.[67] To fulfil a requirement to favour Australian industry, holders of intellectual property may have to develop the

---

62 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

63 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 12–1.

64 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Australian Research Council, *Submission P108*, 19 April 2004; Unisearch, *Consultation*, Sydney, 15 March 2004.

65 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

66 Centre for Law and Genetics, *Submission P104*, 22 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

67 For example, successful commercialisation of biotechnology research often requires collaboration with large pharmaceutical companies, which are generally based overseas. A number of reports have stated that there is a lack of local industry receptors to develop intellectual property transferred from research organisations in Australia: Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 18; Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii.

technology with a less competitive company, which would be counterproductive to effective commercialisation of Australian research.[68]

- A general requirement to favour, or avoid disadvantaging, Australian industry is inconsistent with the ARC and NHMRC policies that commercialisation of intellectual property in research should be determined on a case-by-case basis.[69]

- Australian research success rests in part on overseas funding and investment, and collaboration with international research organisations, which might be inhibited by requirements to favour links with Australian companies.[70]

- Requirements to favour local industry may discourage investment in commercialisation of Australian research, as investors may not wish to be subject to such restrictions on commercial development.[71] They may also adversely affect the capacity to licence technology if the requirements will also restrict the licensee.[72]

- Requirements of this kind may be inconsistent with the NHMRC's opposition to proposals by the United States National Institutes of Health (NIH) to introduce similar measures.[73]

11.73 However, the idea of promoting support for local industry was not wholly rejected. A few submissions supported requirements to favour, or avoid disadvantage to, Australian industry.[74] Others submissions suggested a better alternative would be to require Australian industry to be favoured where practicable.[75] The Western Australian Department of Industry and Resources suggested that a broad, principled approach might also be more practical and effective than a strict requirement to favour local industry.[76] The Centre for Law and Genetics stated that the preferable approach is to

---

68 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.

69 Australian Research Council, *Submission P108*, 19 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.

70 Centre for Law and Genetics, *Submission P104*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Australian Research Council, *Submission P108*, 19 April 2004.

71 Queensland Government, *Submission P103*, 22 April 2004.

72 Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

73 National Health and Medical Research Council, *Submission P107*, 19 April 2004; Australian Research Council, *Submission P108*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

74 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.

75 Queensland Government, *Submission P103*, 22 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

76 Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

focus on the best means of commercialising the technology and how to achieve the greatest national benefit from it.[77]

11.74 The ALRC concurs with the objections expressed in submissions and does not consider it desirable to require that local industry is favoured, or not disadvantaged, when commercialising intellectual property in genetic research.

Options for reform

11.75 There are a number of possible mechanisms for promoting the flow of public benefit from publicly funded research. One option is the introduction of broad principles into the National Principles to ensure that publicly funded research, where commercialised, results in appropriate public benefit. Including directives at this level would require research organisations receiving public funding to incorporate similar principles into their intellectual property policies. This may shape the direction taken by organisations in developing and commercialising research.

11.76 This approach does not preclude commercialisation of research results. Rather, it aims to encourage intellectual property holders to select the most appropriate means of capturing public benefits from research, which may often be through commercialisation. Such an approach is taken in guidelines released by the Rural Industries Research and Development Corporation (RIRDC), which requires the research it funds to be managed 'in such a way as to maximise the benefit to its stakeholders'.[78] The RIRDC points out that:

> In some cases this will be achieved through commercialisation of research results … Commercialisation will be implemented when it provides a faster, more sustainable or more practical avenue for making new products, processes and services available to the RIRDC's primary stakeholders.[79]

11.77 Similar provisions are also contained in the conditions for grant funding by the Wellcome Trust in the United Kingdom. The provisions state:

> Should any Trust-funded IP arise from the Grant, then the Trust requires the Institution to consider whether the protection, management and exploitation of such Trust-funded IP is an appropriate means of achieving the public benefit.[80]

11.78 A related reform option is to increase the responsibilities placed on research organisations by the National Principles.[81] This could be done as part of a review of the National Principles. The DEST Report made a number of suggestions for increasing these responsibilities, which included:

---

77 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

78 Rural lndustries Research and Development Corporation, *Commercialisation of Intellectual Property*, <www.rirdc.gov.au/researchpriorities/commpolicy.html> at 16 June 2004, Principle 1.

79 Ibid, Principles 1 and 3.

80 The Wellcome Trust, *Grant Conditions: Conditions under which a Grant is Awarded to Institutions in the United Kingdom* (2003), Condition 7(ii).

81 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), xii.

- requiring organisations to notify funding bodies of any identified, valuable inventions created using public funds;

- emphasising that the ultimate responsibility for commercialising inventions rests with the organisation by adopting a time limit for applying for a patent;

- requiring organisations to establish an intellectual property management infrastructure, or to allocate a certain proportion of granted funds towards exploitation;

- emphasising the need to ensure employees' work arrangements and responsibilities do not act as a disincentive to commercialise and to counter any existing disincentives; and

- directing organisations to include knowledge transfer or commercialisation as an express component of their mission statement.[82]

11.79 The National Principles are intended to operate as high-level principles rather than to provide detailed guidance on how research should be utilised in particular cases. An additional reform option is to supplement the National Principles with detailed guidelines that provide direction on how the public benefit might be promoted. In particular, such guidelines could cover the range of options for effective commercialisation of research results and the way these may be pursued in a manner that promotes the public benefit.

11.80 Another approach would be to require all research results generated with public funding to be placed into the public domain, precluding anyone from claiming intellectual property rights in the results and excluding the ability to patent them. This approach has the advantage of making research results freely available for other researchers to use and build on.[83]

11.81 The international SNP Consortium (known as the TSC) adopts a variation of this approach. The TSC takes out patents over the single nucleotide polymorphisms (SNP) that the project identifies, but subsequently releases the details of each SNP into the public domain. The TSC does not plan to enforce the patents except to prevent others from patenting the same information.[84] The TSC's stated intellectual property objective

---

82 Ibid, 79–83.

83 This approach is supported by the Bermuda Principles, which advocate placing large scale human genome sequence information in the public domain in order to 'encourage research and development and to maximise its benefit to society': Wellcome Trust, *Summary of Principles Agreed at the International Strategy Meeting on Human Genome Sequencing*, University College London, <www.gene.ucl.ac.uk/hugo/bermuda.htm> at 16 June 2004. See further Ch 28.

84 Human Genome Project, *Genetics and Patenting*, United States Department of Energy, <www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml> at 16 June 2004.

is to ensure the SNP map it produces is 'free of third-party encumbrances such that the map can be used by all without financial or other IP obligations'.[85]

11.82 However, making intellectual property freely available may not always be the most appropriate means of promoting the development of research results into healthcare products and services. Inventions not protected by a patent may not be further developed. Without the incentive of a limited monopoly to allow costs to be recouped, it is unlikely that a biotechnology company will make the significant investment in developing an invention to product stage. Free access may be appropriate for some foundational technology such as genetic sequence information, while patent protection may be necessary for downstream research results to promote investment in commercial development.[86]

11.83 Alternatively, intellectual property might be made available through wide licensing at a low cost. Officials at the NIH have suggested in draft guidelines on licensing of genomic inventions that, where exclusive licensing is not required to secure sufficient private investment to develop research results, it is best practice to license intellectual property widely to provide non profit researchers and public health authorities with easy access to new research.[87] Critics argue that these guidelines take too broad an approach, which may prevent the value of some research from being realised if licensing strategies cannot be determined on a case-by-case basis. Concern that researchers will be required to follow the guidelines to receive funding has also been expressed.[88]

11.84 A final option is to give funding bodies or government some control of research results in the form of 'march-in' rights. This option is considered later in this chapter, although the ALRC believes that it is not appropriate in the Australian context.

Submissions and consultations

11.85 Some submissions suggested that realising public benefit from publicly funded genetic research was an important issue in patent law reform.[89] A number emphasised that commercialisation is often an effective approach to realising public benefit from

---

85 SNP Consortium Ltd, *The SNP Consortium: Full Genome Representative SNP Map Program Summary*, <http://snp.cshl.org/about/program.shtml> at 16 June 2004.

86 See, eg, R Eisenberg, 'A Technology Policy Perspective on the NIH Gene Patenting Controversy' (1994) 55 *University of Pittsburgh Law Review* 633, 640.

87 D Malakoff, 'NIH Roils Academe with Advice on Licensing DNA Patents' (2004) 303 *Science* 1757, 1757. On 5 March 2004, the NIH introduced draft guidelines suggesting that genomic technologies developed with federal funding should not be exclusively licensed if this is unnecessary to get the product to market.

88 A Surendran, 'US NIH Draft Guidelines Threaten Diagnostics Sector' (2004) 22 *Nature Biotechnology* 496.

89 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; D Weston, *Submission P62*, 12 November 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Consumers' Health Forum of Australia, *Consultation*, Canberra, 23 September 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; South Australian Government, *Submission P51*, 30 October 2003.

research.[90] Many submissions also highlighted the need to balance realising public benefit, creating incentives for innovation and promoting wide dissemination of research results.[91]

11.86 DP 68 proposed that the ARC and the NHMRC should review their principles and guidelines on intellectual property and research to ensure that publicly funded research, where commercialised, results in appropriate public benefit.[92] DP 68 also proposed that, as part of this review, the ARC and NHMRC should include guidance on what is meant by 'public benefit' in these principles and guidelines.[93]

11.87 The proposed review of the National Principles received strong support in submissions.[94] Submissions also supported guidance on the definition of 'public benefit'.[95] Both the ARC and NHMRC welcomed the prospect of a review, noting that it would be an opportunity to identify areas where researchers and research organisations want greater guidance on commercialisation and patenting of publicly funded research. The NHMRC also noted that the current National Principles may not provide sufficiently detailed information for researchers and research organisations about intellectual property and that it is timely to review them.[96]

11.88 However, while supporting the need for public benefit to flow from publicly funded research, the Department of Industry, Tourism and Resources (DITR) stated that the National Principles are not the appropriate instrument for this purpose.[97]

11.89 DITR commented that the proposal seemed to suggest that commercialisation does not promote public benefit. It noted that commercialisation is one of the most

---

90 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

91 New South Wales Health Department, *Submission P112*, 30 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Ministry for Science and Medical Research New South Wales, *Submission P109*, 28 April 2004.

92 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 12–1.

93 Ibid, Proposal 12–2.

94 South Australian Department of Human Services, *Submission P74*, 15 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Australian Research Council, *Submission P108*, 19 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

95 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

96 Australian Research Council, *Submission P108*, 19 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.

97 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

effective means of accruing public benefit from publicly funded research due to the cost of developing technology into marketable products.[98] Another suggested the proposal is at odds with government policies to promote the commercialisation of research.[99]

11.90 DP 68 also proposed that the principles and guidelines developed in the proposed review of the National Principles should enable conditions to be attached to the grant of funding for genetic research, to limit the commercialisation of publicly funded research in appropriate circumstances. Such conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.[100]

11.91 This proposal met a mixed reception in submissions. The NHMRC and ARC themselves welcomed the proposal.[101] The NHMRC acknowledged that:

> there may be circumstances in which the NHMRC may wish to fund research, where it would be beneficial for the results of the research to be in the public domain or available for use by others. For example, there may be circumstances under which the NHMRC wishes to fund the development of stem cells lines that are widely available to all researchers.[102]

11.92 The NHMRC indicated that this could be done by calling for tenders for projects, on which it would have the capacity to impose relevant conditions.[103] A number of submissions agreed that there might be circumstances in which the public benefit would be served by promoting broad access to genetic technologies.[104]

11.93 Some submissions agreed with attaching conditions to research funding to ensure wide access to research.[105] The Centre for Law and Genetics submitted:

> We do not see that the implementation of this Proposal would in any way impinge on commercialisation in the normal course of events for 'commercialisable' research. We see that the circumstances in which the NHMRC or ARC would impose such conditions as being strictly limited foundational research discoveries of the nature of the human genome project, the SNP project and the HapMap project. In our view, these projects should be freed from the fetters of commercialisation.[106]

---

98 Ibid.
99 Ministry for Science and Medical Research New South Wales, *Submission P109*, 28 April 2004.
100 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 12–3.
101 National Health and Medical Research Council, *Submission P107*, 19 April 2004; Australian Research Council, *Submission P108*, 19 April 2004.
102 National Health and Medical Research Council, *Submission P107*, 19 April 2004.
103 Ibid.
104 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Centre for Law and Genetics, *Submission P110*, 28 April 2004; Australian Research Council, *Submission P108*, 19 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.
105 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004.
106 Centre for Law and Genetics, *Submission P110*, 28 April 2004.

11.94 The Centre also supported imposing conditions because this would justify researchers and organisations in decisions not to commercialise where it would be inappropriate to do so.[107]

11.95 However, a number of submissions noted that the proposed conditions would be difficult to oversee or enforce.[108] The Queensland Government commented that due to the difficulty of policing the conditions, the NHMRC and ARC would need to rely on the goodwill and honesty of the funding recipients.[109] The Centre for Law and Genetics submitted that conditions might be difficult to enforce if a patent is assigned.[110]

11.96 DITR stated that restricting commercialisation would be unlikely to address any perceived weaknesses with the current system. It pointed out that commercialisation promotes dissemination of research through patent specifications and allows for financial returns from research.[111] The Western Australian Department of Industry and Resources commented that commercialisation is 'often essential for the outcome of the research to be developed and made available or accessed'.[112]

11.97 DITR argued further that there is little evidence that research organisations are granting too many exclusive licences, noting that exclusive licensing is often necessary to ensure successful commercialisation.[113] However, as the Centre for Law and Genetics pointed out:

> some of the most widely licensed patents have been the most lucrative (the Cohen Boyer patent being the most obvious). Hence, wide licensing does not necessarily equate with non-commercialisation (although it does provide public benefit if licence fees are low and other licence obligations are minimal).[114]

11.98 Some submissions also objected to imposing conditions on funding as they may lead to the protection of research results through secrecy;[115] unreasonably restrict or complicate commercial opportunities, including the capacity to attract investment, for developing technology;[116] or result in overseas companies appropriating technology, thereby denying financial returns to Australian research organisations and industry.[117]

---

107 Ibid.

108 Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

109 Queensland Government, *Submission P103*, 22 April 2004.

110 Centre for Law and Genetics, *Submission P110*, 28 April 2004.

111 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

112 Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

113 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004. The Department noted that 'US research also demonstrates that there is a high correlation between the granting of exclusive licenses (compared with non-exclusive licenses) and products reaching the marketplace due to the increased motivation provided by the exclusive license'.

114 Centre for Law and Genetics, *Submission P110*, 28 April 2004.

115 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

116 Queensland Government, *Submission P103*, 22 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; *Confidential Submission P77 CON*, 16 April 2004.

117 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

11.99 The Walter and Eliza Hall Institute of Medical Research commented that the proposal to impose conditions 'ignores the observation that many discoveries and subsequent inventions arise from serendipity. Invention and innovation is not a planned process.'[118]

11.100 The Western Australian Department of Industry and Resources suggested that an alternative could be to require funding recipients to seek approval from the funder for a proposed commercialisation strategy.[119] In consultations, the Garvan Institute pointed out that conditions on funding might cause difficulties where research is jointly funded by public and private funds.[120]

ALRC's views

11.101 The ALRC considers that intellectual property rights in publicly funded research should vest in the individual or organisation that will best exploit them to promote public interest, including the provision of healthcare in Australia and overseas.

11.102 In the ALRC's view, research organisations are well placed to utilise intellectual property resulting from research and the ALRC has no evidence of any need to alter the current framework for ownership of publicly funded research. Although the capacity of some research organisations to commercialise technology may be limited by a lack of commercial expertise or funding to develop products, it is unlikely that government funding agencies or researchers themselves are better able to take on this task. In the ALRC's view, commercialisation problems are better addressed through providing appropriate support to research organisations in the form of funding and advisory services. The options for providing support of this kind are discussed in Chapters 14, 17 and 22.

11.103 There may be differing conceptions of the public benefit and in some instances there may be a variety of benefits that could be generated through exploiting patented research results in different ways. It is clear from submissions that there is a need for greater clarity on what is meant by public benefit. The ALRC considers that in many circumstances commercialisation of genetic inventions will be the best way to maximise public benefit. However, research organisations would benefit from having greater direction in this area.

11.104 In the ALRC's view, there may be merit in the ARC and the NHRMC implementing the DEST Report's 'expanded National Principles approach' to enlarge the content of responsibilities currently applied to research organisations.[121] Although

---

118 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.
119 Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.
120 Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.
121 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), xii.

the ALRC has not made a specific recommendation on this issue, it does consider that there would be merit in drawing on the reform suggestions made in the DEST Report in any future review of the National Principles.[122]

11.105 The ALRC also considers there is no single model for achieving public benefit from genetic research. In some instances greater public benefit may result from making patented genetic materials or technologies freely accessible or widely licensed; in others, by allowing a patent to be exploited by a single company. The most appropriate approach to exploiting or using the results of genetic research can only be considered on a case-by-case basis.

11.106 However, the ALRC is of the view that there is a need to ensure publicly funded genetic research, when commercialised, optimises the public benefit. The ALRC regards the National Principles as the most appropriate location in which to emphasise this need, and recommends that the ARC and NHMRC should review the National Principles to provide guidance on what is meant by public benefit. In doing so, the ARC and NHMRC could draw on the approaches taken by the RIRDC and the Wellcome Trust.

11.107 In addition, as the National Principles are necessarily broad, the ARC and NHMRC should implement guidelines to assist organisations receiving public funding for research in complying with them. These guidelines should:

- give direction on what is meant by public benefit;
- assist organisations in determining whether it is appropriate for particular research results to be commercialised; and
- identify a range of approaches to the exploitation of intellectual property and the circumstances in which they might be used.

11.108 In developing these guidelines, the ARC and NHMRC should also take account of the Australian Vice-Chancellors' Committee's *Ownership of Intellectual Property in Universities: Policy and Good Practice Guide.*[123]

11.109 As part of this review, the ARC and NHMRC should ensure the revised National Principles and related guidelines are widely disseminated to research organisations and other relevant stakeholders.[124]

---

122 See also Ch 14 and 17.

123 Australian Vice-Chancellors' Committee, *Ownership of Intellectual Property in Universities: Policy and Good Practice Guide* (2002).

124 It should be noted that a recent DEST review found that the National Principles are 'not widely recognised, understood or utilised'. DEST commented that this 'might reflect a need for [DEST], ARC, NHMRC, and other appropriate government agencies to communicate the existence and intent of these principles'. See Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), xi.

11.110 The ALRC also considers that in exceptional circumstances the ARC and NHMRC should be prepared to place conditions on grant funding to direct how any resulting technologies are exploited where it is considered that greater public benefit would result from the resulting research being placed in the public domain either with no patent being sought or, where a patent is sought, from being widely licensed. Provision for such conditions to be placed on the grant of public research funding should be incorporated into the National Principles.

11.111 The ALRC acknowledges that many submissions expressed concern about the potentially restrictive impact of such conditions on research commercialisation. However, the ALRC emphasises that conditions of this kind should be imposed only in exceptional circumstances, particularly where the research is foundational and the output of research is a tool that may be widely used by other researchers. The ALRC notes that in many cases, wide licensing of research results can be the most effective commercial strategy.[125]

11.112 Research organisations should also ensure they have clear policies and effective practices in this area, although the ALRC does not seek to be prescriptive about the content of these policies or practices. To avoid problems with determining ownership and rights to intellectual property in genetic research conducted jointly, either between research organisations or collaboratively with industry, organisations should ensure their intellectual property policies include clear guidance on ownership of results of joint research.

Recommendation 11–1 The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles) to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Recommendations 12–1 and 17–2.)

125 Mike Stott and Jill Valentine comment that in many cases, 'probably the best source of revenue for the patent holder is to make the tool commercially available as a product that can be purchased by others or to grant licences widely on non-exclusive basis': M Stott and J Valentine, 'Gene Patenting and Medical Research: A View from a Pharmaceutical Company' (2004) 3 *Nature Reviews Drug Discovery* 364, 365–366.

Recommendation 11–2 The ARC and NHMRC should develop guidelines to assist organisations receiving public funding for research in complying with the National Principles. The guidelines should, among other things:

(a) provide guidance on what is meant by 'public benefit';

(b) assist organisations in determining whether it is appropriate for particular research results to be commercialised; and

(c) identify a range of approaches to the exploitation of intellectual property and the circumstances in which they might be used.

Recommendation 11–3 In exceptional circumstances, where the public benefit would clearly be served by broad dissemination of the results of publicly funded research, the ARC and the NHMRC should consider attaching conditions to the grant of funding. These conditions might include a requirement that research results be placed in the public domain, or that a patented invention be widely licensed.

Recommendation 11–4 Research organisations should ensure that their policies on intellectual property ownership cover research undertaken by visiting researchers, students and staff—whether undertaken solely within the organisation or jointly with other bodies. (See also Recommendation 17–4.)

March-in rights

11.113 Recommendations 11–1, 11–2 and 11–3 are an alternative to a more restrictive approach under which the government maintains residual rights in any publicly funded research, known as 'march-in rights'.

11.114 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 that aimed at improving technology transfer from research organisations receiving public funding to the private sector. In particular, the *Bayh–Dole Act 1980*[126] (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.

11.115 However, unlike in Australia, under the *Bayh–Dole Act* the federal agency that funds research retains certain residual rights to inventions developed from that research. These 'march-in' rights are aimed at allowing the government to step in and

126 35 USC ss 200–212.

commercialise a patented invention where an organisation has failed to do so. The government can also use these rights to take title to an invention and assign it to another organisation that is likely to commercialise it more effectively.[127]

11.116 These 'march-in' rights have been used sparingly. An example of the use of march-in rights is the NIH negotiations in relation to the broad patents held by the Wisconsin Alumni Research Foundation (WARF) over primate embryonic stem cells developed through publicly funded research. In September 2001, the NIH reached an agreement with WARF to provide access for federally funded researchers to the patented human embryonic stem cells. A subsequent agreement was reached providing access to the patented stem cells.[128]

Submissions and consultations

11.117 IP 27 asked whether there was any need in Australia for the government to retain a variety of rights to intellectual property developed from publicly funded research.[129] These rights included 'march-in' rights, the right to a government use license and the right to limit exclusive licences. The introduction of the concept of residual rights found some favour in submissions, albeit with some reservations.

11.118 Submissions that favoured march-in rights suggested that such rights enable the government to:

- address inappropriately wide use of gene patents;[130]
- ensure continued access by the public to the results of publicly funded research;[131]
- retain the right to use gene patents in the provision of public health services, either completely or at a reduced fee;[132]
- address equity of access issues in the public health system;[133] and
- address the lack of incentives for researchers to commercialise their research;[134]

---

127 *Patents Act 1952*, 35 USC s 203.
128 WiCell Research Institute Inc and Public Health Service of the United States Department of Health and Human Services, *Memorandum of Understanding*, 5 September 2001.
129 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 5–3.
130 J Mattick, *Submission P35*, 13 October 2003; South Australian Government, *Submission P51*, 30 October 2003.
131 South Australian Government, *Submission P51*, 30 October 2003; G Suthers, *Submission P30*, 2 October 2003.
132 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
133 Genetic Support Council WA (Inc), *Submission P59*, 7 November 2003.
134 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

11.119 Objections to march-in rights included:

- overuse of march-in rights will erode the confidence of potential commercial users that patents have real value;[135]
- overuse could also lead to greater reliance on reversion to proprietary protection rather than patents, and then such provisions would be powerless;[136]
- governments should not be given the task of commercially exploiting intellectual property as they lack the capacity to do so effectively;[137]
- march-in rights would be ineffective in addressing the barriers to the commercialisation of genetic research in Australia;[138]
- march-in rights may create a disincentive to industry collaboration in commercialising research by restricting potential negotiations between research organisations and commercial partners;[139]
- Crown use and compulsory and statutory licensing provisions in the *Patents Act* are more effective mechanisms for addressing inappropriate use and commercialisation of publicly funded research results;[140] and
- march-in rights would also impose significant management and tracking obligations on funding bodies, which they are not currently in a position to exercise.[141]

ALRC's views

11.120 For a variety of reasons, the ALRC does not consider it necessary to recommend the Australian Government retain residual rights in intellectual property from publicly funded research. First, the ALRC concurs with the view expressed in a number of submissions that the government is not well placed to develop gene patents commercially. This is in part because the Government is neither structured to do so; nor do government agencies generally have the commercial skills and experience to negotiate with industry to develop patented technology.

---

135 Genetic Support Council WA (Inc), *Submission P59*, 7 November 2003.

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

137 Ibid; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Wondu Business & Technology Services Pty Ltd, *Submission P4*, 20 August 2003; A McBratney and others, *Submission P47*, 22 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

138 Queensland Government, *Submission P57*, 5 January 2004; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003. DITR argued that failure to commercialise research in Australia is more often attributable to a lack of venture capital and the risk-averse nature of private sector investors in this country, rather than the lack of incentives the *Bayh–Dole Act* was designed to address.

139 GlaxoSmithKline, *Submission P33*, 10 October 2003.

140 Ibid; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003.

141 Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

11.121 By contrast, research organisations have been developing their capacity to undertake commercialisation over the past decade, through skill-building and the creation of infrastructure. This includes the establishment of dedicated technology transfer offices employing staff with commercial experience, and the provision of a range of educational and networking programs.

11.122 In Australia, commercialisation of gene patents is promoted through a wide range of measures, including the National Principles and other funding requirements, government funding focused on industry linkages and technology transfer, state government programs supporting biotechnology industry development and benefit sharing schemes within research organisations. Given the level of support already provided by these measures, it is unlikely that a lack of commercialisation activity in research organisations is generally attributable to reluctance to commercialise. Instead, as discussed in Chapter 17, commercialisation is better promoted through continuing financial and educational support programs to provide monetary support and raise commercialisation skills.

11.123 In addition, Recommendation 11–3 is intended to allow funding bodies the option of placing conditions on research grants where it is thought that public benefit will be maximised by not patenting the research results. The ALRC anticipates that this option would be utilised very sparingly but it does allow for one purpose of march-in rights to be achieved without the need for the government to retain residual rights.

11.124 There are already a number of mechanisms available for addressing some of the concerns at which march-in rights are directed, for example, restrictions on access to significant patented technology or a failure to exploit a patented invention appropriately. These include the Crown use and compulsory licensing provisions of the *Patents Act*.

11.125 However, the ALRC recognises that these mechanisms have rarely been used and may not provide a complete solution to the issues raised in this chapter. For example, the Crown use provisions enable the Government to exploit a patented invention itself, or authorise another person to do so. To some extent, this provision gives the Government powers similar to those provided under the *Bayh–Dole Act*. However, Crown use is more limited than march-in rights, as it extends only to use for the services of the Commonwealth or of a State.[142] These mechanisms, and recommendations for addressing some of these limitations, are discussed in Chapters 26 and 27.

142 See also Ch 26. There are also practical concerns about the efficacy of compulsory licensing as a solution in this context. Few, if any, compulsory licences have been granted in Australia to date. This may stem from costs involved in applying to a court for an order, or the difficulty in satisfying the legislative test for such an order. Compulsory licences may also be difficult to acquire because of pressure on governments from major trading partners. However, several commentators have suggested that the threat of compulsory licensing can encourage patent holders to negotiate a voluntary licence.

Government contracted research

11.126 Although it is Australian Government policy for researchers or organisations whose research has been publicly funded to own any intellectual property generated by that research, this is not necessarily the case for research that is contracted by government. It is frequently a condition of a contract with a government department that the government retains any intellectual property rights.

11.127 For example, the Department of Health and Ageing indicated that it retains intellectual property rights in research that it has funded to ensure that relevant information can be widely disseminated. In these cases the Department grants non-exclusive licences to the intellectual property.[143]

11.128 IP 27 asked about the implications of government retaining ownership of intellectual property arising from contracted research.[144] A number of submissions objected to government retaining intellectual property in contracted research suggesting it was not best placed to commercialise patented genetic technology or ensure public benefits.[145]

ALRC's views

11.129 The ALRC has insufficient evidence about government contracted genetic research to make a specific recommendation. It notes with approval the Department of Health and Ageing's response that it seeks to disseminate widely the results of contracted research. Indeed this may be an important rationale for the government to contract research and could be an alternative to Recommendation 11–3.[146] However, where public benefit would be maximised through commercialisation of research, the government may not be best placed to do this. In such circumstances, the government may need to ensure that policies are in place to promote appropriate commercialisation.

---

143 Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.

144 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 5–4.

145 AusBiotech Ltd, *Submission P58*, 7 November 2003; A McBratney and others, *Submission P47*, 22 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.

146 DITR made a similar suggestion in submissions: Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

12. Patents and Human Genetic Research

Contents

Introduction

12.1 The Terms of Reference direct the ALRC to consider the impact of patent laws and practices related to genes and genetic and related technologies on the conduct of research. This chapter considers whether gene patents may have a 'chilling effect' on the conduct of research and, if so, what reforms may be needed to address this concern.

12.2 Research may be conducted at all stages of the continuum from basic research to research directed towards marketable end products. This chapter begins by briefly describing the research continuum, the different interests of those involved in 'upstream' and 'downstream' research and inventions, and the different ways in which they may experience the impact of patent laws and practices. The chapter discusses the general impact of gene patents on research, with reference to Australian and international empirical studies and the views expressed in submissions. The chapter describes the specific subject matter and claims of gene patents that are most likely to hinder research—that is, broad patents on upstream or 'foundational' inventions and patents on research tools.

12.3 The ALRC recommends a specific initiative in relation to research tools developed through publicly funded research. The chapter also highlights recommendations made elsewhere in this Report to address the potential for future harm to genetic research that may be attributable to gene patenting.

The research continuum

12.4 The terms 'upstream' and 'downstream' are commonly used to describe two ends of a continuum from basic research through to research directed toward marketable end products or processes.[1] For example, in human genetic research, basic research may involve the identification of genetic sequences associated with particular biochemical functions. Downstream research may focus on the eventual use of these genetic sequences in the diagnosis of disease or in novel therapies, such as gene therapy or the production of therapeutic proteins.

12.5 Patents may be issued at different stages of the research continuum. Researchers developing downstream products will require access to patented inventions, including research tools. Access to many patented inventions may be required in order to develop a marketable product. While downstream researchers may view such inventions as essential research inputs to which open access is important, upstream patent holders may view research tools as valuable end products in themselves.[2]

12.6 It follows that the implications of patent reform may be quite different for different actors in the research and biotechnology sectors. For example, while small or start-up biotechnology firms may need patents on their upstream discoveries in order to attract investors, for pharmaceutical companies patents are needed not to raise capital but to ensure effective commercial exploitation of their products.[3]

12.7 The changing nature of research organisations is another important background factor in considering the impact of patent law and practice on research. Traditionally, upstream research has been the province of the public sector, and the private sector has focused more on the downstream application of that research.[4] However, as discussed in more detail in Chapter 11, Australian Government policy is to promote the commercialisation of publicly funded research, including that conducted by universities. Universities and other recipients of public research funding are now encouraged to patent and facilitate commercialisation of the results of their research. Academic and non-profit research organisations increasingly have interests not only as potential users of patented inventions, but also as patent holders. Australian research institutions use the patent system in order to obtain protection for their inventions and routinely seek to license these rights to commercial enterprises.[5]

---

1 See, eg, D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 15.

2 See R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 228–229; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 15.

3 R Eisenberg, 'Patenting Research Tools and the Law' in National Research Council (ed) *Intellectual Property Rights and Research Tools in Molecular Biology, Summary of a Workshop Held at the National Academy of Sciences, February 15-16* (1996), <http://books.nap.edu/html/property>.

4 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 15.

5 Davies Collison Cave, *Submission P48*, 24 October 2003.

Impact of gene patents on research

12.8 The major debate in this area revolves around whether gene patents have a chilling effect on research and innovation, rather than promoting them. Two reasons are generally advanced for this possible effect. The first is that research may be hindered by researchers' concerns about infringing patents or about the difficulties of obtaining licences to use patented inventions on appropriate terms. The second reason, discussed in Chapters 11 and 14, is that government policies relating to the commercialisation of research, together with certain aspects of patent law and practice, mean that information about research outcomes may not come into the public domain to be used freely by other researchers.

Empirical studies

12.9 Whether the proliferation of upstream intellectual property claims in rapidly advancing fields of technology such as genetics promotes or retards research and innovation has been described as 'an empirical question of considerable complexity'.[6] The Organisation for Economic Co-operation and Development (OECD) has referred to the 'conspicuous absence of rigorous economic studies' that explore the impact of gene patents on research.[7]

12.10 There have been some limited empirical studies about the impact of gene patents and licences on research. In general, their conclusions have been equivocal. For example, a study in the United States by John Walsh, Ashish Arora and Wesley Cohen (Walsh study) noted that, while the patenting of upstream discoveries had increased, almost no-one reported that worthwhile projects had stopped because of restrictions on access to intellectual property rights for research tools.[8] Instead, the Walsh study found that most researchers, both in universities and industry, had adopted 'working solutions'.[9]

12.11 In 2002, the OECD Working Party on Biotechnology Report (OECD Report) identified a number of issues concerning the possible adverse impact of gene patents on research, including blocking patents or overly broad patents; increases in secrecy and a slower pace of research; increased research and transaction costs; and increased litigation involving public research organisations.[10] Despite documenting some specific

---

6 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 223.

7 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 82.

8 J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285, 331.

9 For example, licensing, inventing around, going offshore, court challenges and invoking a research exemption: Ibid, 331.

10 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 12–15.

concerns held by researchers,[11] the OECD Report did not substantiate fears that growth in the number and complexity of biotechnology patents is preventing access to inventions for research purposes.

12.12 In Australia, Dr Dianne Nicol and Jane Nielsen conducted an empirical study in 2003 of medical biotechnology patenting (Nicol–Nielsen Study).[12] They analysed 49 written survey responses from respondents from private sector biotechnology and pharmaceutical companies, 23 from research institutions and 18 from diagnostic testing facilities, together with the results of 40 targeted interviews.[13]

12.13 While it is hard to draw firm conclusions from these studies, their specific findings are important in understanding how researchers and others perceive the impact of gene patents on research. These are discussed throughout this chapter.

Submissions and other views

12.14 The ALRC received a wide range of comments in submissions concerning the impact of gene patents and licensing on the conduct of research. Many submissions maintained that there is no current evidence that gene patents are inhibiting research in Australia.[14] One reason for this is that 'researchers are often oblivious to the patent rights held by commercial entities'.[15] It was said that the absence of infringement proceedings and other enforcement activities means it is unlikely gene patents are stifling innovation, at least in Australian universities.[16] However, submissions cautioned that while gene patents do not appear to have had an adverse effect on research to date, the situation could change in the future, and that increased levels of patent enforcement should be anticipated.[17]

12.15 Submissions highlighted possible adverse impacts on research.[18] The National Health and Medical Research Council (NHMRC) noted that the complexities of the patent system may have a 'dampening' impact on research, particularly where

---

11 For example, about the impact of reach-through licensing agreements: Ibid, 79.

12 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6.

13 Ibid, 64–71.

14 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

15 A McBratney and others, *Submission P47*, 22 October 2003.

16 Ibid. See also Ch 13.

17 South Australian Government, *Submission P51*, 30 October 2003; G Suthers, *Submission P30*, 2 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

18 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

organisations lack expertise in intellectual property management.[19] The Australian Health Ministers' Advisory Council referred to difficulties arising in 'negotiating commercially viable licences with patent holders in order to explore the development of alternative technologies in relation to an already patented gene'.[20] The Royal College of Pathologists of Australasia noted evidence that excessively broad patents have inhibited research in biotechnology.[21]

12.16 The Nicol–Nielsen Study provides other views on patents and research in biotechnology. Respondents from research institutions had predominantly positive views about the impact of patents on research and development.[22] Respondents from biotechnology companies also viewed the impact of patents on their research positively.[23] However, Nicol and Nielsen found that all sectors of the biotechnology industry had greater concern about the potential for gene patents to have a negative impact on research than for any other type of patents.[24]

12.17 Consistently with submissions to this Inquiry, warnings were sounded about the future. Nicol and Nielsen noted that, as Australian companies and institutes gain an international presence, they may attract more attention from patent holders. While vigorous patent enforcement has not been typical, it was said that both overseas and Australian companies are starting to take a more aggressive approach to enforcement.[25]

12.18 Nicol and Nielsen concluded that there has been some evidence in Australia of exclusionary practices in relation to biotechnology patents. This is not surprising, as the right to exclude others from exploiting an invention is a fundamental attribute of patent protection. Nicol and Nielsen found few researchers who were concerned about the long-term effects on research of restricted access to patented inventions and that 'in most cases research was able to proceed albeit in a modified fashion'.[26]

12.19 Many submissions focused on the benefits of patent protection for research, citing opportunities to obtain research funding from commercial sources and to recycle the financial benefits of commercialised research back into the research effort.[27]

> In many cases, the existence of gene and other biotechnology patents has attracted crucial financial support from the biotechnology and pharmaceutical industries (as well as private investors) and has allowed the continuation of medical research.[28]

---

19 National Health and Medical Research Council, *Submission P52*, 31 October 2003.
20 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.
21 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
22 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 85.
23 Ibid, 84–85.
24 Ibid, 90.
25 Ibid, 140.
26 Ibid, 172.
27 See, eg, AusBiotech Ltd, *Submission P58*, 7 November 2003; A McBratney and others, *Submission P47*, 22 October 2003.
28 A McBratney and others, *Submission P47*, 22 October 2003.

Broad patents

12.20 A specific category of concern relates to what may be described as broad patents—patents that grant broad rights to the patent holder and may be seen as covering applications invented later by someone else.

12.21 Unless widely licensed, broad patents can discourage research and innovation either because researchers will be concerned about breaching existing patents, or because downstream inventors will have to pay licence fees to those whose patents were granted first. In contrast, a narrowly expressed patent may encourage others to 'work around' the patent, thereby having less impact on related research. Submissions reflected concern about the impact of broad patents on research.[29]

12.22 When gene patents are described as 'broad', the intended meaning may vary. Genetic discoveries often occur from the top down—that is, the discovery of the gene often precedes discovery of its constituent parts, proteins and functions.[30] As a consequence, patents covering an isolated genetic sequence are the most upstream category of gene patent.[31] Concern about the impact of broad gene patents on the conduct of research is most often expressed in relation to these kinds of gene patents.

12.23 Where gene patents contain 'product per se' or 'composition of matter' claims over isolated genetic materials (such as DNA sequences), the patents may be considered broad because all uses of the product may be covered by the patent. Other gene patents may not claim isolated genetic materials but may nevertheless be considered broad because the claims—for example, over the diagnostic use of a DNA sequence—allow the patent holder, in effect, to assert rights over the DNA sequence itself because any other diagnostic test for the disease specified in the claim would infringe the patent.[32]

12.24 The Nicol–Nielsen Study examined the views of respondents on 'patent breadth and its impact on innovation'.[33] Seven of 23 research institution respondents, and similar proportions of other categories of respondent, said patent breadth had some negative impact on research.[34] Nicol and Nielsen observed that 'most respondents were fairly optimistic about their ability to continue research despite the presence of broad

---

29 For example, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

30 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 42.

31 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 359.

32 See, eg, B Cain, *Legal Aspects of Gene Technology* (2003), 121–122.

33 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 86.

34 Ibid, 87.

patents, and felt that the problem of broad patents was dissipating as patent offices tightened up their examination procedures'.[35]

12.25 In the research context, patents may also be considered 'broad' because they cover a generally applicable research technique or resource. Such patents are better referred to as 'foundational' inventions because the subject matter may facilitate a wide range of further potential discoveries and inventions.[36] Foundational inventions are discussed below in the context of research tools.

Patents and research tools

12.26 The single most important concern has been about the effects on research of patents on genetic materials or technologies that are used as research tools. The literature in Australia and overseas expresses a range of concerns about the impact of patents on the use of research tools. The following material examines these concerns, some of which relate to research tools generally and some of which relate to those used in genetic research specifically.

12.27 In order to assess the significance of the concerns and possible means of addressing them, it is important to distinguish between the types of products and processes that may be referred to as research tools and the different meanings that may be given to this term.

What are research tools?

12.28 Research tools are resources used by scientists, where those resources have no immediate therapeutic or diagnostic value. In biotechnology, research tools may include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools, methods, laboratory equipment and machines, databases and computer software.[37]

12.29 There are many different ways to categorise the range of research tools used in genetic research. For example, three basic categories are:

- *Research techniques*. Some gene patents cover laboratory techniques that molecular biologists use in research, such as the Cohen–Boyer techniques (for gene-splicing) and the polymerase chain reaction (PCR) methodology (for DNA amplification).

- *Research consumables*. Some gene patents cover particular enzymes or reagents that are used in the laboratory, such as Taq polymerase (used in PCR) and restriction enzymes (used in cloning and other applications).

---

35 Ibid, 89.

36 See, eg, Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 12.

37 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

- *Research targets*. Some gene patents cover genetic materials that are targeted in research, for example genes for receptor proteins used in designing new drugs or vaccines, such as the HIV-receptor CCR5.[38] This category also includes expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), which can be targets of research or used to target other genetic materials.

Foundational research tools

12.30 In considering their impact on research, it is useful to distinguish foundational or upstream research tools from other research tools. The most important research tools are said to be 'fundamental research platforms that open up new and uncharted areas of investigation'.[39] It is said that these platforms are best utilised by multiple researchers because 'a single patent holder is unlikely to see the myriad directions in which a broadly enabling research platform could be developed'.[40] However, there is no bright line between foundational research tools and other tools; moreover the characterisation of a specific research tool may vary with time.[41]

12.31 Foundational inventions are of such importance that all or much that follows in the relevant field flows from them.[42] Examples include the Cohen–Boyer and PCR patents. The Cohen–Boyer technique has been described as a 'quintessential' research platform in that these recombinant DNA techniques were used in many different ways by many researchers. Contemporary examples of research platforms might be seen as including human genetic stem cell lines[43] and RNA interference (RNAi) technology.[44]

12.32 Concerns about the impact of patents on foundational inventions were expressed by the Medical Genetics Elective Group of the University of Newcastle which noted, in relation to RNAi technology, that selectivity in granting licences may 'slow, or even halt, the discovery of further beneficial mechanisms of RNAi technology'. Small universities or hospital-based research laboratories may not be able to afford licences, 'limiting the progression of RNAi research'.[45]

12.33 The Walsh study suggests that if a research tool is foundational, the extent to which restricted access is likely to hinder progress in research will depend on whether the tool can be used in the development of a number of inventions that will eventually

---

38 Receptor proteins are proteins that are found on the cell surface. Upon binding a ligand, they set off a signal reaction inside the cell, inducing a response. Many viruses gain entry to the cell by sticking to (or 'docking with') a receptor protein. The CCR5 gene makes a receptor protein that the HIV virus uses as a docking receptor to gain access to an immune cell.

39 A Rai, 'Genome Patents: A Case Study in Patenting Research Tools' (2002) 77 *Academic Medicine* 1368, 1369.

40 Ibid, 1369.

41 See, eg, Ibid, 1369.

42 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 12.

43 A Rai, 'Genome Patents: A Case Study in Patenting Research Tools' (2002) 77 *Academic Medicine* 1368, 1369.

44 RNA-mediated interference is the inhibition of expression of specific genes by double stranded RNA (dsRNA): E Milward and others, *Submission P46*, 20 October 2003.

45 Ibid.

compete with one another. If a foundational invention is fundamental to competing downstream research applications, access is more likely to be restricted in some way, for example, through exclusive licensing.[46]

12.34 Nicol and Nielsen state that 'more prolific patenting' of research tools sets up the main precondition for the concern that research may be impeded.[47] Broad patent claims and demands for reach-through rights may then exacerbate the problem.[48]

12.35 There are important differences between the Australian and United States research environments, which are relevant to the impact of patents on foundational research tools. The Nicol–Nielsen Study investigated the patent status in Australia of a number of foundational biotechnology patents that have been mentioned in the literature as being problematic. Their study found that, in many cases, the patents had not been filed or granted in Australia, meaning that certain avenues of research may not be as restricted in Australia as in the United States.[49]

Research tools and end products

12.36 A characteristic of genetic research is that patents are commonly held over genetic materials and technologies needed for further research, as well as over the ultimate products of research, like diagnostic tests and pharmaceuticals.

12.37 One organisation's end product may be another organisation's research tool. Further, some research tools have uses other than in research. For example, a patented DNA sequence may be used as part of a diagnostic test, as well as in research to understand better the role of the relevant gene in disease.

12.38 Some biotechnology enterprises focus on developing, manufacturing and supplying research tools to researchers. To these enterprises, research tools are commercial end products. They have a strong commercial interest in full recognition of intellectual property rights over them. Organisations that obtain a competitive advantage from proprietary research tools may also be unwilling to make them freely available and may seek to limit access, restrict use, or delay disclosure of research results.[50]

---

46 J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285, 333. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 55.

47 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 54.

48 Ibid, 54. In this context, reach-through rights are rights that derive from the patent claims themselves, as distinct from rights negotiated in reach-through licence agreements.

49 Ibid, 41–49.

50 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

> Institutions tend to be high-minded about the importance of unfettered access to the research tools they want to acquire from others, but no institution is willing to share freely the materials and discoveries from which they derive significant competitive advantage. Thus many … were eager to establish that the term 'research tool' means something other than their own institution's crown jewels.[51]

Use and licensing of research tools

12.39 Access to patented research tools is largely dependent on the availability and terms of licences granted by patent holders to researchers who wish to use them during the term of the patent. There are many models for licensing research tools and other patented inventions. The following material highlights some aspects of licensing practice, as applied to the licensing of research tools in Australia and overseas. General aspects of licensing are discussed in Chapter 22.

12.40 Licences may be exclusive or non-exclusive. For example, the Cohen–Boyer patents held by the University of California San Francisco and Stanford University were subject to the grant of multiple, non-exclusive licences in return for minimal licence fees. This licensing strategy meant that users of the invention were inclined to obtain licences, which led to broad distribution of the technology.[52]

12.41 Alternative strategies for university-based patent holders include granting an exclusive licence to a biotechnology company, which can then develop and apply the technology, making it available by contract to other biotechnology enterprises. Firms with such business plans 'offer services such as the use of genomic array chips, procedures for producing a large variety of candidate drug compounds, and use of proprietary cell culture or identification techniques'.[53]

12.42 Licensing may provide rights to use research tools with the purchase of products. This model is sometimes applied to PCR, where the Taq polymerase that is required for PCR is purchased from a biotechnology company licensed to manufacture and sell the enzyme. The purchase price includes limited, non-transferable rights to use that product for research purposes only. Further, for PCR to be authorised it may have to be performed in thermal cyclers purchased from a licensed supplier.[54]

12.43 It is not uncommon for patent holders to distinguish between academic and commercial researchers in applying a licensing strategy. Licences granted for academic research may involve much lower fees than research licences granted to commercial

---

51 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 229.

52 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 3.

53 J Barton, 'Research Tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the World Health Organization* 121, 122.

54 Qbiogene, *Patent Information for PCR Products*, <www.qbiogene.com/products/pcr/patent.shtml> at 16 June 2004. Thermal cyclers are machines specifically designed to perform the PCR. They are capable of rapidly heating and cooling reaction tubes to specific temperatures. The PCR requires rapid cycling between approximately 50° and 95° C and so must be performed in a thermal cycler.

entities. For example, access to the Cohen–Boyer patents was free to academic researchers, yet involved a substantial fee for commercial researchers. F Hoffmann–La Roche Limited, the PCR patent holder, has established different categories of licence, depending on the application and the users. Research and development licences do not include a right to perform or offer commercial services of any kind using PCR.[55]

12.44 Australian biotechnology companies have also distinguished between academic and commercial research in their patent licensing practices. In July 2003, Genetic Technologies Limited (GTG) granted a licence to the University of Sydney to use GTG's patents on methods of using non-coding DNA polymorphisms (GTG's non-coding patents)[56] in basic research for the remaining duration of the patents. GTG noted that the $1,000 fee was 'several thousand-fold' less than the fee for similar licences granted to 'pure commercial entities'.[57]

Reach-through licence agreements

12.45 Licence agreements for the use of research tools may contain 'reach-through' provisions, which give the patent holder ownership, licence rights or royalties in relation to future discoveries made by licensed researchers.

> In effect, this approach calls for payment in future intellectual property rights or royalties on future products in lieu of cash … Recognizing that most academic users will not discover anything of commercial value, the owner of the tool seeks to recover a substantial profit in the rare case when a valuable discovery is made in order to cover the costs of all the other, unprofitable transfers.[58]

12.46 Reach-through licence agreements may offer advantages to both patent holders and researchers, by permitting researchers to defer payment until the research yields valuable results and by providing patent holders with the opportunity to make profits from sales of downstream products, rather than from defined, but smaller, upfront fees.[59]

12.47 The National Institutes of Health (NIH) Working Group on Research Tools suggested that reach-through licence agreements are more often entered into where a research tool may be used directly to produce another product,[60] rather than in relation to 'more basic research tools that have a more remote relationship to commercial products'.[61] Reach-through rights may be the best way for some patent holders to protect their investment.

---

55 Ibid.

56 Sometimes also referred to as GTG's 'intron sequence patents'.

57 Genetic Technologies Limited, 'Letter from GTG to Medical and Scientific Colleagues', *Press Release*, 21 July 2003, <www.gtg.com.au/Announcements.html>.

58 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

59 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

60 For example, a drug screening tool or a cell line that is used to produce an antibody.

61 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

Infringing use of research tools

12.48 As discussed in Chapter 22, a range of commercial and practical factors are important in determining whether researchers seek to obtain licences from patent holders and, if not, whether patent holders enforce their rights against researchers. In practice, factors that influence whether researchers use patented research tools without obtaining a licence include 'the often secret nature of the experiments, the limited expectation of damages by a patentee, the significant cost of patent litigation, and the often limited impact on a patentee's commercial interests'.[62]

12.49 It can often be difficult to detect patent infringement. The use of research tools occurs behind laboratory doors, making infringement difficult to monitor.[63] For example, even in the case of Taq polymerase and the PCR patents, where a licence fee is incorporated into the purchase price of the product, some laboratories performing PCR or any other reaction reliant on enzymes may decide that it is cheaper to prepare their own enzyme.

12.50 Researchers may be unaware of the legal implications of using patented research tools and, even if they are, the prospect of litigation may appear remote. As discussed in Chapter 13, researchers may also assume that their use of research tools is exempt from claims of patent infringement.

12.51 Patent holders often tolerate academic research infringements. The reasons for this include the possibility that research will increase the value of the patent; the cost of a challenge; the risk that the patent will be narrowed or invalidated if challenged; the negative publicity from suing a university; and a reluctance to upset norms of open access for fear of losing both the goodwill of peers and access to materials and information.[64]

12.52 The remedies for patent infringement include injunctions and compensation, or an account of profits.[65] In the case of infringement by researchers, the most relevant remedy is likely to be an injunction to prevent further infringement. Damages or an account of profits will generally be relevant only where a product has been developed and sold. Most claims of infringement never reach the courts because the parties reach a settlement—possibly involving payment of a licence fee.

---

62 C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 16.

63 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 48.

64 J Walsh, A Arora and W Cohen, 'Working through the Patent Problem' (2003) 299 *Science* 1021. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 88–89: some research institution respondents stated they were 'content to ignore relevant patents and challenge their validity if approached by the patent holder'.

65 *Patents Act 1990* (Cth) s 122(1). See Ch 9.

Concerns about patents on research tools

Access to research tools

12.53 Concern has been expressed that patents on some research tools (particularly foundational tools) can 'pre-empt large areas of medical research and lay down a legal barrier to the development of a broad category of products'.[66] It has been suggested that this result is highly likely in biotechnology because 'there are so many broadly relevant patents; research builds on the use of so many prior discoveries; and solid and clear title to a product is so important to the pharmaceutical industry'.[67]

12.54 The OECD Report referred to concern about the impact of research tool patents on collaboration and sharing of materials between researchers, noting that the terms of licences or material transfer agreements 'can be such that they ultimately make collaboration and communication with other researchers more difficult'.[68]

12.55 In Australia, the Nicol–Nielsen Study found that research tool patents were not considered to be particularly problematic by the majority of respondents. It stated that this may be because industry participants in Australia have not yet been faced with 'the aggressive enforcement practices' of some United States research tool patent holders 'either because the relevant research tools have not been patented in Australia or because attention has not yet been focused on the Australian industry'.[69]

12.56 Their surveys found that refusals to license were not a pervasive issue within the industry.[70] However, researchers and companies stated that they avoided certain areas of research 'if patents were held by competitors, or if it looked like obtaining a licence might prove to be too problematic'.[71] In interviews, some respondents expressed frustration at difficulties in licensing-in enabling technologies, but they were greatly outnumbered by respondents who had not experienced any problems.[72]

12.57 In its submission, the Queensland Government stated that Queensland universities are generally able to obtain fair and reasonable licences to use gene patents.[73] McBratney and others noted they had no experience of research being hindered due to licensing or materials transfer agreements (MTAs), and that most researchers do not obtain licences, relying instead on an assumed research exemption,

---

66 J Barton, 'Research Tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the World Health Organization* 121, 122.

67 Ibid, 122.

68 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

69 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 92. Nicol and Nielsen caveat this conclusion with the observation that their data was collected before it became widely known that GTG was enforcing its non-coding patents, which may change views.

70 Ibid, 146.

71 Ibid, 147.

72 Ibid, 147.

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

obtaining the material through an MTA or producing it themselves.[74] A common theme in consultations was that the marketplace is capable of solving most problems concerning access to patented research tools.

Cost and delay

12.58 Patents on research tools may hinder research by requiring licence fees to be paid by researchers. From the perspective of researchers, the price demanded for use of a genetic invention may be too high.[75]

12.59 Researchers also face transaction costs in negotiating licences. Negotiations over access to technologies can be long and complicated, imposing delays and administrative burdens on research. Even if the total licence fees can be kept low, one 'hold out' may be enough to cause a research project to be cancelled.[76] Researchers may choose not to pursue research using patented research tools where they have to navigate complex sets of patents held by a number of different patent holders.

12.60 In the United States, the NIH Working Group on Research Tools reported that 'many scientists and institutions involved in biomedical research are frustrated by growing difficulties and delays in negotiating the terms of access to research tools'.[77] The reasons for this included that the value of research tools is difficult to assess, and varies greatly from one tool to the next and from one use to the next—so providers and researchers are likely to differ in their assessments of the value of research tools. Users of research tools may also have limited resources for paying up-front fees and be reluctant to share profits from potential future discoveries (under the terms of licensing agreements) with organisations that do not share the risks and costs of product development.[78]

12.61 These complexities mean that case-by-case negotiation for permission to use research tools and materials may create significant administrative burdens, which delay research.[79] The NIH Working Group noted that efforts to standardise licence terms for research tools had experienced 'limited success' and that differences in the nature and value of research tools and needs of patent holders and users of research tools make it 'difficult and perhaps undesirable to standardize terms of access to research tools across the broad spectrum of biomedical research'.[80] Chapter 22 recommends reforms to facilitate patent licensing in the Australian biotechnology sector, including through the development of model agreements for licences involving genetic materials and technologies.

---

74 A McBratney and others, *Submission P47*, 22 October 2003.

75 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

76 J Barton, 'Research Tool Patents: Issues for Health in the Developing World' (2002) 80 *Bulletin of the World Health Organization* 121, 122.

77 National Institutes of Health Working Group on Research Tools, *Report of the National Institutes of Health (NIH) Working Group on Research Tools* (1998).

78 Ibid.

79 Ibid.

80 Ibid.

12.62 Summarising information gathered from scientists, university technology transfer professionals, and private firms in the pharmaceutical and biotechnology industries, Professor Rebecca Eisenberg has stated that 'there seems to be a widely-shared perception that negotiations over the transfer of proprietary research tools present a considerable and growing obstacle to progress in biochemical research and product development'.[81]

12.63 Eisenberg concludes that the exchange of research tools within the United States research community may cause delay in or abandonment of research, and that transaction costs have remained 'persistently high'.[82] In Australia, Nicol and Nielsen reported that a number of respondents had experienced difficulties in conducting negotiations, particularly in terms of delay.[83]

Licence terms

12.64 Objections have been raised about the terms that may be proposed by patent holders in licensing agreements or MTAs.[84] These may include reach-through rights and restrictions on the publication of research results.

12.65 Researchers may perceive reach-through rights as having the potential to benefit patent holders disproportionately, in the event that research outcomes are commercialised. Further, reach-through rights may prejudice researchers' later technology transfer and commercialisation prospects. Potential commercial partners are likely to demand that intellectual property be unencumbered by competing interests.

12.66 In the United States, reach-through rights are said to have led to some of the 'more intractable disagreements' about the terms of licensing agreements.[85] Universities and other non-profit research institutions may baulk at reach-through licence agreements for the use of research tools.[86] The terms proposed for the use of the DuPont Cre-lox gene-splicing tool were one such example.[87] This research tool was initially developed by Harvard University but licensed exclusively to DuPont Pharmaceutical Co, which required public sector researchers to sign agreements that limited their use of the technique and required pre-publication vetting of articles.

---

81 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 225.

82 Ibid, 248.

83 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 158.

84 MTAs are discussed in Ch 17.

85 R Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is the Market Failing or Emerging?' in R Dreyfuss, D Zimmerman and H First (eds), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (2001), 223, 230.

86 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

87 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

DuPont also sought reach-through rights to future inventions that might result from experiments using the technique. These licence terms were said to permit DuPont to 'leverage its proprietary position in upstream research tools into a broad veto right over downstream research and product development'.[88]

12.67 In Australia, the Walter and Eliza Hall Institute of Medical Research expressed concern about problems where materials suppliers 'seek inappropriate levels of control or commercial reach-through into the recipients' research activities'.[89]

12.68 Ultimately, it is up to patent holders and prospective licensees to reach mutually acceptable contractual terms. In some cases, patent holders have been unsuccessful in seeking to impose reach-through rights, for example in relation to the PCR patents, where reach-through rights were abandoned as a licensing model after strong resistance from downstream users.[90]

12.69 Nicol and Nielsen reported complaints from some respondents that patent holders over some research tools unreasonably demanded reach-through royalties.[91] They observed that a number of variables will determine whether or not reach-through rights to future inventions are likely to be included in a licensing arrangement, including the nature of the technology or product being licensed; whether or not the licensed technology is core to the activities of the licensee; and the relative bargaining power of the negotiating parties.[92]

12.70 Heller and Eisenberg have suggested that while reach-through licence agreements may offer advantages in principle, in practice they 'may lead to an anticommons as upstream owners stack overlapping and inconsistent claims on potential downstream products'.[93] Chapter 17 discusses issues relating to patents and the commercialisation of research by the biotechnology industry.

---

88 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698. The NIH objected and the issue was resolved with a memorandum of understanding in 1998: Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14. One colourful criticism of the DuPont's approach referred to it as the 'Steinway Piano Model' of licensing—'if you sell me a piano, do you deserve royalties if I write a song on it?': N Freundlich, 'Cre-lox Controversy Divides Institutions, Prompts NIH Panel', *Signals Magazine*, 6 December 1998, <www.signalsmag.com>.

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

90 See M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

91 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 147.

92 Ibid, 166.

93 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 699.

Concerns about patents on isolated genetic materials

12.71 Particular concerns have been raised about patents over isolated genetic materials and the genetic sequences they contain.[94] As discussed above, an important category of research tools comprises isolated genetic materials that are targeted in research or used to target other genetic materials.[95]

12.72 The United States Patent and Trademark Office has summarised concerns about patents restricting access to genetic research tools as follows:

> Many feel that by allowing genetic information to be patented, researchers will no longer have free access to the information and materials necessary to perform biological research. This issue of access to research tools relates to the ability of a patent holder to exclude others from using the material. Further, if a single patent 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.[96]

12.73 The United Kingdom's Nuffield Council on Bioethics has suggested a number of ways in which patents covering genetic sequences, whose primary function is as research tools, might inhibit innovation. These included increased costs of research; impediments to research if licences 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').[97]

12.74 While the Nuffield Council stated that the granting of patents that assert rights over DNA sequences as research tools should be discouraged, it conceded that there was insufficient evidence to assess the extent to which patents over DNA sequences as research tools is producing negative effects on research.[98]

Concerns about other research tools

12.75 Some concerns were expressed in submissions and consultations about the implications for research of GTG's non-coding patents. These patents are fundamental to many key applications in genetic analysis, molecular diagnostics and genomics.

12.76 GTG has offered non-exclusive licences for basic research using GTG's non-coding patents for modest fees. Much higher payments have been negotiated with commercial organisations.[99] In the United States, a major biotechnology company, Applera Corporation, is facing an infringement action for refusing to obtain a licence to

---

94 Including in relation to ESTs and SNPs: see also Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [13.99]–[13.104].

95 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 3.

96 Ibid, 3.

97 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), [5.39].

98 Ibid, [5.40].

99 For example, Sequenom ($US500,000): Z Moukheiber, 'Junkyard Dogs', *Forbes Magazine*, 29 September 2003.

use GTG's non-coding patents.[100] Other suits against United States biotechnology companies have been settled.[101]

12.77 Another set of concerns relate to the effects on research of Chiron Corporation's patents relating to the Hepatitis C virus, which include claims to the composition of the virus itself and its use in diagnostic tests, vaccines and drug development.[102]

ALRC's views

12.78 The ALRC believes that there is little evidence that gene patents have had any significant adverse effect to date on the conduct of genetic research in Australia. Consistently with the conclusions of a literature review conducted in 2003 for the United Kingdom Department of Health, the evidence that does exist is limited and anecdotal.[103] In relation to concerns about the impact of a proliferation of fragmented and overlapping patent rights on biotechnology research, it has been stated that 'five years on from its publication, there is no evidence to support the existence of Heller and Eisenberg's tragedy of the anticommons on anything other than an anecdotal scale'.[104]

12.79 International empirical studies suggest that patent holders and those in the research and biotechnology sectors are capable of developing 'a robust combination of working solutions' for dealing with problems that emerge.[105] These solutions sometimes take time to work out, and may not be optimal, but research generally moves forward.

12.80 However, the current position may change, particularly if patent holders become more active in enforcing patent rights. It is not possible to rule out future problems, including those resulting from patents currently under review, court decisions, new technology, and assertions of patents on foundational discoveries.[106] While this potential justifies ongoing monitoring of the position, it is difficult to assess the nature and extent of future problems for the conduct of genetic research, and whether existing legal mechanisms to address them provide appropriate and effective remedies.

---

100 Ibid.

101 Genetic Technologies Limited, 'GTG Law Suits Against Nuvelo and Covance Now Settled', *Press Release*, 17 November 2003, <www.gtg.com.au/Announcements.html>.

102 L Palombi, *Submission P28*, 1 October 2003. Another submission maintained that the existence of Chiron's Hepatitis C patents was no deterrent to subsequent research: AusBiotech Ltd, *Submission P58*, 7 November 2003. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 48.

103 See, W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 43. See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 251.

104 M Stott and J Valentine, 'Gene Patenting and Medical Research: A View from a Pharmaceutical Company' (2004) 3 *Nature Reviews Drug Discovery* 364, 368, referring to M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

105 J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285, 335.

106 Ibid, 335.

12.81 In view of the equivocal nature of evidence about any present or future impact on research, the ALRC considers that it should adopt a cautious approach towards recommending radical changes in patent law and practice in this area. However, the ALRC's recommendations are intended to result in a pattern of laws and practices that is flexible enough to anticipate and respond to future problems. Some of these reforms are intended to ensure that problems are identified at an early stage, for example, through the monitoring activities of the Human Genetics Commission of Australia (Chapter 19). Other recommendations encourage the use of existing mechanisms through which problems might be addressed if they emerge.

12.82 In particular, in Chapter 19, the ALRC recommends that, where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research, Commonwealth, state and territory health departments should consider whether to exercise any existing legal options to facilitate access to the inventions.[107] These existing mechanisms include rights of Crown use and compulsory licensing under the *Patents Act 1990* (Cth) (*Patents Act*),[108] and recourse to laws dealing with anti-competitive conduct.[109]

12.83 With some limitations,[110] there is nothing to prevent research organisations from examining these same options where gene patents are considered to be hindering the conduct of genetic research. There are overseas precedents for intervention by research organisations. For example, many European research organisations and professional associations contributed to opposition proceedings concerning European gene patents granted to Myriad Genetics Inc over the BRCA1 mutation.[111]

12.84 Elsewhere in this Report, the ALRC has made recommendations to address the potential for harm arising from the exploitation of gene patents, including harm to genetic research. These recommendations include changes to laws and practices concerning patentability (Chapter 6); the development of new Australian Research Council (ARC) and NHMRC principles and guidelines on intellectual property management for publicly funded research (Chapter 11 and below); enacting a new experimental use exemption (Chapter 13); the development of model agreements and interpretative guidelines for patent licences involving genetic materials and technologies (Chapter 22); and amendments to clarify the compulsory licensing provisions of the *Patents Act* (Chapter 27).

---

107 See rec 19–3.

108 See Ch 26–27.

109 See Ch 24.

110 For example, in relation to the entities that may constitute 'an authority of the Commonwealth or of a State' for the purposes of the Crown use provisions: see Ch 26.

111 See Ch 19. The parties to the opposition included the Institut Curie, the Institut Gustave-Roussy, the Belgian Society for Human Genetics and the Associazione Angela Serra per la Ricerca sul Cancro: European Patent Office, '"Myriad/Breast Cancer" Patent Revoked after Public Hearing', *Press Release* (Munich), 18 May 2004.

New principles and guidelines on patents and research tools

12.85 A particular focus of this chapter has been on genetic materials or technologies used as research tools. In addition to recommendations made elsewhere in this Report, the ALRC recommends a specific initiative in relation to research tools, aimed at using the leverage of the Australian Government's research funding to encourage and maintain widespread access.

12.86 One model for such an approach is found in the NIH's *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (NIH principles and guidelines), which apply to recipients of NIH research grants and contracts.[112] With specific reference to research tools, the NIH guidelines provide, among other things, that:

- exclusive licences for research tools should generally be avoided except in cases where the licensee undertakes to make the research tool widely available to researchers through unrestricted sale, or the licensor retains rights to make the research tool widely available*;*

- when an exclusive licence is necessary to promote investment in commercial applications of a subject invention that is also a research tool, the recipient should ordinarily limit the exclusive licence to the commercial field of use, retaining rights regarding use and distribution as a research tool;

- recipients are expected to avoid signing agreements to acquire research tools that are likely to restrict a funding recipients' ability to promote broad dissemination of additional tools that may arise from the research;

- in determining the scope of licence or option rights that are granted in advance to a provider of materials, recipients should balance the relative value of the provider's contribution against the value of the rights granted, the cost of the research, and the importance of the research results; and

- recipients should reserve the right to negotiate licence terms that will ensure the continuing availability to the research community of any resulting new invention that is a unique research resource.[113]

12.87 DP 68 proposed that the ARC and NHMRC should develop principles and guidelines for researchers to ensure that the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.[114] It was noted that such an approach would be consistent

---

112 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

113 Ibid.

114 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 13–1.

with the conclusions of the OECD Report, which suggested that governments should give attention to the development, in consultation with industry, of guidelines on acceptable licensing practices.[115]

12.88 This proposal was broadly supported in submissions to the Inquiry.[116] For example, the Centre for Law and Genetics agreed that the NIH principles and guidelines were an appropriate model and suggested that:

> Key features might include directions to engage in non-exclusive licensing in most instances and ensuring that the research community has access to fundamental research resources. However, the guidelines must also reflect commercial realities. For example, in some circumstances broad non-exclusive licensing will not be appropriate. The guidelines should be cast in terms that allow for the best technology transfer options to be pursued, based on all relevant considerations, including the broader public benefit.[117]

12.89 A number of submissions opposed, or expressed reservations about, the proposal on the basis that it implied that the commercial exploitation of research tools is necessarily inimical to the public benefit.[118] This was not the intent of the proposal and the ALRC recognises that patent protection, and the prospect of commercialisation, may encourage the development and dissemination of research tools.[119]

12.90 In Chapter 11, the ALRC recommended that the ARC and the NHMRC should review the *National Principles of Intellectual Property Management for Publicly Funded Research*, and should develop related guidelines, to ensure that publicly funded research, where commercialised, results in appropriate public benefit.[120] The ALRC also recommended that, in exceptional circumstances, where the public benefit would clearly be served by broad dissemination of the results of publicly funded research, the ARC and the NHMRC should consider attaching conditions to the grant

---

115 See Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 82. As discussed in Ch 22, the OECD's Working Party on Biotechnology has established a steering group of experts to develop best practice guidelines for the licensing of genetic inventions.

116 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Australian Research Council, *Submission P108*, 19 April 2004. One submission stated that principles and guidelines would not be needed if there were a 'clear experimental use provision': Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

117 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

118 See, eg, Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

119 See rec 11–3.

120 Rec 11–1 and 11–2.

of funding.[121] These conditions might include a requirement that new research tools be freely available or widely licensed.

12.91 In implementing these recommendations, the ARC and NHMRC should recognise the public benefit in ensuring the wide dissemination of research tools—a consideration of particular importance to genetic materials and technologies and the conduct of genetic research.

Recommendation 12–1 The Australian Research Council and the National Health and Medical Research Council, in implementing Recommendations 11–1 to 11–3, should recognise the public benefit in ensuring the wide dissemination of research tools.

121 Rec 11–3.

13. An Experimental Use Exemption

Contents

Introduction

13.1 At present, there is significant legal uncertainty about the existence and scope of any implied experimental use defence to patent infringement in Australia. This chapter examines the law concerning experimental and research use of patented inventions in Australian law and in the law of other jurisdictions, including New Zealand, the United States, Canada, the United Kingdom and other member States of the European Union.

13.2 The chapter examines current practices regarding the experimental and research use of gene patents and the justifications for reform. The ALRC has concluded that experimental use of patented inventions is consistent with important goals of patent

law, namely, promoting the attainment of new knowledge and the development of new and improved inventions. For this reason, the law should be amended to make it clear that experimental use of a patented invention does not infringe patent rights.

13.3 The ALRC recommends the enactment of a new experimental use exemption in the *Patents Act 1990* (Cth) (*Patents Act*). An experimental use exemption is recognised in many jurisdictions and applies to all patented subject matter, not just gene patents. However, reform should be limited to protecting experimental use on the subject matter of a patented invention—that is, research with a focus on discovering more about the invention and its properties.

13.4 The terms 'defence', 'exemption' and 'exception' are often used interchangeably in the literature on patents and experimental use. This chapter uses the term experimental use 'defence' to refer to any provision that protects against a claim of patent infringement on the basis of experimental use. Further, unless otherwise indicated, the term 'use' in this chapter is used in its general sense and does not distinguish 'use' from other acts included within the definition of 'exploit' in the *Patents Act*.[1]

Existing law

Australia

13.5 The *Patents Act* does not expressly except experimental or research use of patented inventions from liability for infringement. However, an implied experimental use defence may exist in Australian patent law, as it does in other common law jurisdictions. One source of an experimental use defence in case law is said to be the 19th century English case of *Frearson v Loe*, which suggested that acts might not constitute 'use' of an invention where there is no commercial purpose.[2]

13.6 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 sets out the activities that a patent holder has the exclusive right to conduct, including making, hiring, selling, using or importing a patented product, or a product resulting from use of a patented process. It has been argued that 'exploitation' is implicitly limited to the commercial context; but the words of the statute are not limited in this way.[3]

---

1 *Patents Act 1990* (Cth) sch 1.

2 *Frearson v Loe* (1876) 9 ChD 48.

3 The Explanatory Memorandum to the Patents Bill 1990 stated that cl 13 of the Bill (s 13 of the Act) was not intended to 'modify the present law relating to certain acts which have been held not to constitute infringement—for example, use of an invention for certain experimental or trial purposes': Explanatory Memorandum, Patents Bill 1990 (Cth), [25].

13.7 Another factor that may be consistent with the existence of an experimental use defence is that s 9 of the *Patents Act* excludes use 'for the purpose of reasonable trial or experiment' from the definition of 'secret use'.[4] This provision allows the patent holder to undertake trial and experimentation prior to filing a patent application.[5] It has also been suggested that the reference in the *Patents Regulations 1991* (Cth) to the release of deposits of microorganisms for 'experimental purposes'[6] is consistent with an understanding that experimental use does not infringe patent rights.

13.8 While no Australian court has ruled on the matter, the existence of an experimental use defence is often assumed. For example, Australia's third party arguments in the *Canada–Patent Protection* case stated (somewhat elliptically) that 'an experimental use exception did apply, but only to the extent that a court would find that specific experimental activities did not constitute infringing use'.[7] However, others have argued that the *Patents Act* does not appear to imply an experimental use defence, especially given the breadth of the exclusive rights given to patent holders.[8] Submissions to the Inquiry cast doubt on the existence of an experimental use defence in Australian law.[9] Even if a defence were held to exist, it would probably not be available in situations where experimentation is conducted for commercial advantage.

13.9 The Advisory Council on Intellectual Property (ACIP) is currently undertaking a review of patents and experimental use.[10] ACIP released an Issues Paper in February 2004,[11] with a request for written submissions by 30 April 2004. ACIP's final report is expected late in 2004. Given the ALRC's own timetable for reporting, it has not been possible to take ACIP's views into account in formulating the recommendations in this Report, although the ALRC has held discussions with ACIP about the issues raised by their inquiry.

---

4 *Patents Act 1990* (Cth) ss 9(a), 18(1)(d).

5 However, the purpose and the nature of the experiments that an alleged infringer might want to conduct will differ from those of a prospective patent holder: See C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 15.

6 *Patents Regulations 1991* (Cth) r 3.25(4)(c).

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

8 See C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14.

9 See, eg, A McBratney and others, *Submission P47*, 22 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

10 ACIP's terms of reference direct it to examine whether some types of patents are inhibiting research and development in Australia and to determine whether Australian researchers and business would benefit from introducing an experimental use defence (or some other provision) into Australian patent legislation: Advisory Council on Intellectual Property, *Patents and Experimental Use: Issues Paper* (2004), (i).

11 Ibid.

Other jurisdictions

13.10 In some countries, including New Zealand, the United States and Canada, experimental use defences are recognised in case law—although there remains some dispute over the scope of these defences. Other jurisdictions, including the United Kingdom and some other member States of the European Union, have express statutory provisions relating to the experimental use of patented inventions. The laws in these jurisdictions are briefly discussed below.[12]

New Zealand

13.11 As in Australia, New Zealand patents legislation does not provide an express exception for experimental use of a patented invention. However, in at least two cases, the courts appear to have accepted that such a defence is available.[13]

13.12 Although the New Zealand courts have drawn distinctions between experimental research and commercially directed research,[14] the law is said to remain 'uncertain as to where the line actually falls between pure research and research for gaining a commercial advantage'.[15]

United States

13.13 United States case law recognises a limited experimental use defence. In *Roche Products Inc v Bolar Pharmaceutical Co*[16] the United States Court of Appeals for the Federal Circuit found that the defence was dependent on the experiments involved being 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry', and not for business reasons.[17]

13.14 In *Madey v Duke University*[18] (*Madey*) the Court stated that earlier cases had emphasised that the defence is 'very narrow and strictly limited' and that, in particular, 'use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defence'. The Court held that the non-profit (or educational) status of the alleged infringer does not determine the availability of the experimental

---

12 Options for reform of experimental use defences have been under active consideration in several jurisdictions, including the United States, Canada and the United Kingdom. Some of these proposals were discussed in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [14.46]–[14–57].

13 *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515; *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560.

14 See *Monsanto Co v Stauffer Chemical Co (NZ)* [1984] FSR 559.

15 G Lynch and J Scarlett, *Experimental Defence to Patent Infringement*, Baldwin Shelston Waters, <www.bsw.com/articles/xfactor9.html> at 16 June 2004.

16 *Roche Products Inc v Bolar Pharmaceutical Co* 733 F 2d 858 (Fed Cir, 1984).

17 In *Embrex Inc v Service Engineering Corp* 216 F 3d 1343 (Fed Cir, 2000), the Court of Appeals reaffirmed that the exception should be interpreted narrowly and that a use is disqualified from the defence if it has even the 'slightest commercial implication': 1353.

18 *Madey v Duke University* 307 F 3d 1351 (Fed Cir, 2002).

use defence. Rather, the focus should be on whether the act was in furtherance of the alleged infringer's legitimate business.[19]

13.15 In the United States it has been argued that the *Madey* decision will render the experimental use defence unavailable to research institutions simply because their legitimate business is research.[20] Critics of the decision argue that the Court's decision will have a significant chilling effect on academic scientific research[21] and fails to recognise adequately that the purposes of the patent system include facilitating research into the patented subject matter by persons other than the patent holder.[22]

Canada

13.16 Case law in Canada establishes an experimental use defence, which is available when experimentation is 'not for profit'.[23] The Canadian Biotechnology Advisory Committee (CBAC) has concluded that the ambit of the defence is 'vague' and that case law does 'little to amplify the meaning of the exception'.[24]

13.17 The existence of an experimental use defence is recognised in s 55.2(6) of the *Patent Act 1985* (Canada). This provides that the Canadian 'springboarding' provisions, which are intended to permit activities directed to obtaining regulatory approval,[25] do not affect any exception in respect of use 'for the purpose of experiments that relate to the subject-matter of the patent'.[26]

United Kingdom

13.18 The United Kingdom enacted an experimental use defence in s 60(5) of the *Patents Act 1977* (UK) in part to ensure that United Kingdom law conformed to the Community Patent Convention (CPC).[27] The United Kingdom provision states that:

---

19 Ibid, 1362–1363. The Court noted that even university research projects of no commercial application may further an institution's legitimate business objectives by increasing the status of the university and helping secure research grants, students and faculty. The Court was not required to determine whether the experimental use defence was made out on the facts. In June 2003, the Supreme Court of the United States denied a petition for review of the *Madey* decision.

20 Another view is that this approach is not compelled by the *Madey* decision when read as a whole. Research institutions are neither automatically entitled, nor automatically ineligible for the experimental use defence: see *Duke University v Madey* No 02–1007 Supreme Court of the United States, 2003): Brief for the United States as Amicus Curiae (May 2003).

21 Ibid: Brief for the Association of American Medical Colleges et al, as Amicus Curiae (January 2003).

22 See T Sampson, 'Madey, Integra and the Wealth of Nations' (2004) 26 *European Intellectual Property Review* 1; and the dissenting judgment of Newman J in *Integra Life Sciences v Merck KgaA* 307 F 3d 1351 (2002).

23 *Micro Chemicals Ltd v Smith Kline & French Inter-American Corporation* (1971) 25 DLR (3d) 79.

24 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 14.

25 *Patent Act 1985* (Canada) s 55.2(1). Springboarding (regulatory review) provisions are discussed below.

26 Ibid s 55.2(6).

27 See *Patents Act 1977* (UK) s 130(7).

> (5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if— …
>
> (b) it is done for experimental purposes relating to the subject-matter of the invention.[28]

13.19 In *Monsanto Co v Stauffer Chemical Co*,[29] Dillon LJ held that use for 'experimental purposes' may have a commercial end in view.[30] However, the underlying purpose of the experiments must be technical—'to discover something unknown or to test a hypothesis' relating to the patented invention.[31]

13.20 The other important element of s 60(5) is that the experimental purposes must relate to the subject matter of the invention. United Kingdom cases have held that this relationship is 'in the sense of having a real and direct connection with that subject matter'[32] and that, in determining what constitutes the subject matter of the patent, the court is to look at the entire patent document, including its aim.[33]

European Union

13.21 Article 27(b) of the CPC[34] provides that the rights conferred by a Community patent shall not extend to 'acts done for experimental purposes relating to the subject-matter of the patented invention'—words virtually identical to those enacted in United Kingdom legislation. This provision has been widely incorporated into the national laws of other member States of the European Union,[35] in most cases without any significant variation in its English wording.[36]

13.22 The scope of permissible experimental use has expanded since art 27 began to be incorporated into national laws.[37] While the experimental use exception was previously confined, at least in some countries, to 'private and personal' experimental use, the exception is no longer confined to 'strictly non-commercial' use.[38]

---

28 Ibid s 60(5).
29 *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515.
30 Ibid, 538.
31 Ibid, 542.
32 *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] FSR 513, 524.
33 *Auchinloss v Agricultural & Veterinary Supplies Ltd* [1999] RPC 397.
34 *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01. The Convention must be ratified by all European Union member States before it takes effect. Fewer than half of the member States have ratified it: European Union, *Patents*, <www.eurunion.org/legislat/iiprop/patents.htm> at 5 August 2003.
35 C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 18.
36 W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 736. See also, Commission of the European Communities, *Proposal for a European Council Regulation on the Community Patent, 1 August 2000, Commission of the European Communities, COM (2000) 412*, art 9.
37 W Cornish, 'Experimental Use of Patented Inventions in European Community States' (1998) 29 *International Review of Industrial Property and Copyright Law* 735, 752.
38 Ibid, 752.

13.23 European case law is said to establish that experimentation to seek further knowledge about the patented invention,[39] or to determine the adequacy of the disclosure in the patent application, or other matters going to the validity of the patent are permissible.[40] However, acts undertaken merely to satisfy regulatory requirements will fall outside the exception.[41]

13.24 Courts are likely to search for the primary motivation behind experimentation when deciding whether a defence is available and will not insist that the motivation must be 'solely' or 'exclusively' to gain more scientific knowledge.[42] In other words, where scientific or technical improvement forms one genuine reason for the experimentation, a defence against infringement may be available, even if there are other motivations.[43]

Summary of comparative law

13.25 Although the precise scope of experimental use defences in other jurisdictions varies, experimentation *on* a patented invention must generally be distinguished from experimentation *using* a patented invention for broader research purposes: only the former is covered by the defence. In particular, the patent laws of the United Kingdom and other member States of the European Union explicitly state that the experimental use defence applies only where the experimentation relates to the subject matter of the patented invention. The defence is limited to research that 'builds upon the knowledge provided by the patent, and aims to discover something unknown about the subject matter of the patent or to test a hypothesis about it'.[44]

13.26 An important difference in the content of national laws concerns the extent to which experimental use of a patented invention may have a commercial motivation. In this respect, United States law (especially after the *Madey* decision) is significantly more restrictive than the law in the United Kingdom and other member States of the European Union. In New Zealand and Canada, the significance of commercial motivations is unclear due to the paucity of case law. However, the law in these jurisdictions appears to be closer to the European Union than the United States in that permissible experimentation may have some commercial objectives.

Related defences

13.27 Some jurisdictions, including Australia, recognise other defences that may protect some forms of experimental or research use of patented inventions. These defences are discussed below and relate to the private and non-commercial use of a

---

39 Possibly including clinical tests of formulations of a patented active substance, as this will necessarily involve seeking new knowledge about clinical effectiveness, side-effects and so on: Ibid, 752, 753.

40 Ibid, 738, 752.

41 Ibid, 753.

42 Ibid, 753.

43 For example, the European Union experimental use exception may permit all clinical testing of a drug which genuinely seeks further information about its uses and about side-effects and other consequences of treatment: Ibid, 750–751.

44 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 71.

patented invention; and the use of a patented invention for regulatory review purposes (or 'springboarding'). There is also an analogous provision with respect to plant breeder's rights.

Private and non-commercial use

13.28 Article 27(a) of the CPC provides that the rights conferred by a community patent shall not extend to 'acts done privately and for non-commercial purposes'.[45] As with art 27(b), discussed above, this provision has been incorporated into the national laws of the United Kingdom and other member States of the European Union.[46]

13.29 In Australia, a defence for private and non-commercial use of a patented invention is not expressly included in the *Patents Act*. However, the Act may imply such a defence on the same basis that the Act may imply an experimental use defence, namely, that the definition of 'exploit' imports a degree of commerciality.

13.30 There has been limited consideration of the ambit of the private and non-commercial use defence and exactly how it differs from the experimental use defence.[47] It appears, however, that a private use defence will apply only where activities involving the patented invention have not been carried out in public, are intended for the benefit of the person who has conducted those activities, and do not have a commercial purpose.[48] At least in the United Kingdom, even a possible commercial application of activities involving a patented invention has been held to preclude the application of the defence.[49]

Regulatory review

13.31 The experimental use defence is broad enough in some jurisdictions to cover some activities connected with regulatory review and approval processes, but in others it is not. Some jurisdictions have, therefore, enacted regulatory review or 'springboarding' provisions designed expressly to permit activities directed to obtaining regulatory approval.

13.32 In the United States, these provisions are sometimes referred to as the '*Bolar* exemption', after a law that was enacted to overturn a case bearing that name.[50] In the *Bolar* case, the United States Court of Appeals for the Federal Circuit held that an experimental use defence did not entitle a generic pharmaceutical manufacturer to conduct experiments with a patented pharmaceutical in order to prepare a regulatory

---

45 *Council Agreement relating to Community Patents No 89/695/EEC*, 15 December 1989, OJ L 401/01.

46 See, eg, *Patents Act 1977* (UK) s 60(5).

47 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 59.

48 M Fysh, 'Infringement, Experimental Use and Clinical Trials: The Experience of the United Kingdom and Ireland' (Paper presented at Legal Issues in Exploiting Drug Patents in Europe, Licensing Executives Society Italy Conference, Milan, 12-13 December 2002).

49 *McDonald v Graham* [1994] RPC 407.

50 *Roche Products Inc v Bolar Pharmaceutical Co* 733 F 2d 858 (Fed Cir, 1984).

application to the United States Food and Drug Administration (FDA). Shortly after the *Bolar* decision, the United States Congress passed the *Drug Price Competition and Patent Term Restoration Act 1984* (*Hatch–Waxman Act*) to overrule it. The relevant provision states it is not an infringement to 'make, use, or sell' a patented invention 'solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products'.[51]

13.33 Canadian legislation contains a broader regulatory review exception, the application of which is not restricted to approval processes for drugs or veterinary products.[52] New Zealand enacted a similar provision in 2002.[53]

13.34 In Australia, the *Patents Act* has included a regulatory review exception since 1999.[54] This provision is applicable only to patented pharmaceutical substances and only where an extension of patent term has been granted under the Act.[55] It is not an infringement if a person exploits a patented pharmaceutical substance solely for purposes in connection with obtaining regulatory approval for therapeutic use in Australia or any foreign country.

Plant breeder's rights

13.35 An existing example of an experimental use defence in Australian intellectual property law can be found in the *Plant Breeder's Rights Act 1994* (Cth) (*Plant Breeder's Rights Act*).[56] The High Court has held that plant breeder's rights are, in effect, a form of patent right.[57] The *Plant Breeder's Rights Act* provides in s 16 that any act done in relation to a plant variety covered by plant breeder's rights does not infringe plant breeder's rights if done:

> (a) privately and for non-commercial purposes; or
> (b) for experimental purposes; or
> (c) for the purpose of breeding other plant varieties; …

---

51 35 USC s 271(e)(1). Whether an activity is 'reasonably related' to seeking FDA approval has been narrowly interpreted in the case law. The legislative history of the *Bolar* exemption indicates that only a limited amount of testing to establish the bioequivalence of a generic drug substitute is permitted: S Michel, 'The Experimental Use Exception to Infringement Applied to Federally Funded Inventions' (1992) 7 *Berkeley Technology Law Journal* 369, 374.

52 *Patent Act 1985* (Canada) s 55.2(1).

53 *Patents Act 1953* (NZ) s 68B.

54 *Patents Act 1990* (Cth) s 78.

55 See Ibid ss 70–79A.

56 In Australia, it is possible to obtain dual protection over a plant variety using both the *Patents Act* and the *Plant Breeder's Rights Act*. Intellectual property protection for new varieties of plants is required by the *International Convention for the Protection of New Varieties of Plants*, [2000] ATS 6, (entered into force on 1 March 1989).

57 At least for the purposes of s 51(xviii) of the Constitution, which empowers the Parliament to make laws with respect to 'patents of inventions': *Grain Pool of Western Australia v Commonwealth of Australia* (2000) 202 CLR 479.

13.36 There is very limited guidance on the scope of this provision, other than that based on patent law cases, referred to above.[58] It has been stated that 'bona fide' experiments on a protected plant variety—for example to discover if it resists a particular disease or can be cultured from tissue—are covered by the term 'experimental purposes', but that 'the balance should fall on the side of the holder of the breeder's right where the experiments are directed at commercial exploitation of the protected variety'.[59]

Research defence in practice

13.37 Academic researchers often assume that their use of patented inventions is immune from claims of patent infringement.[60] Research conducted by Dr Dianne Nicol and Jane Nielsen confirms that many Australian researchers and research institutions harbour erroneous assumptions about the existence or scope of an existing experimental or research use defence. They note that some respondents to their 2003 survey of research institutions 'put forward the argument that all research as such is exempt, whether it is conducted in research institutions or private sector'.[61] Other respondents commented on the difficulties of determining whether an exemption from patent infringement applies and confirmed that enforcement by patent holders is rare.[62]

13.38 Based on the survey results, Nicol and Nielsen looked at the scope of what they term the 'practice-based research exemption'; that is, where the line is drawn between basic research, which is assumed to be exempt, and commercial research, about which there is no such assumption.[63] The scope of the practice-based research exemption is dependent on the enforcement practices of patent holders. A number of company respondents said that they would not 'seek licences from participants in the research institution sector because this was not a wise decision from a business perspective'.[64] However, they stated that patents would be enforced once research became commercial.

