The Senate

Community Affairs References Committee

Gene Patents

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Participating Members for this inquiry

Senator the Hon. Bill Heffernan	LP, New South Wales
Senator Gary Humphries	LP, Australian Capital Territory

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Senator Gary Humphries	LP, Australian Capital Territory

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TABLE OF CONTENTS

ABBREVIATIONS

ACCC	Australian Competition and Consumer Commission
ACIP	Advisory Council on Intellectual Property
the Act	*Patents Act 1990* (Cth)
AHMAC	Australian Health Ministers' Advisory Council
the ALRC report	The report by the Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health* (June 2004)
ASX	Australian Securities Exchange
AUSFTA	Australia-United States Free Trade Agreement
BCNA	Breast Cancer Network Australia
BRCA genes	The BRCA1 and BRCA2 genes, which are associated with a predisposition to developing breast and ovarian cancer
CCA	Cancer Council Australia
the Commissioner	Commissioner of Patents
CVNSW	Cancer Voices NSW
the Department	Department of Health and Ageing
DIISR	Department of Innovation, Industry, Science and Research
the Ergas Report	*Review of intellectual property legislation under the Competition Principles Agreement*
HCV	hepatitis C virus
HGSA	Human Genetics Society of Australasia
ICGC	International Cancer Genome Consortium
IP	intellectual property
IPAC	Intellectual Property Advisory Committee
IPC	International Patent Classification
IPCRC	Intellectual Property and Competition Review Committee

IPRIA	Intellectual Property Research Institute of Australia
IPTMAA	Institute of Patent and Trade Mark Attorneys of Australia
JJFC	Johnson & Johnson Family of Companies
LCA	Law Council of Australia
the MPO case	*Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others*
Myriad	Myriad Genetics Ltd
NHMRC	National Health and Medical Research Council
the NRDC case	*National Research Development Corporation v The Commissioner of Patents* (1959) 102 CLR 252
PBS	Pharmaceutical Benefits Scheme
PMCC	Peter MacCallum Cancer Centre
RCPA	Royal College of Pathologists of Australasia
SACGHS	United States Secretary's Advisory Committee on Genetics, Health, and Society
TPA	*Trade Practices Act 1974* (Cth)
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
USPTO	United States Patent and Trademark Office
WEHI	Walter and Eliza Hall Institute of Medical Research
WTO	World Trade Organization

EXECUTIVE SUMMARY

Chapter 1

The terms of reference for the inquiry directed the Committee to consider the impacts of gene patents on healthcare, medical research and the health and wellbeing of Australians. The length of the inquiry was indicative of the complexity of many of the legal and scientific issues underpinning the inquiry's terms of reference, and the equally complex way in which these interact with the development and delivery of healthcare services and the conduct of medical research in Australia. The Committee regards the subject matter of the inquiry as being of fundamental importance to the quality and accessibility of Australia's health system.

Chapter 2

The background to the inquiry, discussed in Chapter 2 of the report, was concerns arising from the attempts by Genetic Technologies in 2002-03 and 2008 to enforce its patent rights over the BRCA1 and BRCA2 genes in Australia. Testing for these genes can indicate a predisposition to developing breast and ovarian cancer. Although Genetic Technologies did not ultimately enforce its patent rights, had it been successful in doing so it would have been able to become the sole tester for the BRCA genes in Australia, or to charge a licence fee to third parties for conducting the test. The potential for such a critical test to be subject to commercial exploitation on these terms led to widespread community concern, and resulted in the inquiry into gene patents being referred to the Committee.

Chapter 3

Chapter 3 of the report discusses the impact of gene patents on the provision of healthcare, training for medical specialists, medical research and the health and wellbeing of the Australian people. While the Committee heard of a number of cases where the provision of healthcare or the conduct of medical research in Australia has been impeded, the evidence did not show that gene patents are systematically leading to adverse impacts in these areas. The Committee's ability to make definitive conclusions in relation to these arguments was ultimately frustrated by the lack of comprehensive, systematic and accessible data in relation to gene patents. Accordingly, the Committee has made recommendations (Recommendations 1 and 2) which seek to improve the quality of available data and information regarding the impacts and use of patents (and gene patents in particular) in Australia. These measures would involve the Australian Health Ministers' Advisory Council (AHMAC) establishing processes for the economic evaluation of medical genetic testing and other new genetic medical technologies, and for examination of the financial impact of gene patents on the delivery of healthcare services in Australia. The Committee has also called for the establishment of consultative processes as a basis for establishing a transparency register for patent applications as well as other measures to track the use of patents dealing with genes and genetic materials.

Given the present uncertainty around the impacts of gene patents, the Committee intends to maintain a watching brief on this area, and improved capture of data and information on the impacts of gene patents will be critical to guide any future deliberations of the Committee. This approach is also justified by the high level of uncertainty about the impacts of gene patents on future, as yet unknown, developments in genetic science.

Chapter 4

Chapter 4 of the report discusses the proposal for an express prohibition on gene patents, and this was the central issue addressed in much of the evidence submitted to the inquiry. To the extent that this proposal was supported by claims that gene patents are, or could, adversely impact on healthcare and medical research, the Committee's ability to make a definitive conclusion was, as above, significantly frustrated by a lack of relevant data.

Further, the Committee heard conflicting evidence as to whether a prohibition on the patenting of genes and other biological materials (a) would be effective and (b) would not lead to unforeseen consequences in other fields of technology, particularly biotechnology research and development.