13.39 It appears that patent holders' decisions about whether or not to require licence fees from research organisations are often pragmatic and commercial, rather than legal in nature. Patent holders may choose not to seek licence fees in respect of some gene

---

58 For example, *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515.

59 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [29,090].

60 See, eg, C Dennis, 'Geneticists Question Fees for Use of Patented "Junk" DNA' (2003) 423 *Nature* 105.

61 See D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 218. The research institutions surveyed included universities, government institutions, publicly funded independent research institutions and private research institutions.

62 Ibid, 219–220.

63 Ibid, 218.

64 Ibid, 219. Company respondents referred to the benefits to be derived from encouraging research in areas in which they have an interest; the adverse consequences of enforcing patent rights for a company's reputation in the academic community; and problems in recovering damages from public sector researchers: D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 220.

patents because research may add value to the invention. The use of patented inventions in research without a licence may be encouraged by the small size of the Australian market, which makes enforcement less worthwhile for patent holders.[65] Enforcement of patent rights may prejudice the ongoing sale of equipment or consumables to major clients.[66] Research organisations may make decisions about seeking licences based on similar risk or financial assessments.

13.40 Submissions to the ALRC confirmed that Australian researchers frequently rely on the existence of an experimental or research use 'exemption',[67] although the extent to which this is based on legal understandings or on expectations about the enforcement practices of patent holders is not entirely clear.[68] Reference was made to 'a long standing scientific convention that non-commercial research is exempt from patent enforcement'.[69]

13.41 Further, researchers may simply be unaware of patents. Bio21 Australia Ltd (Bio21) stated that, while there was no evidence of research being impeded by the absence of an experimental use defence, 'this is most likely due to researchers being unaware if they infringe patent rights'—a situation that may change with heightened awareness of the issue.[70] Similarly, the Cancer Council New South Wales referred to a lack of understanding among researchers about patent law and practice and stated that 'it has not really occurred to many researchers that their work could be subject to a gene patent'.[71]

Views on experimental or research use defences

13.42 The justifications for an experimental or research use defence may be summarised as follows. The defence:

- enables the validity of existing patents to be properly tested by experimentation;
- enables experiments to be conducted to determine whether a patentable invention falls within the scope of an existing patent;
- promotes the attainment of new knowledge about patented inventions;

---

65 BresaGen Limited, *Consultation*, Adelaide, 15 September 2003.
66 Australian Genome Research Facility, *Consultation*, Melbourne, 4 September 2003.
67 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Queensland Government, *Submission P57*, 5 January 2004; National Health and Medical Research Council, *Submission P52*, 31 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.
68 For example, the Queensland Government stated: 'Universities are often able to obtain free licences or "peppercorn" licence fees for research purposes, by adopting the research use defence': Queensland Government, *Submission P57*, 5 January 2004.
69 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
70 Bio21 Australia Ltd, *Submission P80*, 16 April 2004.
71 Cancer Council New South Wales, *Submission P99*, 20 April 2004.

- promotes the development of new and improved inventions and reduces the likelihood of monopolisation of a new area of technology by a patent holder;

- removes a burden from researchers, who might otherwise need to conduct extensive patent searches and obtain advice from lawyers and patent attorneys; and

- involves minimal interference with the patent holder's economic interests in exploiting its patent.[72]

General views

13.43 Submissions revealed broad support, from a broad cross-section of stakeholders, for a new experimental or research use defence, although they were often not explicit about the desirable scope of the defence.[73]

13.44 A number of submissions argued that an experimental use defence should be recognised as consistent with principles on which patent law is, or should be, based—the exchange of monopoly rights in return for disclosure of an invention, the specifications of which may then be tested and improved upon by others.[74] A focus of submissions was on the need to encourage innovation, research and development, including through the enactment of an experimental or research use defence.[75]

---

72 See C Smith, 'Experimental Use Exception to Patent Infringement: Where Does Australia Stand?' (2003) 53 *Intellectual Property Forum* 14, 15.

73 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Bio21 Australia Ltd, *Submission P80*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; J Hinojosa, *Submission P87*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; I Turnbull, *Submission P91*, 16 April 2004; AusBiotech Ltd, *Submission P94*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; G Suthers, *Submission P116*, 4 May 2004; Queensland Law Society, *Submission P118*, 7 May 2004. See also Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [14.77] fn 118.

74 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Bio21 Australia Ltd, *Submission P80*, 16 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

75 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.

13.45 Submissions emphasised the importance of eliminating uncertainty as to the existence and scope of an experimental use defence. This was seen as central to establishing 'freedom to operate' in specific research fields.[76] Bio21 stated that, if the scope for non-infringing experimental use is presently as limited as may be suggested, 'this would place a huge administrative and financial burden on researchers and research organisations and would essentially stop innovative academic research as we know it'.[77]

13.46 The Centre for Law and Genetics noted that, while a practice-based research exemption currently operates in Australia, the absence of a statutory exemption 'may encourage some patent holders to change their enforcement practices in the future'. The Centre stated that the creation of a narrow common law exemption by the courts could have a stultifying effect on non-commercial research.[78] The Department of Health and Ageing identified a risk that, without reform, Australia could lose research programs to countries that do have experimental use defences.[79]

13.47 Submissions also highlighted the difficulties in framing an appropriate experimental or research use defence and, in particular, in distinguishing between commercial and non-commercial activity, and in dealing with the exploitation of research tools. These issues, and others related to the framing of a new defence, are examined in more detail below.

Commercial objectives

13.48 In framing a statutory experimental use defence an important consideration is the extent to which experimental use may have a commercial objective. If the immediate purpose of the experimentation is technical—that is, to discover more about the patented invention—to what degree should the presence of potential commercial interests be permissible?

13.49 Some submissions suggested that the defence should be available only for non-commercial research, or research conducted by not-for-profit entities.[80] However, in practice, it is difficult to distinguish between 'pure' or 'basic' research and research whose purpose or effect is to produce a commercial outcome.[81]

---

76 R Barnard, *Submission P32*, 7 October 2003; I Turnbull, *Submission P11*, 25 September 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Bio21 Australia Ltd, *Submission P80*, 16 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.

77 Bio21 Australia Ltd, *Submission P80*, 16 April 2004.

78 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

79 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

80 Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Voices NSW Inc, *Submission P7*, 16 September 2003.

81 See, eg, Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 58–59; Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 60–61.

13.50 This difficulty is exacerbated by policies promoting the commercialisation of publicly funded research.[82] These policies mean that commercial objectives are defined early in the research cycle—making it harder to argue that the research has no commercial motivation. For example, commercialisation prospects may be identified in research funding applications to bodies such as the National Health and Medical Research Council (NHMRC) or the Australian Research Council.

13.51 It has been suggested that, for any new experimental or research use defence to be workable, it should avoid, as far as possible, the need to decide whether research is commercial or non-commercial in nature.[83] In many jurisdictions, courts have struggled to determine the level of commerciality that will disqualify an alleged infringer from relying on an experimental use defence.

13.52 This difficulty was highlighted in submissions.[84] Some suggested that any attempt to construct a defence based on distinctions between commercial and non-commercial research would be unlikely to work.[85] A particular problem is that it is often unclear when research with potential application to the development of a new product or process becomes directed to commercial purposes.[86] Where research starts out as non-commercial but acquires a commercial intent, questions may be raised about exactly when the defence would cease to apply and infringement commence.[87]

13.53 Several submissions indicated that a defence based on distinctions between commercial and non-commercial purposes would be misconceived.[88] Rather, the defence should distinguish between the types of acts carried out, rather than the nature or intentions of the parties, or whether experimentation is 'commercial' or 'non-commercial'.[89]

Experimentation or research?

13.54 A second key issue concerns the relationship that must exist between experiments and the patented invention in order for use to be protected by an experimental or research use defence. Existing experimental use defences distinguish

---

82 See Ch 11.

83 South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003; Gene CRC, *Consultation*, Melbourne, 3 September 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.

84 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

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

86 The Walter and Eliza Hall Institute of Medical Research observed that 'contemporary science is converging with fast iterations between basic and applied experiments'. This may make it difficult to justify different legal treatment for 'basic' research under the *Patents Act*: Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

87 A McBratney and others, *Submission P47*, 22 October 2003.

88 See, eg, GlaxoSmithKline, *Submission P33*, 10 October 2003.

89 Ibid; I Turnbull, *Submission P91*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

between experimental use 'relating to the subject matter of a patented invention'[90] and other forms of research use. The defence covers only the former category.

13.55 This distinction has been explained in various ways. One simple explanation is that while research *on* a patented invention is exempt from claims of patent infringement, research simply involving the *use* of a patented invention is not.[91] In other words, the defence 'does not cover any use without a licence of a patented research tool or medium which is needed for the research but is not being experimented upon for its own sake'.[92] For example, work to provide an improved polymerase chain reaction (PCR) methodology would probably qualify as experimental use, but work which simply used PCR as a standard methodological step would not.[93]

13.56 The problem with a broader defence—extending to research *using* a patenting invention—is that it would render patent rights over research tools illusory. Where the only use of the patented invention is in the conduct of research, the invention may not be able to be exploited effectively by the patent holder. Such a situation might penalise the Australian biotechnology industry by devaluing inventions that assist research.[94]

13.57 Some submissions explicitly supported the introduction of an experimental use defence limited to research on a patented invention.[95] For example, in response to IP 27,[96] GlaxoSmithKline submitted that the exemption should apply to 'activities carried out seeking to discover new knowledge about the patented invention, irrespective of whether that research is undertaken for commercial purposes or not and irrespective whether it is undertaken in an academic or commercial organisation'. It also noted that this is the basis of the European Union defence,[97] which received explicit support in a number of other submissions to the Inquiry.[98]

13.58 DP 68 proposed the establishment of a new defence based on the use of a patented invention to 'study or experiment on the subject matter of the invention'.[99] While there was wide support for this approach,[100] a number of submissions

---

90 These are the words used in CPC, art 27(b) and *Patents Act 1977* (UK) s 60(5).

91 See Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 60.

92 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 71.

93 Ibid, 71–72.

94 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.

95 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

96 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 14–1.

97 GlaxoSmithKline, *Submission P33*, 10 October 2003.

98 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Bio21 Australia Ltd, *Submission P80*, 16 April 2004.

99 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 14–1.

100 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; J Hinojosa, *Submission P87*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Cancer

highlighted the potential difficulties involved in distinguishing between research on the subject of an invention and research using an invention.[101] For example, the Department of Health and Ageing stated '[i]n the case of patented genes, particularly with product *per se* patents, there may be significant difficulty in discriminating between research *on* the subject of the invention and research *with* or *using* the subject of the invention'.[102]

13.59 Some submissions suggested factors that may assist in distinguishing between experimentation that should be exempt and other research activity. The Institute of Patent and Trade Mark Attorneys of Australia (IPTA) suggested that the amount of use being made of the invention, having regard to the nature of the study or experiment, should be relevant.[103] AusBiotech Ltd referred to the concept of Standard Operating Procedures and noted that:

> if the technique is used 1-3 times, it could be classed as experimental. If the procedure is carried out many times through something like a clinical trial, then that would be considered as use of the technology for a process rather than an experimental use and therefore be an infringement.[104]

13.60 A number of submissions stated that the ALRC's proposal for an experimental use defence did not go far enough to protect the conduct of research and to promote innovation.[105] Bio21 expressed concern that the ALRC's proposal did not provide explicitly that researchers are able to conduct research on patented DNA sequences if the research relates to improving, further developing or testing the sequence.[106] The Australian Centre for Intellectual Property in Agriculture (ACIPA) supported the adoption of reforms similar to those proposed in the United States,[107] which would exempt the use of patented genetic sequence information for non-commercial research.[108]

13.61 The NHMRC stated that limiting the defence to experimentation (as defined in the ALRC's proposal) may 'unduly limit the defence and therefore its value to the research community'.[109] The Queensland Government submitted that the scope of the

---

Council Australia, *Submission P96*, 19 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004.

101 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004.

102 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

103 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

104 AusBiotech Ltd, *Submission P94*, 16 April 2004.

105 Bio21 Australia Ltd, *Submission P80*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; I Turnbull, *Submission P91*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.

106 AusBiotech Ltd, *Submission P94*, 16 April 2004.

107 See Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [14.49]–14.51]; Genomic Research and Diagnostic Accessibility Bill 2002 (US).

108 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

109 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

proposed defence should be extended to 'the creation of a new product or process using the claimed invention'.[110]

13.62 The Centre for Law and Genetics agreed with the ALRC's proposal but submitted that, in addition, a broader exemption should be implemented to 'protect non-commercial research, irrespective of whether this is research on or research with the patented invention'.[111] The Centre submitted that:

> the non-commercial research exemption is justified on the basis that the patent grant only allows the holder to exclude others from exploitation. It should not be used in a way that stifles non-commercial research because this could negate the incentive goal of the patent system.[112]

13.63 However, the Centre also recognised the problems involved in distinguishing between commercial and non-commercial research, or between basic and applied research—which might make a non-commercial research exemption difficult to apply. It suggested that one solution to this problem would be to permit researchers to self-define themselves as non-commercial users of patented invention, provided they undertake to publish their work and refrain from patenting their research results.[113]

Private and non-commercial use

13.64 The Inquiry asked whether the *Patents Act* should be amended to include a defence for private and non-commercial use of a patented invention.[114] Submissions offered a mixed response to this question. Some submissions supported the idea of such a defence,[115] which would be useful in giving 'a greater sense of security to the truly private user'.[116] Other submissions opposed the introduction of a private and non-commercial use defence, mostly on the basis that it would be unlikely to serve any useful purpose, given its narrow ambit.[117] The Department of Industry, Tourism and Resources noted that genetic technologies are unlikely to be used for private and non-commercial purposes, as they require use by experts under controlled conditions.[118]

---

110 Queensland Government, *Submission P103*, 22 April 2004.
111 Centre for Law and Genetics, *Submission P104*, 22 April 2004.
112 Ibid.
113 Ibid. The Centre noted that it may be necessary to provide for a buyout from the undertaking, to enable patenting and commercial development. The Queensland Government noted that organisations wishing to rely on an experimental or research use defence might first be required to notify a Commonwealth body (such as IP Australia): Queensland Government, *Submission P103*, 22 April 2004.
114 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 14–2.
115 GlaxoSmithKline, *Submission P33*, 10 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.
116 GlaxoSmithKline, *Submission P33*, 10 October 2003.
117 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.
118 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

Defence or exemption?

13.65 While legal usage is not always consistent, an experimental use provision may be described as an 'exemption' where experimental use is defined as a non-infringing act.[119] This may be contrasted with a 'defence', where the use infringes patent rights but the user is protected from liability with respect to patent infringement claims.

13.66 It has been suggested that any new experimental use provision should be framed as an exemption rather than as a defence because of the implications for the burden of proof in patent infringement proceedings.[120] Where the provision is framed as an exemption, the patent holder has the burden of proving that use by another party was *not* experimental. In contrast, an experimental use defence may require the user to establish experimental use.[121]

13.67 The full implications of the distinction between an exemption and a defence for the burden of proof in patent infringement proceedings are unclear. Even where the patent holder has the legal burden of proving that use is not experimental, the alleged infringer may still have an evidential burden of showing a reasonable possibility of experimental use, particularly as aspects of the use of a patented invention are likely to be within its sole knowledge.

13.68 The Intellectual Property Research Institute of Australia (IPRIA) suggested that it would be 'more principled, and more desirable' to conceive of the role of any provision as both:

> a. clarifying (or defining) the *scope of the patent owner's rights*, so that certain uses are not 'infringements but for the defence', but rather, uses outside the purview of the patent owner's right; and
> b. resolving the genuine conflict between the rights of the patent owner and the needs of the researcher in the specific set of circumstances where it arises.[122]

13.69 A number of submissions suggested that the exemption should be drafted so that any other defences relating to experimental or research use that may be available, including defences implied by other provisions of the *Patents Act*, are not precluded.[123]

13.70 Bio21 expressed concern that patent holders and the courts may interpret the existence of an express experimental use exemption as meaning that all research activities 'not clearly and explicitly within the scope of the defence will be an infringement' and that this would encourage patent holders to enforce their patents

---

119 See, eg, *Patents Act 1990* (Cth) s 118 (infringement exemptions: use in or on foreign vessels, aircraft or vehicles); s 119 (infringement exemptions: prior use).

120 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

121 See, eg, *Madey v Duke University* 307 F 3d 1351 (Fed Cir, 2002), 1361.

122 Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

123 Bio21 Australia Ltd, *Submission P80*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004.

'more aggressively against researchers, including non-profit and university sector researchers'.[124] IPRIA submitted that the ALRC should 'explicitly acknowledge that the exemption does not preclude further judicial interpretations of, and refinements to, the concept of exploitation'.[125]

The TRIPS Agreement and experimental use

13.71 Any proposed new experimental use defence needs to be consistent with Australia's obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[126] Of particular importance are art 27, which requires that member States make patent protection available without discrimination by field of technology; and art 30, which allows member States to provide only limited exceptions to patent rights.

13.72 The TRIPS Agreement places significant constraints on the allowable ambit of exceptions to the exclusive rights conferred by patents. While the precise extent of these constraints is uncertain, the ALRC considers that the enactment of an experimental use exemption, covering acts done for experimental purposes relating to the subject matter of the patented invention, is unlikely to conflict with the provisions of the TRIPS Agreement.[127]

13.73 In the *Canada–Patent Protection* case[128] (discussed in Chapter 4), both parties accepted that experimental use defences, which are found in the laws of most members of the World Trade Organization (WTO), comply with the TRIPS Agreement.[129] It was stated that there was no conflict with the normal exploitation of the patent because it is a consequence of the 'basic patent deal' that others may use the patent holder's invention to further develop the state of the art. The patent holder's legitimate interests do not include a monopoly on research and, therefore, there is no need to balance those interests with those of third parties.[130] The WTO Panel noted that experimental use defences are 'based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge' and

---

124 Bio21 Australia Ltd, *Submission P80*, 16 April 2004.

125 Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004. See also Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

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

127 ACIPA submitted that the ALRC's proposed new experimental use defence would be 'entirely consistent' with Australia's obligations under the TRIPS Agreement: Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

128 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R. The complaint concerned the patent protection of pharmaceutical products and the operation of regulatory review provisions contained in the *Patents Act 1985* (Canada), but provides some guidance on the allowable extent of experimental use defences under the TRIPS Agreement.

129 Ibid, 56, 75.

130 Ibid, 56.

that both society and scientists have a 'legitimate interest' in using patent disclosure to support the advance of science and technology.[131]

13.74 The position becomes more uncertain if it is proposed to provide protection for acts extending beyond experimentation relating to the subject matter of an invention. The broader the classes of experimental or research activity given protection, the more likely an exception will conflict with the TRIPS Agreement. A significant uncertainty concerns the extent to which any exemption could extend beyond experimental use to broader research use—for example, all 'pure' or 'basic' research that does not have immediate commercial application—and still comply with the TRIPS Agreement.

13.75 Article 27 of the TRIPS Agreement does not 'prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.[132] It might be possible to craft a broader research use exception that is specific to some defined subset of gene patents, so that the provision does not discriminate by field of technology in terms of the TRIPS Agreement. However, there would need to be strong arguments to justify differentiating a relevant category of gene patents from patents in other fields of technology.

13.76 The ALRC received some comments on the implications of the TRIPS Agreement for any experimental or research use defence. In consultations it was suggested that, so long as any such defence applied only to non-commercial research, there would be minimal interference with the rights of the patent holder, helping ensure the reform was TRIPS–compliant.[133] GlaxoSmithKline considered that reform along the lines of the European Union model would comply with the TRIPS Agreement as long as the defence was technology-neutral.[134] ACIPA noted that the European Union and the United States have long recognised research use defences as 'a legitimate limited exception to the exclusive rights conferred by a patent'.[135]

ALRC's views

13.77 The ALRC believes it is desirable to remove uncertainty about the existence and scope of an experimental use exemption in Australian law. This approach received broad support in submissions. The existing uncertainty is unhelpful to the research community and commercial organisations. It has the potential to result in under-investment in basic research; and to hinder innovation if researchers become concerned that their activities may lead to legal action by patent holders.

131 Ibid, 165.
132 Ibid, 170–171.
133 Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003.
134 GlaxoSmithKline, *Submission P33*, 10 October 2003.
135 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

13.78 It is implicit in the 'basic underlying deal' embodied in the grant of a patent by the state that experimental use of an invention does not infringe the patent holder's rights.[136] The patent holder is given the exclusive right to exploit the invention for the term of the patent but in return agrees to disclose the invention at an early stage. This avoids duplication of research investment, and makes the invention available as the basis for further research. In a sense, an experimental use defence may be seen as a corollary to the disclosure requirement because, without it, researchers would be allowed only to read the description of the patented invention, without being able to experiment with the invention to see if and how it works.[137]

Framing the defence

13.79 The ALRC's view is that the *Patents Act* should be amended to incorporate an express experimental use provision that: (a) is framed as an exemption; (b) applies to all patented inventions; and (c) does not derogate from any experimental or research use that may otherwise be permitted under the *Patents Act*.

13.80 The provision should be framed as an exemption so that experimental use is considered a non-infringing act. This is consistent with the ALRC's view that experimental use is not part of the exclusive rights granted to a patent holder. Existing defences to claims of patent infringement in the *Patents Act*, other than those based on the validity of a patent, are generally characterised as 'exemptions'.[138]

13.81 The experimental use exemption should apply to all patented inventions, not just those concerning genetic materials and technologies. Submissions and consultations emphasised that the problems encountered in relation to the experimental use of patented genetic technologies are similar to those applicable to other subject matter, such as business methods and pharmaceuticals.[139] In addition, the TRIPS Agreement imposes constraints on the extent to which the national laws of signatory countries may

---

136 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 55.

137 Ibid, 56. See also T Sampson, 'Madey, Integra and the Wealth of Nations' (2004) 26 *European Intellectual Property Review* 1. Other arguments may be used to justify the existence of an experimental use exemption. For example, it has been suggested that because, in principle, the rights of a patent holder should extend no further than the scope of the substantial utility disclosed in the specification, experimental uses of a product are outside the appropriate scope of a patent owner's rights. Further, the use of a product as an object of scientific inquiry should not qualify as a substantial utility for the purposes of patent law because the benefit of such use is not in 'currently available form': Intellectual Property Research Institute of Australia, *Submission P88*, 16 April 2004 referring to *Brenner v Manson* 383 US 519 (1966), 535.

138 See, eg, *Patents Act 1990* (Cth) ss 118–119. United Kingdom patents legislation provides that an act done for experimental purposes does not constitute an infringement of a patent—a provision that may be characterised as an exemption: *Patents Act 1977* (UK) s 60(5).

139 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Institute of Patent and Trade Mark Attorneys of Australia, *Consultation*, Melbourne, 5 September 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

discriminate by 'field of technology'.[140] This provides another important reason why it is appropriate to extend this reform beyond gene patents to all patented inventions.

13.82 The legislation should make it clear that the exemption is not intended to derogate from any experimental or research use that may otherwise be permitted under the *Patents Act*, for example, based on the meaning of the word 'exploit' as used in s 13 of the Act. The ALRC's recommendation also leaves open the possibility that the pending ACIP review of patents and experimental use may recommend a broader provision protecting a wider class of research use of patented inventions.

13.83 The full benefit of reform will not be achieved unless the scope of any new experimental use exemption is carefully defined. In those jurisdictions in which common law defences are more firmly established than in Australia, significant doubts exist about their ambit. Doubts may persist even where statutory exemptions exist, as in the United Kingdom and other member States of the European Union, unless the scope of the exemption is articulated carefully.

Relationship with the patented invention

13.84 There are several possible criteria that might be used to delineate the boundary between permissible and impermissible experimentation or research involving a patented invention. For example, distinctions might be drawn between:

- experimentation *on* a patented invention and research involving the *use* of a patented invention;
- the purpose or intention of experimentation or research, in terms of its technical, scientific or commercial motivations;
- the technical, scientific or commercial outcomes of experimentation or research; or
- the nature of the organisation conducting the experimentation or research, for example whether the organisation is a commercial or not-for-profit entity.

13.85 The ALRC's view is that the key element should be the first listed criterion—that is, the relationship between the experimentation or research and the patented invention. At a minimum, experimentation that seeks further knowledge about the patented invention and its uses should be covered. The exemption should also extend to experimentation or research on the patented invention aimed at improving the invention.[141]

---

140 TRIPS Agreement, art 27(1).

141 However, the right to exploit any improvement may be subject to earlier patent rights. Depending on the scope of the original patent claims, the improvement, if patented, may be a 'dependent patent' that cannot

13.86 It is not a simple matter to describe what kinds of experimental uses of genetic materials or technologies should be regarded as involving experimentation *on* a patented invention, and therefore protected by an experimental use exemption. However, a good starting point is that study or experimentation on patented genetic materials or technologies for the purpose of improving, further developing, or testing them should be covered.

13.87 For example, the ALRC suggests that experimentation on patented genetic materials aimed at discovering another function of a genetic sequence or its interrelation with another genetic sequence should generally be covered by the exemption. On the other hand, the use of some genetic materials, such as gene promoters and repressors,[142] should not be covered because the material is not itself being investigated, but is being used as a research tool to investigate a gene and its expression.

13.88 In some cases, study or experimentation will not be the only purpose for which a patented invention is being used. For example, research may be intended to learn more about the function of a genetic sequence, but also to learn how to develop a commercialisable genetic testing kit. For the exemption to apply, study or experimentation should be the 'sole or dominant purpose'.[143] The exemption should not apply where the use of the invention is directed to other purposes—such as to enable processes for the manufacture of an invention to be developed or improved.

Commercial objectives

13.89 In the ALRC's view, it would be unrealistic to insist that study or experimentation on a patented invention have no, or minimal, commercial objectives. An important purpose of the patent system is to promote experimentation as a stepping stone to the development and commercialisation of new or improved inventions. Whether experimentation is conducted by a non-profit or commercial entity, or with altruistic or commercial motivations, does not seem important to this purpose.

13.90 This position is reflected by comments expressed by Newman J, in her dissenting judgment in *Integra Life Sciences v Merck KgaA*,[144] in the United States Court of Appeals for the Federal Circuit. Newman J stated, in response to arguments that commercial motivations should disqualify researchers from relying on the United States common law defence, that:

---

be worked without exploiting the original patent. Where the original patent holder wants to exploit the improvement, cross-licensing may be required.

142 For example, a CMV (cytomegalovirus) promoter: US Patent No 5,168,062 and 5,385,839.

143 The terms 'sole or dominant purpose' and 'dominant purpose' are well understood in Australian law. The terms are used in many contexts in Commonwealth statutes: see, eg, *Trade Practices Act 1974* (Cth) s 45DD (situations in which boycotts may be permitted); *Income Tax Assessment Act 1936* (Cth) s 82KUB (deductions for car expenses); *Social Security Act 1991* (Cth) s 1207P (designated private trusts).

144 *Integra Life Sciences v Merck KgaA* 307 F 3d 1351 (2002). The case was heard at the same time as *Madey v Duke University* 307 F 3d 1351 (Fed Cir, 2002).

> an ultimate goal or hope of profit from successful research should not eliminate the exemption. The better rule is to recognize the exemption for research conducted in order to understand or improve upon or modify the patented subject matter, whatever the ultimate goal. That is how the patent system has always worked: the patent is infringed by and bars activity associated with development and commercialization of infringing subject matter, but the research itself is not prohibited, nor is comparison of the patented subject matter with improved technology or with designs whose purpose is to avoid the patent.[145]

13.91 Provided that experimentation is on the subject matter of the patented invention, the existence of a commercial objective should not preclude the application of the exemption because the patent system is intended to facilitate research and promote innovation and commercialisation. The patent system 'both contemplates and facilitates research into patented subject matter, whether the purpose is scientific understanding or evaluation or comparison or improvement'.[146] It may be that some commercially-orientated research falls outside the scope of the exemption. If so, this will not be because the research has a commercial objective but because it is not 'study or experimentation on the subject matter of the patented invention'. This may be the case, for example, where trials are conducted not to find out more about the subject matter of a patented invention but simply to prove known characteristics of the invention to the satisfaction of a regulator.

13.92 Whatever its exact formulation, the statutory exemption should more closely resemble the law of the United Kingdom and other member States of the European Union (which permit experimentation to have commercial objectives) than the more restrictive position reflected in United States case law. Member States of the European Union have included experimental use exemptions in their national legislation without any apparent negative effects. Moreover, basing a new provision on the European Union model would promote harmonisation of Australian patent law with the law of a major trading bloc, and would give Australian courts the benefit of considering European case law in applying the new provisions.

13.93 As noted above, the CPC and the *Patents Act 1977* (UK) incorporate a private and non-commercial use exemption. While there may be some advantage in also incorporating this exemption into the *Patents Act* in terms of promoting the harmonisation of Australian patent law with European laws, the ALRC does not find the arguments in favour of it compelling. Such an exemption would have little practical application to the use of genetic materials and technologies, and it did not receive any significant support in submissions to the Inquiry.[147]

---

145 *Integra Life Sciences v Merck KgaA* 307 F 3d 1351 (2002).

146 Ibid.

147 ACIPA supported the introduction of such a defence: Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

13.94 The ALRC's recommendation provides additional legal protection and certainty to researchers using patented inventions, when compared with the current law. Moreover, the recommendation does not derogate from any research activities involving patented inventions that may otherwise be permitted under the *Patents Act*. Nevertheless, concerns have been expressed that introducing a new statutory exemption, applying only to experimentation on a patented invention, may encourage more extensive enforcement of patent rights against researchers. The concern is that, by drawing attention to the limited ambit of exempt experimental use, reform may encourage new interest in enforcement by patent holders. However, as discussed above, there are many reasons why patents are not enforced against non-commercial researchers—many of them relating to commercial considerations. The ALRC does not anticipate that there will be any significant change in patterns of enforcement as a result of implementing its recommendation, particularly since any existing experimental use defences are expressly preserved.

Recommendation 13–1 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:

(a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;

(b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and

(c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the *Patents Act*.

Application of the new exemption

13.95 Submissions emphasised the need for a clear explanation, in this Report and in the Explanatory Memorandum to any amending legislation, of what uses of patented inventions are covered by the recommended new experimental use exemption.[148]

148 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Bio21 Australia Ltd, *Submission P80*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004. It was suggested that the legislation should be supported by guidelines, issued by IP Australia, explaining the application of the exemption to researchers and others: Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004.

13.96 The way in which the ALRC foresees the exemption operating in various contexts, including those identified as problematic in submissions and consultations, is discussed below. Where it is essential to establish in advance whether use is covered by the experimental use exemption, a 'non-infringement declaration' may be sought under existing provisions of the *Patents Act*.[149]

13.97 An important aim of the ALRC's recommendation is to reduce the uncertainty faced by researchers and others using patented inventions for experimental or research purposes. However, in some circumstances, uncertainty about the application of the exemption will remain and may ultimately require resolution by the courts. This is inevitable given that, in common with other provisions of the *Patents Act,* a new experimental use exemption must be applied to an unlimited range of possible situations and technologies.

Genetic materials and technologies

13.98 In most circumstances it will be clear whether research or experimentation involving genetic materials or technologies constitutes acts done to 'study or experiment on the subject matter of the invention'.

13.99 The experimental use exemption would not cover most laboratory use of patented genetic research tools, such as the enzymes or reagents used in PCR, cloning and other applications. Such inventions are generally used in the conduct of research that is not directed to investigating the properties of the research tool itself, but for other purposes. On the other hand, the experimental use exemption should apply where a patented genetic sequence is being used to investigate the function of a gene, its interrelation with other genetic sequences, or its association with disease.

13.100 The way in which an experimental use exemption would operate in other situations may be less certain. Particular complexities arise with regard to the use of genetic sequences and other isolated genetic materials in the development of pharmaceuticals where use is aimed at discovering new biological pathways on which pharmaceuticals can act or finding pharmaceuticals that change the expression of the sequence.

13.101 Questions have been raised about whether an experimental use exemption should apply to the use of a genetic sequence aimed not only at investigating the properties of the genetic sequence itself but at discovering new products through the use of the genetic material.[150] To clarify this issue, CBAC found it desirable to incorporate the words 'to investigate its properties, improve upon it, *or create a new product or process*' into the wording of its proposed experimental use defence.[151] This

149 *Patents Act 1990* (Cth) ss 124–127.

150 R Gold and A Gallochat, *The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation, and Lessons for Canada* (2001), 10.

151 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 15.

was intended to make it clear that researchers can rely on the experimental use provision 'to use a DNA sequence, for example, to find molecules that bind to it or act upon it'.[152]

13.102 While this interpretation of experimental use may be seen as extending too far into activities involving the use of a patented invention as a research tool—such as for screening candidate molecules in pharmaceutical research and development—it is difficult to distinguish between investigating the properties of a genetic sequence and using a genetic sequence to study whether other molecules react with it. It may be necessary, in such circumstances, to establish the dominant purpose of the research in order to resolve whether the experimental use exemption applies.

13.103 Another issue that may arise in relation to genetic materials and technologies is whether experimental use should encompass research activities that involve the medical diagnosis of particular, identifiable, individuals. For example, genetic testing using patented genetic materials or technologies may be conducted on a cohort of individuals primarily to investigate whether a form of genetic test identifies a specific genetic mutation. As part of the research program, the results of testing may be used to diagnose individual research participants. Research testing and medical genetic testing may involve functionally identical use of a patented genetic invention. To what extent should an ancillary clinical use of the patented invention affect the application of an experimental use exemption? Again, it may be necessary to establish whether the acts are done for the sole or dominant purpose of studying or experimenting on the subject matter of the invention.

Experimental use and clinical trials

13.104 Some concern has been expressed about the implications of a new experimental use exemption for the conduct of clinical trials of pharmaceutical substances. Clinical trials are research studies conducted to determine whether new pharmaceuticals or medical treatments are safe and effective.[153] At present, even assuming the existence of an implied experimental use defence, such use would constitute patent infringement, as clinical trials are generally conducted for commercial advantage, namely, as a step towards the marketing of a new pharmaceutical.

13.105 The ALRC's recommended experimental use exemption may protect some uses of patented inventions in clinical trials from patent infringement claims. However, patented inventions are often used in clinical trials (by parties other than the patent

---

152 Ibid, 15.

153 Clinical trials are conducted in a series of steps, called phases. Phase I trials test a new pharmaceutical in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. In Phase II trials the pharmaceutical is given to a larger group of people to see if it is effective and to further evaluate its safety. In Phase III, the pharmaceutical is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely: National Library of Medicine, *ClinicalTrials.gov—What is a Clinical Trial?*, National Institutes of Health, <www.nlm.nih.gov/services/ctclintrial.html> at 16 June 2004.

holder) for the purpose of comparison with new products. In these circumstances, the new experimental use exemption might not apply because the patented invention may not itself be the subject of experimentation—its properties may already be well established.

13.106 Further, where the dominant purpose of a clinical trial is no longer to find out more about the properties of a patented pharmaceutical invention but to satisfy regulatory requirements, the experimental use exemption will not be available. An example of such a situation is when a generic pharmaceutical manufacturer conducts tests to prove the bioequivalence of a patented pharmaceutical and a generic counterpart. Currently, manufacturers of generic pharmaceuticals will often rely on clinical trial and other data submitted in relation to the equivalent innovator pharmaceutical when seeking regulatory approval from the Therapeutic Goods Administration (TGA).[154]

13.107 In future, the suppliers of some forms of medical genetic tests may also have to provide some form of clinical data before the TGA will grant approval for supply.[155] Whether the clinical trials using, for example, a patented DNA sequence will fall within the proposed experimental use exemption will, again, be determined by whether the sole or dominant purpose of the experiments is to find out more about the subject matter of the patent, rather than to collect data for regulatory approval purposes.

Experimental use and springboarding

13.108 A related issue concerns the relationship between the proposed experimental use exemption and regulatory review or 'springboarding' provisions.[156] It has been suggested that, if experiments conducted in preparing to enter the market after a patent term expires are exempt from patent infringement, the existing springboarding provisions in the *Patents Act* may not be required.[157]

---

154 The Australia–United States Free Trade Agreement provides that in such a case, the TGA must reject the application if the equivalent innovator pharmaceutical is covered by a patent. If the generic manufacturer submits that the patent is invalid, or will not be infringed by its generic pharmaceutical, the patent holder is to be notified of that submission. See Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.10.5.

155 See, 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). Genetic tests are currently classed as 'in vitro diagnostic devices' (IVDs). At present, IVDs can be supplied without requiring prior approval by the TGA, with the exception of tests for high-risk infectious diseases such as HIV and Hepatitis B.

156 As discussed above, the current regulatory review provisions in the *Patents Act* provide that it is not an infringement, where an extension of patent term has been granted under the Act, if a person exploits a patented pharmaceutical substance solely for purposes in connection with obtaining regulatory approval for therapeutic use in Australia or any foreign country or other than for a therapeutic use (eg, to trial manufacturing processes): *Patents Act 1990* (Cth) s 78.

157 IP Australia, *Submission P86*, 16 April 2004.

13.109 Further, as there is normally a period after the patent term expires in which the patent holder has a de facto monopoly while competitors develop manufacturing processes or seek regulatory approvals, an experimental use exemption may result in a reduction in the effective period of monopoly enjoyed by patent holders—possibly justifying a new scheme for patent term extension.[158]

13.110 In this context, IPTA submitted that any experimental use defence should be 'very narrow and explicitly limited to research' and, for example, not apply to 'production for regulatory approval in the case of pharmaceutical patents'.[159]

13.111 As discussed above, under the ALRC's recommended exemption, study or experimentation on the subject matter of the invention must be the sole or dominant purpose of use. Use of an invention in springboarding activities—whether concerned with obtaining regulatory approval or with developing manufacturing processes—would not be exempt unless 'study or experimentation' remained the dominant purpose of the use.

158 Ibid.

159 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.

14. Research Culture, Patents and Commercialisation

Contents

Introduction

14.1 Failure to patent genetic research may affect healthcare provision if it discourages development of new technology. This may occur where researchers fail to obtain patent protection through lack of experience with the patenting process; through resistance to the need to protect and commercially exploit research; or if the research is made public before a patent application has been filed, as the invention may no longer be novel.

14.2 This chapter considers the impact of patenting on research practice. It examines the role of academic researchers in the patenting and commercialisation process and considers some factors that may adversely affect this process.

14.3 This chapter also explores the relationship between the need for secrecy to protect the novelty of a new invention prior to obtaining a patent and the scientific tradition of peer review and replication of studies, and briefly considers how this

affects research practice. The effect of the provisions for non-prejudicial disclosures and the grace period that are provided under the *Patents Act 1990* (Cth) (*Patents Act*) are considered in relation to early publication of research results and the ability to obtain a patent.

Researchers, patenting and commercialisation

14.4 It is Australian Government policy to promote the commercial exploitation of innovative research.[1] As discussed in Chapter 11, the responsibility to obtain intellectual property protection and pursue commercialisation of research lies with the institution where the research is conducted. Within institutions, it is researchers who are usually best placed to initially identify research with commercial potential.

14.5 The emphasis on commercialisation is a relatively new development in the culture of research. As John O'Connor has suggested:

> Before the advent of the commercial potential of biotechnology, researchers were not motivated to seek patent protection. This is because it was regarded as being against scientific norms to claim exclusive rights in research discoveries. Consequently, commercial potential of recent advances in biotechnology has created a conflict between traditional policies of patent law and scientific research.[2]

14.6 Dr Dianne Nicol and Jane Nielsen have also observed that academics involved in upstream research must now respond to commercial considerations, noting:

> Many of the scientists who are involved in upstream research and for whom academic kudos has in the past been sufficient reward are now required to consider the best ways to protect their intellectual property rights and transfer their technology to industry. This introduces sharper focus on commercial considerations in the research environment.[3]

14.7 The skills, experience and attitudes of academic researchers may affect the capture and exploitation of intellectual property in genetic research. This is particularly so in relation to genetic research. More than 50% of Australian organisations filing applications locally for patents over human DNA sequences are universities and not for profit organisations.[4]

---

1 See Ch 17.

2 J O'Connor, 'The Commercialisation of Human Tissue: The Source of Legal, Ethical and Social Problems: An Area Better Suited to Legislative Resolution' (1990) 24 *Loyola of Los Angeles Law Review* 115, 137.

3 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 35.

4 See Ch 16, figure 16–2.

Resistance to commercialisation

14.8 One factor that may prevent genetic research from being patented and subsequently commercialised is researcher resistance to obtaining and exploiting patents. It has been suggested that some academic researchers resist patenting and commercialisation because of perceptions that commercially focused work is 'dirty' science.[5] A recent study of biotechnology patenting and technology transfer practices by Nicol and Nielsen (Nicol–Nielsen Study) reported:

> one respondent said that researchers hate patents, and see patenting as prostitution, but they pay the bills. Another said that some researchers just don't want to know about patents and others make jibes about the patent system. He described attempts to change attitudes about patents in the research sector as 'trying to turn around a big ship'.[6]

14.9 In 2003, Research Australia released the *Health & Medical Researcher Opinion Poll 2003* (*Researcher Opinion Poll*), a survey of health and medical researcher attitudes to, among other issues, research commercialisation.[7] Respondents, who included researchers at universities, hospitals, medical research institutes, and pharmaceutical and biotechnology companies, were asked to rate the importance of a variety of research outcomes. Only 55% of respondents rated patenting research results as important, while 99% rated improving health outcomes as important. The survey findings also suggested that researchers were reticent about commercialising their research. Only 40% agreed that they would like to be involved in the commercialisation process, while 34% said that they would not like to be involved at all.[8]

14.10 Some comments received in submissions and consultations also suggested that there is an anti-commercialisation attitude prevalent among researchers.[9] Bio Innovation SA suggested that this might in part be because some researchers do not regard commercially focused science as 'real' science, or because of a belief that placing research results in the public domain without patenting them will allow others to benefit from the research.[10] Another stated that:

> Observation suggests that most scientists see patents and IP generally as a necessary evil that they wish would simply go away because of the work involved and costs of administration, associated with licensing for example. All of which interferes with their actual job of doing science.[11]

---

5 T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 5.

6 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 125.

7 Research Australia, *Health & Medical Researcher Opinion Poll 2003* (2003), 3.

8 Ibid, 6.

9 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003; Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

10 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

11 I Turnbull, *Submission P11*, 25 September 2003.

14.11 Scientists may also resist commercialisation due to the practice within the scientific community of disseminating their research results freely and widely. This freedom may be restricted by the need to keep results confidential prior to making a patent application or due to contractual terms in licensing or collaborative agreements. The impact of secrecy requirements on scientific research is discussed further below.

14.12 Researchers may also not seek patents or pursue commercialisation because they regard other aspects of research activity as more important. Although most publicly funded research institutions provide for researchers to share in royalties flowing from the successful commercialisation of an invention, this may not be a sufficient incentive for some researchers to put in the time required to apply for and exploit a patent.[12]

14.13 Another cause of this resistance is that applying for patents may reduce the time available for researchers to pursue other activities that may be more likely to contribute to career progression. For academic researchers, publishing research results is an important factor in obtaining funding grants and career progression, as a good publication record affords both prestige and evidence of research excellence.[13]

14.14 The 2003 Department of Education, Science and Training report, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (DEST Report) suggested that wariness about patenting can be partially attributed to that fact that:

> academic performance appraisal is still often based on publication or grants received rather than efforts to commercialise. Not only does this provide inadequate incentive to commercialise, but when 'commercialisation activities remove them from "mainstream" activities' it can jeopardise academics' chances for promotion and thus act as a disincentive.[14]

14.15 Similarly, a 1999 survey by Toss Gascoigne and Jenni Metcalfe (Gascoigne–Metcalfe Survey) of 126 scientists across Australia reported that some participants criticised research organisations 'for making promotions and appointments on the basis of the number of academic papers an applicant had published rather than commercial activities, notwithstanding formal policies to the contrary'.[15]

---

12 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72.

13 M Berry and A McBratney, *Submission to the Senate Standing Committee on Regulations & Ordinances: An Analysis of Issues Relevant to the Patents Amendment Regulations 2002 (No 1) which Introduced a Grace Period into Australian Patent Law* (2002), 16.

14 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72.

15 T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 1.

14.16 According to the DEST Report, although some universities have begun to include commercialisation activity as a criterion for assessing performance, the practice is still not widespread: 'Instead, it seems that grants and publications are the primary criterion used in promotions'.[16]

14.17 On the other hand, the ALRC also heard that promotion panels and research grant committees have procedures for taking patents into account in assessing researchers' track records.[17] For example, the Australian Research Council (ARC) commented that it is relatively straightforward to balance publications and patents in assessing the research record of applicants for grants or before promotion panels. An assessment of an applicant's research ability can be made even where they hold patents but have no publications.[18] The National Health and Medical Research Council (NHMRC) also commented that it is possible, when assessing funding applications, to develop a 'record of research achievement' that includes the applicant's patents and publications.[19]

14.18 Research culture appears to be changing, and resistance to commercialisation among researchers decreasing.[20] Respondents to the Nicol–Nielsen Study suggested a number of reasons for the change. These included the preference of funding bodies such as the ARC and the NHMRC for funding research with commercial potential; the need to obtain funding from the private sector due to a lack of public sector funding; the desire for economic viability, and for some, the view that successful commercial exploitation may be lucrative.[21] Changed attitudes have also been attributed to researcher experience working within Cooperative Research Centres.[22]

---

16 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 82. See also R Johnston, M Matthews and M Dodgson, *Enabling the Virtuous Cycle: Identifying and Removing Barriers to Entrepreneurial Activity by Health and Medical Researchers in the Higher Education Sector* (2000), 17.

17 Australian Research Council, *Consultation*, Canberra, 22 September 2003; National Health and Medical Research Council, *Consultation*, Canberra, 24 September 2003; Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

18 Australian Research Council, *Consultation*, Canberra, 22 September 2003.

19 National Health and Medical Research Council, *Consultation*, Canberra, 26 March 2004.

20 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 125–126. This view was confirmed in submissions and consultations: Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; Unisearch, *Consultation*, Sydney, 15 March 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Medical Researchers, *Consultation*, Adelaide, 15 September 2003; Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.

21 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 126.

22 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), xxii.

Submissions and consultations

14.19 It was generally recognised that in the increasingly commercialised research environment, publication is often delayed because organisations seek to protect their positions with regard to intellectual property.[23] While this does not necessarily have a significant impact on the overall progress of science,[24] some concern was expressed about the possible impact of publication constraints on the careers of individual researchers.[25] It was suggested that there is a need to change the system of grant assessment to recognise experience in commercialisation and obtaining patents, as well as research record as indicators of research success.[26]

14.20 DP 68 asked for comments on disincentives to patenting of genetic research that affect researchers, including the weight given to patents in assessing the research record of grant applicants. Generally, submissions commented that the weight given to patents in these procedures is correct, and that patents are increasingly recognised as an indicator of achievement.[27]

14.21 The NHMRC stated that it takes account of a grant applicant's track record, including patenting and commercialisation, in assessing applications. However, it noted that the weight given to patenting in assessing research records varies with the type of grant. The NHMRC also stated that it is currently reviewing its processes for assessing the track record of research achievement, including how patenting and commercialisation should be considered as part of the overall achievement of the applicant.[28]

Options for reform

14.22 One solution to researchers' reluctance to patent and commercialise is to seek to change the research culture. A range of measures to promote a culture that is positive towards commercialisation has been recommended in recent reports. These include suggestions and recommendations that:

- Australian academic, research and funding bodies should develop ways to incorporate commercial measures of research outcomes, such as patents and receipt of industry funding, when assessing the performance of a researcher, project or institution;

---

23 Australian Academy of Science, *Consultation*, Canberra, 22 September 2003; Gene CRC, *Consultation*, Melbourne, 3 September 2003.

24 Australian Academy of Science, *Consultation*, Canberra, 22 September 2003; Gene CRC, *Consultation*, Melbourne, 3 September 2003.

25 Australian Academy of Science, *Consultation*, Canberra, 22 September 2003.

26 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

27 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

28 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

- successful commercialisation role models should be highlighted and networks for mentorship be established and promoted to researchers;

- institutions should create the right academic environment, in which individuals and institutions are 'committed to increasing the opportunities and rewards for commercialisation' by improving understanding of the commercialisation process within the institution and establishing policies for intellectual property ownership and management;[29] and

- researchers should be provided with incentives to develop technology commercially, including royalty-sharing arrangements, the ability to hold equity and accept directorships in biotechnology companies; and the capacity to move between academia and industry should be facilitated.[30]

14.23 Such arrangements are in place at many research organisations. In 2001, the ARC released the *National Principles of Intellectual Property Management for Publicly Funded Research* (National Principles), which stipulate that publicly funded research institutions should provide researchers with adequate incentives to participate in the commercialisation process.[31]

14.24 The DEST Report recommended implementing an expanded National Principles model, placing greater emphasis on the need for institutions to ensure competing demands on researchers do not act as a disincentive to participation in commercialisation. It suggested this should include recognising commercialisation activity as a criterion for assessing performance.[32]

ALRC's views

14.25 The ALRC supports the policies and actions of the ARC and NHMRC in seeking to promote commercialisation in appropriate cases. The ALRC endorses moves that are being made by funding bodies and research organisations to ensure adequate weight is given to patents as an indicator of research achievement. However, given the perception among some researchers that patents are not adequately valued, the ALRC, while not making a recommendation in this area, suggests there is a need for funding bodies and research organisations to continue to address this perception.

---

29 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 39.

30 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 125–127.

31 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), Principle 3.

32 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 82.

Lack of skills and experience

14.26 As discussed above, researchers are increasingly encouraged to participate in the process of patenting and commercialising genetic research.[33] The first stage in translating genetic research into healthcare benefits is the identification of new technology with potential healthcare applications. Once identified, the next stage is obtaining patent protection and subsequently developing the technology into a usable product. Hence, the initial identification stage is crucial to ensuring the benefits of genetic research reach the community.

14.27 While researchers are obviously well placed to identify new technologies, where they lack the skills to do so effectively, the potential health benefits of these technologies may not be realised. Researchers may also lack the commercial skills and experience to contribute effectively to the process of commercialisation.

14.28 The Gascoigne–Metcalfe Survey suggested that 'thinking commercially does not come naturally to scientists. They do not see careers in the commercial world or recognise the problems that industry is trying to solve'.[34] Some participants in the Gascoigne–Metcalfe Survey commented that they found it difficult to recognise when their research had potential commercial value and lacked knowledge of the commercialisation process. One participant noted, 'we don't know what we don't know' and reported that this lack of knowledge extended to the process for obtaining patents and intellectual property management.[35]

14.29 Participants in the Gascoigne–Metcalfe Survey also reported that they needed access to advice on commercialisation and 'translators' able to 'speak both the language of industry and the language of research'.[36] Responses to the *Researcher Opinion Poll* were similar, with a significant number of respondents stating that they did not feel they had the skills to commercialise their research results. About one third said they would not know how to find advice on developing the commercial potential of their discoveries.[37]

14.30 The National Principles require organisations to inform staff about their responsibilities in relation to intellectual property protection.[38] Most research organisations also have pre-publication review procedures, where papers to be submitted for publication are reviewed to identify potentially patentable inventions,[39] and technology transfer offices to manage intellectual property and commercialisation.

---

33 T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 1.

34 Ibid, 5.

35 Ibid, 5, 7.

36 Ibid, 5.

37 Research Australia, *Health & Medical Researcher Opinion Poll 2003* (2003), 7.

38 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001), Principle 2.

39 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72.

These offices assist researchers in applying for and commercialising patents, and may take on a considerable portion of the responsibility for the process of commercialisation.[40] However, it appears that not all researchers are aware of the functions of these offices, and do not access the support available to them.

Education programs and support

14.31 Research organisations and industry bodies are addressing some of these concerns about researcher skills and experience through education programs.[41] Many organisations provide seminars and workshops on intellectual property protection and commercialisation for researchers.[42] Advice and educational resources for staff are also provided through technology transfer offices established in most organisations. Some organisations take a pro-active approach to assist researchers to identify commercially valuable technology by placing technology managers in each faculty where they are able to work closely with researchers.[43]

14.32 A number of recent reports on patenting and research commercialisation have recommended that the capture of valuable intellectual property could be improved by building researcher skills and expertise in recognising potentially patentable inventions. Suggested mechanisms for doing so include the provision of extra training and support personnel to identify inventions, the inclusion of subjects covering commercialisation and business skills in undergraduate and postgraduate courses, and mechanisms to encourage researchers to form links with industry partners.[44]

Submissions and consultations

14.33 Submissions and consultations also emphasised the need for ongoing skill building to ensure the value of Australian research is not lost through failure to obtain appropriate protection. Improving researchers' skills in capturing and exploiting the

---

40 The role of technology transfer offices in patenting and commercialising biotechnology research is discussed in Ch 17.

41 For example, the Australian Technology Network, a coalition of five universities, has introduced online programs to develop the skills of research students in intellectual property and project management: Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 34.

42 For example, the University of Melbourne Research and Innovation Office runs workshops for staff members covering commercialisation and license agreements and may tailor the contents of programs to suit the needs of faculties and departments: Melbourne Research and Innovation Office, *Workshop and Information Sessions*, University of Melbourne, <www.research.unimelb.edu.au/infosessions> at 16 June 2004. UniQuest, at the University of Queensland, also holds intensive workshops to assist students to gain an understanding of intellectual property principles and commercialisation: UniQuest, *Consultation*, Brisbane, 3 October 2003.

43 See, eg, UniQuest, *About UniQuest*, <www.uniquest.com.au/?id=13> at 16 June 2004.

44 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 72; T Gascoigne and J Metcalfe, *Scientists Commercialising their Research: Federation of Australian Scientific and Technological Societies (Occasional Paper No 2)* (1999), 5.

results of research was also considered crucial to the development of a mature and internationally competitive biotechnology industry in Australia.[45]

14.34 DP 68 asked whether researchers in human genetics possess sufficient expertise to participate in the process of applying for and exploiting gene patents. Some comments received suggested that researchers lack the skills to identify new inventions that may be commercially valuable.[46] Others suggested that some researchers lack the expertise to be involved in the patenting process or are naïve about the process.[47]

14.35 However, it was also noted that researchers are becoming more active about commercialisation now that they are expected to make returns on their research.[48] Researchers' awareness of, and skills in dealing with, patenting and commercialisation may be increasing.[49] There were suggestions that the difficulty is not a lack of awareness among researchers, but a lack of funding to support their efforts to commercialise.[50]

14.36 Submissions confirmed that there is considerable variability in skill levels among researchers.[51] The Walter and Eliza Hall Institute of Medical Research (WEHI) commented that research expertise in patenting is partly linked to the institution's ability to capture and develop intellectual property.[52]

14.37 One problem cited was that patent protection may not be available for some valuable research results produced by public institutions if they are published before a patent application is filed. Researchers may be unaware of the need to protect their ideas, and once publication has occurred, subject to a grace period, the research is no longer novel and cannot be patented.[53] Grace period provisions are discussed below.

---

45 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003; Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

46 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; Medical Researchers, *Consultation*, Adelaide, 15 September 2003; J McKeough, *Consultation*, Sydney, 23 March 2004.

47 Unisearch, *Consultation*, Sydney, 15 March 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.

48 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

49 Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Government, *Submission P57*, 5 January 2004; UniQuest, *Consultation*, Brisbane, 3 October 2003; AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

50 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003.

51 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

52 Ibid.

53 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

14.38 Educating scientists about patenting issues was recognised as a continuing challenge, and support was shown for including subjects covering intellectual property and commercialisation issues in health sciences and biotechnology degree programs.[54]

14.39 DP 68 proposed that:

- universities and other publicly-funded research institutions should continue to take steps to raise the awareness of researchers in the health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required;[55] and

- universities should ensure that students undertaking degrees in the health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.[56]

14.40 Submissions were overwhelmingly in favour of these proposals and supported the need for researchers and institutions to increase their awareness of intellectual property and commercialisation issues. Submissions also particularly supported the inclusion of subjects covering intellectual property and commercialisation as part of degrees in health sciences and biotechnology.[57]

14.41 Some noted that research institutions are already raising awareness through education programs.[58] Others commented that awareness-raising programs do appear to be improving researcher skills and awareness.[59] The ALRC also heard that research institutions are incorporating courses in intellectual property and commercialisation into science and biotechnology degrees at the undergraduate and postgraduate levels.[60]

---

54 Western Australian Department of Health and others (legal issues), *Consultation*, Perth, 17 September 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003; Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; UniQuest, *Consultation*, Brisbane, 3 October 2003.

55 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 15–1.

56 Ibid, Proposal 15–2.

57 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004; Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P57*, 5 January 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

58 Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Government, *Submission P57*, 5 January 2004; Unisearch, *Consultation*, Sydney, 15 March 2004; UniQuest, *Consultation*, Brisbane, 3 October 2003.

59 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

60 J McKeough, *Consultation*, Sydney, 23 March 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; IP Australia, *Submission P86*, 16 April 2004.

14.42 IP Australia noted that it has the capability to assist research institutions in improving research skills through online resources and the provision of seminars.[61] The Department of Industry and Resources Western Australia suggested that the Australian Government, in collaboration with the States, should take a leading role in aiding research institutions to improve researcher skills.[62]

ALRC's views

14.43 There is evidence that Australian research culture has shifted toward general acceptance of the role of patent protection for the results of genetic research. Significant steps are already being taken to improve researcher knowledge and skills in patenting and commercialising research. The ALRC recognises that many research organisations are already undertaking this task, and endorses this action. These programs should inform researchers about the basic elements of intellectual property law, including patenting, and the processes for obtaining patent protection for their research. Researchers should also be aided to improve their skills in identifying research results with commercial potential and dealing with the commercial aspects of patent exploitation and technology transfer.

14.44 Developing these skills may improve the exploitation of patented inventions. But, importantly, it may also assist researchers in avoiding the expenditure of time and effort in seeking to patent inventions that do not have sufficient potential for commercial development. The ALRC also considers there would be merit in ensuring that familiarisation with intellectual property and commercialisation begins at the undergraduate level.

Recommendation 14–1 Research organisations should continue to take steps to raise the awareness of researchers in health sciences and biotechnology about intellectual property issues and the commercialisation of research, and should provide relevant advice to researchers as required.

Recommendation 14–2 Universities should ensure that students undertaking degrees in health sciences or biotechnology are made familiar with intellectual property issues and the commercialisation of research.

Secrecy and publication

14.45 While scientific research necessarily involves a period of non-publication for testing and developing the relevant hypotheses, scientific research is built on a tradition of peer review and replication of studies—which are dependent on the critical analysis of published research.

61 IP Australia, *Submission P86*, 16 April 2004.
62 Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

> This public exposure has two main functions. One is to maintain high standards of quality control through peer review. This is through both the refereeing process and the later replication of the research. The other function is to promote rapid advances in critical research areas.[63]

14.46 It has been suggested that the commercialisation of research, and the consequent obligations on researchers and links with industry partners, may have the potential to constrain this tradition by delaying publication or placing restrictions on sharing of data.[64] A 2002 report from the Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (OECD Report) found that:

> There is some evidence in the biomedical sciences that research delays (before the publication of research results) are increasing … The withholding of data, research materials and research results is reputed to be more common in genetics and especially in human genetics than in other fields.[65]

14.47 The Report stated that 'the effect of increased secrecy might be to slow the pace of research, by making it impossible to confirm published research and by increasing duplicate research efforts'.[66]

14.48 Scientists who perform research with private funding may be required to delay publication of research outcomes, at least until the commercial partner has had time to evaluate an invention.[67] In the United States, the National Institutes of Health (NIH) recommends that universities allow commercial partners to prohibit publication for no more than one or two months.[68] However, survey evidence indicates that much longer delays may be common. A 1994 study found that 58% of 210 life science companies that sponsor research required delays of more than six months before publication.[69]

14.49 Problems with the withholding of research results in human genetics may extend beyond the time at which research results are published. A 2000 survey found that 47% of geneticists who had asked other academics for additional information, data, or

---

63 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 249–250.

64 See, eg, D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 51; See also Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 1.

65 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 13. See also E Campbell and others, 'Data Withholding in Academic Genetics' (2002) 287 *JAMA* 473, 473.

66 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 14.

67 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 250.

68 E Press and J Washburn, 'Secrecy and Science', *The Atlantic Online*, March 2000, <www.theatlantic.com/issues/2000/03/press2.htm> at 18 June 2004.

69 Ibid.

materials regarding published research reported that at least one of their requests had been denied in the preceding three years.[70]

14.50 Patent law and practice may significantly contribute to publication delays and reluctance to share information. In particular, since patent law depends on novelty, publication before a patent application has been filed may prevent a patent being granted (see Chapter 6). For this reason it is said that:

> delays in publication may arise where preliminary findings need more work before patent filing is possible or desirable, or to permit the aggregation of incremental advances over a period of time (none of which on their own would be patentable) into a patentable invention.[71]

14.51 Another United States survey conducted in 1994–95 of 2,167 scientists in universities receiving NIH funding revealed that nearly 20% had delayed publication for more than six months at least once in the preceding three years in order to allow for a patent application, protect their scientific lead, slow the dissemination of undesired results, allow time to negotiate a patent, or resolve disputes over the ownership of intellectual property.[72] The study concluded that while withholding of research results was not a widespread phenomenon, it was more common among the 'most productive and entrepreneurial faculty'.[73]

14.52 Restraints on publication may also affect the free exchange of new technology. As Nicol and Nielsen comment, 'Where, in the past, researchers often freely exchanged newly developed research reagents and other research tools, public sector institutes now often require recipients to enter into contractual arrangements in the form of material transfer agreements'.[74]

14.53 On the other hand, patents may sometimes aid research because, without patent protection, some results might be kept as trade secrets, and potentially never revealed. Information that is the subject of a patent application is available in the public domain 18 months after the application is filed, through publication in the *Official Journal of Patents*.[75] This can be a valuable source of technical information for use in further research and development.

14.54 In the United States, the NIH has taken steps to help researchers gain access to information for research through the promulgation of the NIH's *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and*

---

70 E Campbell and others, 'Data Withholding in Academic Genetics' (2002) 287 *JAMA* 473, 473.

71 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 250.

72 D Blumenthal and others, 'Withholding Research Results in Academic Life Science' (1997) 277 *JAMA* 1224.

73 Ibid.

74 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 51–52.

75 *Patents Act 1990* (Cth) s 49 (standard patents), s 62(2) (innovation patents).

Disseminating Biomedical Research Resources (NIH Principles and Guidelines).[76] The principles include that institutions should:

- Ensure academic freedom and publication. 'Recipients are expected to avoid signing agreements that unduly limit the freedom of investigators to collaborate and publish' and 'excessive publication delays or requirements for editorial control, approval of publications, or withholding of data all undermine the credibility of research results and are unacceptable'.

- Ensure appropriate implementation of the *Bayh–Dole Act*.[77] 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'.[78]

- The NIH Principles and Guidelines provide that agreements to acquire materials for use in NIH funded research should address the timely dissemination of research results: 'Recipients should not agree to significant publication delays, any interference with the full disclosure of research findings, or any undue influence on the objective reporting of research results.[79]

14.55 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.[80] 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.[81]

Submissions and consultations

14.56 A variety of opinions about the effect of patenting on openness in research were expressed in submissions. Some suggested that the necessity of keeping new research secret until a patent application had been filed reduced the free exchange of information between researchers.[82]

---

76 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

77 See Ch 11.

78 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

79 A delay of 30–60 days to allow for patent filing or review for confidential proprietary information is generally viewed as reasonable: Ibid.

80 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.

81 United States, *Congressional Debates, House of Representatives*, United States, 14 March 2002, E353 (L Rivers).

82 For example, Cancer Council New South Wales, *Submission P1*, 5 June 2003.

14.57 The Department of Health Western Australia submitted that the need to apply for patents may result in publication delays, slow dissemination of undesired results or suppression or selectivity in publishing results.[83]

14.58 Others were more positive about the effects of patenting requirements on research culture. AusBiotech Ltd suggested that delays in publication due to the need to maintain confidentiality until a patent application has been filed will be minimal because submitted manuscripts are still regarded as confidential, and because scientific publication lead times are already long.[84] In addition, GlaxoSmithKline pointed out that 'confidential information can be shared with others without jeopardising the subsequent filing of a patent application if the disclosure takes place under an appropriate agreement'.[85]

14.59 Some submissions also recognised that strong patent protection can promote, rather than impede, knowledge sharing by removing the need to protect innovations through commercial secrecy.[86]

The general grace period

14.60 As discussed in Chapter 6, a patent will only be granted for an invention that is 'novel' and involves an 'inventive step'.[87] 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.[88] Whether an invention involves an inventive step is also assessed against the prior art base at that date.

14.61 An invention may be deprived of novelty by prior use, information disclosed in oral communications or information contained in documents. Similarly, prior use or publicly available information may prejudice claims that an invention involves an inventive or innovative step.[89]

14.62 The *Patents Act 1990* (Cth) provides that for the purposes of deciding whether an invention is novel or involves an inventive or innovative step certain uses or information must be disregarded (disclosures of this nature are referred to below as 'non-prejudicial disclosure').[90]

---

83 Department of Health Western Australia, *Submission P53*, 3 November 2003, citing P Baird, 'Getting It Right: Industry Sponsorship and Medical Research' (2003) 168 *Canadian Medical Association Journal* 1267, 1267–1269.

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

85 GlaxoSmithKline, *Submission P33*, 10 October 2003.

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

87 *Patents Act 1990* (Cth) s 18(1)(b) (standard patents), s 18(1A)(b) (innovation patents).

88 Ibid s 18(1)(b)(i) (standard patents), s 18(1A)(b)(i) (innovation patents), sch 1.

89 However, under the *Patents Act*, examiners are specifically directed not to include information made publicly available only through the doing of an act as part of the prior art base when examining a patent application: Ibid s 45(1A).

90 Ibid s 24.

14.63 Non-prejudicial disclosure includes any information made publicly available, through any publication or use of the invention, in circumstances prescribed by regulation. The circumstances prescribed are set out in the *Patents Regulations 1991* (Cth) (*Patents Regulations*) and include publication or use of the invention:

- by the showing or use of the invention at a recognised exhibition, or the publication of the invention during an exhibition where the invention was shown or used;[91]
- by the publication of the invention in a paper written by the inventor and read before a learned society or published by a learned society;[92] or
- by the working in public of the invention within a period of 12 months before the priority date for the purposes of reasonable trial.[93]

14.64 In each of these cases, the protection only applies if a patent application is made for the invention within a prescribed period. The prescribed periods range from between six or 12 months after the publication or public use of the invention, depending on the circumstances.[94] In order to comply with these requirements and protect patent rights, it is usual to lodge a provisional patent application to secure a priority date, after which disclosure becomes possible.[95]

14.65 The above categories of non-prejudicial disclosure are recognised in many other jurisdictions. For example, national laws dealing with disclosure at official or international exhibitions are obligatory for all member States of the *Paris Convention for the Protection of Industrial Property 1883*.[96] The other categories of non-prejudicial disclosure mentioned above are harmonised in the law of member States of the *European Patent Convention*.[97]

14.66 Australia has had general grace period provisions since 2002.[98] These apply to any publication or use by, or with the consent of, the prospective patent holder within 12 months of the filing date of the complete patent application provided it is filed within 12 months after the information was made publicly available.[99] These more

91 *Patents Regulations 1991* (Cth) r 2.2(2)(a)–(b).
92 Ibid r 2.2(2)(c)(i)–(ii).
93 Ibid r 2.2(2)(d)(i).
94 Ibid r 2.3.
95 A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475.
96 *Paris Convention for the Protection of Industrial Property 1883*, [1972] ATS 12, (entered into force on 27 September 1975), art 11(1).
97 See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 477.
98 The provisions apply to publication or use on or after 1 April 2002: *Patents Amendment Regulations 2002 (No 1) 2002* (Cth) r 2.
99 *Patents Act 1990* (Cth) s 24(1)(a); *Patents Regulations 1991* (Cth) rr 2.2(1A), 2.3(1A).

lenient requirements apply only to disclosures made on or after 1 April 2002.[100] These provisions are referred to in this Report as the 'grace period provisions'.

14.67 While some other countries have similar grace period provisions,[101] most European countries do not.[102] Whether such provisions should be introduced into European patent law has been the subject of extensive debate.[103]

14.68 The grace period provisions followed recommendations of the Intellectual Property and Competition Review Committee (IPCRC).[104] However, the IPCRC also stated that:

> the introduction of a grace period in Australia should be coordinated with an introduction in Europe. However, if it appears that such moves in Europe will take more than five years from October 2000, then Australia should seriously consider proceeding before its European counterparts.[105]

14.69 While the primary reason for introducing the grace period was directed to problems that inventors face when they wish to publish their inventions immediately following the filing of a provisional application,[106] the potential benefits of grace periods are said to include encouraging the sharing of research results between inventors and allowing researchers and academics to publish results in journals and peer reviewed literature without putting at risk any patentable subject matter that may be disclosed.[107]

14.70 However, disclosure permitted by the grace period provisions may destroy the novelty of the invention in countries that do not have equivalent provisions—notably in Europe. Associate Professor Ann Monotti and Professor Sam Ricketson argue that:

---

100 *Patents Regulations 1991* (Cth) r 2.2(1A), 2.3(1A).

101 For example, Japan and Canada: see W Condon and R Hoad, 'Amazing Grace: New Grace Period for Patents in Australia' (2002) 15 *Australian Intellectual Property Law Bulletin* 73, 74. The position in the United States is somewhat different as it has a 'first to invent' system. The critical date is the date on which the inventor made the invention, and novelty is not prejudiced by disclosures during the year prior to the date of the application for a patent. See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 477.

102 J Straus, *Expert Opinion on the Introduction of a Grace Period in the European Patent Law: Submission to the European Patent Organisation* (2000).

103 See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475.

104 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 161.

105 Ibid.

106 See Ibid, 159–161; A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 261–262.

107 W Condon and R Hoad, 'Amazing Grace: New Grace Period for Patents in Australia' (2002) 15 *Australian Intellectual Property Law Bulletin* 73, 74.

> The new grace period will do nothing to promote prompt dissemination of university research while significant markets operate within countries that apply the absolute novelty test. It will continue to be important to delay public disclosure of inventions until after a priority date is secured.[108]

14.71 On the other hand, Monotti and Ricketson conclude that the grace period provisions provide a 'safety net' for those who make inadvertent disclosures and that the grace period must be seen as a 'positive development' from the point of view of academics and universities.[109]

The Australia–United States Free Trade Agreement

14.72 In May 2004, Australia and the United States concluded negotiations for an Australia–United States Free Trade Agreement (AUSFTA).[110] The AUSFTA includes a requirement that each party provides for a grace period. Specifically, article 17.9.9 provides:

> Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure (a) was made or authorised by, or derived from, the patent applicant and (b) occurs within 12 months prior to the date of filing of the application in the territory of the Party.[111]

14.73 Article 17.9.9 of the AUSFTA reflects current Australian law. It also acts as a constraint on reform and would preclude shortening the current length of the grace period, or removing it altogether.

Submissions and consultations

14.74 In response to IP 27, a number of submissions indicated that the grace period provisions do not significantly encourage early publication,[112] mainly because not all countries recognise grace periods.[113]

---

108 A Monotti and S Ricketson, *Universities and Intellectual Property: Ownership and Exploitation* (2003), 264.

109 Ibid, 265.

110 See Ch 4.

111 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.9.

112 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; Davies Collison Cave, *Submission P48*, 24 October 2003. The Queensland Government stated that the grace period has overcome some of the problems associated with secrecy and delay in publication of research findings: Queensland Government, *Submission P57*, 5 January 2004.

113 See also D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 57. Respondents noted that 'whilst it is good to have a grace period in Australia, it will not really assist them because there is a lack of uniformity with regard to this provision world wide'.

14.75 Dr Amanda McBratney and others submitted that it is 'highly doubtful' that the grace period works to encourage scientific disclosure or overcome secrecy because most scientists will want to patent not just in Australia or the United States, but in Europe as well.[114]

14.76 The motivations of academic researchers were also cited as a reason why the grace period was not seen as important in encouraging scientific publication. McBratney and others stated that, based on surveys of university research practices, for researchers 'publication of [research] results is the dominant driving paradigm. Issues of secrecy, commercialisation and patentability are a distant concern'.[115]

14.77 Some negative effects of the grace period provisions were identified. For example, GlaxoSmithKline stated that, from a pharmaceutical industry perspective, grace periods 'increase the uncertainty around decisions to invest without encouraging earlier publication of the invention'.[116]

14.78 Some submissions also expressed concerns that researchers may not be aware or understand the implications of the grace period provisions.[117] In contrast, AusBiotech Ltd expressed the view that scientists in Australia have become much more aware of the importance of patent protection over the past 10 years, so the need to rely on the grace period is relatively rare.[118]

14.79 DP 68 proposed that:

- the responsible Minister should request the Advisory Council on Intellectual Property (ACIP) to review the grace period provisions in the *Patents Regulations* to ascertain whether these provisions are having an adverse impact on the commercialisation of Australian research in Australia or overseas;[119] and

- universities and other publicly funded research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the *Patents Regulations*, particularly in relation to the effect of publication before filing a provisional patent application, and the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.[120]

---

114 A McBratney and others, *Submission P47*, 22 October 2003.
115 Ibid.
116 GlaxoSmithKline, *Submission P33*, 10 October 2003.
117 Department of Health Western Australia, *Submission P53*, 3 November 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.
118 AusBiotech Ltd, *Submission P58*, 7 November 2003.
119 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 15–3.
120 Ibid, Proposal 15–4.

14.80 Submissions strongly supported a review of the grace period provisions.[121] The Department of Industry, Tourism and Resources (DITR) pointed out that the successful operation of the grace period requires it to be implemented at a global level, which has not yet occurred. It suggested that a review of the grace period provisions in Australia was important to discover whether the provisions are adversely affecting patenting of Australian inventions in jurisdictions that do not allow grace periods.[122]

14.81 IP Australia noted that the Australian Government made a commitment to review the grace period two years after its commencement in April 2002. It noted that the impact of the grace period provisions on the commercialisation of Australian research would be one of the main issues investigated.[123] IP Australia also commented that the Government has not yet determined who is best placed to conduct a review: ACIP, IP Australia or the Intellectual Property Research Institute of Australia.[124]

14.82 Submissions also supported measures to ensure researchers are fully informed about the operation of the grace period provisions.[125]

14.83 However, the Queensland Government suggested that some universities and government departments prefer not to educate researchers about the grace period provisions, as using the provisions limits the jurisdictions in which a patent application can be filed. It suggested the provisions were used only to address inadvertent publication, and that in these cases, the provisions were beneficial in avoiding invalidation of the potential patent.[126]

ALRC's views

14.84 The Australian Government introduced the general 12 month grace period despite the IPCRC's recommendation that Australia should try to coordinate any changes with Europe, where the issue remains alive and unresolved.

14.85 One view is that it may be too early to assess the effect of the introduction of the grace period provisions in Australia.[127] However, submissions highlighted the dangers that reliance on the grace period may have for patentability in other jurisdictions.

---

121 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

122 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

123 IP Australia, *Submission P86*, 16 April 2004.

124 Ibid.

125 New South Wales Health Department, *Submission P112*, 30 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

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

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

14.86 Given the limited progress towards introducing equivalent provisions in Europe,[128] the ALRC recommends that the responsible Minister should initiate a review of the grace period provisions to examine whether they are well understood by the research community; and how they have affected the commercialisation of Australian research in Australia or overseas (Recommendation 14–3). The ALRC recognises that there are a number of bodies that could undertake this review, and has not made a recommendation as to which one should undertake it.

14.87 The review should cover the operation of the grace period in Australia since its inception. Given the terms of the AUSFTA, it is unlikely that the grace period will be revoked, and the review should therefore not focus on whether the grace period ought to be retained. Rather, the review should examine any adverse impacts of the grace period and ways to address them. In particular, the review should investigate awareness and understanding of the novelty provisions of the *Patents Act* by researchers to ascertain whether it is operating as intended.

14.88 The IPCRC stated that, when a grace period is introduced, IP Australia should actively inform inventors 'of the risks that disclosure may incur to patentability in jurisdictions without a grace period'.[129] Concerns about inventors misunderstanding the grace period were raised during debate over the introduction of the grace period provisions.[130] Monotti has concluded that 'it is critical that there be adequate education and publicity campaigns about the effect of these changes so that university (and other) inventors are not misled into believing that they can now publish before they file an Australian patent application'.[131]

14.89 The ALRC recommends that universities and other publicly funded research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions, particularly in relation to the effect of publication before filing a provisional patent application, and the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.

---

128 See A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 477–479.

129 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 161.

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

131 A Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475, 481.

Recommendation 14–3 The responsible Minister should initiate a review of the grace period provisions in the *Patents Regulations 1991* (Cth) (*Patents Regulations*) to examine:

(a) whether they are well understood by the research community; and

(b) how they have affected the commercialisation of Australian research in Australia or overseas.

Recommendation 14–4 Research organisations should ensure that their researchers are fully informed about the operation of the grace period provisions in the *Patents Regulations*, particularly in relation to:

(a) the effect of publication before filing a patent application; and

(b) the effect of publication on the patentability of their inventions in countries that do not have equivalent provisions.

15. Stem Cell Technologies

Contents

Introduction

15.1 The Terms of Reference require the ALRC to consider the impact of current patenting laws and practices related to 'genes and genetic and related technologies'. One such group of technologies relates to stem cells. Many of the concerns that have been expressed about gene patents apply to the patenting of stem cell technologies. As stem cell research progresses, and as understanding about the potential application of stem cell technologies improves, the role of patents in the commercialisation of such research is likely to receive more attention.

15.2 The first part of this chapter provides an overview of stem cell science. The approach to the patentability of inventions involving stem cell technologies under Australian law is then compared to legal developments in the United States, Canada, the European Union and the United Kingdom. The chapter also examines concerns that

have been raised about access to stem cell lines and licensing practices involving patented stem cell technologies.

Scientific background

What are stem cells?

15.3 Stem cells are biological materials present in all human beings, and in other animals.[1] Stem cells have two characteristics that distinguish them from other cell types: they are able to differentiate into specialised cell types; and they are able to renew themselves, allowing stem cell populations to be maintained for long periods through cell division.[2]

15.4 Stem cells are typically characterised according to the tissue from which the cells are derived. As described below, stem cells may be obtained from embryos, foetal tissue and certain adult tissue. Depending on the tissue source, stem cells may have particular characteristics for potential development, which scientists call 'pluripotent' or 'multipotent'.

Embryonic stem cells

15.5 A fertilised ovum and the cells comprising an embryo in the earliest stages following fertilisation—up until about the eight-cell stage—are totipotent.[3] These cells have the capacity to form the placenta and other supporting tissue necessary for the development of an embryo *in utero*, as well as post-embryonic tissues and organs.

15.6 Embryonic stem cells appear at the blastocyst stage of embryonic development, approximately four days after fertilisation. A blastocyst is a hollow sphere of about 120 cells with an outer layer (which later develops into the placenta and other supporting foetal tissue) and an inner cell mass. The inner cell mass comprises embryonic stem cells, which are pluripotent. Pluripotent embryonic stem cells are capable of giving rise to almost all of the different types of cells found in humans, but cannot produce the placenta and other supporting tissues necessary for foetal development in the uterus. Thus, if placed in a woman's uterus, pluripotent embryonic stem cells do not have the capacity to develop into a human being.

15.7 Embryos from which stem cells may be obtained can be acquired in different ways. The most widely used source is surplus embryos from assisted reproductive technology (ART) programs. In Australia, embryonic stem cell lines may be lawfully derived only from such surplus embryos. Embryos could also be created specifically

---

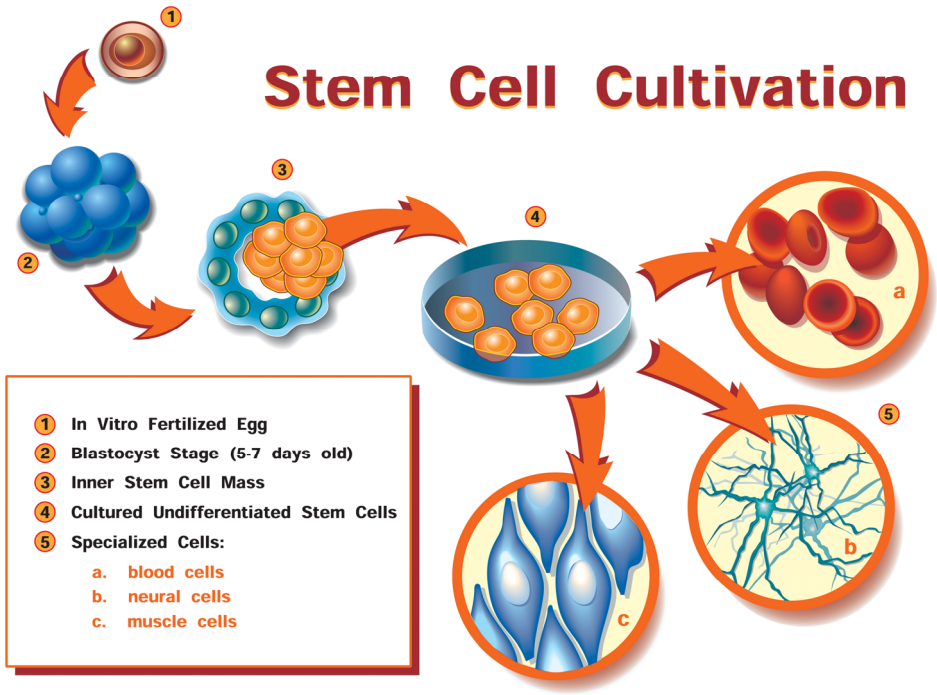
1 Certain types of stem cells—in particular, embryonic stem cells—occur naturally only for a short period of time in the earliest stages of development. Such stem cells do not exist naturally in an isolated state.

2 See further: House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Ch 2–4; Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), Ch 2; National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/index.asp> at 16 June 2004.

3 Some literature refers to the embryo during this stage of development as comprising 'totipotent cells', but scientists generally consider it inaccurate to describe totipotent cells as stem cells.

for use in research; for example, through somatic cell nuclear transfer[4]—commonly referred to as 'cloning'. To date, however, only one research team, based in South Korea, has reported successfully developing an embryonic stem-cell line from a cloned human embryo.[5]

Figure 15–1 Stem cell cultivation



Foetal stem cells

15.8 Foetal stem cells may be isolated from primordial germ cells in the incipient gonads (ovaries and testes) of aborted foetuses and are often referred to as 'embryonic germ cells'. Embryonic germ cells are pluripotent. Multipotent stem cells—that is,

4 Somatic cell nuclear transfer involves a nucleus being removed from a mature (somatic) cell and inserted into an egg cell (ovum) from which the nucleus has previously been removed.

5 W Suk Hwang and others, 'Evidence of a Pluripotent Embryonic Stem Cell Line Derived from a Cloned Blastocyst' (2004) 303 *Science* 1669. Other anecdotal accounts of human embryos being successfully produced by cloning have been called into question by the scientific community—such as claims by the company Clonaid to have cloned a human. See AAP, 'Outcry Over 'UFO' Sydney Clone Birth Claim', *Sydney Morning Herald*, 12 February 2004; 'Controversial Group Claims Sixth Cloned Baby Born at a Sydney Hospital', *Canberra Times*, 12 February 2004, 2.

stem cells that can give rise to various types of cells but only within a certain tissue type—have also been derived from foetal neural tissue and from umbilical cord blood.[6]

Adult stem cells

15.9 Adult stem cells[7] exist in human organs and tissues and are responsible for the normal replacement and repair of different organs and tissues. Currently, about 20 different types of adult stem cells have been identified, though scientists have found such cells difficult to identify, isolate and grow in culture.[8] Adult stem cells are multipotent. They are thought to be less flexible than embryonic stem cells, and to be capable of differentiating into a more restricted range of specialised cells. However, there is some evidence that adult stem cells may be able to give rise to cell types outside their own lineage—that is, cells of a different tissue type.[9]

Potential of stem cell research

15.10 There has been widespread discussion about the potential applications of stem cell research.[10] Research into the events that lead to cell specialisation in humans and the stages of human development may increase scientific understanding of the causes of birth defects and abnormal cell activity, such as cancer.

15.11 Stem cells may also be used to generate cells and tissue for transplantation in the treatment of diseases of the nervous system such as Alzheimer's disease and Parkinson's disease, as well as treatment for spinal cord damage, strokes and burn injuries. The use of stem cells to regenerate damaged organs or to create new organs for transplantation purposes has also been proposed. Such therapeutic applications of embryonic stem cells are unlikely to be available for some years.[11] However, some therapeutic applications of adult stem cells are already in use; for example, bone marrow transplants and regrowth of skin cells for burn victims.

---

6 Some scientists classify stem cells derived from umbilical cord blood as adult, rather than foetal, stem cells.

7 'Adult stem cells' can be found in foetuses and newborns, as well as in adults. The more accurate terms for this type of stem cells are 'multipotent stem cells' or 'progenitor cells'. The term 'adult stem cells' is, however, used in this Report as it is the most common term used in the literature.

8 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [2.48]-[2.51]; Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), [2.16].

9 National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/index.asp> at 16 June 2004.

10 See, eg, House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), Ch 4; Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), [2.51]–[2.136]; National Institutes of Health, *Stem Cell Basics*, <http://stemcells.nih.gov/index.asp> at 16 June 2004; President's Council on Bioethics, *Monitoring Stem Cell Research* (2004), Ch 4.

11 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [4.14]-[4.17].

15.12 In the future, stem cell lines might be used for pharmacological testing of candidate drugs—known as cell-based drug screening—although research use of embryonic stem cell lines for this purpose is speculative and controversial. Promising drugs might then be further tested on animals and finally in clinical trials.

Issues and problems

15.13 Stem cell research has generated much controversy in Australia and in other countries. In particular, objections have been raised to research involving human embryonic stem cells on the basis that the potential for an embryo to develop into a human being should preclude the use or destruction of embryos in scientific research. Critics of stem cell research also object to the patenting of inventions involving human embryonic stem cell technology.[12]

15.14 More specific objections to the patenting of inventions involving stem cell technologies have also been raised, including that stem cell patents may:

- represent an inappropriate commodification of human biological material, and in particular human reproductive material;[13]
- violate fundamental principles regarding the ownership of human beings and the free and informed consent of the donor;[14] and
- inhibit continued research and development relating to stem cell technologies.[15]

15.15 Some of the ethical objections to patenting human stem cell technologies are similar to those that have been articulated about gene patents. As DP 68 discussed, the ethical concerns that may be raised about whether it is acceptable to grant gene (or stem cell) patents are sometimes based upon objections to the way in which the research is conducted or the way in which patents are exploited, rather than the grant of patents per se.[16]

15.16 The issues surrounding human embryonic stem cell research, and research involving human embryos generally, were considered in the 2001 report of the House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell*

---

12 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 13.

13 Ibid, 13.

14 Ibid, 13.

15 Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002), [4.56]–[4.61]; M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448.

16 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [3.60]–[3.72]. See Ch 3.

Research (Andrews Report).[17] Following this report, a new national regime governing embryo research is being implemented, beginning with Commonwealth legislation enacted in 2002.[18] Corresponding legislation is in the process of being adopted by the States and Territories.[19] Relevant aspects of this regime are outlined in the following section. However, beyond this, the chapter does not address the moral and ethical concerns related to the conduct of human stem cell research.

Stem cell research in Australia

15.17 Research conducted by Australian scientists has made, and continues to make, a valuable contribution to knowledge about human stem cells and the potential applications of stem cell technologies, particularly in relation to adult stem cells.[20]

15.18 Both publicly funded organisations and companies are involved in adult and embryonic stem cell research in Australia. The establishment of the National Stem Cell Centre (NSCC) in 2002 has augmented these research efforts.[21] Australian companies also feature in the international arena in the research and development of stem cell technologies. A 2003 report produced by Invest Australia indicated that these companies include BresaGen Limited, ES Cell International Pte Ltd, Norwood Abbey Ltd, and Stem Cell Sciences Pty Ltd.[22]

---

17 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001). See also Council of Australian Governments, 'Human Cloning, Assisted Reproductive Technology (ART) and Related Matters', *Communiqué*, 5 April 2002, <www.pm.gov.au/news/media_releases/2002>; Senate Community Affairs Legislation Committee, *Provisions of the Research Involving Embryos and Prohibition of Human Cloning Bill 2002* (2002); National Health and Medical Research Council and Australian Health Ethics Committee, *Scientific, Ethical and Regulatory Considerations Relevant to Cloning Human Beings* (1998). The ethical and legal issues surrounding stem cell research and cloning technologies have also been considered in other jurisdictions: see President's Council on Bioethics, *Monitoring Stem Cell Research* (2004); United Kingdom Department of Health, *Stem Cell Research, Medical Progress With Responsibility: A Report from the Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human Health* (2000); Royal Society, *Whither Cloning?* (1998).

18 *Prohibition of Human Cloning Act 2002* (Cth); *Research Involving Human Embryos Act 2002* (Cth).

19 See, eg, *Research Involving Human Embryos (New South Wales) Act 2003* (NSW); *Human Cloning and Other Prohibited Practices Act 2003* (NSW) and cognate legislation in Queensland, South Australia, Tasmania, Victoria and the Australian Capital Territory. Bills addressing this issue are also pending in Western Australia.

20 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [4.8]-[4.10]. According to estimates by the University of Adelaide, Australia contributes about 25% of the world's research on stem cells, compared with about 2.5% of the world's biotechnology research generally: Invest Australia, *Australian Biotechnology* (2003), 9.

21 The NSCC initiative is part of the Australian Government's Innovation Statement: Commonwealth of Australia, *Backing Australia's Ability: An Innovation Statement for the Future* (2001). See also Biotechnology Australia, 'Centre for Stem Cells and Tissue Repair', *Fact Sheet*, <www.biotechnology.gov.au>.

22 Invest Australia, *Australian Biotechnology* (2003), 9. ES Cell International is incorporated in Singapore, but has an Australian subsidiary, ES Cell International (Australia) Pty Ltd. Since the publication of the Invest Australia report, BresaGen Limited has entered voluntary administration: BresaGen Limited, 'BresaGen Appoints Administrator', *Press Release*, 20 January 2004, <www.bresagen.com.au>.

15.19 Various aspects of research involving stem cells are subject to Commonwealth, state and territory legislation, and guidelines and standards issued by the Australian Health Ethics Committee (AHEC), which is a Principal Committee of the National Health and Medical Research Council (NHMRC). However, Australia does not currently have a comprehensive legislative scheme, or set of guidelines, regulating all research involving human embryonic and adult stem cells, whether conducted by publicly funded institutions or private entities.

Regulation of the use of excess ART embryos

15.20 In December 2002, the Australian Parliament passed the *Prohibition of Cloning Act 2002* (Cth) (*Prohibition of Cloning Act*) and the *Research Involving Human Embryos Act 2002* (Cth) (*Research Involving Human Embryos Act*).[23] These Acts prohibit certain practices, including human cloning,[24] and regulate uses of excess human embryos created through ART.

15.21 Under this legislation, human embryo research (and, therefore, the use of embryos for the derivation of human embryonic stem cells) is permitted only in limited circumstances. The research may involve only embryos that are 'excess ART embryos'.[25] It is an offence to use an embryo that is not an excess ART embryo for a purpose other than one relating to the assisted reproductive treatment of a woman. Therefore non-excess ART embryos cannot be used to derive embryonic stem cells.[26] Further, any use of excess ART embryos must either be conducted pursuant to a licence granted in accordance with the procedures set out in the *Research Involving Human Embryos Act*, or be subject to a statutory exemption, in which case a licence is not required.[27]

15.22 Licences to conduct research involving excess ART embryos are granted by the Embryo Research Licensing Committee of the NHMRC (NHMRC Licensing Committee) in accordance with the procedures set out in the legislation.[28] Only those excess ART embryos created prior to 5 April 2002 may be used if the activities proposed under the licence will involve the damage or destruction of such embryos.[29]

---

23 There are corresponding requirements in cognate state and territory legislation.

24 *Prohibition of Human Cloning Act 2002* (Cth) ss 9–23.

25 An excess ART embryo is one that has been determined in writing by the couple for whom it was created to be excess to their needs: *Research Involving Human Embryos Act 2002* (Cth) s 9.

26 Ibid s 11.

27 Exempt activities include the storage, removal and transport of excess ART embryos, and the use of such embryos by an accredited ART centre to achieve pregnancy for a woman other than the woman for whom the embryo was initially created: Ibid ss 8, 10(2).

28 Ibid ss 10(1)(a), 12. The NHMRC Licensing Committee is a new principal committee of the NHMRC established by law: *Research Involving Human Embryos Act 2002* (Cth) ss 13, 14; *National Health and Medical Research Council Act 1992* (Cth) ss 4, 35.

29 *Research Involving Human Embryos Act 2002* (Cth) ss 21(3)(b), 24(1)(c), 24(3). This limitation will, however, be repealed on 5 April 2005, or an earlier date pursuant to a declaration by the Council of Australian Governments: *Research Involving Human Embryos Act 2002* (Cth) s 46.

15.23 On 16 April 2004, the NHMRC Licensing Committee announced that the first licences allowing research using excess ART embryos had been issued.[30] One of these licences was issued to Sydney IVF Ltd to isolate human embryonic stem cells for use in research into the diagnosis, and eventual treatment, of diseases such as juvenile diabetes and Parkinson's disease.[31] Other licence applications are pending.

Regulation of other types of stem cell research

15.24 The regulatory scheme described above is relevant only to the *derivation* of human embryonic stem cells from excess ART embryos. As noted above, *research* involving the use of human embryonic stem cell lines, including human embryonic stem cell lines that have been imported into Australia, is not subject to specific legislation. It is, however, covered by guidelines issued by the NHMRC.[32]

15.25 In 2001, AHEC issued an interim advice to human research ethics committees (HRECs) relating to the review of research protocols that involve human stem cell research (AHEC Interim Advice).[33] The AHEC Interim Advice requires that, to obtain the approval of an HREC, stem cell lines proposed for use in research should have been derived in a manner that is consistent with the NHMRC's *Ethical Guidelines on Assisted Reproductive Technology*[34] and *National Statement on Ethical Conduct in Research Involving Humans*.[35] AHEC is in the process of reviewing the *Ethical Guidelines on Assisted Reproductive Technology*, and related publications, and intends to address the conduct of stem cell research in the revised guidelines that will flow from this review.

15.26 Research involving tissue from which foetal or adult stem cells may be derived is regulated by a mixture of legislation and guidelines, including:

- state and territory Human Tissue Acts, which require consent for the donation of blood, and regenerative and non-regenerative human tissue for research;[36] and
- ethical guidelines and policy statements, including the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans*.[37]

---

30 National Health and Medical Research Council, 'Licences Granted for Research Using IVF Embryos', *Media Release*, 16 April 2004, <www.health.gov.au/nhmrc/media/index.htm>. Four licences were granted to Sydney IVF Ltd and one to Melbourne IVF Ltd.

31 National Health and Medical Research Council and Sydney IVF Ltd, *Licence for Development of Human Embryonic Stem Cells (No 309703)*, 16 April 2004.

32 The application of NHMRC guidelines and the mechanisms for enforcing compliance with them were considered in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 13, 14.

33 Australian Health Ethics Committee, 'Information for HRECs: Stem Cell Research', *Information Sheet*, 1 September 2001, <www.nhmrc.gov.au/issues/hrec5.htm>.

34 National Health and Medical Research Council, *Ethical Guidelines on Assisted Reproductive Technology* (1996). See, in particular, ss 6 and 11.

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

36 See *Human Tissue Act 1983* (NSW) and cognate legislation in other States and Territories.

Existing patents and patent applications

15.27 Patent applications claiming animal and human stem cells and stem cell technologies have been filed in Australia and other jurisdictions.[38] A 2002 report of the European Group on Ethics in Science and New Technologies (EU Stem Cell Report) indicated that, by May 2002, over 2,000 patent applications involving human and animal stem cells had been filed worldwide, one quarter of which related to embryonic stem cells.[39] Approximately one third of all stem cell patent applications have been granted.[40]

15.28 The types of products and processes claimed in patent applications include stem cells, stem cell lines, and differentiated and genetically modified stem cells. They also include processes for: the creation of embryos by somatic cell nuclear transfer and parthenogenesis; isolating and culturing stem cells; inducing stem cells to differentiate; and genetically modifying stem cells for particular applications.[41]

15.29 A number of granted stem cell patents have been identified as particularly significant because of the scope of the patent claims and the specific stem cell technologies covered by the patents. These include certain patents over human and primate embryonic stem cell technology held by the Wisconsin Alumni Research Foundation (WARF).[42] These patents are often referred to as the 'Thomson patents', after Dr James Thomson who led the team that first reported the isolation and differentiation of human embryonic stem cells.[43] The Thomson patents cover methods for isolating embryonic stem cells[44] and for transplanting them into human beings.[45]

---

37 National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (1999); National Health and Medical Research Council, *Supplementary Note 5: The Human Fetus and Use of Human of Human Fetal Tissue* (1983).

38 As of February 2000, IP Australia had granted four patents for cloning processes applicable to non-human mammals and 'routinely grants patents for both human and animal cell lines' that satisfy the statutory requirements for patentability: IP Australia, *Submission to House of Representative Standing Committee on Legal and Constitutional Affairs Inquiry into the Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, Commonwealth of Australia, <www.aph.gov.au/house/committee/laca/humancloning/sub274.pdf> at 16 June 2004.

39 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 11. This figure does not make any adjustment for patent applications that may be filed in a number of jurisdictions but relate to the same invention.

40 Ibid, 11. For a survey of United States patents covering embryonic stem cells, see G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243.

41 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 11–12.

42 WARF is an intellectual property holding entity established by the University of Wisconsin.

43 J Thomson and others, 'Embryonic Stem Cell Lines Derived from Human Blastocysts' (1998) 282 *Science* 1145.

44 US Pat No 5,843,780 and 6,200,806.

45 US Pat No 6,280,718.

One of the Thomson patents also claims unmodified human embryonic stem cell lines per se, regardless of their 'creator'.[46]

15.30 In Australia, stem cell patents have been granted to a number of companies, including BresaGen Limited, Geron Corporation, and ES Cell International Pte Ltd.[47] A preliminary search of IP Australia's online patents databases also revealed pending applications claiming inventions involving human embryonic stem cells, or processes involving such cells.[48]

15.31 Patents have also been granted over adult stem cell lines. For example, Johns Hopkins University holds a patent on the processes for isolating adult bone marrow stem cells;[49] and MorphoGen Pharmaceuticals Inc has obtained a patent claiming 'purified pluripotent mesenchymal stem cells' obtained from cultured muscle cells.[50]

Application of patent law to stem cell technologies

15.32 On one view, the patenting of inventions involving stem cell technologies does not raise issues different from those raised by the patenting of other human biological material, such as genetic sequences. From another perspective, the patenting of inventions involving stem cell technologies should be treated differently from other inventions involving human biological material because:

- the material at issue has been derived from a human embryo, and embryos have a special status because of their potential to develop into a human being; or
- the capacity of stem cells to develop into various tissue types justifies the application of special rules.

Australia

15.33 As discussed in Chapters 6 and 7, s 18 of *Patents Act 1990* (Cth) (*Patents Act*) provides that a 'patentable invention' under Australian law is one that is a 'manner of manufacture', is novel, involves an inventive step, is useful, and is not expressly excluded from patentability under the Act. As a general matter, inventions involving biological materials may be patented if they have been isolated from their natural state.[51] IP Australia has indicated that human cell lines are patentable on this basis.[52]

---

46 US Pat No 6,200,806.

47 See, eg, AU Pat No 755176; AU Pat No 751321; and AU Pat No 764684.

48 See, eg, AU App No 2002322379 filed by Geron Corporation; AU App No 2002334378 filed by Reliance Life Sciences Pvt Ltd; and AU App No 2002340638 filed by ES Cell International Pte Ltd.

49 US Pat No 5,130,144.

50 US Pat No 5,827,735.

51 IP Australia, *Australian Patents for: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and their Use; & Genetically Manipulated Organisms*, <www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf> at 16 June 2004.

52 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1].

15.34 However, s 18(2) of the *Patents Act* excludes 'human beings and the biological processes for their generation' from patentability under Australian law. It has been suggested that this provision may prevent patent protection being available for inventions involving human embryonic stem cells.[53] The Act does not define 'human beings' or 'biological processes for their generation' and, to date, there has been no judicial consideration of this provision.

Legislative history of s 18(2) of the Patents Act

15.35 Parliamentary debates in 1990 surrounding the adoption of s 18(2) provide little guidance as to whether this provision was intended to cover inventions involving human embryonic stem cells. This is not surprising because the ability to isolate human embryonic stem cells was not announced until 1998.

15.36 Section 18(2) was based on a proposal made by Senator Brian Harradine during parliamentary debate of the Patents Bill 1990 (Cth) (Patents Bill). The proposed amendment originally provided that inventions involving 'human life forms', 'genetic manipulations of the human species' and 'trans-species procedures involving human cells' would not be patentable.[54] Foreshadowing the amendment, Senator Harradine indicated that he was concerned that insufficient consideration was being given by Parliament to 'the possibility of patenting new forms of animal life',[55] and that the Australian Patents Office (as it then was) might grant patents on a human or a genetically-modified human.[56] The Senate Standing Committee on Science, Industry and Technology altered Senator Harradine's proposal during its consideration of the Patents Bill. A majority of the Committee supported Senator Harradine's proposal in principle but was concerned about the proposal's apparent breadth and ambiguity. It agreed instead on the formulation of s 18(2) as it now appears in the *Patents Act*.[57]

15.37 Little consideration was given to the meaning of the term 'human beings' during the parliamentary debates, but the debates provide some assistance as to the intended scope of the term 'biological processes for the generation of human beings'. Senator Harradine indicated that 'techniques for cloning an embryo at the four-cell stage'—a reference to the technique of 'embryo splitting'—would be an example of the type of

---

53 See, eg, Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [8.70]–[8.75]; M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448, 491, 494–495, 504.

54 Commonwealth of Australia, *Parliamentary Debates*, Senate (In Committee), 12 September 1990, 17 (P Button).

55 Commonwealth of Australia, *Parliamentary Debates*, Senate, 22 August 1990, 1917 (B Harradine).

56 Commonwealth of Australia, *Parliamentary Debates*, Senate (In Committee), 12 September 1990, 11 (B Harradine). The Australian Democrats also expressed concerns about deficiencies in the Patents Bill for being 'silent on the question of the patenting of biological material', in particular genetic material: Commonwealth of Australia, *Parliamentary Debates*, Senate, 22 August 1990, 1910 (J Coulter). See Ch 7.

57 Commonwealth of Australia, *Parliamentary Debates*, Senate (In Committee), 12 September 1990, 10–11, 16–17 (P Button). Senator Harradine's proposal and details of the Senate Standing Committee's considerations were outlined in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [16.43]–[16.45].

invention prohibited by s 18(2).[58] The Opposition suggested that s 18(2) would preclude patenting of inventions involving 'in-vitro fertilisation and cloning for reproductive purposes'.[59] The Government did not elaborate on the intended scope of the provision, except to note that it did not represent 'a change in policy in relation to the patentability of life forms'.[60]

IP Australia's current practice

15.38 Section 18(2) has been interpreted narrowly by IP Australia. IP Australia's *Manual of Practice and Procedure* (the *Manual*) indicates that, while the precise scope of the provision is unclear, certain inventions are 'clearly encompassed'[61] by the exception, including:

- human beings, foetuses, embryos or fertilised ova;
- methods of *in vitro* fertilisation or cloning methods that generate human beings; and
- processes—beginning with fertilisation and ending with birth—that are wholly biological and result in a human being.[62]

15.39 The *Manual* also sets out the inventions that IP Australia regards as being 'clearly outside' the scope of s 18(2), namely 'human genes, tissues and cell lines', which will be patentable if the requirements for patentability set out in the *Patents Act* are satisfied.[63] In its submission to the Andrews Report, IP Australia explained that its interpretation is based on 'a widely accepted view that human genes, cell lines and tissues are not regarded as human beings'.[64] IP Australia indicated that a human cell line may meet the statutory requirements for patentability because:

> [it] is different from naturally occurring cells in the human body. It is capable of continuous propagation in an artificial environment by continual division of the cells, unlike naturally occurring cells which die after a limited number of divisions.[65]

15.40 IP Australia has stated that what constitutes a human being or the biological processes for the generation of a human being may be ambiguous.[66] In its submission

---

58 Commonwealth of Australia, *Parliamentary Debates*, Senate, 20 September 1990, 2654 (B Harradine).
59 Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 16 October 1990, 2945 (G Prosser).
60 Ibid, 2954 (S Crean).
61 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1].
62 Ibid, [8.5.1], [8.5.2].
63 Ibid, [8.5.1]. See also D Nicol, 'Should Human Genes be Patentable Inventions under Australian Patent Law?' (1996) 3 *Journal of Law and Medicine* 231, 241.
64 IP Australia, *Submission to House of Representative Standing Committee on Legal and Constitutional Affairs Inquiry into the Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research*, Commonwealth of Australia, <www.aph.gov.au/house/committee/laca/humancloning/sub274.pdf> at 16 June 2004.
65 Ibid.

to this Inquiry, IP Australia outlined its approach when determining whether s 18(2) is applicable to a particular invention:

> Although IP Australia's position will no doubt change as the technology evolves, the organisation's current interpretation [of s 18(2)] is that anything which has an inherent capability to mature and become a human being should be excluded. According to this, the more complex the subject matter, the more likely it is to be excluded … complexities arise for subject matter such as fertilised ovum, stem cells, foetuses, genetically modified animals containing human genes, and humans treated with animal tissue.[67]

15.41 As a matter of practice, IP Australia has developed a policy by which patent applications that might fall within this 'grey area' must be referred to supervising examiners, who then discuss the matter with a Deputy Commissioner.[68] The ALRC understands that inventions involving human embryonic stem cells are currently covered by this policy.

Approaches in other jurisdictions

15.42 Other jurisdictions have also addressed the issue of whether patent protection should be available for stem cell technologies and have adopted different conclusions.

United States and Canada

15.43 Like Australia, consideration of the patentability of stem cell technologies in the United States and Canada has focused upon whether inventions involving stem cell technologies fall within the scope of an exclusion from patentability for inventions involving human beings.

15.44 Until recently, there was no express prohibition in United States law equivalent to s 18(2) of the *Patents Act.* However, it has been a long-standing policy of the United States Patent and Trademark Office not to grant such patents.[69] In January 2004, the United States Congress passed appropriations legislation that included a provision prohibiting the use of any funds made available under the legislation to 'issue patents on claims directed to or encompassing a human organism'.[70] Representative Dave Weldon, who originally proposed the provision, indicated that patents on embryonic stem cells would not be covered by the ban.[71] However, United States researchers and

---

66 IP Australia, *Submission P56*, 4 November 2003. See also IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1]; House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), 146–147.

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

68 IP Australia, *Patent Manual of Practice and Procedure Volume 2: National* (2002), [8.5.1].

69 United States Patent and Trademark Office, *Manual of Patent Examining Procedure (8th Edition)* (2003), [2105].

70 United States Public Law No 188–199, s 634.

71 United States, *Congressional Debates, House of Representatives*, 5 November 2003, E2234 (D Weldon); United States, *Congressional Debates, House of Representatives*, United States, 22 November 2003, E2471 (D Weldon).

biotechnology organisations have suggested that the scope of the provision is unclear and they will oppose attempts to include such a prohibition in future budgets.[72]

15.45 In Canada, the Canadian Biotechnology Advisory Committee (CBAC) recommended that the *Patent Act 1985* (Canada) be amended to include a provision that: 'No patent shall be granted on human bodies at any stage of development'.[73] CBAC indicated that the proposed provision should be narrowly construed and was not intended to prevent patent claims being granted with respect to stem cell lines, (adult) cell lines or DNA sequences as 'these are removed from a multi-cellular precursor of the human body (except for the zygote) and thus do not comprise a human body at any stage of development'.[74]

Europe

15.46 The European Patent Office (EPO) and the European Group on Ethics in Science and New Technologies have considered the patentability of stem cell technologies under the European Parliament's *Directive on the Legal Protection of Biotechnological Inventions* (EU Biotechnology Directive)[75] and the *European Patent Convention* (EPC).[76] These institutions have adopted different positions on the patentability of these technologies, and in particular human embryonic stem cells.

15.47 The EPO has interpreted the *ordre public* or morality exclusion in art 53(a) of the EPC as preventing the patentability of human embryonic stem cells.[77] In 1999, the EPO granted a patent to Edinburgh University that related to a method of using genetic engineering to isolate animal stem cells—including embryonic stem cells—from more differentiated cells in a cell culture.[78] The patent was opposed.[79] Among other matters, opponents argued that the claims encompassed human stem cells, including human

---

72 D Wilkie, 'Stealth Stipulation Shadows Stem Cell Research' (2004) 18 *The Scientist* 42; R Weiss, 'Funding Bill Gets Clause on Embryo Patents', *Washington Post*, 17 November 2003, A04; Biotechnology Industry Organization, *New Patent Legislation Sets Dangerous Precedent and Stifles Research, 2 September 2003*, <www.bio.org/ip/cloningfactsheet.asp> at 16 June 2004. Because the provision is contained in annual appropriations legislation, it must be adopted each year to remain in effect.

73 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), rec 1. In proposing this amendment, the CBAC made reference to Australian law and, in particular, s 18(2) of the *Patents Act*: Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 9.

74 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002). CBAC also noted that, in their view, the provision would not be interpreted to include ova or sperm cells, but would cover 'precursors' to human bodies from zygotes to foetuses.

75 *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).

76 *European Patent Convention*, (entered into force on 7 October 1977).

77 See further Ch 7 for a discussion of the *ordre public* or morality exclusion.

78 EP0695351.

79 European Patent Office, *Status of Patent No EP0695351*, 5 January 2004. There were 14 opponents, including the governments of Germany, the Netherlands and Italy.

embryonic stem cells and the genetic modification of such cells, because the term 'animal' in the claims could be interpreted as including humans.[80]

15.48 The Opposition Division of the EPO held that the patent did not comply with art 53(a) of the EPC because it involved uses of human embryos for industrial and commercial purposes.[81] The Opposition Division, therefore, required the patent to be amended to exclude human and animal embryonic cells from the scope of the claims.[82] Since 1999, no further patents relating to human embryonic stem cells appear to have been granted by the EPO.[83]

15.49 In May 2002, the European Group on Ethics in Science and New Technologies published a report that considered issues surrounding the patentability of inventions involving stem cells.[84] Unlike the EPO, the EU Stem Cell Report did not interpret the EU Biotechnology Directive (and the corresponding provisions of the EPC) as precluding all inventions involving human embryonic stem cells from patentability.[85]

15.50 The position adopted in the EU Stem Cell Report as to the patentability of stem cell technologies under European law is as follows:[86]

- Isolated stem cells that have not been modified do not fulfil the legal requirements for patentability, particularly the requirement of industrial application. Further, unmodified stem cell lines should not be patentable because the cell lines may have a large range of undescribed uses, which could result in the grant of overly broad patents.[87]

---

80 European Patent Office, 'Opposition Hearing on Genetic Stem-Cell Patent at the European Patent Office', *Press Release*, 18 July 2002, <www.european-patent-office.org/news/pressrel>; European Patent Office, 'Background Information on the "Edinburgh" Patent', *Press Release*, July 2002, <www.european-patent-office.org/news/pressrel/pdf/backgr_3.pdf>.

81 Uses of embryos for industrial and commercial purposes presumptively fall within the scope of art 53(a) of the EPC: Administrative Council, *Implementing Regulations to the Convention of the Grant of European Patents of 5 October 1973* (2001) r 23(d)(c); *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.

82 Societa Italiana Brevetti, *European Patent Decisions: 'Edinburgh' Patent to be Maintained in Amended Form*, <www.sib.it/engsib/novita/pat/270902.htm> at 16 June 2004.

83 National Health and Medical Research Council, *International IP Laws in Relation to Stem Cells: An Information Paper* (2003), 22–23. See also Fédération Internationale des Conseils en Propriété Industrielle, *Opinion on the Patenting of Embryonic Stem Cells* (2004), 5.

84 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002).

85 The report stated that art 6 of the EU Biotechnology Directive leaves open the question of patentability of cells obtained from donated embryos and does not indicate which embryos, if any, are subject to the exclusion: Ibid, 14.

86 The opinions expressed in the EU Stem Cell Report were not limited to inventions involving human embryonic stem cells.

87 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 16.

- Stem cell lines that have been modified by *in vitro* treatments, or genetically modified so that they have acquired characteristics for a specific industrial application, may satisfy the requirements for patentability.[88]

- Patents on inventions involving stem cells should be granted only if the application refers to a specific and sufficiently accurately described stem cell line and its industrial application.

- Patenting processes involving human stem cells, regardless of the source of the cells, does not raise any specific ethical obstacles if the requirements for patentability are otherwise satisfied.[89] However, patent applications claiming stem cell technologies may require specific ethical evaluation; for example, by 'advisory panels of independent experts' established for such purposes.[90]

United Kingdom

15.51 In April 2003, the United Kingdom Patent Office (UK Patent Office) issued a Practice Note setting out its general approach to patent applications claiming stem cells derived from human embryos and processes involving human embryonic stem cells.[91] The Practice Note indicates that each patent application will be assessed on its merits, but goes on to provide as follows:

- processes for obtaining stem cells from human embryos are not patentable because the *Patents Act 1977* (UK) provides that uses of embryos for industrial or commercial purposes are not patentable inventions;[92]

- 'human totipotent cells' are not patentable because they have the potential to develop into an entire human body, and the human body at its various stages of its formation and development is excluded from patentability under the *Patents Act 1977* (UK);[93]

- 'human embryonic pluripotent stem cells' will be patentable if such inventions satisfy the statutory criteria for patentability because such stem cells do not have the potential to develop into an entire human body; and

88 Ibid, 15.
89 Ibid, 16.
90 Ibid, 18. Ch 7 considers the potential role of ethicists in advising patent examiners.
91 United Kingdom Patent Office, 'Inventions Involving Human Embryonic Stem Cells', *Practice Notice*, April 2003, <www.patent.gov.uk/patent/notices/index>. The Practice Note does not address the patentability of inventions involving foetal and adult stem cell lines, which it appears may be assessed for patentability in the same manner as inventions involving any other type of technology.
92 *Patents Act 1977* (UK) sch A(2), [3(d)]. This provision implemented art 6 of the EU Biotechnology Directive.
93 Ibid sch A(2), [3(a)]. This provision implemented art 5(1) of the EU Biotechnology Directive.

- the commercial exploitation of inventions involving human embryonic pluripotent stem cells is not, as a general matter, contrary to public policy or morality in the United Kingdom.[94]

15.52 The Practice Note has adopted an interpretation of the EPC and EU Biotechnology Directive—as implemented in the *Patents Act 1977* (UK)—that differs from the opinions of both the EPO and the EU Stem Cell Report in some respects. Unlike the EPO, the UK Patent Office will grant patents on inventions claiming certain types of embryonic stem cells. Further, in determining which types of embryonic stem cells are eligible for patent protection, the UK Patent Office has drawn a different distinction to the EU Stem Cell Report: the UK Patent Office distinguishes between types of cells on the basis of their potential to develop into an entire human being, rather than according to whether the cell lines are modified or unmodified.

Submissions and consultations

15.53 DP 68 proposed that IP Australia should develop examination guidelines consistent with the *Patents Act*, *Patents Regulations 1991* (Cth) (*Patents Regulations*) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cell technologies.[95] The ALRC considered that the guidelines would clarify the patentability of such inventions under Australian law, including the application of s 18(2) of the *Patents Act* to inventions involving stem cell technologies.

15.54 A wide range of submissions and consultations expressed support for the proposed examination guidelines.[96] The Human Genetics Society of Australasia suggested that 'it is important to develop guidelines to avoid the difficulties that have been encountered with the validity of gene patents'.[97] The Walter and Eliza Hall Institute of Medical Research considered that guidelines would ensure consistency in the examination of inventions involving stem cell technologies.[98] Other submissions suggested guidelines would assist researchers and biotechnology organisations in understanding the patentability of particular inventions in this area of technology.[99]

---

94 Ibid s 1(3), 1(4).

95 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 16–1.

96 See, eg, M Rimmer, *Submission P73*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004; National Stem Cell Centre, *Consultation*, Melbourne, 1 April 2004.

97 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004.

98 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

99 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

15.55 Two submissions expressed the view that, in addition to the proposed guidelines, amendments to the *Patents Act* are required to clarify the patentability of stem cell technologies.[100] Dr Matthew Rimmer submitted:

> There remains a need for the Federal Government to revise s 18(2) of the *Patents Act 1990* (Cth). The current provision is a legislative aporia—it is a puzzle and a mystery that it is difficult to decode. The [ALRC] should seize the opportunity to offer a legislative solution. Problems could arise in respect of the judicial interpretation of section 18(2), if the ambiguity of the provision is left unresolved. It is possible that a court could read the provision narrowly, and conclude that stem cell technologies were not patentable subject matter in the jurisdiction of Australia.[101]

15.56 Rimmer and the Australian Centre for Intellectual Property in Agriculture suggested that the distinction drawn by the UK Patent Office between totipotent cells and pluripotent stem cells should 'be codified in legislative form'.[102]

15.57 Some submissions commented on the types of stem cell technologies that should be patentable. A few submissions supported the patentability of processes involving stem cell technologies—including processes related to the isolation, cultivation and differentiation of stem cells—but expressed concern about the grant of patent rights over stem cells per se.[103] Other submissions did not draw this distinction, but commented generally that patents are important to encourage investment in stem cell research and the development of therapeutic applications for stem cells.[104]

15.58 If examination guidelines for stem cell technologies were to be adopted, a small number of submissions emphasised the importance of engaging in consultations as part of the process for developing them.[105] However, other submissions suggested that examination guidelines relating specifically to stem cell technologies were not necessary, or that consideration of these issues was premature.[106]

15.59 A few submissions considered that patents on stem cell technologies raised ethical issues and that there should be greater scope within patent law to address ethical

---

100 M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. See also Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

101 M Rimmer, *Submission P73*, 15 April 2004.

102 Ibid; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

103 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Sydney IVF Limited, *Submission P98*, 19 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

104 GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003.

105 AusBiotech Ltd, *Submission P94*, 16 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

106 Centre for Law and Genetics, *Submission P104*, 22 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.

concerns related to the patenting stem cell technologies.[107] The place of ethical concerns in the patent system is discussed further in Chapter 7.

ALRC's views

15.60 The patenting of stem cell technologies raises a number of issues. These include: uncertainty about how patent law will apply to inventions involving stem cell technologies; ethical concerns about the patenting of inventions involving human biological material, particularly embryos; objections to research involving human embryos; and the circumstances under which such research is conducted (if it is permitted at all). It is important to distinguish between these various issues and, in particular, between concerns directed to the conduct of stem cell research and those directed to the patenting of inventions that may be developed in the course of research.

15.61 Uncertainty currently exists about the application of the requirements for patentability to stem cell technologies. To address this, the ALRC considers that IP Australia should develop clear examination guidelines setting out the types of inventions involving stem cell technologies that it regards as patentable and, to the extent that any inventions involving stem cell technologies may not be patentable, the basis on which patent protection may not be available. Guidelines are desirable for similar reasons to those set out in Chapter 8 in support of the development of guidelines for the examination of biotechnological inventions generally. In the remainder of this chapter, the proposed guidelines are called the Stem Cell Examination Guidelines,

15.62 It is unclear from IP Australia's *Manual* exactly how Australian patent law is applied to inventions involving stem cells, particularly human embryonic stem cells. However, patent applications claiming stem cell technologies have been filed with IP Australia, and in some cases patents have been granted. It would assist potential applicants in understanding the scope of patent protection available under Australian law if IP Australia's approach with respect to inventions relating to stem cells were articulated more clearly. The ALRC agrees with IP Australia's suggestion that the proposed guidelines should be included within the *Manual* in order to maintain all instructions on patent examination practices in a single source.[108]

15.63 Although the primary responsibility for developing the proposed Stem Cell Examination Guidelines should lie with IP Australia, that body should consult with the NHMRC and other relevant stakeholders before adopting any guidelines in final form. The Stem Cell Examination Guidelines should be consistent with the *Patents Act*, *Patents Regulations* and existing case law. However, the ALRC recognises that the final interpretation of the Act and the Regulations lies with the courts, which may ultimately reject an interpretation adopted by IP Australia.

---

107 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; W Neville, *Submission P50*, 29 October 2003; M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

108 IP Australia, *Submission P86*, 16 April 2004.

15.64 In developing the guidelines, the UK Patent Office's Practice Note provides a worthwhile model. The distinctions drawn by the UK Patent Office between totipotent and pluripotent cells may provide a helpful way to approach the application of s 18(2) of the *Patents Act* to inventions involving embryonic stem cell technologies. Distinguishing between types of cells on the basis of their potentiality is preferable to the approach adopted in the EU Stem Cell Report of distinguishing between modified and unmodified stem cell lines. The EU Stem Cell Report does not explain why isolated human biological material may constitute a patentable invention under European law,[109] but an isolated stem cell line requires an additional step—that is, further modification—in order to be patentable. It appears that the distinction between modified and unmodified stem cells lines is a response to concerns about access to patented stem cell technologies and the effect of broad claims in stem cell patents. The ALRC considers that it is preferable to address any problems relating to the exploitation of stem cell technologies directly, if necessary (see below).

15.65 The ALRC does not favour amendments to the *Patents Act* that would expressly address the patentability of inventions involving stem cell technologies. As discussed in Chapters 6 and 7, the requirements for patentability in the *Patents Act* are nearly all technology-neutral and are therefore capable of adapting to new technologies as they arise. Technology-specific exceptions affect the flexibility of the current statutory framework. Further, such provisions may conflict with Australia's obligations under the *Agreement on Trade-Related Intellectual Property Rights*.[110] The express exclusion of inventions involving stem cell technologies—or a subset of such inventions—is also likely to have an adverse effect on research in this burgeoning field.[111] Moreover, the emergent state of stem cell science and the uncertainty about its potential applications must be borne in mind. Specific amendments to the *Patents Act* that address the patentability of inventions involving stem cell technologies are unlikely to be sufficiently flexible to adapt to future scientific developments.

15.66 Existing provisions in the *Patents Act* may be used in appropriate circumstances to reject patent applications claiming human embryonic stem cells or related processes in particular. The Commissioner of Patents has a discretion to refuse a patent application claiming an invention whose use would be contrary to law.[112] Because it is an offence under s 10 of the *Research Involving Human Embryos Act* to use an excess ART embryo without a licence from the NHMRC Licensing Committee (unless the use falls within a statutory exemption), inventions involving human embryonic stem cells

---

109 *European Patent Convention*, (entered into force on 7 October 1977), r 23e; *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*, (entered into force on 6 July 1998), art 5. See also Fédération Internationale des Conseils en Propriété Industrielle, *Opinion on the Patenting of Embryonic Stem Cells* (2004), 5.

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

111 A similar concern was articulated in the EU Stem Cell Report: European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 15.

112 *Patents Act 1990* (Cth) s 50(1)(a). See further Ch 7.

lines that are derived from the use of an excess ART embryo without a licence, or in breach of the conditions in any such licence, could fall within the 'contrary to law' provision in the *Patents Act*. Similar considerations could apply to inventions involving human embryonic stem cell lines derived from non-excess ART embryos.[113] Further, as discussed in Chapter 6, the incorporation of the *Statute of Monopolies 1623* into the definition of 'invention' in the *Patents Act* may provide a basis for excluding from patentability inventions that are 'generally inconvenient'.[114]

15.67 In the ALRC's view, amendments to the *Patents Act* to address ethical concerns about the patenting of stem cells are not required as an additional layer of ethical consideration. Objections to the patenting of inventions involving embryonic stem cells are often founded on ethical concerns about the conduct of research involving embryos and embryonic stem cells, rather than the grant of patent protection over these inventions. As described above, regulation of embryo research is the subject of Commonwealth, state and territory laws, which themselves draw a delicate balance between competing interests, taking ethical considerations into account.

Recommendation 15–1 IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cells and related technologies.

Exploiting patents over stem cell technologies

15.68 In addition to concerns about the patentability of inventions involving stem cell technologies, other issues have been raised about stem cell patents. These focus on the impact of stem cell patents on access to, and the licensing of, stem cell lines and stem cell technologies. The balance of this chapter examines these issues, including those in relation to broad claims in stem cell patents; the licensing practices of stem cell patent holders; and access to, and the commercialisation of, stem cell technologies.

Broad stem cell patents

15.69 Various reports and academic commentators have identified broad claims in stem cell patents as a concern because such patents could have adverse effects on further innovation.[115] For example, the EU Stem Cell Report noted that stem cell

113 See *Research Involving Human Embryos Act 2002* (Cth) s 11. However, research involving human embryonic stem cell lines imported into Australia may not currently be subject to the same considerations.

114 *Patents Act 1990* (Cth) s 18, sch 1.

115 See, eg, Nuffield Council on Bioethics, *Stem Cell Therapy: The Ethical Issues* (2001); House of Lords Select Committee on Stem Cell Research, *Report*, HL 83(i) (2002), [6.8]; M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448; G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243.

patents may cover important research tools and recommended that stem cell patents should be granted only where 'the patent claim refers to a specific and sufficiently accurately described stem cell line and its industrial application'.[116] Similarly, in its submission to this Inquiry, the Nuffield Council on Bioethics stated that 'the granting of over-generous patents with broad claims … should be discouraged' to minimise restrictions on stem cell research.[117]

15.70 Some commentators have suggested that the majority of human embryonic stem cell research could fall within the scope of the claims of the Thomson patents.[118] However, despite the broad foundational stem cell patents owned by entities such as WARF and Geron Corporation, other biotechnology companies have derived stem cell lines that may fall outside the scope of these patents. For example, BresaGen Limited, an Australian biotechnology company with facilities in Georgia, USA, has developed four pluripotent embryonic stem cell lines derived from embryos at a later stage of embryonic development than that claimed in the Thomson patents.[119]

15.71 Broad claims are characteristic of patents granted early in the development of a new technological field, like stem cell science. However, the prior art against which any subsequent patent applications may be assessed is likely to significantly limit the scope of the claims in any stem cell patents that may be granted in the future.[120] Further, broad claims may not be objectionable if access to stem cell technologies covered by such claims is not unduly restricted.

Licensing stem cell patents

15.72 It has also been suggested that stem cell patents may impede further research and innovation in relation to stem cell technologies, particularly if stem cell patent holders license such patents exclusively, or only on restricted terms.[121] These concerns

---

116 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 18.

117 Nuffield Council on Bioethics, *Submission P102*, 22 April 2004.

118 S Shulman, 'Owning the Future: The Morphing Patent Problem' (2001) *Technology Review* 33; G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243, 259; J Lee, 'The Ownership and Patenting of Inventions Resulting from Stem Cell Research' (2003) 43 *Santa Clara Law Review* 597, 626; M Rimmer, 'The Attack of the Clones: Patent Law and Stem Cell Research' (2003) 10 *Journal of Law and Medicine* 448. However, a 2003 study of biotechnology patenting practices in Australia conducted by Dr Dianne Nicol and Jane Nielsen was unable to identify corresponding Australian patents or patent applications for two of the Thomson patents—that is, US Pat No 6,200,806 and 6,280,718: D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 42–43.

119 S Kincaid, 'Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research' (2003) 30 *Pepperdine Law Review* 553, 581–582.

120 National Stem Cell Centre, *Consultation*, Melbourne, 4 September 2003.

121 Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

are similar to those addressed elsewhere in this Report about the licensing and exploitation of gene patents.[122]

15.73 Currently, the extent to which access to stem cell technologies is being restricted is unclear. Licences over stem cell patents and other collaborative arrangements relating to the development of stem cell technologies have been reported in connection with Australian commercial entities, including BresaGen, ES Cell International, and Stem Cell Sciences.[123]

15.74 Concerns about the licensing of stem cell patents have been particularly acute in the United States. This is largely the result of a government policy relating to funding embryonic stem cell research.[124] On 9 August 2001, President George W Bush announced that human embryonic stem cell research using federal funds could be conducted only on existing stem cell lines.[125] This policy sought to balance the potentially valuable therapies that stem cell research may produce against concerns in some sections of United States society that research involving human embryos should not be permitted.

15.75 President Bush indicated that there were then more than 60 'genetically diverse stem cell lines' in existence, which had been created from embryos that had already been destroyed.[126] However, concerns have now been raised that an insufficient number of human embryonic stem cell lines are available[127] and that there are deficiencies in existing cell lines.[128] Further, many of these human embryonic stem cell lines are covered by patents.[129] It has been suggested that President Bush's policy has rendered existing embryonic stem cell lines (and patents over such cell lines) more

---

122 See Ch 12, 18 and 22.

123 Invest Australia, *Australian Biotechnology* (2003), 10.

124 See, eg, S Kincaid, 'Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research' (2003) 30 *Pepperdine Law Review* 553; C Carroll, 'Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences' (2002) *Journal of Law, Technology and Policy* 435; J Lee, 'The Ownership and Patenting of Inventions Resulting from Stem Cell Research' (2003) 43 *Santa Clara Law Review* 597.

125 President Bush and United States Office of the Press Secretary, 'Embryonic Stem Cell Research', *Fact Sheet*, 9 August 2001, <www.whitehouse.gov/news>. See also National Institutes of Health, *Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Stem Cell Registry, 7 November 2001*, <http://stemcells.nih.gov/fedPolicy/NIHFedPolicy.asp> at 16 September 2003. President Bush's policy does not, however, apply to privately funded research involving embryos.

126 President Bush and United States Office of the Press Secretary, 'Embryonic Stem Cell Research', *Fact Sheet*, 9 August 2001, <www.whitehouse.gov/news>.

127 An April 2004 letter to President Bush, signed by 206 United States Members of Congress, stated that only 19 cell lines of the original 78 that were identified as falling within the ambit of President Bush's policy are actually available for use: Letter to President Bush from Various Members of Congress, *Federal Policy Concerning Embryonic Stem Cell Research*, 28 April 2004.

128 For example, some are frozen inner cell masses that, upon thawing and culturing, have not been viable cell lines; see: National Institutes of Health, *NIH Human Embryonic Stem Cell Registry*, <http://stemcells.nih.gov/registry> at 16 June 2004.

129 G McGee and E Banger, 'Ethical Issues in the Patenting and Control of Stem Cell Research' in D Magnus, A Caplan and G McGee (eds), *Who Owns Life?* (2002), 243, 247, 258.

significant.[130] Professor Rebecca Eisenberg has been reported as saying: 'what constrains the monopoly power of a patent holder is the prospect of new technology being developed that will make it unnecessary to deal with them … [the] President's decision limits that threat'.[131]

15.76 The United States National Institutes of Health (NIH) and private institutions in the United States have endeavoured to facilitate access to human embryonic stem cell lines. The NIH maintains a registry of all stem cell lines that fall within the ambit of President Bush's policy.[132] Further, it has entered into agreements with a number of entities to ensure access to proprietary embryonic stem cell lines—including those covered by the Thomson patents—for researchers funded by the NIH.[133] Privately funded research centres in the United States have also begun to make embryonic stem cell lines available to researchers. For example, in April 2004, the newly established Harvard Stem Cell Institute indicated that it would make 17 new human embryonic stem cell lines available for free to qualified researchers.[134]

Stem cell banks

15.77 Other overseas initiatives have also been implemented to facilitate access to existing and newly created stem cell lines. In the United Kingdom, the National Institute for Biological Standards and Controls has established the world's first stem cell bank (UK Stem Cell Bank). The UK Stem Cell Bank opened in May 2004 and plans to supply stem cell lines of all types for use in research in the United Kingdom and other countries, as well as for direct use in the production of human therapeutic products.[135] A code of practice for the UK Stem Cell Bank is expected to be available in late 2004, regulating the use of stem cell lines in the bank. Terms and conditions about related intellectual property issues are also being developed.

15.78 The establishment of a stem cell bank has also been considered in a number of other jurisdictions. For example, the EU Stem Cell Report proposed the creation of an EU registry of unmodified human stem cell lines, which would include both embryonic

---

130 S Kincaid, 'Oh, the Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research' (2003) 30 *Pepperdine Law Review* 553, 574; C Carroll, 'Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences' (2002) *Journal of Law, Technology and Policy* 435, 444.

131 S Stolberg, 'Patent Laws May Determine Shape of Stem Cell Research', *New York Times*, 17 August 2001, A1.

132 National Institutes of Health, *NIH Human Embryonic Stem Cell Registry*, <http://stemcells.nih.gov/registry> at 16 June 2004.

133 By April 2004, agreements with the NIH had been entered into by: WiCell Research Institute Inc (a subsidiary of WARF, which has rights to license the Thomson patents); ES Cell International Pte Ltd; BresaGen Inc (a United States affiliate of the Australian company, BresaGen Limited); the University of California; Technion-Israel Institute of Technology; and MizMedi Hospital—Seoul National University: National Institutes of Health, *Stem Cell Transfer Agreements*, <http://stemcells.nih.gov> at 16 June 2004.

134 'Stem-Cell Science', *Harvard Magazine*, May/June 2004, 59.

135 UK Stem Cell Bank, *UK Stem Cell Bank*, <www.ukstemcellbank.org.uk> at 16 June 2004; A Jha, 'UK Opens Pioneer Cell Bank', *The Guardian* (London), 19 May 2004, <www.guardian.co.uk>.

stem cells and embryonic germ cells.[136] In January 2003, the United Kingdom Medical Research Council convened the International Stem Cell Forum for the discussion of international policy issues relating to stem cells.[137] One of the projects under consideration by the Forum relates to potential collaboration between countries in connection with stem cell banks.

15.79 In Australia, the *Research Involving Human Embryos Act* and the *Prohibition of Human Cloning Act* provide for independent reviews of the operation of this legislation, which will include consideration of the applicability of establishing 'a National Stem Cell Bank'.[138] The reviews are to be conducted as soon as possible after 19 December 2004 and reports are to be submitted to the Council of Australian Governments and both Houses of Parliament upon completion.[139]

Commercialisation of stem cell technologies in Australia

15.80 To date, consideration of issues relating to stem cell technologies in Australia has focused on the circumstances in which stem cell research may be conducted and whether it is appropriate for intellectual property rights to be granted in relation to inventions involving stem cell technologies. Regulation of the way in which stem cell patents might be exploited and commercialised has not been addressed in any detail.

15.81 The Andrews Report recommended that a licensing body be established to regulate any research involving the isolation, use and creation of embryonic stem cell lines.[140] The Report contemplated that this licensing body should have regard to 'the potential commercialisation of the products' of such research and would 'issue guidelines to other Commonwealth agencies'.[141] However, the functions of the licensing body contemplated by the Andrews Report were more extensive than those ultimately conferred upon the NHMRC Licensing Committee pursuant to Commonwealth, state and territory legislation.[142]

---

136 European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells: Opinion to the European Commission* (2002), 18. No action has been taken to implement this proposal to date. However, plans to establish are Spanish stem cell bank are in progress: X Bosch, 'Spain's Stem Cell Battle Ends', *The Scientist*, 6 May 2004, <www.biomedcentral.com/news/20040506/04>.

137 The Forum comprises nine international research agencies, including the NHMRC: United Kingdom Medical Research Council, *International Stem Cell Forum*, <www.mrc.ac.uk/index/strategy-strategy/strategy-science_strategy/strategy-index.htm> at 16 June 2004.

138 *Research Involving Human Embryos Act 2002* (Cth) s 47(4)(d); *Prohibition of Human Cloning Act 2002* (Cth) s 25(4)(d).

139 *Research Involving Human Embryos Act 2002* (Cth) ss 47(1), 47(3); *Prohibition of Human Cloning Act 2002* (Cth) ss 25(1), 25(3).

140 Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), recs 6 and 7.

141 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001), [12.82].

142 Standing Committee on Legal and Constitutional Affairs, *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (2001) rec 1, 2, 5–8, [12.41]–[12.55].

15.82 Only limited reforms have been implemented to address specific aspects of the commercialisation of stem cell technologies at this stage. For example, in 2003, the *Therapeutic Goods Regulations 1991* (Cth) were amended to include provisions requiring manufacturers of prescription medicines to provide consumers with information about whether medicines have been manufactured or tested using human embryonic stem cells.[143] In the future, additional regulatory provisions directed specifically to stem cell technologies may have a significant effect on the way in which these technologies are developed and commercialised.[144]

Submissions and consultations

15.83 DP 68 asked whether specific mechanisms should be established to regulate the exploitation of patented stem cell technologies. DP 68 suggested that these mechanisms might include: establishing an Australian stem cell bank, or collaborative agreements with existing stem cell banks in other countries; conferring responsibility on a specific body to monitor the potential exercise of stem cell patent rights; or requiring the NHMRC and the Australian Research Council (ARC) to develop guidelines for researchers relating to the commercial exploitation of inventions involving stem cell technologies.[145]

15.84 Submissions generally did not support the implementation of specific mechanisms to regulate the exploitation of stem cell patents, or the commercialisation of stem cell technologies.[146] A few submissions commented that if mechanisms to regulate the exploitation of stem cell patents were introduced, they should operate independently of the *Patents Act*.[147]

15.85 A range of submissions commented on the establishment of a stem cell bank in Australia.[148] Most of these indicated that further consideration of this issue should await the review scheduled to occur under the *Research Involving Human Embryos Act* and the *Prohibition on Human Cloning Act*, which is specifically required to consider the need for 'a National Stem Cell Bank'.[149] A few submissions observed, however,

---

143 *Therapeutic Goods Amendment Regulations (No 3) 2003* (Cth); AusBiotech Ltd, *Proposed Amendments to Therapeutic Goods Regulations 2003*, <www.ausbiotech.org/policy.php> at 16 June 2004.

144 National Stem Cell Centre, *Consultation*, Melbourne, 1 April 2004.

145 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 16–1.

146 Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Queensland Government, *Submission P103*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004.

147 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004.

148 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

149 South Australian Department of Human Services, *Submission P74*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Ministry for Science and Medical Research New South Wales, *Submission P109*, 28 April 2004.

that even if a stem cell bank were established, it might not be able to compel access to patented stem cell technologies.[150] The issue of access could be addressed contractually.[151] Rimmer suggested that a stem cell bank could play 'an important role as a fair broker between parties to encourage the sharing and exchange of stem cell lines at reasonable prices'.[152]

15.86 Only a few submissions expressed support for conferring responsibility on a new or existing body to monitor the potential exercise of stem cell patent rights.[153] The Centre for Law and Genetics suggested that the proposed Human Genetics Commission of Australia could perform this function.[154] However, another submission commented that the need for such a body had not been demonstrated.[155] The NHMRC suggested that there may be practical difficulties in determining the scope of any organisation's role in this regard, including:

> the point at which the 'potential exercise of patent rights' would be considered, the criteria that any Committee would use to assess the potential impact of the exercise of patent rights, the means by which the Committee would enforce its decisions and how any decisions would 'cut across' general patents law.[156]

15.87 Some submissions expressed support for the development of guidelines to ensure that the public interest in the commercial exploitation of inventions involving stem cell technologies is balanced with the public interest in dissemination of such technologies.[157] However, others suggested that separate guidelines relating solely to stem cell technologies were not desirable because balancing these competing public interests is an issue for all patented technologies.[158] In addition, the Department of Health Western Australia observed that the NHMRC and ARC can only 'encourage compliance [with such guidelines] through provision of funding for research, but this does not apply to commercial organizations'.[159]

---

150 M Rimmer, *Submission P73*, 15 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004.

151 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

152 M Rimmer, *Submission P73*, 15 April 2004.

153 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004.

154 Centre for Law and Genetics, *Submission P104*, 22 April 2004. The ALRC and AHEC recommended the establishment of the Human Genetics Commission of Australia: see Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1 to 5–9.

155 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

156 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

157 M Rimmer, *Submission P73*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

158 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004.

159 Department of Health Western Australia, *Submission P89*, 16 April 2004.

ALRC's views

15.88 No firm evidence has been presented to the Inquiry to support the establishment of new mechanisms to regulate the exploitation of patented stem cell technologies. Views expressed in submissions and consultations indicated that existing mechanisms and guidelines would be more appropriate to address any concerns that might arise in this area.

15.89 Recommendations made elsewhere in this Report to facilitate access to genetic materials and technologies could also apply to stem cell technologies. These recommendations include: amendments to the existing Crown use and compulsory licensing regime provisions in the *Patents Act* to facilitate access to patented technologies in appropriate circumstances; and amendments to the *Patents Act* to incorporate an experimental use exemption.[160] The ALRC has also recommended that the NHMRC and ARC review the *National Principles of Intellectual Property Management for Publicly Funded Research* to ensure that publicly funded research, where commercialised, results in appropriate public benefit.[161] Issues arising in publicly funded research involving stem cell technologies should be addressed as part of this review.

15.90 The ALRC believes that any assessment of whether a stem cell bank should be established in Australia should be addressed as part of the reviews to be conducted under the *Research Involving Human Embryos Act* and the *Prohibition of Human Cloning Act*. The desirability of establishing a stem cell bank in Australia will be affected by a variety of factors. These include the need for controlled conditions that comply with good manufacturing practices to maintain stem cell lines, as well as privacy, ethical and legal considerations. Another important issue will be the existence of patent rights over any stem cell lines included in the bank, or technologies related to those stem cell lines. Patent rights could affect the types of stem cell lines that are deposited and the terms on which such stem cell lines may be accessed. These issues should be specifically addressed when the establishment of a National Stem Cell Bank is considered in the forthcoming reviews.

Recommendation 15–2 As part of the independent reviews to be conducted under the *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning Act 2002* (Cth), the responsible Minister and the National Health and Medical Research Council should require an examination of the exploitation of intellectual property rights over stem cells when considering the establishment of a National Stem Cell Bank.

160 See rec 13–1, 26–2 and 27–1. See also Ch 19.
161 See rec 11–1 and 12–1.

PART D

Patents and Commercialisation of Biotechnology

16. Overview of the Biotechnology Sector

Contents

Introduction

16.1 The Terms of Reference require the ALRC to consider the impact of current patenting laws and practices related to genes and genetic and related technologies on the Australian biotechnology sector. The biotechnology sector, including pharmaceutical companies, is heavily dependent on patents because of the large costs involved in developing some products and because many products are readily copied.

16.2 This chapter describes the structure and features of the biotechnology sector in Australia. It also describes the pharmaceutical industry in Australia, as the pharmaceutical industry is part of the biotechnology sector, and biotechnology drug products form an important output of the sector. However, the pharmaceutical industry also operates in areas outside biotechnology and the industry is often differentiated from other biotechnology companies in statistics about the biotechnology sector.

16.3 The biotechnology sector also encompasses areas outside the scope of this Inquiry, including those related to agriculture, food processing, manufacturing and environmental management. The *Australian Biotechnology Report 2001* defines biotechnology as:

> The application of all natural sciences and engineering in the direct or indirect use of living organisms or parts of organisms, in their natural or modified forms, in an innovative manner in the production of goods and services (including for example therapeutics, foodstuffs, devices, diagnostics, etc) and/or to improve existing industrial processes. The market application of outputs is typically in the general areas of human health, food production, industrial bio-processing and other public good and environmental settings.[1]

1 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 3. The Australian Bureau of Statistics is currently considering the development of a formal definition for biotechnology to work as a generally accepted standard: Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 310.

16.4 As the Terms of Reference require the ALRC to focus on the human health implications of gene patenting, this definition of biotechnology encompasses areas that fall outside the scope of this Inquiry. Consequently, much of the description in this chapter is of the sector as a whole because it is not always possible to find statistics that differentiate between industries within the sector.[2]

Global context

16.5 Biotechnology is one of the world's fastest growing industrial sectors.[3] In mid-April 2003, the total value of publicly traded biotechnology companies at market prices was US$206 billion.[4] The United States Department of Commerce has described biotechnology as 'the most research-intensive industry in civilian manufacturing'.[5] The United States dominates the biotechnology sector. In 2003, the Biotechnology Industry Organization reported that the United States biotechnology industry generated 72% of global revenue in biotechnology. In 2002, these revenues amounted to US$33.6 billion.[6]

16.6 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.[7]

16.7 Globally, the sector has been characterised by a high attrition rate especially among the start up firms whose only significant assets may be patents or patent applications. Capital-raising and cash flow may also present problems and many companies have become insolvent after a few years or have been absorbed by larger companies.[8]

Australian biotechnology sector

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

---

2 The Australian Bureau of Statistics has recognised the lack of statistical information about biotechnology in Australia, and has indicated that development work is now underway on a biotechnology survey to be conducted in respect of 2003–04: Australian Bureau of Statistics, 'Biotechnology Statistics', *Science and Technology Statistics Update*, December 2003, [4], [4.2].

3 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 1.

4 Biotechnology Industry Organization, *Editor's and Reporter's Guide 2003–2004: Biotechnology, A New Link to Hope* (2003), 3.

5 Office of Technology Policy, *The US Biotechnology Industry* (1997), 30.

6 Ernst & Young, *Resilience: Americas Biotechnology Report 2003* (2003), 3.

7 Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 10.

8 B Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, <http://genethics.ca/personal/HistoryPatent.pdf> at 16 June 2004, 6.

- core biotechnology companies;[9]
- pharmaceutical companies;
- genomic companies; and
- public research institutions.[10]

16.9 The sector comprises a mix of small and medium sized enterprises (SMEs) together with larger companies, including subsidiaries of multinationals. Most major international pharmaceutical companies have Australian subsidiaries. In 2003, there were more than 300 core biotechnology companies, with an industry growth rate of over 50% in the previous two years.[11] There were also around 450 'diversified' biotechnology companies. The sector employs about 6,400 full-time equivalent employees.[12]

16.10 Total revenue generated by the core biotechnology companies is estimated to be almost $1 billion annually.[13] The biggest contributors to revenue growth have been royalties, licensing and milestone fees.[14] The *Australian Biotechnology Report 2001* suggested that 'one of the challenges for most Australian biotechnology companies is generating sufficient funds to achieve their product development objectives'.[15] It described the sector as growing, but small in global terms.[16]

16.11 Internationally, Australia compares favourably with the United States in terms of the number of biotechnology companies relative to the size of the labour force, and is well ahead of the European Union. Australia now ranks sixth in the world for the number of biotechnology companies, behind the United States, Canada, the United Kingdom, Germany and France.[17] Australia's revenue as a proportion of the labour force is well below the United States, but ahead of the European Union.[18]

---

9 The term 'core' has been used to describe companies whose business depends on 'exploiting intellectual property embedded in molecular, cellular and tissue biology': Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 4.

10 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.

11 Invest Australia, *Australian Biotechnology* (2003), 1.

12 Invest Australia, *A Snapshot of Biotech and Pharma in Australia*, <www.investaustralia.gov.au> at 16 June 2004.

13 Ibid.

14 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 20. 'Milestone fees' are lump sum payments made by a licensee upon reaching specified stages in the development or commercialisation of a product.

15 Ibid.

16 Ibid, 8.

17 Invest Australia, *Australian Biotechnology* (2003), 5; Ernst & Young, *Beyond Borders: The Global Biotechnology Report 2002* (2002), 6.

18 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 22.

16.12 The *Australian Biotechnology Report 2001* described the Australian biotechnology sector as being numerically 'dominated by small to medium players', lacking geographic proximity to a large market, and therefore also lacking the 'wealth of information' provided through conferences, workshops, networking and industry associations.[19] Larger companies are frequently involved with the smaller ones through strategic alliances, in particular licence agreements.[20] The Report noted that alliances are the main means by which Australian biotechnology companies gain access to international markets:

> The best Australian companies are now able to joint venture with, or even acquire entities overseas … Low and slow commercialisation successes are still, however, an ongoing issue for many Australian companies.[21]

16.13 In a 2002 survey, Kelvin Hopper and Lyndal Thorburn reported that 50% of Australian core biotechnology companies aim to develop new therapeutic or diagnostic products directed at human diseases.[22] The survey also found that human health and therapeutics dominated among the new companies, with a significant increase in the number of companies established to supply to the sector in areas such as protein and gene sequencing.[23]

16.14 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.[24] This is particularly likely to be the case for drug discovery companies. Interview data from a recent study of the Australian medical biotechnology sector by Dr Dianne Nicol and Jane Nielsen suggests that this could be attributed to a lack of infrastructure and resources to exploit patents within Australian.[25]

16.15 Companies that produce other downstream products (such as tests, therapies or devices), or intermediate products (such as reagents, formulations and bioinformatics tools) may not necessarily seek to license offshore.

16.16 Spin-off companies are the preferred approach to commercial development of biotechnology innovations in the Australian industry. This approach may be preferred in part because most Australian scientific research that results in new technologies occurs in the public sector. It may also be due to the support for new companies

---

19 Ibid, 8.

20 This is also a feature of the industry in the United States and, increasingly, the European Union: Department of Industry Science and Resources Business Competitiveness Division, *Invisible Value: The Case for Measuring and Reporting Intellectual Capital* (2001), 354.

21 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 46.

22 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 29.

23 Ibid, 11.

24 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 46.

25 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 103.

available through the Biotechnology Innovation Fund.[26] Government grants are the largest source of capital for the new companies, followed by funds from parent organisations and venture capital.[27] It has been suggested that the Australian industry is overpopulated with small companies relying on a single idea to be successful.[28]

16.17 The *Australian Biotechnology Report 2001* described funding for research and development (R&D) as 'an ongoing challenge' for SMEs.[29] It suggested that a problem for the sector is the capacity to generate sufficient funds to achieve its objectives, whether in licensing or manufacturing.[30] In submissions, the Department of Industry, Tourism and Resources (DITR) identified the 'extremely high levels of financial risk' in the sector as the primary reason for the difficulty involved in attracting venture capital. The result has been to make the 'pace of commercialisation of Australian biotechnology innovations … less than optimum'. DITR also suggested that 'low levels of capital inflow' is one of the major impediments to the growth of the sector.[31]

16.18 R&D expenditure by Australian companies is well below that in the United States and the European Union.[32] 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.[33]

Pharmaceutical industry

16.19 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).[34]

---

26 In one recent study of 24 biotechnology companies listed on the Australian Stock Exchange between 1998 and 2002, all but two were developing technology originating from academic institutions, medical research institutes or the Commonwealth Scientific and Industrial Research Organisation: D Sparling and M Vitale, *Australian Biotechnology: Do Perceptions and Reality Meet?* (2003) Australian Graduate School of Management, 5.

27 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 3.

28 D Crowe, 'Testing Time for Biotech', *Financial Review* (Sydney), 7 October 2003, 61.

29 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 11.

30 Ibid, 20.

31 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

32 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 22.

33 Ibid, 10.

34 Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), [1.2]. For the purpose of the Productivity Commission's report, the pharmaceutical industry was defined as 'all those who contribute to the discovery, development, manufacture and supply of human-use pharmaceutical products and services in Australia, including the biomedical sector'.

16.20 Globally, the pharmaceutical industry is dominated by horizontally and vertically integrated multinational entities.[35] Some of these are engaged in joint ventures with universities, other research institutions, or smaller biotechnology firms.

16.21 Australia's population represents 0.3% of the world's population yet consumes around 1% of total global pharmaceutical sales. In 2002, the Australian human-use pharmaceuticals manufacturing industry generated revenue of about $6.1 billion. Around 143 separate firms are listed as suppliers to the Pharmaceutical Benefits Scheme, and these employ up to 16,000 people.[36]

16.22 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.[37] Pharmaceutical R&D involves drug discovery, pre-clinical testing and clinical trials to test new drugs for their effectiveness and safety. Total R&D spending by pharmaceutical companies in Australia is around $300 million annually.[38]

16.23 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.[39]

Biotechnology patents

16.24 The Organisation for Economic Co-operation and Development has noted:

> Patents are especially important for biotechnology firms as many of them have no activity other than R&D and therefore do not directly exploit their inventions: they sell them, or the right to exploit them, to other firms. A legal property right is therefore needed for the seller to be protected.[40]

16.25 Regulatory requirements can mean the process of developing technology into a marketable product is long and costly. As one biotechnology sector analyst has commented, companies need 'tons of time and buckets of money' to bring products to market.[41] Intellectual property rights afford producers protection during this period, and the monopoly gained by a patent allows for the high initial investment in development to be recouped.

---

35 Department of Industry Tourism and Resources, *Pharmaceuticals Industry Profile*, <www.industry.gov.au> at 16 June 2004.

36 Ibid. See Ch 19.

37 Government programs to support R&D in the pharmaceutical industry are discussed in Ch 11.

38 Department of Industry Tourism and Resources, *Pharmaceuticals Industry Profile*, <www.industry.gov.au> at 16 June 2004. Clinical trials are the largest component of such spending.

39 Ibid.

40 Organisation for Economic Co-operation and Development, *An Overview of Biotechnology Statistics in Selected Countries* (2003), 13.

41 D Crowe, 'Testing Time for Biotech', *Financial Review* (Sydney), 7 October 2003, 61.

16.26 The majority of all biotechnology patents originate in the United States. United States companies account for 65.5% of all biotechnology patents issued by the United States Patent and Trademark Office and almost 50% of those issued by the European Patent Office.[42]

16.27 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 a gene patent. As outlined in Chapter 3, this Report uses 'gene patent' to refer to patents on genetic materials or technologies, and not just to patents on isolated genetic materials. 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,[43] and because of the limited amount of published patent information.

16.28 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.

16.29 It appears clear, however, that most gene patents granted in Australia relate to inventions that are developed overseas. One research study, conducted for the United States National Science Foundation,[44] examined the source of patent applications in relation to 'international patent families' covering human DNA sequences.[45] 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 16–1).[46]

16.30 Of the 42 applications filed by Australian organisations, 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 16–2).

---

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

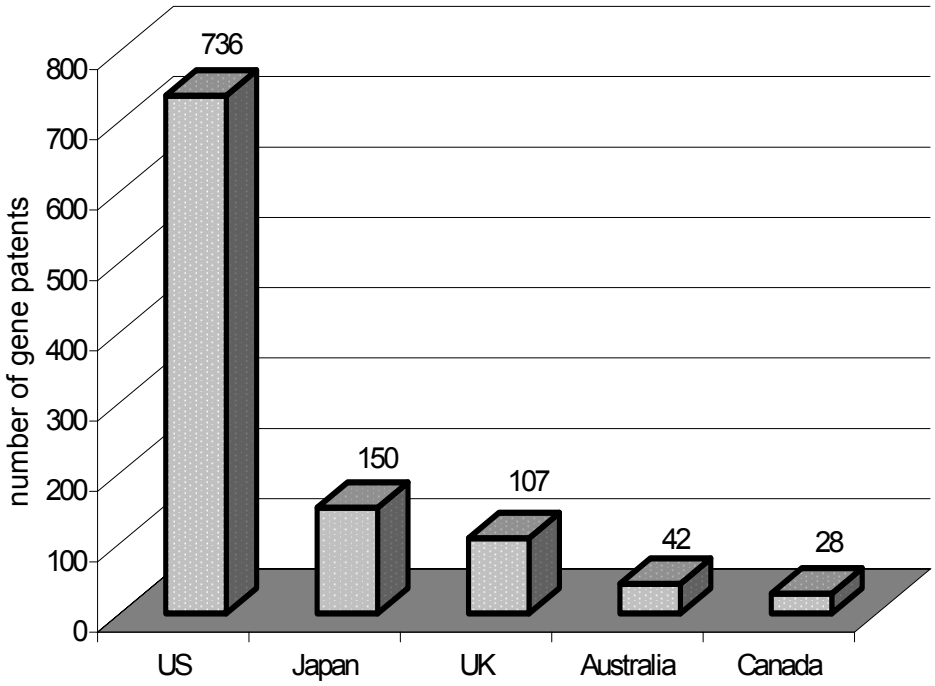
43 See Ch 8 for more detail.

44 L Rausch, 'International Patenting of Human DNA Sequences: InfoBrief (NSF 02–333)', *Division of Science Resource Statistics, National Science Foundation*, September 2002, 1.

45 A 'patent family' was defined as consisting of all patent documents published in a country and associated with a single invention. An 'international patent family' was defined as an invention for which patent protection has been sought in more than one country: see Ibid, 1–2.

46 Ibid, Table 2.

Figure 16–1 Country of origin of patent applications on human DNA sequences filed in Australia 1995–1999

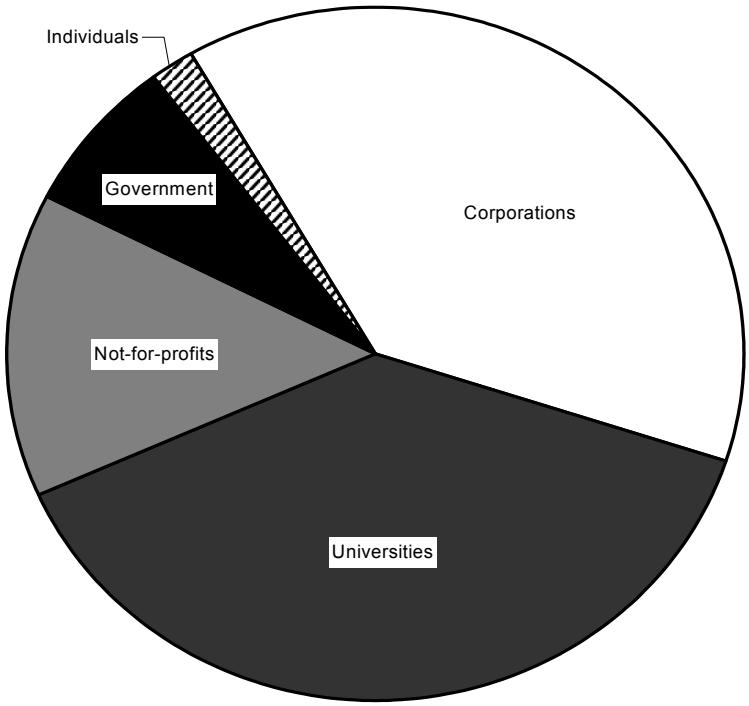


16.31 Studies relating to Australian biotechnology patents also indicate that most of these are foreign owned. Nielsen reports that only about 2% of biotechnology applications filed in Australia originate from Australian inventors.[47] She notes that 'by far the greatest number of biotechnology patents are held by US inventors, both in the US and in other jurisdictions including Australia'.[48]

47 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 39.

48 Ibid, 39.

Figure 16–2 Australian organisations filing Australian patent applications on human DNA sequences by sector, 1995–1999



16.32 Nielsen also notes that of the biotechnology patent applications in the United States, around 2% originate from Australia.[49] A report by CHI Research Inc found that, of Australian patents granted in the United States, Australia was 'relatively strong in pharmaceuticals and biotechnology and quite weak in most other high-tech areas'. The report suggested that 'combined pharmaceuticals and biotech [Australian-invented US patents] … may in fact represent an area of actual or potential great strength for Australia'.[50]

16.33 The number of patents granted does not tell the whole story in relation to the biotechnology sector. Licensing arrangements to make technology available to others are also an important feature of the biotechnology industry. These arrangements are discussed in Chapter 22.

---

49 Ibid, 39.

50 CHI Research Inc, *Inventing Our Future: The Link between Australian Patenting and Basic Science* (2000), 29.

17. Technology Transfer

Contents

Introduction

> The ivory tower academy has had to learn the language of business economics.[1]

17.1 As noted in Chapter 11, most upstream human health related biotechnology research conducted in Australia is funded by the Australian Government and occurs in universities, other research institutions, health departments and government agencies (together referred to as 'research organisations'). This chapter considers the transfer of upstream research to the biotechnology sector for commercial development. It focuses on the interface between research organisations and the biotechnology industry. As transfer most often occurs between universities or other research institutions and industry, the chapter will particularly focus on intellectual property management within these organisations.

17.2 This chapter addresses some of the potential impediments to transfer for commercialisation. These include lack of commercial experience or institutional support, researcher attitudes, difficulty in finding industry receptors and lack of resources. Variability in transfer practices and lack of clear ownership of patented technology may also hamper effective transfer for commercialisation. A variety of options for addressing these issues are examined. This chapter also considers transfers that are not specifically aimed at commercialisation and briefly discusses issues surrounding materials transfer agreements (MTAs).

Technology transfer and research commercialisation

17.3 As discussed in Chapter 11, there are a number of routes to end use for research results. One of these is research commercialisation, where research outputs are developed by industry to product stage for supply to the public. Often this development occurs after new research results have been transferred out of research organisations and into industry. This is one aspect of 'technology transfer'.

17.4 Technology transfer is the process of moving new technology from one person or organisation to another to enable sharing of resources or to facilitate further development and commercialisation. This may include transfers of materials, information or the details of new technologies.

17.5 Technology transfer is also sometimes referred to as 'utilisation' of research so as to include the transfer of research outputs to other researchers and organisations for further development that is not specifically aimed at producing a marketable product.[2] In this chapter, technology transfer refers to the subset of transfers within the broad term 'utilisation' that are directed at eventual transfer to industry for development into products.

---

1 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 50.

2 Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 29. Utilisation is discussed further in Ch 11.

17.6 Technology transfer is important because basic research is only the first stage in the development of genetic tests and therapies that will eventually have healthcare benefits for the community. Moving from invention to product requires considerable investment to fund further research into the medical applications of the technology; to undertake validation research and clinical trials; and to develop and produce a marketable test or therapy. The cost of this developmental phase will usually be high and require specialised skills and facilities.

17.7 Most research organisations lack the financial capacity and skill base to undertake the developmental phase. It is generally considered that the industry sector is better placed to take on this role to ensure the community receives the benefits of genetic research.

17.8 It is Australian Government policy for research organisations to work with industry to commercialise the products of their research.[3] This policy is based on the view that patenting by research organisations and licensing of technologies to the private sector will increase the rate of commercial application of knowledge.[4]

Technology transfer offices

17.9 In recent years, most research organisations have established dedicated units or companies to facilitate technology transfer. These units take a variety of forms and have differing responsibilities, including obtaining patent protection, negotiating licensing and MTAs and, in some cases, establishing spin-off companies. They are also referred to by a range of titles, including 'business liaison offices', 'technology transfer units' or 'commercialisation arms'. They may be units within the organisations or companies wholly owned by the organisation. In this chapter they are collectively referred to as 'technology transfer offices'.

17.10 The overall functions of technology transfer offices include:

- identifying technology developed within the organisation that may have a commercial application;
- managing intellectual property issues, including facilitating patent applications, licensing university innovations to the commercial sector and advising on the terms of research agreements;
- coordinating industry access to research projects within the university that require financial investment to develop the commercial potential of innovative technologies and products; and

3 See Ch 11.
4 Commonwealth of Australia, *Backing Australia's Ability: An Innovation Action Plan for the Future* (2001), 18.

- offering assistance with gaining government support for research and development, including tax incentives and grant and loan schemes, such as the Australian Government R&D Start program.[5]

17.11 Technology transfer offices take different approaches to aiding technology identification and transfer. These include:

- Taking a decentralised approach, where managers of innovation and commercial development are appointed to each faculty to assist with identifying innovative technology, to work with the faculty on business development matters and to liaise with the technology transfer office's staff.[6] This approach allows for the development of expertise around particular areas of research and commercialisation.

- Maintaining a register of companies and consultants who are willing to assist university researchers in the management and commercial development of intellectual property.[7]

- Taking an active role in helping researchers through the process of transfer and commercialisation, including through the provision of educational programs.[8]

Transferring for commercialisation

17.12 Research commercialisation begins with the identification of new technology and an evaluation of its possible applications and commercial potential. Patents may be sought and, if obtained, the technology may be transferred to other researchers or industry for further development.[9]

17.13 Chapter 16 noted the importance of patent protection in attracting commercial interest in developing genetic technologies.[10] Consequently, as a result of government policy favouring commercialisation, organisations are now more inclined to patent the results of research rather than simply allowing them to be published and placed in the public domain.

---

5 DP 68 provided an overview of the funding support programs available for research commercialisation: Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Ch 11.

6 See, eg, UniQuest, *About UniQuest*, <www.uniquest.com.au/?id=13> at 16 June 2004.

7 Melbourne Research and Innovation Office, *Technology Transfer*, University of Melbourne, <www.research.unimelb.edu.au/ridg/techtrans> at 16 June 2004.

8 For example, the Garvan Institute of Medical Research's Business Development Unit works closely with researchers to keep abreast of research progress and runs small, focused educational seminars on intellectual property and commercialisation issues to raise awareness and increase skills: Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003; Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003.

9 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 15.

10 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 2.

17.14 As discussed in Chapter 11, since most research organisations claim ownership of intellectual property developed within their organisation, the capacity and the responsibility to obtain patent protection and develop or transfer their intellectual property lies with the organisation.

17.15 There is a broad range of approaches to transferring technology for commercialisation. These include research-industry linkages, creating spin-off companies to develop the technology, licensing-out and assignment. Each of these approaches is discussed below. The most appropriate approach will depend on the nature of the technology and the capacity of the organisation to develop it further.[11]

17.16 Some difference of opinion was expressed in consultations about the capacity of universities and research organisations to commercialise research results effectively. Some suggested that universities and other research institutions are becoming better at commercialisation. It was also observed that research organisations are becoming more sophisticated in their approach to intellectual property and are often holding on to it longer, to add value and get better returns by licensing at a later stage.[12] However, doubts were expressed about whether these organisations would develop the same level of skill and experience as industry.[13]

17.17 The Department of Education, Science and Training's 2002 report, *Best Practice Processes for University Research Commercialisation* (DEST Report), noted that some research-focused universities are developing a new approach that takes account of Australia's strengths in basic research and lack of strong industry capability to translate innovation successfully into commercial success. This new approach features a more decentralised process of intellectual property identification and development; increased focus on growing start-ups; direct equity investment by universities; and selection and pursuit of strategic commercialisation areas.[14]

17.18 There is also evidence that the nature of business–university interactions is undergoing a shift from 'the traditional donor–recipient contracts' to formalised joint projects between universities and businesses.[15] The Australian Research Council (ARC) has suggested that this shift has resulted from changes in the business and economic environments that have made the process of developing new products for commercialisation more costly and specialised. These changes have meant that:

---

11 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.
12 UniQuest, *Consultation*, Brisbane, 3 October 2003.
13 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003.
14 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 5.
15 Australian Research Council, *Mapping the Nature and Extent of Business-University Interaction in Australia* (2001), 14.

> the concept of the individual inventor or research laboratory achieving commercial success on the basis of one activity, and without expert management, marketing and substantial ongoing financial support, is a misrepresentation of the nature of innovation. Innovation requires cooperation and collaboration within an organisation as well as with organisations external to it.[16]

17.19 Transfer and commercialisation are also increasingly understood as two-way processes, rather than as a linear movement of technology from the research sector to industry. The research and industry sectors appear to be working more closely together to shape research objectives to fit economic objectives. This approach fosters research that is more readily exploitable by industry.[17]

17.20 Despite these improvements, DEST stated in its March 2004 report, *Review of Closer Collaboration Between Universities and Major Publicly Funded Research Agencies* (DEST Collaboration Review), that 'challenges remain in fostering science and innovation collaboration and linkages, especially between publicly funded research providers and industry'.[18]

17.21 Similarly, the Australian Institute for Commercialisation (AIC) has commented that while Australia has improved markedly in commercialising publicly funded research, 'there is considerable scope for further improvements to be made'.[19]

Linkages

17.22 The ARC has noted that 'successful commercialisation of university research requires a champion … a lot of hard work is involved in finding and developing the initial partner in the commercialisation of a new discovery'.[20] Strong, well-developed linkages between research organisations and the industry sector facilitate identification of such 'champions'.

17.23 Linkages can take the form of relationships between individual organisations and commercial bodies, personal networks between researchers and entrepreneurs, or more formalised and broad-reaching relationships through overarching arrangements supported by organisations, industry or government.

17.24 An example of the latter type of relationship is the New South Wales project, BioLink, a business initiative designed to improve commercialisation of medical research. BioLink's stated aim is to 'complete the development chain by establishing

---

16 Ibid, 14.

17 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 5.

18 Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), ix.

19 Australian Institute for Commercialisation Ltd, *AIC Connect*, <www.ausicom.com/01_about/aic_connect.htm> at 16 June 2004, 1.

20 Australian Research Council, *University Research: Technology Transfer and Commercialisation Practices* (1999), xxiii.

[a] platform for a research–industry–government partnership providing world's best practice business development service for NSW medical researchers'.[21]

17.25 There is a range of similar programs and initiatives across Australia. These include networking forums and linkage initiatives. A study by Dr Dianne Nicol and Jane Nielsen (Nicol–Nielsen Study) shows that 'one of the dominant features of the biotechnology industry in Australia is widespread alliance activity between the public and private sectors'.[22] The ARC has commented that 'the traditional boundaries between education and commercialisation, basic research and applied research, and universities and industry are all blurring'.[23]

17.26 Government policy has also led to the development of Cooperative Research Centres (CRCs) and other linkage programs between the public and private sector. A CRC for the Discovery of Genes for Common Human Diseases was established in 1997, linking the Murdoch Childrens Research Institute, the Walter and Eliza Hall Institute of Medical Research (WEHI), the Menzies Centre for Population Health Research and a number of other research organisations, with Cerylid Biosciences Ltd as an industry partner.

Licensing-out

17.27 According to the DEST Report, across the university sector generally, licensing-out patented technology to established companies is 'the most common form of research commercialisation and generates by far the most revenue' for universities.[24]

17.28 However, the Nicol–Nielsen Study reported a low level of licensing-out activity in relation to gene patents. While 19 of the 23 responding research institutions indicated they owned biotechnology patents, only 12 reported licensing-out patented genetic technologies.[25] Nicol and Nielsen suggest that this level of licensing-out activity can be explained in part by the growth phase currently being experienced by the industry. A number of respondents reported that they were in the process of finding parties to whom they could license, while institutions may still be developing technology to a point where it is capable of being licensed. Nicol and Nielsen also suggest that institutions face difficulties in finding parties to license to, with some respondents reporting that it was challenging to attract commercial interest.[26]

---

21 Garvan Institute of Medical Research, *Bio-Link*, <www.garvan.org.au/garvan.asp?sectionid=48> at 16 June 2004.

22 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 75, 85.

23 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 9.

24 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii.

25 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 100.

26 Ibid, 102.

17.29 The DEST Collaboration Review also noted that: 'Licensing payments and royalties are not a significant source of revenue for the university sector … However, licensing is viewed as the simplest and lowest risk vehicle for commercialisation by universities.'[27]

Assignment

17.30 Assignment of gene patents is generally not the preferred approach to technology transfer by patent holders. This may be because patent owners do not wish to lose all control of the technology and because assignment will reduce their patent portfolio. Conversely, industry recipients of technology may prefer assignment because it involves complete transfer of all rights.[28]

Spin-off companies

17.31 Research organisations create spin-off companies as a means of holding and developing patented technology, generally because of a lack of industry receptors or because large returns are expected from developing the technology. Spin-off companies are also thought to 'contribute to innovation, growth, employment and revenues' while 'the prospects of winning big make spin-offs an attractive gamble'.[29]

17.32 According to the DEST Collaboration Review, university spin-off companies are often established out of necessity because of a lack of companies seeking to develop university generated intellectual property in Australia.[30]

17.33 Spin-off companies may take one of a number of forms. Research organisations may establish a new company to develop technology arising out of its research activities or may move technology into a company already established by the organisation for the purpose of value-adding and subsequent transfer. In other cases, staff or former staff of the organisation may establish their own company if ownership of the technology has been assigned to them.

17.34 Research organisations may favour establishing spin-off companies over other approaches to technology transfer because they are capable of generating revenues for the organisation if it retains a share in the company. With this in mind, organisations often hold an equity interest.

---

27 Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 30.

28 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 103–104.

29 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 7.

30 Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 30.

17.35 Kelvin Hopper and Lyndal Thorburn have commented that 'the continued fast growth in start-ups is essential to capture the public sector research outputs and ensure there is a pipeline for the industry as a whole'.[31] In consultations, UniQuest emphasised that spin-off companies are more effective than licensing for moving technology out of universities and into industry.[32] Establishing spin-off companies is also a particularly important mechanism for transfer in Australia due to the lack of industry receptors for biotechnology innovations coming out of the public research sector.[33] Despite this, smaller organisations appear to prefer licensing to establishing spin-off companies.[34]

17.36 A large proportion of Australian biotechnology companies were established as spin-offs from universities and other research organisations and the rate of establishing spin-off companies is increasing. Figures from one survey show that universities and CRCs established 38 spin-off companies in 2000, a 40% increase on the previous year.[35] However, despite this growth in the number of spin-offs, such companies are declining as a proportion of the biotechnology sector as a whole. According to the 2002 Bioindustry Review, in 2000–01 these companies made up 55% of the biotechnology sector in Australia, dropping to 41% in the following year.[36]

17.37 Although spin-off companies may be effective in facilitating technology transfer, they may not always be the best mechanism for generating returns for the research organisation. The DEST Report stated that 'while a great deal of attention has been directed to spin-offs at least partly driven by a small number of spectacular successes, the major return to universities remains through licensing to well-established firms'.[37]

17.38 Spin-off companies established around one patent or product face a high failure rate, as the company stands or falls on the success of that one product. If the company fails, the organisation that generated the technology will likely lose all control of it as the patent will be sold off during liquidation.[38] Spin-off companies are often staffed by researchers, as they lack the funds to employ professional managers. There is consequently often a lack of commercial expertise within the company.

---

31 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 67.
32 UniQuest, *Consultation*, Brisbane, 3 October 2003.
33 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 50.
34 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 33.
35 Ibid, 33.
36 K Hopper and L Thorburn, *2002 Bioindustry Review: Australia & New Zealand* (2002), 18.
37 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 28.
38 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 75.

Other mechanisms

17.39 Technology also moves between research organisations and industry through other mechanisms. These include joint industry–organisation research projects, research contracts, public–private sector partnerships, shared infrastructure and the movement of personnel.[39]

Potential impediments to transfer for commercialisation

17.40 There is a danger of repeating outdated perceptions of Australia's ability to commercialise research, including genetic research, when considering potential impediments to technology transfer. The DEST Report described this view as a 'myth', pointing out that:

> The data available demonstrate that the best-performing Australian universities are achieving research commercialisation outcomes broadly comparable with the best in the US and Europe, and way above their average … Australian universities have significantly strengthened their research commercialisation capacities and performance in the past five years.[40]

17.41 In 2002, the Prime Minister's Science, Engineering and Innovation Council (PMSEIC),[41] the National Health and Medical Research Council (NHMRC), the ARC and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) released a study into the performance of Australian universities and other research institutions in commercialising their research. The study suggested that Australia performed better than both Canada and the United States in commercialising its research, measured in terms of income generated from licences and start-up company formation relative to research expenditure and the size of the national economy. However, Australia lags behind both countries in terms of the number of licences executed and behind the United States in terms of the number of patents issued.[42]

17.42 Despite the improvement in Australia's capacity to commercialise its research, a number of potential impediments to transfer of genetic technology for commercialisation remain. These are discussed below and include:

- lack of commercial experience;
- lack of institutional support for commercialisation;

---

39 Prime Minister's Science Engineering and Innovation Council, *University–Industry Linked Research in Australia* (1998), 4; Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 11.

40 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vi.

41 Prime Minister's Science Engineering and Innovation Council, *University–Industry Linked Research in Australia* (1998).

42 Australian Research Council, Commonwealth Scientific and Industrial Research Organisation and National Health and Medical Research Council, *National Survey of Research Commercialisation* (2002), 43–44.

- decision making structures and attitudes;
- researcher attitudes and experience;
- difficulty in finding industry receptors; and
- lack of resources.

Lack of commercial experience

17.43 Effective commercialisation is promoted where research groups have developed business skills and experience with intellectual property. These groups are then more able to produce sound business plans, appreciate patenting laws, establish workable commercial structures for spin-off companies and negotiate agreements.[43]

17.44 Lack of experience in managing intellectual property and dealing with the biotechnology industry may be an impediment to the effective transfer of technology from research organisations. The Report of the Health and Medical Research Strategic Review Committee (Wills Report) suggested that:

> professional business development management within the research enterprise is crucial and generally lacking in Australia. Together with increased investment in fundamental research … it is probably the most important initiative for developing a dynamic industry sector. Commercialisation success depends on an intimate knowledge of the industry, intense commitment to researchers and the research, and high-level management skills that can match the research to a commercialisation strategy and negotiate a favourable agreement.[44]

17.45 Similar concerns were voiced more recently in submissions to the DEST Collaboration Review. The Review reported that many submissions stated that the level of entrepreneurial management skills available in Australia was a barrier to commercialisation in Australia. In particular, they highlighted 'the need to develop and maintain a critical mass of experienced commercialisation managers to assist [publicly funded research agencies], universities and industry'.[45]

17.46 Lack of experience may occur in part because technology transfer within an organisation is dealt with by one central office covering all areas of research, which may not have the experience to deal with issues particular to individual areas of research, such as the commercialisation of genetic research. As might be expected, it appears that smaller organisations are more likely to lack transfer and commercialisation expertise. The DEST Report noted that there is a relationship

---

43 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 5.

44 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 128.

45 Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 33–34.

between the productivity of technology transfer offices and scale, with large organisations generating greater returns.[46]

17.47 Inexperience in technology transfer offices might also stem from a failure to employ people with adequate or appropriate skills. For example, the DEST Report noted that employing staff with business and entrepreneurial skills, rather than legal skills, appears to promote new business formation.[47]

17.48 Lack of appropriate skills and experience with gene patenting and technology transfer may result in a variety of problems, including inefficient management of patents, failure to add sufficient value to technology before licensing and inappropriate business strategies. The ALRC received suggestions that technology transfer offices can actually hinder the process of commercialisation where they lack the appropriate expertise.[48]

Lack of institutional support

17.49 Research may fail to be commercialised where organisations choose not to pursue commercialisation but do not assign the patented technology elsewhere to enable others to do so.[49] This may also create a disincentive for researchers to work with commercialisation offices in future if the organisations are unreceptive to potential commercialisation.

17.50 Effective technology transfer requires an integrated approach, with transfer office staff working closely with researchers to identify, protect and develop technology. Lack of institutional support, either due to lack of funding to provide sufficient staff and facilities, or lack of support for integrative programs, may prevent this interaction from occurring. As the DEST Report has commented:

> What emerges strongly from experience is that if the research commercialisation function is set up without strong links with, and support from, the institution, it will be marginalised and, in all probability, fail. Research commercialisation is not simply an 'add-on' function; it requires a reworking of strategy and resource allocation to make it an integral part of the university's objectives and operations.[50]

Decision making structures and attitudes

17.51 Negotiations for technology transfer between research organisations and commercial organisations may be slow due to the sometimes complex decision making

---

46 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 35.