The Committee notes also that, in fact, current Australian law does not allow the patenting of 'a mere discovery' (that is, a product of nature as opposed to an invention) and, in the Committee's view, there is substantial doubt that IP Australia's approach to the granting of patents over genes conforms with the general prohibition in law on the patenting of a discovery. While the Committee acknowledges IP Australia's defence of the current approach as being analogous to other classes of patents, such as chemical products, the Committee strongly rejects the reasoning which says that, for the purposes of the *Patents Act 1990* (the Act), genetic information that is 'isolated' from its naturally occurring state in the human body may be classed as an invention, and therefore properly be the subject of a patent (where the other requirements of patentability are satisfied). The Committee considered this to be the strongest justification for recommending that the Act be amended to include an express prohibition. However, a number of considerations persuaded the Committee that it would not, at this point in time, recommend that the Act be amended to expressly prohibit the patenting of genes.

First, as noted above, there was a level of the uncertainty around the potential effectiveness and effect of such a prohibition. With improved data and information collection on the impacts of gene patents (as the Committee's first two recommendations seek to achieve), the case for or against such an express prohibition may be clearer in future.

Second, the Committee noted legal developments, both nationally and internationally, which are directly relevant to the application of the invention-discovery distinction to isolated genetic materials. In the USA, a legal challenge to the validity of the BRCA gene patents has recently been decided in the US District Court for the Southern

District of New York.[1] This case found that isolated genetic materials are not patentable subject matter (that is, are not inventions) and, in the event that this decision is confirmed by a higher court on appeal, this finding will become binding on the practices of the United States Patent and Trademark Office (USPTO). Further, on 29 October 2010, the US Department of Justice indicated that the US federal government had altered its policy to reflect the US District Court's finding (although it was not clear whether the USPTO would implement the revised policy). While changes to the law in the US will not be directly binding on IP Australia, the Committee notes evidence that IP Australia considers that a high degree of conformity between Australia's patent system and jurisdictions such as the US is desirable. The Committee therefore expects that the Government and IP Australia will seek to adopt any substantive changes to US patent law and practice around the granting of patents over isolated genetic materials.

In Australia, a similar challenge to the BRCA gene patents was commenced in the Federal Court in June 2010. If the court finds that isolated genetic materials are not patentable subject matter, IP Australia will be required to adjust its approach to conform to that decision.

The Committee will continue to monitor these important international and national legal developments, and notes that these cases may bring greater clarity to the application of the invention-discovery distinction to isolated genetic materials. As part of its watching brief on this area, the Committee may wish to revisit this issue if the area remains problematic following the outcomes of these cases.

Third, the Committee notes that the Australian Council on Intellectual Property (ACIP) is currently considering reforms to the manner of manufacture test, and that its recommendations in this area may also clarify the application of the invention-discovery distinction to isolated genetic materials. The Committee awaits the publication of ACIP's final report with interest.

Finally, the Committee notes that the international and national legal developments described above, as well as the ACIP review of patentable subject matter, may ultimately be superseded by the introduction of a private member's Bill, the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill), into the federal Parliament. The Bill is intended to prevent the patenting of human genes and biological materials existing in nature, and would amend the Act to 'reinforce the distinction between discovery and invention and…apply that distinction by expressly excluding from patentability biological materials which are identical or substantially identical to those existing in nature, however made'.[2]

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1 *Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others* (the MPO case).

2 Draft Explanatory Memorandum, p. 3.

The Committee believes that the introduction of the Bill to the Senate will provide a further, and much-needed, opportunity for the arguments and questions around the impacts and effectiveness of an express prohibition on gene patents to be considered. The Committee is of the view that a Senate inquiry into the Bill should be undertaken, with a focus on the specific terms of the proposed amendments and the implications of their implementation for human health and other potentially affected fields of innovation. The Committee notes that its inquiry into gene patents has served a valuable purpose in bringing the issue of gene patenting to the light of public interest and attention, and provides a sound basis on which a targeted inquiry into the Bill can build. Accordingly, Recommendation 3 of the report requests that the Senate refer the Bill to a relevant Senate Committee for inquiry and report.

Chapter 5

Chapter 5 of the report discusses proposals for measures that would ameliorate the impacts arising from the granting of gene patents, including possible amendments to the Act. The Committee agreed on a number of recommendations that it believes could substantially address concerns about the impacts of gene patents on healthcare services and medical research, by improving patent quality and the operation of the patent system more generally. The recommendations are collectively intended to:

- increase the threshold requirements of patentability (improve patent quality);
- reduce the scope of patent claims;
- reinforce mechanisms and policies by which governments can and should intervene with the rights of patent holders; and
- assist judicial interpretation of the Act and establish an external accountability and quality control mechanism for the patent system.

The recommendations increasing the threshold requirements for patentability (Recommendations 6 to 8 and 10) are intended to improve patent quality. In simple terms, these recommendations seek to ensure that patents (including patents over genes and genetic materials) are granted only where an invention is, for example, sufficiently novel, inventive and useful. This will help to ensure that patents (which effectively grant an inventor a monopoly to exploit their invention) are not granted where their costs outweigh their intended economic and social benefits.

Recommendation 9 goes to the criteria for 'full description' and 'fair basis'. These requirements relate to the way in which a patent application sets out the scope of the patent claim and provides the information necessary for the invention to be replicated by others. This recommendation is intended to ensure that a patentee may not monopolise a greater field than they have disclosed to the public, and thus to prevent the granting of patents in relation to overly broad patent claims (including those relating to human genes).