47 Ibid, 35.

48 Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.

49 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

50 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 52.

structures within research organisations.[51] Research organisations may also be risk-averse, which may lead them to be overly cautious in making decisions about the transfer and commercialisation of patented research.[52]

Researcher attitudes and experience

17.52 The Wills Report suggested in 1999 that Australian researchers had a relatively low rate of involvement in research commercialisation in comparison with other countries.[53] Consequently, Australia's failure to commercialise its intellectual property was in part attributed to a lack of researcher involvement in new business ventures to exploit technology. Researchers may resist commercialisation and hence not facilitate transfer or work in cooperation with technology transfer offices. The need to publish may also be a disincentive for researchers to participate in commercialisation if the requirements of a patent application mean publication must be delayed.[54]

17.53 However, the Australian research community's attitude to patenting and commercialisation appears to be changing, with researchers becoming more receptive to the need to patent and commercially develop the results of genetic research.[55]

Difficulty in finding industry receptors

17.54 As noted in Chapter 16, the Australian biotechnology industry is small, and consists largely of upstream companies that license their patented technology to larger international companies for further development. The industry is also quite fragmented and characterised by relatively low research and development spending by international standards.[56]

17.55 The DEST Report concluded that, consequently, Australian industry has a fairly poor capacity to absorb technology generated within universities.[57] As a result, research organisations may sometimes face a lack of industry receptors to which they can transfer technology. This may make it difficult for organisations to establish working partnerships with industry, and may require them to negotiate with overseas firms. The ARC has expressed concern about this shortage of industry receptors for Australian research, suggesting that some of the benefits of Australia's public

---

51 Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003.

52 UniQuest, *Consultation*, Brisbane, 3 October 2003.

53 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 121, 123. Lack of venture capital to support new companies and low levels of industry investment in research and development were also cited as barriers to commercial development of biotechnology research. See Ch 19.

54 See, eg, Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 33.

55 See further Ch 14.

56 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii. See also Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 318.

57 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii.

investment in genetic research might consequently be lost overseas.[58] Research organisations also report difficulty in identifying appropriate commercial partners.[59]

Lack of resources

17.56 Some organisations may lack the funds to support a patent application.[60] The Nicol–Nielsen Study reported that 'although quality research may be performed in Australian research institutions, there are insufficient resources to support large scale patenting'.[61] This may be generally attributed to the cost of applying for and maintaining a patent and, in many cases, a research organisation may choose not to support an application beyond the provisional stage without external financial support. An inability to obtain appropriate patent protection may prevent organisations from transferring technology.

17.57 Successful technology transfer rests in part on technology transfer offices having staff with the appropriate skills and experience. Lack of resources may prevent technology transfer offices from employing staff with the expertise to deal with gene patenting and negotiations with the biotechnology industry.[62]

Other issues and concerns

17.58 The impediments outlined above will, in some cases, inhibit technology transfer. This may have a variety of consequences, such as the inadequate capture and exploitation of Australia's research outputs. This in turn may prevent the Australian community from deriving maximum benefit from public spending on genetic research in the form of tests and therapies and in economic growth.

17.59 Two other specific concerns arise in relation to technology transfer practices—variability in practice across organisations, and lack of clear ownership of patents. These are discussed below.

Variability in practice between organisations

17.60 DEST and the ARC have each suggested that skills and experience of technology transfer offices vary between organisations. This may leave technology transfer to what has been called 'a lottery' with regard to the skills and resources available at each organisation.[63]

---

58 Australian Research Council, *Research in the National Interest: Commercialising University Research in Australia* (2000), 18.

59 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 106.

60 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

61 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 78.

62 UniQuest, *Consultation*, Brisbane, 3 October 2003.

63 D Nicol, *Consultation*, Sydney, 21 October 2003.

17.61 This concern is more likely to arise in relation to universities rather than other research organisations. Universities undertake research across a broad spectrum of activities in diverse fields, and may not build up sufficient expertise in transferring genetic research and dealing with the biotechnology industry. Research organisations focusing specifically on medical or biotechnology research may have greater experience with the particular features of the biotechnology sector and therefore be better equipped to manage gene patents and transfer technology.

Collaborative research and lack of clear ownership of patents

17.62 It is not always clear where ownership of intellectual property generated through publicly funded research lies. This is largely due to the cumulative nature of many breakthroughs in genetic research, and collaborative research across a number of research organisations. The problem of unclear ownership may be exacerbated where researchers have joint appointments to several organisations, or where research is conducted by visiting researchers or students. This section examines issues that may arise where ownership of intellectual property is shared across a number of organisations or with industry partners.[64]

17.63 Unencumbered ownership of patents is of considerable importance in attracting investment for further development. Fragmented or unclear ownership of patents may deter potential investors.[65] Also, as Bio Innovation SA commented, difficulties in determining ownership may contribute to the length of time it can take to move intellectual property out of the public sphere into industry.[66]

17.64 Another problem raised in consultations was that research institutions, universities and public sector organisations may have different approaches to, and policies for, intellectual property management. This can create problems for technology transfer and commercialisation where organisations cannot agree on how to address transfer issues.[67] Similarly, researchers are sometimes employed by more than one organisation, and the diversity of approaches may cause confusion.

Support programs

17.65 A variety of programs and dedicated organisations have been established to support technology transfer and commercialisation. Some of these focus specifically on the biotechnology industry and provide specialised expertise to aid transfer and commercial development of innovation in biotechnology research. These include the provision of educational materials by the Australian Government; industry

---

64 Issues about ownership of research within institutions, rather than ownership shared between institutions, are considered in Chapter 11.

65 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), 51.

66 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.

67 Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.

organisations and groups providing specialised expertise and advice; state government support agencies and programs; and funding support.

17.66 Biotechnology Australia and the Department of Foreign Affairs and Trade, among others, have released educational materials to promote understanding of intellectual property issues in biotechnology.[68] For example, the *Biotechnology Intellectual Property Manual* released by Biotechnology Australia gives an overview of the types of intellectual property, patent procedure in Australia and overseas and issues in patenting biotechnological inventions. It includes information on identifying inventive subject matter, strategic management of intellectual property resources and commercial exploitation.[69]

17.67 There are also a number of industry organisations providing support for technology transfer in Australia, including the following:

- Knowledge Commercialisation Australasia (KCA) is the peak body representing organisations and individuals associated with knowledge transfer from the public sector. KCA's stated purpose is to advance knowledge commercialisation and achieve greater returns from public sector research investment. KCA also contributes to government and industry discussions on technology transfer policies.[70]

- The AIC is a not-for-profit company that 'delivers programs to improve commercialisation of Australia's research investment'. The AIC has implemented a number of programs to address the key barriers to commercialisation. These include 'AIC Connect', which fosters engagement between the research and business communities and 'AIC Know How', which coordinates educational programs on technology transfer for researchers, managers and directors.[71]

- The Licensing Executives Society (LES) is a not-for-profit professional society concerned with technology transfer and intellectual property right protection. One of its objectives is to educate its members on licensing issues and skills.[72]

---

68 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001); Department of Foreign Affairs and Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001). IP Australia provides more general information on intellectual property issues at its website: IP Australia, *What is Intellectual Property?*, <www.ipaustralia.gov.au/ip/index.shtml> at 16 June 2004.

69 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001).

70 Knowledge Commercialisation Australasia, *Home Page*, <www.kca.asn.au> at 16 June 2004. KCA was previously known as the Australasian Tertiary Institutions Commercial Companies Association (ATICCA) and was involved in the development of the National Principles *of Intellectual Property Management for Publicly Funded Research*.

71 Australian Institute for Commercialisation Ltd, *Annual Report 2002–03* (2003), 10.

72 Licensing Executives Society Australia and New Zealand, *LES ANZ Inc*, <www.lesanz.org.au> at 16 June 2004.

- AusBiotech Ltd is 'the peak body for the Australian Biotechnology industry', which provides a 'platform' to bring together all the relevant players involved in the Australian biosciences community. Its mission is to facilitate the commercialisation of Australian bioscience in the international marketplace.[73]

- The Australian Industry Group (AIG) is a 'not-for-profit association … created to assist Australian industry to become more competitive on a domestic and international level'.[74] AIG assists companies across many industry sectors by providing seminars and training workshops. It has also introduced the InnovationXchange, a 'virtual network' of collaborative linkages in the innovation cycle between innovators, such as universities, and industry.[75]

17.68 One example of a state government organisation developed to provide particular expertise on the development and exploitation of biotechnology innovations is Bio Innovation SA. Bio Innovation SA is a South Australian public corporation established in 2001 with the task of creating 50 new bioscience companies over ten years—it has established 18 to date. Bio Innovation SA has developed strategies to identify research being produced by South Australian research organisations. It provides free advice on intellectual property protection and commercial development to researchers, and may guide them through the patent application process, including helping them to meet the requirements for experimental support of the invention.[76] It does not hold patents itself.[77] It also works with technology transfer offices within research organisations where they lack the necessary expertise to develop an invention.

Options for reform

17.69 As noted above, some of the impediments to technology transfer and commercialisation are caused by the size of the Australian biotechnology industry. Other impediments arise from a lack of expertise, but as recent surveys demonstrate, this problem is diminishing as research organisations increase their skills and experience. These may best be addressed through facilitating continued education.

Education and support programs

17.70 A wide variety of education and support programs are already in place to promote the development of expertise and it is likely that improvements in technology transfer practices over the past five years can be in part attributed to these programs. However, from submissions and consultations, it appears that there is room for further

---

73 AusBiotech Ltd, *What is AusBiotech?*, <www.ausbiotech.org/whataus.php> at 16 June 2004.
74 Australian Industry Group, *About Australian Industry Group*, <www.aigroup.asn.au/> at 16 June 2004.
75 Australian Industry InnovationXchange Network, *About: the InnovationXchange Network*, <www.innovationxchange.com.au/about.html> at 16 June 2004.
76 Bio Innovation SA, *Consultation*, Adelaide, 16 September 2003.
77 Ibid.

continuing education to improve skills across the research sector.[78] This should include education and support programs for technology transfer offices to aid them in improving the specific skills needed to deal with transferring and commercialising genetic research.

17.71 Such programs and materials should focus on building skills that will enable technology transfer offices to overcome the impediments outlined above, including:

- the basics of intellectual property with specific reference to genetic research;
- techniques for identifying, protecting and managing technology with commercial potential;
- methods for encouraging researchers to identify and prevent premature disclosure of such technology;
- strategic management of intellectual property resources;
- approaches to commercialisation of technology; and
- aspects of good commercial practice, such as good licensing practice and approaches to attracting commercial interest in new technologies.

17.72 Programs might also include training in basic science where appropriate. For example, the Wills Report recommended programs to cross-train managers in science.[79]

17.73 One possible model for such training is the technology transfer training website created by the United States National Institutes of Health (NIH). The site provides information about patenting, cooperative research and development arrangements, MTAs, licensing, royalties and ethics and includes links to any relevant NIH policies. It also takes the participant through a series of interactive scenarios that apply the knowledge gained in the information sections.[80]

17.74 However, education programs alone may not provide sufficient skills. PMSEIC has pointed out that it is difficult to instil all the expertise required for successful research commercialisation through education programs.[81] Other programs might

---

78 The ALRC notes that submissions to the DEST Collaboration Review also suggested that the lack of expertise in technology transfer could be addressed in part by the provision of further training programs: Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), 34.

79 Health and Medical Research Strategic Review Committee, *The Virtuous Cycle: Working Together for Health and Medical Research* (1998), 128.

80 National Institutes of Health, *NIH On-line Technology Transfer Training*, <http://tttraining.od.nih.gov/> at 16 June 2004.

81 Prime Minister's Science Engineering and Innovation Council, *Profiting from the Biotechnology Revolution* (1998), 6.

therefore be directed at helping researchers and industry to draw on each other's experiences.[82] This might be achieved through developing fora for exchanging know-how and improving organisation–industry interaction.[83]

Best practice models

17.75 Best practice for transfer and commercialisation involves researchers and technology transfer offices working closely to identify, protect and exploit research. Researchers are better placed to understand what is new or unique about the research, while transfer office staff should have the appropriate skills in intellectual property and commercialisation to obtain patents and undertake the commercialisation process.

17.76 DEST has advised that potentially valuable intellectual property is best identified 'through decentralised processes close to the researcher, but with effective partnership with the research commercialisation office. Researchers hence need to be assisted to develop these skills'.[84] This might include practices such as the UniQuest model of placing a 'commercialisation manager' in each faculty to identify and develop potentially valuable intellectual property.[85]

17.77 Publication of guidelines for best practice in technology transfer and commercialisation might aid the dissemination of knowledge and expertise to less experienced organisations.

Clarifying ownership of patents

17.78 One solution to the issue of 'dirty IP', including patents that do not have a clearly defined, single owner, is to revise the *National Principles of Intellectual Property Management*[86] (National Principles) to provide guidance on negotiation of ownership where the research leading to the patented invention was conducted jointly, or with funds from overseas bodies that have staked an ownership claim.[87]

Addressing problems of scale

17.79 DEST has suggested that the problems of scale faced by smaller and regional research organisations should be addressed by encouraging networking to share their expertise. It suggested that this might be facilitated by KCA or the AIC, and by case managers involved in local incubators.[88] The ALRC has also heard suggestions that research organisations, especially universities, could address issues of scale by

82 Ibid, 6.
83 Ibid, 5–6.
84 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), vii.
85 Ibid, ix.
86 Australian Research Council and others, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001). The National Principles are discussed in Ch 11.
87 Department of Education Science and Training, *Best Practice Processes for University Research Commercialisation* (2002), ix.
88 Ibid, ix.

developing a centralised technology transfer office. Organisations could also focus on developing experience in commercialising particular technologies and outsource transfer and commercialisation of other research to organisations with relevant skills and experience.[89]

Other options

17.80 The DEST Report suggested some approaches that might encourage greater commercialisation of research results. These were to: (a) give academics greater rights over the inventions they produce when publicly funded; or (b) revert ownership of inventions to the government or the government funding body.[90]

17.81 Commercialisation might be promoted by assigning the intellectual property to the inventor where the research organisation has chosen not to transfer or commercially develop it. The inventor will have an incentive to pursue commercial development, as any profits from exploitation will now flow to them directly. This option is considered in Chapters 11 and 14. Reverting ownership to government or government funding bodies is also considered in Chapter 11.

17.82 Finally, there may be a need to conduct a study of technology transfer office practice that focuses specifically on the commercialisation of biotechnology. Although a number of studies of technology transfer practice have been carried out, these have been general in scope. A more directed survey could identify any particular difficulties faced by technology transfer offices when commercialising genetic research.

Submissions and consultations

17.83 Submissions and consultations generally acknowledged that research organisations are becoming more adept at protecting and commercialising research. However, despite this continuing improvement, it appears from comments received that there is still considerable variation in skill and experience with commercialisation across organisations. While some researchers and technology transfer offices have developed considerable expertise, others are less able.[91]

17.84 It was also noted that in some cases technology transfer offices lack the funding needed for effective commercialisation of intellectual property.[92] GlaxoSmithKline suggested that governments could support commercialisation by 'distinct and separate

---

89 J Hearn, *Consultation*, Sydney, 4 May 2004; A Bennett, *Consultation*, Sydney, 15 March 2004.

90 Department of Education Science and Training, *Analysis of the Legal Framework for Patent Ownership in Publicly Funded Research Institutions* (2003), 75.

91 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Biotechnology Advisory Council, *Consultation*, Brisbane, 2 October 2003; Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.

92 UniQuest, *Consultation*, Brisbane, 3 October 2003.

funding for technology transfer offices in academic institutions' and suggested there was a need for training programs for technology transfer offices.[93]

17.85 In DP 68, the ALRC made three proposals directed at improving technology transfer practices, all of which received strong support in submissions.[94] DP 68 proposed that to improve technology transfer practices, Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should:

- continue to develop and implement programs to assist technology transfer offices in universities and publicly funded research institutions in commercialising inventions involving genetic materials and technologies; and

- develop strategies to ensure widespread participation of technology transfer offices in these programs.[95]

17.86 The Department of Industry, Tourism and Resources (DITR) noted that Biotechnology Australia has introduced a number of successful commercialisation initiatives. However, it suggested that such programs need to be sanctioned by broader governmental processes and, therefore, it may be better to emphasise the need for 'government' action rather than activities by a specific organisation.[96]

17.87 DP 68 proposed that the ARC and NHMRC should review their principles and guidelines on intellectual property and research to emphasise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research.[97]

17.88 WEHI noted that joint ownership, particularly in the public and academic research sectors is a major obstacle to commercialisation (particularly with offshore partners). It suggested that joint ownership should be avoided whenever possible.[98]

---

93 GlaxoSmithKline, *Submission P33*, 10 October 2003.

94 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

95 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 18–1.

96 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

97 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 18–2.

98 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

17.89 The NHMRC commented that, as part of the review of the National Principles, it could consider the desirability of providing more detailed guidance on intellectual property resulting from collaborative or jointly funded research.[99] It suggested that it could consider whether this guidance should be included in revised guidelines or high-level principles, or alternatively, whether organisations should be left to develop their own policies on this issue.[100]

17.90 DP 68 also proposed that universities and other publicly funded research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research.[101] This proposal received strong support in submissions.[102] The NHMRC commented that this issue could be addressed as part of the review of the National Principles.[103] The Queensland Government noted that some organisations are currently taking steps to address problems of ownership of intellectual property resulting from collaborative research.[104]

ALRC's views

17.91 The ALRC acknowledges that Australian research organisations have markedly improved their performance in capturing the value of intellectual property and commercialising research. Technology transfer practices within research organisations appear to be improving, particularly because organisations, government and industry are recognising and acting on the need to build skills and linkages. However, it appears that there is a need to continue the process of skill-building within technology transfer offices especially, thereby improving each organisation's capacity for technology transfer.

17.92 The ALRC considers that patent management in relation to genetic research and interaction with the biotechnology industry requires specialised knowledge. This knowledge should encompass a basic understanding of genetics to enable offices to recognise potentially valuable technology, and an understanding of the commercial issues particular to the biotechnology industry. This may include an understanding of the time frames for product development in biotechnology; regulatory requirements

---

99 The ALRC's recommendation for a review of the National Principles is discussed in Chapter 11. See also rec 11–1 and 11–2.

100 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

101 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 18–3.

102 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

103 The ALRC's recommendation for a review of the National Principles is discussed in Chapter 11. See also rec 11–1 and 11–2.

104 Queensland Government, *Submission P103*, 22 April 2004.

such as clinical trial requirements and regulation of medical therapies; and awareness of industry structure. Technology transfer offices may sometimes lack this specialised knowledge because they are charged with managing intellectual property and commercialisation across a broad spectrum of research fields.

17.93 For these reasons, the ALRC considers that there is a need to continue to improve awareness of, and skills for dealing with, patent management and technology transfer in relation to gene patents. The ALRC recommends that Biotechnology Australia, in conjunction with its member departments, should further develop and implement programs to assist technology transfer offices in developing these skills. In doing so, Biotechnology Australia should collaborate with the peak national bodies with an interest in technology transfer from the public sector. These will include KCA, the AIC, AusBiotech Ltd, the LES and the AIG.

17.94 Such programs should include the provision of educational seminars and resource materials that focus on issues specific to patenting and commercialising genetic technologies. These could present models of best practice for technology transfer and commercialisation, including methods for identifying innovative technology and developing business liaisons. These programs should also encourage networking and sharing of expertise between organisations.

17.95 The ALRC believes that technology transfer practices could be improved by a consolidation of resources and expertise. This could be achieved by the creation of centralised technology transfer offices to commercialise technology from a number of research organisations. Such offices could be jointly administered and pool the resources and expertise from each organisation. However, the ALRC considers that such consolidation is best achieved through negotiation between research organisations and has no specific recommendations to make on this issue.

17.96 The ALRC regards the potential lack of clear ownership of patents over technology developed through collaborative research or funding arrangements as a significant impediment to the transfer and commercialisation of genetic technologies. The ALRC considers that these issues would best be dealt with through requirements that ownership of intellectual property be clearly delineated in the early stages of research. Such requirements are best incorporated into the National Principles, which should be revised to include clear guidance on the need to negotiate ownership of patents where there is more than one potential owner.[105]

17.97 The ALRC therefore recommends that, as part of the review of the National Principles recommended in Recommendation 11–1, the NHMRC and ARC should recognise the importance of clear ownership of intellectual property resulting from

105 However, it should be noted a recent DEST review of collaboration between universities and publicly funded research agencies found that the National Principles are 'not widely recognised, understood or utilised': Department of Education Science and Training, *Review of Closer Collaboration between Universities and Major Publicly Funded Research Agencies* (2004), xi. See further Ch 11.

collaborative or jointly funded research. This recognition should be reflected in the guidelines to the National Principles that are to be developed in accordance with Recommendation 11–2. These should provide guidance on ensuring clear ownership of intellectual property and should identify a range of approaches to ensuring clarity of ownership.

17.98 The ALRC considers that these measures should be supported by research organisations. The ALRC consequently recommends that research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research.

Recommendation 17–1 Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector:

(a) to further develop and implement programs to assist technology transfer offices in research organisations in commercialising inventions involving genetic materials and technologies; and

(b) to develop strategies to ensure widespread participation of technology transfer offices in these programs.

Recommendation 17–2 The Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC), in implementing Recommendation 11–1, should recognise the importance of clear ownership of intellectual property resulting from collaborative or jointly funded research.

Recommendation 17–3 The ARC and NHMRC, in implementing Recommendation 11–2, should:

(a) provide guidance on ensuring clear ownership of intellectual property resulting from collaborative or jointly funded research; and

(b) identify a range of approaches to ensuring clarity of ownership.

Recommendation 17–4 Research organisations should ensure that their policies and practices address the problems of ownership of intellectual property resulting from collaborative or jointly funded research. (See also Recommendation 11–4.)

Materials transfer agreements

17.99 The sharing of genetic materials within the research community is important for the progress of research. Living organisms are difficult to describe and often impossible to duplicate from a written patent description.[106] While some genes may be isolated easily, cloning into vectors and generating transgenic cell lines and animals can be costly and time consuming. In fact, it may be impossible to improve upon a biotechnology invention without a physical exchange of genetic material.

17.100 In the past, this often occurred informally. However, the increased commercialisation of research results has created a need to develop more formalised arrangements, often referred to as materials transfer agreements (MTAs). An MTA is a written agreement defining the terms and conditions governing the transfer of biological or other research materials from the owner or authorised licensee to a third party for internal research purposes only. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives created during the ensuing research.

17.101 For the provider, the advantages of having an MTA include the ability to restrict the use of the material to non-commercial research and reduce legal liability for the recipient's use of the material.[107] Importantly, the terms of an MTA may enable the provider of material to gain access to the results of research and to manage and extend its intellectual property rights. A provider may be entitled to outright ownership or to a licence in respect of intellectual property generated by the recipient's research.[108]

17.102 Most commercial organisations, and an increasing number of research organisations, will only release genetic materials if there is an MTA in place between the provider and the recipient.[109] It was suggested in consultations that although Australian universities sometimes negotiate MTAs, this is not always the case.[110] Informal transfers may exacerbate problems involving patent ownership and reach-through claims to subsequent inventions.

Model materials transfer agreements

17.103 One Australian approach to streamlining processes for materials transfer for research purposes is that initiated by the Garvan Institute of Medical Research (Garvan Institute). The Garvan Institute uses an MTA based on the uniform agreement recommended by the United States Association of University Technology Managers

106 S Jong and R Cypress, 'Managing Genetic Material to Protect Intellectual Property Rights' (1998) 20 *Journal of Industrial Microbiology and Biotechnology* 95, 99.

107 Technology Transfer Office, *Facts about Materials Transfer Agreements (MTAs)*, University of Cambridge, <www.admin.cam.ac.uk/offices/tto/material/mta.html> at 16 June 2004.

108 Ibid.

109 Ibid.

110 Western Australian Department of Health and others (research issues), *Consultation*, Perth, 17 September 2003.

and has created an automated, web-based system to streamline processes for settling the terms of MTAs with researchers wishing to have access to the Garvan Institute's research materials.[111]

Submissions and consultations

17.104 DP 68 proposed that Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should develop model MTAs for use by universities and other research organisations, along the lines of the models developed by the United States Association of University Technology Managers.[112]

17.105 Most submissions supported this proposal strongly.[113] The Queensland Government noted, however, that the 'danger of model licence agreements is that they are not sufficiently tailored to the particular circumstances of each individual case'. However, it supported the proposal:

> [on] the basis that these agreements contain a number of different clauses, consider different scenarios and are used only as guidance. It should be clear that these agreements need to be tailored to meet the requirements of the particular circumstances and that independent legal advice may also be required.[114]

17.106 The Centre for Law and Genetics noted that concerns about using model agreements may be less acute for MTAs than for licensing agreements generally as MTAs are often more uniform.[115] DITR commented that Biotechnology Australia may not be the appropriate body to develop these model agreements. It suggested that AusBiotech Ltd or KCA may be better placed to do so.[116]

ALRC's view

17.107 The ALRC is of the view that there is a need to encourage better practice in the transfer of technology and materials between research organisations. The ALRC considers that some of the concerns surrounding materials transfer could be met by the introduction of model MTAs to reduce arbitrary variation across agreements and to encourage organisations to formalise transfer arrangements.

---

111 Garvan Institute of Medical Research, *Consultation*, Sydney, 10 September 2003. See also Garvan Institute of Medical Research, *Garvan Technology Transfer*, Garvan Institute of Medical Research, <www.garvan.org.au/garvan.asp?sectionid=13> at 16 June 2004.

112 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 18–4.

113 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Government, *Submission P103*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

114 Queensland Government, *Submission P103*, 22 April 2004.

115 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

116 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

17.108 To address this concern, the ALRC recommends that Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer to develop model MTAs. In doing so, they should draw on those developed by the United States Association of University Technology Managers. The ALRC considers that, in particular, Biotechnology Australia should collaborate with the Australian Institute for Commercialisation, Knowledge Commercialisation Australia and the Licensing Executives Society to draw on their expertise in this area.[117]

Recommendation 17–5 Biotechnology Australia, in conjunction with its member departments, should collaborate with the peak national bodies with an interest in technology transfer from the public sector to develop model materials transfer agreements for use by research organisations, along the lines of the models developed by the United States Association of University Technology Managers. (See also Recommendation 22–2.)

117 Model licence agreements are discussed further in Ch 22.

18. Patents and the Biotechnology Industry

Contents

Introduction

18.1 Chapter 17 described the structure and features of the biotechnology industry in Australia. As discussed in that chapter, the biotechnology industry (including pharmaceuticals) is heavily dependent on patents. The Australian biotechnology sector is also primarily an upstream industry, with many companies holding intellectual property as their only or main asset.

18.2 This chapter examines the impact of patents on the downstream section of the biotechnology sector, which refers to companies focused on developing commercial products such as drugs, tests and therapies. It considers a number of ways in which gene patents may act as a barrier to commercial development of genetic research, including through patent thickets, royalty stacking, broad patents, reach-through provisions, blocking and dependent patents. The chapter also considers licensing practices, investment issues and commercialisation expertise within the sector.

Upstream and downstream issues

18.3 As discussed in Chapter 12, the process of moving new technology from the research stage through to product development is sometimes divided into 'upstream' and 'downstream' phases. However, this division does not form a bright line between genetic research and commercialisation. Upstream research takes place across the entire biotechnology sector, in commercial ventures as well as research institutions. Hence, many of the issues discussed in Chapter 12 are also relevant to the sector as a whole.

18.4 Within the biotechnology industry, upstream companies generally focus on conducting further research to add value to technology. The technology is then generally transferred to companies further downstream to be developed into commercial products.

18.5 Some of the potential barriers to commercialisation considered in this chapter are more likely to affect downstream companies—royalty-stacking and reach-through provisions are examples. Other concerns will also be relevant to upstream genetic research. For example, blocking patents and patent thickets may prevent researchers from accessing technology for research purposes, either for use in research (such as research tools) or to improve upon it. The cumulative nature of genetic research means that reach-through provisions in licences of foundational patents, including patents on research tools, may affect further research. These issues are discussed in Chapter 12.

Importance of patents for industry

18.6 Gene patents play an important part in enabling biotechnology companies to develop healthcare products, due to the high costs of research and commercialisation in this sector.[1] The ability to stop others exploiting a patent for a limited period gives biotechnology companies an opportunity to recoup the investment made in developing the patented invention, including potentially by creating a marketable healthcare product.

18.7 The importance of gene patents in the biotechnology industry is also recognised in the Australian Government's National Biotechnology Strategy, which states that:

> The development of capabilities for the effective management of Intellectual Property (IP) is an important element in securing the benefits of public and private sector research in biotechnology for the Australian community, industry and the environment.[2]

18.8 However, it is important to bear in mind that gene patents will have varying effects on companies depending on each company's structure and commercial activities. Most biotechnology companies are both consumers and producers of

---

1 Biotechnology Australia, *IP Management*, <www.biotechnology.gov.au> at 16 June 2004.

2 Biotechnology Australia and Commonwealth Biotechnology Ministerial Council, *Australian Biotechnology: A National Strategy* (2000), 19.

technology. The biotechnology industry is characterised by companies using the inventions of others in their own research and as part of the products they market, such as tests or therapies. Gene patents may, therefore, be seen as having both positive and negative effects. The gene patents of others might block a company's activity if access to the patented technology is necessary for its research or the creation of products it seeks to sell. However, the possibility of obtaining patent protection for its own products may stimulate innovation.

Barriers to commercialisation

18.9 As discussed elsewhere in this Report, a primary purpose of patent laws is to provide an incentive for innovation. Intellectual property rights, 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. However, inadequate intellectual property protection and management has been identified as one of the major barriers to commercialisation in the Australian biotechnology sector.[3]

18.10 Dr Dianne Nicol and Jane Nielsen have argued that 'the regimes protecting IPRs [intellectual property rights] may prove to be a significant barrier for the development of the Australian industry'.[4] They suggest 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'.[5]

18.11 As noted above, patents may also act as a barrier to research and a disincentive to commercialisation. The problems cited in Chapter 12 are generally as relevant to product development as they are to further research. In particular, as Nicol and Nielsen suggest, biotechnology companies face unique challenges due to: 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; and the reliance of downstream companies on access to patented research tools and techniques.[6]

---

3 Biotechnology Australia, Freehills and Ernst & Young, *Australian Biotechnology Report* (2001), 49. Other identified barriers include: access to capital, the availability of skilled human resources, and the relatively small size of the domestic market. See also 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.

4 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.

5 Ibid, 348–349.

6 Ibid, 374.

Patent thickets

18.12 'Patent thickets' are a consequence of multiple upstream patents.[7] 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'.[8]

18.13 The existence of multiple patents has 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.[9] The proliferation of gene patents, including multiple patents on research tools, may impede downstream research and innovation if access to tools required for further development is difficult to negotiate. Nicol and Nielsen suggest that in extreme cases projects may even be abandoned. They argue that:

> If negotiations are required to be undertaken with a number of parties, the risk of negotiation breakdown is increased … Depending on the stage at which breakdown occurs, this may mean that projects are either not commenced or are abandoned at some stage into the research process … As the number of relevant intellectual property rights increases, the task of inventing around becomes more onerous, and project abandonment may become inevitable.[10]

18.14 Patent thickets may also raise production costs. Even if multiple licences are successfully negotiated, the cost of obtaining numerous licences may add to the cost of development and may also be passed on to consumers in the form of higher prices.[11] These increased production costs may affect commercial incentives for pursuing downstream product development and marketing.

18.15 The issue is not confined to gene patents, but it arises in relation to gene patents 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.[12] Conceivably, separate patent claims might be made on each of the exons as expressed gene fragments; another claim could be made over the complete expressed sequence; another on a promoter sequence; and others over mutations known to have the potential to cause diseases. Patent thickets could present a problem in this area, for example in the development of genetic diagnostic tests or therapeutic proteins, where access is required to genetic information covered by multiple patents. Professors

---

7 For example, patents over isolated genetic materials that might be used to develop further inventions such as diagnostic tests or pharmaceutical products (downstream products).

8 C Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting* (2001), 1-2.

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

10 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 174.

11 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 15.

12 The majority of introns serve no currently identifiable function.

Michael Heller and Rebecca Eisenberg have expressed concern that 'a patent anti-commons could prove more intractable in biomedical research than in other settings'.[13]

18.16 One of the questions Nicol and Nielsen addressed in their empirical study of patents and the medical biotechnology industry (Nicol–Nielsen Study) was whether an anti-commons had emerged in Australia.[14] They reported that respondents to the Study did not describe significant problems with the enforcement of multiple research tool patents:

> In part this is because a number of the most aggressively enforced research tool patents do not exist in Australia, or, if they do exist, they do not appear to be enforced. However, we expect that these or other patents may well be enforced in the future. Hence, it would be premature to say that the Australian industry is free from the rigors of research tool patent enforcement.[15]

18.17 Nicol and Nielsen also reported that, although the Australian patent landscape is becoming increasingly complex, the number of problematic patents affecting research is quite small. They suggested that:

> in part the reason for this is that if there is a higher level of encumbrance research will be redirected. We are unable to state with any level of precision the number of research projects that are abandoned because there are too many problematic patents in the area. However, we know that this problem does exist.[16]

18.18 On balance, Nicol and Nielsen concluded that their results did not provide conclusive evidence of either the existence or absence of an anti-commons in Australia, although they did note the potential for one to develop due to 'ongoing increases in the number of patents, more vigilant enforcement and the increasing complexity of research paths'.[17]

Royalty stacking

18.19 Royalty stacking is a problem caused by a multiplicity of overlapping patents, especially over upstream products. The need to pay multiple licence fees may force up prices and discourage innovation and product development. In the context of pharmaceutical patents, Phillip Grubb suggests royalty payments for the use of research tools may be problematic because:

> it will often be the case that a number of different tools or technologies have contributed to the drug development, and whereas a single royalty of one or two per cent may be an acceptable burden, an accumulation of such royalties soon adds up to an unacceptable amount.[18]

---

13 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700. See discussion of the anti-commons in genetic research in Ch 12.

14 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, x.

15 Ibid, 255.

16 Ibid, 255.

17 Ibid, xi–xii, 194.

18 P Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (3rd ed, 1999), 375.

18.20 The Organisation for Economic Co-operation and Development Report, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (OECD Report), linked concerns about patents over research tools 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.[19]

18.21 Often, however, companies are able to address stacking problems by contractual solutions, for example through placing limits on cumulative royalties or requiring up front payments rather than royalties.[20] The OECD Report noted that contractual solutions are generally pursued because it is in the interests of companies to accommodate reduced royalties to enable agreements to be made for the use of patents. It suggested that biotechnology projects that require patented technology to be licensed-in rarely fail due to royalty stacking concerns.[21]

18.22 It is unclear whether royalty stacking is a serious problem for the Australian biotechnology industry. However, given that the industry is largely comprised of upstream companies, it may be a lesser problem here than in industries overseas with a more significant downstream component. Respondents to the Nicol–Nielsen Study reported mixed experiences of royalty stacking. One intermediate company stated that they had not encountered it, while one upstream company predicted that 'in the future, when conducting licensing negotiations, companies may well be exposed to licence stacking and overlapping royalty structures'. In addition, mixed views were expressed about the reactions of downstream pharmaceutical companies to royalty stacking:

> One respondent said that large pharmaceutical companies abhor royalty stacking. However, a pharmaceutical company respondent noted that although reach-through royalties and divided ownership don't help in the drug development process, 'they are not showstoppers'.[22]

18.23 Patent pools[23] are a mechanism for overcoming some of the difficulties of access to research tools and technologies caused by a multiplicity of patents.[24] Commercial products such as therapeutic proteins or diagnostic genetic tests are likely to require access to many gene fragments; a bundle of licences collected in a single licence arrangement can overcome the problem of dealing with multiple patent holders

---

19 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 15.

20 Ibid, 62.

21 Ibid.

22 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 192.

23 '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 their rights as a bundle. See Ch 22.

24 See J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office.

or licensees.[25] Patent pools are discussed further in Chapter 22. Patent pools also raise competition issues, which are discussed in Chapter 24.

Broad patents

18.24 Chapter 12 described broad patents as patents that grant broad rights to the patent holder and which may be seen as covering applications invented later by someone else. As noted in that chapter, such patents may discourage further research and innovation because researchers may be concerned about infringing them, or because of the potential cost of licence fees associated with the use of the patented invention. These concerns are also relevant to industry, both as constraints on further research, and more particularly, because potentially the cost of licence fees may decrease the returns on products developed using the patented technology. Companies may then attempt to offset this decrease through charging higher prices for products.

18.25 The flow on effect of these problems may include:

- increases in the cost of healthcare products;
- fewer products may be available if the development of some products is abandoned; and
- inefficient use of resources due to paying licence fees or 'inventing around' unnecessarily.[26]

18.26 The Nicol–Nielsen Study reported that 12 of the 49 company respondents to the survey believed the grant of broad patents had an inhibitory effect on their research. Respondents also noted that, despite this, they continued to seek patents that were as broad as possible.[27] However, some respondents commented that for some companies, 'inventing around' might be a workable strategy for dealing with broad patents. In particular, respondents from the pharmaceutical sector 'were generally of the view that it is not possible to obtain broad patents that block research in the pharmaceutical industry because of the ability of researchers to invent around'.[28]

18.27 Some concern about the stifling effect of broad patents was also expressed in submissions.[29] However, one submission noted that overly broad patents are unlikely to be enforceable.[30] Others commented that there is little clear evidence that research is

25 See further Ibid.
26 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 86.
27 Ibid, 86–87.
28 Ibid, 144.
29 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Queensland Government, *Submission P57*, 5 January 2004.
30 AusBiotech Ltd, *Submission P58*, 7 November 2003.

being stifled or that such patents are adversely affecting the Australian biotechnology industry.[31]

18.28 Broad claims are often a feature of patents granted in the early stage 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.

18.29 The ALRC has developed recommendations that may help to address some of the concerns about inappropriately broad patent claims. These include amending the *Patents Act 1990* (Cth) (*Patents Act*) to include 'usefulness' as a requirement in the examination of patent applications; and to require patent examiners to be satisfied on the balance of probabilities when assessing all the requirements for patentability that are relevant at the stage of examination.[32]

18.30 In addition, Chapter 8 makes recommendations directed at improving the education and training of patent examiners and developing guidelines to assist examiners in applying the requirements for patentability to inventions involving genetic materials and technologies.[33]

Reach-through provisions

18.31 Chapter 12 discusses the problem of reach-through provisions in licence agreements in the context of research. This section discusses the implications of reach-through provisions for the biotechnology industry.

18.32 Reach-through provisions in a licence agreement grant a patent holder future rights in new products that might result from the use of a licensed patent. Reach-through provisions may include the right to own or license the intellectual property in future products. Reach-through provisions are most common when the holder of a patent over an upstream technology licenses it to other companies further downstream. They may also be included in materials transfer agreements.[34] Reach-through provisions, therefore, effectively give the patent holder what Heller and Eisenberg have described as 'a continuing right to be present at the bargaining table as a research project moves downstream toward future product development'.[35]

18.33 Reach-through provisions may deter investment in developing technology if it is unclear whether the technology can be freely exploited. They may also deter future development by restricting the rights of the licensee to exploit new technology that

---

31 Ibid; A McBratney and others, *Submission P47*, 22 October 2003.

32 Rec 6–3 and 8–3. The ALRC also recommends that guidelines to assist patent examiners in applying the usefulness requirement be developed (Rec 6–4).

33 See Rec 8–1 and 8–2.

34 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 163.

35 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700.

results from working with the patented technology. This may be particularly problematic if a number of reach-through rights are stacked on downstream technologies.

18.34 The Nicol–Nielsen Study suggested that reach-through provisions are frequently included in licensing agreements entered into by participants in the Australian biotechnology sector and appear to be problematic in a large number of negotiations.[36] Heller and Eisenberg suggest that reach-through provisions may contribute to the emergence of an anti-commons.[37] The Nicol–Nielsen Study did not hear complaints about stacking of reach-through provisions, however, it noted that this did not mean problems of this kind did not exist.[38]

18.35 Submissions expressed some concern about reach-through provisions, although this concern was often focused on reach-through patent claims.[39] Whereas reach-through provisions are conditions on the use of a licence of a patent, reach-through patent claims seek to claim rights to a future invention on the basis of a currently disclosed invention, thereby extending the scope of the patent holder's monopoly.[40] Reach-through patent claims are discussed further in Chapter 6.

Blocking patents

18.36 Broadly defined, blocking patents are patents which stifle developments by others. They may occur where one patent holder has a broad patent over an invention (a dominant patent), and another patent holder has a narrower patent over an improvement to that invention or a new invention that relies on access to the original invention (a dependent patent).[41] The holder of a dependent patent will be precluded from practising the improved invention unless it can obtain a licence over the dominant patent. Similarly, the dominant patent holder may not exploit the improved invention without a licence from the dependent patent holder.[42]

18.37 Blocking patents may cover broad or foundational technology—a patent over a gene sequence is an example—which is not exploited or licensed, thereby blocking others from using the technology. The effect of a broad blocking patent may be to

---

36 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 164.

37 M Heller and R Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700.

38 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 193.

39 Queensland Clinical Genetics Service, *Consultation*, Brisbane, 2 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

40 S Kunnin and others, 'Reach-through Claims in the Age of Biotechnology' (2002) 51 *American University Law Review* 609, 618–619.

41 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 141.

42 The term 'blocking patents' has a specific legal meaning in the United States, where it refers to dominant and subservient (dependent) patents, rather than the broader definition, used in this chapter, as any patents that block access to technology.

prevent whole areas of research, particularly where the patent holder chooses not to exploit the patent themselves. In such cases, or where the patent is foundational to other research, the capacity for others to undertake further research may be curtailed and the benefits from the technology may not flow to the public.[43]

18.38 The value of a patent is highly dependent on the patent holder's ability to exploit it.[44] Patents that block a patent holder from exploiting their patent may devalue the patent, and consequently affect the holder's ability to attract investment.

18.39 The existence and effects of blocking patents were examined in the Nicol–Nielsen Study. The Study found that a significant number of respondents regarded blocking patents as a real issue in the biotechnology industry, although many commented that they could not see the value of companies obtaining patents purely for blocking or defensive purposes.[45] However, Nicol and Nielsen commented:

> many respondents who participated in interviews either had patents that they did not currently exploit, or knew of companies who did not currently exploit. In many cases, these patents were not licensed or otherwise transferred, although this may have been due to a number of reasons.[46]

18.40 The Nicol–Nielsen Study also found that several respondents to the company survey had altered their research program due to a patent blocking access to research tools or materials.[47] Some respondents commented that they avoided areas of research where they did not think they would be able to get access to necessary technology due to the presence of blocking patents. Others changed the direction of research where they found themselves blocked, or invented around the patented technology.[48]

18.41 Despite the reported concerns, responses suggested that successfully negotiating a licence could solve issues created by potentially blocking patents, and one respondent commented that research is blocked only in exceptional cases.[49] However, Nicol and Nielsen observed that in many instances, respondents did not even try to negotiate as they regarded the patent holder as unlikely to negotiate.[50]

18.42 Another mechanism for dealing with blocking patents is compulsory licensing, where the holder of the patent can be required to license the technology to allow others in the industry to exploit it, or to practise their own patents. The compulsory licensing provisions in the *Patents Act* are discussed in Chapter 27. There may also be competition issues, which are discussed in Chapter 24.

---

43 Ibid.
44 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003.
45 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 142.
46 Ibid, 142.
47 Ibid, 140–141.
48 Ibid, 143.
49 Ibid, 143–144.
50 Ibid, 144.

Dependency and uncertainty

18.43 As discussed above, a dependent patent is a patent on an invention, the exploitation of which is prevented by 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'[51] leading to uncertainty about which patent holder would be able to prevent the others from using the later invention. The OECD Report stated that 'while licensing under uncertainty about the extent of property rights is not new to the pharmaceutical industry, too much litigation could again slow progress, raise end-product costs or discourage entry to certain fields of enquiry'.[52]

18.44 The OECD Report further 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.[53]

18.45 Compulsory licences may offer a solution where the holder of a dependent patent is unable to obtain a licence over the dominant patent. Chapter 27 discusses the way in which the compulsory licence provisions under the *Patents Act* apply to dependent patents.

Refusals to license

18.46 As discussed in Chapter 22, licensing is a means by which rights in patented technology may be transferred.[54] There are two main types of licences:

- those where a party needs to acquire the rights to use a patent in order to do further research or development (licence-in); and
- those where the right to use patented technology is granted by a patent holder to another party to allow further research, the development of a new product, or the exploitation of a product (licence-out).

18.47 Chapter 16 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

---

51 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 16.

52 Ibid, 16.

53 Ibid, 45. However, the OECD Report also indicated difficulties in assessing the extent to which dependency and uncertainty were really a problem for industry.

54 Chapter 22 discusses licensing generally. Part E discusses the role of licensing in healthcare, particularly in relation to genetic tests.

licence.[55] However, only six of the 49 companies that responded to the Nicol–Nielsen Study reported being refused licenses.[56] Interview responses reinforced the perception that refusals to licence are not a pervasive problem.[57]

18.48 One reason for the refusals cited in the Nicol–Nielsen Study was that exclusive licences had been granted to other companies. Competition between the patent holder and the company seeking to licence was also cited. In some cases, refusals also occurred because of an inability to agree on reasonable licence terms.[58] Nicol and Nielsen commented that:

> One interpretation of this data is probably that refusals to license were not encountered because often it did not get to the stage that licences were requested. This was acknowledged by many of our respondents. As reported elsewhere, researchers and companies stated that they avoided particular areas of research if patents were held by competitors, or if it looked as though obtaining a licence might prove to be too problematic … in line with the survey results a few interview respondents expressed frustration at difficulties in licensing-in enabling technologies, but these were greatly outnumbered by the number of respondents who had not experienced any problems. Some respondents complained that owners of research tool patents, while willing to license, unreasonably demanded reach-through royalties.[59]

18.49 The need to licence-in patented technology may be a barrier to commercialisation if licences are not widely available. In particular, exclusive licences have the potential to be anti-competitive because they restrict access to important genetic materials or research tools.[60] Compulsory licensing, discussed in Chapter 27, may provide some solutions to problems resulting from refusals to license. That chapter also recommends that an additional ground for obtaining a compulsory licence based on a competition test be included in the *Patents Act* (see Recommendation 27-1).

Lack of experience with commercialisation

18.50 It has been suggested that there is a lack of appropriate commercialisation experience related to biotechnology within the Australian industry.[61] A related problem is that Australia lacks a large enough pool of people with the skills to manage intellectual property effectively in the biotechnology context.[62] This concern was raised in the Australian Science and Innovation Mapping Taskforce report, *Mapping Australian Science and Innovation*, which stated that scientists, when taking on the role

---

55 Ernst & Young, *Australian Biotechnology Report* (1999), 35.
56 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 145.
57 Ibid, 145.
58 Ibid, 145–146. Refusals to license are also discussed in Ch 22.
59 Ibid, 146.
60 Competition issues related to gene patenting are discussed in Ch 24.
61 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.
62 D Sparling and M Vitale, *Australian Biotechnology: Do Perceptions and Reality Meet?* (2003) Australian Graduate School of Management, 6–7.

of Chief Executive Officer, 'often do not have the specialist business skills to enable the company to survive in early-stage commercialisation'.[63]

18.51 In consultations, Benitec Ltd noted that Australia's ability to commercialise its research will improve as the country's skill base grows as a result of experience.[64] AusBiotech Ltd noted that there is a need to educate the research sector and industry further about intellectual property protection to ensure that future marketing applications for product development are considered early in the patent strategy.[65] Intellectual property protection and technology transfer from research organisation are discussed in Chapter 17.

Lack of investment and venture capital

18.52 One possible barrier to effective commercialisation of genetic research within the biotechnology industry in Australia is the lack of long term venture capital funding.[66] It has been suggested that it is very difficult to attract venture capital in Australia due to the lack of a mature venture capital base in this country.[67] It has also been suggested that there is a need for venture capital with at least a five-year term.[68]

18.53 Seed funding[69] rates are also much lower in Australia compared with the United States. In Australia, the usual level of seed funding is around $1,000, while in the United States the level is closer to $1 million.[70] In consultations, UniQuest suggested that higher funding at this stage enables United States companies to establish effective management structures, initially staffed by professional managers.[71] Lack of investment can lead small, early stage companies to license their intellectual property too early in an effort to maintain cash flow. The original intellectual property may therefore be undervalued.[72]

---

63 Science and Innovation Mapping Taskforce, *Mapping Australian Science and Innovation* (2003), 318.
64 Benitec Ltd, *Consultation*, Brisbane, 3 October 2003.
65 AusBiotech Ltd, *Correspondence*, 12 May 2004.
66 'Venture capital funding' is funding provided by investors to early stage companies, generally after they have demonstrated strong growth potential and good management. Venture capital differs from seed funding (see below) because it is often provided in return for equity in the company and the investor will expect greater control of the company and a quicker return on the investment. See D Zahorsky, *Venture Capital*, What You Need to Know About: Small Business Information, <http://sbinformation.about.com/library/glossary/bldef-venture.htm> at 16 June 2004.
67 UniQuest, *Consultation*, Brisbane, 3 October 2003.
68 Medical Researchers, *Consultation*, Adelaide, 15 September 2003.
69 'Seed funding' is an initial or early stage investment in a start up company or project, which is usually used to develop an idea to proof-of-concept stage, to conduct market research, or for initial product development. See InvestorWords.com, *Seed Capital*, <www.investorwords.com/4453/seed_capital.html> at 16 June 2004.
70 UniQuest, *Consultation*, Brisbane, 3 October 2003.
71 Ibid.
72 Medical Researchers, *Consultation*, Adelaide, 15 September 2003.

18.54 Insufficient early stage funding prevents new companies from establishing effective management structures.[73] As a result, some biotechnology start-up companies are managed by academic researchers, rather than professional managers with experience in commercial negotiations and intellectual property management. As discussed in Chapter 14, most academic researchers do not possess the specialised skills necessary to manage a commercial venture. Consequently, some companies may be managed inexpertly and intellectual property exploited ineffectively.

18.55 Many Australian biotechnology inventions fail to be exploited effectively because of a lack of funding at the proof-of-concept stage. At this stage, an invention has been created and its commercial potential must be demonstrated to attract investment for its development into a marketable product. Passing the proof-of-concept stage involves demonstrating the commercial potential of an invention to attract investment for development of a marketable product.

18.56 In some cases, an invention at this stage will not be exploited at all. In others, the invention is licensed to an international company prematurely and its potential value to Australia is lost.[74] Biotechnology Australia has suggested that this commercialisation gap 'is widely recognised as the most critical barrier to biotechnology development in Australia'.[75] For the most part, this issue is beyond the scope of this Inquiry.

Industry assistance programs

18.57 The Australian Government has introduced a number of programs to address some of the issues outlined above. These include:

- *Pre-Seed Fund*—four early-stage venture capital funds established to invest in projects or companies spinning out from universities or government agencies, and to provide management and technical advice;[76]

- *Commercial Ready Programme*—provides financial assistance to small to medium-sized enterprises for research and development, proof-of-concept, technology diffusion, and early-stage commercialisation;[77] and

---

73 UniQuest, *Consultation*, Brisbane, 3 October 2003.

74 Biotechnology Australia, *Australian Biotechnology: Progress and Achievements* (2000), 13.

75 Ibid, 13.

76 Australian Government, *The Pre-Seed Fund*, Backing Australia's Ability, <http://backingaus.innovation.gov.au/2004/commercial/pre_seed.htm> at 16 June 2004.

77 Australian Government, *The Commercial Ready Programme*, Backing Australia's Ability, <http://backingaus.innovation.gov.au/2004/commercial/commercial_ready.htm> at 16 June 2004. The Commercial Ready Programme was announced as part of the second Backing Australia's Ability initiative, *Building Our Future through Science and Innovation*, in May 2004. It amalgamates the R&D Start programme, the Biotechnology Innovation Fund and the Innovation Access Programme introduced in the original Backing Australia's Ability initiative.

- *COMET Programme*—provides innovators with advice and financial assistance to plan their commercialisation, attract capital for their project, and establish strategic partnerships to take innovation to the market.[78]

18.58 Other funding programs designed to support the biotechnology industry were outlined in DP 68.[79]

18.59 AusBiotech Ltd, the peak national body for the biotechnology industry, has developed programs to support the Australian biotechnology industry. It addresses education issues through seminars, professional development workshops, networking events in each state and an annual conference.[80] A range of state and territory based programs is also in place to promote the biotechnology industry.[81]

Submissions and consultations

18.60 In response to IP 27, submissions generally recognised the importance of the biotechnology industry in fostering innovation and facilitating the delivery of healthcare benefits from genetic research.[82] Submissions and consultations also recognised that patents are vitally important for the biotechnology industry to stimulate technological innovation and attract investment.[83]

18.61 A variety of comments were received on the operation of the biotechnology industry in Australia generally. It was suggested that the Australian biotechnology industry is somewhat risk averse in commercialising technology, preferring to license patented inventions to overseas firms rather than developing them to product stage.[84] AusBiotech Ltd suggested in consultations that the Australian biotechnology industry suffers from an inward looking culture.[85]

---

78 Australian Government, *Commercialising Emerging Technologies (COMET) Programme*, Backing Australia's Ability, <http://backingaus.innovation.gov.au/2004/commercial/comet.htm> at 16 June 2004.

79 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Ch 11. As noted above, some of the programs have now been amalgamated into the Commercial Ready Programme.

80 AusBiotech Ltd, *Latest Events*, <www.ausbiotech.org/latest.php> at 7 May 2004.

81 For example, the New South Wales Government's BioFirst Strategy, which provides funding and a range of programs to support the local biotechnology industry: New South Wales Government, *BioFirst Strategy*, <www.biofirst.nsw.gov.au/biotechnsw/strategy.asp> at 16 June 2004. For an overview, see Department of Education Science and Training, *The Contributions of the States and Territories to Australia's Science and Innovation System* (2003).

82 D McFetridge, *Submission P23*, 30 September 2003; Children's Cancer Institute Australia for Medical Research, *Submission P13*, 30 September 2003.

83 A Bankier, *Submission P19*, 30 September 2003; Queensland Department of Innovation and Information Economy, *Consultation*, Brisbane, 2 October 2003; *Confidential Submission P54 CON*, 3 November 2003; A Johnston, *Submission P15*, 30 September 2003; Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003; D Jackson, *Submission P43*, 20 October 2003; R Barnard, *Submission P32*, 7 October 2003.

84 South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.

85 AusBiotech Ltd, *Consultation*, Melbourne, 5 September 2003.

18.62 In addition, the Department of Health and Ageing noted that the commercial sector is not skilled at research into gene function, which requires access to patient data and longitudinal studies.[86] Linkages with research institutions and health departments are therefore necessary to undertake this research.

18.63 Others commented that Australian biotechnology companies face difficulties when attempting to move from the proof-of-concept stage to the commercialisation stage. This may be due to the lack of a well-developed venture capital industry in this country.[87] In one consultation it was suggested that companies need to be more aware that for the value of technology to be increased, the risks in developing it into a commercial product need to be reduced by developing the technology to a more advanced stage, to make it more attractive to venture capitalists.[88]

18.64 Submissions and consultations suggested measures to address some of the problems raised by gene patents for the biotechnology industry, while others made more general comments about how these problems might be approached. For example, the Department of Health and Ageing suggested that concerns about gene patents have arisen from the way patent holders behave, and that there needed to be policy solutions to control 'rogue players'.[89] The Human Genetics Society of Australasia cited a need to collect data about the impact of patents and licensing practices on the biotechnology sector.[90]

18.65 One suggested solution to the problem of inadequate venture capital was for government to provide investment-equity schemes, like the Biotechnology Innovation Fund.[91] In relation to patent thickets and overlapping licences, patent pools were also suggested as a possible solution.[92] Patent pools are discussed in Chapter 22.

18.66 DP 68 proposed that lack of experience within the industry could be addressed by continuing to provide assistance programs for biotechnology companies. Specifically, the ALRC proposed that Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should:

(a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and

(b) develop strategies to ensure widespread participation of biotechnology companies in these programs.

---

86 Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.
87 Commonwealth Government Departments, *Consultation*, Canberra, 5 May 2003.
88 Ibid.
89 Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.
90 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
91 Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003. See Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [11.44].
92 Department of Industry Tourism and Resources, *Consultation*, Canberra, 22 September 2003.

18.67 This proposal received widespread support in submissions.[93] The Queensland Government commented that a number of assistance programs are already in place.[94] In particular, the Department of Industry, Tourism and Resources noted that the Australian Government is aware of the need for continuing support to the industry and strongly agreed with 'the need to maintain policy and program thrust to achieve better results in this area'.[95]

18.68 As noted in Chapter 17, submissions were divided over the appropriate body to carry out the proposed programs. For example, the Centre for Law and Genetics considered that Biotechnology Australia was the appropriate organisation, although it would require increased resources.[96] However, the Department of Industry, Tourism and Resources suggested that the proposal would be better directed to government generally 'to enable more comprehensive government consideration'.[97] Others commented that Biotechnology Australia might currently lack the capacity to develop and implement programs of this kind.[98]

ALRC's views

18.69 Many of the problems facing the biotechnology industry, and possible reforms to address them, lie beyond the scope of this Inquiry. However, the ALRC considers that continuing current education programs, and developing further programs to address particular issues faced by the Australian biotechnology sector, may assist to improve the ability of Australian biotechnology firms to compete in the world market.

18.70 The ALRC recognises that considerable efforts are being made at both the federal and state levels to support the biotechnology industry, including the provision of information and training about intellectual property issues. These programs should continue, and should focus on providing companies with the specific skills and knowledge to deal with the issues raised by gene patents (Recommendation 18–1).

18.71 The ALRC considers that Biotechnology Australia, in conjunction with its member departments, is best placed to continue the development of education and support programs for the biotechnology industry. Biotechnology Australia has responsibility for managing the Australian Government's non-regulatory

---

93 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; AusBiotech Ltd, *Submission P94*, 16 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004.

94 Queensland Government, *Submission P103*, 22 April 2004.

95 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

96 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

97 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

98 National Health and Medical Research Council, *Consultation*, Canberra, 26 March 2004; Unisearch, *Consultation*, Sydney, 15 March 2004.

biotechnology activities.[99] It also administers the *National Biotechnology Strategy*, which includes:

- improving management of research, intellectual property and technology within established firms and new enterprises;
- developing programs and systems to foster entrepreneurship;
- monitoring emerging skill needs and developing appropriate responses;
- promoting opportunities for research and industry groups to share experiences in intellectual property management from innovation through to commercialisation; and
- identifying biotechnology intellectual property management needs of researchers, technology managers and other stakeholders and developing programs to address these needs.[100]

18.72 The success of the ALRC's proposed programs rests in part on effective coordination with state and territory government initiatives directed at similar objectives. Biotechnology Australia is well placed to achieve this coordination as it has responsibility for maintaining cooperation between the Commonwealth and the States and Territories on biotechnology policies and activities.[101]

18.73 Success also rests on cooperation with the biotechnology industry to ensure the programs developed meet its needs. AusBiotech Ltd has indicated that it is willing to work in partnership with Biotechnology Australia to develop programs and provide support through: promotion and provision of information to its members; holding high-level workshops, forums and CEO roundtables; and utilising the high-level strategic 'think tank' capabilities of its advisory groups.[102]

18.74 The ALRC considers that AusBiotech Ltd, as the peak body representing the biotechnology industry, should be consulted by Biotechnology Australia when developing programs to assist industry.[103]

18.75 Solutions to some of the other concerns raised in this chapter are discussed elsewhere in this Report. Broader licensing issues, including support for skill development in relation to licensing negotiations, are discussed in Chapter 22. Compulsory and statutory licensing, as mechanisms for dealing with other licensing issues, are considered in Chapters 23 and 27 respectively.

---

99 Biotechnology Australia and Commonwealth Biotechnology Ministerial Council, *Australian Biotechnology: A National Strategy* (2000), 27.
100 Ibid, 20, 24.
101 Ibid, 27.
102 AusBiotech Ltd, *Submission P94*, 16 April 2004.
103 See also Ch 22.

18.76 Further, Recommendation 11–3 suggests that the Australian Research Council (ARC) and the National Health and Medical Research Council (NHMRC) should review their principles and guidelines to provide for conditions to be placed on research funding, in exceptional circumstances, where the public benefit would clearly be served by broad dissemination of the results of publicly funded research. These conditions may be used to promote the dissemination of research results by wide licensing, or by precluding patenting entirely. Chapter 12 recommends that, as part of this review, the ARC and NHMRC should ensure the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.[104] Some industry concerns about access to research tools may be met by this proposal.

18.77 In addition, the role of competition law in addressing patenting issues within the biotechnology sector is considered in Chapter 24. In that chapter the ALRC makes a number of recommendations directed at addressing anti-competitive behaviour in relation to intellectual property.

18.78 Taken together, these recommendations address suggestions that commercialisation guidelines are required in relation to restrictive and anti-competitive practices in the biotechnology industry.

Recommendation 18–1 Biotechnology Australia, in conjunction with its member departments, and in consultation with state and territory governments and other stakeholders, should:

(a) develop further programs to assist biotechnology companies in commercialising inventions involving genetic materials and technologies; and

(b) develop strategies to ensure widespread participation of biotechnology companies in these programs.

104 Rec 12–1.

PART E

Patents and Human Health

19. Gene Patents and the Healthcare System

Contents

Introduction

19.1 The ALRC is required 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. The Terms of Reference refer to the potential for rapid advances in human genome research and genetic technologies to improve human health.

19.2 This chapter discusses the possible impact of gene patents on the healthcare system. It begins by presenting background information on the Australian healthcare system, how it is funded, and how decisions are made about funding medical services and pharmaceuticals through the Medicare Benefits Scheme (MBS) and the Pharmaceutical Benefits Scheme (PBS).

19.3 The chapter discusses how gene patents may contribute to the cost of healthcare, and the possible implications of gene patents for healthcare funding. The chapter examines whether the healthcare system is able to accommodate the introduction of

new genetic medical technologies and, in particular, to deal with any problems of cost or access attributable to gene patents. The chapter makes recommendations with respect to:

- the need for economic evaluation of genetic medical technologies and examination of the financial impact of gene patents on the delivery of healthcare services in Australia;
- the possible role of government funding and purchasing power in controlling the cost to the healthcare system of genetic materials and technologies; and
- how Commonwealth, state and territory health departments, with advice from the proposed Human Genetics Commission of Australia (HGCA),[1] may better manage legal and other issues relating to gene patents.

Overview of the Australian healthcare system

19.4 The healthcare system in Australia is complex, involving many funders and healthcare providers.[2] Responsibilities are split between different levels of government, and between the government and non-government sectors. As a generalisation, the Australian Government is primarily responsible for the funding of healthcare, through health insurance arrangements and direct payments to the States and Territories, while the States and Territories are primarily responsible for the direct provision of services.[3]

19.5 The Australian Government operates universal benefits schemes—the MBS for private medical services and the PBS for pharmaceuticals. It also contributes to the funding of public hospitals in the States and Territories through the Australian Health Care Agreements. Public hospital services, including outpatient clinics such as those that are part of clinical genetics services, are usually delivered by state and territory governments. The private sector's provision of healthcare includes private medical practitioners, private hospitals, pathology services and pharmacies.

Healthcare funding

19.6 The Australian Institute of Health and Welfare has estimated that total Australian health expenditure was $66.6 billion in 2001–2002.[4] This represented 9.3% of gross domestic product.[5] The healthcare system is largely government funded. In 2001–2002, governments funded an estimated 68.4% of the total amount spent on health services. The Australian Government met 46.1%, and state, territory and local governments met 22.3% of total funding.[6]

---

1 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1.
2 See Australian Institute of Health and Welfare, *Australia's Health 2002* (2002), 238–243.
3 See G Palmer and S Short, *Health Care and Public Policy in Australia: An Australian Analysis* (3rd ed, 2000), 10.
4 Australian Institute of Health and Welfare, *Health Expenditure Australia 2001–02* (2003), 6.
5 Ibid, 8.
6 Ibid, 23.

19.7 Most of the Australian Government's healthcare funding was applied to medical services, including those provided under the MBS (30.7% of federal funding), and public hospitals (27.3%).[7] A further 16% of federal funding was directed to pharmaceuticals, including those provided under the PBS. Most state, territory and local government healthcare funding was applied to public hospitals (64.4% of state, territory and local government funding).[8]

Funding decisions under the MBS and PBS

19.8 Decisions about Australian Government funding under the MBS and PBS are made by applying clinical and economic criteria to determine whether, and in what circumstances, the cost of new medical services or pharmaceuticals should be subsidised.[9] These criteria apply, for example, if funding is sought under the MBS for medical genetic testing or under the PBS for drugs based on therapeutic proteins.

19.9 The Medical Services Advisory Committee (MSAC) provides advice to the federal Minister for Health and Ageing about the strength of evidence relating to the safety, effectiveness and cost-effectiveness of new and emerging medical services and technologies and under what circumstances public funding, including listing on the MBS, should be supported. 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.

19.10 Where items are recommended by PBAC for listing on the PBS, the Pharmaceutical Benefits Pricing Authority makes recommendations on the price to be paid by government. In doing so, the Pricing Authority takes account of a range of factors, including PBAC advice on clinical and cost-effectiveness; prices of alternative brands; comparative prices of drugs in the same therapeutic group; cost data information; prescription volume and economies of scale.[10] The pricing methodology does not provide a mechanism for the recognition of patent rights by way of a price premium. Price determination under the PBS is based on price referencing using comparative price and cost-effectiveness data, and does not take into consideration the patent status of a drug.[11]

---

7 Ibid, 27.

8 Ibid, 29.

9 See Medicare Services Advisory Committee, *Funding for New Medical Technologies and Procedures: Application and Assessment Guidelines*, Department of Health and Ageing, <www.health.gov.au/msac/pdfs/guidelines.pdf> at 16 June 2004; Pharmaceutical Benefits Advisory Committee, *1995 Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee: Including Major Submissions Involving Economic Analyses*, Department of Health and Ageing, <www.health.gov.au/pbs/general/pubs/pharmpac/gusubpac.htm> at 16 June 2004.

10 Pharmaceutical Benefits Pricing Authority, *Procedures and Methods* (2003).

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

The challenge of new medical technology

19.11 New medical technologies have the potential to strain the capacity of the healthcare system 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.

19.12 Most experts consider that new technology is a driving force behind the long-term rise of healthcare spending.[12] However, costs attributable to patent rights are only one component of the costs that may be involved when new medical technologies are introduced. For example, while it is sometimes claimed that patents are the predominant cause of high prices for new pharmaceuticals, the price of pharmaceuticals depends on a wide variety of factors, including the cost of research and development, production, distribution and marketing.[13]

19.13 The effect of technological developments on the practice of medicine is one of the most important problems facing health policy makers in Australia. It has been asserted that genetic technologies will come to affect every sector of healthcare provision.[14] If so, health expenditure attributable to genetic technology may increase.[15] Moreover, the extent of any increase in expenditure, or compensating savings through better diagnostics or therapeutics, in other areas is uncertain.[16]

19.14 Whether new genetic diagnostics and therapeutics will be as costly to bring to the market as the products of today, or whether greater knowledge of genetic sequences will shorten development times and reduce their costs is a matter for debate. It is also uncertain whether patients will demand new genetic tests or new medicines that give only marginal health benefit.[17]

Gene patents and healthcare costs and funding

19.15 Gene patents are relevant to the provision of healthcare in two broad categories:

- medical genetic testing, including pharmacogenetic testing; and

---

12 Other factors include population growth, demographic changes, increasing fees and costs of delivering health care services, growth in the medical workforce and greater community expectations. See M Fett, *Technology, Health and Health Care* (2000) Department of Health and Ageing.

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

14 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 61.

15 See Ibid, 61; R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), 3–4.

16 While many genetic technologies offer the promise of longer term savings through better disease management, in the short to medium term they are likely to increase healthcare costs, eg, certain medical genetic tests may allow disease prevention to be practised, and consequently reduce health care costs, but the clinical benefits may not be observable for many years: Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 61.

17 R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), 4.

- novel therapies, such as gene therapy, the production of therapeutic proteins, and the use of stem cells.

19.16 The existence of gene patents may make the provision of these kinds of healthcare more expensive. A patent grants exclusive rights to exploit the patented invention. This exclusivity may enable the patent holder to charge higher prices and make greater profits than would otherwise be possible. However, the extent to which this is so depends on whether the patent holder has effective monopoly control and, in particular, on the availability of substitute products and processes.[18] It will also depend on the nature of demand, which is strongly influenced by government funding decisions in the case of healthcare. For example, decisions about whether a certain medical genetic test will be funded through the MBS are likely to influence consumer demand for the test. Demand may also be influenced by marketing and other activities of suppliers of healthcare products and services.

19.17 Gene patents may also increase healthcare costs if restrictions on access to medical genetic testing mean that preventable or treatable genetic diseases are not identified, or if gene patents on research tools contribute to the time and expense involved in developing new healthcare products or services.

19.18 Concerns about the implications of gene patents for public healthcare funding have arisen primarily in relation to medical genetic testing (see Chapter 20). Most medical genetic tests are ordered as part of healthcare services provided by state and territory clinical genetics services. Testing is most often carried out by public sector laboratories, often attached to public hospitals or significantly funded by state or territory governments.[19] There are presently around 220 medical genetic tests available in Australia[20]—but the MBS funds medical genetic testing under only six MBS items.[21] Most tests are funded 'ad hoc through cost recovery or public hospital laboratories'.[22]

19.19 This situation may change in future as genetic medicine develops. The Australian Health Ministers' Advisory Council (AHMAC) observed that as genetic technologies become more mainstream it is likely that the private sector will play a greater role in provision, with rebates under the Medicare Benefits Schedule.[23]

---

18 See Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 138.

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

20 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html> at 16 June 2004. Not all tests are available from all laboratories. The register does not include newborn screening laboratories.

21 These items concern testing for haemochromatosis, factor V Leiden, protein C or S deficiencies, antithrombin 3 deficiency, and fragile X syndrome: Department of Health and Ageing, *Medicare Benefits Schedule (MBS)* (2003).

22 R Trent, *Correspondence*, 23 September 2003.

23 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

Assessing the implications for healthcare costs and funding

19.20 Concerns about future healthcare costs attributable to gene patents have been at the centre of the Inquiry.[24] In particular, submissions highlighted the problems that gene patents may pose for the cost and funding of clinical genetics services.[25] For example, the South Australian Department of Human Services expressed concern that 'high licence fees would limit the ability of the health system to provide or develop genetic testing, diagnosis and therapy, seriously threatening the delivery of health care services to a vulnerable section of the population'.[26]

19.21 However, it was recognised that the extent and impact of such costs is uncertain and may, in the event, be manageable. Further, the costs attributable to gene patents are only one component of the overall costs of providing genetic testing and other medical technologies and they need to be considered in the context of other influences on costs.[27] AusBiotech Ltd noted that 'the cost of a patented therapeutic or diagnostic is far more dependent on research and development, production, distribution and marketing costs than it is on whether or not the product or method is patented'.[28] Many other submissions also observed that cost problems are not unique to genetic technologies, but occur in other fields such as pharmaceuticals.[29]

19.22 Gene patents have the potential to create cost problems for particular health services—for example, where state clinical genetics services are obliged to pay licence fees or royalties for medical genetic testing from existing fixed budgets. In these circumstances, governments will have to reduce service provision, increase user charges, or obtain increases in their budget allocations. However, the extent to which increased expenditure on medical genetic testing and novel therapies will pose a challenge to overall healthcare funding is not clear; nor is it clear what contribution gene patents may make to this increased expenditure.

19.23 The additional expenditure attributable to gene patents is one component of the broader challenge for health policy arising from the introduction of any new medical

---

24 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; South Australian Government, *Submission P51*, 30 October 2003.

25 South Australian Government, *Submission P51*, 30 October 2003; D McFetridge, *Submission P23*, 30 September 2003; G Suthers, *Submission P30*, 2 October 2003; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

26 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

27 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

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

29 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Queensland Government, *Submission P57*, 5 January 2004; GlaxoSmithKline, *Submission P33*, 10 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003; IP Australia, *Submission P56*, 4 November 2003; G Suthers, *Submission P30*, 2 October 2003; Queensland Government, *Submission P57*, 5 January 2004; A McBratney and others, *Submission P47*, 22 October 2003; Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

technology. The economic and financial implications of gene patents for the healthcare system need to be assessed in this broader context.

19.24 DP 68 discussed two mechanisms that might be used to assist in planning and resource allocation in relation to genetic medical technologies generally and to assess the cost and funding implications of gene patents in particular.[30] The first of these involves an economic evaluation of the costs and benefits of genetic medical technologies. The second involves examination of the financial impact of gene patents on the delivery of healthcare. These mechanisms are discussed below.

Economic evaluation of genetic medical technologies

19.25 The Australian healthcare system is regarded by some as a world leader in carrying out detailed economic evaluation of the costs and benefits of pharmaceuticals and other medical technologies prior to inclusion in the MBS and PBS.[31] These skills may be applied to evaluate the economic implications of genetic medical technologies.

19.26 The term 'economic evaluation' is used to encompass a wide range of techniques for comparing the costs and benefits of an activity. These techniques may be used to evaluate interventions in healthcare and other contexts.[32] Costs, outcomes and quality of life measurements are usually included in an economic evaluation.[33]

19.27 Economic evaluation involves comparing costs and benefits for maximum societal wellbeing. Therefore, anything that adds to or subtracts from wellbeing can be included in the framework. In practice—because ethical, distributional and other intangible considerations are often difficult to quantify—economic evaluation may deal only with readily measurable costs and benefits.[34] Another characteristic of economic evaluation of health services is that its validity depends on clinical or epidemiological analysis of health impacts.[35]

19.28 While the economic evaluation of health services is complex, standard approaches have been developed to the measurement of costs and benefits, particularly where evaluation is linked to funding decisions, such as those under the MBS and PBS. However, as Professor Jane Hall has noted, the application of economic evaluation to genetic services presents several challenges beyond those relevant to other health service interventions. These include the following:

---

30 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 20–1(a) and (b).

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

32 The techniques applied in the economic evaluation of healthcare are derived from the same theoretical base as in other contexts, but differ in how benefits are measured and valued. For example, the 'benefits' of health services usually include both the extension and the quality of life.

33 J Richardson, 'The Economic Framework for Health Service Evaluation and the Role for Discretion' (Paper presented at Health Outcomes Conference, Canberra, 21 July 1999), 1.

34 Ibid, 2.

35 Ibid, 3.

- the health impact may not be immediate or related directly to the intervention, such as when a test reveals a susceptibility to the development of a disease that will be manifest only if certain environmental conditions prevail and, even then, only at some considerable time in the future;

- even if the condition cannot be prevented, more careful monitoring may lead to earlier intervention and less severe cases of the disease;

- more careful monitoring will add to healthcare costs, even though these may be offset by savings in future treatment; and

- some genetic testing will not affect the health of the patient, but rather the health of the patient's children, so that there is an inter-generational effect, which may make discounting for time preference inapplicable.[36]

19.29 The complexity of economic evaluation is substantially greater for genetic tests that demonstrate increased susceptibility to disease (which may be followed by on-going monitoring, medical interventions, or the need to consider risk to children), than for genetic tests that demonstrate the absence of genetic susceptibility (which may lessen or remove the need for further expenditure on particular medical services for an individual).

19.30 Evaluation methodologies for emerging medical genetic testing look at ethical, legal and social implications, as well as at scientific factors such as analytical validity, clinical validity and clinical utility. Such systematic evaluation can be contrasted with the generally *ad hoc* process by which genetic tests may be introduced in the Australian health care system.[37] At present, systematic evaluation is carried out only if a test is proposed for listing on the MBS, in which case the safety, effectiveness and cost-effectiveness of testing will be assessed by MSAC.

19.31 Gene patents are of less concern if they relate to medical genetic tests that are of marginal clinical benefit than if they relate to tests that may yield significant improvements in health outcomes. Economic evaluation can identify which medical genetic tests or other genetic medical technologies are the most beneficial or cost-effective for the community. While the focus of economic evaluation is on individual medical procedures, such as particular medical genetic tests, it is also capable of contributing to the planning and management of genetic health services as a whole if the results of individual evaluations are aggregated across the healthcare system.

---

36 See J Hall, R Viney and M Haas, 'Taking a Count: The Evaluation of Genetic Testing' (1998) 22 *Australian and New Zealand Journal of Public Health* 754; J Hall, 'Evaluation of Genetic Testing: How are We Going to Assess the Costs, Risks and Benefits of this New Technology?' in G O'Sullivan, E Sharman and S Short (eds), *Good-bye Normal Gene* (1999), 30.

37 Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [23.49].

Financial impact of gene patents

19.32 It may be problematic to assess the impact of gene patents separately as part of an economic evaluation of genetic medical technologies because of the many intangibles in the evaluation—such as whether the benefit of a particular genetic medical technology would have become available, or become available when it did, without the incentive of patent protection.

19.33 A financial or budgetary analysis of the impact of gene patents is more straightforward. Such an analysis would estimate current and projected costs of providing genetic healthcare services, taking patent rights into account.

Submissions

19.34 DP 68 proposed that AHMAC should establish processes for: (a) economic evaluation of medical genetic testing and other new genetic medical technologies; and (b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.[38] These proposals received broad support.[39]

19.35 The Department of Industry, Tourism and Resources (DITR) submitted that the process used in decision making under the PBS could easily be applied to genetic and related technologies, but noted the methodological difficulties involved in 'accurately recognising and quantifying the direct and indirect benefits of the new technologies'.[40] The Human Genetics Society of Australasia (HGSA) observed that the evaluation of best practice in the use of medical genetic technologies 'lags far behind' current medical developments.[41]

19.36 The South Australian Department of Human Services submitted that 'social impact' should be a factor in any economic evaluation:

> Given the concerns of the public about the ethical and social issues in gene patenting, it is proposed that the economic evaluation should include social impact. This wider scope of the evaluation would provide more useful information, and would give due recognition to social concerns about the implications of gene patenting on equity, affordability and quality of healthcare service provision.[42]

---

38 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 20–1.

39 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004. DITR supported economic evaluation of genetic medical technologies but not examination of the financial impact of gene patents because it considered that 'gene patents do not have a quantifiable direct financial impact on the delivery of healthcare services': Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

40 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

41 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004.

42 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

19.37 Several submissions suggested that economic evaluation of genetic medical technologies should be conducted or assisted by MSAC,[43] which has conducted similar assessments in the past, for example with respect to the genetic test for fragile X syndrome.[44] However, the HGSA stated that existing MSAC processes are not an appropriate model for evaluating how best to deliver predictive and screening genetic testing as MSAC's processes are focused primarily on assessing whether individual medical procedures should be put on the MBS. The HGSA submitted that 'the role of MSAC may need to be revised to address broad technology changes rather than individual tests'.[45]

19.38 The Department of Health Western Australia noted that comprehensive economic models have been developed in Western Australia for breast, ovarian and colon cancer treatment and that it would be possible to expand the analysis to look at other aspects of genetic testing services.[46] The HGSA and the Queensland Government referred to the United Kingdom Health Technology Assessment Programme as a possible model.[47] It was also suggested that there may be a role for the HGCA in the economic evaluation of genetic medical technologies.[48] The Department of Health Western Australia submitted that, until the HGCA is established, AHMAC would be the appropriate body to coordinate economic evaluation of new genetic medical technologies and financial analysis of the impact of gene patents.[49] The Department of Health and Ageing also supported a role for AHMAC in examining the financial impact of gene patents.[50]

ALRC's views

19.39 The impact of new genetic technologies on healthcare needs to be monitored closely by health policy makers in Australia. The ALRC highlighted some aspects of

---

43 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

44 Medicare Services Advisory Committee, *Genetic Test for Fragile X Syndrome: Assessment Report*, Department of Health and Ageing, <www.health.gov.au/msac/pdfs/msac1035.pdf> at 16 June 2004.

45 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004.

46 Department of Health Western Australia, *Submission P89*, 16 April 2004.

47 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004. 'The purpose of the programme is to ensure that high quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most effective way for those who use, manage and provide care in the NHS': see NHS R&D Health Technology Assessment Programme, *About the HTA Programme*, National Health Service, <www.hta.nhsweb.nhs.uk> at 16 June 2004.

48 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004.

49 Through the AHMAC Advisory Group on Human Gene Patents and Genetic Testing: Department of Health Western Australia, *Submission P89*, 16 April 2004; see also Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004. The Department noted that the resources available to the AHMAC Advisory Group would need to be increased.

50 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

the need for long term planning in genetics in its 2003 report, *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC 96).[51]

19.40 While the ALRC's Terms of Reference are directed to the impact of patent laws and practices, submissions highlighted a more general need for economic evaluation of genetic medical technologies.[52] Private sector involvement in medical genetic testing has led to concern that commercial interests may be in a position, to 'dictate which genetic tests are performed, how and where they are performed, and the price of the tests without any consideration of societal needs or input from professional and government stakeholders'.[53]

19.41 An effective system for the economic evaluation of genetic medical technologies would help address these concerns. It would place Commonwealth, state and territory health departments in a better position to influence the way medical genetic testing and other new genetic medical technologies are introduced to the Australian healthcare system. It would also assist in deciding which products or services should receive government funding or other support.

19.42 Economic evaluation may also assist health departments in decision making about gene patents. For example, decisions about whether to challenge a patent, and strategies for negotiation with patent holders, may be informed by an assessment of the value of particular inventions to the health of the community. This approach would be consistent with the more active role in managing patent issues recommended by the ALRC.[54] Further, such an evaluation can directly assist decision making by health departments about how to absorb any future costs attributable to patent licence fees or royalty payments.

19.43 Submissions emphasised the importance of a national approach to the economic evaluation of new genetic medical technologies and examination of the financial impact of gene patents.[55] The ALRC considers that a national program for economic evaluation of genetic medical technologies is important to counteract the 'fear of unknown' in the public health sector about the implications of gene patents for healthcare delivery. Such a program would allow principled and comprehensive policies to be developed.

---

51 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 23–1, 23–4, 23–5.

52 The need for economic evaluation of new genetic medical technologies has also been identified by inquiries overseas: See Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 84; R Zimmern and C Cook, *Genetics and Health: Policy Issues for Genetic Science and their Implications for Health and Health Services* (2000), 76. In relation to pharmacogenetics, see Nuffield Council on Bioethics, *Pharmacogenetics: Ethical Issues* (2002); P Lipton, 'Pharmacogenetics: The Ethical Issues' (2003) 3 *Pharmacogenomics Journal* 14, 14–15.

53 Cancer Council Victoria, *Submission P101*, 20 April 2004.

54 See rec 19–3.

55 See, eg, Department of Health Western Australia, *Submission P89*, 16 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004.

19.44 The ALRC considers that AHMAC is the appropriate body to take this forward. AHMAC is a committee of the heads of the Commonwealth, state and territory health departments. It is the major policy making body on national health matters, advising the Australian Health Ministers' Conference on policy, resource and financial issues.

19.45 In May 2002, AHMAC established an Advisory Group on Human Gene Patents and Genetic Testing (AHMAC Advisory Group). Its terms of reference include advising AHMAC on matters relating to the planning, management, regulation, provision and delivery of human genetic testing and screening services. In addition, AHMAC may be assisted by MSAC. MSAC's terms of reference include undertaking health technology assessment work referred to it by AHMAC, and reporting its findings to AHMAC.[56]

19.46 The ALRC therefore recommends that AHMAC establish processes for the economic evaluation of medical genetic testing and other new genetic medical technologies, and for the examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

Recommendation 19–1 The Australian Health Ministers' Advisory Council (AHMAC) should establish processes for:

(a) economic evaluation of medical genetic testing and other new genetic medical technologies; and

(b) examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

Control through government funding and purchasing

19.47 Government decisions about healthcare funding can indirectly influence patent holders' decisions about licensing and the level of licence fees. 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 patent rights. The ALRC has examined whether government funding and purchasing power should be used to influence the cost of medical genetic testing that is subject to gene patents and, if so, how this might be achieved.[57]

19.48 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

56 Department of Health and Ageing, *Medicare Services Advisory Committee Terms of Reference*, <www.health.gov.au/msac/terms.htm> at 16 June 2004.

57 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 12–7.

national funding program that is limited to tests of proven clinical utility and cost-effectiveness', with the price to be negotiated by government.[58] The AHMAC Working Group on Human Gene Patents[59] recommended in 2001 that government funding for genetic testing should be restricted initially to genetic testing performed by publicly funded facilities, in part to assist in controlling healthcare costs.[60]

19.49 The PBS has been cited as an example of how government purchasing power may assist in controlling the cost of healthcare.[61] There is evidence that the PBS allows relatively low prices for drugs to be maintained because the government acts as a single buyer in a market with a number of sellers (a monopsony).[62]

19.50 The MBS and PBS are already used to control the cost of medical procedures and pharmaceuticals. In DP 68, the ALRC proposed that AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.[63]

19.51 This proposal received wide support.[64] For example, the Department of Human Services Victoria stated that there should be 'a national mechanism for using government funding and purchasing power to control a reasonable licence fee to those tests covered by gene patents'—through either the proposed HGCA or a body equipped to perform economic analysis.[65] The HGSA stated that government funding and central purchasing might lead to 'equitable provision' of testing in both the public and private sectors.[66]

---

58 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001).

59 The predecessor to the AHMAC Advisory Group.

60 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 27, rec 7.

61 In 1999–2000 the Commonwealth Government contributed $3,522 million in benefits under the PBS and the Repatriation Pharmaceutical Benefits Scheme, out of a total expenditure on all pharmaceuticals of $7,563 million: Australian Institute of Health and Welfare, *Australia's Health 2002* (2002), 255.

62 See M Rickard, *The Pharmaceutical Benefits Scheme: Options for Cost Control: Current Issues Brief No 12 2001–02 (28 May 2002)*, Parliament of Australia, <www.aph.gov.au/library/pubs> at 16 June 2004; Productivity Commission, *International Pharmaceutical Price Differences: Research Report* (2001); Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program* (2003), [3.12].

63 See Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 20–2.

64 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

65 Department of Human Services Victoria, *Submission P111*, 30 April 2004.

66 Human Genetics Society of Australasia, *Submission P76*, 16 April 2004.

ALRC's views

19.52 Governments have considerable control over healthcare expenditure in Australia through budget appropriations,[67] fixing health benefit levels, taxation arrangements, and setting the parameters for private health insurance arrangements. The MBS and PBS are relevant where funding is sought through federal funding programs. There are also funding and other mechanisms that may be used by state and territory health departments. AHMAC noted that 'jurisdictions regularly make decisions in order to manage the costs resulting from new health technologies through the application of appropriate efficacy and cost effectiveness analysis, funding and targeting mechanisms'.[68]

19.53 There may be other ways in which funding mechanisms might be used to address concerns about the impact of gene patents on healthcare provision, including by placing conditions on the public funding of new medical services. For example, Medicare funding of a medical genetic test might be made conditional on broad licensing of the test.

19.54 The ALRC recommends that options for using government funding and purchasing power to control the cost of genetic medical technologies subject to gene patents should be examined by Commonwealth, state and territory health departments (Recommendation 19–2). The ALRC recognises that this may have competition policy ramifications.[69] Depending on the mechanism chosen, cooperation by Commonwealth, state and territory governments could be anti-competitive. However, this does not prevent the options being examined. Further, if the public interest warrants it, the application of national competition policy can be excluded by legislation or by seeking authorisation from the Australian Competition and Consumer Commission (ACCC) under the *Trade Practices Act 1974* (Cth).

Recommendation 19–2 AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

Role of health departments

19.55 Health departments and other public health organisations are directly affected by the patenting of genetic materials and technologies. Health departments are the main funders and users of these technologies and have a major stake in the effects of the

67 In the case of the Australian Government, appropriations include grants to the States and Territories that are specifically targeted to healthcare purposes, payments of health benefits to individuals, subsidies paid to providers of healthcare services, and reimbursements to private health insurance funds.

68 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003.

69 See, eg, Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

patent system on healthcare provision and medical research. The ALRC has examined whether health departments should take a more active role in monitoring patents over genetic materials and technologies and, where appropriate, intervening in the patent process.

19.56 DP 68 noted that recommendations made in 2003 to the United Kingdom Department of Health provide an important lead. The report *Intellectual Property Rights (IPRs) and Genetics*, by Professor William Cornish, Dr Margaret Llewelyn and Dr Michael Adcock (the UK Report)[70] was commissioned by the United Kingdom Department of Health because of its 'serious concern' about the impact of intellectual property rights upon 'research and the use of novel developments in genetics affecting health care'.[71] The UK Report recommended that the Department of Health should take an active role in monitoring developments in relevant areas of intellectual property law (most notably patent law); have in place a mechanism for assessing whether to challenge patent applications or granted patents; instigate a policy for 'licensing in' designed to moderate excessive demands by licensors by considering the use of compulsory licensing, competition law and Crown use; and make full use of existing monitoring and horizon scanning work being undertaken by groups such as the Human Genetics Commission and the Nuffield Council on Bioethics.[72]

Intervening in the patent system

19.57 DP 68 proposed that where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should consider legal intervention, including by challenging patents or patent applications and exercising Crown use powers.[73]

19.58 This proposal received qualified support in submissions.[74] The Department of Health and Ageing agreed in principle with the ALRC's proposal and noted that the AHMAC Advisory Group may consider legal options 'on a case by case basis, when addressing concerns with particular gene patents'.[75] The Royal College of Pathologists of Australasia stated that it is 'imperative that government health departments take a more pro-active role in ensuring continuous and equitable access to genetic testing'.[76]

---

70 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003).