Recommendations 11 and 12 relate to the development of clear policies regarding the circumstances in which the Crown use provisions contained in the Act should be employed by Government; and to clarification of the operation of the compulsory

licence provisions. In making these recommendations, the Committee observes that successive Australian governments have failed to properly engage with the Commonwealth's responsibility to ensure that such measures are contemplated and exercised where this is justified by relevant social or economic considerations. This failure to engage with and to oversight the operation of Australia's patent system is exemplified by the failure of successive governments to respond to the comprehensive review of gene patents conducted by the Australian Law Reform Commission (ALRC) in 2004. Noting the imminent completion of the ACIP review of patentable subject matter, as well as IP Australia's review of Australia's patent system, the Committee has recommended that the Government provide a response to the final reports of these reviews by mid-2011 (Recommendation 4). A comprehensive response to the work of these reviews should form the basis of the Commonwealth's ongoing engagement with the patent system into the future. To underpin the Committee's commitment to maintaining a watching brief on the impact of gene patents and the implementation of suggested reforms to the patent system, the Committee has also recommended that, following the tabling of the Government's response or at an appropriate time, the Committee be tasked with inquiring into the extent and impact of the implementation of any such reforms (Recommendation 5).

Recommendation 13 calls for the Act to be amended to include a broad research exemption. Such an exemption was widely supported by stakeholders, and is necessary to ensure certainty for both researchers and patent holders. The intent behind the Committee's recommendation is that any such research exemption should be sufficiently generous and broad to ensure that research, particularly medical research, can proceed without concern that a patent holder could sue for patent infringement.

Recommendations 14 and 15 call for the inclusion of anti-avoidance and objects provisions in the Act. These amendments are intended to assist in judicial interpretation of the Act, and to enable challenges to patents based on strategic or creative drafting of patent claims.

Finally, Recommendation 16 calls for the establishment of an external oversight authority in the form of a patent audit committee. The Committee envisages that this body will be comprised of members with relevant technical, scientific, economic and other relevant expertise, and be tasked with broadly assessing the operation and performance of the patent system, particularly in relation to areas of complex or emerging technology such as gene patents. Critically, the patent audit committee would act as an independent source of credible advice to guide and inform the Government's engagement with the patent system.

RECOMMENDATIONS

Recommendation 1

3.156 The Committee recommends that the Government support and expand on the collection of data, research and analysis concerning genetic testing and treatment in Australia, in line with recommendation 19-1 of the 2004 Australia Law Reform Commission report *Genes and ingenuity*.

Recommendation 2

3.157 The Committee recommends that the Government conduct a public consultation and feasibility study regarding establishing a transparency register for patent applications and other measures to track the use of patents dealing with genes and genetic materials.

Recommendation 3

4.137 The Committee recommends that the Senate refer the Patent Amendment (Human Genes and Biological Materials) Bill 2010 to the relevant Senate committee for inquiry and report.

Recommendation 4

5.161 The Committee recommends that the Government provide a combined response addressing the Committee's inquiry into gene patents; the 2004 report on gene patents by the Australian Law Reform Commission; the review of patentable subject matter by the Australian Council on Intellectual Property (ACIP); and the review of Australia's patent system by IP Australia. The Committee recommends that the response be provided not later than mid-2011 or three months after the release of the findings of all reviews.

Recommendation 5

5.162 The Committee recommends that, at an appropriate time following the release of the ACIP review of patentable subject matter and the IP Australia review of the patent system, the Community Affairs References Committee be tasked with inquiring into the Government's response to, and implementation of, the recommendations of those reviews, as well as the recommendations of the Committee's report on gene patents.

Recommendation 6

5.172 The Committee recommends that the *Patents Act 1990* be amended so that the test for obviousness in determining inventive step is that a claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.

Recommendation 7

5.173 The Committee recommends that the *Patents Act 1990* be amended to remove the limitation that 'common general knowledge' be confined to that

existing in Australia at the time a patent application is lodged (that is, that 'common general knowledge' anywhere in the world be considered).

Recommendation 8

5.174 The Committee recommends that the *Patents Act 1990* be amended to remove the requirement that 'prior art information' for the purposes of determining inventive step must be that which could reasonably have been expected to be 'ascertained' (that is, that the 'prior art base' against which inventive step is assessed not be restricted to information that a skilled person in the relevant field would have actually looked for and found (ascertained)).

Recommendation 9

5.175 The Committee recommends that the *Patents Act 1990* be amended to introduce descriptive support requirements, including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.

Recommendation 10

5.179 The Committee recommends that the *Patents Act 1990* be amended to provide that an invention will satisfy the requirement of 'usefulness' in section 18(1) only in such cases as a patent application discloses a 'specific, substantial and credible' use; the Committee recommends that such amendments incorporate the full set of recommendations on this issue from the Australian Law Reform Commission's 2004 report, *Genes and ingenuity* (Recommendations 6-3 to 6-4).

Recommendation 11

5.185 The Committee recommends that the *Patents Act 1990* be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. The Committee recommends that the Government adopt the Australian Law Reform Commission's recommendations on this issue from its 2004 report, *Genes and ingenuity* (Recommendations 26-1 to 26-3).