71 Ibid, 8.

72 Ibid, rec 1, 4, 7 and 10.

73 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 20–3.

74 South Australian Department of Human Services, *Submission P74*, 15 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

75 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004. The Department of Health and Ageing emphasised that compulsory licensing and Crown use should be a 'last resort'.

76 Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004.

The South Australian Department of Human Services stated that it could collaborate with other governments in monitoring patent applications, 'developing awareness at an early stage of particular patent applications that may be problematic to healthcare', and 'providing early warning signals to other healthcare agencies where a patent application has contentious ethical and social dimensions'.[77]

19.59 However, submissions highlighted the resource and political constraints on health departments in monitoring or challenging gene patents.[78] Queensland Health noted that the 'real issue is the time and cost involved' in pursuing existing legal options.[79] The Department of Human Services Victoria stated:

> The resources required and the necessity to gain agreement/approval means that it is very difficult to mount such a challenge in the current environment. This may be more easily achieved if the HGCA is established.[80]

19.60 DITR strongly objected to the idea of government departments challenging patent applications or granted patents. DITR submitted that, in general, the prospect of governments 'adopting a litigious approach towards industry is not considered an economically viable option and is incompatible with the broader government policy'.[81] DITR observed that, in any case, opposing particular gene patent applications would be ineffective in addressing potential adverse impacts.

> [I]t is impossible to make judgements at this stage on the potential adverse impact of a particular patent application on medical research, or, in particular, the cost-effective provision of healthcare. Opposing such applications has the potential to severely stifle industry R&D and commercial activity leading to product development in the biotechnology industry.[82]

Establishing specialist offices

19.61 DP 68 also proposed that the Commonwealth, States and Territories establish specialist offices within their health departments to monitor and manage intellectual property issues relating to genetic materials and technologies.[83] This proposal received a mixed response in submissions. Some supported the proposal.[84] Others expressed reservations, or opposed it, because it would require an undesirable duplication of

---

77 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

78 Ibid; Queensland Government, *Submission P103*, 22 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004.

79 Queensland Government, *Submission P103*, 22 April 2004.

80 Department of Human Services Victoria, *Submission P111*, 30 April 2004.

81 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

82 Ibid. DITR noted that only one in 2,500 patented pharmaceutical compounds reach the clinical trials stage.

83 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 20–4.

84 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.

resources, place an unnecessary burden on state and territory health departments, and not encourage a national approach to gene patenting and healthcare issues.[85]

19.62 In particular, submissions expressed concern about the resource implications of specialist offices, especially for the smaller States and Territories, and about the possible waste of scarce resources through duplication.[86] The Department of Health and Ageing observed that 'duplication of capabilities will need to be avoided in order to contain administrative costs and avoid overlaps in responsibilities'.[87]

19.63 Submissions proposed other, more centralised, means to ensure health departments can intervene effectively in the patent system. These generally involved one State taking a co-ordinating role, or relying on the establishment of the HGCA or some other new national advisory body.

19.64 The Department of Health Western Australia submitted that it was unlikely that Australia would need separate offices in each State and that, until the HGCA is established, it would be appropriate for one state health department to monitor gene patents, and all jurisdictions contribute towards the costs.[88] The South Australian Department of Human Services submitted that there were two options:

> devolving the role to the HGCA once it is established; [or] assigning the role to one well resourced state health department with support from all the other health departments. The second option may need to be considered as an interim measure until the HGCA is up and running. This would enable coordinated strategies to be adopted, with consistent national outcomes.[89]

19.65 Other submissions expressed a preference for leadership by a single national body, such as the HGCA, with responsibility for advising Commonwealth, state and territory health departments on gene patenting issues.[90] The New South Wales Health Department submitted:

---

85 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Queensland Government, *Submission P103*, 22 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

86 South Australian Department of Human Services, *Submission P74*, 15 April 2004; Ministry for Science and Medical Research New South Wales, *Submission P109*, 28 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004.

87 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

88 Department of Health Western Australia, *Submission P89*, 16 April 2004. It submitted that its Genomics Directorate could take on this role, as 'the best resourced public health genetics unit in Australia'. See also, Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

89 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

90 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Ministry for Science and Medical Research New South Wales, *Submission P109*, 28 April 2004.

> Although each state should retain the freedom to choose to undertake proceedings individually if it wished, as the states have common interests and goals and limited resources, and the cost of patent litigation is prohibitive, HGCA should assume responsibility for co-ordinating or raising the possibility of collective state action in relation to individual patents. A co-ordinated system would enable smaller states to mount challenges that they may not otherwise have the resources for, and ensure that larger states do not find themselves running 'test cases' while other states avoid contributing to the cost of litigation but enjoy any subsequent benefits.[91]

The role of the HGCA

19.66 DP 68 proposed that the HGCA should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. The HGCA would have a number of functions, including liaising with AHMAC, health departments, and other stakeholders about the advisability of legal intervention in the patents process, such as by challenging patents or patent applications or exercising the right of Crown use. Pending the establishment of the HGCA, it was proposed that AHMAC should perform these functions.[92]

19.67 These proposals were widely supported.[93] The involvement of the HGCA was seen as important in developing a national approach to gene patents and human health. The New South Wales Health Department observed that, given the Commonwealth's responsibility for patent law 'it is logical that it should be the HGCA, rather than each state government, that should monitor issues relating to human gene patents'.[94] Submissions also highlighted the importance of the HGCA having appropriate expertise, especially with regard to legal matters.[95]

19.68 Some submissions suggested that the HGCA should perform additional functions to those proposed by the ALRC. The South Australian Department of Human Services suggested that the HGCA should assume 'leadership in the setting up of an expert committee that would consider patent applications where ethical and social concerns are evident' and 'co-ordinate the economic and social evaluation of the impact of gene patenting on healthcare and research, with particular focus on access

---

91 New South Wales Health Department, *Submission P112*, 30 April 2004.

92 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposals 20–4 and 20–5.

93 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; New South Wales Health Department, *Submission P112*, 30 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

94 New South Wales Health Department, *Submission P112*, 30 April 2004.

95 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Human Genetics Society of Australasia, *Submission P76*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

and equity in healthcare provision'. The Department also suggested that there would be advantages in the HGCA being linked closely with 'a national body such as the NHMRC which has existing infrastructure for the provision of ethical advice'.[96]

19.69 The NHMRC suggested that the HGCA should, across much of the subject matter dealt with in this Report, provide 'an overarching monitoring and review role and, where appropriate, make recommendations to other bodies to implement particular strategies that may best be carried out by other agencies'. The NHMRC further stated that, 'while it is recognised that this would be a difficult role, it would ensure that following the completion of the ALRC Inquiry, the important issues surrounding gene patenting and human health do not simply "fall off the agenda"'.[97]

ALRC's views

19.70 There are overseas precedents for intervention by public sector authorities in patent processes. In May 2004, an Opposition Division of the European Patent Office decided to revoke a patent granted in early 2001 to Myriad Genetics Inc (Myriad), the University of Utah Research Foundation and the United States of America.[98] This patent covered methods and materials used to isolate and detect a human breast and ovarian cancer gene (BRCA1), some mutant alleles of which cause susceptibility to breast and ovarian cancer.[99] Oppositions to the patent were filed in October 2001 by a number of parties including the Assistance Publique–Hôpitaux de Paris, the Paris public hospitals authority.[100] The Belgian, Netherlands and Austrian Ministries for Health are among the bodies that have filed oppositions to another Myriad patent.[101]

19.71 The Myriad patent was revoked on the grounds that, in view of relevant prior art, it did not satisfy the requirements for patentability under European law, in particular as regards inventive step.[102] While the grounds for the decision were based on legal requirements for patentability, the reasons behind opposition to the patent were firmly based on concerns about the impact of Myriad's patents on healthcare provision and the conduct of genetic research.[103]

---

96 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

97 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

98 European Patent Office, '"Myriad/Breast Cancer" Patent Revoked after Public Hearing', *Press Release* (Munich), 18 May 2004.

99 EPO699754. Myriad's BRCA1 and BRCA2 patents are discussed further in Ch 20.

100 Other opponents included: the Institut Curie, the Institut Gustave-Roussy, the Belgian Society for Human Genetics and the Associazione Angela Serra per la Ricerca sul Cancro: European Patent Office, '"Myriad/Breast Cancer" Patent Revoked after Public Hearing', *Press Release* (Munich), 18 May 2004.

101 EPO705902. 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), 7.

102 European Patent Office, '"Myriad/Breast Cancer" Patent Revoked after Public Hearing', *Press Release* (Munich), 18 May 2004. This ruling may be challenged by the parties involved, in second-instance proceedings before an EPO technical board of appeal.

103 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).

19.72 There are other instances of similar intervention in the patent system by government authorities. For example, the Ontario provincial government, through the Attorney-General for Ontario, intervened in a court case involving genetically modified crops, in part because of concern about the impact of gene patents on healthcare and research.[104] In New Zealand, the Pharmaceutical Management Agency—the Crown entity responsible for managing New Zealand's equivalent of the PBS—has challenged the grant of patent claims directed to methods of medical treatment.[105]

19.73 The ALRC remains of the view that health departments should develop the capacity to monitor patent processes and intervene where appropriate. The ALRC does not suggest that in-house departmental capacity needs to be extensive or comprehensive. There should, however, be some 'horizon-scanning' capacity and a willingness to engage in a detailed way with specific issues of patent law and practice as they emerge. In some circumstances, health departments should be willing to challenge patents, or their exploitation, in the public interest. Patent holders will have an incentive to ensure that the exploitation of their patent rights does not prejudice public healthcare or medical research if they face the realistic prospect that their patents will face detailed scrutiny by government authorities.

19.74 It is often unclear—even to experts—what the ultimate impact of a patent will be at the time the patent is applied for or granted. The vast majority of patents are never exploited or enforced, and therefore will be unlikely ever to have adverse consequences on the provision of healthcare. It is often only many years after the grant of a patent that healthcare providers become aware of its existence and its possible implications. For example, the patents on methods of using non-coding DNA polymorphisms held by Genetic Technologies Limited were first granted in 1994, but it was eight or nine years before the possible implications of these patents for the provision of medical genetic testing became a focus of health department concern. Therefore, while opportunities to challenge the grant of patent rights exist at each stage of the patenting process,[106] it is much more likely that any intervention by health departments will be at the 'tail-end' of the process, namely involving the way in which granted patents are licensed or otherwise exploited.

19.75 Even assuming the existence of an active and well-resourced HGCA, the ALRC considers that health departments should develop the expertise and resources necessary to play a more active role in the patent system. Obtaining access to such specialist legal and policy advice and other relevant expertise may be easier for some jurisdictions than for others. In some contexts, further departmental expertise could be obtained through out-sourcing. Health departments should also be able to draw on expertise in

---

104 *Monsanto Canada Inc v Schmeiser* [2004] SCC 34; C Freeze, 'Ontario Seeks to Intervene in Biofoods Court Case', *The Globe and Mail* (Toronto), 9 October 2003, A5.

105 See, eg, *Pharmaceutical Management Agency Limited v The Commissioner of Patents & Ors* [2000] 2 NZLR 529.

106 See Ch 9.

other government departments and agencies to advise and assist them in dealing with intellectual property issues arising from gene patents. The ALRC does not wish to be prescriptive about how health departments should approach this challenge and no longer proposes that specialist offices should necessarily be established within health departments.[107]

19.76 However, consistently with the proposal made in DP 68,[108] the ALRC recommends that where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should consider whether to exercise any existing legal options to facilitate access to the inventions (Recommendation 19–3).

19.77 These options include challenging a patent application or granted patent by initiating proceedings to oppose a patent application,[109] requesting re-examination of a patent, or applying for revocation of a patent under the *Patents Act*; making a complaint to the ACCC where evidence arises of a potential breach of Part IV of the *Trade Practices Act*; exploiting or acquiring a patent under the Crown use and acquisition provisions of the *Patents Act*; or applying for the grant of a compulsory licence under the *Patents Act*. In some situations, it may also be appropriate for health departments or their agencies to continue using a patented invention without the authority of the patent holder where, after obtaining appropriate legal advice, the patent is considered to be invalid. Section 20 of the *Patents Act* expressly states that nothing in the Act or in the *Patent Cooperation Treaty*[110] guarantees that a patent is valid.

19.78 It has sometimes been suggested that government legal services policies may constrain the options open to health departments in dealing with patent issues. For example, the Legal Services Directions issued by the Commonwealth Attorney-General provide that the Commonwealth has an obligation to act as a 'model litigant', which requires it to act honestly and fairly in handling claims and litigation, including by 'paying legitimate claims without litigation' and 'not taking advantage of a claimant who lacks the resources to litigate a legitimate claim'.[111] Such policies do not prevent health departments from robustly protecting important public interests in healthcare provision or medical research by selective intervention in the patent system through use of existing legal mechanisms—especially since nothing in the *Patents Act* guarantees that a patent is valid, and that patents by their nature are open to

107 As proposed in Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 20–4.

108 Ibid, Proposal 20–3.

109 For example, as discussed in Ch 7, there may be some scope to argue that considerations of public policy may render some inventions 'generally inconvenient' in terms of the definition of 'manner of manufacture' in s 6 of the *Statute of Monopolies 1623*.

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

111 Commonwealth Attorney-General's Department, *Legal Services Directions (issued by the Attorney-General pursuant to s 55ZF of the Judiciary Act 1903)* (1999), Appendix B.

challenge.[112] The Legal Services Directions state that the obligation to act as a model litigant does 'not prevent the Commonwealth from acting firmly and properly to protect its interests'.[113]

19.79 In practice, the implications of gene patents are likely to affect all health departments in similar ways. To avoid duplication of activities, initiatives should be coordinated at a national level, where practicable. The ALRC considers that the establishment of the HGCA is vital to the capacity of the Australian healthcare system to respond in a rational and informed way to the issues raised by gene patents. Without a centralised source of expertise and legal policy guidance, there is a risk that future developments in gene patenting and enforcement by patent holders will create uncertainty and confusion among front-line healthcare providers.[114] While AHMAC may, in the interim, be able to perform some of the roles suggested for the HGCA, it is not currently equipped to do so in a systematic way.

19.80 The membership, structure and proposed functions of the HGCA, as recommended by the ALRC and AHEC, [115] make the HGCA potentially well equipped to perform the sort of monitoring and horizon-scanning work that is undertaken in the United Kingdom by the UK Human Genetics Commission and the Nuffield Council on Bioethics. There would also be synergy with the HGCA functions recommended in ALRC 96.[116]

19.81 Consistently with proposals made in DP 68,[117] the ALRC recommends that the HGCA should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. The HGCA should liaise with and provide advice to AHMAC, health departments and other stakeholders about ways to facilitate access to inventions; for example, by challenging patents or patent applications, or exercising the right of Crown use (Recommendation 19–4). Pending the establishment of the HGCA, AHMAC should establish a mechanism to perform these functions.

19.82 Neither the HGCA nor AHMAC are appropriate bodies to initiate and prosecute litigation involving patents in their own right because they have purely advisory and policy making roles. Health departments and other healthcare providers are the bodies most likely to incur liability for patent infringement where patented inventions are used

---

112 *Patents Act 1990* (Cth) s 20. See also Ch 9.

113 Commonwealth Attorney-General's Department, *Legal Services Directions (issued by the Attorney-General pursuant to s 55ZF of the Judiciary Act 1903)* (1999), Appendix B.

114 For example, on some accounts, confusion about validity and enforcement of the BRCA1 and BRCA2 patents associated with testing for pre-disposition to breast and ovarian cancer resulted in sudden cessation of some testing: Cancer Council New South Wales, *Submission P99*, 20 April 2004.

115 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1 to 5–9.

116 For example, one of the roles of the HGCA is to 'identify genetic tests that have particular concerns or sensitivities attached to them, and thus may require special treatment': Ibid, rec 5–3.

117 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 20–5 and 20–6.

in healthcare, or to take any financial advantage arising from a successful challenge to patent rights. Although strategies for patent negotiation or litigation could be coordinated at a national level, it is likely that an individual health department, hospital or medical research institute would take any necessary legal proceedings.

Recommendation 19–3 Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should consider whether to exercise any existing legal options to facilitate access to the inventions. These options should be exercised only with appropriate legal or patent attorney advice, and include:

(a) challenging a patent application or granted patent by initiating proceedings to oppose a patent application; requesting re-examination of a patent; or applying for revocation of a patent under the *Patents Act 1990* (Cth) (*Patents Act*) (see Chapter 9);

(b) making a complaint to the Australian Competition and Consumer Commission where evidence arises of a potential breach of Part IV of the *Trade Practices Act 1974* (Cth) (see Chapter 24);

(c) exploiting or acquiring a patent under the Crown use and acquisition provisions of the *Patents Act* (see Chapter 26); or

(d) applying for the grant of a compulsory licence under the *Patents Act* (see Chapter 27).

Recommendation 19–4 The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. The HGCA should liaise with and provide advice to AHMAC, health departments, and other stakeholders about ways to facilitate access to inventions, in accordance with Recommendation 19–3. Pending the establishment of the HGCA, AHMAC should establish a mechanism to perform these functions.

20. Gene Patents and Healthcare Provision

Contents

Introduction

20.1 Gene patents may have an impact on the development and provision of healthcare involving medical genetic testing and novel therapies such as gene therapy, the production of therapeutic proteins, and the use of stem cells. This chapter focuses on the impact of patent laws and practices on medical genetic testing. In Australia and overseas, concerns about the impact of gene patents on healthcare have most often been expressed in relation to this aspect of healthcare.[1] Issues relating to stem cells are addressed in Chapter 15.

20.2 There is a range of possible adverse consequences of existing patent laws and practices, including: monopoly control and the cost of testing; the quality of testing and medical practice; and innovation in the development of new or improved testing techniques. This chapter discusses these concerns and the ALRC's views in relation to them. The Inquiry has examined a number of questions about the impact of gene

1 A particular focus has been on gene patents over the BRCA1 and BRCA2 genes, mutations of which are implicated in the development of some forms of breast and ovarian cancer.

patents on various aspects of healthcare provision and submissions and consultations comprehensively addressed these issues. This chapter discusses the responses received by the Inquiry and the implications for reform of patent law and practice.

Medical genetic testing

Access to medical genetic testing

20.3 Medical genetic tests are generally ordered by medical practitioners. Some genetic testing may involve referral of the patient to a clinical geneticist, as well as to a genetic counsellor for pre-test and post-test counselling. Genetic testing for research purposes may also be conducted in concert with medical practitioners, who liaise with participating patients.

20.4 Individuals generally cannot obtain direct access to medical genetic testing by laboratories in Australia. At present, most medical genetic testing is provided through state and territory clinical genetics services and the public sector laboratories associated with these services,[2] and a medical practitioner must refer individuals to them. However, the range of genetic testing available to the public is likely to expand in the future.[3]

20.5 The Human Genetics Society of Australasia (HGSA) maintains a register of medical genetic tests that are available in Australasia and a list of the laboratories that provide them. According to the HGSA, there are presently around 220 medical genetic tests available from 44 laboratories across Australia.[4] Some genetic tests offered overseas are not available in Australia. Likewise, some types of tests offered in Australia are not available, or not widely performed, in other countries.

20.6 A range of factors, other than patent laws and practices, affect access to medical genetic testing. These include the cost of the test; whether the test is listed under the Medicare Benefits Scheme (MBS); the level of funding provided for testing by state and territory governments; technical and ethical standards; laboratory protocols and accreditation; and regulation of testing provided direct to the public (rather than through a medical practitioner).[5] The availability of a genetic test in a particular

---

2 Of those laboratories listed on the HGSA's website as offering diagnosis of genetic disorders, 81% were located in public hospitals (as at November 2002): D Nicol, 'The Impact of Patents on the Delivery of Genetic Tests in Australia' (2003) 15(5) *Today's Life Science* 22, 25.

3 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [11.50]–[11.63].

4 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html> at 16 June 2004. Not all tests are available from all laboratories. The register does not include newborn screening laboratories.

5 The ALRC and the Australian Health Ethics Committee (AHEC) have 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 related 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

laboratory may also reflect the research interests of that laboratory. For example, a laboratory that undertakes research into a particular genetic disease might also offer, as part of its research work, a diagnostic service for that disease

20.7 The availability of genetic testing in Australia may also depend on decisions about which tests are ethically acceptable,[6] and on a cost-benefit analysis of a particular test. Medical genetic testing is still a relatively slow and expensive process. However, the technology is advancing rapidly. The development of automated 'DNA chip' technology[7] may soon make it technically possible and financially practicable to test for numerous genetic mutations simultaneously in a single procedure.

Cost of medical genetic testing

20.8 As with other health services, access to medical genetic testing depends on the cost to consumers of testing procedures and on the rebates provided by public and private health insurers. The cost of genetic testing procedures varies, from less than $100 to more than $1,000, depending on a number of factors including the complexity and methodology of the testing procedure.[8]

20.9 In 2002, a report by the Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (OECD Report) noted that while economies of scale may help reduce costs in the long term, other factors are likely to increase prices. These include the need for better epidemiological and genetic population data; increasing regulatory costs; laboratory certification costs; increased needs for counselling; and liability costs.[9]

20.10 In Australia, depending on the test and the laboratory, testing may be free to the patient or fees may be charged.[10] In some cases, Medicare funds genetic testing. However, the MBS currently funds medical genetic testing under only six MBS items (see Chapter 19).

---

identify genetic tests, or categories of genetic tests, requiring special treatment in relation to procedures for ordering, testing and ensuring access to genetic counselling. See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 11–1, 11–5, 23–3.

6 For example, predictive testing of minors for late onset disorders (such as Huntington's disease) may be considered unethical.

7 Also known as 'gene chips', 'biochips' and 'DNA microarrays'.

8 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), [10.20]–[10.21].

9 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 71.

10 See D Nicol, 'The Impact of Patents on the Delivery of Genetic Tests in Australia' (2003) 15(5) *Today's Life Science* 22, Table 2.

Patents and medical genetic testing

20.11 Patents may be granted over isolated genetic material that has been separated from the human body or manufactured synthetically, provided the patent application satisfies the threshold tests for patentability.[11] Genetic sequences provide the basis for diagnostic tests—that is, mutations in genes can be detected by testing techniques based on knowledge of the genetic sequence. This may require the use of the genetic sequence of the normal gene, as well as that of the mutations.

20.12 Patents may also be granted over methods or products used in testing for mutations in a gene or genetic sequence. For example, a United States company, Myriad Genetics Inc (Myriad), holds patents internationally on isolated genetic materials associated with breast and ovarian cancer.[12] Myriad's patents also cover methods for predictive testing[13] and products and processes involved in its breast cancer predisposition test, which is called 'BRACAnalysis'. Similarly, another United States company, Bio-Rad Laboratories, holds gene patents associated with hereditary haemochromatosis, covering both isolated genetic materials and methods for testing.[14]

20.13 A patent that asserts rights to isolated genetic material per se may cover all uses of that material. These uses often include diagnostic or predictive testing for genetic conditions. For example, Myriad is said to have a dominant patent position covering the use of the BRCA1 genetic sequence for predictive testing relating to breast and ovarian cancer.[15] In other words, any technique for BRCA1 testing is likely to require use of Myriad's patents.

20.14 Patents may be granted on general methods for identifying genetic sequences, mutations or deletions in an individual's genetic sequence. For example, United States patents for the process known as polymerase chain reaction (PCR), which enables the DNA from a genetic sample to be reproduced in large quantities for testing, were granted to Cetus Corporation in 1989, and assigned to Roche Diagnostics in 1991.[16]

---

11 See Ch 6.

12 In the United States: US 5753441; in Australia: AU 691958, AU 686004 and AU 691331. As discussed below, Myriad has granted an exclusive licence in Australia and New Zealand relating to predictive genetic testing for breast and ovarian cancer to Australian biotechnology company Genetic Technologies Limited.

13 See M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20, 21–23.

14 In the United States: US 5705343; US 5712098; US 5753438; in Australia AU 733459. A list of United States and equivalent Australian patents associated with medical genetic testing can be found in D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, Table 1.

15 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 33.

16 A division of F Hoffmann-La Roche Ltd: Roche Diagnostics, *Roche Molecular Diagnostics Patents Portfolio*, <www.roche-diagnostics.com/ba_rmd/patent_list.html> at 16 June 2004. PCR is discussed further in Ch 3.

20.15 The subject of most concern has been patents that assert rights over isolated genetic material and the use of genetic sequences in diagnostic or predictive genetic testing. The ALRC understands that these patents generally include claims over isolated genetic materials containing sequences that code for proteins. Patents over methods for using 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 used to design primers for PCR assays. An analysis of Australian patents relating to medical genetic testing conducted by Dr John Abbott reveals a wide divergence in the scope of patent claims.

> At one extreme are patents which contain very broad claims, which may include all mutations within a gene (including those in intron, exons and regulatory sequence regions) … At the other extreme are patents which have only narrow claims, to include a specific mutation or a relatively small well-defined mutation set.[17]

20.16 As noted above, there are about 220 medical genetic tests available in Australia.[18] Many of these medical genetic tests, particularly the common ones, are likely to be subject to patents on isolated genetic materials. Dr Abbot's analysis, which correlated patent applications and granted patents with genetic tests available in Australia, identified 60 genetic tests that are subject to patent rights. This was said to suggest that 'at least 30% of the genetic tests offered are, or may be in the future, subject to patent protection'.[19]

Enforcement of patents and medical genetic testing

20.17 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.[20] Myriad has sought to enforce its patent rights against Canadian provincial health authorities.[21] In the United Kingdom, the Department of Health entered into an agreement with Rosgen Limited, the exclusive licensee of the Myriad patents in the United Kingdom. However, Rosgen went into liquidation and the Department of Health commenced negotiations with Myriad.[22] Myriad's patents led to

---

17 J Abbot, *Submission P83*, 16 April 2004.

18 J Brasch, *DNA Diagnosis of Genetic Disorders in Australasia*, Human Genetics Society of Australasia, <www.hgsa.com.au/labs.html> at 16 June 2004.

19 J Abbot, *Submission P83*, 16 April 2004. See also M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, Table 1.

20 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.

21 As of mid-2002, all but one Canadian province (British Columbia) had decided to continue to provide genetic testing that might infringe the patents granted to Myriad: R Gold, 'Gene Patents and Medical Access' (2000) 49 *Intellectual Property Forum* 20, 23. British Columbia resumed testing in February 2003: British Columbia Government Decision to Ignore Myriad Patent', *CanWest News Service*, 16 February 2003.

22 M Llewelyn, *Intellectual Property Rights on Public Healthcare: A UK Response* (2003).

calls for patent law reform in France and Canada.[23] As discussed in Chapter 19, in May 2004, an opposition division of the European Patent Office decided to revoke Myriad's BRCA1 patent in Europe, in view of relevant prior art.[24]

20.18 In the United States, research indicates that gene patent holders are actively enforcing their rights against laboratories.[25] In contrast, the results of a survey of Australian laboratories that perform medical genetic testing found that there was 'little indication that holders of patents related to disease genes were actively enforcing their patents against Australian genetic test laboratories'.[26]

20.19 Consultations confirmed that, while there is a high degree of concern about the potential impact of patents over isolated genetic materials on public sector laboratories, enforcement by patent holders has been limited.[27] The ALRC understands that Australian public sector laboratories currently do not pay licence fees for the use of isolated genetic materials in medical genetic testing, and generally have not been approached by patent holders seeking to enforce their rights over such materials. The situation is different with respect to gene patents over genetic technologies, such as PCR, where royalties are commonly paid, often as part of the purchase price of equipment or consumables.[28]

20.20 There has been much conjecture about the future enforcement of gene patents against public sector laboratories. Much of this conjecture has concerned patents held by Australian biotechnology company Genetic Technologies Limited (GTG). There are two sets of patents involved. The first set is associated with testing for pre-disposition to breast and ovarian cancer (the BRCA patents). The second set of patents relates to methods of using non-coding DNA polymorphisms (the non-coding patents).[29]

20.21 In May 2003, Myriad granted GTG an exclusive licence in Australia, New Zealand and South East Asia relating to predictive genetic testing for breast and ovarian cancer using the BRCA patents.[30] GTG has stated publicly that the rights it has obtained from Myriad for breast cancer testing 'will not be enforced against other

---

23 See R Gold, 'Gene Patents and Medical Access' (2000) 49 *Intellectual Property Forum* 20, 23.

24 European Patent Office, '"Myriad/Breast Cancer" Patent Revoked after Public Hearing', *Press Release* (Munich), 18 May 2004.

25 M Cho and others, 'Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services' (2003) 5 *Journal of Molecular Diagnostics* 3.

26 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 201.

27 Department of Human Services Victoria, *Consultation*, Melbourne, 3 September 2003; New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003.

28 Issues relating to the enforcement and licensing of gene patents are also discussed in Ch 22.

29 Sometimes referred to as GTG's 'intron sequence patents'.

30 Genetic Technologies Limited, 'Genetic Technologies and Myriad Genetics Announce Strategic Licensing Agreement', *Press Release*, 28 October 2002, <www.gtg.com.au/Announcements2002.html>. As part of this arrangement GTG granted Myriad a non-exclusive licence for the use of GTG's non-coding patents.

health service providers in Australia and New Zealand'.[31] In July 2003, GTG reiterated that it did not intend to enforce the BRCA patents and confirmed that it has allowed the existing public hospital cancer genetics laboratories in both Australia and New Zealand to continue to perform tests on the BRCA genes unhindered.[32]

20.22 The position is different with regard to enforcement of the non-coding patents. In March 2003, GTG advised public sector laboratories in Australia and New Zealand that they would need to negotiate licences in relation to its non-coding patents.[33] GTG claimed that its non-coding patents may be infringed by medical genetic testing for a range of genetic conditions, including cystic fibrosis, Duchenne muscular dystrophy, Friedreich's ataxia, fragile X syndrome, haemophilia, myotonic dystrophy and prothrombin (Factor II). In the United States, Applera Corporation, is facing an infringement action for refusing to obtain a licence to use GTG's non-coding patents for, among other things, a diagnostic test for cystic fibrosis.[34]

20.23 There is growing concern in Australia about the possibility that gene patent holders and licensees might enforce their patents against medical genetic testing laboratories. However, actual enforcement activity remains more limited than in the United States. Dr Dianne Nicol and Jane Nielsen comment:

> Could Australian testing laboratories face demands for licence fees from a number of different patent holders in the future? The small size of the Australian market suggests that it may not be worthwhile for foreign companies to pursue Australian laboratories. In addition, most laboratories are in public hospitals and many do not charge for their services, further suggesting that there may be little financial incentive in targeting them.[35]

The need for patents on medical genetic testing

20.24 Patent law creates an incentive to invest in the research and development of new products by providing a limited monopoly on the manufacture, use or sale of the patented invention. In the context of medical genetic testing, patent rights may be justified if they encourage investment in research that leads to the development of new, clinically useful, medical genetic tests.

20.25 Such an incentive may be required for the development of some medical genetic tests.[36] 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

---

31 Genetic Technologies Limited, 'Genetic Susceptibility Testing: A Third Progress Report', *Press Release*, 22 May 2003, <www.gtg.com.au/Announcements.html>.

32 Genetic Technologies Limited, 'Letter from GTG to Medical and Scientific Colleagues', *Press Release*, 21 July 2003, <www.gtg.com.au/Announcements.html>.

33 See also Genetic Technologies Limited, 'Licensing the "Non-Coding" Patents: A Third Report to the ASX', *Press Release*, 2 April 2003, <www.gtg.com.au/Announcements.html>.

34 Z Moukheiber, 'Junkyard Dogs', *Forbes Magazine*, 29 September 2003.

35 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 203.

36 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 51.

reliable and clinically useful medical genetic test. An empirical study in 2003 of medical biotechnology patenting by Nicol and Nielsen (Nicol–Nielsen Study) found that some individuals who work in public sector laboratories have a positive view of the impact of patents on medical genetic testing, depending on what the patents are and how they are exploited.[37]

20.26 It has been suggested that patent law incentives may not be as necessary to the development of genetic tests as they are to the development of other therapeutic goods, notably drugs. Professor Lori Andrews has argued that, while proponents of gene patents have tried to justify such patents by reference to arguments in favour of patenting drugs, drug patenting is not the appropriate analogy.[38] A study of clinical laboratories in the United States found that laboratories are able to translate published data into clinical tests quickly, without the incentive provided by patents.[39] The study suggested that patents are not critical to the development of genetic testing into a commercially viable service.[40]

20.27 Some submissions to the Inquiry doubted that patents are necessary to the development of new genetic tests.[41] The HGSA noted that many genetic tests are not expensive to develop and, for some tests, the costs involved in determining the gene sequence 'are not the issue'. Instead, the real expense 'relates to the cost of developing the platform that is used to perform the test eg sequencing or array technology or meeting regulatory requirements prior to marketing'.[42] Other submissions were clear about the importance of patents to genetic testing research and development, and focused on the role of patents in facilitating the development of research results into usable tests or therapeutics.[43]

Impact of gene patents on medical genetic testing

20.28 There has been worldwide concern about the possible adverse consequences of existing patent laws and practices for the provision of healthcare. The following section describes concerns about the impact of patent laws and practices on medical

37 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 202.

38 L Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law & Policy* 65, 77–79.

39 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.

40 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.

41 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003.

42 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

43 GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Queensland Government, *Submission P57*, 5 January 2004; AusBiotech Ltd, *Submission P58*, 7 November 2003.

genetic testing and asks about the extent to which these concerns apply to the Australian healthcare system. Many of these concerns are traceable to concerns about monopoly control of genetic testing. The section thus begins by discussing monopoly control and then examines the effects of this on: the cost of medical genetic testing; access to public sector testing and related services; access to genetic counselling; the quality of medical genetic testing; the professional relationships between medical practitioners and laboratory scientists; and the further development of medical genetic testing.

Monopoly control and competition

20.29 Where a 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. The patent holder (or an exclusive licensee) may control a particular genetic test by licensing a single service provider or a number of laboratories may perform the test.

20.30 Particular concerns have been expressed about exclusive licensing of gene patents relating to genetic testing.[44] Exclusive licensing occurs where a patent holder grants exclusive rights to one licensee to exploit the patent. The exclusive licensee may require that all testing, regardless of its geographical origin, be performed at a single laboratory. At least in the United States, exclusive licensing of gene patents for medical genetic testing is common[45]—the BRCA patents being a notable example, where all testing must be done by Myriad.

20.31 Although a patent grants a patent holder the right to exclude or control the exploitation of a patented invention by others for the term of the patent, patents do not inevitably lessen competition. Patents may promote competition if the goods and services created pursuant to a patent compete with other like goods and services. The relationship between patent and competition law is discussed in Chapter 24.

20.32 Some submissions stated that, even if patent and other intellectual property laws favour the development of monopolies in medical genetic testing, this is not necessarily detrimental to society because of the beneficial effects on investment in research and the development of testing.[46]

20.33 Patent law is only one of many factors that may contribute to monopolistic behaviour.[47] The OECD Report noted that licence exclusivity may be necessary to make a genetic testing service economically viable, depending on the market and the

---

44 See the discussion of patent licensing in Ch 22.

45 J Merz and others, 'Diagnostic Testing Fails the Test' (2002) 415 *Nature* 577, 578.

46 GlaxoSmithKline, *Submission P33*, 10 October 2003; A McBratney and others, *Submission P47*, 22 October 2003.

47 A McBratney and others, *Submission P47*, 22 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

rarity of the disease.[48] In Australia, GTG stated that the size of markets in medical genetic testing will be the most significant factor in determining their structure.[49]

20.34 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'.[50]

20.35 Many submissions focused on the possible adverse effects of monopoly genetic testing on healthcare.[51] The South Australian Government stated that the 'one-to-one' relationship between gene patents and disease, which is not the case for other biotechnology patents, poses particular problems:

> An in-house test which is an alternative to a patented test can be used legally as it is not subject to licence or royalty fees provided the method used is different from any patented method. However, where a gene is subject to a patent, low cost in-house tests cannot be legally used without compensating the patent holder.[52]

20.36 The Royal College of Pathologists of Australasia (RCPA) emphasised that the RCPA, the HGSA and the American College of Medical Genetics all recommend that 'diagnostic genetic tests' be 'broadly and non-exclusively' licensed.[53] The RCPA submitted that monopolistic genetic testing is 'fundamentally wrong' because of its effects on equitable access to healthcare and innovation in testing.[54]

20.37 Many other submissions expressed concerns about patents promoting medical genetic testing monopolies and the consequences for healthcare.[55] Specific concerns about the effects of patents on medical genetic testing, including those said to derive from monopoly testing, are discussed in more detail throughout this chapter.

---

48 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 71.

49 Genetic Technologies Limited, *Submission P45*, 20 October 2003.

50 I Walpole and others, 'Human Gene Patents: The Possible Impacts on Genetic Services Health Care' (2003) 179 *Medical Journal of Australia* 203, 203.

51 Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

52 South Australian Government, *Submission P51*, 30 October 2003.

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

54 Ibid.

55 R Edson, *Submission P9*, 23 September 2003; Children's Cancer Institute Australia for Medical Research, *Submission P13*, 30 September 2003; D McAndrew, *Submission P14*, 30 September 2003; Australian Huntington's Disease Association (NSW) Inc, *Submission P27*, 1 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Cancer Foundation of Western Australia Inc, *Submission P34*, 10 October 2003; A Bankier, *Submission P19*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Genetic Support Council WA (Inc), *Submission P59*, 7 November 2003.

Cost of medical genetic testing

20.38 The cost of medical genetic testing is an important factor affecting access to testing. One consequence of patent rights is that genetic tests may be more expensive. The extent of any increased cost will depend on many factors, including the licensing model used by the patent holder.

20.39 Submissions and consultations reflected concern about the impact of monopoly control on the cost of genetic testing to patients and the healthcare system, and about the effect of cost in limiting access to medical genetic testing.[56]

20.40 The BRCA patents have often been used to illustrate concerns about the future cost of genetic testing in Australia.[57] However, as discussed in DP 68,[58] increases in the cost of BRCA testing attributable to patent rights have not occurred because GTG—the exclusive licensee of the BRCA patents in Australia—has not sought to enforce its patent rights against public sector laboratories. In any case, GTG is able to offer BRCA testing conducted in its Melbourne laboratory for a lower price than that charged by Myriad in the United States, and it anticipates that investment in new robotic technology will reduced future costs further.[59]

20.41 A number of submissions also expressed concern about increases in the cost of medical genetic testing attributable to future enforcement of GTG's non-coding patents.[60] As discussed above, the position with regard to the enforcement of these patents remains uncertain.

Access to public sector testing and related services

20.42 Concerns have also been expressed about the implications of patents for other aspects of access to testing and related healthcare services, such as clinical advice and genetic counselling. In submissions and consultations, access issues were most often

---

56 Cancer Council New South Wales, *Submission P1*, 5 June 2003; Cancer Voices NSW Inc, *Submission P7*, 16 September 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; D McFetridge, *Submission P23*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Australian Huntington's Disease Association (NSW) Inc, *Submission P27*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; South Australian Government, *Submission P51*, 30 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

57 See, eg, Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 11.

58 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [21.66]–[21.68].

59 Genetic Technologies Limited, *Consultation*, Melbourne, 5 September 2003.

60 New South Wales Health Department, *Submission P37*, 17 October 2003. Such concerns were frequently raised in consultations: New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003; Department of Health and Ageing, *Consultation*, Canberra, 24 September 2003.

raised in relation to the viability of public sector genetic testing and related services.[61] It was said that monopoly provision of medical genetic testing would have adverse ramifications for the public health system:

> by enabling some health providers with sole control over testing for several genetic conditions to dominate the market. Equally it places the public health system at a significant disadvantage in terms of providing genetic testing as part of a subsidised health care system.[62]

20.43 The Department of Health Western Australia stated that, where genetic testing monopolies exist 'publicly funded genetic services will still be required to provide other non-patented and thus not commercially attractive tests, as well as counselling and clinical services, compromising their budgetary capacity to maintain viability and expertise'.[63]

20.44 A specific focus of concern was the possible diversion of expertise from public sector testing facilities.[64] 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 leaving public laboratories less able to provide a full range of services.[65]

20.45 It has been stated 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.[66] Further, in the event that an exclusive licensee for a genetic test were to cease operations, Australia could be left without an expert testing service, at least for a time.[67]

20.46 A different perspective is that, in many other areas of medical and pathology practice, there is a mix of public and private sector provision, and personnel move freely from one sector to another. While the development of new services in the private

---

61 Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

62 Cancer Council Australia, *Submission P25*, 30 September 2003. See also Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

63 Department of Health Western Australia, *Submission P53*, 3 November 2003.

64 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

65 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 6.

66 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001), 4.

67 Ibid, 4. See also Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003.

sector may have short term negative effects, it may ultimately deepen the pool of expertise available to the public system.[68]

20.47 It is clear that most concern about access is predicated on the existence of private sector monopolies on genetic tests, supported by patent rights. The possibility of an expanded role for private medical genetic testing services did not attract criticism in itself. There is acceptance that some level of private provision is inevitable, and may even be desirable.[69] In the future, there could be advantages in state clinical genetics services sub-contracting genetic testing to private providers, particularly if there are benefits in cost or speed of reporting.[70]

20.48 Nor was there any fundamental objection to the idea that individuals who may not qualify for public testing services should be able to seek private testing, if they so wish.[71] However, private service provision should not be at the expense of accepted standards, especially those relating to the interpretation of test results and the provision of genetic counselling.[72]

Access to genetic counselling

20.49 State and territory genetics services provide comprehensive services in relation to diagnosis, testing, counselling and the ongoing management of genetic conditions, through medical practitioners, genetic counsellors and social workers. Concerns have been expressed that 'commercial testing might [dissociate] genetic testing from proper screening and genetic counselling'[73] and have consequences in relation to access to genetic counselling.[74] In particular, it has been suggested that exclusive licensing of genetic tests may disrupt publicly funded clinical genetic services—which closely link

68 Genetic Technologies Limited, *Consultation*, Melbourne, 5 September 2003.

69 See, eg, Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003.

70 Department of Human Services Victoria, *Consultation*, Melbourne, 3 September 2003; New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003. GTG pointed to existing problems in some States with turnaround times for BRCA1 and BRCA2 testing: Genetic Technologies Limited, *Consultation*, Melbourne, 5 September 2003. The Queensland Government noted that 'Genetic testing monopolies already exist with State laboratories because of enterprise bargaining and funding arrangements. Due to these constraints, state laboratories must do the test regardless of whether other laboratories are capable of doing the tests more efficiently or cost effectively': Queensland Government, *Submission P57*, 5 January 2004.

71 For reasons of funding and testing capacity, public clinical genetics services may restrict access to genetic testing to individuals who fit certain criteria, for example, based on family history or clinical indications.

72 Cancer Councils of NSW and Australia, *Consultation*, Sydney, 8 September 2003; New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003.

73 See M Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20, 26.

74 The role and importance of genetic counselling is described in Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 23.

medical advice, genetic testing and counselling—by requiring that the testing component be performed elsewhere.[75]

20.50 However, others suggested that private sector testing will not necessarily affect access to related medical and other services.[76] Rather, this will depend on the model of service delivery—for example, if a private laboratory conducts the genetic testing component of services provided by a public clinical genetics service there is no reason why other elements of healthcare delivery need be affected.

20.51 The ALRC agrees there is no real basis for claims that private genetic testing services will necessarily lead to substandard service delivery. All medical genetic testing, like other forms of health and pathology service, is subject to regulation and standards, including the national laboratory accreditation scheme,[77] standards and guidelines issued by the National Pathology Accreditation Advisory Council, and ethical and other standards applying to health professionals.[78] If there are inadequacies in service delivery, mechanisms exist to deal with them.

Quality of testing

20.52 Concerns have also been expressed about the possible impact of patent laws and practices on the quality of genetic testing and associated medical practice,[79] including in relation to the technical quality and quality assurance of genetic testing.

20.53 It has been claimed that patent laws and practices may prejudice medical practice by preventing the use of a more appropriate test for the same genetic condition.[80] Laboratories in Australia use a range of methodologies for medical genetic testing.[81] Submissions suggest that exclusive licensing of medical genetic testing may constrain laboratories from choosing the most clinically appropriate test.[82] For

---

75 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 11; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Breast Cancer Action Group NSW Inc, *Submission P8*, 19 September 2003.

76 New South Wales Genetics Service, *Consultation*, Sydney, 9 September 2003.

77 Administered by the National Association of Testing Authorities Australia and the RCPA, and based on policy guidance provided by the National Pathology Accreditation Advisory Council: See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), Ch 11.

78 In ALRC 96, the ALRC and AHEC recommended a number of reforms to enhance laboratory accreditation standards to promote high ethical standards in genetic testing, to provide an enhanced level of oversight for ordering genetic tests and ensure better access to genetic counselling: see Ibid, rec 11–1 to 11–4; rec 23–1; rec 23–3.

79 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 19–20.

80 J Merz, 'Disease Gene Patents: Overcoming Unethical Constraints on Clinical Laboratory Medicine' (1999) 45 *Clinical Chemistry* 324, 327.

81 Department of Human Services Victoria, *Consultation*, Melbourne, 3 September 2003; South Australian Department of Human Services, *Consultation*, Adelaide, 15 September 2003.

82 Department of Health Western Australia, *Submission P53*, 3 November 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Western Australian Department of

example, the HGSA contended that medical practice may be adversely affected where patents and licensing operate to limit testing to technologies that detect 'only a proportion of mutations in a gene'.[83] The RCPA submitted:

> Ultimately, commercial considerations will dictate priorities and products, not the public need. Patents grant companies the ability to dictate what kind of test may be done (eg sequencing instead of less sensitive but substantially less costly screening methods such as dHPLC or protein truncation tests) or limit the condition in which testing may be done (eg refusing to perform prenatal testing for late-onset diseases).[84]

20.54 Submissions also noted quality assurance as a concern.[85] External quality assessment schemes allow participating laboratories to test the reliability and accuracy of their testing methods by testing, on a scheduled basis, material of known or agreed composition.[86] Such programs may be difficult to establish where only one or a small number of laboratories perform genetic testing.

20.55 The HGSA submitted that restricted licensing can 'make independent assessment of quality assurance more difficult, by reducing relevant independent expertise'.[87] Dr Suthers stated that testing monopolies can result in the loss of quality assurance programs because a key component of the quality assurance program in any laboratory is comparison of test results between laboratories.[88]

Professional relationships

20.56 Another issue, which is related to genetic test quality, is the relationship between medical practitioners and laboratory scientists. It has been claimed that monopoly control of genetic testing may have adverse effects on medical practice by changing the interface between medical practitioners, who order genetic testing for their patients, and those who conduct the tests.[89] The HGSA has stated that genetic testing monopolies:

Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003; Queensland Government, *Submission P57*, 5 January 2004.

83 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

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

85 Ibid; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; G Suthers, *Submission P30*, 2 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003.

86 National Coordinating Committee for Therapeutic Goods In Vitro Diagnostic Device Working Group, *A Proposal for a New Regulatory Framework for In Vitro Diagnostic Devices: Discussion Paper* (2003), 42.

87 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

88 G Suthers, *Submission P30*, 2 October 2003.

89 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Clinical Genetics Service, *Consultation*, Adelaide, 16 September 2003.

> 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.[90]

20.57 Communication between practitioners and scientists develops mutual expertise, particularly in interpreting scientific information, and this is important in providing best practice care.[91] For example, clinicians often provide relevant patient history and results from earlier investigations to the testing laboratory, in many cases directly to the scientists performing the testing.[92] The interpretation of results may 'suffer from lack of discussion regarding abnormalities in testing the accuracy of the test results'.[93] The RCPA submitted that genetic testing should be performed by 'laboratories with close links to clinical genetics services'.[94]

20.58 However, there may be no reason why good communication cannot be developed between medical practitioners and private laboratories operating under an exclusive licence to use a particular genetic testing technology. GlaxoSmithKline noted that 'public laboratories do not have a monopoly on good customer service'.[95]

Further development of medical genetic testing

20.59 It has been suggested that where patents contain claims to all or most conceivable diagnostic tests related to a particular gene, there might be less incentive to develop new or improved tests.[96] Innovation in medical genetic testing at the clinical and laboratory level may be hindered.[97]

20.60 Concerns about the development of new tests were highlighted in the OECD Report: 'When clinical testing centres are also research laboratories investigating the genetic basis of a disease, the inability to obtain a licence impedes research and can mean that higher-quality tests may not emerge'.[98]

20.61 One reason for this is that genetic sequences covered by gene patents are typically the single most prevalent sequence carried by healthy individuals. Medical genetic testing is directed at identifying mutations in this sequence that are associated with disease. Medical practitioners with access to family pedigrees discover many such mutations over time. It this way, medical genetic testing is routinely subject to

---

90 Human Genetics Society of Australasia, *HGSA Position Paper on the Patenting of Genes* (2001).
91 Australian Health Ministers' Advisory Council Working Group on Human Gene Patents, *Final Draft Report of the AHMAC Working Group on Human Gene Patents* (2001), 19.
92 Ibid, 19.
93 Ibid, 20.
94 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
95 GlaxoSmithKline, *Submission P33*, 10 October 2003.
96 See, eg, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
97 The ways in which gene patents may restrict the conduct of research are discussed further in Ch 12.
98 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 18.

incremental improvement as more is learned about the genetics of a disease.[99] It has been suggested that 'limiting the number of laboratories permitted to do the testing could slow this incremental process of discovery'.[100]

20.62 A recent study of clinical laboratories in the United States, based on published data about disease-gene associations and information sharing between laboratories, concluded that gene patents and licences have inhibited the development of new genetic tests for clinical use.[101]

20.63 Submissions expressed negative views about the impact of gene patents on the development of new or improved genetic tests.[102] In particular, submissions and consultations highlighted constraints on the conduct of clinical research where a patent holder has exclusive rights to test for a genetic disease.[103] Dr Suthers expressed concern about patent holders or exclusive licensees maintaining private holdings of population genetic data compiled from test results. This, it was claimed, may constrain the further development of tests on the gene, resulting in genetic tests of limited utility and efficiency, and lack of data about genetic variants in populations.[104] Similarly, the HGSA stated that gene patents and restricted licensing may:

- enable the licence holder to control details of the variations detected in a given gene, enhancing the monopoly by controlling the means of interpreting test results;
- slow the accumulation of information about variations in genes and the relationship of the variations to the disorder in question, by reducing the number of laboratories providing testing; and
- restrict rapid publication of information about variations in the gene and their relationship to the disorder in question.[105]

20.64 Particular concerns were expressed about the barriers gene patents may pose for the development of new forms of comprehensive genetic testing using DNA microarrays, which are capable of testing thousands of genes at one time. The Medical

---

99 R Eisenberg, 'Why the Gene Patenting Controversy Persists' (2002) 77 *Academic Medicine* 1382, 1382–1383.

100 Ibid, 1383.

101 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.

102 Australian Health Ministers' Advisory Council, *Submission P49*, 23 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; Breast Cancer Network Australia, *Submission P22*, 30 September 2003; Department of Health Western Australia, *Submission P53*, 3 November 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

103 G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Government, *Submission P51*, 30 October 2003; Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003.

104 G Suthers, *Submission P30*, 2 October 2003.

105 Human Genetics Society of Australasia, *Submission P31*, 3 October 2003. See also Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.

Genetics Elective Group of the University of Newcastle stated that such testing will be a viable diagnostic tool in the near future but the need for multiple licences may make this development economically impractical.[106]

20.65 Other submissions contested the idea that gene patents adversely affect the development of new or improved tests[107] and noted that concerns were 'founded on the assumption that the existence of the patent necessarily limits the numbers of users'—which was not necessarily the case.[108] More recognition, it was said, should be given to the likelihood that gene patenting might 'improve medical practice by encouraging the investment needed to develop improved medical genetic tests'.[109] Those expressing concern about patents hindering innovation in genetic testing sometimes disregard the incentive that patents provide to develop new tests. The likelihood that any single gene patent could be enforced over all conceivable testing methodologies relating to a gene may also be overstated.

Impact of gene patents on novel genetic therapies

20.66 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 use of stem cells and the production of therapeutic proteins. However, as these therapies remain largely experimental, gene patents have as yet had little practical impact.[110]

20.67 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 constrain the development of gene therapy in Australia. Further, if the gene is patented, treatment for gene therapy may depend, at least in part, on the availability of a licence from the patent holder.

20.68 Gene patents may also affect the use of therapeutic proteins in healthcare.[111] 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.[112]

---

106 E Milward and others, *Submission P46*, 20 October 2003.

107 GlaxoSmithKline, *Submission P33*, 10 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003.

108 GlaxoSmithKline, *Submission P33*, 10 October 2003.

109 Ibid.

110 As at June 2004, the Gene and Related Therapies Research Advisory Panel (GTRAP) of the National Health and Medical Research Council had approved 14 gene therapy studies: National Health and Medical Research Council, *Australian Gene Therapy Studies Approved by GTRAP*, <www.health.gov.au/nhmrc> at 16 June 2004. The possible therapeutic uses of stem cells are discussed in Ch 15.

111 Drugs based on proteins produced by the body include beta interferon and Epo (erythropoietin). Beta interferon is used to treat multiple sclerosis. Epo is used as a treatment for persons with certain types of anaemia.

112 Nuffield Council on Bioethics, *The Ethics of Patenting DNA* (2002), 63.

20.69 Gene patents may also be relevant to the use of stem cells in medical treatment (see Chapter 15). The Ontario Government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*, has commented that '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'.[113]

20.70 While patent rights are essential in encouraging investment in the development of novel genetic therapies, the RCPA submitted that the 'broad scope of many patents on genetic material' is likely to discourage such investment.[114]

20.71 Dr McBratney and others submitted that patenting these kinds of therapeutics raises the same kind of issues as the patenting of drugs or medical methods generally and should be treated no differently.[115] The Department of Industry, Tourism and Resources observed that restricting gene patenting would be likely to have a negative impact on capital inflows into Australia, which may deny the community the benefit of new gene based therapies.[116] Similarly, GlaxoSmithKline referred to the major investment needed to develop new treatments based on genetics and emphasised that patents are no less essential to the development of these forms of treatment than they are in relation to pharmaceutical development.[117]

ALRC's views

20.72 The ALRC remains of the view that there is little evidence to date that gene patents and licensing practices with respect to genetic testing have had any significant impact on the cost of healthcare provision in Australia. Similarly, there is no firm evidence of any adverse impact, as yet, on access to medical genetic testing, the quality of such testing, or clinical research and development.

20.73 Expressions of concern about gene patents—from health authorities, health consumer groups, health professionals and others—have generally been based on assumptions about the future development of the market in medical genetic testing and about the intentions of patent holders with regard to the exploitation and enforcement of gene patents. In particular, they have been based on assumptions that patent holders will use exclusive licences as their business model and that exclusive licensees will charge monopoly prices.

20.74 In this regard, health sector concerns in Australia have been influenced, directly or indirectly, by overseas experience of the patent enforcement activities and business model of Myriad, with respect to its BRCA patents. The extent to which this

---

113 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), 39.
114 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003.
115 A McBratney and others, *Submission P47*, 22 October 2003.
116 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.
117 GlaxoSmithKline, *Submission P33*, 10 October 2003.

experience may be replicated in relation to other gene patents is uncertain. While the behaviour of Myriad is not an isolated example of 'rogue behaviour' by gene patent holders,[118] it remains uncommon. The extent to which such business models will be adopted in Australia is unclear and it is problematic to extrapolate from the experience in other countries, like the United States, which have very different healthcare systems.

20.75 Concerns about the cost of, and access to, medical genetic testing are also influenced by broader concerns about Australian healthcare policy, that are applicable to all new medical technologies. These concerns include the future of Medicare, the respective roles of tax-financed healthcare and private health insurance, and the mix of public and private healthcare provision generally.[119]

20.76 One view of the impact of gene patents is that the problem, if any, does not lie in the patenting of genetic material and technologies but in the way in which such patents may be commercially exploited. While some individuals and organisations involved in the healthcare sector hold 'in principle' objections to the patenting of isolated genetic materials,[120] it is the level of future royalties or licence fees, and how these may be funded, that provokes most anxiety within this sector. For example, the South Australian Department of Human Services noted that:

> no one can predict whether patent holders might impose exorbitant licence fees in the future … Given that licence fees that well exceed the entire budgets of Australian testing laboratories have been sought overseas in the recent past, it is possible that just one such challenge could devastate genetic testing services across Australia.[121]

20.77 Leaving aside issues of cost, there is no doubt that some people in the Australian public health sector harbour genuine and serious concerns about the implications of gene patents for the quality of healthcare provision. In particular, there are arguments, discussed at length in this chapter, suggesting that the exclusive licensing of patents relating to medical genetic testing may have adverse consequences, depending on the behaviour of licensees.

20.78 As medical genetic tests are developed for more common diseases—for example in relation to attention deficit hyperactivity disorder, diabetes or osteoarthritis—commercial opportunities and pressures can be expected to increase and lead to more intense enforcement of gene patent rights. The nature of any such trend, and whether existing legal mechanisms such as those in patent law and competition law may be used effectively to address problems for healthcare, is not certain. What is clear is the need for healthcare providers and healthcare policy makers to be proactive in responding to problems as they emerge.

---

118 Ontario Ministry of Health and Long-Term Care, *Consultation*, Toronto, 7 May 2004.
119 A McBratney and others, *Submission P47*, 22 October 2003.
120 See, eg, Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.
121 South Australian Department of Human Services, *Submission P74*, 15 April 2004.

20.79 Elsewhere in this Report, the ALRC has made recommendations intended to ensure that any such problems are identified at an early stage, for example, through economic evaluation of genetic medical technologies and examination of the financial impact of gene patents, and through the monitoring activities of the Human Genetics Commission of Australia. There are also existing mechanisms through which problems might be addressed should they emerge. For instance, there are ways in which Commonwealth, state and territory governments, as funders and purchasers of healthcare services, may be able to influence the way in which patent holders exploit or enforce patent rights (Chapter 19).

20.80 Importantly, in Chapter 19 the ALRC recommends that where particular gene patents have an adverse impact on the provision of healthcare, Commonwealth, state and territory health departments should consider whether to exercise existing legal options to facilitate access to the inventions. These include rights of Crown use and compulsory licensing under the *Patents Act 1990* (Cth) (*Patents Act*)[122] and recourse to laws dealing with anti-competitive conduct.[123] Patent holders should be on notice that, if patent rights are exploited in a manner that threatens the public interest in cost-effective and high quality healthcare, health authorities may take action.

20.81 Finally, other recommendations are intended to address possible adverse effects of gene patents on healthcare provision. These include the development of new Australian Research Council and National Health and Medical Research Council principles and guidelines on intellectual property management for publicly funded research (see Chapter 11); changes to laws and practices concerning patentability, which are relevant to some gene patents (Chapters 6 and 8); enacting a new experimental use exemption (Chapter 13); and amendments to clarify the Crown use and compulsory licensing provisions of the *Patents Act* (Chapters 26 and 27).

122 See Ch 26–27.
123 See Ch 24.

21. Medical Treatment Defences

Contents

Introduction

21.1 Chapter 20 examined the impact of gene patents on the provision of healthcare, and concluded that it has not been established that gene patents have had any significant adverse impact, to date, on healthcare provision in Australia. However, there is clear potential for the exclusive licensing of patents relating to medical genetic testing to have adverse consequences for the cost of testing, access to testing, the quality of testing, and the development of new or improved testing techniques in the future.

21.2 Other chapters in this Report make recommendations intended to help address these and other possible adverse effects of gene patents on healthcare provision—as well as effects on the conduct of research and its subsequent commercialisation. This chapter considers the possible introduction of a medical treatment defence—a reform option directed specifically to healthcare provision.

21.3 The chapter describes the existing law in Australia and other jurisdictions in relation to patents and medical treatment. It also examines reforms that have been proposed overseas and the issues involved in framing any new medical treatment defence. For the reasons set out in this chapter, the ALRC has concluded that a new medical treatment defence should not be introduced in Australia.

A defence or an exclusion from patentability?

21.4 Some jurisdictions have addressed concerns about the impact of patents on healthcare by excluding certain diagnostic, therapeutic or surgical methods of treatment from the scope of patentable subject matter—that is, by treating methods of

medical treatment as an exclusion from patentability. This is the case in the United Kingdom and in Canada.[1]

21.5 Australia has not adopted this approach. Provided an invention meets the requirements for patentability set out in the *Patents Act 1990* (Cth) (*Patents Act*), the Patent Office will grant patents on diagnostic, therapeutic or surgical methods of treatment. As discussed in Chapter 7, the ALRC does not support the introduction of a new exclusion from patentability for methods of medical treatment. In particular, the ALRC is concerned that such an exclusion would have adverse effects on investment in biotechnology, medical research and innovation in healthcare.

21.6 However, to reject such an exclusion does not answer the question whether there should be a defence to a claim of infringement for methods of medical treatment. Where an exclusion from patentability exists, a patent cannot be granted and no question can arise about infringement of patent rights. In contrast, a defence does not affect the existence of patent rights but constrains the enforcement of these rights by providing protection against actions for infringement in specified circumstances. For this reason, a defence may involve a less dramatic diminution in the rights of inventors: while an exclusion from patentability means that the relevant subject matter is not patentable at all, a defence may be drafted to permit patents to be enforced in some circumstances but not in others. Yet, a broad a defence may also have adverse effects on investment and innovation.

21.7 Article 27(3)(a) of the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*[2] (TRIPS Agreement) permits World Trade Organization (WTO) member states to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability. However, this exclusion may be limited to methods performed on or inside the body (*in vivo* procedures).

21.8 In practice, gene patents most often relate to products and processes for use outside the human body, notably in connection with genetic sequencing and diagnostic genetic testing. These are commonly described as *in vitro* procedures, meaning literally that they are performed within a glass (a test tube). Even in the case of gene therapy, patents are most likely to relate to processes carried out *in vitro*—such as inserting genes into a gene carrier (or 'vector') and using the vector to carry the genes into somatic cells. However, some procedures for introducing vectors, modified cells or stem cells into the human body (for example, by injection) are performed on the human body and may be 'methods of medical treatment' as understood by patent law.

21.9 The ALRC has concluded that if reform in relation to gene patents and medical treatment were justified, the introduction of a new defence—as opposed to an exclusion from patentability—would be the preferable approach because such a

---

1 See *Patents Act 1977* (UK) s 4(2). The exclusion in Canada is based on case law interpreting patentability criteria.

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

defence could apply to both *in vivo* and *in vitro* procedures, and could be more targeted in its application to patented inventions. However, as discussed below, there are many difficulties in introducing such a defence and the ALRC has concluded that such a change is not warranted.

A medical treatment defence

21.10 The United States, like Australia, allows patent protection to be obtained for diagnostic, therapeutic or surgical methods of treatment. However, United States law has sought to address some of the objections that have been raised to such patents by introducing a limited statutory defence to infringement claims asserted against a 'medical practitioner' or a 'related health care entity' in connection with their performance of a 'medical activity'.[3] This provision is the only defence of its kind to be found in the patent laws of comparable developed nations.

21.11 The drafting of the United States medical treatment defence reflects its legislative history. The defence was proposed in the aftermath of the United States District Court case of *Pallin* v *Singer*, in which it was claimed that a physician had infringed certain patents in performing cataract surgery.[4]

21.12 The United States medical treatment defence covers any 'medical practitioner', defined as any natural person who is licensed by a State to provide the medical activity, and any person who is acting under the direction of such a person.[5] The defence also covers a 'related health care entity', namely, an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity 'including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic'.[6]

21.13 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.[7] Certain activities are expressly excluded from the ambit of the defence. These include the use of a patented machine, manufacture, or composition of matter in violation of the patent; the practice of a patented use of a composition of matter in violation of the

3 This defence was introduced in 1996 and does not apply to any patent with an effective filing date before 30 September 1996: 35 USC s 287(c).

4 *Pallin v Singer* 36 USPQ 2d 1050 (1995). The case caused a great deal of controversy within the medical community in the United States and provoked an immediate push for legislation. Originally, it was proposed that medical procedures should be an exclusion from patentability. This was opposed by the biotechnology and pharmaceutical industries, resulting in compromise legislation that addressed the remedies available to patent holders: See E Lee, '35 USC §287(c): The Physician Immunity Statute' (1997) 79 *Journal of the Patent and Trademark Office Society* 701, 702–709.

5 35 USC s 287(c)(2)(B).

6 35 USC s 287(c)(2)(C).

7 35 USC s 287(c)(2)(A), (E), (F).

patent; the practice of a process in violation of a biotechnology patent;[8] and clinical laboratory services (other than those provided in a physician's office).[9]

21.14 In summary, the United States defence has been described as limited to 'patents claiming "pure" medical, diagnostic or surgical methods—those which do not encompass the novel uses of drugs, chemicals or biological reagents'.[10] The limited ambit of the defence means that, in practice, it does not apply to most medical applications of genetic materials and technologies. As discussed above, medical treatment involving gene patents is conducted mostly outside the body and in a laboratory. Further, relevant gene patents cover isolated genetic materials and genetic products and their uses, which are patents on biotechnology.

21.15 There have been proposals to extend the scope of United States medical treatment defences, notably in the Genomic Research and Diagnostic Accessibility Bill 2002.[11] This Bill proposed to extend the definition of medical activity covered by the defence to include 'performance of a genetic diagnostic, prognostic, or predictive test'.[12] The co-sponsor of the Bill, the Hon Lynn Rivers, stated that this provision would 'exempt medical practitioners utilizing genetic diagnostic tests from patent infringement remedies'.[13]

Framing a new defence

21.16 If a new medical treatment defence were to be recommended by the ALRC, it would need to be carefully framed to remedy specific problems resulting from the enforcement, or potential enforcement, of gene patents against healthcare providers. A new medical treatment defence could be framed to cover the use in medical treatment of all patented inventions or, more specifically, of patented genetic materials and technologies. However, in view of this Inquiry's Terms of Reference, it would be difficult to recommend a defence unless it applied to *in vitro* procedures because most gene patents of relevance to medical treatment relate to procedures performed outside the body.

21.17 There are many difficulties involved in framing the scope of any new medical treatment defence. What class of patents should be covered by the defence? For the defence to be of practical application to the infringement of gene patents in the provision of healthcare, it seems clear that it would need to apply to *in vitro* testing and other procedures, and not just to procedures performed on or inside the body. Yet, the

---

8 35 USC s 287(c)(2)(A)(i)–(iii).

9 35 USC s 287(c)(3). While the term 'biotechnology patent' in the third listed exclusion is not defined, the use of isolated genetic materials would generally be considered a core element of biotechnology: E Lee, '35 USC §287(c): The Physician Immunity Statute' (1997) 79 *Journal of the Patent and Trademark Office Society* 701, 709.

10 V Bennett, *Limitation on Patents Claiming Medical or Surgical Procedures*, Myers Bigel, <www.myersbigel.com/pat_articles/pat_article3.htm> at 16 June 2004.

11 The Bill was referred to the House Subcommittee on the Courts, the Internet, and Intellectual Property on 5 May 2002, but lapsed at the end of the 107th Congress.

12 Genomic Research and Diagnostic Accessibility Bill 2002 (HR 3967) (US) s 3.

13 United States, *Congressional Debates, House of Representatives*, United States, 14 March 2002, E353 (L Rivers), E354.

implications of exempting a broad class of diagnostic or therapeutic methods from claims of patent infringement would be significant, especially in relation to effects on investment and innovation in healthcare technology. These implications would have to be the subject of specific investigation and consultation. In addition, enactment of a new medical treatment defence specific to gene patents would need to be justified carefully in order to be consistent with Australia's obligations under the TRIPS Agreement, which provides that patent rights shall be enjoyable without discrimination as to field of technology.[14]

21.18 The second major question in framing a new medical treatment defence is how to define the class of persons or organisations who should be able to invoke the defence. As discussed above, the United States medical treatment defence applies to medical practitioners, their assistants, and 'related healthcare entities'. The latter term includes entities with which a medical practitioner has a professional affiliation under which the medical practitioner performs a medical activity,[15] for example, a hospital or clinic.

21.19 An important consideration in defining the class of persons protected from infringement proceedings is that most genetic testing is conducted by laboratories, rather than by medical practitioners. In Australia, most medical genetic tests are ordered by a clinical geneticist or other medical practitioner as part of the healthcare services provided by state and territory clinical genetics services. The testing itself is usually, but not always, carried out by public sector laboratories attached to public hospitals.[16] If the intention behind the defence is to protect the delivery of healthcare services—rather than to protect only medical practitioners from liability—the defence should also cover laboratories.

21.20 Whether medical practitioners need special protection in relation to gene patent infringement is an open question. It is arguable that medical practitioners should be entitled to refer patients for medical genetic testing as they see fit, without having to concern themselves with the existence or otherwise of relevant patent rights. It is not clear whether a medical practitioner would infringe a patent simply by referring a patient to a laboratory for testing.

21.21 A medical practitioner can be liable for indirect infringement of a patent where he or she has procured the infringement through inducement, incitement or persuasion (that is, contributory or indirect infringement); joined in a common design with someone else to engage in acts that infringe a patent (that is, as a joint tortfeasor); or authorised the infringement.[17] For liability to be established, the medical practitioner must have done something more than merely facilitate the infringement of the patent by another. He or she must have been a party to the act of infringement by taking part

14 TRIPS Agreement, art 27(1).

15 35 USC s 287(c)(2)(C).

16 In these cases, the medical practitioner and the laboratory will often be part of the same public health organisation (eg in New South Wales, the same area health service or statutory health corporation). See *Health Services Act 1997* (NSW) Ch 2.

17 See J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [18,270].

in it, such as by taking some positive step designed to produce the infringement, even though further action by others (that is, the laboratory) is also required.[18] Referral of a patient to a testing laboratory may be regarded as contributory infringement, but this may depend on the exact relationship between a referring medical practitioner and the testing laboratory.[19]

21.22 It is possible that patent holders may protect their patents by seeking injunctions or other remedies against medical practitioners who refer patients for unauthorised testing, as well as by taking action directly against the offending laboratory. However, the ALRC has received no evidence that patent holders have adopted such an approach to patent enforcement in Australia. Indeed, it is uncertain whether it would serve any useful purpose for a patent holder to do so, given the remedies available against laboratories.

The TRIPS Agreement and medical treatment defences

21.23 Any new medical treatment defence should be drafted to be consistent with Australia's obligations under the TRIPS Agreement, and particularly art 27 and 30.

21.24 Article 27(1) of the TRIPS Agreement provides that patent rights shall be enjoyable without discrimination as to the field of technology. This non-discrimination provision places constraints on the extent to which gene patents may be singled out for special treatment, including through new defences to claims of patent infringement. Article 27 does not 'prohibit bona fide exceptions to deal with problems that may exist only in certain product areas'.[20] It may be possible to craft a medical treatment defence that is specific to some defined subset of gene patents, such that the provision does not discriminate by field of technology within the terms of art 27. However, there would need to be strong arguments to justify differentiating a relevant category of gene patents from patents in other fields of technology.

21.25 Article 30 provides for limited exceptions to the exclusive rights conferred by a patent. Unlike experimental use exceptions, which are found in the laws of most members of the WTO, only the United States has enacted a medical treatment defence to claims of patent infringement and, because it is limited to medical activities 'on a body', it would not address the exploitation of most healthcare-related gene patents. The United States medical treatment defence has come under scrutiny as part of the review of the implementation of the TRIPS Agreement.[21]

---

18 See Ibid, [18,270].

19 Another consideration in such circumstances is the concept of innocent infringement. If a defendant has infringed a patent, it does not matter whether he or she knows of the existence of the patent, or whether he or she intended to infringe. However, a court will take account of the defendant's innocence in determining the nature of the relief to be awarded. The extent to which a medical practitioner knows about the existence of patent rights may therefore be relevant to the remedies available against him or her: See Ibid, [18,345]; *Patents Act 1990* (Cth) s 123.

20 *Canada: Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States*, 17 March 2000, WT/DS114/R, 170–171.

21 The European Communities and their member States asked the United States to explain how this provision complies with the TRIPS Agreement. See *Review of Legislation in the Fields of Patents,*

21.26 The TRIPS Agreement allows member States to exclude 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' from patentability.[22] It might be argued that, as an exclusion from patentability is permissible, a defence cast in similar terms should also be permissible, because it is less prejudicial to patent rights than an exclusion. However, the position is not clear. It has been suggested, for example, that while member States may exclude diagnostic, therapeutic and surgical techniques from patentability, if they make patents available, they must accord full rights under the TRIPS Agreement.[23] Further, as discussed in Chapter 7, it is not clear whether the TRIPS Agreement permits exceptions for *in vitro* procedures.

Reform proposals in other jurisdictions

21.27 In those jurisdictions that exclude methods of medical treatment from patentability based on the interpretation of patentability criteria, the rationale for the exclusion is that the success of such treatments depends largely on the skill of the physician administering them.[24] In patent law terms, this has been taken to mean that methods of medical treatment fail to meet the utility and related criteria for patentability of some jurisdictions.[25]

21.28 The United States medical treatment defence also recognises the role of physicians in medical treatment. The intention of the provision has been said to be to ensure that physicians 'performing life saving or health enhancing medical or surgical procedures are not inhibited by fear of lawsuits for patent infringement'.[26]

21.29 The introduction of a medical treatment defence to address concerns about the impact of gene patents specifically has been considered in some jurisdictions. The focus has been on options for ensuring access by patients to patented genetic technologies and involves a broader conception of medical treatment, which includes *in vitro* diagnosis.

21.30 In Canada, the 2002 Ontario Government report, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare* (Ontario Report), recommended that the current Canadian medical treatment exclusion be replaced with a medical treatment defence. The Ontario Report stated that adopting the United States approach, with an extension to cover diagnostic procedures, could address concerns about access to

---

Layout-designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: United States, 1 May 1998 (1998) World Trade Organization.

22 TRIPS Agreement, art 27(3)(a). The Australia-United States Free Trade Agreement contains an identical provision: Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004 art 17.9.2(b).

23 The Office of the United States Trade Representative opposed the legislation that eventually became the United States medical treatment defence on this basis. See J Duffy, 'Harmony and Diversity in Global Patent Law' (2002) 17 *Berkley Technology Law Journal* 685, 722, fn 122.

24 Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002), 31.

25 See Ch 7.

26 *Review of Legislation in the Fields of Patents, Layout-designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: United States, 1 May 1998* (1998) World Trade Organization, 13.

patented genetic technologies. It recommended an amendment to prevent patent holders from bringing an action for infringement against a medical practitioner for providing medical services (including treatment and diagnosis) to patients.[27]

21.31 In 2002, a report by the Organisation for Economic Co-operation and Development noted suggestions that 'clinical use' exceptions should be enacted into national laws. The report observed that a difficulty with such an approach would be to 'distinguish clinical use from commercial use'.[28]

21.32 A 2003 report for the United Kingdom Department of Health referred to a 'groundswell of opinion' in countries that exclude methods of medical treatment from patentability that the exemption should be removed.[29] It concluded that, if this were done in the United Kingdom, clinicians would require the benefit of a defence against infringement.[30]

Submissions

21.33 Many submissions favoured the introduction of some form of medical treatment defence.[31] The scope of the desirable defence was expressed in varying ways, often as an exemption for genetic (or all diagnostic) testing from claims of patent infringement, at least where performed on a 'non-commercial' basis.[32] In addition to such broad prescriptions for reform, which tended to focus on ensuring that medical genetic testing conducted by public sector laboratories was covered by the defence, submissions suggested a range of ways in which the defence should be framed. These submissions sometimes referred to the United States medical treatment defence as a model.[33]

21.34 A number of submissions were opposed outright to the idea of a new medical treatment defence[34] because such a reform might unjustifiably undermine patents on genetic technologies[35] and would permit 'free-riding' in relation to medical

---

27 Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* (2002), rec 13(e), 51.

28 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 73.

29 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 23.

30 Ibid, 83.

31 Australian Association of Pathology Practices Inc, *Submission P10*, 24 September 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; Breast Cancer Network Australia, *Submission P22*, 30 September 2003; Cancer Council Australia, *Submission P25*, 30 September 2003; Cancer Council Tasmania, *Submission P40*, 29 September 2003; Cancer Council South Australia, *Submission P41*, 9 October 2003; Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Caroline Chisholm Centre for Health Ethics Inc, *Submission P38*, 17 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

32 See Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [22.40]–[22.41].

33 See, eg, Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

34 Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

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

inventions.[36] It was noted that such a defence had never been considered necessary to protect the use of pharmaceuticals by medical practitioners and was unlikely to be needed in respect to genetic materials and technologies.[37]

21.35 After highlighting the difficulties involved in framing the scope of a new medical treatment defence, DP 68 asked whether, in the absence of a general defence relating to medical treatment, the *Patents Act* should be amended to enact a new defence to claims of patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment.[38]

21.36 There was some support for this idea.[39] The Department of Health and Ageing, stated that a defence for the use of genetic materials and technologies in medical treatment would be appropriate 'based on the relative simplicity, or lack of genuine inventive step, in most instances, in developing diagnostic tests once the location and structure of a gene has been characterised'.[40] However, most of the submissions that addressed the issue opposed the introduction of a new defence.[41] The potential adverse effects on innovation and development in medical technology were highlighted.[42]

21.37 Submissions suggested that there was insufficient justification for any new defence, and no reason to distinguish genetic technologies from other medical technologies.[43] The constraints of the TRIPS Agreement were also noted.[44] The Institute of Patent and Trade Mark Attorneys of Australia stated:

---

36 A McBratney and others, *Submission P47*, 22 October 2003.

37 Davies Collison Cave, *Submission P48*, 24 October 2003.

38 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 22–1.

39 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004. Others supported the introduction of a general medical treatment defence: J Hinojosa, *Submission P87*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004.

40 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

41 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004. The Department of Health and Ageing and the Department of Industry, Tourism and Resources specifically opposed the introduction of a general medical treatment defence: Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

42 Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.

43 F B Rice & Co, *Submission P84*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

44 Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.

> limitations as to the scope of protection for genetic materials and information will significantly reduce the attractiveness for investment in research and may significantly hamper development. It is difficult to see any justification for treating genetic materials and information in a different manner to the regime that operates in respect of pharmaceutical substances. The existence of patent protection for pharmaceuticals undoubtedly nurtures significant investment in research and development.[45]

ALRC's views

21.38 DP 68 acknowledged the strong support in submissions for the introduction of some form of medical treatment defence, while noting that much of this support was from organisations involved in providing healthcare or representing the interests of healthcare consumers. Even within this group of stakeholders, support for the idea was not universal: some submissions presented reasons for rejecting a medical treatment defence because of concerns about the effect of such a defence on investment and innovation in genetic medical technologies, or medical technologies generally.

21.39 The ALRC does not recommend any amendment to the *Patents Act* to enact either: (a) a medical treatment defence of general application; or (b) a defence applying specifically to the use of patented genetic materials and technologies in medical treatment.

21.40 The United States is the only developed country to have enacted a medical treatment defence, although the need for such a defence does not arise in many jurisdictions because methods of medical treatment are excluded from patentability.[46] There is little experience in the practical application of such a defence.

21.41 There may be sound arguments for a United States-style medical treatment defence in order to protect medical practitioners who engage in medical or surgical procedures on the human body from patent infringement actions. However, this is a matter beyond the Terms of Reference of this Inquiry, with its more limited focus on patents over genetic materials and technologies.

21.42 The limited ambit of the United States defence means that it probably does not apply to medical treatment involving gene patents. Gene patents most often relate to products and processes for use outside the human body, notably in connection with genetic sequencing and diagnostic genetic testing. While gene patents are sometimes used in procedures on the human body, for example in connection with gene therapy, such use is rare and still largely experimental.

21.43 There are genuine difficulties in framing the scope of any new medical treatment defence. These include defining what medical activities the defence should cover, and defining the persons or organisations that should be able to invoke it. These difficulties would be exacerbated if the defence were to apply only to patents on

---

45 Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004.
46 IP Australia, *Submission P86*, 16 April 2004.

genetic materials and technologies. Distinguishing genetic medical technology from other medical technology would be difficult, especially in relation to *in vitro* diagnostics,[47] as would any distinctions required between commercial and non-commercial genetic testing.

21.44 Other problems would arise in relation to framing the defence in a way that is consistent with Australia's obligations under the TRIPS Agreement. As discussed above, a medical treatment defence applicable to genetic materials and technologies may be inconsistent with those provisions that require technological neutrality.

21.45 The ALRC remains of the view that it would be premature to propose a medical treatment defence where there is no demonstrated harm. Such a significant diminution of patent rights would have the potential to reduce innovation and investment in some areas of medical technology.

21.46 As discussed in Chapter 20, it has not been established that gene patents have had any significant adverse impact, to date, on healthcare provision in Australia. Patent holders have not been active in enforcing gene patents against healthcare providers. If gene patents are found to have an adverse impact on healthcare provision, a number of reforms are available to address the problem, other than the enactment of a new medical treatment defence. These include: changes to laws and practices concerning patentability, which are relevant to some gene patents (Chapter 6); enacting a new experimental use exemption from infringement (Chapter 13); encouraging Commonwealth, state and territory health departments to exercise existing legal options to facilitate access to patented inventions where particular gene patents have an adverse impact on the provision of healthcare (Chapter 19);[48] and clarification of the Crown use and compulsory licensing provisions of the *Patents Act* (Chapters 26 and 27). These options present fewer practical difficulties than the introduction of a medical treatment defence.

47 Genetic testing can refer to molecular genetic testing that directly analyses DNA or RNA, but other biochemical tests of non-genetic substances, as well as some medical imaging processes, may provide strong indicators of particular genetic disorders.

48 These include rights of Crown use and compulsory licensing under the *Patents Act 1990* (Cth) and recourse to laws dealing with anti-competitive conduct.

PART F

Licensing and Commercial Arrangements

22. Licensing of Patent Rights

Contents

Introduction

22.1 Much of the concern about the potential adverse impact of gene patents has entailed criticism of the way in which gene patents are exploited and the possibility that licences for gene patents may be granted on a restrictive basis. Chapters 12 and 20 considered these concerns in the context of licences to genetic research tools and gene patents used in healthcare provision.

22.2 This chapter provides a more general consideration of issues relating to the licensing of gene patents. The various types of patent licences and the typical terms of such agreements are outlined. The chapter then examines available evidence about licensing practices relating to genetic materials and technologies in Australia. It

concludes with a discussion of particular issues that have been identified as impediments to the licensing of gene patents in the Australian biotechnology sector, and recommends reforms to facilitate licensing in this area.

22.3 Other chapters of this Report address other aspects of gene patent licensing practices. Chapter 17 outlines the licensing practices of Australian publicly funded research organisations. Chapters 24 and 27 consider the remedies that may be available if patent holders engage in anti-competitive conduct or unreasonably restrict access to patented genetic inventions. In addition, Chapter 23 considers various statutory licensing schemes for certain types of gene patents.

Licensing patent rights

22.4 As discussed in Chapter 5, the grant of a patent confers upon a patent holder the exclusive right to exploit an invention, or to authorise another person to exploit an invention, during the patent term.[1] A patent holder may license any or all of its patent rights to a third party.[2] A licence of a patent does not transfer ownership of the patent rights, as is the case if a patent is assigned; rather it establishes terms upon which a third party (the licensee) may exercise specified patent rights without such use constituting infringement.[3]

22.5 A licence to exploit one or more gene patents may be a stand-alone transaction or part of a larger commercial arrangement. Patent licences are frequently involved when establishing a spin-off company, a joint venture or a strategic alliance. Patent licences are also typical in collaboration and consortium arrangements, sponsored research agreements, and manufacture and supply agreements.

22.6 Patent licence agreements may be divided into two categories: 'in-licences' and 'out-licences'. An in-licence is an agreement by which a party acquires the rights to use a patent. An out-licence is an agreement by which a patent holder grants the right to use a patent to a third party.

22.7 The decision to license gene patents may be based on a number of factors.[4] Licensing arrangements allow companies to exchange resources and information, thereby reducing research and development expenditure and time delays in bringing a product to market. Licensing of patent rights may also be necessary to gain access to domestic or foreign markets, by providing access to manufacturing facilities or

---

1 *Patents Act 1990* (Cth) s 13(1). A patent holder's right to exploit its invention is not absolute; it may be subject to other legal requirements, as well as earlier patents not owned by the patent holder.

2 Any licence of a co-owned patent requires the consent of all patent holders: Ibid s 16(1)(c).

3 However, the grant of an exclusive licence may carry with it some of the indicia of ownership: see Ibid ss 103, 120(1), 187.

4 For a general discussion of the relevant factors, see Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), Ch 8; Department of Foreign Affairs and Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001), Module 9; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 97–99.

distribution networks without additional expense, or lowering the cost and risk associated with entry into a market through partnership with a more experienced entity. A company's strategic patent licensing may also result in the establishment of profitable, long-term alliances leading to future research collaborations. A patent licence may provide a company with access to significant third party intellectual property, or provide a means of avoiding or settling patent litigation—particularly where an agreement involves cross-licences of patent rights among competitors.

Types of patent licences

22.8 A licensee may be granted exclusive, sole or non-exclusive rights to a gene patent. An exclusive licence provides that only the licensee (and, where permitted, persons authorised by the licensee) may exploit the rights licensed under the agreement—even the patent holder is prevented from exploiting such rights.[5] 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. A patent holder may, therefore, retain the right to exploit the invention in other territories or fields of use, or to license patent rights to a different entity, perhaps also on an exclusive basis.

22.9 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. A non-exclusive licence allows the patent holder to license some or all of the rights under a patent to an unlimited number of third parties, and also to retain the right to exploit a patented invention itself. Like exclusive licences, licences that authorise the use of gene patent rights on a sole or non-exclusive basis may be restricted to a particular territory, field of use, or period of time.

Common terms in patent licences

22.10 The *Patents Act 1990* (Cth) (*Patents Act*) does not specify any formalities that must be satisfied for a patent licence to be valid and enforceable. However, as a matter of commercial practice, the terms of a patent licence are typically set out in a written document executed by the parties to the agreement.

22.11 Patent licences usually address the following matters:[6]

- 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, and any restrictions on the use of the licensed patent rights (for example, restrictions on the right to sub-license, or rights retained by the licensor);

---

5 *Patents Act 1990* (Cth) sch 1.

6 This list is not comprehensive and is intended only as a guide to issues that a patent holder may wish to regulate by licence.

- duration of the licence;
- financial terms—such as licence fees,[7] 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 licence;
- obligations of the licensee—such as performance obligations to exercise best efforts to develop and exploit the technology covered by the licence;[8]
- 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 licence, and new inventions that may be developed;
- reversion of rights in the licensed patents—for example, upon termination of the licence, or upon failure of the licensee to satisfy performance obligations stipulated in the agreement;
- reporting and record keeping requirements—including the ability of the licensor to conduct periodic audits of the licensee's records;
- confidentiality obligations; and
- responsibility for liability claims—typically addressed in the form of indemnification provisions covering issues such as patent infringement and product liability claims.

22.12 While most patent licences address the issues identified in the preceding paragraph, parties to a licence typically negotiate the precise terms of the arrangement, including the scope of the licence granted, the obligations and liabilities of each of the parties, and the quantum and terms of payment. These negotiations will be influenced by a number of factors, including: the nature of the technology being licensed, the identity and business of the patent holder and potential licensee, the proposed use of the patented technology, and revenue considerations. The way in which these factors affect licences of Australian gene patents is considered in the following section.

---

7 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.

8 An agreement may also provide that a licensee is responsible for matters that are typically the obligation of the licensor—such as maintenance and enforcement of the licensed patent rights—particularly if patent rights are licensed on an exclusive basis.

Licensing of gene patents in Australia

22.13 The size and character of the Australian biotechnology industry (which is discussed in Chapter 16) 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 makes it unlikely that companies will be able to sustain long-term growth or profitability based solely on activities in the domestic market.[9] In addition, the primary expertise of many Australian biotechnology companies is in the area of research. The resources and expertise of more established—and frequently foreign-owned—companies are typically required to commercialise the results of research and produce a diagnostic or therapeutic product.[10] Australian biotechnology entities are, therefore, unlikely to raise substantial revenue from the sale of genetic products or processes and are often dependent upon licence fees as a source of revenue.[11]

22.14 Publicly available information about gene patent licensing practices in Australia is limited and has been largely anecdotal to date.[12] Some information about patent licence agreements may be gleaned from: patent licences filed with IP Australia;[13] disclosures made by publicly-listed Australian companies pursuant to the Australian Stock Exchange listing rules (and equivalent disclosure requirements imposed by securities exchanges in other jurisdictions);[14] and an individual company's press releases. Such sources will, however, reveal only a portion of concluded transactions. Moreover, public sources of information about patent licences generally exclude details of the commercial terms of such agreements to preserve confidentiality.[15] It is therefore difficult to obtain a clear picture of what patented genetic materials and technologies are being licensed in Australia, to whom, and on what terms.[16]

---

9 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001), 115.

10 D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 358–360; J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 39, 43. Participants in the medical device and non-human research sectors are more likely to have the capacity to bring a product to market: D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 103, 110, 253.

11 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 93, 110.

12 GlaxoSmithKline, *Submission P33*, 10 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003.

13 *Patents Act 1990* (Cth) ss 187, 193; *Patents Regulations 1991* (Cth) r 19.1.