Recommendation 12

5.190 The Committee recommends that the Government amend the *Patents Act 1990* to clarify the scope of the 'reasonable requirements of the public' test, taking into account the recommendation of the Australian Law Reform Commission on this issue in its 2004 report, *Genes and ingenuity* (Recommendation 27-1); the Committee recommends that the Government review the operation of the competition based test for the grant of a compulsory licence, with particular reference to its interaction with the *Trade Practices Act 1974*.

Recommendation 13

5.195 The Committee recommends that the *Patents Act 1990* be amended to include a broad research exemption.

Recommendation 14

5.197 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the *Patents Act 1990*, the Government consider amending the Act to include anti-avoidance provisions.

Recommendation 15

5.198 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the *Patents Act 1990*, the Government consider amending the Act to include objects provisions.

Recommendation 16

5.202 The Committee recommends that the Government establish a patent audit committee.

CHAPTER 1

INTRODUCTION

Terms of reference

1.1 On 11 November 2008, the Senate referred matters relating to the patenting of human genes and genetic materials to the Senate Community Affairs Committee (the Committee) for inquiry and report by the last sitting day of 2009.[1] On the basis of the official schedule of sittings, the Committee was therefore required to report by 26 November 2009.

1.2 On 24 November 2009, the Senate agreed to an extension of time for the Committee to present its report. The Committee sought this extension because it required more time to consider the extensive evidence received and the complex nature of many issues associated with this inquiry. Further extensions were granted on 23 February 2010 (until 17 June 2010) and 16 June 2010 (until 2 September 2010).

1.3 On 19 July 2010, the Governor-General prorogued the 42nd Parliament. The Committee tabled a brief report on 26 August 2010, which stated that, after due consideration, the Committee had determined it was unable to provide a comprehensive report and would reconsider these issues in the event that the inquiry was re-referred to the Committee in the new parliament. On 30 September 2010, the Senate agreed to a request by the Committee for the inquiry to be re-referred with the original terms of reference and a reporting date of 25 November 2010.

1.4 The terms of reference for the inquiry directed the Committee to inquire into:

> The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:
>
> (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
>
> (i) the provision and costs of healthcare;
>
> (ii) the provision of training and accreditation for healthcare professionals;
>
> (iii) the progress in medical research; and
>
> (iv) the health and wellbeing of the Australian people;

1 Following the restructuring of Senate Committees on 13 May 2009, the inquiry was continued by the Senate Community Affairs References Committee.

(b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry; and

(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.[2]

Conduct of the inquiry

1.5 Information about the inquiry was advertised in *The Australian* and on the Committee's website, which included an invitation to make submissions on the terms of reference by 19 March 2009 (due to extensions to the reporting date, submissions were in fact accepted throughout the course of the inquiry). The Committee also wrote to relevant organisations and individuals to notify them of the inquiry and inviting submissions. The Committee received 78 public submissions. A list of the submissions authorised for publication by the Committee is provided in Appendix 1.

1.6 The Committee held eight public hearings for the inquiry. These took place in Canberra (19 March 2009, 20 August 2009, 14 September 2009, 18 May 2010 and 15 June 2010); Melbourne (3 & 4 August 2009); and Sydney (5 August 2009). Witnesses who appeared at the hearings are listed in Appendix 2.

The report

1.7 Chapter 2 of the report provides the background to the inquiry, and briefly outlines those aspects of the patent system, both in Australia and internationally, that are most relevant to the inquiry terms of reference. Chapter 3 considers the extent and impacts of the granting of patents over human genes and genetic material (term of reference (a)(i) to (iv)); Chapter 4 considers whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials (term of reference (c)); and Chapter 5 identifies measures to ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended (term of reference (b)).

Terminology used in this report

1.8 The inquiry terms of reference directed the Committee to consider the impacts of granting patent monopolies over 'human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form'. As noted by IP Australia, there is no internationally recognised definition or common understanding of what is a 'gene patent' other than that they are a subset of

2 The terms of reference for the inquiry, as well as submissions and other information on the Committee, is available from the Committee's website at http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/index.htm.

biotechnology patents.[3] The report uses the term 'gene patent' to refer to patents that specifically relate to gene sequences. More general references such as to 'human genes and genetic materials' may be understood as referring to all substances listed in the inquiry terms of reference.

1.9 The Committee notes that patent law, genetic science and health research are all areas which rely on specific and technical vocabularies, and the report seeks to avoid unnecessary use of technical terms wherever possible. The Committee wishes to acknowledge the patience and assistance of the many witnesses who assisted the Committee in developing an understanding of the complexities of patent law and genetic science.

3 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 5.

CHAPTER 2

BACKGROUND TO THE INQUIRY

INTRODUCTION

2.1 This chapter provides a brief description of the broader context in which the inquiry occurred, including:

- the events surrounding the attempted enforcement of rights relating to patents for the so called 'breast cancer genes', BRCA1 and BRCA2, by Genetic Technologies Ltd (Genetic Technologies) in Australia; and
- previous and current inquiries into issues relevant to gene patents.

2.2 To frame the analysis and discussion in following chapters, this chapter also provides an outline of:

- the definition of and rationale for the patent system;
- the nature of patent rights;
- the criteria for the grant of a patent; and
- processes for challenging the validity of patents.[1]

The BRCA1 and BRCA2 gene patents

2.3 The gene patents inquiry was instigated largely in response to concerns arising from attempts by Genetic Technologies in 2002-03 and 2008 to enforce its patent rights over the BRCA1 and BRCA2 genes (the BRCA genes) in Australia.

2.4 The BRCA gene patents relate to methods and materials used to isolate and detect mutations in two genes that may indicate a predisposition to certain cancers, notably breast cancer and ovarian cancer. The patent holder is an American company, Myriad Genetics Ltd (Myriad), which has granted Genetic Technologies the exclusive rights to BRCA1 and BRCA2 testing in Australia. Associate Professor Judy Kirk, Director, Familial Cancer Service, Westmead Hospital, explained the significance of the BRCA genes:

> …[Some] families have an inherited fault in a gene which puts them at an incredibly high risk of developing breast and ovarian cancer, and prostate cancer in the men. The two genes that we test in these families are known as BRCA1, the breast cancer 1 gene, and BRCA2…These are genes that we all have and these sequences are in every human being. They are normally involved in cell growth…We will not all have an identical BRCA1 gene.

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1 The discussion of the patent system in this chapter is not intended to provide an exhaustive description of the patent system, but focuses on those aspects that are most relevant to the issues raised in evidence to the inquiry.

> But some of us…will have a fault or a mutation that is big enough to cause a problem with the protein that that gene makes. Those are the people who are at very high risk of cancer. If we can identify those high-risk individuals we have a great deal to offer them in terms of cancer screening and cancer prevention and even targeted therapies.[2]

Attempted enforcement of rights over BRCA genes by Genetic Technologies

2.5 In 2002-03 and 2008, Genetic Technologies sought to enforce its rights in relation to the BRCA genes in Australia. As is discussed below, the grant of a patent gives a patentee exclusive rights to exploit their patented invention, which means that they can prevent other parties from using or exploiting that invention. In the case of the BRCA genes, Genetic Technologies wrote to research bodies and other entities seeking to prevent these entities from engaging in any further testing for the BRCA genes. For example, representatives of the Peter MacCallum Cancer Centre (PMCC) advised that in both 2002-03 and 2008 the Centre had received 'cease and desist' letters from Genetic Technologies. The letters instructed PMCC to stop conducting BRCA testing and refer all future samples to Genetic Technologies for testing.[3]

2.6 Ultimately, however, Genetic Technologies dropped its legal demands in relation to testing for the BRCA genes. In a report to shareholders on 9 July 2003, Genetic Technologies noted that it was not seeking to enforce its rights over the genes and stated that the BRCA genes 'are our gift to the Australian people'.[4] Similarly, in relation to the attempt in 2008, Genetic Technologies announced that it had reviewed its decision to assert its rights over the testing, and had 'resolved to immediately revert to its original decision to allow other laboratories in Australia to freely perform BRCA testing'.[5]

2.7 In relation to the 2008 demands, the Committee understands that state health departments negotiated with Genetic Technologies following the issuing of the 'cease and desist' letters. While the inquiry did not receive any definitive account of Genetic Technologies' reasons for withdrawing its demands, a number of reasons were suggested. These included that:

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2 Associate Professor Judy Kirk, *Committee Hansard*, 5 August 2009, p. 50.

3 Professor Stephen Fox, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, pp 119-120.

4 Genetic Technologies Limited website, 'A report to shareholders', 9 July 2003, http://www.gtg.com.au/index.asp?menuid=060.070.130.010&artid=98 (accessed 7 October 2009).

5 Genetic Technologies Limited website, 'New position re BRCA testing', 2 December 2008, http://www.gtg.com.au/index.asp?menuid=060.070.130&artid=10748&function=NewsArticle (accessed 7 October 2009).

- there was widespread public and professional criticism of Genetic Technologies for seeking to enforce its rights, and the company wished to avoid further negative publicity;
- Genetic Technologies' purported gifting of the test to the Australian people in 2002-03 may have rendered the enforcement of its rights problematic;
- negotiations with health departments may have indicated that the demands and/or the patents would be legally contested on certain grounds;[6] and/or
- the Australian Competition and Consumer Commission (ACCC) was considering, or had instituted,[7] an investigation into whether the matter raised issues of anti-competitive behaviour.

2.8 In correspondence to the Committee, the ACCC advised that, in response to Genetic Technologies' attempt to enforce its rights over the BRCA testing in 2008, the Commission had begun to consider concerns that the attempt by Genetic Technologies to withdraw access to its intellectual property rights raised issues under section 46 of the *Trade Practices Act 1974* (TPA), which relates to misuse of market power. In determining this question, the ACCC was considering:

- whether Genetic Technologies had market power in a market concerning the provision of testing services for susceptibility to breast cancer by way of its exclusive licence over the patents;
- whether Genetic Technologies took advantage of any market power or had taken advantage of its exclusive licenses; and
- if Genetic Technologies had taken advantage of its market power, whether it was for the purpose of eliminating, or substantially damaging, its competitors.

2.9 However, following advice that Genetic Technologies had decided not to seek to enforce its rights over the BRCA patents, the ACCC advised that it was not ultimately required to form a view as to whether Genetic Technologies had breached section 46 or any other provision of the TPA.[8]

2.10 The attempts by Genetic Technologies to enforce its rights over the BRCA genes in Australia highlighted significant concerns about the potential impacts of gene patents on the healthcare industry, particularly in terms of medical research and the delivery of healthcare (as reflected by this inquiry's terms of reference). Despite the withdrawal of Genetic Technologies' demands, there has been much public discussion and debate about the potential for the BRCA or other gene patents to adversely impact

6 Dr Gerard Cudmore, Office for Science and Medical Research, Department of Industry and Investment, New South Wales, *Committee Hansard*, 5 August 2009, p. 91.