14 Listing rules generally 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. See also Australian Stock Exchange and AusBiotech Ltd, *Code of Best Practice for Reporting by Biotechnology, Medical Device and Other Life Sciences Companies: Working Draft* (2004).

15 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

16 Limitations on the available information have been noted elsewhere: Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 45.

22.15 Studies of biotechnology licensing practices are now being undertaken in a number of jurisdictions to improve policy makers' understanding in this area and inform their decisions about the appropriate regulation of biotechnology patents.[17]

Nicol–Nielsen Study

22.16 In 2003, Dr Dianne Nicol and Jane Nielsen published the results of an empirical study of patenting and technology transfer practices in the Australian medical biotechnology industry (Nicol–Nielsen Study).[18] The Nicol–Nielsen Study examined licensing practices relating to biotechnological inventions, including genetic materials and technologies, among publicly listed and private companies, research organisations and genetic testing laboratories within the Australian medical biotechnology sector.[19] While the focus of the Study was broader than gene patents, its findings in relation to licensing practices are instructive.

22.17 The Nicol–Nielsen Study reported significant levels of collaborative and licensing activity on the part of each type of entity surveyed.[20] Respondents to the survey from the 'research institute' and 'company' sectors reported lower levels of licensing-out of patent rights than might be expected.[21] However, Nicol and Nielsen commented that this result was 'reflective of an industry in a growth phase'.[22] Some entities are still developing their technology and are not yet in a position to enter into licence agreements. Others favour assignment or co-ownership of patents, or establishing a spin-off entity, as a means of providing access to patented technology. Nicol and Nielsen concluded that 'most patent holders are able to find ways to license-out their technology or to find other means of transferring their technology to other sectors of the industry'.[23]

22.18 Nicol and Nielsen also concluded that 'licensing on an exclusive basis is commonplace' within the Australian medical biotechnology sector,[24] and that there is some evidence of restricted access to patented biotechnological inventions. However, they found that Australian entities currently have little difficulty accessing broadly applicable research tools and technologies because there is liberal licensing of

17 See, eg, J Walsh, A Arora and W Cohen, 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W Cohen and S Merrill (eds), *Patents in the Knowledge-Based Economy* (2003), 285 (United States study); D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6 (Australian study).

18 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6.

19 Survey responses were received from 49 companies, 23 research institutions and 18 diagnostic testing facilities. Forty interviews were also conducted with representatives from research institutes, companies, and diagnostic testing facilities: Ibid, 64–71.

20 Ibid, 95–97, 104, 123.

21 Ibid, 100–101.

22 Ibid, 102.

23 Ibid, 102.

24 Ibid, 150.

foundational biotechnological inventions.[25] To the extent that access to biotechnological inventions is being restricted, Nicol and Nielsen suggested that it typically occurs where providing a third party with access to patented technology could result in a competing product.[26]

22.19 Responses to the survey and interview data collected by Nicol and Nielsen suggest that a variety of factors affect the terms on which a biotechnology patent will be licensed. The principal considerations are as follows.[27]

- The nature of the technology—non-exclusive licences are more common for patents on research tools and gene sequences than for a genetic invention that might result in a drug-based therapy; and patent holders are likely to be more willing to license technology that is not critical or central to their business plans.

- Identity and business of the patent holder—academic institutions and biotechnology start-ups appear to be more likely to license patented technology to a third party on an exclusive basis in order to find a partner for the commercial development of the research.[28]

- Identity and number of potential licensees—'downstream' entities such as pharmaceutical companies often insist on exclusive licences to justify investment in the research and development of a drug target or therapeutic product, but favour non-exclusive licensing of research tools; and the scope of rights granted under a licence and the fees payable may differ if the licensee is an academic institution rather than a commercial enterprise.

- Payment considerations—the larger the licence fees sought by a patent holder, the more likely a potential licensee is to require exclusive rights to the patented technology. In the case of research tool patents, seeking a modest fee from many licensees may be the best means to maximise profit from the patent.[29]

22.20 Respondents to the Nicol–Nielsen Study indicated that refusals to license gene patents are relatively low.[30] In the small number of cases in which a licence had been refused, respondents suggested that a justifiable commercial explanation might exist. These include that: a licence would conflict with a patent holder's own business strategy or an agreement already in place with another party; the potential licensee was problematic (in terms of their financial position or reputation in the market place); the

25 Ibid, 254. See also Ch 12.
26 Ibid, 254.
27 Ibid, 109–122, 149–155.
28 Similarly, a United States study of entities operating in the biotechnology field has suggested that non-profit entities (including universities) are more likely to rely on exclusive licensing arrangements than private companies: M Henry and others, 'DNA Patenting and Licensing' (2002) 297 *Science* 1279.
29 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 151–152.
30 Six out of 49 companies and two out of 23 research institutes had been refused a licence: Ibid, 145–148.

proposed terms of the licence (for example, financial terms) were unsatisfactory; or the proposed application of the patented technology by the potential licensee was unethical.[31] However, Nicol and Nielsen noted that statistics relating to the frequency with which licences are refused in the Australian medical biotechnology sector do not take into account instances in which an entity chooses not to request a licence because it expects the licence to be refused or offered on unreasonable terms.[32]

Submissions and consultations

22.21 Consistently with responses to the Nicol–Nielsen Study, a number of submissions indicated that licences are being granted over a broad range of gene patents and that the inventions claimed in these patents are being further developed.[33]

22.22 Submissions also supported Nicol and Nielsen's conclusion that refusals to license gene patents do not appear to be a significant issue in the Australian biotechnology market at this stage.[34] Submissions suggested that failures to negotiate a licence generally reflected the normal operation of the market, rather than concerted efforts by Australian patent holders to limit access to gene patents.[35]

22.23 A few submissions suggested that Australian entities might be using patented genetic technologies without a licence from the relevant patent holder. Comments indicated that Australian researchers might operate on the understanding that research involving patented genetic materials or technology does not require a licence.[36] In addition, the Royal College of Pathologists of Australasia (RCPA) suggested that, as a matter of practice, licences to patents covering genetic materials are 'rarely requested by the testing laboratory or demanded by the patent holder'.[37] These observations are consistent with the conclusions of the Nicol–Nielsen Study, which found that one approach adopted by respondents 'when a particular area of research is discovered to

---

31 Ibid, 145, 148–149.

32 Ibid, 161.

33 GlaxoSmithKline, *Submission P33*, 10 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

34 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; GlaxoSmithKline, *Submission P33*, 10 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; Genetic Technologies Limited, *Submission P45*, 20 October 2003; A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

35 Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003; Walter and Eliza Hall Institute of Medical Research, *Submission P39*, 17 October 2003; AusBiotech Ltd, *Submission P58*, 7 November 2003.

36 A McBratney and others, *Submission P47*, 22 October 2003; Davies Collison Cave, *Submission P48*, 24 October 2003; National Health and Medical Research Council, *Submission P52*, 31 October 2003; Queensland Government, *Submission P57*, 5 January 2004.

37 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003. See Ch 20 for a discussion of Australian patents relating to medical genetic testing.

be infringing a patent is to ignore it'.[38] The impact of patents on genetic research and the introduction of a statutory experimental use exemption are addressed in Chapters 12 and 13.

22.24 Although the available evidence suggests that Australian licensing practices are not unduly restrictive, a small number of submissions nonetheless encouraged the ALRC to address the potential adverse effects if patent holders were to refuse to license gene patents or offer licences on unreasonable terms.[39] Submissions were concerned that gene-based healthcare services would be severely affected if licence fees of the magnitude that has reportedly been requested by patent holders in overseas jurisdictions were to occur in Australia.[40] The RCPA proposed that legislation be introduced to prohibit the exclusive licensing of human diagnostic genetic tests and to impose 'severe penalties on patent holders that use their restrictive market powers irresponsibly'.[41] Similarly, the Nuffield Council of Bioethics proposed that public institutions and private entities should be encouraged to license patents over DNA sequences on a non-exclusive basis.[42]

Impediments to gene patent licensing in Australia

22.25 The Nicol–Nielsen Study suggests that, in addition to the financial factors that might have an impact on an entity's ability to commercialise its gene patents, impediments continue to exist in the licensing of genetic inventions.[43] Respondents commented that gene patent holders and potential licensees of gene patents in Australia face difficulties in negotiating licence agreements, particularly if the other party is a more experienced commercial entity:

> One of the big problems identified for Australian companies is lack of the ruthlessness that many of their international counterparts have developed. Hence they tend to cave in too easily when negotiations become difficult. In part this may be because they don't appreciate the value of what they are acquiring and giving.[44]

22.26 In interviews conducted in connection with the Study, many respondents made reference to 'difficulties in negotiating' patent licences and that 'often these difficulties stemmed from the fact that they held an inferior bargaining position'.[45] Nicol and Nielsen concluded that Australian entities lack 'deal precedents' and that 'one of the

---

38 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 257.

39 Royal College of Pathologists of Australasia, *Submission P26*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003.

40 See, eg, South Australian Department of Human Services, *Submission P74*, 15 April 2004.

41 Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004. See also Cancer Council Victoria, *Submission P101*, 20 April 2004.

42 Nuffield Council on Bioethics, *Submission P102*, 22 April 2004.

43 See further Ch 17.

44 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 114.

45 Ibid, 158, 162.

biggest problems is naivety in bargaining'.[46] Their Study also found that a relatively standard set of licence terms are at issue in most negotiations,[47] and certain terms are consistently matters of substantial disagreement—in particular, payment provisions, field of use restrictions, and provisions claiming reach-through rights.[48]

22.27 Australian entities may also have difficulties in identifying the patents for which a licence is needed. Respondents to the Nicol–Nielsen Study indicated that identifying the patents that may need to be licensed is an onerous and expensive exercise, and is becoming more so as the gene patent landscape becomes more complex.[49]

Facilitating gene patent licensing

22.28 The rest of this chapter discusses mechanisms to assist patent holders and patent users in identifying and licensing gene patents. These mechanisms include education programs, the development of model licence agreements for genetic inventions, and industry-based initiatives such as patent pools and patent clearinghouses.

22.29 Other chapters of this Report also recommend reforms to facilitate the licensing of Australian gene patents. Chapter 9 recommends that IP Australia develop a comprehensive on-line patents database, which will assist patent holders and users of patent rights in conducting preliminary prior art searches.[50] Chapter 27 recommends reforms to the compulsory licensing provisions in the *Patents Act* to facilitate access to patented genetic inventions under a compulsory licence in appropriate circumstances.[51]

Education programs about licensing practices

Government initiatives

22.30 Chapters 17 and 18 discuss the programs that exist to support commercialisation of research by Australian entities, including programs directed specifically to the Australian biotechnology sector.[52] To date, the focus of government initiatives has been to provide support (including funding) to aid the commercial development of innovation in biotechnology research.

22.31 The *National Biotechnology Strategy*, released by the Australian Government in 2000, included as one of its overall objectives 'strengthening capabilities for the commercial and strategic management of Intellectual Property in biotechnology'.[53]

---

46 Ibid, 108.
47 Ibid, 115–119, 158.
48 Ibid, 160, 162–163. Reach-through provisions in patent licences may provide for the licensor to obtain ownership of or a licence to intellectual property in future inventions arising as a result of activities conducted under a licence: see further Ch 12 and 18.
49 Ibid, 181–182.
50 Rec 9–1.
51 Rec 27–1.
52 See also Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Ch 11.
53 Biotechnology Australia and Commonwealth Biotechnology Ministerial Council, *Australian Biotechnology: A National Strategy* (2000), 7, 18–19.

Pursuant to this objective, Biotechnology Australia and the Department of Foreign Affairs and Trade (DFAT), among others, have published educational materials to promote understanding of intellectual property issues in biotechnology, including about how intellectual property rights in biotechnological inventions can be used and managed most effectively.[54]

22.32 In 2001, Biotechnology Australia released a manual providing a practical guide to the identification, protection and management of biotechnology-related intellectual property (Biotechnology IP Manual).[55] The manual is a resource for research organisations, companies and entities funding biotechnology research, to be used in conjunction with their existing intellectual property management policies and practices. The Biotechnology IP Manual includes a separate chapter on commercial exploitation of intellectual property, which addresses topics such as conducting due diligence, valuation of intellectual property, factors relevant to a decision whether to license patent rights, as well as common terms in patent licences and their significance.[56] Views expressed in a number of consultations indicated that the Biotechnology IP Manual is a very useful resource.[57]

22.33 DFAT has also published the *Intellectual Property and Biotechnology: A Training Handbook* (DFAT IP Handbook).[58] Its purpose is to provide an introduction to key intellectual property concepts, and an understanding of how they apply in practice.[59] The DFAT IP Handbook includes a section on licensing and enforcing intellectual property rights, which provides an overview of issues that Australian organisations may encounter in negotiating licences to gene patent rights.[60] The section outlines factors relevant to the decision to commercialise an invention and the various ways in which patent rights can be exploited. It also includes information relating to negotiating biotechnology licences—from conducting due diligence on a potential licence partner, to the type of provisions that commonly appear in patent licence agreements and the purpose of these provisions.

---

54 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001); Department of Foreign Affairs and Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001).

55 Biotechnology Australia, *Biotechnology Intellectual Property Manual* (2001).

56 Ibid, Ch 8.

57 For example, Unisearch, *Consultation*, Sydney, 15 March 2004; National Health and Medical Research Council, *Consultation*, Canberra, 26 March 2004. The Department of Industry, Tourism and Resources reported that the Biotechnology IP Manual has been downloaded more than 20,000 times from the Biotechnology Australia website: Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

58 Department of Foreign Affairs and Trade and AusAID, *Intellectual Property and Biotechnology: A Training Handbook* (2001).

59 The DFAT IP Handbook indicates that it is intended for use as a resource in connection with a training course, either in a group or on an individual basis: Ibid, vii.

60 Ibid, Module 9.

22.34 The Department of Industry, Tourism and Resources (DITR) informed the ALRC that Biotechnology Australia, in conjunction with certain patent attorney firms, has conducted intellectual property education programs—such as the Australian Biotechnology Intellectual Property Management Seminar Series.[61]

Industry initiatives

22.35 Organisations have been established to develop the commercial skill base of Australian entities, including those in the biotechnology sector. These organisations and the type of programs offered in this regard include the following.[62]

- AusBiotech Ltd (AusBiotech) is the peak national industry body whose membership includes entities from all aspects of the Australian biotechnology sector.[63] AusBiotech provides its members with access to training and information resources,[64] and is also actively involved in government and industry initiatives relevant to the biotechnology sector.[65]

- The Australian Institute for Commercialisation Ltd (AIC) offers programs to improve commercialisation of research in Australia.[66] These include the 'AIC Know-How' program, which focuses on courses for public and private sector organisations for the purpose of improving knowledge about technology commercialisation practices.[67]

- The Licensing Executives Society (LES) is involved in activities related to licensing and other transfers of intellectual property,[68] including: educating members in licensing skills; monitoring licensing developments; and conducting research on issues related to domestic and foreign licensing.[69]

---

61 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

62 See Ch 17 for a discussion of support programs directed toward technology transfer from publicly funded research organisations.

63 AusBiotech Ltd, *What is AusBiotech?*, <www.ausbiotech.org/whataus.php> at 16 June 2004; AusBiotech Ltd, *AusBiotech's Corporate Members*, <www.ausbiotech.org> at 21 January 2004.

64 AusBiotech Ltd, *Membership Benefits*, <www.ausbiotech.org> at 21 January 2004.

65 See, eg, AusBiotech Ltd, 'Policy Insight' (2004) 14 *Australasian Biotechnology* 24 for an outline of AusBiotech's involvement in policy initiatives from December 2003 to January 2004.

66 Australian Institute for Commercialisation Ltd, *About the AIC*, <www.ausicom.com> at 16 June 2004. AIC was established by a Queensland government initiative, but also receives a small amount of funding from the Australian Government and other state and territory governments.

67 Australian Institute for Commercialisation Ltd, *AIC Know-How*, <www.ausicom.com/01_about/aic_know-how.htm> at 16 June 2004.

68 Licensing Executives Society Australia and New Zealand, *LES ANZ Inc*, <www.lesanz.org.au> at 16 June 2004. LES International comprises 28 separate country or regional societies, including LES Australia and New Zealand Inc.

69 Licensing Executives Society Australia and New Zealand, *LES Objectives*, <www.lesanz.org.au> at 16 June 2004.

22.36 In addition, as discussed in Chapter 17, Knowledge Commercialisation Australia (KCA) represents Australian public sector organisations involved in technology transfer. It has organised a series of conferences on technology commercialisation.[70]

Submissions and consultations

22.37 DP 68 proposed that Biotechnology Australia, in consultation with state and territory governments and other relevant stakeholders, should continue to develop and implement education programs to assist research organisations and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies.[71] Although a few consultations questioned whether Biotechnology Australia possesses adequate capacity and resources to implement education and training programs,[72] this proposal was generally supported.[73]

22.38 DITR, which is one of five member departments of Biotechnology Australia, strongly agreed with the proposal.[74] DITR indicated that Biotechnology Australia is engaged in programs to increase awareness of intellectual property management on an on-going basis: 'The government fully recognises that the more effective commercialisation of IP is vital for the growth of a dynamic biotechnology industry in Australia'.[75]

22.39 DITR observed that there were already some projects directed to improving industry awareness of intellectual property management and commercialisation, including the Biotechnology IP Manual and IP Australia's *IP Toolbox*.[76] Further, DITR commented that the Australian Government is also addressing other factors that affect the commercialisation of biotechnology in Australia; in particular, the difficulties biotechnology companies face in attracting venture capital funds.[77]

---

70 Knowledge Commercialisation Australasia, *Home Page*, <www.kca.asn.au> at 16 June 2004.

71 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 23–1.

72 Unisearch, *Consultation*, Sydney, 15 March 2004; National Health and Medical Research Council, *Consultation*, Canberra, 26 March 2004. See also Ch 18.

73 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; South Australian Department of Human Services, *Submission P74*, 15 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; National Health and Medical Research Council, *Submission P107*, 19 April 2004; Walter and Eliza Hall Institute of Medical Research, *Consultation*, Melbourne, 1 April 2004.

74 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004. The other four government departments are: the Department of Agriculture, Fisheries and Forestry; the Department of Environment and Heritage; the Department of Health and Ageing; and the Department of Science Education and Training.

75 Ibid.

76 *IP Toolbox* is a multimedia package that provides information for businesses on the protection and commercialisation of intellectual property: IP Australia, *About IP Toolbox*, <www.ipaustralia.gov.au/toolbox/about.shtml> at 22 June 2004.

77 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

ALRC's views

22.40 The results of the Nicol–Nielsen Study, and submissions to the ALRC's Inquiry, suggest that restrictive licensing of gene patents is not currently pervasive in the Australian biotechnology industry. Further, as outlined in other chapters of this Report, no significant adverse impact on genetic research, commercialisation, or the healthcare system has been demonstrated at this stage. In light of this, the ALRC is not inclined to make recommendations aimed specifically at regulating gene patent licensing practices, or prohibiting certain types of licensing arrangements.

22.41 However, there is evidence to suggest that some participants in the Australian biotechnology sector find the negotiation of patent licences to be problematic. These difficulties stem from a variety of causes, including lack of commercial experience in licensing patents, the unequal bargaining power of the parties, and inadequate resources to commit to extended licence negotiations.[78] In addition, the increasing complexity of the Australian patent landscape may make it difficult to identify relevant patents and negotiate licences.

22.42 An effective way to address these matters is to assist Australian entities in developing commercial skills and negotiation skills by enhancing education programs about the licensing of inventions involving genetic materials and technologies. Biotechnology Australia, in conjunction with its member departments, would be an appropriate body to coordinate the development of such programs, in collaboration with state and territory governments, peak national bodies with an interest in the licensing and commercialisation of intellectual property—such as AusBiotech, AIC, LES and KCA—and other relevant stakeholders.

22.43 Education programs about patent licensing would expand upon projects already undertaken by Biotechnology Australia and federal, state and territory departments to assist Australian entities in commercialising the results of biotechnology research. Education programs for research organisations and biotechnology companies would also complement initiatives recommended in Chapters 17 and 18 to assist research organisations and biotechnology companies in commercialising inventions involving genetic materials and technologies (see Recommendations 17–1 and 18–1).

22.44 The proposed education programs should address issues such as: structuring deals aimed at the licensing of inventions involving genetic materials and technologies; alternative mechanisms by which rights to a patent may be obtained by a third party (such as a patent assignment) and when these mechanisms might be preferable to licensing patent rights; common terms in gene patent licences; typical licensing practices; and negotiation strategies for gene patent holders and licensees of gene patent rights. The programs should also address other issues relevant to the licensing and enforcement of patent rights, including patent litigation insurance.[79]

---

78 Other difficulties faced by Australian research organisations and biotechnology companies in patenting and commercialising research results are considered in Ch 11, 17 and 18.

79 Patent litigation insurance is discussed in Ch 9.

Recommendation 22–1 Biotechnology Australia, in conjunction with its member departments, should develop and implement programs to assist research organisations and biotechnology companies in licensing and commercialising inventions involving genetic materials and technologies. The programs should be developed in collaboration with state and territory governments, peak national bodies with an interest in licensing and commercialisation of intellectual property, and other relevant stakeholders. (See also Recommendations 17–1 and 18–1.)

Model agreements and licensing guidelines

International initiatives

22.45 In a 2002 report, the Organisation for Economic Co-operation and Development (OECD) concluded that concerns about gene patents are often about access to patents through licensing arrangements, rather than about the grant of gene patents per se.[80] The OECD proposed that one means of addressing these concerns is for governments, in consultation with industry, to develop 'good practice guidelines or codes of conduct'.[81] In a report released in 2004, the OECD commented that 'licensing guidelines or model contracts are self-regulatory solutions to some of the perceived problems associated with the patenting of biotechnology'.[82]

22.46 The OECD's Working Party on Biotechnology is currently developing best practice guidelines for the licensing of genetic inventions.[83] It is anticipated that the guidelines will include voluntary, non-binding recommendations as examples of best practice.[84] In November 2003, a steering group of experts met to discuss this issue, and a draft of the licensing guidelines is scheduled to be released in mid-2004. Australia has provided experts to assist in the project.[85]

22.47 Best practice guidelines and model agreements are already an aspect of technology transfer in the United States. As discussed in Chapter 12, the United States National Institutes of Health (NIH) have developed *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating*

80 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), Ch 5.
81 Ibid, 82.
82 Organisation for Economic Co-operation and Development, *Patents and Innovation: Trends and Policy Challenges* (2004), 23.
83 Organisation for Economic Co-operation and Development, *Guidelines for Good Licensing Practices*, <www.oecd.org> at 16 June 2004.
84 Organisation for Economic Co-operation and Development, *Brief Explanation of the Working Party on Biotechnology's Project on Best Practice Guidelines for the Licensing of Genetic Inventions*, <www.oecd.org/dataoecd/2/39/9230380.PDF> at 16 June 2004.
85 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

Biomedical Research Resources (NIH Principles and Guidelines).[86] While the NIH Principles and Guidelines apply specifically to the recipients of NIH research grants and contracts, the NIH has expressed its hope that they 'will be adopted by the wider research community'.[87] The NIH has also developed a 'Simple Letter Agreement for the Transfer of Materials' in conjunction with the NIH Principles and Guidelines. In addition, in 2004 the NIH released a set of draft guidelines providing best practices for the licensing of genomic inventions. However, the draft is not yet publicly available and no timetable for finalising the guidelines has been set.[88]

22.48 Industry organisations (such as LES) and industry publications may also be a source of examples of standard form licence agreements. In addition, a model Materials Transfer Agreement developed by the Association of University Technology Managers (AUTM) is widely used in the United States and other countries.[89]

Submissions and consultations

22.49 DP 68 proposed that AusBiotech, in consultation with Biotechnology Australia, state and territory governments and other relevant stakeholders, should develop model licence agreements and interpretative guidelines for patent licences involving genetic materials and technologies.[90]

22.50 A broad range of submissions supported this proposal.[91] AusBiotech indicated that it could develop 'a pro forma of various model agreements' in partnership with industry groups and anticipated it could have a role in the 'development, facilitation and testing' aspects of such a project.[92]

22.51 However, some submissions and consultations questioned the utility of developing model licence agreements.[93] Submissions noted the wide variety of arrangements pursuant to which gene patents may be licensed and observed that the terms of any licence agreement must be adapted to the particular circumstances and the technology involved. The Queensland Government commented:

---

86 National Institutes of Health, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources' (1999) 64 *FR* 72090.

87 Ibid, 72090.

88 D Malakoff, 'NIH Roils Academe with Advice on Licensing DNA Patents' (2004) 303 *Science* 1757.

89 Materials transfer agreements are discussed in Ch 17.

90 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 23–2.

91 See, eg, Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004.

92 AusBiotech Ltd, *Submission P94*, 16 April 2004. See also AusBiotech Ltd, *Consultation*, Melbourne, 2 April 2004.

93 Centre for Law and Genetics, *Submission P104*, 22 April 2004; Unisearch, *Consultation*, Sydney, 15 March 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

> Licensing agreements need to be tailored in each case, to ensure that the particular circumstances are accounted for. The danger of model licence agreements is that they are not sufficiently tailored to the particular circumstances of each individual case.[94]

22.52 Nonetheless, the Queensland Government supported the development of model licence agreements 'on the basis that these model agreements contain a number of different clauses and consider different scenarios that will assist in tailoring the agreement to meet the requirements of the particular circumstances'.[95]

22.53 Some submissions commented that organisations that are regularly involved in patent licensing often develop their own standard agreements.[96] If so, model licence agreements would be of most benefit to smaller enterprises in the biotechnology sector, which do not have the resources to develop their own standard agreements.

22.54 It was also observed that a number of similar projects are being implemented in this area and that these initiatives should be closely coordinated.[97] DITR suggested that 'the development of any Australian model should preferably await the culmination of the OECD process [to develop best practice guidelines for licensing genetic inventions] in order to benefit from the international developments in this area'.[98]

ALRC's views

22.55 Transaction costs in negotiating licences to gene patents have been identified as an issue for Australian entities. The Nicol–Nielsen Study suggested that licence negotiations often follow a well-trodden path in which certain types of terms generate recurrent controversy. The ALRC agrees in principle with the solutions proposed by the OECD and considers that these problems would be ameliorated by the development of model agreements for the licensing of inventions involving genetic materials and technologies. Model licence agreements could reduce the financial costs and time involved in negotiating licences to gene patents, and would be particularly useful for small and medium sized Australian enterprises, which have limited resources.

22.56 AusBiotech would be an appropriate body to coordinate the development of such model agreements. As the peak industry body in the Australian biotechnology sector, AusBiotech's membership includes entities whose businesses involve diverse aspects of the research, development and commercialisation of genetic materials and technologies. Further, AusBiotech is actively involved in other initiatives to assist entities in the Australian biotechnology sector. For example, the Australian Stock

---

94 Queensland Government, *Submission P103*, 22 April 2004. See also Centre for Law and Genetics, *Submission P104*, 22 April 2004.

95 Queensland Government, *Submission P103*, 22 April 2004.

96 Ibid; Unisearch, *Consultation*, Sydney, 15 March 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

97 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; Walter and Eliza Hall Institute of Medical Research, *Consultation*, Melbourne, 1 April 2004.

98 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

Exchange and AusBiotech have jointly developed a draft code of best practice for reporting by publicly listed biotechnology companies, which is designed to improve the Australian investment community's understanding of biotechnology companies.[99]

22.57 AusBiotech is well placed to seek opinions about the issues that model agreements should address and to balance the interests of patent holders and licensees in developing these agreements. Government involvement in this process (at federal, state and territory levels) would also be desirable to ensure that the public interest in maintaining access to genetic materials and technologies—for example, to genetic research tools—is taken into account in developing model agreements. AusBiotech should, therefore, collaborate with Biotechnology Australia, state and territory governments and other relevant stakeholders in developing the model agreements.

22.58 The ALRC envisages that a number of model agreements could be developed to address the particular issues raised by different types of gene patents and the various purposes for which a licence may be required. Further, each type of model agreement could contain alternative clauses relevant to particular situations to allow the agreements to be adapted to the circumstances of a deal. Entities that choose to use the model agreements would be able to adopt the terms of an appropriate agreement in full, or to modify an agreement by negotiation, in whole or part, in a manner that best suits the needs of the parties. Some terms of the model agreements—for example, financial provisions—are more likely than others to require adaptation to meet the needs of the parties. However, model agreements could offer useful examples of the way in which these terms might be structured, as a starting point in negotiations.

22.59 Agreements developed by bodies such as the NIH and AUTM in the United States,[100] and the licensing guidelines currently being developed by the Biotechnology Working Group of the OECD, may be useful resources in developing the proposed model agreements. The model agreements should include provisions relating to: definitions of particular types of genetic materials and technologies; the scope of rights granted under a licence (including both exclusive and non-exclusive licences); restrictions on the exercise of licence rights (such as reservations of rights for research use); and payment terms (including desirable royalty structures, fixed fee and milestone payment provisions). The agreements might also include model provisions relating to more controversial licensing issues, such as reach-through rights.

22.60 Interpretative guidelines should be developed in conjunction with the model agreements to assist users in understanding the circumstances in which each of the agreements could be used and the scope and purpose of particular terms.

---

99 Australian Stock Exchange and AusBiotech Ltd, *Code of Best Practice for Reporting by Biotechnology, Medical Device and Other Life Sciences Companies: Working Draft* (2004); Australian Stock Exchange, 'ASX Launch World-First Reporting Code for Biotechnology Industry', *Media Release*, 29 April 2004, <www.asx.com.au/about/Media_AA2.shtm>.

100 Aspects of these agreements that address particular requirements of United States law would, however, need to be appropriately adapted for the Australian context.

Recommendation 22–2 AusBiotech Ltd, as the peak industry body in the biotechnology sector, should develop model agreements and interpretative guidelines for patent licences involving genetic materials and technologies. The model agreements should be developed in collaboration with Biotechnology Australia, state and territory governments, and other relevant stakeholders as a non-binding model of desirable licensing practices. (See also Recommendation 17–5.)

Other industry initiatives

22.61 It has been suggested that the biotechnology industry should adopt self-regulatory solutions to address difficulties in obtaining access to patented genetic materials and technologies. The OECD has proposed that 'novel solutions, such as patent pools, clearinghouses and collective licensing organisations, should be further explored to understand their potential utility and their real impact on the biopharmaceutical sector'.[101] This section considers these initiatives in further detail.

Patent pools

22.62 A 'patent pool' is an agreement between two or more patent holders to license their respective patents to one another, or to third parties, on a non-exclusive basis.[102] Participants in a patent pool typically retain ownership of their respective patent rights, and license the pooled patents directly, or through an administering intermediary established for the purpose.

22.63 The establishment of patent pools has been considered in the biotechnology industry as a means of addressing the perceived difficulties created by a growing interdependence among gene patents owned by multiple patent holders and increasingly burdensome transaction costs associated with gene patent licences.[103] The OECD has suggested that patent pools may: (a) help integrate complementary technologies; (b) reduce transaction costs; (c) clear blocking positions; (d) avoid costly infringement litigation; and (e) promote the dissemination of technology.[104]

---

101 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 82. See also Organisation for Economic Co-operation and Development, *Patents and Innovation: Trends and Policy Challenges* (2004), 23.

102 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 4; Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 66. See also Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

103 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 67.

104 Ibid, 66–67. See also J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 8–10.

22.64 However, patent pools have been criticised on the basis of the perceived anti-competitive effects of such arrangements—including that they encourage collusion and price fixing.[105] These issues are discussed further in Chapter 24. In addition, some critics have suggested that patent pools may shield invalid patents.[106]

22.65 Questions have also been raised about the feasibility of establishing patent pools in the biotechnology sector. The OECD has commented that the biotechnology industry is unlike other industries in which patent pools have been established, where defining standards and interoperability of technologies appears to have acted as an incentive.[107] Further, Professor Arti Rai has argued that:

> the relevant players in the biotechnology industry include institutions ranging from federal agencies and academic institutions to various types of private companies, each of which has a different agenda. In the context of a patent pool, these heterogeneous parties would probably have difficulty reaching agreement on the licensing policy the pool should adopt.[108]

22.66 However, Rai considered that a patent pool might be formed in the biotechnology context where multiple patents are absolutely necessary to conduct basic research on a gene or a particular disease.[109] The OECD has also suggested that some of the impediments to patent pools in the biotechnology sector might be overcome if limited fields of application and essential patents can be defined.[110]

Patent clearinghouses

22.67 Patent clearinghouses—or collective rights organisations—are, in effect, formalised patent pools.[111] Clearinghouses may cover a broader range of technologies than a particular patent pool and are more likely to rely on a single entity to coordinate the administrative functions associated with the licensing of patent rights.

---

105 J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 10–11.

106 Ibid, 11.

107 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 67. Patent pools have been created in relation to technologies including sewing machines, aircraft, radio parts, semiconductors and DVD technology: J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office, 4–5.

108 A Rai, 'Intellectual Property Rights in Biotechnology: Addressing New Technology' (1999) 34 *Wake Forest Law Review* 827, 840–841. See also F Scherer, 'The Economics of Human Gene Patents' (2002) 77 *Academic Medicine* 1348, 1363–1364.

109 A Rai, 'Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust' (2001) 16 *Berkeley Technology Law Journal* 813, 847.

110 Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002), 67.

111 The terms 'collective rights organisations' and 'clearinghouses' are sometimes used interchangeably. For the purposes of this Report, the term 'clearinghouses' is used to refer to arrangements with the features identified in this section. See, eg, G Graff and D Zilberman, 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 3 *IP Strategy Today* 1, 3–4.

22.68 Patent clearinghouses are analogous to collecting societies that administer licences over certain types of copyright works.[112] Professor Robert Merges has identified a number of distinctive features of such arrangements including: establishment by knowledgeable industry participants who are able to divide intellectual property rights into categories based on their knowledge and experience; and setting a pre-determined price for the rights within each category (either individually or as a package), which applies equally to all similarly situated licensees.[113] Gregory Graff and David Zilberman have suggested that an effective patent clearinghouse would also provide an arbitration mechanism for monitoring and enforcing contracts.[114]

22.69 The advantages of patent clearinghouses are similar to those identified in the case of patent pools, namely: 'the consolidation of intellectual property rights by intellectual property holders so that negotiating contracts with numerous rights holders is streamlined and transaction costs are consequently reduced'.[115]

22.70 Nicol and Nielsen have proposed that the use of patent clearinghouses in the Australian biotechnology industry warrants further consideration. They suggested that a clearinghouse arrangement may be particularly useful in the context of patented genetic sequences and genetic research tools, but may not be suitable for patent licences relating to drug development.[116]

Submissions and consultations

22.71 DP 68 proposed that AusBiotech should consider ways in which industry initiatives can facilitate the licensing of patented genetic materials and technologies, for example through the establishment of patent pools or patent clearinghouses.[117] A number of submissions encouraged AusBiotech to explore ways in which gene patent licensing might be facilitated.[118] Some submissions supported further consideration

112 See Ch 28.

113 R Merges, 'Contracting Into Liability Rules: Intellectual Property Rights and Collective Rights Organizations' (1996) 84 *California Law Review* 1293, 1296, 1327. See also G Graff and D Zilberman, 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 3 *IP Strategy Today* 1, 9.

114 G Graff and D Zilberman, 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology' (2001) 3 *IP Strategy Today* 1, 9.

115 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 242.

116 Ibid, 243.

117 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 23–3.

118 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004. The Centre for Law and Genetics suggested that Biotechnology Australia and LES would be more appropriate bodies: Centre for Law and Genetics, *Submission P104*, 22 April 2004.

being given to the feasibility of establishing biotechnology patent pools or patent clearinghouses.[119]

22.72 However, other submissions expressed reservations about the need for patent pools or clearinghouses at this stage.[120] The Queensland Government suggested that such initiatives might be premature and, if implemented too early, could have adverse effects—such as to 'hinder industry when there are no real problems; and not be adequate to deal with subsequent problems'.[121] The Garvan Institute of Medical Research observed that a patent pool that included only Australian patents would not be particularly useful, given the global nature of the biotechnology industry.[122]

22.73 Some submissions commented on reasons why biotechnology patent holders might be reluctant to enter into patent pools. The Centre for Law and Genetics suggested that patent pools are most likely to occur when parties in the pool each hold blocking positions—'where this is not the case, a patent pool is unlikely to be a desirable option'.[123] The Centre also noted that low levels of cross-licensing in the Australian biotechnology sector might make patent pools difficult to establish at this stage.[124] Similarly, GlaxoSmithKline submitted that 'voluntary patent pools can help reduce patent thickets and transaction costs, although patentees unwilling to license their patents widely may well be unwilling to add their patents to the pool'.[125]

22.74 The competition law issues associated with patent pools were raised in some submissions. These matters are considered further in Chapter 24.

ALRC's views

22.75 The development of education programs and the creation of model licence agreements will address some of the issues faced by Australian biotechnology companies and research organisations in licensing gene patent rights (see Recommendations 22–1 and 22–2). However, these reforms may not address all the difficulties that Australian entities face in identifying gene patents for which a licence may be required, and in meeting the high transaction costs of negotiating patent licences. Although there is no evidence that further reforms are necessary at this stage, additional mechanisms may be required in the future to facilitate licensing of genetic materials and technologies within the Australian biotechnology sector.

---

119 Nuffield Council on Bioethics, *Submission P102*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004. A few submissions to IP 27 considered that patent pools or patent clearinghouses might facilitate access by laboratories to patented genetic inventions for use in diagnostic genetic testing: G Suthers, *Submission P30*, 2 October 2003; Human Genetics Society of Australasia, *Submission P31*, 3 October 2003; South Australian Government, *Submission P51*, 30 October 2003.

120 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

121 Queensland Government, *Submission P103*, 22 April 2004.

122 Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

123 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

124 Ibid. See also Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004.

125 GlaxoSmithKline, *Submission P33*, 10 October 2003.

22.76 The ALRC believes that a representative industry body should monitor these issues and consider whether additional industry initiatives are needed. As noted above, AusBiotech is the peak biotechnology industry body in Australia, with a diverse membership base. It would be an appropriate body to encourage and coordinate the consideration of industry-based initiatives, including examining the feasibility of establishing patent pools or patent clearinghouses over particular types of patented genetic materials or technologies.

Recommendation 22–3 AusBiotech Ltd should consider whether additional industry initiatives are necessary or desirable to facilitate the licensing of patent rights over genetic materials and technologies.

23. Statutory Licensing Schemes

Contents

Introduction

23.1 This Report makes a range of recommendations intended to facilitate access to patented genetic inventions for use in research and healthcare provision. These include: the enactment of a new experimental use exemption;[1] industry-based initiatives to facilitate licensing;[2] clarifying the terms of the Crown use and compulsory licensing provisions of the *Patents Act 1990* (Cth) (*Patents Act*); and encouraging their use.[3]

23.2 This chapter discusses another option that could facilitate access to patented genetic inventions. This involves the creation of a statutory licensing scheme for certain patented inventions under the *Patents Act*. The primary difference between industry-based licensing and statutory licensing is that a statutory scheme operates pursuant to statutory requirements and conditions.

Statutory licensing for patents

23.3 As discussed elsewhere in this Report, the way in which a patent holder exploits, or chooses not to exploit, a patented invention could impact adversely on the conduct of research, or on the cost effective provision of healthcare.

23.4 Dr Dianne Nicol and Jane Nielsen have suggested establishing a statutory licensing scheme under the *Patents Act* to facilitate third party access to certain types of biotechnology patents. They suggested that this could reduce the time and cost involved in patent searches, monitoring and pursuing infringers, and negotiating

1 See Ch 13.
2 See Ch 22.
3 See Ch 26, 27.

licences; lessen the risk of anti-competitive conduct; increase certainty of access; and decrease individual licence fees. It would also provide an ongoing income for the patent holder through licence fees. In their view, such a scheme could be appropriate for those patented inventions for which broad access is clearly in the public interest—such as patented research tools and diagnostic tests. In these cases, the scheme would provide a means of balancing access and incentive to innovate.[4]

Possible models

23.5 There are several possible models for facilitating the licensing of patented genetic inventions under the *Patents Act.* Briefly, these could involve:

- a statutory framework facilitating the voluntary licensing of patented inventions subject to specified terms and conditions—for example, by enabling patent holders to enter inventions into a public register for licensing;

- a statutory framework facilitating the compulsory licensing of certain patented inventions, subject to specified terms and conditions; or

- a *sui generis* system that permits third party use of genetic inventions in certain circumstances, in return for reasonable remuneration.

Voluntary licensing

23.6 One model for voluntary licensing is the 'licence of right' that exists in the United Kingdom. Under s 46 of the *Patents Act 1977* (UK), a patent holder may apply to the Comptroller of Patents for an entry into the patent register to the effect that licences under a patent are available 'as of right'.[5] Once entered, the patented invention is available for licensing to any third party. The parties must agree on the licence terms or, failing agreement, the Comptroller of Patents may set them.[6] Where a patent holder has registered its patent for such licensing, it is entitled to a reduction in the renewal fees for the patent.[7]

23.7 Part VI of the *Copyright Act 1968* (Cth) (*Copyright Act*) also contains a model in relation to copyright works. Under Part VI, a copyright owner (or collecting society) may refer a 'licence scheme' to the Copyright Tribunal for approval. The licence scheme outlines the circumstances in which the copyright owner would be willing to grant a licence for its copyright work, and stipulates the fees and conditions for such use. The Copyright Tribunal may make an order confirming or varying the scheme, as it considers reasonable in the circumstances. The Tribunal may determine disputes

---

4 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 240–241.

5 *Patents Act 1977* (UK) s 46(1).

6 Ibid s 46(3).

7 Ibid s 46(3)(d).

arising under a licence scheme, including disputes arising from the licensor's refusal to grant a licence in accordance with the scheme.[8]

23.8 Nicol and Nielsen suggested an alternative form of licensing, based on the educational licensing scheme operating under the *Copyright Act*. While that scheme is a form of compulsory licensing, Nicol and Nielsen appear to support a system of voluntary participation. In their view, the scheme would involve:

- patent holders registering patents—putting the onus on them to notify users that they have a patent and will pursue infringers;
- the payment of standard licence fees;
- the collection of fees by approved collecting agencies; and
- the creation of a Patent Tribunal to resolve disputes and determine fee structures.[9]

Compulsory licensing

23.9 The *Copyright Act* contains several statutory licensing schemes that permit the use of copyright material without the copyright owner's consent, subject to the payment of equitable remuneration, and compliance with certain statutory conditions.[10] These schemes are generally administered through collecting societies, which collect and distribute fees on behalf of the copyright owners. The Copyright Tribunal has jurisdiction to settle disputes regarding the determination of royalties or equitable remuneration for uses under the statutory licences, and to arbitrate disputes regarding the terms of licences or proposed licensing schemes.[11]

23.10 These schemes could provide a model for a statutory licensing scheme under the *Patents Act*. For example, the educational licensing scheme operating under Part VB of the *Copyright Act* provides that educational and other institutions may reproduce and communicate works for the proper purposes of the institution, provided that they do so in accordance with the procedures specified in the Act for recording, noting, giving notice, and limiting access to the work.[12] The institution relying on the scheme must give the collecting society a 'remuneration notice', undertaking to pay equitable remuneration for the licensed copies and communications that it makes. Where the licence fees and other conditions cannot be agreed between the institutions and the collecting society, the Copyright Tribunal may determine them.[13]

---

8 See *Copyright Act 1968* (Cth) Part VI. See also R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 216.

9 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 240.

10 For example, see *Copyright Act 1968* (Cth) ss 47, 54–64, 70, 107–109, 183, Pt VA, VB, VC. See also J McKeough, A Stewart and P Griffith, *Intellectual Property in Australia* (3rd ed, 2004), 206.

11 J McKeough, A Stewart and P Griffith, *Intellectual Property in Australia* (3rd ed, 2004), 206.

12 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [12.100].

13 Ibid, [12.130].

23.11 In the United States, Assistant Professor Donna Gitter has proposed a form of statutory licensing for patented DNA sequences. Under her proposed scheme, the patent holder would be required to license a patented sequence to any scientist pursuing commercial research in return for a reasonable licence fee. The scientist would be required to give the patent holder written notice before commencing research using the sequence, and the licence fee would be dependent on the commercial value of the end product developed through the research. This would eliminate the need for licence negotiations and up-front payments, while still protecting the patent holder's right to a reasonable royalty.[14]

A sui generis system

23.12 Luigi Palombi suggested another option under which the person who first discloses a specified genetic sequence, together with a description of its function or utility, would be granted a 'genetic sequence right' as an alternative to a patent. The right would subsist for a period of 20 years. The right owner would receive a royalty for any use of the material, and could enforce the right through national courts in a similar manner to that applying to copyright infringement. In his view, this would facilitate the publication of genetic sequence information but remove the right to withhold licences for such technology.[15]

Nature of participation

23.13 Where a patent holder intends to license its patented invention widely, a statutory licensing scheme could provide an effective and efficient mechanism to facilitate such licensing. For example, a patent holder might choose to register a generic research tool in order to notify all other researchers that the product is subject to a patent, and to provide a mechanism for collecting licence fees for use of the tool. This would avoid the time and cost involved in tracking each individual use. It would also reduce the time and cost of searches in relation to biotechnology patents, and increase certainty for those using these inventions.[16]

23.14 However, a voluntary scheme is unlikely to address all of the circumstances in which a researcher or health provider might seek access to a patented invention. For example, where a patented invention has few substitutes, and is therefore a highly valuable commodity, the patent holder may prefer to enter into an exclusive licence, or not to license the invention at all.

23.15 Where a patent holder has a broad patent over an upstream genetic research tool, but refuses to license the tool to other researchers, there may be a public interest in facilitating access on a compulsory basis. However, this would represent a significant

---

14 D Gitter, 'International Conflicts over Patenting Human DNA Sequences in the United States and The European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption' (2001) 76 *New York University Law Review* 1623, 1679, 1683. See also I Turnbull, *Submission P91*, 16 April 2004.

15 L Palombi, *Submission P28*, 1 October 2003.

16 D Nicol, 'Gene Patents: The Ultimate Snatch' (Paper presented at Hatching, Matching, Snatching and Dispatching, AIHLE 7th Annual Conference, Newcastle, 27–30 June 2002), 13.

exception to the exclusive right of exploitation generally granted by a patent, and may be more appropriately addressed through the Crown use and compulsory licensing provisions of the *Patents Act*.

TRIPS implications

23.16 Any new statutory licensing scheme should be consistent with Australia's obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement).[17] In particular, art 27(1) provides that patent rights generally must be enjoyable without discrimination as to the field of technology. Article 30 deals with exceptions to patent rights, and art 31 deals with other uses without the patent holder's authorisation.

23.17 Article 30 states that members may provide limited exceptions to the exclusive rights conferred by a patent, provided that these exceptions do not unreasonably conflict with the normal exploitation of the patent, and do not unreasonably prejudice the patent holder's legitimate interests, taking into account the legitimate interests of third parties.

23.18 Article 31 provides that members may permit the use of a patented invention without the patent holder's consent, subject to specified conditions. For example, authorisation must be considered on a case-by-case basis, and the applicant must have previously attempted to negotiate a licence from the patent holder (except in circumstances of national emergency, other extreme urgency, or for public non-commercial use).[18]

23.19 It is unlikely that a voluntary statutory licensing scheme would violate Australia's obligations under the TRIPS Agreement. Such a scheme does not constitute an exception to the rights conferred by a patent, or a use without the right holder's authorisation. A voluntary licensing scheme that applied only to patented genetic inventions would not adversely affect a patent holder's enjoyment of its patent rights.

23.20 By contrast, a compulsory statutory licensing scheme for patented inventions could have TRIPS implications. A compulsory scheme that applied only to patented genetic inventions could be inconsistent with art 27(1) if it constitutes 'discrimination' by field of technology.[19]

23.21 A compulsory scheme would be unlikely to comply with art 31 if it authorises the use of a patented invention without considering the individual merits of the case and does not require prior negotiation with the patent holder. There may, however, be scope under art 30 for a compulsory scheme, provided that it is a limited exception to

---

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

18 TRIPS Agreement, art 31(a), (b). See Ch 26, 27 for more detail.

19 See Ch 4.

the exclusive rights conferred by the patent, which does not unreasonably conflict with the normal exploitation of the patent, and does not unreasonably prejudice the patent holder's legitimate interests, taking into account the legitimate interests of third parties. The ALRC notes that the TRIPS Agreement contains a similar provision for exceptions to copyright, which provides a basis for compulsory statutory licensing schemes.[20]

Submissions and consultations

23.22 DP 68 noted that the ALRC had heard some 'in principle' support for a statutory licensing scheme in consultation meetings.[21] However, other stakeholders had raised practical concerns about it. One concern was that the scheme might not be necessary because of the small number of participants, in terms of patent holders and potential licensees in the biotechnology industry.[22] In contrast, another stakeholder suggested that the potentially limited use of the scheme should not be fatal to it.[23] Concerns were also raised about the means of calculating and collecting licence fees;[24] and whether the scheme would be TRIPS compliant.[25] One stakeholder suggested that informal patent pooling might be better than a statutory licensing scheme.[26]

23.23 DP 68 asked whether the Commonwealth should amend the *Patents Act* to insert a statutory licensing scheme for patented inventions. It further asked whether any such scheme should be available only to a limited class of patents or users; whether participation should be voluntary or compulsory; how a reasonable royalty would be determined; and who should administer the scheme.[27]

23.24 The ALRC received mixed responses to this question. Several submissions supported establishing a statutory licensing scheme.[28] For example, the Centre for Law and Genetics supported a voluntary scheme for certain types of patented invention, particularly research tools used in hybrid and applied research. The Centre suggested that this would operate as a type of clearinghouse mechanism, in much the same way as voluntary licensing operates under copyright law.[29]

---

20 TRIPS Agreement, art 13. This article provides that members must confine limitations or exceptions to exclusive rights to certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

21 For example, Western Australian Department of Health and others (healthcare issues), *Consultation*, Perth, 17 September 2003; Intellectual Property Research Institute of Australia, *Consultation*, Melbourne, 4 September 2003; J McKeough, *Consultation*, Sydney, 15 October 2003.

22 Australian Centre for Intellectual Property in Agriculture, *Consultation*, Brisbane, 3 October 2003.

23 J McKeough, *Consultation*, Sydney, 15 October 2003.

24 Australian Copyright Council, *Consultation*, Sydney, 9 September 2003; J McKeough, *Consultation*, Sydney, 15 October 2003.

25 Intellectual Property Research Institute of Australia, *Consultation*, Melbourne, 4 September 2003.

26 Australian Centre for Intellectual Property in Agriculture, *Consultation*, Brisbane, 3 October 2003.

27 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 28–1.

28 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004.

29 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

23.25 The Department of Health and Ageing supported a statutory licensing scheme for research tools and medical diagnostic tests, and suggested that other genetic technologies—such as gene therapies—could be included later if problems emerged. The Department considered that the scheme should be based on voluntary participation, given Australia's obligations under the TRIPS Agreement. However, it noted that such a scheme might not be necessary, depending on the scope of possible exemptions from patent infringement.[30]

23.26 The Department of Health Western Australia noted that a statutory licensing scheme would benefit participants by avoiding the time and costs involved in negotiating licences, and providing a steady income to patent holders. It preferred a broad scheme but, if necessary, would support a scheme that was limited to use in public non-commercial research, healthcare provision, or applied to medical diagnostic tests and research tools generally. The Western Australian Department supported compulsory participation in the scheme. It suggested several options for determining royalties, and expressed general support for a system modelled on the statutory licensing schemes existing in copyright law.[31]

23.27 The Royal College of Pathologists of Australasia also supported the scheme, but emphasised the need for caution in order to avoid disturbing what it characterised as the current equilibrium that has been achieved by the practice of 'ignoring' patents for non-commercial research and testing. It considered that facilitating payment for the use of patented inventions in these contexts could have adverse consequences for basic research and genetic testing, without a commensurate increase in government funding.[32] The Cancer Council Victoria expressed a similar view, noting that, in practice:

> most genetic patents are ignored, for a variety of reasons, by academic and health institutions and patent holders alike. Patent holders generally do not seek royalty and licence fees from researchers and health care providers performing non-commercial research and genetic testing. Proposals that aim to facilitate such payments might disturb the current 'working equilibrium'.[33]

23.28 Ian Turnbull suggested an alternative approach in which departments and institutions would maintain registers of the research tools and patents they use. If this results in the development of a commercial or patentable product, the original patent holder would be entitled to a royalty. However, if this approach were not adopted, he supported the introduction of a statutory licensing scheme that applied for all patents and to all users.[34]

---

30 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.
31 Department of Health Western Australia, *Submission P89*, 16 April 2004.
32 Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004.
33 Cancer Council Victoria, *Submission P101*, 20 April 2004.
34 I Turnbull, *Submission P91*, 16 April 2004.

23.29 Several submissions opposed the creation of a statutory licensing scheme.[35] Some submissions suggested that there is insufficient evidence of a demand or need for such a scheme at this time. The Queensland Government commented that its consultations had indicated that such a regime would be premature at this stage due to the small number of gene patents that have been granted, and the few problems faced by industry and research institutions in obtaining licences in Australia.[36]

23.30 The Department of Industry, Tourism and Resources commented that the *Patents Act* already has a mechanism for facilitating access to patented inventions, in the form of the compulsory licensing provisions.[37] The Australian Centre for Intellectual Property in Agriculture raised competition policy concerns, suggesting that 'collective licensing would only exacerbate competition problems that exist with patents'.[38] GlaxoSmithKline considered that statutory licensing would 'wholly undermine the exclusive rights conferred by patents for the statutorily defined class'. It also considered that it would be very unlikely that such a scheme would be TRIPS compliant.[39]

ALRC's views

23.31 The ALRC has decided not to recommend the creation of a statutory licensing scheme under the *Patents Act,* due to the lack of a demonstrated need for such a scheme at this time, and in the light of other recommendations made in this Report to facilitate access to patented genetic inventions.

23.32 For example, the ALRC recommends a statutory exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention (Chapter 13). The ALRC also recommends that AusBiotech Ltd should consider whether additional industry initiatives are necessary or desirable to facilitate the licensing of patent rights over genetic materials and technologies (Chapter 22) and makes recommendations to clarify the Crown use and compulsory licensing provisions of the *Patents Act* (Chapters 26 and 27).

23.33 However, if evidence arises in the future of a need for such a scheme, the ALRC considers that a voluntary register of patented inventions would provide a useful model. This could be based on the United Kingdom's 'licence of right' for patented inventions, or the *Copyright Act's* Part VI regime for licensing schemes. If a model based on compulsory participation were considered in the future, the ALRC notes that

---

35 See, eg, Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; IP Australia, *Submission P86*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

36 Queensland Government, *Submission P103*, 22 April 2004.

37 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

38 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

39 GlaxoSmithKline, *Submission P85*, 16 April 2004.

care would need to be taken to ensure its compliance with Australia's obligations under the TRIPS Agreement, and any other relevant international instruments to which Australia is a party.

24. Competition Law and Intellectual Property

Contents

Introduction

24.1 The major concerns of competition policy in relation to intellectual property rights are the market power that may result from granting such rights, and the effect of the anti-competitive exercise of these rights.[1] The way in which an intellectual property rights holder exploits, or chooses not to exploit, its rights in genetic materials or technologies could have implications for competition, and may affect access to, and the pricing of, research tools and healthcare services.

24.2 This chapter discusses to what extent competition law can be used to address the anti-competitive exercise of intellectual property rights over genetic materials and technologies. Part IV of the *Trade Practices Act 1974* (Cth) (TPA) proscribes a range of anti-competitive conduct, including the misuse of market power.

---

1 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 25.

24.3 The *Patents Act 1990* (Cth) (*Patents Act*) also addresses certain competition concerns relating to patented inventions.[2] For example, an individual or organisation could apply for a compulsory licence for a patented invention where the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied.[3] In addition, this Report recommends that the *Patents Act* be amended to insert a competition-based test for the grant of a compulsory licence over a patented invention.[4]

Intellectual property and competition

24.4 DP 68 discussed the tension between intellectual property laws and competition law in promoting innovation. While both ultimately seek to increase competition and efficiency within markets to benefit of consumers, their modes of achieving this goal differ:

> competition law strives to maintain a consistently competitive market whilst intellectual property law is content to allow mild distortions in market conditions to realise long term benefits. Thus, despite the common goal, intellectual property law's mode of achieving market efficiencies is antithetical to competition law's view of acceptable behaviour. It is this ideological impasse that produces tension.[5]

24.5 The Australian Competition and Consumer Commission (ACCC) suggested that the interaction between these laws raises several crucial questions, including what types of incentives are necessary to encourage innovation to the level that is best for society; and whether society benefits most if it rewards initial innovation through broad intellectual property protection, or fosters successive innovation by requiring access to such intellectual property.[6]

Existing provisions

Trade Practices Act

24.6 The purpose of the TPA is 'to enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection'.[7]

Anti-competitive conduct

24.7 Part IV of the TPA regulates restrictive dealings affecting competition within a market. Part IV prohibits certain anti-competitive conduct, including:

---

2 For example, through the criteria for patentability; the Crown use and compulsory licensing provisions; and provisions dealing with 'tie-in' conditions in licence arrangements and assignments.

3 *Patents Act 1990* (Cth) s 133.

4 Rec 27–1.

5 P Tucker, 'Refusal to Licence Intellectual Property Rights and Misuse of Market Power: Where is the Line in the Sand?' (1999) 10 *Australian Intellectual Property Journal* 78, 79–80.

6 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

7 *Trade Practices Act 1974* (Cth) s 2.

- contracts, arrangements or understandings which have the purpose or effect of substantially lessening competition, or contain 'exclusionary provisions';[8]
- exclusive dealing and resale price maintenance;[9]
- the misuse of market power;[10] and
- anti-competitive mergers or acquisitions.[11]

24.8 Certain conduct is prohibited if it has the purpose or effect of 'substantially lessening competition' in a market, while other conduct is prohibited on a per se basis. Per se breaches do not involve an analysis of the impact of the conduct on competition because the conduct is presumed, by its nature, to substantially lessen competition.

24.9 Section 51(3) of the TPA exempts conditions in intellectual property licences and assignments from Part IV to the extent that they 'relate to' the subject matter of an intellectual property right. However, this exemption does not extend to the misuse of market power (ss 46, 46A) or prohibitions against resale price maintenance (s 48).

24.10 In addition, conduct that would otherwise breach Part IV of the TPA may, in certain circumstances, be permitted though authorisation or notification. The ACCC may authorise conduct—other than a misuse of market power—if it is satisfied that the proposed agreement or arrangement would be likely to result in a public benefit that outweighs the detriment to the public caused by any lessening of competition.[12]

24.11 A firm may notify the ACCC of conduct, or proposed conduct, constituting exclusive dealing (s 47) under Part IV of the TPA. Generally, the notified conduct will be permitted until the notification is cancelled.[13] The ACCC may withdraw this protection if it is satisfied that the conduct is likely to substantially lessen competition and that no public benefit will result from the conduct, or that the likely public benefit would not outweigh the public detriment constituted by the lessening of competition.[14]

---

8 Ibid ss 45, 4D. An 'exclusionary provision' is a provision of a contract, arrangement or understanding between persons who are in competition with each other, that excludes or limits dealings with a particular supplier or customer, or a particular class of suppliers or customers. Section 4D outlines the circumstances in which a provision is taken to be an 'exclusionary provision' for the purposes of Part IV: In addition, ss 45A–45EB regulate specific types of conduct, including price-fixing and secondary boycotts.

9 Ibid ss 47, 48.

10 Ibid s 46.

11 Ibid ss 50, 50A.

12 Ibid s 88. The ACCC may authorise certain conduct that is per se illegal if the public benefit resulting from the conduct justifies the grant of the authorisation. Section 46 is not directly subject to the authorisation and notification provisions, however if conduct is lawful pursuant to an authorisation or notification, s 46 does not render it unlawful: *Trade Practices Act 1974* (Cth) s 46(6).

13 With the exception of third line forcing, in which case other notification provisions apply: see R Steinwall and others, *Butterworths Australian Competition Law* (2000), 426–427.

14 *Trade Practices Act 1974* (Cth) s 93.

Misuse of market power

24.12 Section 46(1) of the TPA provides that a firm with a substantial degree of power in a market must not take advantage of that power for the purpose of:

- eliminating or substantially damaging a competitor;
- preventing entry into that market or into any other market; or
- deterring or preventing a person from engaging in competitive conduct in that or any other market.[15]

24.13 In order to determine whether a firm has misused its market power, a court first identifies the relevant market in which it is operating. Section 4E of the TPA defines a 'market' as a market in Australia, including 'a market for those goods or services and other goods or services that are substitutable for, or otherwise competitive with, the first-mentioned goods or services'. A market has been described as 'an area of potential close competition in particular goods and/or services and their substitutes'.[16] Markets generally have several dimensions, including product, function, geographic scope and time.[17]

24.14 To determine the degree of power a firm has in a market, a court considers the extent to which its conduct is constrained by the conduct of competitors (or potential competitors), suppliers or customers.[18] The traditional test of market power is a firm's ability 'to raise prices above supply cost without rivals taking away customers in due time, supply cost being the minimum cost an efficient firm would incur in producing the product'.[19] In *Boral Besser Masonry Limited v ACCC*, Gleeson CJ and Callinan J stated that market power is the capacity to act without constraint.[20]

24.15 One indicator of market power is the existence of barriers to entry into the relevant market.[21] Barriers can arise in several forms, including restrictions on access, economies of scale, product differentiation and legal restrictions.[22] In certain circumstances, intellectual property rights could create significant barriers to entry into a market. For example, a biotechnology invention may be so advanced that competitors

---

15 Ibid s 46(1).
16 *Queensland Wire Industries Pty Ltd v The Broken Hill Proprietary Co Ltd* (1989) 167 CLR 177, 195.
17 See generally, G Adams and D McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, 13.
18 *Trade Practices Act 1974* (Cth) s 46(3).
19 *Queensland Wire Industries Pty Ltd v The Broken Hill Proprietary Co Ltd* (1989) 167 CLR 177, 188.
20 *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609, 635.
21 R Steinwall and others, *Butterworths Australian Competition Law* (2000), 216.
22 G Adams and D McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, 14.

must develop new technologies in order to achieve similar results and compete. In addition, a patent holder could aggregate a sufficient number of patents to cover the field in a particular market for a product.[23]

24.16 The ACCC has suggested that the High Court's decision in *Boral Besser Masonry Limited v ACCC* may have limited the application of s 46 because the majority appeared to indicate that an absolute freedom from competitive constraint would be required to establish a substantial degree of market power.[24]

24.17 A firm with substantial market power must not 'take advantage' of that power. The term 'take advantage' means 'use', and does not require a hostile intent.[25] A firm takes advantage of its market power if there is a connection between the conduct at issue and its market power. Recent decisions indicate that where a firm acts in a manner that is consistent with the way it would have acted in a competitive market, its conduct is unlikely to constitute taking advantage of market power.[26]

24.18 Finally, to breach s 46, the firm must have taken advantage of its market power for the purpose of eliminating or substantially damaging a competitor, preventing or deterring a person from entering a market, or engaging in competitive conduct in that or any other market.[27] A firm's purpose may be inferred from its or another person's conduct, or from other relevant circumstances.[28] The proscribed purpose must be a 'substantial' purpose of the conduct, but need not be the sole or dominant purpose.[29]

24.19 The ACCC submitted that, in the absence of a 'smoking gun', it would be particularly difficult to prove that a firm has acted with a proscribed purpose in the intellectual property context.[30]

24.20 According to a Trade Practices Commission[31] background paper, a firm is most likely to misuse its market power in relation to an intellectual property right where it seeks to obtain an advantage greater than that conferred by the relevant statute, or

---

23 Ibid, 14–15.

24 Australian Competition and Consumer Commission, *Submission to the Senate Economics References Committee Inquiry into the Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, 18. See also *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609.

25 *Queensland Wire Industries Pty Ltd v The Broken Hill Proprietary Co Ltd* (1989) 167 CLR 177.

26 See *Melway Publishing Pty Ltd v Robert Hicks Pty Ltd* (2001) 178 ALR 253, 269; *Rural Press Limited v Australian Competition and Consumer Commission* (2003) 203 ALR 217; *Boral Besser Masonry Limited v Australian Competition and Consumer Commission* (2003) 195 ALR 609; *Australian Competition and Consumer Commission v Australian Safeway Stores Pty Ltd* (2003) 198 ALR 657.

27 *Trade Practices Act 1974* (Cth) s 46(1).

28 Ibid s 46(7).

29 Ibid s 4F.

30 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

31 The Trade Practices Commission is now known as the ACCC.

seeks to extend the monopoly conferred into markets other than those protected by the statutory grant.[32]

Access to services

24.21 Part IIIA of the TPA provides a regime to facilitate access to services provided by infrastructure facilities of national importance. This Part does not apply to a service that is the use of intellectual property, except to the extent that this is an integral, but subsidiary part of the service.[33]

Penalties and remedies

24.22 Part VI of the TPA deals with penalties and remedies. Pecuniary penalties may be ordered for a breach of Part IV.[34] Other remedies include divestiture, injunctive relief, damages, ancillary orders and declarations.[35] Section 87 grants the court wide powers to make orders to compensate persons who have suffered, or are likely to suffer, loss or damage as a result of a breach of Part IV. This may include the power to grant a compulsory licence.[36]

Other legislation

Patents Act

24.23 Several provisions of the *Patents Act* address competition concerns related to patented inventions. For example, s 144 makes void contractual conditions that require the purchaser, licensee or lessee to acquire a product from the patent holder which is not covered by the patent; or that prohibit or restrict the use of a product or process supplied or owned by a third party.[37] In addition, ss 128–132 address unjustified threats of patent infringement proceedings; and ss 133–135 provide a scheme for compulsory licensing and forfeiture of patents.[38]

24.24 Several submissions suggested that the ALRC should focus on the breadth of gene patents granted over genetic materials and technologies in addition to the potentially anti-competitive exploitation of such patents. In their view, the granting of

---

32 Trade Practices Commission, *Misuse of Market Power: Section 46 of the Trade Practices Act 1974 (Background Paper)* (1990) Commonwealth of Australia, 35.

33 *Trade Practices Act 1974* (Cth) s 44B.

34 Ibid s 76.

35 See Ibid ss 76, 80–82, 87.

36 Ibid s 87. See also H Ergas, *Treatment of Unilateral Refusals to License and Compulsory Licensing in Australia* (2002), 3–4; R Hoad, 'Compulsory Licensing of Patents: Balancing Innovation and Competition' (2003) 54 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 28, 30. See Ch 27.

37 *Patents Act 1990* (Cth) s 144(1), subject to the exceptions specified in s 144(2). The Intellectual Property and Competition Review Committee recommended that ss 144–146 be repealed, as such conduct would be better addressed through an amended s 51(3) of the *Trade Practices Act 1974* (Cth): Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 161–162. The Australian Government has accepted this recommendation, but has not yet implemented legislation to give it effect: IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 16 June 2004.

38 See generally C Lawson, *Submission P67*, 4 March 2004, 116. See Ch 27.

narrower patents over upstream genetic inventions would lessen the scope of a patent holder's monopoly and, therefore, the opportunity for anti-competitive exploitation of the patented invention.[39] Dr Charles Lawson submitted that the breadth of the patent claim effectively sets the boundaries between patent and competition law. In his view, 'the existing competition laws in the *Trade Practices Act* are unlikely to be found by a court to limit the patent holder's conduct, unless the conduct is outside the "purpose and scope" of the "exclusive rights" granted by the patent'.[40]

24.25 Chapter 6 of this Report discusses the patentability of genetic materials and technologies, and makes several recommendations in that area.

24.26 The ACCC emphasised the importance of ensuring that the scope of intellectual property rights is appropriately defined in the relevant intellectual property legislation. It noted that the scope of such rights could have a significant bearing on the structure of markets. As a general principle, it considered it more important to ensure that markets are structured properly than to engage in ongoing regulation of market conduct:

> Where upstream or downstream markets, or future innovations, require access to a patented invention, there can be a substantial adverse effect on competition in those markets where access is refused, or refused on reasonable terms. There may also be adverse effects in the long run on innovation … The ACCC considers that the long term interests of end users should be the predominant consideration.[41]

24.27 The United States Federal Trade Commission report, *To Promote Innovation: the Proper Balance of Competition and Patent Law and Policy*, recommended various amendments to the United States patent system to ensure a proper balance between competition and patent law and policy.[42]

Copyright Act

24.28 Chapter 28 discusses whether copyright may subsist in the written representation of gene and protein sequences, and in compilations of genetic information. Copyright protects the copyright owner's right to exclude others from reproducing, or otherwise exercising copyright in the work without authorisation. The *Copyright Act 1968* (Cth) has several mechanisms to facilitate access to works that are protected by copyright, including fair dealing exceptions to copyright infringement; and statutory licensing schemes, which permit certain uses of copyright material in exchange for the payment of equitable remuneration.[43]

---

39 See, eg, L Palombi, *Submission P28*, 1 October 2003; G Suthers, *Submission P30*, 2 October 2003; C Lawson, *Submission P67*, 4 March 2004.

40 C Lawson, *Submission P67*, 4 March 2004.

41 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

42 United States Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003).

43 See Ch 28.

Other jurisdictions

24.29 The *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement) provides that members may adopt appropriate measures to prevent or control anti-competitive practices in relation to intellectual property licensing.[44]

United States

24.30 The United States antitrust laws are set out in several statutes. Broadly, the *Sherman Act 1890* (US) prohibits agreements between unrelated entities that unreasonably restrain trade, and the maintenance of monopolies.[45] The *Federal Trade Commission Act 1914* (US) provides that the Federal Trade Commission (FTC) may challenge unfair methods of competition.[46] The United States Department of Justice and the FTC (the Agencies) have issued *Antitrust Guidelines for the Licensing of Intellectual Property* (US Licensing Guidelines), to assist those involved in intellectual property licensing.[47]

24.31 The US Licensing Guidelines provide that licensing arrangements will raise antitrust concerns if they are likely to adversely affect the prices, quantities, qualities, or varieties of goods and services either currently or potentially available.[48] While most intellectual property licensing conditions are assessed under the 'rule of reason';[49] some arrangements are considered so anti-competitive that they are treated as unlawful per se.[50] The US Licensing Guidelines provide a 'safety zone', in which the Agencies generally will not challenge a restraint in a licence arrangement if: (a) it is not facially anti-competitive;[51] and (b) the licensor and its licensees collectively account for no more than 20% of each relevant market significantly affected by the restraint.[52]

24.32 In addition, the Agencies generally will not challenge a restraint that may affect competition in a technology market if: (a) the restraint is not facially anti-competitive; and (b) there are four or more independently controlled technologies—in addition to

---

44 Provided that these measures are consistent with other provisions in the TRIPS Agreement: *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995), art 40.

45 *Sherman Act 1890* (US) ss 1, 2.

46 *Federal Trade Commission Act 1914* (US) s 5. See generally C Oddie and P Eyers, 'Erosion of Rights or Redressing the Balance: Competition Challenges to Intellectual Property Rights' (2004) 12 *Trade Practices Law Journal* 6, 10.

47 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995).

48 Ibid, 7.

49 Ibid, 16. Under the 'rule of reason', the Agencies consider whether the restraint is likely to have an anti-competitive effect and, if so, whether it is reasonably necessary to achieve pro-competitive benefits that outweigh this effect.

50 These include price fixing, output restraints, market division among horizontal competitors, and certain group boycotts and resale price maintenance: see Ibid, 16.

51 'Facially anti-competitive' means restraints that normally warrant per se treatment, and other restraints of a kind that would always, or almost always, tend to reduce output or increase prices.

52 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), 22.

those controlled by the parties—that may be substitutable for the licensed technology at a comparable cost to the user.[53]

European Union

24.33 The European Community Rules of Competition are set out in Title VI of the *European Community Treaty*. Articles 81 and 82 are the primary treaty provisions dealing with competition law.

24.34 Article 81 prohibits restrictive agreements or concerted practices between firms that may affect trade between member States, and which have anti-competitive objects or effects.[54] This is subject to individual exemptions, and block exemptions that are granted to certain categories of agreements.[55]

24.35 In May 2004, a new technology transfer block exemption commenced operation. The block exemption provides a short list of restrictive licensing provisions that generally will be prohibited; and a 'safe harbour' below certain market share thresholds—20% for licensing agreements between competitors and 30% for agreements between non-competitors. The European Commission has published a new set of guidelines on the application of art 81 to licensing agreements.[56]

24.36 Article 82 prohibits an abuse by one or more firms of a dominant position within the common market, or in a substantial part of it, to the extent that it may affect trade between members. The European Court of Justice (ECJ) has held that, in exceptional circumstances, the refusal to license an intellectual property right could constitute an abuse of a dominant position.[57] In *Radio Telefis Eireann v EC Commission* (*Magill*), the ECJ held that a copyright owner's refusal to license its copyright information in a derivative market constituted 'exceptional circumstances' because the refusal had prevented the emergence of a new product and monopolised a derivative market.[58]

---

53 Ibid, 23. The Agencies have also issued antitrust guidelines for collaborations among competitors: Federal Trade Commission and United States Department of Justice, *Antitrust Guidelines for Collaborations among Competitors* (2000).

54 A 'restrictive agreement' is an agreement between two or more firms that requires one or more of the parties to adopt a specific type of conduct. A 'concerted practice' involves co-ordination among firms that falls short of a formal agreement.

55 A Gutterman, *Innovation and Competition Policy* (1997), 78–79.

56 *Commission Regulation (EC) No 772/2004 of 27 April 2004 on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements* (2004).

57 This is an application of the 'essential facilities' doctrine, which generally provides that where access to a facility is essential in order for a person to operate in a particular market, the owner of the facility may, in certain circumstances, be obliged to grant access to that person: see C Oddie and P Eyers, 'Erosion of Rights or Redressing the Balance: Competition Challenges to Intellectual Property Rights' (2004) 12 *Trade Practices Law Journal* 6, 7–10.

58 *Radio Telefis Eireann v EC Commission (Magill)* [1995] ECR 743. See also C Oddie and P Eyers, 'Erosion of Rights or Redressing the Balance: Competition Challenges to Intellectual Property Rights' (2004) 12 *Trade Practices Law Journal* 6, 7–8; A van Melle, 'Refusals to License Intellectual Property Rights: The Impact of RTE v EC Commission (Magill) on Australian and New Zealand Competition Law' (1997) 25 *Australian Business Law Review* 4; C Lawson, *Submission P67*, 4 March 2004.

24.37 More recently, in *IMS Health v NDC Health*, the ECJ held that the refusal by a company with a dominant position in the market to grant a licence to use a copyright product could amount to an abuse of a dominant position within a market where:

- the company requesting a licence intends to offer new products or services not offered by the copyright right owner, where there is consumer demand;
- the refusal is not justified by objective considerations; and
- the refusal eliminates all competition by reserving to the copyright owner the entire relevant market.[59]

Application of competition law

Anti-competitive conduct

24.38 A patent holder, or its licensee, could engage in various forms of anti-competitive conduct in relation to its patent (or other intellectual property right) over genetic material or technologies.

Licences and assignments

24.39 Chapter 22 discusses licensing practices in relation to patented genetic materials and technologies. A patent holder could choose to enter into an exclusive licence for a patented invention; or a non-exclusive licence, which permits several licensees to exploit the invention. A licence for a patented genetic invention could contain conditions that have a beneficial or detrimental effect on competition within a market.

24.40 Intellectual property licences could be anti-competitive where: competitors enter into a licence to divide markets, fix prices or limit output; the licence has an exclusionary effect, for example where it involves a 'tie-out' arrangement that excludes other potential licensors of substitutable intellectual property; or facilitates the licensee's accumulation of market power in competing technologies.[60]

24.41 Other examples of potentially anti-competitive licence conditions are: grant-back provisions, which require the licensee to license back improvements that it makes to the licensed intellectual property; price or quantity restrictions on the licensee; reach-through provisions, which are claims by the licensor to intellectual property rights in new products that might be produced through use of the licensed invention;

---

59 *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* (Case C–418/01, European Court of Justice, 29 April 2004), [52].

60 G Adams and D McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, 20.

and tying conditions, where the patent holder includes non-patented products in the licence.[61]

Refusal to license

24.42 A patent holder could seek to protect its monopoly by refusing to license its patented genetic invention. Alternatively, it could charge prohibitive licence fees, constituting a constructive refusal to licence. For example, the owner of a broad patent over an upstream genetic research tool, such as a DNA sequence, could refuse to license the tool to other researchers. This refusal to license could affect competition within the relevant market for the research tool, or within downstream markets for goods and services developed using the tool.

24.43 The holder of a patent for a genetic diagnostic test could refuse to license the test to other laboratories. For example, in 2002 Myriad Genetics Inc (Myriad) declared that it would not license its patent over testing for BRCA1–linked predisposition to breast and ovarian cancer. As a result, laboratories in Canada and Europe that previously had tested for BRCA1 were informed they would be required to forward all samples to Myriad for testing.[62]

Infringement actions

24.44 A patent holder could use the threat of infringement proceedings to protect its monopoly rights in the patented invention. The Cancer Council Victoria suggested that:

> the disparity between the cost of performing genetic tests and the cost of a legal challenge means that the mere threat of receiving an infringement notice is sufficient to force the vast majority of diagnostic laboratories to immediately stop testing, even if the laboratory believes the patents are not being infringed, are being misrepresented or are of dubious validity or scope. It is simply cheaper and less risky to cease providing the test.[63]

24.45 Section 128 of the *Patents Act* provides a mechanism for obtaining relief from unjustified threats of patent infringement. Where a person threatens infringement proceedings, an aggrieved person may apply to a court for a declaration that the threats are unjustifiable; an injunction against continuance of the threats; and the recovery of any damages sustained by the applicant as a result of the threats.[64]

---

61 See J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 40, 46–47.

62 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).

63 Cancer Council Victoria, *Submission P101*, 20 April 2004.

64 *Patents Act 1990* (Cth) s 128(1).

Patent pools and cross-licensing

24.46 A 'patent pool' is an aggregation of patent rights held by an individual or organisation for the purpose of licensing the patents as a joint package.[65] 'Cross-licences' are mutual arrangements between rights holders granting rights to use the intellectual property owned by each party to the other parties.[66]

24.47 Depending on their nature, patent pools and cross-licensing arrangements could have either positive or negative implications for competition. The US Licensing Guidelines state that pooling may be pro-competitive when it: integrates complementary technologies; reduces transaction costs; clears blocking positions; avoids costly infringement litigation; and promotes the dissemination of technology.[67]

24.48 By contrast, pooling and cross-licensing may be anti-competitive if: the excluded firms cannot compete effectively in the relevant market for the goods or services that incorporate the licensed technologies; the pool participants collectively possess market power in the relevant market; and the limitations on participation are not reasonably related to the efficient development and exploitation of the pooled technologies. A patent pool could also be anti-competitive if it deters participants from engaging in research and development, thus retarding innovation.[68]

24.49 The ACCC noted the potential for price fixing, market sharing, or agreements among competitors without any possible pro-competitive justification. It suggested that patent pools would be less likely to raise competition concerns if:

- they combine complementary patents;
- licensing arrangements do not restrict access to the pool's technology by competitors, potential entrants, or third parties; and
- pooling arrangements do not facilitate sharing or access to competitors' commercially sensitive information in the relevant or downstream markets.[69]

---

65 See Ch 22.

66 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

67 United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), 28.

68 Ibid, 28–29. See also J Clark and others, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (2000) United States Patents and Trademarks Office; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6; W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003).

69 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

Application of the Trade Practices Act

Anti-competitive conduct

24.50 The exploitation of a patent (or other intellectual property right) in a genetic invention could raise various competition concerns. The anti-competitive licensing of a patented genetic research tool or patented medical genetic test could inhibit innovation, or effectively extend the scope of the monopoly granted.[70]

24.51 For example, s 45 of the TPA could apply where a patent holder licenses a patented genetic research tool to a licensee who has the potential to develop an improvement that would compete with the licensed tool. If the licence provides the licensor with rights to any improvements in the invention, this could substantially lessen competition in the market. Section 47 of the TPA could apply where a patent holder licenses a patented medical genetic test to a licensee on the condition that the licensee also accepts unrelated goods, and this has the purpose or effect of substantially lessening competition in the market for the tied goods.

Intellectual property exemption

24.52 Section 51(3) of the TPA exempts conditions in licences and assignments from Part IV to the extent that they 'relate to' the subject matter of an intellectual property right. As noted above, this exemption does not extend to the misuse of market power or resale price maintenance.

24.53 There is some uncertainty as to the scope of the s 51(3) exemption, due to ambiguity regarding the term 'relates to'. The National Competition Council (NCC) has noted that there are three possible interpretations of the section:

- narrow interpretation—a condition relates to intellectual property or the goods produced using it if it relates directly to those goods produced;
- intermediate interpretation—a condition relates to intellectual property or the goods produced using it if the condition seeks to protect and exploit the intellectual property owner's exclusive rights, or to secure an advantage that is not collateral to those rights; or
- broad interpretation—a condition relates to intellectual property or the goods produced using it unless it seeks to apply to an almost entirely unrelated transaction or arrangement.[71]

---

70 J Nielsen, *Reach–Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-competitive Reach (Working Paper)* (2004), 26.

71 National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999), 184. See also C Oddie and P Eyers, 'Erosion of Rights or Redressing the Balance: Competition Challenges to Intellectual Property Rights' (2004) 12 *Trade Practices Law Journal* 6, 12.

24.54 Section 51(3) has been subject to little judicial consideration. In *Transfield Pty Ltd* v *Arlo International Ltd*, Mason J stated that the exemption would not apply where a licence term seeks to obtain an advantage collateral to the subject matter of the invention.[72] In a 1991 background paper, the Trade Practices Commission stated that, where there is any doubt about whether a condition 'relates to' the subject matter of a licence, it would consider the purpose and scope of the exclusive rights granted by the intellectual property regime to determine whether the licence condition provides an advantage outside the scope of these rights.[73]

24.55 Section 51(3) of the TPA has been subject to a number of reviews.[74] The Intellectual Property and Competition Review Committee (IPCRC) concluded that the current section is inappropriate, due to the uncertainty surrounding its scope, and the possibility that it might exempt from relevant sections of the TPA virtually all agreements that touch on intellectual property. The IPCRC also stated that it could not see a clear policy reason for the uneven coverage of the exemption.[75]

24.56 The IPCRC concluded that the exemption should be reframed in order to achieve an appropriate balance between the needs of the intellectual property system and the wider goals of competition policy. It recommended that s 51(1)(a)(i) be amended to list all the relevant intellectual property statutes; and that s 51(3) and related provisions be repealed. In addition, it recommended that new provisions be inserted to provide that a breach of Part IV or s 4D of the TPA does not occur by reason of the inclusion of conditions in a licence, contract, arrangement or understanding, that relate to the subject matter of an intellectual property statute, so long as those conditions do not result, or are not likely to result, in a substantial lessening of competition.[76]

24.57 The Australian Government accepted this recommendation in part. In its response to the IPCRC Report, the Government stated that intellectual property rights would continue to be accorded distinctive treatment under the TPA, and ss 46, 46A and 48 would continue to be excluded from the scope of the exemption. Intellectual property licence conditions would be subject to the provisions of Part IV, but a contravention of the per se prohibitions of ss 4D, 45, 45A and 47 would instead be subject to a substantial lessening of competition test.[77] The Australian Government has not yet implemented this amendment, but has indicated that it intends to introduce it into Parliament later this year.

---

72 *Transfield Pty Ltd v Arlo International Ltd* (1980) 144 CLR 83.

73 Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property: Background Paper* (1991), 13.

74 National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999); Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000).

75 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 212.

76 Ibid, 215.

77 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 16 June 2004.

24.58 Geoff Adams and Dan McLennan have suggested that very few intellectual property licence terms will be likely to lead to a substantial lessening of competition. In their view, intellectual property owners will usually be incapable of influencing competition in a market. In any case, the pro-competitive aspects of a licence restriction will often outweigh any anti-competitive aspects.[78]

Misuse of market power

24.59 Possible conduct that could amount to a misuse of market power includes the refusal to license an intellectual property right, the use of restrictive licensing conditions, and abusive infringement suits.[79]

24.60 In many cases, a patent will not confer market power on the patent holder because there will be numerous substitutes available for the patented invention. However, as some biotechnology inventions may be so unique that they cannot be substituted for other products, the grant of a patent may confer market power. Where this is the case, it would be necessary to establish that the conduct in question constituted taking advantage of that market power for a proscribed purpose under the TPA. However, if the firm has acted in a manner that is consistent with the way it would have acted in a competitive market, it would not have taken advantage of this market power.[80]

24.61 Adams and McLennan argue that a unilateral refusal to license an intellectual property right generally will not constitute a breach of s 46, on the basis that:

> To hold otherwise could weaken or remove the economic benefits created by IPRs [intellectual property rights], could completely nullify what would otherwise be a right available under an IP regime, and would be inconsistent with the now widely accepted view that IP and competition laws are generally complementary.[81]

24.62 They argue that there may be limited exceptions to this general rule, including where the refusal to license intellectual property adversely affects other markets; or the intellectual property owner refuses to license its intellectual property because the proposed licensee would not accept terms that were unreasonably restrictive of competition.[82] Jane Nielsen has commented similarly that, on the basis of current case law, a refusal to license would breach s 46 only where it stifles competition in a

---

78 G Adams and D McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, 18.

79 Trade Practices Commission, *Application of the Trade Practices Act to Intellectual Property: Background Paper* (1991), 35.

80 See R Hoad, 'Compulsory Licensing of Patents: Balancing Innovation and Competition' (2003) 54 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 28, 30.

81 G Adams and D McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, 16.

82 Ibid, 16–17.

downstream or secondary market, preventing a competitor from exploiting a new product in that market.[83]

24.63 In any case, few cases brought under s 46 have been successful. In the Senate Economics References Committee's report, *The Effectiveness of the Trade Practices Act 1974 in Protecting Small Business*, the Government Senators stated:

> It would, in Government Senators' view, be naïve to think that the striking lack of success of s 46 cases demonstrates that anticompetitive behaviour is seldom, if ever engaged in the Australian economy … A more realistic explanation is that it reflects the formidable difficulties of proof, the expense and complexity of such proceedings, and the high hurdles which this section, as currently drafted, raises.[84]

Reform of the Trade Practices Act

24.64 The ALRC has not heard evidence that the exploitation of intellectual property rights in genetic materials and technologies has raised significant competition problems to date. Nevertheless, the ALRC notes the potential for such problems to arise in the future and the concerns expressed in other reviews about the lack of clarity in relation to intellectual property rights under the TPA.[85] The ALRC considered several options to strengthen and clarify the TPA in addressing the anti-competitive exploitation of intellectual property rights in genetic materials and technologies.

Amend the intellectual property exemption

24.65 In a submission to this Inquiry, the ACCC commented that the IPCRC's proposed amendment to the intellectual property exemption would significantly enhance its ability to deal with anti-competitive conduct resulting from the licensing and assignment of patent rights. It noted that licensing and assignment conditions that constitute anti-competitive agreements—including price fixing, exclusionary provisions or exclusive dealing—might breach Part IV if they substantially lessen competition. However, such agreements could be authorised or notified under Part VII.[86]

24.66 DP 68 discussed the concerns arising in relation to the s 51(3) exemption. However, as the Australian Government had indicated that it would amend the provision, the ALRC did not make any reform proposal in this area.

---

83 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 45.

84 Senate Economics References Committee, *The Effectiveness of the Trade Practices Act 1974 in Protecting Small Business* (2004), 82–83.

85 For example, Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000); Trade Practices Act Review, *Review of the Competition Provisions of the Trade Practices Act* (2003).

86 Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004.

24.67 There was considerable support for amendment of the exemption in submissions and consultations.[87] The Queensland Government submitted that clarification of the relationship between Part IV of the TPA and intellectual property laws would assist industry, especially in relation to patented genetic materials and technologies.[88] The Department of Health and Ageing submitted that the application of competition policy through the TPA could achieve clarity regarding the appropriate use of licensing.[89]

24.68 However, others argued that the proposed amendment might not adequately address existing concerns raised in relation to this exemption.[90] For example, Dr Amanda McBratney and others submitted that, even after the proposed amendments, s 51(3) would remain unclear and unworkable. They argued that the section should be substantially redrafted to make it more clear and certain.[91]

24.69 Lawson cautioned against the retention of the 'relates to' terminology in the s 51(3) exemption. He noted that the retention of this term would permit patent holders to construct their commercial arrangements so that their licence and assignment terms would retain protection from Part IV of the TPA. The breadth of the patent will delineate the 'purpose and scope' of the exclusive rights, which will impact on the boundaries of the exemption. In his view, broad gene patents could therefore have considerable exemption from competition law.[92]

24.70 The Centre for Law and Genetics suggested that, in the light of the significant delay in amending s 51(3), the ALRC should recommend such amendment. The Centre suggested that the ALRC could:

- endorse the IPCRC's recommendation (however, in the Centre's view, the Australian Government's response to this recommendation would significantly ameliorate its force, and should not be endorsed);
- give further consideration to the NCC's recommendations;[93] or
- recommend a new approach based on the US Licensing Guidelines, or at least recommend that this model be investigated by an appropriate body.[94]

---

87 J McKeough, *Consultation*, Sydney, 23 March 2004; Centre for Law and Genetics, *Submission P117*, 5 May 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004; Australian Competition and Consumer Commission, *Consultation*, Canberra, 26 March 2004; Queensland Government, *Submission P103*, 22 April 2004.