7 Mr Chris Reid, Department of Health and Ageing, *Committee Hansard*, 20 August 2009, p. 45.

8 Australian Competition and Consumer Commission, correspondence dated 16 October 2009, p. 2.

on these areas both now and in the future. These issues are fully considered in Chapter 3.

AUSTRALIA'S PATENT SYSTEM

2.11 An understanding of the operation of Australia's patent system is fundamental to any consideration of the issues around gene patents and their effect on the matters described by the inquiry's terms of reference: healthcare, medical research and the health and wellbeing of Australians.

2.12 The legislation which governs the patent system in Australia is the *Patents Act 1990*.

Definition of a patent

2.13 A patent is a private property right granted by the Crown to the inventor of a product, method or process in a field of technology.[9] A patent allows the patent holder to prevent others from exploiting the invention, and so to maximise the commercial potential of the invention for the duration of the patent. In simple terms, a patent grants a monopoly to the patent holder.

Purpose of the patent system

2.14 Unlike many Acts, the *Patents Act 1990* (the Act) does not specifically set out any objects (objectives). However, as noted in the 2004 Australian Law Reform Commission report, *Genes and ingenuity: gene patenting and human health* (the ALRC report), the goal of the patent system is 'fundamentally economic'.[10] The patent system seeks to encourage the availability of new and useful technologies to society through the incentive of a monopoly to commercially exploit an invention for a given period, usually 20 years.[11]

2.15 The patent system further promotes innovation through encouraging the diffusion of knowledge, as it is a condition of the grant of a patent that the inventor is required to publicly disclose their invention. This ensures that others can utilise and build on an innovation to further develop new and useful technologies.

2.16 Mrs Fatima Beattie, Deputy Director-General, IP Australia, summarised the rationale of the patent system in the following way:

> The objective of Australia's patent system is to benefit Australia by stimulating industrial innovation and encouraging technology access and

9 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 377.

10 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 53, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

11 *Patents Act 1990*, section 67.

> transfer. The system rewards inventors with a period of exclusivity to prevent others from exploiting their invention in return for disclosing their invention to the public. Diffusion of knowledge in the public domain helps to facilitate research in emerging fields of the patented invention.[12]

Nature of patent rights

Scope of patent rights

2.17 As noted above, the grant of a patent gives the patent holder a monopoly, or exclusive rights, over an invented product or process. In relation to a product, the Act defines the term 'exploit' as:

- the making, hiring, selling or otherwise disposing of the product;
- offering to make, sell, hire or otherwise dispose of the product;
- the use or import of the product; and
- the keeping of the product for any of the above purposes.

2.18 In relation to a process, the term 'exploit' is defined as using the process or method to do any of the acts outlined above in respect of a product resulting from such use.[13]

2.19 A patent holder might seek to exercise their patent rights in any number of the ways described above in seeking to maximise the profit potential of their patent. It is also common for patent holders to enter into a licence agreement with a third party to allow that party to exploit an invention in certain ways. Such agreements may be entered into exclusively or concurrently with a number of parties. As noted above, the patent holder for the BRCA gene patents is an American company, Myriad, which has granted exclusive rights to Genetic Technologies for the exploitation of those patents in Australia.

Limits on patent rights

2.20 Despite the theoretical breadth of patent rights, in practice a patent does not grant an absolute right to exploit an invention in any way the inventor may choose. The ALRC report explains:

> 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

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12 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 19 March 2009, p. 3. For a brief overview of the historical development of the patent system see Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, pp 378-381.

13 *Patents Act 1990*, Schedule 1, Dictionary, p. 160.

> 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.[14]

2.21 Further, and of particular significance to the inquiry, a patent holder's rights might also be limited or constrained by operation of certain provisions of the Act, pertaining to compulsory licences and Crown use.[15] These are discussed in more detail in Chapter 5.

2.22 In Australia, it is uncertain as to whether a research exemption exists in relation to the patent system. This issue is discussed in more detail in Chapter 5.

Requirements for grant of a patent

2.23 The Act contains a number of criteria or requirements for patentability of an invention under Australian law. Together, these criteria establish a threshold for the patentability of an invention. The Act provides that an invention will be patentable if, inter alia, it:

- is a 'manner of manufacture';
- is novel;
- involves an inventive step;
- is useful; and
- the details of the invention are sufficiently well disclosed or described.[16]

Manner of manufacture

2.24 The Act requires that an invention be a 'manner of manufacture'.[17] This relates to the question of what can be the subject matter of a patent. Put simply, it means that a patent must relate to 'an artificial state of affairs':[18] a product, process or method that

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14 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 55, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

15 *Patents Act 1990*, sections 133 and 163. The Act also contains provisions under which the Governor-General may direct that a patent or invention that is the subject of a patent application be acquired by the Commonwealth (for payment of compensation). These provisions were not addressed in the submissions and evidence to the inquiry and are not discussed further in this report.

16 The requirements discussed here are not exhaustive but focus on those aspects of patent law that are most relevant to the issues raised by the inquiry.

17 *Patents Act 1990*, section (18)(1)(a).

18 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 3.

arises through some form of 'human intervention with nature to bring about some physical change'.[19]

2.25 The Act does not define 'manner of manufacture' but merely states that an invention must be a 'manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*', a law from 1623 pertaining to monopolies.[20] The decision not to specifically define the term in the Act reflects a view at the time of its creation that it would be 'difficult to draft a definition that would adequately reflect the body of law that had progressively fleshed out the concept of a manner of manufacture'.[21]

2.26 Moreover, a number of reviews of Australia's patent system preceding the passage of the Act had concluded that the 'manner of manufacture' test should be retained because its flexibility allows it to respond to or encompass new developments in technology or human ingenuity.[22] Prior to 1959, judicial interpretations had driven a significant evolution of the term 'manner of manufacture' in respect of the scope of patentable subject matter. Along with the extension of the term to include processes as well as products, a number of general and specific classes of unpatentable inventions had been identified, including:

- a general prohibition on the patenting of intellectual information and conceptions, such as business schemes, instructions, mathematical formulae, discoveries and principles of nature; and
- specific prohibitions on the patenting of certain subject matter, such as methods for medical treatment of humans and living matter.

2.27 However, in 1959, the basis of the current legal conception of the term 'manner of manufacture' was established by the High Court case *National Research Development Corporation v The Commissioner of Patents* (the NRDC case).[23] In simple terms, the court endorsed a more expansive definition of 'manner of manufacture', whereby patentability is determined by reference to the policy intent of the (then) Act rather than by application of a strict definition.[24] The ALRC report provides the following summary of the present approach to interpreting 'manner of manufacture':

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19 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 377.

20 The *Statute of Monopolies* may be understood as the originator of modern patent law statutes.

21 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 409.

22 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 118, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

23 (1959) 102 CLR 252.

24 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, pp 408-9.

> 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. 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.[25]

2.28 IP Australia identified the following principles from the NRDC case:

- the distinction between discovery (which is unpatentable) and invention is very fine;
- it is the practical application of information to a useful end that takes a discovery into the realm of 'manufacture';
- 'manner of manufacture' should not be rigidly defined: its purpose is to encourage national development in 'excitingly unpredictable fields'; and
- an invention is patentable if it gives rise to an 'artificially created state of affairs' in the 'field of economic endeavour'.[26]

2.29 A second significant element in the approach of Australian courts in determining whether an invention is a 'manner of manufacture' is that the Act contains few specific limitations on patentable subject matter. These are:

- human beings and the biological processes for their generation; and
- plants and animals, and the biological processes for the generation of plants and animals.[27]

2.30 A number of judicial comments have indicated that the absence of express statutory exclusions has been influential in the willingness of courts to accept broader subject matter as a manner of manufacture.[28] Together, the NRDC case and the lack of express prohibitions on patentability in the Act have had an expansive effect on the limits of patentable subject matter in Australia:

> The lack of express statutory exceptions combined with the breadth of the *NRDC* judgment has enabled courts to remove the fetters that may otherwise prevent new developments from being patentable. The result has been a piecemeal erosion of formerly perceived classes of excluded subject

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25 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 118, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

26 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 13.

27 Section 18(2) and (3). The second limitation applies in respect of innovation patents, a form of patent not further discussed in this report. For further information on innovation patents see IP Australia website, http://www.ipaustralia.gov.au/patents/what_innovation.shtml (accessed 10 September 2009).

28 See for example *Rescare Ltd v Anaesthetic supplies Pty Ltd* (1992) 25 IPR 119, 151 (Gummow J); and *Bristol-Myers Squibb Co v F H Faulding & Company Ltd* (2000) 97 FCR 524.

> matter. *NRDC* itself rejected the former exclusion of patents for horticultural and agricultural methods. Subsequent decisions declared patents valid for computer programs and methods of medical treatment for humans with the result that a number of formerly excluded classes of subject matter are now regarded as patentable. Patents are granted for computer programs, computer implemented systems used in business, living plants, animals, genetic materials and recombinant DNA techniques.[29]

2.31 In relation to gene patents in particular, the IP Australia submission advises:

> Despite the long judicial history, to date no court decision in Australia has considered specifically whether isolated and purified gene sequences are proper subject-matter for patents. In the absence of Australian precedents, IP Australia has turned for guidance to decisions and practice relating to chemical compounds.[30]

Discovery v invention

2.32 In the context of genes and genetic materials, the requirement that an invention be a manner of manufacture assumes particular importance in relation to a longstanding distinction between inventions and discoveries under the law, and this issue was raised in numerous submissions to the inquiry.

2.33 Patent law recognises only 'inventions' as being patentable; 'discoveries' are not patentable. Evidence to the inquiry revealed strong differences of opinion over IP Australia's current practice of accepting isolated or purified genetic sequences as 'inventions'. This issue is discussed in detail in Chapter 4.

'Contrary to law' and 'generally inconvenient' exclusions

2.34 The Statute of Monopolies provides that a patent may not be granted on the grounds that a new manner of manufacture is 'contrary to law' or otherwise 'generally inconvenient'. The Advisory Council on Intellectual Property (ACIP) options paper on patentable subject matter explains:

> Section 6 of the Statute of Monopolies provides that patents are only available for manners of new manufacture that are 'not contrary to law nor mischievous to the state by raising prices of commodities at home or hurt of trade or generally inconvenient'. This results in a definition of invention that

29 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 410. For further discussion of the development of exclusions in the *Patents Act 1990* see Dr Hazel Moir, *Submission 20*, p. 25.

30 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 13.