88 Queensland Government, *Submission P103*, 22 April 2004.

89 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

90 For example, A McBratney and others, *Submission P47*, 22 October 2003; D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 247.

91 A McBratney and others, *Submission P47*, 22 October 2003.

92 C Lawson, *Submission P67*, 4 March 2004.

93 The NCC recommended, among other things, that the exemption in s 51(3) be retained, but amended to remove protection for price and quantity restrictions and horizontal agreements: National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974: Final Report* (1999), 243.

94 Centre for Law and Genetics, *Submission P117*, 5 May 2004.

24.71 The European Union and the United States have taken a different approach to the application of competition law to intellectual property licensing. These jurisdictions have not provided direct legislative exemptions for intellectual property licence conditions, but have established a 'safety zone' or 'safe harbour' within which certain licence conditions will not normally be subject to competition analysis.[95] As DP 68 noted, an amended s 51(3) of the TPA would appear to provide an effective 'safety zone' or 'safe harbour' for certain licence conditions that relate to intellectual property, but only to the extent that they do not substantially lessen competition within the market.[96]

Intellectual property guidelines

24.72 DP 68 noted that several review bodies, including the IPCRC and the Trade Practices Act Review Committee, have recommended the development of guidelines to clarify the application of Part IV of the TPA to intellectual property.[97]

24.73 The IPCRC recommended that the ACCC should issue guidelines as to the manner in which it will implement any enforcement activities relating to s 51(3) of the TPA. It stated that the guidelines should provide sufficient direction to holders of intellectual property rights to clarify the types of behaviour likely to result in a substantial lessening of competition. The guidelines should also provide for potential contractors to obtain written clearances from the ACCC as to whether proposed behaviour is likely to result in a substantial lessening of competition.[98]

24.74 The Australian Government has asked the ACCC to issue such guidelines,[99] and the ACCC has advised the ALRC that it intends to do so, once s 51(3) of the TPA has been amended.[100] Adams and McLennan have commented that:

---

95 See United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), 22; *Commission Regulation (EC) No 772/2004 of 27 April 2004 on the Application of Article 81(3) of the Treaty to Categories of Technology Transfer Agreements* (2004).

96 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [24.117].

97 For example, Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 215; Trade Practices Act Review, *Review of the Competition Provisions of the Trade Practices Act* (2003), Rec 3.3. See also I Eagles and L Longdin, 'Competition in Information and Computer Technology Markets: Intellectual Property Licensing and Section 51(3) of the Trade Practices Act 1974' (2003) 3 *Queensland University of Technology Law Journal* 28.

98 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 213, 215.

99 See Trade Practices Act Review, *Review of the Competition Provisions of the Trade Practices Act* (2003), 87.

100 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

> the development of regulatory guidelines by the ACCC will alleviate … concerns and assist in the development of a coherent approach to trade practices regulation of IP licensing. Such guidelines would address these concerns through the development of clear policies and assist in the identification of conditions that would or would not attract scrutiny from competition regulators.[101]

24.75 As noted above, both the United States and the European Union have released guidelines on the application of antitrust and competition laws to licensing agreements and other collaborations involving intellectual property.[102] These guidelines advise intellectual property rights holders and other market participants about the possible competition implications of certain licence arrangements. As a result, they provide greater certainty to the parties to these agreements about whether their arrangements are likely to comply with competition law.

24.76 DP 68 proposed that the ACCC should develop guidelines regarding the relationship between Part IV of the TPA and intellectual property, with particular regard to patented genetic materials and technologies. The guidelines should extend to patent pools and cross-licensing involving patented genetic materials and technologies.[103]

24.77 Many submissions supported this proposal.[104] However, some submissions emphasised that these guidelines should address intellectual property rights broadly, rather than focusing on patented genetic materials and technologies.[105] For example, the Centre for Law and Genetics suggested that the guidelines should be sufficiently general to 'take into account the multitude of technologies that may come within their ambit'. The Centre also noted that many dealings in patented genetic technologies involve considerable complexity. Accordingly, while guidelines could assist industry in delineating the reach of competition law with respect to intellectual property dealings, 'attempting to be too prescriptive might have an adverse effect on the operation of the industry'.[106]

---

101 G Adams and D McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10, 23.

102 See United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995); United States Department of Justice and Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995); European Commission, *Guidelines on the Application of Article 81 of the EC Treaty to Technology Transfer Agreements* (2004).

103 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 24–1.

104 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

105 See, eg, Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

106 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

24.78 In a supplementary submission, the Centre for Law and Genetics suggested that the ACCC could sponsor codes of conduct within the technology industry, to regulate the licensing of biotechnology. The Centre suggested that the biotechnology industry could be persuaded to enter these codes of conduct by the threat of more punitive legislation.[107]

24.79 The Department of Health and Ageing suggested that in developing the proposed guidelines, the ACCC could draw on the best practice guidelines for the licensing of genetic inventions that are currently being developed by the Organisation for Economic Co-operation and Development (OECD).[108] In addition, the Queensland Government suggested that the US Licensing Guidelines might be of assistance.[109] Another submission stated that full consultation with affected industries should take place before such guidelines are introduced.[110]

24.80 In its submission, the ACCC confirmed that it would issue guidelines outlining the way it will approach the application of Part IV of the TPA to intellectual property in its enforcement work. The ACCC stated that such guidelines would assist intellectual property rights owners, license holders, potential assignees and their legal advisers to understand their obligations under Part IV. They would also seek to provide guidance as to the types of intellectual property rights licensing conditions on which the ACCC might focus in its enforcement of the TPA. The ACCC stated that the proposed guidelines would cover the circumstances in which licensing or assignment conditions might:

- be exempt under s 51(3) of the TPA;
- breach Part IV of the TPA; and
- be eligible for authorisation by the ACCC under Part VII of the TPA.[111]

24.81 The ACCC noted that the process for developing the proposed guidelines would involve public consultation, and that this would provide the ideal opportunity for input on specific issues relating to intellectual property in genetic material and technologies—including licensing arrangements, patent pooling and cross-licensing.[112]

---

107 Centre for Law and Genetics, *Submission P117*, 5 May 2004.

108 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004. See also Organisation for Economic Co-operation and Development, *Brief Explanation of the Working Party on Biotechnology's Project on Best Practice Guidelines for the Licensing of Genetic Inventions*, <www.oecd.org/dataoecd/2/39/9230380.PDF> at 16 June 2004; and Ch 22.

109 Queensland Government, *Submission P103*, 22 April 2004.

110 *Confidential Submission P77 CON*, 16 April 2004.

111 Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004.

112 Ibid.

ALRC's views

24.82 The ALRC agrees with the IPCRC about the importance of maintaining an appropriate balance between intellectual property rights and competition principles, and agrees that the current wording of the TPA might not achieve that balance. In particular, the ALRC is concerned that the scope for exploitation of intellectual property rights should be more clearly defined.

24.83 DP 68 noted that the Australian Government has said that it will amend the intellectual property exemption under the TPA generally in accordance with the IPCRC's recommendation. The ALRC received strong support for clarification of this exemption in submissions and consultations. While some submissions supported the IPCRC's recommendation, others supported the Government's approach, and several argued that the exemption should be completely redrafted.

24.84 The ALRC considers that clarification of the exemption would provide greater certainty for intellectual property right holders, and those seeking to license or acquire intellectual property rights in genetic materials and technologies. It would also provide greater transparency for market participants regarding the application of competition law to these dealings. Accordingly, the ALRC recommends that the Commonwealth should amend s 51(3) of the TPA to clarify the relationship between Part IV of the Act and intellectual property rights.

24.85 The ALRC believes the amendment is especially important because of its nexus with the development and release of the proposed ACCC guidelines on intellectual property licensing. The ALRC considers that such guidelines will provide the opportunity for much needed clarity as to the circumstances in which intellectual property licensing may be anti-competitive.

24.86 Accordingly, the ALRC also recommends that the ACCC should develop guidelines to clarify the relationship between Part IV of the TPA and intellectual property rights. This recommendation is broader than that proposed in DP 68, as it acknowledges the need for clarification of the relationship between Part IV of the TPA and intellectual property rights generally. However, the ALRC considers that there is also a need for the ACCC to address the specific issues raised in relation to the exploitation of intellectual property rights in genetic materials and technologies.

24.87 The guidelines should therefore address: when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV; and when conduct that would otherwise breach Part IV might be authorised under Part VII of the TPA. The guidelines should also deal with the exploitation of intellectual property rights in genetic materials and technologies, including by patent pools and cross-licensing.

24.88 These guidelines must be consistent with Part IV of the TPA and existing case law. While the final interpretation of the Act lies with the courts, the ALRC considers that a clear explanation of the ACCC's approach in assessing whether the exploitation of a patented genetic invention would breach the TPA would be useful; and would provide greater certainty for market participants when entering into licences or assignments of intellectual property rights. As noted above, most submissions supported this approach, as have several other reviews.

24.89 The ALRC considers that the guidelines operating in the United States and the European Union would be a useful resource in developing the ACCC guidelines. In addition, the ALRC suggests that the guidelines being developed by the OECD in regard to the licensing of genetic inventions may provide further assistance in relation to particular problems in the licensing of genetic materials and technologies.

Recommendation 24–1 The Commonwealth should amend s 51(3) of the *Trade Practices Act 1974* (Cth) (*Trade Practices Act*) to clarify the relationship between Part IV of the Act and intellectual property rights.

Recommendation 24–2 The Australian Competition and Consumer Commission (ACCC) should develop guidelines to clarify the relationship between Part IV of the *Trade Practices Act* and intellectual property rights. The guidelines should address:

(a) when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV; and

(b) when conduct that would otherwise breach Part IV might be authorised under Part VII of the *Trade Practices Act*.

The guidelines should extend to the exploitation of intellectual property rights in genetic materials and technologies, including patent pools and cross-licensing.

Monitoring and enforcement

Role of the ACCC

24.90 The ACCC is the statutory authority responsible for enforcing the TPA. Generally, it deals with complaints and inquiries about possible breaches of the Act; proposed mergers; applications for authorisation and notifications; determinations and undertakings under the access regime; inquiries made on its own initiative; and government directions and references.[113]

113 R Baxt, R Blunt and A Tonking, *Australian Trade Practices Reporter: Looseleaf Service* (1980) Vol 1, [800], [910].

24.91 Nielsen has commented that although various forms of conduct in relation to gene patents could contravene Part IV of the TPA, very few of these dealings are ever queried or litigated. She suggested several possible reasons for this, including:

- the resources necessary to monitor the licensing practices of companies;
- the confidential nature of most patent licence agreements;
- the resources necessary to challenge the terms on which a patent licence is granted, or a refusal to licence a patent; and
- the uncertain outcome of any proposed litigation, which may deter potential litigants from bringing proceedings.[114]

Submissions and consultations

24.92 DP 68 proposed that the ACCC should review the conduct of firms dealing with patented genetic materials and technologies, as the need arises, to determine whether their conduct is anti-competitive within the meaning of Part IV of the TPA.[115] Most of the submissions supported this proposal.[116]

24.93 The Centre for Law and Genetics agreed in principle with the proposal, but considered that it would be difficult to monitor all potentially anti-competitive dealings, given their commercial nature. The Centre emphasised the practical difficulty of identifying anti-competitive conduct, its investigation and enforcement.[117]

24.94 In a supplementary submission, the Centre suggested several alternatives to this approach, including:

- Resourcing the ACCC so that it may conduct a comprehensive investigation into the structure, conduct and performance of biotechnology companies to ensure the market is sufficiently competitive.

---

114 J Nielsen, 'Biotechnology Patent Licensing Agreements and Anti-competitive Conduct' in Centre for Law and Genetics (ed) *Regulating the New Frontiers: Legal Issues in Biotechnology Symposium (Occasional Paper No 4)* (2002), 38, 48–49.

115 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 24–2.

116 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004. One submission noted the importance of defining the events that would trigger a review: Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

117 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

- Providing a comprehensive education regime to all stakeholders in the biotechnology industry, to ensure that they are fully aware of the benefits of a competitive marketplace, and the risks associated with non-compliance.

- Examining the contractual arrangements between stakeholders within the biotechnology industry to ensure that they accord with competition policy.

- Promoting the 'leniency policy' that is available under the ACCC's policies and procedures, to open the channel of communication between market participants adversely affected by anti-competitive conduct. According to the Centre, this would enable a greater appreciation of existing conduct, and would increase the prospect of civil action against those engaging in conduct that is contrary to Part IV of the TPA.[118]

24.95 The ACCC submitted that it did not consider it necessary to monitor the impact of gene patents and licences on competition specifically. Instead, it noted that it would 'vigorously enforce the TPA as it applies to intellectual property, including gene patents, in the same way as it enforces the TPA for all other forms of property'.[119]

24.96 The ACCC noted that it has developed enforcement priorities, which are regularly reviewed and targeted to react to trends in the economy, and areas that it identifies as strategically important—including new areas of the law or industries resulting from technological change. It noted that a key element in identifying its priorities is that they reflect the public interest. In selecting matters to prioritise for investigation or litigation, it will consider whether the conduct falls within one or more of its enforcement priorities.[120]

24.97 The ACCC has specific objectives and priorities in regard to anti-competitive conduct in developing and innovative markets. It noted that the amendment of s 51(3) might focus its attention on matters relating to intellectual property—but stated that it is too early to say with certainty that this will occur.[121]

24.98 The ACCC emphasised that it is predominantly a complaint-driven regulator. Once it receives a complaint it must determine whether and how to proceed with an investigation, and the appropriate enforcement response. This could involve informal resolution, court enforceable undertakings, or litigation. In deciding on an appropriate course of action, the ACCC will be influenced by factors that include:

- the nature of the alleged breach in terms of its impact on third parties in the community; the type of practice; the product or service involved; and the size of the business or businesses involved;

---

118 Centre for Law and Genetics, *Submission P117*, 5 May 2004.
119 Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004.
120 Ibid.
121 Ibid.

- the history of complaints against the business or businesses, and of complaints involving the practice; the product or the industry generally; and any relevant previous court or similar proceedings;

- the cost effectiveness for all parties of pursuing an administrative resolution instead of court action; prospects for a resolution of the matter; and

- the apparent good faith and culture of the business involved.[122]

24.99 The Queensland Government submitted that, provided the ACCC conducted informal price monitoring of patented medical genetic tests and other genetic inventions involved in the provision of healthcare services, this approach would not be necessary.[123]

Role of health departments

24.100 DP 68 proposed that the ACCC should liaise, on an ongoing basis, with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns in the genetics field.[124] While many submissions supported this proposal,[125] the ACCC raised concerns regarding the appropriateness of such ongoing liaison. It considered that this might be seen to compromise its capacity to determine an appropriate, impartial response to the complaints of health departments and other stakeholders.[126] In addition, it suggested that such liaison could, in itself, have competition implications.[127] The ACCC suggested that other entities would be more appropriate to facilitate the identification and exchange of information on emerging issues relating to gene-based medical technologies.[128]

24.101 In addition, the ACCC suggested that participants in the genetic materials and technology market, including Commonwealth, state and territory health departments, could refer any concerns of possible anti-competitive conduct to it for consideration; and that it could engage in communication and liaison activities in relation to genetic material and related technologies as, and if, the need arises.[129]

---

122 Ibid.
123 Queensland Government, *Submission P103*, 22 April 2004.
124 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 24–2.
125 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.
126 Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004.
127 Australian Competition and Consumer Commission, *Consultation*, Canberra, 26 March 2004.
128 Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004.
129 Ibid.

ALRC's views

24.102 The ALRC considers that there is a public interest in ensuring that firms with intellectual property rights in genetic materials or technologies do not abuse these rights for anti-competitive purposes. This is particularly so where such conduct might adversely affect healthcare provision or further research and development.

24.103 Accordingly, the ALRC recommends that, as the need arises, the ACCC should review the conduct of firms dealing with intellectual property rights in genetic materials and technologies to determine whether their conduct is anti-competitive within the meaning of Part IV of the TPA.

24.104 The ALRC initially proposed that the ACCC should conduct ongoing liaison with Commonwealth, state and territory health departments, and other stakeholders, to identify and assess any emerging concerns in this field. While this proposal received general support, the ALRC accepts the ACCC's argument that this may not be appropriate because of the ACCC's investigation and enforcement responsibilities and the need for it to remain impartial.

24.105 However, while it may not be appropriate for the ACCC and health departments to establish a system of on-going liaison, the ALRC suggests that it would be appropriate for health departments and other stakeholders to make use of existing complaint procedures where evidence arises of potentially anti-competitive conduct. This would reflect that the ACCC is a complaint-driven regulator.

24.106 The ALRC recommends that the Commonwealth, state and territory health departments, and other stakeholders, should make use of existing complaint procedures under the TPA where evidence arises of conduct that may breach Part IV and have an adverse impact on medical research or the cost-effective provision of healthcare.

Recommendation 24–3 As the need arises, the ACCC should review the conduct of firms dealing with genetic materials and technologies protected by intellectual property rights, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act.*

Recommendation 24–4 Commonwealth, state and territory health departments, and other stakeholders, should make use of existing complaint procedures under the *Trade Practices Act* where evidence arises of conduct that may breach Part IV and have an adverse impact on medical research or the cost-effective provision of healthcare.

25. Prices Oversight

Contents

Introduction

25.1 The existence of gene patents may make the provision of certain kinds of healthcare more expensive. A patent grants exclusive rights to exploit the patented invention. This exclusivity may enable the patent holder, or its licensee, to charge higher prices and make greater profits for the invention than would otherwise be possible in a competitive market.[1] Higher prices for patented genetic inventions may also have an adverse effect on the conduct of research.

25.2 While there is little evidence to date that gene patents and licensing practices have had any significant impact on the cost of healthcare provision in Australia, expressions of concern about gene patents are often based on assumptions that patent holders or their exclusive licensees will charge monopoly prices.

25.3 This Report makes a range of recommendations intended to facilitate access to patented genetic materials and technologies, on reasonable terms. These include encouraging industry-based initiatives to facilitate patent licensing,[2] and clarifying, and encouraging the use of, the Crown use and compulsory licensing provisions of the *Patents Act 1990* (Cth).[3]

1 See Ch 19.
2 See Ch 22.
3 See Ch 26, 27.

25.4 In addition, various forms of prices oversight are available to the Australian Government, and are examined in this chapter. If evidence arises that the pricing of patented genetic inventions is having an adverse impact on access to healthcare services, the Government could use these mechanisms to investigate firm or industry pricing practices.

Regulatory framework

Prices surveillance

25.5 Part VIIA of the *Trade Practices Act 1974* (Cth) (TPA) regulates the conduct of prices surveillance in Australia in relation to selected goods and services.[4] The Australian Competition and Consumer Commission (ACCC) is the regulatory body responsible for prices surveillance.[5] Part VIIA provides for three forms of prices oversight.

- *Monitoring*. The Minister may direct the ACCC to monitor the prices, costs and profits relating to the supply of goods or services in an industry or firm, and to report the results to the Minister.[6]

- *Price notification*. The Minister, or the ACCC with the Minister's approval, may declare goods or services of a specified description, or a particular firm in relation to goods or services, to be notified. Once notified, firms must advise the ACCC of any proposed price increases for these goods or services. The ACCC must make a determination about the notified price increase within a specified period (unless the firm agrees to an extension).[7]

- *Inquiries*. The Minister may direct the ACCC, or another body, to conduct a public inquiry into matters relating to the prices for the supply of particular goods or services, or the supply of goods or services by a particular firm or firms, or within an industry. Alternatively, the ACCC may conduct an inquiry on its own initiative with the Minister's approval. The inquiry body must report the results to the Minister.[8]

---

4 Prices surveillance was previously regulated under the *Prices Surveillance Act 1983* (Cth). The new Part VIIA of the *Trade Practices Act 1974* (Cth) contains most of the provisions of the previous Act, with some variations.

5 See *Trade Practices Act 1974* (Cth) s 95G.

6 Ibid Pt VIIA, Div 5. As at 2003, the ACCC's formal price monitoring was restricted to stevedoring and airport services: Department of the Parliamentary Library, *Trade Practices Legislation Amendment Bill 2003 (Bills Digest No 9, 2003–04)* (2003), 3.

7 *Trade Practices Act 1974* (Cth) Pt VIIA, Div 4. As at 2003, the services that had been declared for price notification were harbour towage services, letter services reserved to Australia Post, air services and aeronautical services: Department of the Parliamentary Library, *Trade Practices Legislation Amendment Bill 2003 (Bills Digest No 9, 2003–04)* (2003), 4.

8 *Trade Practices Act 1974* (Cth) Pt VIIA, Div 3.

25.6 The ACCC also conducts informal monitoring as part of its general objective to promote greater transparency of pricing and price competition. The areas subject to informal monitoring include public liability, professional indemnity and medical indemnity insurance; bank fees and charges; and petrol prices. This informal monitoring relies on publicly available information, and the co-operation of the monitored firms.[9]

Pricing review

25.7 The Productivity Commission is the Australian Government's principal advisory body on all aspects of microeconomic reform.[10] The Commission's functions include: holding public inquiries on matters relating to industry, industry development and productivity; investigating and reporting on complaints about the implementation of the Australian Government's competitive neutrality arrangements; advising the Minister on matters relating to industry and productivity, as requested; initiating research on industry and productivity issues; and promoting public understanding of matters related to industry and productivity.[11]

25.8 Under the *Productivity Commission Act 1998* (Cth) (PCA), the Minister may refer a matter to the Productivity Commission for a commissioned study.[12] A study could cover a particular sector of the economy or an industry, or it could involve wider social or environmental issues. For example, in 2001 the Productivity Commission released a research report, *International Pharmaceutical Price Differences*. The Minister had directed the Commission to examine the differences between the prices of pharmaceutical benefit items in Australia and the price of the same items in comparable overseas countries; and to identify, as far as possible, the reason for any differences.[13]

25.9 The Commission may invite comment in the form of written submissions. Once complete, the final report is forwarded to the Government.[14]

Pricing inquiry

25.10 Pricing inquiries are another form of prices oversight that is available to the Australian Government. There are two primary mechanisms available for initiating a pricing inquiry.

---

9 Australian Competition and Consumer Commission, *Industry Regulation and Price Monitoring*, <www.accc.gov.au/content/index.phtml/itemId/3671> at 16 June 2004. See also Department of the Parliamentary Library, *Trade Practices Legislation Amendment Bill 2003 (Bills Digest No 9, 2003–04)* (2003), fn 6.

10 Productivity Commission, *About the Commission*, <www.pc.gov.au/commission/role.html> at 16 June 2004.

11 *Productivity Commission Act 1998* (Cth) s 6(1).

12 Ibid ss 6, 17.

13 Productivity Commission, *International Pharmaceutical Price Differences: Research Report* (2001).

14 Productivity Commission, *About the Commission*, <www.pc.gov.au/commission/role.html> at 16 June 2004.

25.11 As noted above, the TPA provides that the Minister may direct the ACCC, or another body, to conduct a public inquiry into matters relating to the prices for the supply of particular goods or services by a firm or firms, or within an industry.[15] These pricing inquiries may investigate market situations to determine the nature, significance and causes of alleged pricing problems. The inquiry body makes recommendations to the Australian Government as to the appropriate response.[16]

25.12 Pricing inquiries have been used for several purposes in the past, including to: determine whether pricing outcomes reflect competitive market forces; advise the Minister on what types of prices oversight, if any, should be applied to the firm or firms under inquiry; assess price notifications in greater depth; encourage compliance with determinations about notified price increases; and play an educational role by bringing information into the public domain, facilitating public understanding of the pricing matters at issue.[17]

25.13 The Minister may also direct the Productivity Commission to conduct an inquiry under the PCA.[18] These inquiries may deal with matters relating to industry, industry development and productivity. In formulating its recommendations, the Commission must consider the interests of the community as a whole, and the interests of those most immediately and directly affected by the recommendations. It also must have regard to the economic, social, regional and environmental consequences of its recommendations.[19]

Pricing and access to healthcare services

25.14 The grant of exclusive rights over patented genetic inventions could result in higher prices being charged for these inventions than might be the case in a competitive market. This could have adverse implications for access to medical genetic tests and related healthcare services. However, any assessment of the costs charged by a patent holder or licensee should take account of the underlying policy rationale for the patent system, which is to encourage innovation.

25.15 As discussed in Chapter 19, there is little evidence to date that gene patents and licensing practices have had any significant adverse impact on the cost of healthcare provision in Australia.

25.16 Internationally, Myriad Genetics Inc—which holds patents associated with testing for ovarian and breast cancer—appears to have charged prices for its BRCA1 tests at levels well beyond those charged by other laboratories. For example, in 2002

---

15 *Trade Practices Act 1974* (Cth) s 95H.
16 Productivity Commission, *Review of the Prices Surveillance Act 1983* (2001), 3.
17 Ibid, 4.
18 *Productivity Commission Act 1998* (Cth) ss 6, 11.
19 Productivity Commission, *About the Commission*, <www.pc.gov.au/commission/role.html> at 16 June 2004.

the Institut Curie and others stated that Myriad charged € 2,744 for its initial family mutation searches, while French laboratories could conduct such testing at an estimated cost of € 914.[20]

25.17 In New Zealand, concerns have been expressed about the licensing fees charged by an Australian company, Genetic Technologies Ltd (GTG), for its patents relating to the use of non-coding DNA. A paper prepared by the New Zealand Offices of the Minister of Health and Associate Minister of Commerce noted that a number of organisations had expressed concern about the relatively high licence fees being requested by GTG.[21]

25.18 Chapter 19 recommends several reforms to ensure that the Australian healthcare system is able to manage the introduction of new genetic medical technologies and, in particular, any problems of cost or access attributable to gene patents. For example, the ALRC recommends that the Australian Health Ministers' Advisory Council (AHMAC) should establish processes for examining the financial impact of gene patents on the delivery of healthcare services in Australia;[22] and should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.[23]

25.19 These measures may be sufficient to deal with pricing issues relating to gene patents in Australia. However, if evidence arises that gene patenting is having an adverse impact on the cost-effective provision of healthcare, it may be necessary to consider other options available to government, including reviews or inquiries into pricing activity within the biotechnology industry. These could help to identify the impact of pricing outcomes on healthcare, and assist in determining the appropriate policy response to this concern.

Submissions and consultations

25.20 DP 68 suggested that informal prices monitoring might be a desirable vehicle for addressing community concerns regarding the pricing of patented genetic inventions. The ALRC proposed that the ACCC should conduct informal price monitoring of patented medical genetic tests and other genetic inventions involved in the provision of healthcare services, if evidence emerges that such prices are having an adverse impact on healthcare services.[24]

---

20 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).

21 Offices of the Minister of Health and Associate Minister of Commerce, *Cabinet Paper: Implications of the Granting of Patents over Genetic Material* (2003) New Zealand Government, [18]–[19].

22 Rec 19–1.

23 Rec 19–2.

24 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 25–1.

25.21 Many submissions supported this proposal.[25] The Queensland Government submitted that ongoing price monitoring is necessary due to the rapidly changing nature of the biotechnology industry. It suggested that informal monitoring of the price of medical genetic tests, and other genetic inventions generally, could restrict excessive prices; provide the Minister with evidence that remedial action is required; and be useful in addressing any new issues that may emerge.[26]

25.22 Several submissions suggested that the ACCC could conduct formal price monitoring in certain circumstances.[27] The Department of Health and Ageing noted that price monitoring would provide a means to determine whether conduct is anti-competitive under Part IV of the TPA.[28]

25.23 The ACCC did not support the option of informal price monitoring. It commented that price regulation might be appropriate in certain limited circumstances to constrain excessive pricing and its consequent effects. However, such price regulation should be limited to very specific circumstances where the industry is characterised by high market power; the benefits of regulation exceed the costs; and where no other appropriate policy measures can be taken.[29]

25.24 The ACCC emphasised the desirability of first establishing whether there is a problem in the cost and delivery of services to consumers before imposing any form of price regulation on a particular industry. It suggested that this could be done through a government review or specific inquiry into whether gene patents, or the exclusive licensing of genetic testing, have had any significant adverse impact on the cost of healthcare provision in Australia. This could assist policy makers by establishing:

- whether or not the consideration of regulatory options is warranted;
- the objectives of price monitoring, if it were adopted; and
- a body of industry information, which would provide a useful context and background for developing an approach to price monitoring, if it were adopted.[30]

---

25 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

26 Queensland Government, *Submission P103*, 22 April 2004.

27 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

28 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

29 Australian Competition and Consumer Commission, *Submission P64*, 12 December 2003.

30 Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004.

25.25 The Centre for Law and Genetics also did not support informal price monitoring. It considered that 'informal monitoring would be marginalised within the regulator and unlikely to be given sufficient resources to enable it to be carried out in any useful or substantive manner'. The Centre commented that regulation would only be necessary where monopoly prices are being charged in a market without sufficient competition. They suggested that if evidence is available that the competitive structure associated with patented medical genetic tests and other genetic inventions is monopolistic, 'the role of government should be to end the monopoly and allow competitive conditions to evolve'.[31]

25.26 The Cancer Council Australia commented that patent enforcement action in Canada and the United States provides sufficient evidence that gene patents adversely impact on the affordability of genetic testing for the public health system. It noted that the speed of change in genetic science requires a structured, rather than ad hoc, approach to pricing. Accordingly, it suggested that the ACCC should conduct a review of prices and affordability of patented medical genetic tests.[32]

Role of price monitoring

25.27 The ACCC provided a detailed discussion of the role of price monitoring in its response to DP 68. It considered the extent to which price monitoring of patented medical genetic tests and other genetic inventions would be aligned to the objectives, industry and product characteristics, and circumstances in which price monitoring is likely to be effective.[33]

25.28 The ACCC noted that in order for price monitoring to be effective, it must meet its stated objective. In its view, a government review or specific inquiry into the cost of patented genetic inventions would assist to determine whether such monitoring is necessary and, if so, the possible objectives of such a project. The ACCC suggested that the degree of industry concentration, the level of product differentiation, and the stage of production at which monitoring is focused, are all likely to influence the feasibility and effectiveness of price monitoring. For example, in the case of a monopoly or oligopoly it may be possible to obtain all required information directly from one or a few firms. However, if the monitored product is sold by a number of suppliers, the only effective way to obtain pricing information may be to obtain an appropriate price survey.

25.29 The ACCC stated that price monitoring is likely to be more effective when it involves direct monitoring of observable prices. It noted that, in practice, it is often difficult to obtain specific information in relation to prices that are the subject of confidential and commercially sensitive contracts. In addition, where products are

---

31 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

32 Cancer Council Australia, *Submission P96*, 19 April 2004. See also Cancer Council New South Wales, *Submission P99*, 20 April 2004.

33 Australian Competition and Consumer Commission, *Submission P114*, 3 May 2004.

highly differentiated in terms of price and/or quality, this could lead to difficulties in comparing input and final product prices between products, and in establishing benchmark prices.

25.30 The ACCC also commented that there could be inherent difficulties in determining what would constitute excessive pricing in the biotechnology industry. In its view, these markets are likely to provide high returns on a small number of viable products, so as to absorb the upfront investment costs generally associated with funding research and development across a number of developing products. Accordingly, these types of pricing signals could encourage further research and innovation in a growing industry. It commented that:

> there is therefore potential for price regulation to stifle innovation. In some circumstances, high prices can act as a signal to new entry by highlighting profitable opportunities and may encourage further innovation. High prices and the expectation that profits may be accrued could be seen as reward for innovation in an industry that might be characterised as 'high risk'.[34]

25.31 The ACCC further noted that even if a review or inquiry identified excessive pricing, Part VIIA of the TPA does not empower it to set price levels. Its pricing powers apply to price changes, not to absolute price levels. Accordingly, the ACCC could not compel a regulated firm to reduce its prices. The ACCC therefore considered that there was no suitable role for it in monitoring the prices charged for medical genetic tests or any other products or services arising from the grant of gene patents or licences.[35]

ALRC's views

25.32 DP 68 proposed that the ACCC should conduct informal price monitoring of patented medical genetic tests and other genetic inventions involved in the provision of healthcare services, if evidence emerges that such prices are having an adverse impact on healthcare services. The purpose of such monitoring would be to accumulate pricing information to assist the Australian Government to determine an appropriate response to such conduct.

25.33 As indicated above, while many submissions supported this proposal, the ACCC expressed significant concerns about the effectiveness of this approach. In particular, the ACCC considered that there could be inherent difficulties in determining what would constitute excessive pricing in the biotechnology industry—given the highly differentiated products involved—and the need to encourage innovation. In addition, it noted that its powers in relation to pricing apply to price changes, not to absolute price levels. The ALRC agrees with the Centre for Law and Genetics that the role of competition law is not necessarily to prohibit monopoly pricing, but to ensure competition within a market.

---

34 Ibid.
35 Ibid.

25.34 As discussed above, several other mechanisms exist for prices oversight in relation to the supply of goods and services in Australia. For example, the Minister could commission a research study or inquiry by the Productivity Commission. Alternatively, the Minister could commission an inquiry by the ACCC, or another body, into the pricing of specified patented inventions within a market, or into pricing within the biotechnology industry generally.

25.35 The ALRC considers that these options may be more appropriate if evidence arises that the pricing of patented medical genetic tests or other genetic inventions is having an adverse impact on equitable access to healthcare services. Informal price monitoring generally relies on publicly available information, and the cooperation of the monitored organisations. The advantage of a commissioned study or inquiry is that it could facilitate public involvement through a submission and consultation process; and provide detailed information to the Australian Government as to current pricing practices, the concerns arising from these practices, and the options available to the Government to respond to these concerns. These options could include price regulation in the form of price monitoring, or some other appropriate action.

25.36 Accordingly, if evidence arises that the pricing of patented genetic materials or technologies has impacted adversely on access to healthcare services in Australia, the responsible Minister should consider whether to: (a) refer the matter to the Productivity Commission for a study or inquiry pursuant to the PCA; or (b) direct the ACCC, or another body, to conduct an inquiry pursuant to Part VIIA of the TPA.

25.37 This Report recommends that AHMAC should establish processes for examining the financial impact of gene patents on the delivery of healthcare services in Australia.[36] AHMAC would then be in a position to determine whether pricing is having an adverse effect on the delivery of healthcare. In such circumstances, it may be appropriate for the Minister for Health and Ageing to request the responsible Minister to consider the need for an inquiry in accordance with Recommendation 25–1.

36 Rec 19–1.

Recommendation 25–1 If evidence arises that the prices of patented genetic materials and technologies have adversely affected access to healthcare services in Australia, the responsible Minister should consider whether to:

(a) refer the matter to the Productivity Commission for a study or inquiry pursuant to the *Productivity Commission Act 1998* (Cth); or

(b) direct the Australian Competition and Consumer Commission, or another body, to conduct an inquiry pursuant to Part VIIA of the *Trade Practices Act 1974* (Cth).

PART G

Non–Voluntary Uses

26. Crown Use and Acquisition

Contents

Introduction

26.1 This chapter examines the Crown use and acquisition provisions of the *Patents Act 1990* (Cth) (*Patents Act*). These provisions are an important existing mechanism through which the governments and their agencies may address, in specific cases, concerns that gene patents are hindering research or the provision of healthcare.

26.2 The Crown use provisions allow the Commonwealth or a State[1] either to exploit a patented invention (or an invention that is the subject of a patent application) without infringement, or to authorise another person to do so. The Crown acquisition provisions allow the Commonwealth to acquire compulsorily all rights in a patented invention (or an invention that is the subject of a patent application).

26.3 The Crown use provisions are similar to those relating to compulsory licensing (discussed in Chapter 27) in allowing the exploitation of an invention without the consent of the patent holder or applicant—in effect creating a compulsory licence in favour of the Crown. Like compulsory licensing, the terms of remuneration or

1 For the purposes of the Crown use provisions, 'State' includes the Australian Capital Territory, the Northern Territory and Norfolk Island: *Patents Act 1990* (Cth) sch 1.

compensation are agreed or, in the absence of agreement, determined by a court. However, unlike compulsory licensing, the Crown may invoke the Crown use and acquisition provisions without first seeking agreement of the patent holder. Further, there is no requirement to satisfy a court that the reasonable requirements of the public with respect to the patented invention have not been met.[2]

26.4 For reasons discussed later in this chapter, the Crown use and acquisition provisions seem to be used only rarely. Nevertheless, they constitute an important safeguard in helping ensure that patent protection does not have an adverse impact on significant public interests. In this chapter, the ALRC recommends that policies should be developed about the circumstances in which it is appropriate for government to invoke Crown use or acquisition for the purposes of promoting human health. Minor legislative amendments to clarify the operation of the Crown use provisions are also recommended.

26.5 The Advisory Council on Intellectual Property (ACIP) is currently undertaking a review of the Crown use provisions in patents and designs legislation. ACIP released a Discussion Paper in December 2003 (ACIP Discussion Paper),[3] with a request for written submissions by 20 February 2004. ACIP's final report is expected late in 2004. Given the ALRC's own timetable for reporting, it has not been possible to take ACIP's recommendations into account in formulating the recommendations in this Report, although the ALRC has held discussions with ACIP about the issues raised by their inquiry.

Crown use

26.6 Crown use provisions were introduced into English patents legislation in 1883.[4] Earlier case law had held that the Crown may retain rights to exploit inventions for which a patent had been granted, although this depended on the terms of the particular 'letters patent' issued under the *Statute of Monopolies 1623*.[5] With the enactment of the Crown use provisions in 1883, the Crown agreed to be bound by patents, but obtained the protection of these provisions when using patented inventions.[6] In 1903, Crown use and acquisition provisions were included in Australian patents legislation.[7]

26.7 Historically, the two main justifications for Crown use provisions have been that: (a) the Crown should not be impeded from acting in the public interest by patents, which are Crown grants; and (b) the Crown, through its departments and authorities is

2 See Ibid s 133.
3 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003).
4 *Patents, Designs, and Trade Marks Act 1883* (UK) s 27.
5 *Feather v The Queen* (1865) 6 B & S 257, cited in *Pfizer Corporation v Ministry of Health* [1965] AC 512, 533.
6 See *Pfizer Corporation v Ministry of Health* [1965] AC 512, 533.
7 *Patents Act 1903* (Cth) ss 92–93.

ordinarily engaged in public service, rather than commercial activities, and therefore should be in a special position in regard to the use of patented inventions.[8]

26.8 At the time the Crown use provisions were first enacted, the scope of government activities was much more limited than at present.[9] Expansion in government services, including the provision of healthcare, has greatly broadened the potential application of the Crown use provisions.

26.9 The frequency with which the provisions have been used is difficult to establish.[10] Some evidence that the provisions have been used may be found in the two reported cases in which the application of the Crown use provisions has been contested.[11] Submissions in response to the ACIP Discussion Paper also provide some examples of Crown use being invoked, although not with respect to genetic materials or technologies. While the Crown use provisions may be used only rarely, their importance may lie more in their potential for use. One view is that the primary purpose of the Crown use provisions is 'to force an unwilling licensor to the negotiating table' and that the 'threat of resort to the Crown use provisions may assist in ensuring an acceptable result from those negotiations'.[12]

26.10 There are various reasons why the Crown might seek to exercise the Crown use or acquisition provisions in respect of genetic inventions used in scientific research or healthcare provision. These reasons include:

- facilitating genetic research by organisations such as the Commonwealth Scientific and Industrial Research Organisation (CSIRO);
- providing medical genetic testing through public sector genetics laboratories; or
- providing novel therapies (such as those involving gene therapy, therapeutic proteins or stem cells) through public sector health organisations or other healthcare providers.

---

8 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 2. See also *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125, 133–134.

9 As noted in *Pfizer Corporation v Ministry of Health* [1965] AC 512, 533.

10 In a 1997 report to the TRIPS Council, Australia stated 'it is difficult to determine the frequency of [Crown] use, though we expect this has been minimal': *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997* (1997) World Trade Organization. The TRIPS Council comprises all World Trade Organization members. It is responsible for monitoring the operation of the TRIPS Agreement, and, in particular, how members comply with their obligations under it.

11 These involved the use of patented inventions in water meters by local government: *Stack v Brisbane City Council* (1994) 131 ALR 333; and central bearing structures for railway carriage construction by a state Commissioner for Railways: *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125.

12 W Cornish, M Llewelyn and M Adcock, *Intellectual Property Rights (IPRs) and Genetics* (2003), 74.

26.11 The Crown use provisions involve significant interference with the rights that patent holders otherwise have under the patent system. It is arguable that the Crown use provisions should not be relied upon too readily and should be invoked only in exceptional circumstances if confidence in the patent system is to be preserved. For example, reliance upon the provision may be justifiable in the case of public health emergencies, such as those in which the United States and Canadian governments contemplated compulsory use of Bayer AG's patent on the ciprofloxacin antibiotic following bioterror attacks using the anthrax organism in the United States.[13]

26.12 However, even in these circumstances, Crown use of a patent may be controversial and this factor may act as a political constraint on the exercise of these provisions of the *Patents Act*. Another constraint is that, as discussed below, where the provisions are invoked, adequate remuneration or compensation must still be paid to the patent holder.

TRIPS Agreement

26.13 The *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*[14] (TRIPS Agreement) contains detailed provisions dealing with the use of patented inventions 'without the authorization of the right holder, including use by the government or third parties authorized by the government'.[15] There are detailed provisions in relation to the permissible duration and scope of such use, remuneration of the patent holder, and judicial or other independent review of decisions.[16] These provisions apply to Crown use of patented inventions, which is considered to be 'public non-commercial use' for the purposes of the TRIPS Agreement.[17] Importantly, art 31(b) of the TRIPS Agreement, permits Crown use without efforts being made to obtain prior authorisation from the patent holder.

The Patents Act

26.14 Section 163(1) of the *Patents Act* allows the exploitation of a patented invention by the Commonwealth or a State, or by a person authorised by the Commonwealth or a State, without liability for infringement of the patent, provided that the exploitation is 'for the services of the Commonwealth or the State'.[18] The permitted exploitation expressly includes exploitation by an authority of the Commonwealth or of a State.[19]

---

13 Consumer Project on Technology, *Ciprofloxacin: The Dispute over Compulsory Licenses*, <www.cptech.org/ip/health/cl/cipro> at 16 June 2004.

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

15 TRIPS Agreement, art 31. See also Ch 4.

16 TRIPS Agreement, art 31(c)–(l).

17 See *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997* (1997) World Trade Organization.

18 The right to exploit an invention under s 163(1) includes the right to sell products made in exercise of that right: *Patents Act 1990* (Cth) s 167(1).

19 Ibid s 162.

26.15 The relevant Crown authority must notify the patent holder of the exploitation as soon as practicable after the invention has been exploited and must give the patent holder or exclusive licensee information about the exploitation, as reasonably required from time to time.[20] The terms of the exploitation, including remuneration payable to the patent holder, are to be agreed between the patent holder and the relevant authority or determined by a prescribed court.[21] The exploitation of the patented invention by the Crown must cease upon a prescribed court declaring that the exploitation of the invention is no longer necessary for the proper provision of services of the Commonwealth or of the State.[22]

Who is the Crown?

26.16 The Crown use provisions may be exercised by the Commonwealth or a State, by an authority of the Commonwealth or of a State,[23] or by a person authorised in writing by the Commonwealth or a State.[24]

26.17 Case law provides some guidance on the entities that may constitute an authority of the Commonwealth or of a State for the purposes of the Crown use provisions.[25] In *Stack v Brisbane City Council* (*Stack*),[26] the Federal Court of Australia held that the primary focus in determining whether a body was an authority of the State was on the functions of government. A body would be an authority of the State if its functions were 'impressed with the stamp of government', or if the body had been given the power to direct or control the affairs of others on behalf of the State. The role and involvement of the executive, through the Governor in Council or the appropriate Minister, was also a relevant factor.[27]

26.18 In considering what entities may constitute the Crown or a Crown authority, the law on Commonwealth immunity (sometimes referred to as the 'shield of the Crown') is relevant.[28] In *Stack*, Cooper J stated that the long line of cases relating to Crown privileges and immunities were of limited relevance because the phrase 'authority of a State' carried a 'different emphasis'.[29] However, he conceded that there is some overlap in the concepts of the Crown for immunity purposes and authorities of the Commonwealth or of a State for the purposes of the *Patents Act*.[30] It seems likely that

---

20 Ibid s 164.
21 Ibid s 165.
22 Ibid s 165A.
23 Ibid s 162.
24 Ibid s 163(1).
25 See *Stack v Brisbane City Council* (1994) 131 ALR 333; *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125; *Committee of Direction of Fruit Marketing v Delegate of the Australian Postal Commission* (1980) 144 CLR 577.
26 *Stack v Brisbane City Council* (1994) 131 ALR 333.
27 Ibid, 339.
28 Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation*, DP 64 (2000), Ch 5.
29 *Stack v Brisbane City Council* (1994) 131 ALR 333, 337.
30 Ibid, 337.

entities that are entitled to Crown immunity will also be authorities of the Commonwealth or of a State for *Patents Act* purposes.

26.19 The ACIP Discussion Paper observed that the Crown use provisions are applicable to a 'vast number of municipal councils and statutory authorities throughout Australia'.[31] The ACIP Discussion Paper suggested that consideration be given to limiting the range of government bodies that can exploit patents under the Crown use provisions—in particular so that 'deregulated and corporatised' statutory bodies do not obtain an 'unfair advantage in the market place'.[32]

26.20 The ACIP Discussion Paper noted that one option would be to amend the legislation so that any Crown use of patents by any council, statutory corporation or other like body requires Ministerial approval.[33] This, it was said, would centralise the responsibility for invoking the Crown use provisions and would ensure that they are not contrary to the principles of competitive neutrality.[34]

Services of the Commonwealth or of a State

26.21 The Crown use provisions apply to exploitation 'for the services of the Commonwealth or the State'.[35] Under s 163(3) of the *Patents Act*, an invention is taken to be exploited 'for the services of the Commonwealth or of a State' if the exploitation is 'necessary for the proper provision of those services within Australia'.[36]

26.22 In *Stack*,[37] the Federal Court considered the reasoning of the House of Lords in *Pfizer Corporation v Ministry of Health* (*Pfizer*),[38] in which it was held that the use of a patented drug (tetracycline) in National Health Service hospitals for patients was 'for the services of the Crown'.[39] The House of Lords held that the phrase was not to be limited to the internal activities of Crown authorities, but that the services at issue could ultimately benefit individual members of the public. The House of Lords held, by majority, that an act was done 'for the services of the Crown' if it was done for the purpose of performing a duty or exercising a power which was imposed upon or invested in the executive government by statute or by prerogative, including providing services to the general public.[40]

---

31 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 6.
32 Ibid, 7.
33 Ibid, 6.
34 Ibid, 6.
35 *Patents Act 1990* (Cth) s 163(1).
36 Ibid s 163(3).
37 *Stack v Brisbane City Council* (1994) 131 ALR 333.
38 *Pfizer Corporation v Ministry of Health* [1965] AC 512.
39 Ibid.
40 See Ibid, 535, 543, 551–552. See also *Stack v Brisbane City Council* (1994) 131 ALR 333, 345.

26.23 The ACIP Discussion Paper referred to *Pfizer* and noted that the case shows how the Crown use provisions could be applied to the supply of drugs used in the treatment of disease.[41] The ACIP Discussion Paper questioned whether the sale of patented products to members of the public should be characterised as a use necessary for the proper provision of Commonwealth or State services.[42] It also suggested that one option was to identify and limit the circumstances in which government can invoke the Crown use provisions, for example by restricting Crown use to situations involving the national interest or to use in times of national emergency, or for defence or public health purposes.[43]

Remuneration for Crown use

26.24 The *Patents Act* provides that remuneration for Crown use of a patent is payable to the patent holder on such terms as are agreed, or in the absence of such agreement, as are determined by a prescribed court.[44]

26.25 The reference to remuneration was inserted by the *Patents (World Trade Organisation Amendments) Act 1994* (Cth), which made a suite of amendments to the *Patents Act* to enable Australia to ratify the TRIPS Agreement.[45] Article 31 of the TRIPS Agreement requires the patent holder to be paid 'adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'.[46] The Australia–United States Free Trade Agreement appears to set a higher level for remuneration, by providing that patent holders must be entitled to 'reasonable' compensation.[47]

26.26 There is, however, no guidance in the *Patents Act* on the quantum of remuneration for Crown use. In contrast, the compulsory licensing provisions of the Act state that a patent holder is entitled to be paid for use of a patent under a compulsory licence at an agreed rate or, failing agreement, such amount as is determined by a prescribed court to be 'just and reasonable having regard to the economic value of the licence'.[48]

---

41 Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 10–11.

42 Ibid, 10–11. The minority in *Pfizer* considered that re-supply by a government department to members of the general public in competition with the patent holder should not be covered by the Crown use provision: *Pfizer Corporation v Ministry of Health* [1965] AC 512, 568. In *Stack*, Cooper J stated that he was not required to express a view as to which view more closely reflected the law in Australia: *Stack v Brisbane City Council* (1994) 131 ALR 333, 348.

43 See Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 8.

44 *Patents Act 1990* (Cth) s 165.

45 *Patents (World Trade Organisation Amendments) Act 1994* (Cth) s 15(c); *Patents Act 1990* (Cth) s 165(2).

46 TRIPS Agreement, art 31(h). It also requires any such decision to be subject to judicial or other independent review in the member State: art 31(j).

47 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.7(b)(ii).

48 *Patents Act 1990* (Cth) s 133(3)(a), 133(5).

Other jurisdictions

26.27 The patents legislation of other jurisdictions, including the United Kingdom, New Zealand and Canada, contains Crown use provisions similar to those in the *Patents Act*.

26.28 In the United Kingdom, the *Patents Act 1977* (UK) provides for the exploitation of a patented invention 'for the services of the Crown' by 'any government department and any person authorised in writing by a government department'.[49] The Act provides specifically that the term 'services of the Crown' includes 'the production or supply of specified drugs and medicines'.[50]

26.29 In New Zealand, the *Patents Act 1953* (NZ) provides for the exploitation of a patented invention by 'any Government Department and any person authorised in writing by a Government Department … for the services of the Crown'.[51]

26.30 In Canada, Crown use is subject to prior authorisation by the Commissioner of Patents. The *Patent Act 1985* (Canada) provides that the Commissioner of Patents may 'on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government',[52] on terms set by the Commissioner.[53] There is no requirement in the Act that the use must be for the services of the Government.

26.31 The United States has 'government use' provisions, which limit the remedies that can be obtained from the United States Government as a result of use of a patented invention by it or a party authorised by it. The patent holder is entitled to 'reasonable and entire compensation'.[54]

26.32 There is no evidence that the Crown use provisions in the United Kingdom, New Zealand or Canada have been used any more frequently than in Australia.[55] In a 1998 report to the TRIPS Council, the United Kingdom stated that, at least since 1996, no Crown use authorisations had been made.[56] The report implies that, in the United

---

49 *Patents Act 1977* (UK) s 55(1).

50 Ibid s 56(2). This provision was not present in the *Patents Act 1949* (UK) and may have been considered desirable in order to remove any doubt about the effect of the decision in *Pfizer Corporation v Ministry of Health* [1965] AC 512. The Act also includes detailed provisions relating to Crown use during an emergency *Patents Act 1977* (UK) s 59.

51 *Patents Act 1953* (NZ) s 55(1).

52 *Patent Act 1985* (Canada) s 19(1).

53 Ibid s 19(2). The terms must comply with principles set out in that subsection.

54 See 28 USC s 1498.

55 There is a small number of reported United Kingdom cases in which the Crown use provisions were at issue: *Pfizer Corporation v Ministry of Health* [1965] AC 512; *Pyrene Co Ltd v Webb Lamp Co Ltd* (1920) 37 RPC 57; *Aktiengesellschaft für Autogene Aluminium Schwiessung v London Aluminium Co Ltd (No 2)* (1923) 40 RPC 107.

56 *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: United Kingdom, 7 January 1998* (1998) World Trade Organization.

Kingdom, the Crown use provisions are most likely to be asserted by the Ministry of Defence.[57] Similarly, New Zealand reported in 1997 that, at least since 1993, there had been no exercise of Crown use provisions.[58] In contrast, in the United States it has been claimed that 'the US has always relied heavily on the non-voluntary licensing of patented inventions to facilitate public, non-commercial uses by the government and its agents', particularly in relation to national defence.[59]

Crown use in research and healthcare

26.33 The Crown use provisions are of broad potential application to the conduct of research and the provision of healthcare. However, as discussed below, there are uncertainties about the application of the Crown use provisions in these areas. These relate to whether particular bodies are the Crown and whether exploitation is for the services of the Crown.

Application to research

26.34 The use of patented genetic materials or technologies in research by a Commonwealth or state organisation, such as the CSIRO or a state public teaching hospital, would clearly involve exploitation by the Commonwealth or a State for the services of the Commonwealth or a State.

26.35 As discussed in Chapter 11, most human health research in Australia is funded by government and occurs in research institutions and universities. However, these bodies may not constitute the Commonwealth or a State, or an authority of the Commonwealth or of a State, for the purposes of the *Patents Act*. For example, publicly funded research is often conducted by medical research institutes, such the Garvan Institute of Medical Research (Garvan Institute) and the Walter and Eliza Hall Institute of Medical Research (WEHI). Such institutes may be established by state legislation[60] and may be affiliated with public sector universities or hospitals.[61] Yet they are self-governing, set their own research priorities, and receive some funding from non-government sources, including private donations.

26.36 Following the approach taken by the Federal Court in *Stack*,[62] such bodies might not constitute authorities of a State for the purposes of the *Patents Act*. They are not 'impressed with the stamp of government' because their functions are not

57 Ibid.

58 *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: New Zealand, 24 October 1997* (1998) World Trade Organization.

59 J Reichman and C Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America: Issue Paper No 5* (2003) UNCTAD–ICTSD Capacity Building Project on IPRs and Sustainable Development, 5.

60 For example, *Garvan Institute of Medical Research Act 1984* (NSW).

61 For example, WEHI is affiliated with the University of Melbourne and the Royal Melbourne Hospital.

62 *Stack v Brisbane City Council* (1994) 131 ALR 333, 344.

governmental or delegated by the State. Further, while institutes such as the Garvan Institute may be established by state legislation, the state executive generally does not retain a prominent role or practical involvement in their governance or day-to-day operation.[63]

26.37 Another issue that arises is whether research is for the services of the Commonwealth or of a State. Where research is conducted by an authority of the Commonwealth or of a State, such as the CSIRO or a public teaching hospital, it could be expected the research would be considered to be for the services of the Commonwealth or of a State. A government authority would be using the patented invention directly for government research purposes.

Application to healthcare

26.38 There are similar questions about the application of the Crown use provisions to the use of patented genetic materials and technologies in the provision of healthcare. In Australia, responsibility for the provision of healthcare is divided between Commonwealth, state and territory governments, and between the government and non-government sectors.[64]

26.39 In most cases, it will be clear whether the use of patented genetic materials or technologies in healthcare involves exploitation by an authority of the Commonwealth or of a State—for example, where medical genetic testing of patients is carried out by a public sector laboratory attached to a state public hospital. It seems equally clear that the same testing carried out by a private sector laboratory or a private medical practitioner would not involve exploitation by an authority of the Commonwealth or a State.

26.40 A more problematic issue is whether the provision of healthcare to patients is for the services of the Commonwealth or of a State. Following the reasoning in *Pfizer* and *Stack*,[65] it seems likely that the use of a patented genetic test by a public hospital would be held to be for the services of the State. The provision of healthcare by public hospitals to their patients is a function of the State and its health authorities. However, the position is not beyond doubt. For example, a firm of patent and trade mark attorneys, F B Rice & Co, submitted that the term 'services of the Commonwealth or the State' should not include those services which, like public health services, are funded by government but provided to members of the public.[66]

---

63 The New South Wales Minister for Health nominates two directors for membership of the 15-person Garvan Institute Board: *Garvan Institute of Medical Research Act 1984* (NSW) sch 1, cl 2(1)(e).

64 See Ch 19.

65 *Stack v Brisbane City Council* (1994) 131 ALR 333.

66 F B Rice & Co, *Submission P84*, 16 April 2004.

Acquisition by the Crown

26.41 Section 171 of the *Patents Act* provides for compulsory acquisition by the Commonwealth of an invention covered by a patent or patent application.[67] The section does not authorise compulsory acquisition by a State or Territory. The Act does not stipulate any limitations on the circumstances in which the Commonwealth may acquire an invention, but the Commonwealth must compensate a patent holder on such terms as are agreed, or in the absence of such agreement, as are determined by a prescribed court.[68] As with remuneration for Crown use, there is no guidance on the quantum of compensation for acquisition of an invention by the Commonwealth.

26.42 There are several situations in which the Commonwealth might wish to acquire a gene patent, such as in dealing with national emergencies or for defence purposes.[69] It is also conceivable that the Australian Government might wish to acquire gene patents so as to provide open access to specific genetic materials or technologies. In 1997, the Australian delegation to the World Trade Organization stated that there are no instances of this provision having been used.[70]

Submissions

26.43 DP 68 proposed that the Australian Health Ministers' Advisory Council (AHMAC), and the Department of Health and Ageing (DHA) develop policies regarding the circumstances in which is it is appropriate for the Crown to exploit a patented invention under the Crown use or acquisition provisions for the purpose of promoting human health.[71] This proposal received considerable support in submissions.[72]

26.44 DHA agreed that AHMAC would be the most appropriate body to develop policies in relation to Crown use because the provision of health services is primarily a state and territory responsibility.[73] However, the Department of Human Services Victoria suggested that the proposed Human Genetics Commission of Australia[74]

---

67 *Patents Act 1990* (Cth) s 171.

68 Ibid s 171(4).

69 *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Australia, 22 October 1997* (1997) World Trade Organization.

70 Ibid.

71 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 26–1.

72 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Department of Human Services Victoria, *Submission P111*, 30 April 2004; G Suthers, *Submission P116*, 4 May 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

73 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

74 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 5–1.

might be a more appropriate body to develop such policies.[75] GlaxoSmithKline questioned the need for national policies and submitted that specific cases where Crown use might be justified should be considered on their merits.[76]

26.45 DP 68 also proposed that the *Patents Act* be amended to clarify that 'the services of the Commonwealth or of a State' include the provision of healthcare services or products to members of the public.[77] Many submissions agreed that such an amendment is desirable to ensure that the Crown use provisions can be used, where necessary, to provide healthcare to the public.[78]

26.46 A number of submissions expressed concern that the reforms proposed by the ALRC could encourage the exercise of Crown use in inappropriate circumstances.[79] For example, the Western Australian Department of Industry and Resources stated that the Crown use provisions 'should be reserved for extreme or emergency situations and should not be used as a standard method for utilising patented inventions in the health system'.[80]

26.47 Finally, DP 68 proposed that the *Patents Act* be amended to provide that the Crown must pay such remuneration or compensation as is agreed between the parties or 'determined by a prescribed court to be just and reasonable having regard to the economic value of the patent'.[81] This formulation follows the language of the equivalent compulsory licensing provision and was seen as important in providing reassurance to affected patent holders that Crown use is not a means of obtaining free use of the invention.[82]

---

75 Department of Human Services Victoria, *Submission P111*, 30 April 2004.

76 GlaxoSmithKline, *Submission P85*, 16 April 2004.

77 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 26–2.

78 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004. However, F B Rice & Co suggested that the Crown use provisions are designed with the intention that the Crown receives the benefit of the service, or product directly (and not the public): F B Rice & Co, *Submission P84*, 16 April 2004.

79 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

80 Western Australian Department of Industry and Resources, *Submission P90*, 16 April 2004.

81 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 26–3.

82 Commonwealth acquisition of a patent under s 171 of the *Patents Act* would, in any case, fall within the scope of s 51(xxxi) of the *Australian Constitution*, which requires that any acquisition of property—including intellectual property—by the Commonwealth must be on 'just terms'.

26.48 While this proposal was generally supported,[83] concerns were raised about the difficulties involved in assessing remuneration or compensation.[84] The DHA agreed with the proposal but expressed reservations about the implications of referring to the 'economic value of the patent'.[85]

26.49 The ACIP Discussion Paper raised concerns about whether the remuneration provisions are fair and equitable for patent holders, especially individuals and small to medium-sized enterprises.[86] A patent holder and a Crown authority may have unequal bargaining power and, where they are unable to agree on remuneration, the only remedy for the patent holder may be to take the matter to court. Such proceedings may be costly and cause further delay in payment.

26.50 More generally, it has been suggested in submissions to the ACIP Discussion Paper that there should be an alternative mechanism for determining remuneration for Crown use of patents—perhaps similar to the Copyright Tribunal.[87] Submissions to ACIP also suggested that, whatever mechanism is used, further guidance is desirable on determining remuneration.

ALRC's views

26.51 Patent law seeks to achieve a balance between encouraging the provision of new and useful goods by rewarding inventiveness, and discouraging ongoing monopolies for critical processes or products. In some circumstances, the exercise of patent rights may have adverse implications for governmental or public interests. Where this is the case, the Crown use provisions ensure that governments can step in to exploit a patent or authorise others to do so. These provisions may be seen as a 'safety valve' in particular cases, preventing the public interest from being subverted by the patent system.

---

83 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

84 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

85 'If the economic value is defined as "what the market will bear", then this will not necessarily yield a just and reasonable outcome in a monopoly situation': Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

86 See Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 9–10.

87 The Copyright Tribunal determines remuneration when copyright material is used for the services of the Crown: see *Copyright Act 1968* (Cth) ss 153E, 183B. The Copyright Tribunal may have regard to the 'going or market rate for the use of material' and place the parties in a notional bargaining situation, where they are 'deemed to act reasonably and treated as willing but not anxious parties to the bargain which has been constructed': see, eg *Seven Dimensions Pty Ltd* (Unreported, Australian Copyright Tribunal, 19 July 1996); J Lahore, *Copyright and Designs: Looseleaf Service* (1996), [30,110].

26.52 Where important public interests are involved, the Australian Government could potentially legislate to permit the use or acquisition of property, including patents, so as to address the particular problem at hand. However, the Crown use provisions may offer a more expeditious and efficient mechanism,[88] and one that is also available to state and territory governments and their health authorities. In practice, as is the case with the compulsory licensing provisions, the Crown use provisions are not often used. However, they may be important in encouraging patent holders to negotiate on reasonable terms with prospective licensees, including government authorities.

26.53 The ALRC recommends a pattern of laws and practices that is flexible enough to anticipate and respond to any future problems for research or healthcare delivery attributable to gene patents. The Crown use provisions add desirable flexibility to the patent system.

26.54 The ALRC's recommendations anticipate that Commonwealth, state and territory governments may, in future, consider exercising the Crown use and acquisition provisions more actively, and that there may be circumstances in which it is appropriate to do so. Notably, in Chapter 19, the ALRC recommends a more active role for health departments, in liaison with AHMAC, in considering whether to exploit or acquire a patent under the Crown use or acquisition provisions.

26.55 The ALRC recommends that AHMAC should develop policies regarding the circumstances in which is it is appropriate for the Commonwealth or a State to exploit a patented invention under these provisions for the purpose of promoting human health (Recommendation 26–1). A prime example of such circumstances is where a patent holder or an exclusive licensee exercises monopoly control over a particular genetic test and this has the potential to affect substantially the price, quality or access to the genetic test, with adverse effects for healthcare.[89] While the patent holder would still be entitled to remuneration, the Crown use provisions are an important mechanism through which governments can ensure that key genetic tests continue to be available through public clinical genetics services.

26.56 The ALRC has concluded that it is desirable to clarify that the Crown use provisions are able to be used, where appropriate, in healthcare delivery.[90] While the case law suggests that this interpretation is open on the current wording, the position is not beyond doubt. It is noted that it was found desirable in the United Kingdom to

---

88 See Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 11–12.

89 As discussed in Ch 20, it has been suggested that monopoly control of medical genetic testing may have an adverse impact on, among other things, the quality of testing and the development of new or improved testing techniques.

90 There appears to be no similar need for an amendment directed at research use by the Crown of patented genetic materials or technologies: see Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [26.68].

expressly define 'services of the Crown' as including the production or supply of specified drugs and medicines.[91]

26.57 The ALRC recommends that the *Patents Act* be amended to clarify that, for the purposes of the Crown use provisions, an invention is exploited 'for the services of the Commonwealth or of a State' if the exploitation of the invention by a Commonwealth or State authority (or by an authorised person) is for the provision of healthcare services or products to members of the public (Recommendation 26–2). The ALRC recognises the broad scope of the term 'healthcare services or products'.[92] However, this recommendation seeks only to clarify what is included within the ambit of an even broader term that is currently used in the *Patents Act*, namely, the 'services' of the Commonwealth or of a State.

26.58 As discussed above, questions have been raised about whether the Crown use provisions are too broad in their potential application. For example, the ACIP Discussion Paper highlights the broad ambit of the Crown use provisions and asks, among other things, whether the availability of the provisions should be limited or denied to certain entities and whether it would be advantageous to restrict the circumstances in which government can invoke them; for example, only with Ministerial approval or in public health or other emergencies.[93]

26.59 The central focus of the ALRC's inquiry has been on the desirability of reforms to address the possible adverse impact of gene patents on research and healthcare. Questions about whether the Crown use provisions should be wound back have not been a focus of consultation. However, it should be noted that any proposal to restrict the circumstances in which Crown use may be invoked has the potential to conflict with the policy underlying recommendations made in this Report.[94] For example, restricting Crown use to circumstances of emergency would reduce the nature of the protection provided for the public interest in healthcare provision. On the other hand, placing an obligation on government authorities to obtain Ministerial approval before invoking Crown use would not necessarily be inconsistent with the ALRC's recommendations.[95] Such an obligation could be implemented, with respect to Commonwealth, state and territory health authorities, through development of the policy recommended in Recommendation 26–1.

---

91 *Patents Act 1977* (UK) s 56(2).

92 The *Health Insurance Act 1973* (Cth) uses the term 'health service' to mean, in part, 'medical, surgical, obstetric, dental or optometrical treatment' and 'service' to include the supply of goods: s 3C(8).

93 See Advisory Council on Intellectual Property, *Review of Crown Use Provisions in Patents and Designs Legislation* (2003), 6–9.

94 The ALRC has not found it necessary to reach conclusions about a range of other matters under active consideration by the ACIP review, including whether patent holders have sufficient bargaining power to negotiate with the Crown, and alternative mechanisms for determining remuneration for Crown use.

95 The ALRC expresses no view on whether such an obligation is necessary or desirable.

26.60 Finally, the ALRC recommends that the *Patents Act* be amended to provide that, when a patent is exploited or acquired under the Crown use or Crown acquisition provisions, the remuneration or compensation that is to be paid by the relevant authority must be paid promptly and must be just and reasonable (Recommendation 26–3).

26.61 While it may be desirable to provide additional guidance on what constitutes just and reasonable remuneration or compensation, ultimately this is a difficult factual question that can be answered only by reference to the circumstances of each case. As the *Patents Act* currently provides, the primary obligation should be on the parties to determine remuneration or compensation by agreement, and where they cannot agree it is appropriate for the matter to be resolved by a court. While uncertainty about remuneration or compensation may leave patent holders in a difficult position, the same uncertainty may operate to discourage Crown use, which involves an unquantified financial commitment. Alternative mechanisms for determining remuneration for Crown use are being reviewed as part of ACIP's review of the Crown use provisions in patents and designs legislation.

Recommendation 26–1 The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the *Patents Act 1990* (Cth) (*Patents Act*) for the purposes of promoting human health. Similarly, the Department of Health and Ageing should develop a policy regarding the circumstances in which it may be appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health. Decisions about Crown use in specific cases must be made on their individual merits.

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

Recommendation 26–3 The Commonwealth should amend the *Patents Act* to provide that, when a patent is exploited under the Crown use provisions, the remuneration that is to be paid by the relevant authority must be paid promptly and must be just and reasonable having regard to the economic value of the use. Similarly, the Act should be amended to provide that, when a patent is acquired under the Crown acquisition provisions, compensation must be paid promptly and must be just and reasonable having regard to the economic value of the patent.

Transfer of 'know-how'

26.62 A patent application must fully disclose an invention. The *Patents Act* provides that the specification must 'describe the invention fully, including the best method known to the applicant for performing the invention'.[96] However, the patent holder may later acquire valuable know-how and experience that is necessary to exploit the invention effectively or optimally.

26.63 Where Crown use or acquisition is invoked, or where a compulsory licence is granted, the Crown or the compulsory licensee may encounter problems in exploiting the patented product or process if they do not have the necessary know-how to do so. The mere right to exploit without infringement may be insufficient to enable a patented invention to be used effectively or optimally. Access to the patent holder's know-how may also be required; for example, through the provision of additional information, or access to documentation about the invention.

26.64 In 1984, the Industrial Property Advisory Committee recommended that, in ordering the grant of a compulsory licence, the court be given a discretionary power to order the transfer of related know-how as part of the reasonable terms on which the licence is granted.[97] The Australian Government did not accept this recommendation, citing concerns regarding the imprecise scope of the term 'know-how'; uncertainty as to how the proposal would operate in the absence of parallel legislation overseas; and uncertainty as to whether Australian courts can set enforceable terms for such a compulsory licence, particularly where the licensee has operations outside Australia.[98]

26.65 DP 68 asked whether the *Patents Act* should be amended to:

- require a patent holder to transfer 'know-how' relating to the patented product or process to the Crown when the Crown uses or acquires a patent; and
- authorise a prescribed court, when granting a compulsory licence, to require the transfer of 'know-how' relating to the patented product or process.[99]

96 *Patents Act 1990* (Cth) s 40(2)(a).
97 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), rec 7.
98 J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [5,190].
99 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Questions 26–1, 27–4.

26.66 While some submissions, particularly from the health sector, were supportive of such a change,[100] other submissions highlighted a number of objections.[101] Some suggested that requiring the transfer of know-how would be unnecessary because the 'sufficiency requirement' ensures that a patent contains sufficient information to work the invention.[102] Practical difficulties associated with an obligation to transfer know-how were highlighted.[103] Others emphasised the commercial value of know-how, both in relation to the specific invention and other aspects of the patent holder's business.[104] Concern was expressed that an obligation to transfer know-how could discourage patenting.[105]

26.67 Another reason for not recommending reform in this area is that it would be inconsistent with the terms of the Australia–United States Free Trade Agreement, which provides that, when Crown use is permitted, the parties shall not require the patent holder to 'provide undisclosed information or technical know-how'.[106]

26.68 Reform would involve the complexity of introducing a new concept into the *Patents Act*.[107] Further consideration would also need to be given to the means of determining remuneration for the patent holder and to arrangements to protect the confidentiality of the know-how, once transferred. As a need for reform has not been demonstrated in the context of this Inquiry, the ALRC makes no recommendation about the transfer of know-how in relation to Crown use, Crown acquisition or compulsory licensing.

---

100 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004.

101 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

102 GlaxoSmithKline, *Submission P85*, 16 April 2004.

103 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004. The Department of Industry, Tourism and Resources noted that 'the "know-how" of genetic technologies often involves the application of precise compositions of reagents and conditions of biological reactions'.

104 GlaxoSmithKline, *Submission P85*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

105 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

106 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.7(b)(iii).

107 IP Australia, *Submission P86*, 16 April 2004.

27. Compulsory Licensing

Contents

Introduction

27.1 This chapter discusses the compulsory licensing provisions of the *Patents Act 1990* (Cth) (*Patents Act*). Compulsory licences are a mechanism that may facilitate access to patented genetic materials and technologies for use in research and the provision of healthcare.

27.2 A compulsory licence is an authorisation given by a national authority, without or against the consent of the patent holder, for the exploitation of a patented product or process.[1] Under the *Patents Act*, a prescribed court may grant a compulsory licence to work a patent if it is satisfied that the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied; and the patent holder has not given a satisfactory reason for failing to exploit the patent.[2]

27.3 Few, if any, compulsory licences have been granted under Australian patent law. This chapter considers options for reform to facilitate the use of compulsory licensing,

1 C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 3.

2 *Patents Act 1990* (Cth) s 133(2); *Patents Regulations 1991* (Cth) r 12.1.

in appropriate circumstances, where gene patents have impeded access to healthcare, or the ability to conduct research related to human health.

Compulsory licensing

27.4 The concept of a compulsory licence over patents arose from the historical requirement that a patent holder must 'locally work' a patented product or process. This meant that the patent holder was required to use or produce the patented invention within the country in which the patent was registered. Where a patent holder failed to 'work' the invention locally, the patent was subject to forfeiture.[3]

27.5 Compulsory licences were developed as a less drastic means to ensure a patent was exploited.[4] Compulsory licensing provisions were included in the first Commonwealth patents legislation in 1903.[5]

Patents Act

27.6 Section 133(1) of the *Patents Act* provides that a person may apply to a prescribed court for a compulsory licence to work a patent after a period of three years has lapsed since the patent was granted.[6] The court may make the order if it is satisfied that:

- the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied;
- the patent holder has not given a satisfactory reason for failing to exploit the patent; and
- the applicant has attempted for a reasonable period to obtain a licence on reasonable terms and conditions, but without success.[7]

27.7 Section 135 sets out the various circumstances in which the 'reasonable requirements of the public' with respect to a patented invention are to be taken not to have been satisfied. These are:

---

3 C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 3–4. See also J Reichman and C Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America: Issue Paper No 5* (2003) UNCTAD–ICTSD Capacity Building Project on IPRs and Sustainable Development, 10–11.

4 C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 3–4.

5 *Patents Act 1903* (Cth) s 87.

6 See also *Patents Regulations 1991* (Cth) r 12.1.

7 *Patents Act 1990* (Cth) ss 133(2), 133(3A); *Patents Regulations 1991* (Cth) r 12.1. However, a person cannot apply for a compulsory licence in respect of an innovation patent that has not been certified: s 133(1A).

- A new or existing trade or industry in Australia is unfairly prejudiced, or the demand in Australia for the patented product[8] is not reasonably met, because of the patent holder's failure to: manufacture the whole or part of the patented product to an adequate extent, and supply it on reasonable terms; carry on a patented process to a reasonable extent; or grant licences on reasonable terms.

- A trade or industry in Australia is unfairly prejudiced by the conditions the patent holder attaches to the purchase, hire or use of a patented product or to the use or working of a patented process.

- The patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.[9]

27.8 Additional provisions apply where the patent in question is a 'dependent patent'; that is, an invention that cannot be worked without infringing another patent.[10]

27.9 A compulsory licence must not grant the exclusive right to work the patented invention.[11] The patent holder is entitled to be paid for use of the patent at an agreed rate or, failing agreement, 'such amount as is determined by a prescribed court to be just and reasonable having regard to the economic value of the licence'.[12] A compulsory licence may be revoked where the circumstances that justified its grant have ceased to exist and are unlikely to recur, and the legitimate interests of the licensee are not likely to be adversely affected by the revocation.[13]

27.10 As noted above, few, if any, compulsory licences have been granted under Australian patent law. A report of the House of Representatives Standing Committee on Industry, Science and Technology in 1992 stated that 'no compulsory licences have been granted since Federation'.[14] The ALRC is not aware of any compulsory licences having been granted since that date.

27.11 However, several commentators and submissions to this Inquiry have discussed the benefit of using the threat of compulsory licensing to induce patent holders to enter into voluntary licences for their patented inventions.[15] In its review of similar

---

8 Or for a product resulting from the patented process.
9 *Patents Act 1990* (Cth) s 135(1).
10 Ibid s 133(3B).
11 Ibid s 133(3)(a).
12 Ibid s 133(5).
13 Ibid s 133(6).
14 House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), 227.
15 See, eg, D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 238; C Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, 114; IP Australia, *Submission P56*, 4 November 2003; Australian Centre for Intellectual Property in Agriculture, *Consultation*, Brisbane, 3 October 2003; Department of Industry Tourism and Resources, *Submission P36*, 13 October 2003.

provisions in the *Patents Act 1952* (Cth), the Industrial Property Advisory Committee (IPAC) commented that:

> there is anecdotal evidence that compulsory licences have an impact on licence negotiations, notably between foreign rights' owners and potential users of patents in Australia. It is claimed that the threat of acquiring a compulsory licence often encourages parties to reach agreement where they otherwise would not have.[16]

27.12 However, AusBiotech Ltd submitted that there is no solid evidence that the mere existence of the compulsory licence provisions encourages patent holders to negotiate with potential licensees.[17] The Centre for Law and Genetics commented that the threat of such action is likely to be largely non-existent given the under-utilisation of the compulsory licensing provisions in Australia. The Centre noted that the inequality in bargaining power between many companies reinforces this problem.[18]

Relationship to Crown use

27.13 As discussed in Chapter 26, the *Patents Act* permits the Commonwealth or a State, or a person authorised by the Commonwealth or a State, to exploit a patented invention without infringing the patent, provided that exploitation is 'for the services of the Commonwealth or of a State'. The permitted exploitation by the Crown expressly includes exploitation by an authority of the Commonwealth or of a State.[19]

27.14 A public organisation seeking access to a patented genetic material or technology may have the options of invoking the Crown use provisions or applying for a compulsory licence. In some circumstances, there may be an advantage in exercising Crown use rather than seeking a compulsory licence. For example, a healthcare authority could avoid the costs and delay involved in the negotiations and court proceedings required to obtain a compulsory licence by asserting Crown use. However, the advantage of a compulsory licence is that the remuneration must be settled before the licensee uses the patented invention, providing greater certainty as to the cost of such compulsory use.

Other jurisdictions

27.15 Compulsory licences have been granted on a diverse range of grounds in other jurisdictions, including to address local non-working and lack of appropriate supply; to remedy a refusal to license the patented invention; to remedy anti-competitive conduct; in the public interest; to facilitate the working of dependent patents; and to facilitate access to patented medicines.[20]

---

16 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 28.
17 AusBiotech Ltd, *Submission P58*, 7 November 2003.
18 Centre for Law and Genetics, *Submission P110*, 28 April 2004.
19 *Patents Act 1990* (Cth) s 162.
20 See generally, C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (1999) South Centre, 10–21.

27.16 The *Patents Act 1977* (UK) outlines the circumstances in which a compulsory licence may be granted for a patented invention in the United Kingdom. These circumstances are similar to those specified in s 135 of the Australian *Patents Act,* but are described more clearly. A compulsory licence may be granted for a patent held by a 'WTO proprietor'[21] in the following circumstances:

- in the case of product patents, a demand in the United Kingdom for that product is not being met on reasonable terms;

- the patent holder refuses to grant a licence on reasonable terms, resulting in: prevention or hindrance of the exploitation in the United Kingdom of any other patented invention that involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted; or unfair prejudice to the establishment or development of commercial or industrial activities in the United Kingdom; or

- the conditions imposed by the patent holder on the grant of a licence, or the disposal or use of the patented invention, unfairly prejudice: the manufacture, use or disposal of materials not protected by the patent; or the establishment or development of commercial or industrial activities in the United Kingdom.[22]

27.17 In New Zealand, a compulsory licence may be granted where a domestic market for the patented invention is not being supplied, or is not being supplied on reasonable terms.[23] In Canada, a compulsory licence may be granted to remedy an abuse of the exclusive rights contained in a patent;[24] or to remedy an anti-competitive exercise of a patent.[25] In Japan, a compulsory licence may be granted on non-working, dependency, and public interest grounds.[26]

27.18 Few compulsory licences appear to have been granted in other jurisdictions. In a 1998 report to the Council for Trade-Related Aspects of Intellectual Property Rights, the United Kingdom stated that only two compulsory licences had been issued under the *Patents Act 1977* (UK), and none had been granted since 1993.[27] Similarly, in 1997

---

21 A 'WTO proprietor' is a patent holder who is a national of, or domiciled in, a country which is a member of the World Trade Organization; or has a real and effective industrial or commercial establishment in such a country: *Patents Act 1977* (UK) s 48(5).

22 Ibid s 48A.

23 *Patents Act 1953* (NZ) s 46(2). An order cannot be made if it would be at variance with any treaty convention, arrangement or engagement applying to New Zealand: s 54(3).

24 *Patent Act 1985* (Canada) ss 65, 66.

25 *Competition Act 1985* (Canada) s 32.

26 *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Japan, 13 August 1997* (1997) World Trade Organization, 4.

27 *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: United Kingdom, 7 January 1998* (1998) World Trade Organization, 4, 9.

New Zealand and Japan reported that no compulsory licences had been granted in their jurisdictions since 1993.[28]

International framework

The TRIPS Agreement

27.19 Article 31 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement) deals with the use of patented inventions without the authorisation of the patent holder. This includes Crown use and use pursuant to the grant of a compulsory licence.[29]

27.20 Article 31 does not specify or limit the grounds upon which a compulsory licence may be granted. However, it outlines the procedures that member States must follow when they grant a licence, and specifies certain procedural requirements that must be respected.[30] For example, each case must be considered on its individual merits; the applicant must have attempted to negotiate a licence from the patent holder for a reasonable period, except in specified circumstances; and the right holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation.

Australia–United States Free Trade Agreement

27.21 The Australia–United States Free Trade Agreement (AUSFTA) appears to narrow the circumstances in which either party may permit the unauthorised use of a patented invention. The AUSFTA provides that each party shall not permit the use[31] of the subject matter of a patent without the patent holder's consent except in the following circumstances:

- to remedy a practice determined after judicial or administrative process to be anti-competitive under the party's laws relating to prevention of anti-competitive practices; or

---

28 *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: New Zealand, 24 October 1997* (1998) World Trade Organization, 3; *Review of Legislation in the Fields of Patents, Layout-Designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licences: Japan, 13 August 1997* (1997) World Trade Organization, 13.

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

30 United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2003) UNCTAD–ICSTD Capacity Building Project on IPRs and Sustainable Development, 123.

31 In this context, 'use' refers to use other than that permitted under art 30 of the TRIPS Agreement.

- in the case of public non-commercial use or national emergency or the circumstances of extreme urgency, subject to specified circumstances.[32]

27.22 On its face, the AUSFTA appears to exclude the grant of a compulsory licence where the 'reasonable requirements of the public' have not been satisfied in ways that are not related to competition within a market, and do not involve public non-commercial use. However, the ALRC understands that the Australian Government does not intend to amend the existing test in the light of the AUSFTA.

Compulsory licensing in research and healthcare

27.23 There are various reasons why a person or organisation might seek a compulsory licence to use a patented genetic invention in research or healthcare provision. For example:

- a researcher or research organisation might need access to an upstream genetic invention to develop a downstream product, such as a pharmaceutical drug;

- a researcher or research organisation that has developed an improvement on a patented research tool might require a licence over the primary tool in order to exploit the patented improvement;

- a pharmaceutical company, a private laboratory, or other private organisation might wish to provide a patented medical genetic test, or other healthcare service to the Australian community where demand is not being met; or

- a public sector health authority might wish to provide a patented medical genetic test or other healthcare service where demand is not being met; or where the patent holder has not licensed the patent widely, and this is having an injurious effect on the provision of services, the development of skills and the conduct of further research within Australia.[33]

Grounds for granting a compulsory licence

Reasonable requirements of the public

27.24 Section 133 of the *Patents Act* provides that a person may apply to a prescribed court for a compulsory licence three years after the grant of a patent where the 'reasonable requirements of the public' with respect to the patented invention have not been satisfied; and the patent holder has not given a satisfactory reason for failing to exploit the patent.[34]

---

32 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.9.7. See Ch 26 in relation to Crown use, which is covered by the term 'public non-commercial use'.

33 However, as noted above, public healthcare providers could invoke the Crown use provisions of the *Patents Act* as an alternative to seeking a compulsory licence.

34 *Patents Act 1990* (Cth) s 133(2).

27.25 Section 135 sets out the circumstances in which the 'reasonable requirements of the public' will be deemed not to have been satisfied. This section appears to cover many circumstances in which an applicant might seek compulsory access to a patented genetic invention. For example, where a patent holder refuses to license a research tool on reasonable terms, a researcher or research organisation could apply for a compulsory licence on the basis that the demand in Australia for that tool is not being reasonably met.

27.26 The *Patents Act* does not provide any guidance regarding what would be considered a 'satisfactory reason for failing to exploit the patent'. This would be a matter for the court to determine.

27.27 In practice, few applications have been made for a compulsory licence. IPAC suggested that this might be due to the formulation of the 'reasonable requirements of the public' test and the broad discretion granted to a court in applying it:

> It is something of an enigma that, despite the apparent number of situations in which the compulsory licensing provisions could be invoked, only 2 cases of petitions for compulsory licences are known to have gone to court in Australia. One reason for this might be that in fact the provisions in question are ineffectual; that persons who would be prospective applicants for compulsory licences perceive, and are advised, that the grounds are so hedged with qualifications, discretion on the part of the court, difficulties of proof, and expense, that to petition would be too onerous or useless.[35]

27.28 Several commentators have noted the lack of clarity in the 'reasonable requirements of the public' test.[36] The compulsory licensing provisions have received little judicial consideration.[37] In *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation,* Menzies J interpreted similar provisions in the *Patents Act 1952* (Cth) as follows:

> The demand for the patented article has not been reasonably met if the Court should be satisfied that, because of its superiority over articles already on the market, potential purchasers would have bought it had it been available. A market for a less efficient article indicates, other things being equal, a market for a more efficient article.[38]

---

35 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia* (1984), 28.

36 For example, see D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 237-238. See also C Lawson, 'Patenting Genes and Gene Sequences and Competition: Patenting at the Expense of Competition' (2002) 30 *Federal Law Review* 97, 114.

37 See *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation* (1969) 119 CLR 572; *Wissen Pty Ltd v Lown* (1987) 9 IPR 124. In *Bristol-Myers v Faulding*, Finkelstein J made brief reference to the provisions, commenting that 'they may be cumbersome and expensive to apply': *Bristol-Myers Squibb Co v FH Faulding & Co Ltd* (2000) 170 ALR 439, 480.

38 *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corporation* (1969) 119 CLR 572, 575.

27.29 In that case, the High Court declined to grant a compulsory licence on the basis that, while the reasonable requirements of the public had not been satisfied at the date of the application, they had been satisfied by the date of the hearing.[39]

27.30 Dr Charles Lawson commented that the present s 135 is framed more broadly than the provisions in the 1952 Act, and consequently could be interpreted differently. In his view, the terms 'trade', 'unfairly prejudiced', 'reasonable terms' and 'reasonable extent' may be interpreted in a way that promotes competition principles.[40]

27.31 Dr Dianne Nicol and Jane Nielsen have expressed concern about the lack of judicial guidance on what constitutes the 'reasonable requirements of the public', and the means of assessing the remuneration that must be paid for a compulsory licence. They suggested that the circumstances in which an application for a compulsory licence can be made should be clarified.[41]

27.32 DP 68 asked whether the Commonwealth should amend the *Patents Act* to clarify the test for the grant of a compulsory licence. The ALRC suggested two possible models for reform: (a) clarifying the circumstances in which the 'reasonable requirements of the public' with respect to a patented invention have not been satisfied; or (b) specifying that s 135 is not an exhaustive list of the circumstances in which the 'reasonable requirements of the public' have not been satisfied.[42]

27.33 Many submissions supported clarifying the 'reasonable requirements of the public' test in some way.[43] The Department of Health and Ageing also suggested the need to clarify the requirement that the patent holder has given 'no satisfactory reason' for failing to exploit the patent.[44]

27.34 Several of these submissions supported clarification by amending the *Patents Act* to more clearly define the circumstances in which the reasonable requirements of the public have not been satisfied.[45] In particular, the Department of Health and Ageing suggested that the test should specifically cover the availability and pricing of patented

---

39 Ibid. See also R Hoad, 'Compulsory Licensing of Patents: Balancing Innovation and Competition' (2003) 54 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 28, 29.

40 C Lawson, *Submission P67*, 4 March 2004.

41 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 237–238.

42 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 27–1.

43 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

44 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

45 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

goods or services, and include a reference to supply of the product or service on reasonable terms, unqualified by any other conditions.[46]

27.35 By contrast, most of the submissions that supported amendment of the compulsory licensing provisions considered that the best approach would be to specify that the circumstances listed in s 135 are not exhaustive.[47] Submissions suggested that the test should be drafted to allow for maximum flexibility in determining what are the 'reasonable requirements of the public' with respect to a patented invention.[48]

27.36 The Centre for Law and Genetics noted the difficulty involved in specifying with any precision the circumstances in which the test will be met. At the same time, it commented that 'stating that s 135 is not an exhaustive list is sure to give rise to interpretational difficulties, as the bounds of the test will become increasingly unclear'. The Centre concluded that it would be preferable to attempt to clarify the circumstances in which the test will be satisfied, 'paying close attention to the grounds in other jurisdictions' legislation'.[49]

27.37 On the other hand, several submissions argued that there is no demonstrated need for clarification of the 'reasonable requirements of the public' test.[50] For example, IP Australia commented that it is not aware of any evidence that a lack of clarity has limited the use of compulsory licences.[51] The Queensland Government suggested that clarifying the test 'may complicate rather than simplify the operation of the compulsory licensing provisions'.[52] GlaxoSmithKline noted that compulsory licences are rarely, if ever, granted in other jurisdictions except as a remedy for a breach of competition law. In its view, the likely reason for this is that the patent system does not give rise to problems that would necessitate the grant of a compulsory licence.[53]

Anti-competitive conduct

27.38 Chapter 24 discusses the application of competition law to intellectual property rights over genetic materials and technologies. Given the unique nature of many biotechnology inventions, and hence their possible lack of substitutability, the anti-competitive exploitation of a patent could have significant implications for downstream research or access to certain healthcare services.

---

46 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

47 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Cancer Council Australia, *Submission P96*, 19 April 2004; Cancer Council New South Wales, *Submission P99*, 20 April 2004.

48 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004. See also Cancer Council Victoria, *Submission P101*, 20 April 2004.

49 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

50 IP Australia, *Submission P86*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004.

51 IP Australia, *Submission P86*, 16 April 2004.

52 Queensland Government, *Submission P103*, 22 April 2004.

53 GlaxoSmithKline, *Submission P85*, 16 April 2004.

Existing provisions

27.39 The *Patents Act* does not make specific provision for the grant of a compulsory licence as a remedy for anti-competitive conduct. In some circumstances, the 'reasonable requirements of the public' test may permit the grant of a compulsory licence on competition grounds. For example, where the patent holder of an upstream genetic research tool refuses to grant a licence on reasonable terms, and this unfairly prejudices a trade or industry, a court may find that the reasonable requirements of the public have not been satisfied. However, it is not clear whether this test would address all anti-competitive conduct.

27.40 The *Trade Practices Act 1974* (Cth) (TPA) also appears to permit the grant of a compulsory licence as a remedy for anti-competitive conduct. As discussed in Chapter 24, Part IV of the TPA prohibits certain anti-competitive conduct, including the misuse of substantial market power.[54] Where a court finds a breach of Part IV, and that a party to the proceedings has suffered, or is likely to suffer, loss or damage as a result of the breach, the court may make such order as it thinks 'appropriate' to compensate the party for the loss or damage, or to prevent or reduce the loss or damage.[55] This may provide scope for the grant of a compulsory licence over a patented invention.

27.41 However, many dealings in intellectual property rights are likely to fall outside the scope of the TPA, due to the statutory exemption from certain provisions of Part IV for licence and assignment conditions that relate to the subject matter of intellectual property rights; and the practical difficulty of establishing 'misuse of market power' within the meaning of the TPA.[56]

Proposed test

27.42 In its report, *Review of Intellectual Property Legislation under the Competition Principles Agreement,* the Intellectual Property and Competition Review Committee (IPCRC) concluded that there would be merit in providing for third party access to intellectual property rights in a similar way to that provided for other services under Parts IIIA and XIC of the TPA.[57] However, it considered that this objective would be

---

54 *Trade Practices Act 1974* (Cth) s 46.

55 Ibid s 87(1). Section 87(2) sets out the orders which the court may make in these circumstances, but these do not appear to be exhaustive: see R Steinwall and others, *Butterworths Australian Competition Law* (2000), 478.

56 See, eg, R Hoad, 'Compulsory Licensing of Patents: Balancing Innovation and Competition' (2003) 54 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 28; G Adams and D McLennan, 'Intellectual Property Licensing and Part IV of the Trade Practices Act: Are the TPA's Pro-Competitive Provisions Anti-IP Commercialisation?' (2002) 51 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 10. See Ch 24 for more detail.

57 Part IIIA provides a framework for obtaining access to services provided by infrastructure facilities of national significance. However, this Part does not apply to a service that is the use of intellectual property, except to the extent that this is an integral but subsidiary part of the service. Part XIC provides a telecommunications access regime: *Trade Practices Act 1974* (Cth).

best served by reviewing and, where appropriate, amending the relevant provisions in the intellectual property statutes.[58]

27.43 Accordingly, the IPCRC recommended that the existing 'reasonable requirements of the public' test in the *Patents Act* be replaced with a competition-based test that would contain the following conditions:

- access to the patented invention is required for competition in the (relevant) market;
- there is a public interest in enhanced competition in that market;
- the reasonable requirements for such access have not been met;
- the order will have the effect of allowing these reasonable requirements to be better met; and
- the order will not compromise the legitimate interests of the patent holder, including the patent holder's right to share in the return society obtains from the owner's invention, and to benefit from any successive invention, made within the patent term, that relies on the patent.[59]

27.44 The IPCRC suggested that the conditions for granting a compulsory licence should be stringent. The term 'required for competition in the (relevant) market' should mean that there is no other option for competition in that market, and that the enhancement of competition that would be secured by the grant of the licence would have to be material and substantial.[60]

27.45 The Australian Government accepted the IPCRC's recommendation in part. The Government response noted that the IPCRC's test could be more stringent in some circumstances than the existing test for a compulsory licence. For example, the proposed test would not cover some situations where the non-working of an invention, or other effective denial of reasonable access to it, has a negative effect on the public interest. Accordingly, the Government stated that it would adopt the competition-based test in addition to—rather than instead of—the existing 'reasonable requirements of the public' test.[61]

---

58 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 215.

59 Ibid, 163.

60 Ibid, 163.

61 IP Australia, *Government Response to Intellectual Property and Competition Review Committee Recommendations*, <www.ipaustralia.gov.au/pdfs/general/response1.pdf> at 16 June 2004.

27.46 The Australian Government has not yet implemented the competition-based test recommended by the IPCRC. DP 68 proposed that the Commonwealth should amend the *Patents Act* to insert the test as an additional ground for the grant of a compulsory licence. The ALRC also proposed that an independent review of the operation of the compulsory licensing provisions in addressing the competition concerns relating to patented inventions be conducted within five years.[62]

27.47 Many submissions supported this proposal.[63] The Centre for Law and Genetics commented that there is a risk of anti-competitive conduct in relation to gene patents. It noted that a particular issue for the biotechnology industry might be the misuse of market power through the defensive use of patents by oligopolies to create a barrier to entry for non-oligopoly members. It stated that many compulsory licences have been issued in the United States to remedy anti-competitive conduct.[64]

27.48 A few submissions opposed the proposal on the basis that there is no demonstrated problem with the existing provisions and therefore no need to amend them.[65] The Queensland Government suggested that the Advisory Council on Intellectual Property (ACIP) could review the necessity for the proposed test.[66]

27.49 Ian Turnbull stated that the compulsory licensing provisions would not be invoked, even if they were amended, because 'they are contrary to the culture of traditional science'. This culture, he submitted, is based on free communication of results, peer review, and the need for recognition of hard won success. Compulsory licensing is 'inherently confrontational', and the prospect of applying to a court for access to a DNA fragment from a colleague would be abhorrent to many researchers.[67]

27.50 IP Australia suggested that, as there has been very limited use of the compulsory licensing provisions, and there is no indication that their use will increase significantly in the future, review of any amended provision after five years might not produce any meaningful results.[68]

---

62 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 27–1.

63 Department of Health Western Australia, *Submission P89*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; M Rimmer, *Submission P73*, 15 April 2004; Genetic Support Council WA (Inc), *Submission P119*, 13 May 2004. The Cancer Council Victoria supported the proposal but noted its concern that 'such proposals are likely to remain ineffective because they will be too restricted and seldom used': Cancer Council Victoria, *Submission P101*, 20 April 2004.

64 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

65 F B Rice & Co, *Submission P84*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004.

66 Queensland Government, *Submission P103*, 22 April 2004.

67 I Turnbull, *Submission P91*, 16 April 2004.

68 IP Australia, *Submission P86*, 16 April 2004.

ALRC's views

27.51 The ALRC recommends that the Commonwealth should amend the *Patents Act* to insert the IPCRC's competition-based test as an additional ground for the grant of a compulsory licence.

27.52 This test would address those circumstances in which there is a public interest in enhanced competition in a market, and the patent holder has not met reasonable requirements for access to the patented invention. The test has the potential to enliven the compulsory licensing provisions in the legislation. As the IPCRC noted, such a test would complement the national access regime provided under the TPA for the services of facilities of national significance. The Australian Government has already indicated its intention to implement the IPCRC test, which was supported by many submissions.

27.53 DP 68 proposed a subsequent independent review of the operation of the compulsory licensing provisions in addressing the competition concerns relating to patented inventions. While there was some support for such a review, the ALRC considers that the proposed period of five years may not provide sufficient opportunity to assess their use in practice. Instead, the ALRC suggests that the Australian Government keep the option of a future review under consideration. Such a review could consider the operation of the compulsory licensing provisions generally, once the competition-based test has been introduced and, perhaps, applied by the courts. Such a review could also consider the potential interaction between the court's scope to grant a compulsory licence as a remedy for anti-competitive conduct under Part IV of the TPA, and under the compulsory licensing provisions of the *Patents Act.*

27.54 The ALRC supports the retention of the 'reasonable requirements of the public' test to address other public interest grounds for granting a compulsory licence. The ALRC agrees with the Australian Government that there may be circumstances where the non-working of a patented invention—or other effective denial of reasonable access to it—would have a negative effect on the public interest. For example, the reasonable requirements of the public might not be satisfied where a patent holder's monopoly control of its patented medical genetic test has had an injurious effect on the development of skills within the Australian healthcare sector.

27.55 The ALRC considers that there would be benefit in clarifying the existing test for several reasons. First, the ALRC considers that the existing lack of clarity in the 'reasonable requirements of the public' test may be one reason why few compulsory licences have been sought, or granted, under the *Patents Act*.

27.56 Most of the submissions in response to DP 68 supported clarification of the existing test, but were divided as to the best way to approach it. Generally, there was greater support for an approach that retains the 'reasonable requirements of the public' test, but specifies that s 135 of the *Patents Act* is not exhaustive of the circumstances in which these requirements will not have been satisfied. However, the Centre for Law and Genetics considered that this approach would provide even greater uncertainty, as the bounds of the test would become increasingly unclear.

27.57 The ALRC considers that the scope of the existing test should be clarified in a way that provides greater guidance to those seeking compulsory licences, yet also retains the flexibility necessary to respond to new public interest concerns as they arise. One way to ensure the flexibility of the test would be to amend the *Patents Act* to provide that s 135 is not exhaustive. However, in the absence of judicial interpretation this approach could create even more uncertainty. Therefore, the ALRC considers that it would be more appropriate to clarify the circumstances in which the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied.

27.58 Once the competition-based test is implemented, the *Patents Act* will have two potentially overlapping grounds upon which a compulsory licence could be granted. Therefore, it may be necessary to clarify the scope of each test in so far as they apply to competition-based grounds for granting a compulsory licence. Such clarification could benefit both applicants for compulsory licences, and the courts in applying these tests.

27.59 The ALRC considers that the introduction of the competition-based test provides a good opportunity to clarify both the scope of the 'reasonable requirements of the public' test itself, and its relationship with the competition-based test. Accordingly, the ALRC also recommends that the Commonwealth should amend the *Patents Act* to clarify the scope of the 'reasonable requirements of the public' test.

Recommendation 27–1 The Commonwealth should amend the provisions of the *Patents Act 1990* (Cth) relating to compulsory licences by:

(a) inserting the competition-based test recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence; and

(b) clarifying the scope of the 'reasonable requirements of the public' test.

Dependent patents

27.60 Where a patented invention ('dependent patent') cannot be worked without exploiting an earlier patented invention ('original patent'), the owner of the dependent patent generally must obtain a licence over the original patented invention. If this is not granted, the owner of the dependent patent might seek authorisation through a compulsory licence to use the original patent.

27.61 Under the *Patents Act,* the owner of a dependent patent who seeks a compulsory licence over the original patent must satisfy the 'reasonable requirements of the public' test.[69] However, the position is different where an applicant requires a compulsory licence over both a dependent patent and its original patent, in order to work the dependent patent. In those circumstances, the applicant must satisfy the reasonable requirements of the public test in relation to the dependent patent only. The court may grant a compulsory licence over that patent, and over the original patent, if the dependent patent involves an important technical advance of considerable economic significance on the original patent.[70] This provision is consistent with art 31(l) of the TRIPS Agreement.[71]

27.62 Therefore, an applicant who owns a dependent patent must satisfy the reasonable requirements of the public test in order to obtain a compulsory licence over the original patent. However, where an applicant requires a compulsory licence over both a dependent patent and the original patent, it need only satisfy the reasonable requirements of the public test in relation to the dependent patent. This position has been criticised as illogical.[72] Nicol and Nielsen have commented that:

> Given that circumstances of dependency are likely to arise frequently in the area of biotechnology, there may be justification for amending the existing provisions, making special provision for issuance of compulsory licences to dependent patent holders where the invention covered by the dependent patent 'involves an important technical advance of considerable economic significance' over the invention for which the compulsory licence is sought.[73]

27.63 The United Kingdom's compulsory licensing provisions deal specifically with dependent patents. Under s 48A of the *Patents Act 1977* (UK), a court may grant a compulsory licence where the patent holder has refused to grant a licence on reasonable terms, resulting in the prevention or hindrance of the exploitation in the United Kingdom of any other patented invention that involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted.

27.64 DP 68 asked whether the *Patents Act* should be amended to permit the grant of a compulsory licence to a patent holder who cannot work its patent without using another patent for which authorised use cannot be obtained.[74] For example, DP 68 suggested the Act could be amended to provide that a court could grant a compulsory licence for an original patent where the dependent patent involves an important

---

69 *Patents Act 1990* (Cth) ss 133(2), 135.

70 Ibid s 133 (3B).

71 TRIPS Agreement art 31(l).

72 R Hoad, 'Compulsory Licensing of Patents: Balancing Innovation and Competition' (2003) 54 *Intellectual Property Forum: Journal of the Intellectual Property Society of Australia and New Zealand* 28, 34. See also AusBiotech Ltd, *Submission P58*, 7 November 2003.

73 D Nicol and J Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* (2003) Centre for Law and Genetics Occasional Paper No 6, 239.

74 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 27–2.

technical advance of considerable economic significance on the original patent. In these circumstances, the dependent patent holder would not be required to satisfy the 'reasonable requirements of the public' test.

27.65 The ALRC received mixed responses to this question. Several submissions expressed support for this approach.[75] The Centre for Law and Genetics commented that there are differing degrees of follow-on invention and dependency. It suggested that only the patent holders of new and important applications would be likely to fall within the ambit of the suggested test.[76]

27.66 By contrast, other submissions expressed caution with this approach. Generally, these submissions argued that such a provision would be unnecessary, because dependent patents are already adequately covered by the 'reasonable requirements of the public' test;[77] or that it would be undesirable, because it would undermine the value of the original patent granted, and the patent system.[78]

27.67 IP Australia suggested that if such a provision were introduced, it should be on the condition that the dependent patent has a clear material advantage over the original patent; and that the reasonable requirements of the public are not being met.[79] The Queensland Government suggested that ACIP should review this matter.[80]

ALRC's views

27.68 The ALRC does not now consider it necessary to recommend any reforms to the compulsory licensing provisions to address circumstances involving dependent patents.

27.69 As noted above, some submissions supported amending the *Patents Act* to make specific provision for the owner of a dependent patent to obtain a compulsory licence for an original patent—in particular, where the dependent patent is an important technical advance of considerable economic significance on the original patent. However, other submissions argued that this would be both unnecessary and undesirable. In their view, circumstances of dependency are already adequately addressed under the 'reasonable requirements of the public' test; and any specific provision for dependency could undermine the value of the original patent and the patent system.

---

75 Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

76 Centre for Law and Genetics, *Submission P110*, 28 April 2004.

77 See, eg, IP Australia, *Submission P86*, 16 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004.

78 See, eg, Institute of Patent and Trade Mark Attorneys of Australia, *Submission P106*, 27 April 2004; GlaxoSmithKline, *Submission P85*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

79 IP Australia, *Submission P86*, 16 April 2004.

80 Queensland Government, *Submission P103*, 22 April 2004.

27.70 The ALRC considers it likely that the 'reasonable requirements of the public' test would, in most cases, adequately address circumstances of dependency. For example, a dependent patent holder could argue that the demand in Australia for the original patented invention has not been reasonably met because of the original patent holder's refusal to grant a licence on reasonable terms. While the *Patents Act* appears to deal with original patents differently according to the context of the application, this does not appear to impact on the practical availability of a compulsory licence. Accordingly, the ALRC considers reform of these provisions unnecessary.

Emergency and public non-commercial use

27.71 The *Patents Act* provides that an applicant for a compulsory licence generally must first try for a reasonable period to obtain a licence from the patent holder on reasonable terms and conditions.[81] The requirement of prior negotiation reflects the nature of a patent right, which is an exclusive right to exploit a new invention for a specified period. However, it necessarily delays the process of obtaining a compulsory licence while an individual or organisation seeking a licence attempts to negotiate with the patent holder.

27.72 DP 68 suggested that there may be circumstances where such a delay might not be in the public interest. For example, Australia could face a public health crisis or bio-terror attack that would require a rapid and efficient response. The ALRC suggested that, in most cases, the Australian Government, or a state or territory government or health department would take the initiative in responding to these situations by invoking the Crown use provisions of the *Patents Act*.

27.73 However, the ALRC stated that there might be circumstances where the Crown, for whatever reason, does not act. DP 68 asked whether, given the Crown use provisions, the *Patents Act* should also provide for the grant of a compulsory licence over a patented invention in circumstances of 'a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use'.[82] For example, the Act could provide that the requirement of prior negotiation may be waived in the case of a national emergency or other circumstances of extreme emergency, or in cases of public non-commercial use. This would be consistent with art 31(b) of the TRIPS Agreement.

27.74 Several submissions supported this approach.[83] A few submissions also supported extending the compulsory licensing provisions to enable the supply of drugs

---

81 *Patents Act 1990* (Cth) s 133(3A).

82 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 27–3.

83 See, eg, Centre for Law and Genetics, *Submission P104*, 22 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004. The Walter and Eliza Hall Institute of Medical Research supported the grant of a compulsory licence for the period of a national emergency, but considered that compulsory licensing for public non-commercial use would make Australian patents less attractive and, in any event, could be addressed through the research exemption proposed by the ALRC: Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004.

manufactured under a compulsory licence to countries that lack manufacturing capabilities.[84] The Centre for Law and Genetics suggested that this would fully reflect the provisions of the *Doha Declaration on the TRIPS Agreement and Public Health*, and would reflect well on Australia's role as a good international citizen.[85]

27.75 However, most submissions argued that the Crown use provisions would be a more appropriate mechanism for addressing a national emergency or similar circumstances of extreme urgency, or cases of public non-commercial use.[86] The Department of Industry, Tourism and Resources considered that removing the requirement of prior negotiation in these circumstances would be 'draconian, especially in view of the lack of empirical data to support the existence of a significant problem'.[87]

27.76 IP Australia noted that that compulsory licences are an exception to the exclusive rights granted to a patent holder, and the circumstances of their use should be limited and carefully considered. Any changes to the provisions need to be balanced against the potential to devalue patent rights, and considered in the light of other provisions already available, especially Crown use. It also noted that any changes would need to be carefully considered in the light of Australia's international obligations—particularly under the TRIPS Agreement and the AUSFTA.[88] The Queensland Government suggested that the matter could be referred to ACIP for review.[89]

ALRC's views

27.77 The ALRC does not consider it necessary to recommend any reforms to the compulsory licensing provisions to address circumstances of emergency, or public non-commercial use of patented inventions. Most submissions did not consider it necessary to make specific provision for the grant of a compulsory licence, without prior negotiation, in these circumstances. In their view, the Crown use provisions are a more appropriate mechanism.

---

84 Centre for Law and Genetics, *Submission P104*, 22 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

85 Centre for Law and Genetics, *Submission P104*, 22 April 2004. See *Declaration on the TRIPS Agreement and Public Health*, 14 November 2001, World Trade Organization 4th Ministerial Conference, WT/MIN (01)/DEC/2; *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 30 August 2003, World Trade Organization Council for TRIPS, WT/L/540.

86 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Department of Health Western Australia, *Submission P89*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; F B Rice & Co, *Submission P84*, 16 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

87 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

88 IP Australia, *Submission P86*, 16 April 2004.

89 Queensland Government, *Submission P103*, 22 April 2004.

27.78 The ALRC considers that, while theoretically, an Australian government could choose not to exercise the Crown use provisions in an emergency,[90] such circumstances are likely to be rare, particularly as the Crown use provisions allow for the Crown to authorise others to work the patent on its behalf. In any case, these circumstances may be accommodated under the existing provisions. For example, while the *Patents Act* requires that an applicant must have tried for a reasonable period to obtain a licence from the patent holder before a compulsory licence may be granted, it is likely that the courts would determine the reasonableness of the period in the context of the exigent circumstances.

27.79 Under the existing provisions, an application for a compulsory licence cannot be made within the first three years after the patent was granted. In these cases, the ALRC considers it most likely that an Australian government would invoke Crown use to address any circumstances of serious emergency, rather than face the disapprobation of the Australian community.

27.80 Finally, several submissions suggested that the existing compulsory licensing provisions should be amended to enable the supply of drugs manufactured under a compulsory licence to countries that lack manufacturing capabilities. The ALRC considers that, although such an amendment may have merit, it falls outside the Inquiry's Terms of Reference.

90 For example, the Australian Government may have concerns about the potential cost of such an exercise, or of possible trade retaliation.

PART H

Other Intellectual Property Issues

28. Copyright and Databases

Contents

Introduction

28.1 The Terms of Reference direct the ALRC to consider what changes might be required to encourage the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies. This chapter examines the potential application of copyright law to the written representation of gene and protein sequences, and to databases holding gene sequence and other information.

28.2 Many of the genetic databases that are available online to Australian researchers have been compiled in overseas jurisdictions. These databases are likely to be subject to the laws applying in those jurisdictions, rather than Australian law.[1]

1 See generally, Copyright Law Review Committee, *Copyright and Contract* (2002), Ch 5.

28.3 This chapter discusses the various means by which the owners of genetic databases compiled in Australia might seek to protect their investment in them. In practice, database owners might seek to use a combination of copyright law, technological protection measures, and contractual arrangements. The chapter considers the competing interests of database owners and researchers, and recommends several reforms to effect an appropriate balance between them.

Copyright law

28.4 Copyright protects the form of expression of ideas, rather than the ideas, information or concepts expressed.[2] The *Copyright Act 1968* (Cth) (*Copyright Act*) regulates copyright in Australia in relation to original literary, dramatic, musical and artistic works, and subject matter other than works.

28.5 Copyright is addressed in several international treaties, in particular the *Berne Convention for the Protection of Literary and Artistic Works 1886* (Berne Convention) and the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement). These conventions define minimum periods and levels of protection for copyright in member States, and provide for limitations and exceptions to copyright in certain circumstances.[3]

Current law and practice

Subsistence of copyright

28.6 Copyright in a literary, dramatic or musical work includes the exclusive right to reproduce the work in a material form; publish the work; perform the work in public; communicate the work to the public; make an adaptation of the work; enter into a commercial rental arrangement in respect of the work reproduced in a sound recording; and, for computer programs, enter into a commercial rental arrangement in respect of that program.[4]

28.7 Copyright subsists in an unpublished literary, dramatic, musical or artistic work if the author was a 'qualified person'[5] 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;[6] 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.[7]

---

2 J McKeough, A Stewart and P Griffith, *Intellectual Property in Australia* (3rd ed, 2004), 150.

3 *Berne Convention for the Protection of Literary and Artistic Works* (1886); *Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization)*, [1995] ATS 8, (entered into force on 1 January 1995).

4 *Copyright Act 1968* (Cth) s 31(1).

5 A 'qualified person' is an Australian citizen, resident or an Australian protected person: Ibid s 32(4).

6 'Publication' is the authorised supply of reproductions of a work to the public: Ibid s 29(1).

7 Ibid s 32. In addition, the *Copyright (International Protection) Regulations 1969* (Cth) confer a similar protection on most works that are made or published overseas.

28.8 In order to attract copyright, a work must be an original literary, dramatic, musical, or artistic work.[8] A literary work includes a table or compilation expressed in words, figures or symbols; and a computer program or compilation of computer programs.[9] 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.[10]

28.9 A work need not be the expression of original or inventive thought, but it must originate with an author and must not be a copy. A work originates with an author if it is the product of the author's skill, labour and expertise or experience. The requisite degree of labour, skill and expertise will depend on the facts of the case and will be a question of degree.[11] In Australia, the Federal Court has held that, for compilations, originality can flow purely from the 'sweat of the brow' involved in collecting, verifying and presenting information, even if there is no creativity involved in its selection or arrangement.[12]

28.10 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. This is known as the 'merger doctrine'; where an idea has only one possible form of expression, copyright does not extend to that expression.[13] It is unclear whether the merger doctrine applies in Australian copyright law.[14] In a recent Federal Court case, Lindgren J commented that the doctrine does not apply in relation to 'whole of universe' factual compilations, such as a telephone directory.[15]

Copyright infringement

28.11 Copyright is infringed if a person does or authorises the doing, in Australia, of any act falling within the copyright in a work without the copyright owner's permission.[16] Such 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.[17]

---

8 *Copyright Act 1968* (Cth) s 32.
9 Ibid s 10(1).
10 R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 42–44, citing *Hollinrake v Truswell* [1894] 3 Ch 420.
11 S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [7.50], [7.60].
12 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433. See also J Lahore, *Patents, Trade Marks & Related Rights: Looseleaf Service* (2001), [10,065], [10,115].
13 See J McKeough, A Stewart and P Griffith, *Intellectual Property in Australia* (3rd ed, 2004), 155–156.
14 Some commentators have suggested that Australian courts have accepted the principle, while others suggest that the High Court has impliedly rejected it: see Ibid, 156; R Reynolds and N Stoianoff, *Intellectual Property: Text and Essential Cases* (2003), 21–22.
15 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474. In that case, Telstra's telephone directory was a 'whole of universe' compilation because there was no selection of the subscribers to be included.
16 *Copyright Act 1968* (Cth) s 36(1).
17 J McKeough, A Stewart and P Griffith, *Intellectual Property in Australia* (3rd ed, 2004), 216.

Fair dealing for research or study

28.12 The *Copyright Act* provides for certain acts of 'fair dealing' in a copyright work, which constitute exceptions to copyright infringement.[18] One such exception is fair dealing for the purpose of research or study.[19] Section 40(2) provides guidelines for determining whether the reproduction of the whole or a part of a work constitutes a fair dealing for the purpose of research or study. These factors include:

- the purpose and character of the dealing;
- the nature of the work or adaptation;
- the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;
- the effect of the dealing upon the potential market for, or the value of, the work or adaptation; and
- where only a part of the work is copied, the amount and substantiality of that part compared to the whole work or adaptation.[20]

28.13 Section 40(3) provides that the reproduction of specified amounts of a work will be deemed to be a fair dealing if conducted for the purpose of research or study. These amounts are:

- in the case of a work comprising an article in a periodical publication, the whole or part of the work; or
- in any other case, not more than a 'reasonable portion' of the work.[21]

28.14 In 1998, the Copyright Law Review Committee (CLRC) recommended that the *Copyright Act* be amended to: consolidate the current fair dealing provisions into a single provision; expand fair dealing to an open-ended model that refers to the existing set of purposes, but is not confined to them; and apply the non-exclusive set of factors provided for in s 40(2) to all fair dealing.[22] The Australian Government has not yet announced a decision to implement these recommendations.

---

18 The *Copyright Act* provides for fair dealing in a copyright work for the purpose of research or study, criticism or review, reporting news, judicial proceedings, or giving professional advice: *Copyright Act 1968* (Cth) ss 40–43.

19 Ibid s 40(1).

20 Ibid s 40(2).

21 Ibid s 40(3). A 'reasonable portion' generally means 10% of the work, determined either by page number or, in the case of digital copies, word count: *Copyright Act 1968* (Cth) ss 10(2), 10(2A).

22 Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), rec 6.29, 6.35, 6.44.

Reviews and proposed amendments

28.15 Aspects of the *Copyright Act* have been reviewed by various bodies in recent years. The CLRC examined several options for simplifying the *Copyright Act*,[23] and the relationship between copyright and contract.[24] The Intellectual Property and Competition Review Committee (IPCRC) examined the application of competition principles to copyright law.[25] The Attorney-General's Department conducted a review of the operation of the digital agenda amendments to the *Copyright Act,* and engaged the law firm, Phillips Fox, to conduct a major part of the review.[26]

28.16 On 18 May 2004, the Australian Trade Minister (the Hon Mark Vaile) and the United States Trade Representative (Robert Zoellick) signed the Australia–United States Free Trade Agreement (AUSFTA). Under the AUSFTA, Australia has agreed to bring various aspects of its copyright law into greater harmony with United States copyright law.[27]

Gene sequences and products

28.17 In future, scientific researchers might seek to assert copyright over the written representation of a gene or amino acid sequence in addition, or as an alternative, to applying for a patent or other intellectual property protection.

28.18 Sue Coke has suggested that the written representation of a sequence of modified DNA or protein may be protected as an original literary work under the *Copyright Act*. She argues that as the legislative definition of a 'literary work' includes a table or compilation expressed in words, figures or symbols, the written representation of a genetic sequence or product—being a string of letters representing the four nucleotides, adenine, thymine, guanine and cytosine (A, T, G and C)—is likely to be a 'literary work' within the meaning of the *Copyright Act*. Coke commented that:

> Since copyright was held to subsist in the list of numbers in the 'newspaper bingo' game used to promote the circulation of a Sunday newspaper, it can hardly be asserted that a sequence of letters (which may not be meaningful to a lay person but would be to a molecular biologist) denoting nucleotides of modified DNA or the amino acids making up the protein the product of that modification would not be protected by copyright, provided sufficient skill, labour and effort was involved in elucidating the sequence.[28]

---

23 Ibid.
24 Copyright Law Review Committee, *Copyright and Contract* (2002).
25 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000).
26 Phillips Fox, *Digital Agenda Review Report and Recommendations* (2004). See *Copyright Amendment (Digital Agenda) Act 2000* (Cth).
27 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004.
28 S Coke, 'Copyright and Gene Technology' (2002) 10 *Journal of Law and Medicine* 97, 102.

28.19 In other jurisdictions, commentators have suggested that copyright may not subsist in such a written record because there is only one established way of representing a sequence of nucleotides or amino acids. In this case, the idea and expression merge.[29] 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.[30]

28.20 The United States Copyright Office has stated that it does not consider that copyright may subsist in a gene sequence under United States copyright law.[31]

28.21 As noted above, while it is unclear whether the merger doctrine applies generally in relation to copyright in Australia, it does not apply to 'whole of universe' factual compilations.[32] Therefore, copyright could potentially subsist in the representation of a genetic sequence provided sufficient skill, labour and effort is involved in creating that expression.

28.22 Several submissions expressed concerns regarding the potential implications of copyright protection of gene sequences and proteins that have been reduced to written form.[33] For example, the Department of Health and Ageing submitted that it would be concerned about any application of copyright law that tended to inhibit medical research or the application of such research in healthcare.[34]

28.23 Whether or not copyright subsists in the written representation of a gene or amino acid sequence under the *Copyright Act*, it appears unlikely that this would hinder the use of that sequence in genetic research. As copyright protects only the expression of ideas—rather than the ideas or information expressed—researchers could continue to use the molecule itself in their research, despite the protection of its written representation. If copyright does subsist in the written representation of a sequence, this would be subject to the fair dealing exception to copyright infringement for research or study. In addition, if another researcher independently established the genetic sequence and articulated it in any identical way to that in which it had been first expressed, that independently researched expression would not infringe the copyright in the original expression.

---

29 See the discussion in Ibid, 101, 108.

30 G Karnell, 'Protection of Results of Genetic Research by Copyright or Design Rights?' (1995) 17 *European Intellectual Property Review* 355, 357.

31 L Eckstrom and others, *Eckstrom's Licensing in Foreign and Domestic Operations* (1999) Vol 2, [13.10].

32 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474.

33 For example, South Australian Government, *Submission P51*, 30 October 2003; Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004; A McBratney and others, *Submission P47*, 22 October 2003.

34 Commonwealth Department of Health and Ageing, *Submission P65*, 28 January 2004.

28.24 In her submission, Danielle Andrewartha argued that copyright could subsist in a nucleotide or amino acid molecule itself under Australian copyright law.[35] However, the ALRC considers that this is unlikely. The molecule is unlikely to fall within the legislative definition of a 'literary work' and, in any case, provides no information, instruction or entertainment to human beings—unlike its written representation.

Genetic databases

28.25 Genetic databases may hold compilations of the sequences of the human genome or other genomes—including whole genomes, single genes and gene fragments, such as single nucleotide polymorphisms (SNPs) and expressed sequence tags (ESTs)—or information about the biochemical pathways related to the expression of genes.[36]

28.26 In recent years, there has been a proliferation of both public and private databases created for use in scientific research. They have become essential for research biologists because:

> First, the increasing rate of discovery and the increasingly varied publication options make it difficult for scientists to keep abreast of new knowledge. Second, most of the new scientific data, such as [a] nucleic acid sequence, is no longer being published by conventional means, such as in scholarly journals. Third, an electronic cataloguing of the sequence information within a database facilitates the emerging need for computational analysis of genetic information.[37]

28.27 Publicly available databases have been established by international collaborations including the International Human Genome Sequencing Consortium; the SNP Consortium; and the International HapMap Project. These databases make genomic information widely and rapidly available for use in genetic research.

28.28 Several international statements have recognised the benefits of placing primary genetic information in the public domain. For example, the Bermuda Principles state that primary genomic sequences should be in the public domain; primary genomic sequences should be rapidly released; and the Human Genome Organisation (HUGO) should be advised of large-scale sequencing of particular regions of the genome.[38] These principles have encouraged the producers of large-scale DNA sequencing

---

35 D Andrewartha, *Submission P92*, 16 April 2004. See also the discussion in 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.

36 E Baba, 'From Conflict to Confluence: Protection of Databases Containing Genetic Information' (2003) 30 *Syracuse Journal of International Law and Commerce* 121, 128–132.

37 Ibid, 127.

38 The Bermuda Principles were established in 1996 at an International Strategy Meeting on Human Genome Sequencing, and endorsed in Bermuda the following year: Wellcome Trust, *Genome Data Release*, <www.wellcome.ac.uk/en/1/awtvispoldat.html> at 16 June 2004; Wellcome Trust, *Summary of Principles Agreed at the International Strategy Meeting on Human Genome Sequencing*, University College London, <www.gene.ucl.ac.uk/hugo/bermuda.htm> at 16 June 2004.

collections to release their data immediately for free and unrestricted use by the scientific community. The HUGO Ethics Committee's *Statement on Human Genomic Databases* also declared that primary genomic sequences should be rapidly placed in the public domain.[39]

28.29 Private genetic databases have also been established, and access to these databases is generally subject to a fee. The attraction of private databases lies in the additional information that they contain; that is, the annotations that have been added to the sequence information.

28.30 The Australian Genomic Information Centre operates the Australian National Genomic Information Service (ANGIS), which provides internet-based access to various publicly available nucleotide, protein, structure and reference databases, and other services.[40] Access to ANGIS is based on payment of an annual fee. Academic pricing is available to universities and non-government not-for-profit organisations. Government pricing is available to federally and state funded organisations and institutions.[41]

28.31 In February 2004, a workshop of the Organisation for Economic Co-operation and Development (OECD) Working Party on Biotechnology concluded that the OECD should develop principles of best practice for the management and governance of human genetic research databases.[42]

Copyright protection

28.32 In Australia, copyright may subsist in a database of factual information. In *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd*, the Full Federal Court held that, for the purposes of copyright, originality can flow purely from the 'sweat of the brow' involved in obtaining and compiling factual information, even if there is no creativity involved in its selection or arrangement.[43]

28.33 In that case, the Court held that copyright subsists in Telstra's telephone directory, as an original literary work. Lindgren J stated that a factual compilation would be original if the compiler has exercised sufficient labour and expense in collecting, verifying, recording and assembling the information.[44] Sackville J stated that a factual compilation would be original if the compiler has undertaken substantial

---

39 HUGO Ethics Committee, *Statement on Human Genomic Databases* (2002).

40 Australian Genomic Information Service, *About ANGIS*, <www.angis.org.au/new/about/index.html> at 16 June 2004.

41 Australian Genomic Information Service, *Subscription and Costs*, <www.angis.org.au/new/about/subscription.html> at 16 June 2004.

42 Organisation for Economic Co-operation and Development, *Main Points from the OECD Workshop on Human Genetic Research Databases–Issues of Privacy and Security*, <www.oecd.org> at 16 June 2004.

43 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433. See also J Lahore, *Copyright and Designs: Looseleaf Service* (1996), [10,065], [10,115].

44 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 474.

labour or incurred substantial expense in collecting the information recorded in the compilation.[45] The High Court refused special leave to appeal against this decision.[46] The Attorney-General's Department submitted that:

> The consequence of the decision in *Desktop Marketing v Telstra* is that raw data, including raw data that may only be represented in one particular way, will be subject to protection under the *Copyright Act 1968*, at least where substantial independent skill, labour and effort have been used to compile the data. This would cover most, if not all, databases in existence in Australia.[47]

28.34 Therefore, in Australia, copyright may subsist in a database of factual information on the basis of the 'sweat of the brow' involved in obtaining and compiling the information, as well as the selection and arrangement of the information. In addition, copyright may subsist in the individual items contained within the database.

Contract and other protection

28.35 Online database owners often use technological protection measures (TPMs) to restrict or control access to, or copying of, the contents of their databases. The *Copyright Act* defines a TPM as a device or product, or a component incorporated into a process, that is designed, in the ordinary course of its operation, to prevent or inhibit the infringement of copyright in a work by ensuring that access to the work is only available by use of an access code or process with the copyright owner's authority; or through a copyright control mechanism.[48]

28.36 TPMs may include encryption, password protection, or 'read only' technology.[49] Database owners may permit access on contractual terms, for example through a written licence agreement or a 'click-through' agreement on the website.[50]

28.37 The *Copyright Act* does not currently prohibit the use of a circumvention device or service[51] to avoid the effect of a TPM. Accordingly, a researcher could use a circumvention device to avoid an access or copy control measure for fair dealing purposes, but would remain subject to liability for any infringement involved in thus

---

45 Ibid, 532–533.

46 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (Unreported, High Court of Australia, Hayne and Callinan JJ, 20 June 2003).

47 Attorney-General's Department, *Submission P61*, 11 November 2003.

48 *Copyright Act 1968* (Cth) s 10(1). See also *Kabushiki Kaisha Sony Computer Entertainment v Stevens* (2003) 200 ALR 96.

49 E Dellit and C Kendall, 'Technological Protection Measures and Fair Dealing: Maintaining the Balance between Copyright Protection and the Right to Access Information' (2003) 4 *Digital Technology Law Journal* 1, 17.

50 Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (2003), 24.

51 The *Copyright Act* defines a 'circumvention device' as a device that has only a limited commercially significant purpose or use, or no such purpose or use, other than the circumvention, or facilitating the circumvention, of a TPM. A 'circumvention service' is a service, the performance of which has only a limited commercially significant purpose, or no such purpose or use, other than the circumvention, or facilitating the circumvention, of a TPM: *Copyright Act 1968* (Cth) s 10(1).

gaining access. However, while it may not be unlawful for an individual to use a circumvention device to access and reproduce copyright works for this purpose, it may be difficult to obtain such a device within Australia. Section 116A of the *Copyright Act* prohibits the making, importing, selling, distribution and promotion of such devices and services, subject to certain 'permitted purposes'.[52] These permitted purposes do not include fair dealing.

28.38 In addition, while the use of circumvention measures is not currently prohibited, database owners could insert conditions into licence agreements that require users to agree not to use such measures for fair dealing purposes.[53]

Other jurisdictions

United States

28.39 The United States has rejected the 'sweat of the brow' approach to originality in copyright law. Copyright is extended only to those factual compilations that display a degree of creativity, and can therefore be considered intellectual creations.[54] In addition, or as an alternative, copyright database owners tend to protect their investment through other measures including TPMs and licensing arrangements.[55] Several bills have been introduced into the United States Congress to create a form of *sui generis* protection for databases or collections of information; however none of these has been passed.[56]

28.40 The United States distinguishes between access control and copy control measures in relation to TPMs. The *Digital Millennium Copyright Act 1998* (US) (DMCA) prohibits commercial dealings in circumvention devices or services, and the use of these measures to circumvent an access control measure, subject to limited exceptions. The prohibition does not extend to the circumvention of copy control measures. The DMCA contains an administrative rule-making procedure whereby the Library of Congress must conduct a three yearly review as to whether copyright users are, or are likely to be, adversely affected in their ability to make non-infringing uses of a particular class of copyright works due to these anti-circumvention provisions.[57]

---

52 Ibid s 116A.

53 Phillips Fox, *Digital Agenda Review Report and Recommendations* (2004), [13.27].

54 M Davison, *The Legal Protection of Databases* (2003), 15. See *Feist Publications Inc v Rural Telephone Service* 499 US 340 (1991).

55 Attorney-General's Department, *Submission P61*, 11 November 2003.

56 M Davison, *The Legal Protection of Databases* (2003), 213.

57 *Digital Millennium Copyright Act 1998* (US); 17 USC s 1201. See also E Dellit and C Kendall, 'Technological Protection Measures and Fair Dealing: Maintaining the Balance between Copyright Protection and the Right to Access Information' (2003) 4 *Digital Technology Law Journal* 1, 26–27. In 2002, two bills were introduced into Congress to permit the circumvention of technological protection measures for fair use purposes: Digital Media Consumers' Rights Bill 2002 (US) and Digital Choice and Freedom Bill 2002 (US): J Cunard, K Hill and C Barlas, *Current Developments in the Field of Digital Rights Management* (2003) World Intellectual Property Organization, 64–65.

28.41 The application of the DMCA has been criticised on various grounds: including concerns that it may impair the fair use doctrine under United States law; enclose the public domain through 'digital lock-up'; skew the balance that copyright policy has traditionally aimed to achieve between private rights and the public interest; have a chilling effect on scientific research; and be unworkable due to its complex maze of prohibitions and exemptions.[58] Elouise Dellit and Dr Christopher Kendall have commented that if a researcher cannot gain access to a copyright work due to the operation of a TPM, he or she is not in a position to copy parts of the work for fair use purposes.[59]

European Union

28.42 The European Parliament and Council's *Directive on the Legal Protection of Databases* (EU Database Directive) deals with copyright protection for databases that, by virtue of the selection or arrangements of their contents, constitute the author's own intellectual creation.[60] It also provides for a *sui generis* database right that applies to databases for which the owner has made a substantial investment in obtaining, verifying or presenting the contents.[61]

28.43 The EU Database Directive permits three different sets of rights in relation to a database. First, copyright may subsist in the structure of the information in a database; that is, the selection and arrangement of the database. Second, copyright may subsist in the individual items constituting the database contents. Third, the database right may protect the contents of the database.[62]

28.44 The EU Database Directive prohibits the unauthorised extraction[63] or re-utilisation[64] of the whole or a substantial part of the database contents, whether evaluated quantitatively or qualitatively.[65] The term of protection is 15 years, which may be extended by a substantial change—in qualitative or quantitative terms—to the

---

58 See I Kerr, A Maurushat and C Tacit, *Technical Protection Measures: Part II The Legal Protection of TPMs (paper prepared for the Copyright Policy Branch of the Department of Canadian Heritage)* (2002) Nelligan O'Brien Payne, 55.

59 E Dellit and C Kendall, 'Technological Protection Measures and Fair Dealing: Maintaining the Balance between Copyright Protection and the Right to Access Information' (2003) 4 *Digital Technology Law Journal* 1, 27.

60 *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 II. The European Commission is currently reviewing the operation of the EU Database Directive.

61 Ibid, Ch III.

62 M Davison, *The Legal Protection of Databases* (2003), 50–51.

63 'Extraction' is defined as the permanent or temporary transfer of all or a substantial part of the contents of a database to another medium by any means or in any form: *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 7(2)(a).

64 'Re-utilisation' is defined as any form of making available to the public all or a substantial part of the contents of a database by the distribution of copies, by renting, or by online or other forms of transmission: Ibid, art 7(2)(b).

65 Ibid, art 7(1).

database contents.[66] The European Union may conclude agreements to extend the database right to databases made in third countries.[67] It appears that protection will be offered only on the basis of reciprocity; that is, where the third country offers protection comparable to the database right.[68]

28.45 In 2001, the European Parliament and Council adopted a *Directive on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society* (EU Copyright Directive). The EU Copyright Directive has limited the scope of fair dealing for research purposes. The Directive permits member States to provide exceptions and limitations to the right of reproduction and communication for the purpose of illustration for teaching or scientific research of a non-commercial nature; or for the purpose of research or private study by individual members of the public at dedicated terminals in public libraries, educational establishments and other specified organisations.[69]

28.46 Article 6 of the EU Copyright Directive prohibits the use of, and commercial dealings in, circumvention measures to avoid TPMs, subject to specified exceptions.[70] Member States must promote the use of voluntary agreements to accommodate certain exceptions to copyright infringement and, where necessary, take measures to ensure that beneficiaries of those exceptions can benefit from them. However, the Directive appears to provide that online contracts may prevail over the copyright exceptions.[71]

28.47 The European Commission must report on the operation of the EU Copyright Directive every three years. The report must examine whether art 6 confers a sufficient level of protection and whether acts that are permitted by law are being adversely affected by the use of TPMs.[72]

Impact on genetic research

28.48 The protection of genetic databases against unauthorised use raises significant policy considerations. Limiting access to, and the use of, the information contained in such databases can stifle potentially useful research. However, such protection may be necessary to provide sufficient incentive for a database owner to collect and arrange the data, and make it available for third party use.

---

66 Ibid, art 10.
67 Ibid, art 11(3).
68 Ibid, recital 56.
69 *Directive 2001/29/EC of the European Parliament and of the Council on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society*, (entered into force on 22 May 2001), art 3(a), (n).
70 Ibid, arts 6(1), (2).
71 Ibid, art 6(4). See generally, Copyright Law Review Committee, *Copyright and Contract* (2002), 210, 215–216.
72 *Directive 2001/29/EC of the European Parliament and of the Council on the Harmonisation of Certain Aspects of Copyright and Related Rights in the Information Society*, (entered into force on 22 May 2001), art 12.

28.49 As noted above, genetic databases created in Australia could be protected in various ways, including through copyright law, the use of TPMs, and contractual arrangements.[73] A researcher who seeks access to a genetic database for research purposes may need to negotiate a licence with the database owner, despite any fair dealing provisions that apply under the *Copyright Act.* It has been suggested that:

> An unbridled use of technological measures coupled with anti-circumvention legislation and contractual practices would permit rights owners to extend their rights far beyond the bounds of the copyright regime, to the detriment of users and the free flow of information. The copyright bargain reached between granting authors protection for their works and encouraging the free flow of information would be put in serious jeopardy if, irrespective of the copyright rules, rights owners were able to impose their terms and conditions of use through standard form contracts with complete impunity.[74]

28.50 Where a database owner refuses to grant a licence to use its genetic database, or places unreasonable conditions on such use, this could constitute a breach of competition law. For example, a database owner might be in breach of s 46 of the *Trade Practices Act 1974* (Cth) (TPA) if it has a substantial degree of market power in relation to the database (or the information held in it), and takes advantage of that power for the purpose of eliminating or substantially damaging a competitor, preventing entry into that market or a derivative market, or deterring or preventing a person from engaging in competitive conduct in that or any other market.[75] However, as Chapter 24 discusses, there are practical difficulties in establishing a breach of s 46 of the TPA.

28.51 As noted above, many of the genetic databases that are available online to Australian researchers are likely to be subject to the laws applying in overseas jurisdictions, rather than Australian copyright and contract law. However, the ALRC notes that genetic databases have been compiled in Australia, and has considered various options for reform to Australian copyright law to ensure an appropriate balance between the rights of copyright owners and users in relation to them.

Options for reform

Amend the level of protection

28.52 DP 68 noted that one reform option would be to adopt a *sui generis* database right similar to that existing in the European Union.[76] One reason to adopt such a right

---

73 Database owners may also protect their databases through trade secrets law. In addition, one submission noted that biotechnology firms have applied for patents over databases of genetic information: Australian Centre for Intellectual Property in Agriculture, *Submission P12*, 29 September 2003.

74 L Guibault, 'Contracts and Copyright Exemptions' in B Hugenholtz (ed) *Copyright and Electronic Commerce: Legal Aspects of Electronic Copyright Management* (2000), 125, 160, cited in I Kerr, A Maurushat and C Tacit, *Technical Protection Measures: Part II The Legal Protection of TPMs (paper prepared for the Copyright Policy Branch of the Department of Canadian Heritage)* (2002) Nelligan O'Brien Payne, 21.

75 *Trade Practices Act 1974* (Cth) s 46(1). See Ch 24.

76 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [30.74].

would be to ensure that Australia could enter into an agreement with the European Union for the reciprocal protection of non-original databases.

28.53 The Attorney-General's Department submitted that any proposal to adopt *sui generis* protection in Australia would be likely to meet a significant degree of opposition from within the scientific and academic communities.[77] In addition, Associate Professor Mark Davison submitted that the database right 'provides excessive protection and inadequate exceptions and its introduction into Australia is completely unjustifiable'.[78]

28.54 Another option would be to lower the level of copyright protection of databases to facilitate greater access for third party researchers. One way to achieve this would be to adopt the United States' standard of originality for copyright, which requires independent creation and a minimum degree of creativity. Those databases that do not fulfil these minimum requirements would not be protected by copyright.[79]

28.55 Alternatively, Davison suggested that the *Copyright Act* could be amended to specifically exclude copyright protection for genetic sequences and databases expressed in material form. He suggested that this would have the benefit of harmonising Australian and United States copyright law in this area, and would leave open the possibility of adopting legislation similar to that currently proposed in the United States in relation to database protection.[80]

Fair dealing for research or study

28.56 Another option is to clarify the scope of the fair dealing exception from copyright infringement for the purpose of research or study.

28.57 The Federal Court has interpreted the terms 'research' and 'study' in accordance with their ordinary dictionary meanings. 'Research' means diligent and systematic inquiry or investigation into a subject in order to discover facts or principles. 'Study' has several meanings, including the application of the mind to the acquisition of knowledge, and a thorough examination and analysis of a particular subject. The person who claims the benefit of the fair dealing exception must conduct the research or study.[81]

---

77 Attorney-General's Department, *Submission P61*, 11 November 2003.

78 M Davison, *Submission P70*, 7 April 2004.

79 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

80 M Davison, *Submission P70*, 7 April 2004. Danielle Andrewartha suggested amending the *Copyright Act*, or enacting new legislation, to deal specifically with 'scientific works' and/or 'works of inherent expression': D Andrewartha, *Submission P92*, 16 April 2004.

81 *De Garis v Neville Jeffress Pidler Pty Ltd* (1990) 95 ALR 625. See also S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [11.30].

28.58 The CLRC has commented that fair dealing reflects a broad balancing of competing goals in order to maximise the public interest. These goals include rewarding creators, increasing investment by copyright industries, and maintaining access to copyright materials. The CLRC stated that 'a fundamental component of maximising the public interest is allowing the free flow of knowledge, ideas and information'. However, even if copying is carried out for a socially desirable objective, it does not follow that it should be permitted to unreasonably prejudice the copyright owner's economic rights or other legitimate interests.[82]

28.59 As noted above, the fair dealing exception applies to the reproduction of copyright works for the purpose of research or study. Section 40(2) outlines the factors to be considered in determining the fairness of a dealing. However, where the reproduction involves an article in a periodical publication, or the copying of a 'reasonable portion' of a work only, this is deemed to be fair dealing provided it is done for the purpose of research or study.[83]

28.60 The Australian courts are yet to determine whether fair dealing for the purpose of research or study applies only to non-commercial research, or extends also to research of a commercial nature.[84] The CLRC has commented that the distinction between private and commercial activities undertaken for research or study is often unclear and, in its view, 'the public interest would be maximised if fair dealing for the purpose of research or study did not necessarily exclude some commercial activities'.[85]

Other jurisdictions

28.61 United States legislation provides for 'fair use' of copyright works. The provision is not confined to a specified range of purposes, but outlines factors to be considered in determining whether a proposed use is fair in the circumstances. One of these factors is the purpose and character of the use, including whether such use is of a commercial nature or is for non-profit educational purposes.[86]

28.62 Until 2003, the United Kingdom permitted fair dealing in copyright works for the purpose of 'research or private study'. In October 2003, the *Copyright, Designs and Patents Act 1988* (UK) was amended to implement the EU Copyright Directive. As a result, fair dealing for the purpose of research or study has been limited to research for

---

82 Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), 57.

83 *Copyright Act 1968* (Cth) s 40(3).

84 See Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), 37. See also S Ricketson and C Creswell, *The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service* (1999), [11.30].

85 Copyright Law Review Committee, Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners (1998), 83.

86 *Copyright Act 1976* (US), 17 USC s 107.

a non-commercial purpose.[87] The United Kingdom's database right exception for research is similarly limited to non-commercial research.[88]

28.63 In contrast, a recent Canadian Supreme Court decision held that research of a commercial nature may be fair dealing under the *Copyright Act 1985* (Canada).[89] Chief Justice McLachlin, on behalf of the Court, noted that the fair dealing exception for the purpose of research or private study is 'a user's right' and, in order to maintain the proper balance between the rights of a copyright owner and users' interests, must not be interpreted restrictively.[90] His Honour stated that the term 'research':

> must be given a large and liberal interpretation in order to ensure that users' rights are not too unduly constrained. I agree with the Court of Appeal that research is not limited to non-commercial or private contexts … Lawyers carrying on the business of the law for profit are conducting research within the meaning of s 29 of the *Copyright Act*.[91]

Submissions and consultations

28.64 In order to provide greater certainty for researchers seeking to copy genetic information that is protected by copyright, DP 68 proposed that the *Copyright Act* be amended to clarify the extent to which fair dealing for the purpose of research or study applies to research of a commercial nature.[92]

28.65 Many submissions supported the ALRC's proposal.[93] The ALRC also heard general support for the proposal in consultations. However, views were mixed as to whether this matter should be dealt with in the context of this Inquiry, or referred for review by another body.[94] For example, the Queensland Government suggested that the Advisory Council on Intellectual Property should review the matter.[95]

28.66 The Attorney-General's Department submitted that an expansion of the existing fair dealing provisions to cover commercial research could, potentially, minimise some of the concerns arising from the protection of factual databases. However, the

---

87 *Copyright, Designs and Patents Act 1988* (UK) s 29. See also *The Copyright and Related Rights Regulations 2003* (UK) r 9.

88 *Copyright, Designs and Patents Act 1988* (UK) s 29.

89 *Copyright Act 1985* (Canada) s 29.

90 *CCH Canadian Ltd v Law Society of Upper Canada* [2004] SCC 13, [48]. In that case, the Law Society of Upper Canada operated a reference and research library that provided a photocopy service to law society members, the judiciary and other authorised researchers.

91 Ibid, [50]–[51].

92 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Proposal 29–1.

93 See, eg, Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Royal College of Pathologists of Australasia, *Submission P82*, 16 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Garvan Institute of Medical Research, *Consultation*, Sydney, 17 March 2004; Cancer Council Victoria, *Submission P101*, 20 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004; J McKeough, *Consultation*, Sydney, 23 March 2004; D Andrewartha, *Submission P92*, 16 April 2004.

94 See, eg, Intellectual Property Research Institute of Australia, *Consultation*, Melbourne, 1 April 2004.

95 Queensland Government, *Submission P103*, 22 April 2004.

Department suggested that it would be difficult to envisage a broad exclusion for scientific research that would comply with the Berne Convention.[96]

28.67 Article 9(2) of the Berne Convention provides that members may legislate to permit the reproduction of copyright works 'in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author'.[97]

28.68 Professor Sam Ricketson and Chris Creswell have commented that art 9(2) leaves considerable flexibility to national legislators to determine what are 'special cases', and how the criteria of conflict and prejudice are to be established. They suggested that this article could justify a wide range of exceptions to the reproduction right, including those contained in the fair dealing provisions of the *Copyright Act*.[98]

28.69 Several submissions discussed the difficulty of drawing a distinction between commercial and non-commercial research. For example, Davison emphasised the 'dangers and, indeed, the impossibility of focusing on a distinction between non-commercial and commercial' in relation to fair dealing.[99] The Centre for Law and Genetics suggested that any amendment to the fair dealing provisions should be comprehensive, rather than a 'sui generis amendment only in respect of commercial genetic research'. In any case, the Centre considered that copyright law is likely to have only a minor role in commercial genetic research.[100]

28.70 Two submissions supported adopting the United States' concepts of 'transformative' and 'productive' use into Australian copyright law.[101] Section 107 of the *Copyright Act 1976* (US) provides that, in determining whether a use is 'fair' the factors to be considered include the purpose and character of the use. The concept of 'transformative use' refers to the distinction between productive and reproductive uses of a work. A 'productive use' makes some contribution of new intellectual value and, therefore, promotes the advancement of the arts and sciences.[102]

Fair dealing in practice

28.71 DP 68 noted the practical problems that can arise for researchers in seeking to rely on the fair dealing exception from copyright infringement for the purpose of research or study.[103] Database owners can protect against unauthorised use of their

---

96 Attorney-General's Department, *Submission P61*, 11 November 2003.

97 *Berne Convention for the Protection of Literary and Artistic Works* (1886). This test has been incorporated, in a slightly amended form, into art 13 of the TRIPS Agreement.

98 S Ricketson and C Creswell, The Law of Intellectual Property: Copyright, Designs and Confidential Information: Looseleaf Service (1999), [16.100].

99 M Davison, *Submission P70*, 7 April 2004.

100 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

101 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; D Andrewartha, *Submission P92*, 16 April 2004.

102 See Copyright Law Review Committee, *Simplification of the Copyright Act 1968 Part 1: Exceptions to the Exclusive Rights of Copyright Owners* (1998), 43–44.

103 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [30.55]-[30.57].

databases through TPMs that prevent access to, or copying of, the database contents. Once a database is protected by a TPM, the database owner could make access or copying subject to contractual arrangements, involving payment of a licence fee.

28.72 As noted above, the *Copyright Act* does not currently prohibit the use of a circumvention device or service. Accordingly, a researcher could use a circumvention device to avoid the effect of a TPM in order to access a database for fair dealing purposes. However, as dealings in such devices and services are prohibited—subject to exceptions that do not include fair dealing—it would be difficult for a researcher to obtain a circumvention device in Australia for such use.

Previous reviews

28.73 The IPCRC stated that it was broadly satisfied that the regulatory approach to TPMs preserves a reasonable balance between competing interests. However, it stated that it would be concerned if the use of TPMs—perhaps accompanied by greater reliance on contract—were to displace, or in any way limit, the effectiveness of the fair dealing provisions.[104]

28.74 The CLRC considered the extent to which contract has been used to exclude or modify the copyright exceptions in its report, *Copyright and Contract.* The CLRC found that contracts have been used for this purpose in Australia and overseas. It considered that, while in many instances it may be reasonable to charge a consumer to access material online, attempts to restrict the reproduction of copyright material for lawful purposes would be problematic.[105] The CLRC recommended that the *Copyright Act* be amended to provide that an agreement (or a provision of an agreement) that excludes or modifies the operation of certain statutory provisions—including the fair dealing exceptions—has no effect.[106] The Australian Government has not yet taken a decision to implement this recommendation.

28.75 Phillips Fox made several reform recommendations in its report, *Digital Agenda Review Report and Recommendations*. In order to preserve the balance between copyright owners and users, Phillips Fox suggested that the legislative definition of a TPM be limited to measures that protect or control only rights that fall within copyright, and that:

- section 116A(1) of the *Copyright Act* be amended to prohibit the use of a circumvention device or service to circumvent a TPM, other than for a permitted purpose;

---

104 Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 101.

105 Copyright Law Review Committee, *Copyright and Contract* (2002), [7.03], [7.30]. For example, the CLRC considered that it may be reasonable to expect to pay a fee for subscribing to newspaper online, in the same way that one would expect to pay for a print subscription.

106 Ibid, [7.49].

- the permitted purposes in s 116A(3) be amended to permit the supply or use of a circumvention device or service for any use or exception permitted under the Act, including fair dealing; and

- the integrity of the permitted purposes in s 116A(3) be retained by preventing a copyright owner from making it a condition of access to, or use of, a copyright work or other subject matter that a user will not use a circumvention device or service for the purpose of making a fair dealing.[107]

International instruments

28.76 In 1996, the World Intellectual Property Organization (WIPO) adopted two new treaties. The *WIPO Copyright Treaty* and *WIPO Performances and Phonograms Treaty* (WIPO Internet Treaties) establish new international legal standards to address issues arising in the digital environment. Australia has agreed to ratify or accede to these treaties by the date the AUSFTA enters into force.[108]

28.77 The WIPO Internet Treaties require member States to provide adequate legal protection and effective legal remedies against the circumvention of TPMs that are used by copyright authors to restrict acts, in respect of their copyright works, which are not authorised by the authors or 'permitted by law'.[109]

Australia–United States Free Trade Agreement

28.78 Under the AUSFTA, Australia has agreed to prohibit the circumvention, without authority, of effective TPMs that control access to a copyright work; and commercial dealings in circumvention devices and services.[110] The AUSFTA provides an exhaustive list of permitted exceptions to these prohibitions, which does not include fair dealing.[111] Once implemented, this would bring Australian copyright law into conformity with United States law.[112]

---

107 Phillips Fox, *Digital Agenda Review Report and Recommendations* (2004), rec 17, 19.

108 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.1.4.

109 See *WIPO Copyright Treaty*, 20 December 1996, WIPO/CRNR/DC/94, art 11; *WIPO Performances and Phonograms Treaty*, 23 December 1996, WIPO/CRNR/DC/95, art 18.

110 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.4.7(a). Australia has also agreed to prohibit the making or selling etc of such devices or services.

111 Ibid, art 17.4.7(e), (f).

112 See *Digital Millennium Copyright Act 1998* (US) s 1201. The AUSFTA provides that Australia must implement its obligations under art 17.4.7 within two years of the date the AUSFTA enters into force. In the interim, Australia may not adopt a new measure that is less consistent with this article or apply any new or existing measure to reduce the level of protection provided on the date the AUSFTA enters into force: Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.12.

28.79 Australia may provide an exception to the prohibition on circumvention of access control measures for non-infringing uses of a work—in a particular class of works—if an actual or likely adverse impact on those uses is credibly demonstrated in a legislative or administrative review or proceeding. These 'reviews or proceedings' must be conducted at least every four years.[113]

Submissions and consultations

28.80 DP 68 asked whether the Commonwealth should amend the *Copyright Act* to provide that, in relation to genetic databases protected by copyright, the operation of the provisions for fair dealing for the purpose of research or study must not be excluded or modified by contract or TPMs.[114]

28.81 A number of submissions supported this approach.[115] Several submissions suggested that this would be consistent with the approach taken in relation to the research use exemption from patent infringement.[116] The Department of Industry, Tourism and Resources expressed support 'subject to the availability of empirical evidence that a problem exists'.[117]

28.82 The Caroline Chisholm Centre for Health Ethics commented that this is a difficult area in which to achieve a balance of interests, and accordingly needs careful monitoring in the future. The Centre noted that, given the importance of genetic databases in healthcare and medical research, excluding researchers from these research tools through restrictive licensing 'would appear contrary to progress in this field and certainly not in the public interest'. However, it also recognised that 'compiling genetic databases is time consuming, and recompense for the effort is warranted'.[118]

28.83 The Queensland Government considered that further investigation was necessary to determine the possible impact of the AUSFTA on the ALRC's proposed approach and possible administrative problems that may arise from it. It suggested that encouraging education or research licensing arrangements in which the owner provides a 'key' to unlock access to the database would be more effective, and would allow Australia to become more aligned with overseas jurisdictions. It noted that its own consultations had raised the suggestion that a Commonwealth body should operate a scheme in which copyright users would be required to notify the body before

---

113 Australia and United States, *Australia–United States Free Trade Agreement*, 18 May 2004, art 17.4.7(e)(viii).

114 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 30–1.

115 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004.

116 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

117 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

118 Caroline Chisholm Centre for Health Ethics Inc, *Submission P69*, 2 April 2004.

exercising fair dealing in relation to such databases.[119] The Centre for Law and Genetics suggested that 'it would be inappropriate to make specific recommendations dealing only with genetic databases'.[120]

ALRC's views

28.84 The ALRC has not identified any significant problems currently being experienced by Australian researchers in accessing or using genetic information that is protected by copyright. However, it is possible that copyright law could in future impact on the conduct of genetic research. The ALRC considers that the law should strike an appropriate balance between protecting the investment involved in developing such databases, and facilitating reasonable access to their contents for research purposes.

28.85 One option would be to amend the level of copyright protection of genetic databases. The ALRC has concluded that the level of protection of databases under Australian copyright law is already high, and does not consider it necessary to recommend the introduction of a *sui generis* database right. Submissions generally indicated that copyright law adequately protects genetic databases.[121] The ALRC considers that there is insufficient evidence of a need to change the level of protection.

28.86 The ALRC considers that it would be more appropriate to clarify the scope of the fair dealing exception from copyright infringement for the purpose of research or study. This exception reflects the public interest in promoting an appropriate balance between the interests of copyright owners and users. It permits individuals to reproduce portions of copyright works without payment, provided they do so for the purpose of research or study, and the dealing is fair in the circumstances. This approach is also in keeping with the ALRC's approach to reform elsewhere in this Report. The ALRC considers it is more appropriate to recommend systematic reforms to the application of intellectual property rights generally—including in relation to genetic materials and technologies—than to take a technology-specific approach.

28.87 In the ALRC's view, it is inappropriate to exclude research from the scope of the fair dealing exception merely because of its commercial purpose or objective. As discussed in Chapter 11, various policies promote the commercialisation of publicly funded research in Australia. While a research project might involve some form of commercialisation at some point, this does not undermine the potential public benefit to be gained from the research results. The ALRC also agrees with the approach of the Canadian Supreme Court that, as fair dealing is a 'user's right', in order to maintain the proper balance between the rights of a copyright owner and users' interests, it should not be interpreted restrictively.

---

119 Queensland Government, *Submission P103*, 22 April 2004.
120 Centre for Law and Genetics, *Submission P104*, 22 April 2004.
121 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), [30.58].

28.88 The ALRC heard some concern that this approach might not comply with art 9(2) of the Berne Convention relating to exceptions and limitations on copyright. As noted above, this provides that member States may legislate to permit the reproduction of copyright works 'in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author'.[122]

28.89 The *Copyright Act's* existing fair dealing provisions appear to fall within the scope of art 9(2) of the Berne Convention. The ALRC considers it unlikely that characterising research as commercial would, of itself, conflict with art 9(2). In practice, if a researcher sought to reproduce more than a reasonable portion of a work for fair dealing purposes, the application of the legislative guidelines in s 40(2) would adequately address the balance of interests involved.

28.90 The ALRC recommends that the Commonwealth should amend the *Copyright Act* to provide that research with a commercial purpose or objective is 'research' in the context of fair dealing for the purpose of research or study (Recommendation 28–1).

28.91 By itself, clarification of the scope of fair dealing would have little practical effect where a database owner uses a TPM and contractual arrangements to 'lock up' the database contents. While fair dealing protects the right to reproduce the copyright material, it does not extend to rights to access that material for such use. In practice, a researcher could be forced to enter into a licence agreement, or use a circumvention device or service, to access the work.

28.92 The CLRC recommended that the *Copyright Act* be amended to provide that an agreement or provision that excludes or modifies the operation of statutory provisions, including fair dealing for the purpose of research or study, has no effect. Phillips Fox made a similar recommendation. The submissions generally supported this approach. Accordingly, the ALRC recommends that the Commonwealth should amend the *Copyright Act* to provide that, in relation to databases protected by copyright, the operation of the provisions relating to fair dealing for the purpose of research or study cannot be excluded or modified by contract (Recommendation 28–2). Once implemented, this would ensure that any licence provision that purports to override fair dealing in a copyright work is unenforceable.

28.93 This reform would not affect a database owner's ability to 'lock up' its database through a TPM. The *Copyright Act* currently does not prohibit the use of circumvention devices or services by researchers or any other person. However, as commercial dealings in these devices or services are prohibited, this will limit their availability to Australian researchers.

---

122 *Berne Convention for the Protection of Literary and Artistic Works* (1886).

28.94 In practice, however, this matter has been somewhat overtaken by the AUSFTA. Australia has agreed to prohibit the circumvention of TPMs that control access to a copyright work, subject to an exhaustive list of exceptions that does not include fair dealing. Australia has also agreed to strict limits on the exceptions that it may grant to the existing prohibition on commercial dealings in circumvention devices and services. Australia may, however, provide an exception to the prohibition on circumvention of access control measures for non-infringing uses of a work if an actual or likely adverse impact on those uses is credibly demonstrated in a review.

28.95 The ALRC understands that the Attorney-General's Department intends to undertake consultations prior to implementing the legislative amendments necessary for Australia to comply with these obligations. This process would include consideration of the need for any exceptions to the prohibition on the circumvention of access control measures.

28.96 Accordingly, the ALRC recommends that, prior to the implementation of art 17.4.7 of the AUSFTA, the Australian Government should assess the need for an exception for researchers engaging in fair dealing for the purpose of research or study in relation to databases protected by copyright. Once the prohibition has been implemented, the Australian Government should periodically review the impact of the anti-circumvention provisions on the practical exercise of fair dealing for the purpose of research or study in copyright works (Recommendation 28–3).

Recommendation 28–1 The Commonwealth should amend the *Copyright Act 1968* (Cth) (*Copyright Act*) to provide that research with a commercial purpose or objective is 'research' in the context of fair dealing for the purpose of research or study.

Recommendation 28–2 The Commonwealth should amend the *Copyright Act* to provide that, in relation to databases protected by copyright, the operation of the provisions relating to fair dealing for the purpose of research or study cannot be excluded or modified by contract.

Recommendation 28–3 Prior to the implementation of art 17.4.7 of the Australia–United States Free Trade Agreement—which includes a prohibition on the circumvention of access control measures—the Australian Government should assess the need for an exception for researchers engaging in fair dealing for the purpose of research or study in relation to databases protected by copyright. Once the prohibition has been implemented, the Australian Government should periodically review the impact of the anti-circumvention provisions on the practical exercise of fair dealing for the purpose of research or study in copyright works.

Other options

A statutory licensing regime

28.97 DP 68 discussed the possibility of introducing a statutory licensing regime for databases of genetic information. Such a regime could give researchers the right to access and use genetic databases for the purpose of research, in exchange for a reasonable royalty. An important difference between statutory licensing and fair dealing is that a statutory licence requires the payment of remuneration for use of the copyright material.

28.98 The *Copyright Act* contains several statutory licensing schemes that permit third party use of copyright works without prior negotiation or permission, in exchange for a reasonable royalty. These schemes include copying and communication of works and other material by educational institutions or institutions assisting readers with a print disability or persons with an intellectual disability, and the Crown use of copyright material.[123]

28.99 Justice Sackville raised the possibility of establishing a statutory licensing regime for databases of factual compilations in *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd.* His Honour commented that:

> There may be powerful reasons … for requiring the owner of copyright in the compilation to submit to a compulsory licensing regime. Such schemes are established by statute in other areas … A compulsory licensing regime might appropriately reward the monopolist's labour and expense, yet leave room for innovative competitors who cannot gain access to the basic information required to establish databases of potential commercial value.[124]

28.100 Several commentators have suggested the desirability of establishing a statutory licensing scheme to facilitate access to factual compilations protected by copyright.[125] The ALRC also notes that the HUGO Ethics Committee has recommended that provision be made for compulsory licensing of genetic databases in certain circumstances under the EU Database Directive.[126]

28.101 The Attorney-General's Department submitted that a statutory licensing regime could potentially be used to provide access to information stored in databases. However, the Department suggested that more analysis would be necessary to

---

123 See generally *Copyright Act 1968* (Cth) ss 47(3), 70(3), 107(3); ss 54–64; ss 108–109; Pt VA; Pt VB; Pt VC; ss 182B-183E. See J McKeough, A Stewart and P Griffith, *Intellectual Property in Australia* (3rd ed, 2004), 206.

124 *Desktop Marketing Systems Pty Ltd v Telstra Corporation Ltd* (2002) 192 ALR 433, 538.

125 See, eg, S Givoni, 'Pushing the Boundaries of Copyright: Protection of Databases' (2003) 15 *Intellectual Property Law Bulletin* 8, 17; G Stals, 'Copyright and Competition Policy in the Post-Hilmer Environment' (1997) 2 *Media and Arts Law Review* 77, 88.

126 H Pearson, 'Human Genome Organisation Meeting, Cancun, Mexico, April 2003: Database Free for All', *Nature Science Update*, 30 April 2003, <www.nature.com/nsu/030428/030428-10.html>.

determine whether any benefits would be offset by the administrative burden on the parties involved.[127]

28.102 DP 68 asked whether the Commonwealth should amend the *Copyright Act* to establish a statutory licensing scheme in relation to genetic databases protected by copyright.[128] The Department of Industry, Tourism and Resources supported this approach, provided that it is consistent with Australia's obligations under international agreements.[129]

28.103 By contrast, most other submissions did not consider that a statutory licensing scheme was necessary at this stage.[130] The Department of Health and Ageing suggested that, if other measures directed at facilitating reasonable access to genetic databases do not prove feasible, such a scheme should be considered.[131] The Australian Centre for Intellectual Property in Agriculture (ACIPA) considered that there would be competition concerns involved in the collective licensing of genetic databases.[132]

Database subscriptions

28.104 Another option is to facilitate access to genetic databases through subscriptions that subsidise or otherwise minimise licence fees for individual researchers and research institutions. This option is of particular relevance in relation to those databases that have been compiled in overseas jurisdictions, and therefore fall largely outside the scope of Australian copyright and contract law.

28.105 In June 2000, the National Health and Medical Research Council (NHMRC) negotiated a three-year agreement between the Australian Government and Celera Genomics. The agreement provided publicly funded researchers in Australia with subsidised access to five of Celera's databases. Each participating institution paid an annual licence fee based on the number of teams seeking database access and which databases they accessed.[133] On 1 July 2003, a new three-year academic subscription agreement commenced operation. Under the new agreement, the Applera Corporation administers all subscriptions directly with individual users and institutions.[134] The NHMRC is no longer involved in the administration of the subscription. Fees under the

---

127 Attorney-General's Department, *Submission P61*, 11 November 2003.

128 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 30–2.

129 Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.

130 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004; Centre for Law and Genetics, *Submission P104*, 22 April 2004.

131 Commonwealth Department of Health and Ageing, *Submission P79*, 16 April 2004.

132 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.

133 See generally D Nicol and J Nielsen, 'The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development' (2001) 23 *Sydney Law Review* 347, 351.

134 National Health and Medical Research Council, *About Celera and NHMRC Celera Subscription*, <www.nhmrc.gov.au/research/special/celdesc.htm> at 10 December 2003. The Celera Genomics group and Applied Biosystems group are both part of the Applera Corporation: see <www.applera.com> at 13 February 2004.

new agreement have increased to US$2,000 per person per database, and all users requiring access must register individually.[135]

28.106 IP 27 asked whether the NHMRC's Celera subscription provides an appropriate model for seeking to increase Australian researchers' access to information about the human genome.[136] While few submissions addressed this issue, there was general satisfaction with the NHMRC's subscription in consultation meetings.

28.107 DP 68 asked whether the new Celera subscription agreement had caused any significant concerns for public research institutions or researchers engaging in publicly funded research.[137] DP 68 also asked whether the NHMRC, or another Commonwealth body, should have responsibility for monitoring the operation of agreements between genetic database owners and publicly funded research institutions within Australia.[138]

28.108 Many submissions suggested that the new Celera agreement has not raised any concerns to date.[139] ACIPA commented that the Celera subscription 'is an adequate model for seeking to increase Australian researchers' access to information about the human genome'. In ACIPA's view, the NHMRC should be responsible for monitoring the operation of agreements between genetic database owners and publicly funded research institutions within Australia. ACIPA also considered that Australian guidelines are necessary to ensure that research is not being withheld from the public domain.[140]

28.109 It was suggested in consultations that independent monitoring of the operation of genetic database subscriptions would be of value, in particular in relation to the needs of researchers and research institutions.[141] The NHMRC submitted that a body such as the Human Genetics Commission of Australia (HGCA) should be given responsibility for monitoring and reviewing patent practices generally in relation to genetic materials. It suggested that, as part of this role, the HGCA could monitor the impact—both positive and negative—of any agreements between genetic database owners and publicly funded research institutions.[142]

---

135 Ibid.
136 Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003), Question 11–6.
137 Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004), Question 30–3.
138 Ibid, Question 30–4.
139 See, eg, Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Centre for Law and Genetics, *Submission P110*, 28 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004.
140 Australian Centre for Intellectual Property in Agriculture, *Submission P81*, 16 April 2004.
141 See, eg, National Health and Medical Research Council, *Consultation*, Canberra, 26 March 2004.
142 National Health and Medical Research Council, *Submission P107*, 19 April 2004.

28.110 By contrast, several submissions stated that there was no need for such monitoring.[143] The Queensland Government submitted that monitoring might be of benefit in the future, depending on the practices of the genetic database owners in providing access to their databases.[144]

28.111 Finally, the Centre for Law and Genetics noted that the NHMRC intends to review the *National Statement for Research For Ethical Conduct in Research Involving Humans* with a view to including a new set of principles governing human genetic databases.[145] The Centre suggested that it would be appropriate that:

> the new guidelines include a requirement for those responsible for the genetic database to complete reports on databases as part of the annual compliance system for human research ethics committees. In addition, it may be desirable for the proposed HGCA to monitor the operation of genetic databases and their relation with public funded institutions.[146]

ALRC's views

28.112 The ALRC does not intend to recommend a statutory licensing scheme for genetic databases, or any reforms in relation to database subscriptions. While several submissions indicated general support for these options, they were generally not considered necessary at this time.

28.113 If the need arises in the future, the ALRC suggests that the Australian Government give consideration to implementing a statutory licensing scheme in relation to databases protected by copyright. This approach would have the benefit of facilitating reasonable access to such databases for research purposes in return for reasonable remuneration.

28.114 The ALRC agrees with suggestions that the HGCA should monitor the application of copyright law to genetic databases used in medical research or human health. Recommendation 19–4 anticipates this role.

---

143 Walter and Eliza Hall Institute of Medical Research, *Submission P71*, 13 April 2004; Queensland Government, *Submission P103*, 22 April 2004; Department of Industry Tourism and Resources, *Submission P97*, 19 April 2004; Queensland Law Society, *Submission P118*, 7 May 2004.

144 Queensland Government, *Submission P103*, 22 April 2004.

145 See Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia*, ALRC 96 (2003), rec 18–1.

146 Centre for Law and Genetics, *Submission P104*, 22 April 2004.

Appendix 1. List of Submissions

Name	*Submission Number*	*Date*
Dr John Abbot	P83	16 April 2004
Aboriginal and Torres Strait Islander Services	P55	4 November 2003
Ms Danielle Andrewartha	P92	16 April 2004
Attorney-General for South Australia	P115	3 May 2004
Attorney General's Department	P61	11 November 2003
AusBiotech Ltd	P94	16 April 2004
	P58	7 November 2003
Australian Association of Pathology Practices Inc	P10	24 September 2003
Australian Centre for Intellectual Property in Agriculture	P81	16 April 2004
	P12	29 September 2003
Australian Competition and Consumer Commission	P64	12 December 2003
	P114	3 May 2004
Australian Health Ministers' Advisory Council	P49	23 October 2003
Australian Huntington's Disease Association (NSW) Inc	P27	1 October 2003
Australian Research Council	P108	19 April 2004
Associate Professor Agnes Bankier	P19	30 September 03
Associate Professor Ross Barnard	P32	7 October 2003
Dr Michela Betta	P20	30 September 2003
Bio21 Australia Ltd	P80	16 April 2004
Breast Cancer Action Group NSW Inc	P8	19 September 2003
Breast Cancer Network Australia	P22	30 September 2003
Ms Sonja Brown	P78	16 April 2004
Cancer Council Australia	P25	30 September 2003
	P96	19 April 2004
Cancer Council New South Wales	P1	5 June 2003
	P99	20 April 2004
Cancer Council South Australia	P41	9 October 2003
Cancer Council Tasmania	P40	29 September 2003

Name	*Submission Number*	*Date*
Cancer Council Victoria	P16	30 September 2003
	P101	20 April 2004
Cancer Foundation of Western Australia Inc	P34	10 October 2003
Cancer Voices NSW Inc	P7	16 September 2003
Caroline Chisholm Centre for Health Ethics Inc	P38	17 October 2003
	P69	2 April 2004
Centre for Law and Genetics	P104	22 April 2004
	P110	28 April 2004
	P117	5 May 2004
Children's Cancer Institute Australia for Medical Research	P13	30 September 2004
Mr Justin Cole and Mr Somerset Barnard	P63	12 November 2003
Commonwealth Department of Health and Ageing	P65	28 January 2004
	P79	16 April 2004
Confidential Submission	P17	30 September 2003
Confidential Submission	P54	31 October 2003
Confidential Submission	P77	16 April 2004
Davies Collison Cave	P48	24 October 2003
Associate Professor Mark Davison	P70	7 April 2004
Department of Foreign Affairs and Trade	P29	2 October 2003
	P93	16 April 2004
Department of Health Western Australia	P53	31 October 2003
	P89	16 April 2004
Department of Human Services Victoria	P111	3 May 2004
Department of Industry, Tourism and Resources	P36	13 October 2003
	P97	19 April 2004
Mr Gerard De Ruyter	P3	14 August 2003
Sister Regis Mary Dunne RSM	P105	13 April 2004
Mrs Rae Edson	P9	23 September 2003
Mr Dimitrios Eliades	P24	30 September 2003
Mr Lloyd England	P95	16 April 2004
F B Rice & Co	P84	16 April 2004
Mr B Fenlon	P68	10 March 2004
Genetic Support Council WA (Inc)	P59	7 November 2003
	P119	13 May 2004

Name	*Submission Number*	*Date*
Genetic Technologies Limited	P45	20 October 2003
GlaxoSmithKline	P33	10 October 2003
	P85	16 April 2004
Dr John Graham	P5	26 August 2003
Mr John Hinojosa	P87	16 April 2004
Dr Barbara Hocking	P113	3 May 2004
Mr Anton Hughes	P42	20 October 2003
Human Genetics Society of Australasia	P31	3 October 2003
	P76	16 April 2004
Institute of Patent and Trade Mark Attorneys of Australia	P106	27 April 2004
Intellectual Property Research Institute of Australia	P88	16 April 2004
IP Australia	P56	31 October 2003
	P86	16 April 2004
Professor David Isaacs	P6	12 September 2003
Mr David Jackson	P43	20 October 2003
Mr Adam Johnston	P15	30 September 2003
	P72	14 April 2004
Mr Stephen Karpeles	P44	20 October 2003
Dr Charles Lawson	P67	4 March 2004
Professor John Mattick	P35	13 October 2003
Mr David McAndrew	P14	30 September 2003
Dr Amanda McBratney and others	P47	22 October 2003
Dr Duncan McFetridge MP	P23	30 September 2003
Medicines Australia	P21	30 September 2003
	P75	15 April 2004
Dr Elizabeth Milward and others	P46	20 October 2003
Ministry for Science and Medical Research	P109	28 April 2004
Professor Alec Morley	P18	30 September 2003
National Health and Medical Research Council	P52	31 October 2003
	P107	19 April 2004
Network of Concerned Farmers	P66	28 January 2004
Dr Warwick Neville	P50	29 October 2003

Name	*Submission Number*	*Date*
New South Wales Health Department	P37	17 October 2003
	P112	3 May 2004
Nuffield Council of Bioethics	P102	22 April 04
Ms Carol O'Donnel	P2	13 August 2003
Mr Luigi Palombi	P28	1 October 2003
Mr Malcolm Pryor	P60	6 November 2003
Queensland Government	P57	5 November 2003
	P103	22 April 2004
Queensland Law Society	P118	7 May 2004
Research Unit of Jumbunna Indigenous House of Learning	P100	20 April 2004
Dr Matthew Rimmer	P73	15 April 2004
Royal College of Pathologists of Australasia	P26	1 October 2003
	P82	16 April 2004
South Australian Department of Human Services	P74	15 April 2004
South Australian Government	P51	29 October 2003
Dr Graeme Suthers	P30	2 October 2003
	P116	4 May 2004
Sydney IVF Limited	P98	19 April 2004
Dr Ian Turnbull	P11	25 September 2003
	P91	16 April 2004
Walter and Eliza Hall Institute of Medical Research	P39	17 October 2003
	P71	13 April 2004
Western Australian Department of Industry and Resources	P90	16 April 2004
Del Weston	P62	12 November 2003
Wondu Business & Technology Services Pty Ltd	P4	20 August 2003

Appendix 2. Abbreviations

AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
ACIP	Advisory Council on Intellectual Property, (formerly Advisory Council on Industrial Property)
ACIPA	Australian Centre for Intellectual Property in Agriculture
AHEC	Australian Health Ethics Committee
AHMAC	Australian Health Ministers' Advisory Council
AIC	Australian Institute for Commercialisation Ltd
AIG	Australian Industry Group
ALRC	Australian Law Reform Commission
ALRC 89	Australian Law Reform Commission, *Managing Justice: A Review of the Federal Civil Justice System* (2000)
ALRC 92	Australian Law Reform Commission, *The Judicial Power of the Commonwealth: A Review of the Judiciary Act 1903 and Related Legislation* (2001)
ALRC 96	Australian Law Reform Commission and Australian Health Ethics Committee, *Essentially Yours: The Protection of Human Genetic Information in Australia* (2003)
ANGIS	Australian National Genomic Information Service
APAs	Australian Postgraduate Awards
APPS	AU Published Patent Data Searching
ARC	Australian Research Council
ART	Assisted reproductive technology
ATSIS	Aboriginal and Torres Strait Islander Services
AUSFTA	Australia–United States Free Trade Agreement
AUTM	Association of University Technology Managers (US)
cDNA	Complementary DNA
CBAC	Canadian Biotechnology Advisory Committee
CLRC	Copyright Law Review Committee
CIPO	Canadian Intellectual Property Office
CPC	*Community Patent Convention*
CRCs	Cooperative Research Centres
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DCMA	*Digital Millennium Copyright Act 1998* (US)
DEST	Department of Education, Science and Training
DITR	Department of Industry, Tourism and Resources
DFAT	Department of Foreign Affairs and Trade
DHA	Department of Health and Ageing

DNA	Deoxyribonucleic acid
DOJ	Department of Justice (US)
DP 68	Australian Law Reform Commission, *Gene Patenting and Human Health*, DP 68 (2004)
ECJ	European Court of Justice
EINSHAC	Einstein Institute of Science Health and the Courts
EPC	*European Patent Convention*
EPO	European Patent Office
EST	Expressed sequence tag
EU	European Union
FDA	Food and Drug Administration (US)
FMS	Federal Magistrates Service
FTC	Federal Trade Commission (US)
GTG	Genetic Technologies Limited
HGDP	Human Genome Diversity Project
HGCA	Human Genetics Commission of Australia
HGSA	Human Genetics Society of Australasia
HREC	Human research ethics committee
HUGO	Human Genome Organisation
IP	Intellectual property
IP 27	Australian Law Reform Commission, *Gene Patenting and Human Health*, IP 27 (2003)
IPAC	Industrial Property Advisory Committee
IPC	International Patent Classification
IPCRC	Intellectual Property and Competition Review Committee
IPRs	Intellectual property rights
IPRIA	Intellectual Property Research Institute of Australia
IPTA	Institute of Patent and Trademark Attorneys of Australia
JPO	Japanese Patent Office
KCA	Knowledge Commercialisation Australasia
LES	Licensing Executives Society
MBS	Medicare Benefits Scheme
MRI	Magnetic resonance imaging
MSAC	Medical Services Advisory Committee
MTA	Materials transfer agreement
NCC	National Competition Council
NHGRI	National Human Genome Research Institute (US)
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health (US)
NSCC	National Stem Cell Centre
OECD	Organisation for Economic Co-operation and Development
PatAdmin	Patent Administration System
PatIndex	Patent Indexing System
Patsearch	New Patent Solution system
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme

PCA	*Productivity Commission Act 1998* (Cth)
PCR	Polymerase chain reaction
PCT	*Patent Cooperation Treaty*
PMSEIC	Prime Minister's Science Engineering and Innovation Council
R&D	Research and development
RCPA	Royal College of Pathologists of Australasia
RIRDC	Rural Industries Research and Development Corporation
RNAi	Ribonucleic acid interference
SMEs	Small and medium-sized enterprises
SNP	Single nucleotide polymorphism
TGA	Therapeutic Goods Administration
TPA	*Trade Practices Act 1974* (Cth)
TPM	Technological protection measure
TRIPS Agreement	*Agreement on Trade-Related Aspects of Intellectual Property Rights 1994*
TSC	The SNP Consortium
UNESCO	United Nations Educational Scientific and Cultural Organization
USPTO	United States Patent and Trademark Office
WARF	Wisconsin Alumni Research Foundation
WEHI	Walter and Eliza Hall Institute of Medical Research
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Table of Selected Legislation

Only legislation discussed in some detail is listed. Other legislation can be located using the full text search facility available on the internet and CD versions of this Report. References are to paragraphs in this Report.

Australia

Canada

European Union

Japan

New Zealand

United Kingdom

United States

Table of Selected International Instruments

Only international instruments discussed in some detail are listed. Other international instruments can be located using the full text search facility available on the internet and CD versions of this Report. References are to paragraphs in this Report.

Table of Selected Cases

Only cases discussed in some detail are listed. Other cases can be located using the full text search facility available on the internet and CD versions of this Report. References are to paragraphs in this Report.