> goes beyond technological development and includes social and economic factors.[31]

2.35 However, the ACIP paper notes that under Australian law it is currently unclear whether inventions can be excluded from patenting on public policy grounds, such as for being 'generally inconvenient':

> Arguably, patents may also be refused on public policy grounds where the grant of a patent would be 'generally inconvenient'. This arises from the reference to section 6 of the *Statute of Monopolies* in the definition of invention. Unlike the other exclusions, general inconvenience forms part of the definition of invention rather than a category of inventions to be excluded from patentability. However, its meaning and its ongoing application is unclear.[32]

2.36 The availability of general exclusions such as on the grounds that an invention is 'generally inconvenient' is the subject of an inquiry by ACIP into patentable subject matter. The issue of general and specific exclusions to patentable subject matter and the ACIP review are discussed in Chapter 5.

Novelty

2.37 A claimed invention must be novel or not previously known. This question relates to the issue of whether there has been previous publication or use of an invention.

2.38 The requirement for 'novelty' is simply understood as ensuring that a patent is only granted for an invention that is truly new, in the sense of being not previously known in a given field of knowledge. This means that, at the time of application for a patent, the details of the invention must not have been 'published or made publicly available through use anywhere in the world'.[33]

2.39 Whether an invention is novel is judged by a comparison with the state of knowledge in the field relevant to the invention, which is referred to as the 'prior art base'.

Inventive step

2.40 A claimed invention must involve an 'inventive step'. This question relates to the level of ingenuity required for an invention to be granted a patent.

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31 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 34.

32 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 16.

33 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 377.

2.41 The requirement that an invention involve an inventive step is fundamental to the patent system, as it ensures that a monopoly is not awarded for knowledge that was obvious or that would have been available at the time of the patent application.

2.42 Whether an invention involves an inventive step is judged by a comparison with the state of knowledge in the field relevant to the invention, which is referred to as the 'prior art base'. The prior art base includes information in a document, or information made publicly available by doing an act, anywhere in the world; and 'common general knowledge' in the relevant art in Australia.[34]

2.43 The element of inventive step was relevant to a number of issues raised by submitters and witnesses in relation to gene patents.

Challenging patents

2.44 IP Australia submitted that there are in total four opportunities for the validity of a patent to be tested under the Act:

- each application is examined by IP Australia before it may be accepted or refused (examination);
- each accepted application may be opposed before grant by any party, including the Minister (opposition);
- applications may be re-examined before grant at the discretion of the Commissioner of Patents, and the patent must be re-examined after grant on request from any person in an approved form, including the Minister (re-examination); and
- post-grant, the validity of a granted patent can be challenged in the courts by any party, including the Minister (revocation).

2.45 The evidence to the inquiry concerning the testing of the validity of patents mainly concerned the examination stage of the patent process. The main requirements of patent examination were described above.

Revocation of granted patents

2.46 Evidence concerning post-grant challenges to patents (revocation) highlighted that this is a time-consuming and costly process that is usually only pursued by commercial interests.

2.47 The Committee heard claims that there is a significant number of patents of questionable quality currently in force, and there was therefore some consideration of the possibility of challenging granted patents through post-grant opposition in the courts—that is, by seeking their revocation.

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34 IP Australia, 'Getting the balance right: towards a stronger and more efficient IP rights system', March 2009, p. 10.

2.48 It is important to understand that, under the Act, a grant of a patent by the Commissioner of Patents (the Commissioner) does not guarantee or necessarily imply that a patent is legally valid.[35] This means that the revocation of a patent may always be sought, and in fact the patent system is premised on the idea that patents may or will be tested through legal proceedings. Once a patent is granted, a person may apply to the Commissioner to have the patent revoked. The grounds for any such application are set out in section 59 of the Act, with the most relevant for the purposes of the inquiry being that the 'invention is not a patentable invention' (section 59(b)). This ground encompasses all the aspects of validity set out in sections 18(1) and (2), including that the invention:

- is not a manner of manufacture;
- lacks novelty; and
- is obvious (that is, does not meet the inventive step requirement).

2.49 The Commissioner must determine an application in accordance with the Patents Regulations 1991. Decisions of the Commissioner may be appealed to the Federal Court by any party.[36]

Obstacles to seeking revocation of patents through the courts

2.50 The evidence of many submitters and witnesses pointed to the expense of opposing patents through the courts, given the complex technical and legal aspects of the patent system. As noted above, the grant of a patent does not guarantee that all the requirements of patentability are satisfied, so in fact the patent system is premised on the idea that questionable patents may or will be tested in the courts. Dr Hazel Moir explained that '[no] application which the patent office accepts can be assumed to be valid until it has been tested [in the courts]'.[37]

2.51 However, the Committee heard that there are relatively few court challenges to granted patents, except in cases where there are sufficient commercial motives and resources involved. Dr Luigi Palombi explained:

> …the real problem is that we have no efficient way of testing the validity of these patents. It costs millions of dollars, it costs a lot of time, and you need to be a very sophisticated litigant to actually test the validity of these patents…It is also very difficult for non-profit, charitable organisations, such as the Cancer Council, to run the risk of litigation. Under the rules in Australia, if you sue and you lose you have to pay the costs, even if lawyers were to do that case for free.[38]

35 See *Patents Act 1990*, sections 20 and 21.

36 *Patents Act 1990*, sections 59 and 60.

37 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 6.

38 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 17.

2.52 Dr Palombi noted that a *pro bono* offer to test the validity of the BRCA patents in Australia had been refused by the Cancer Council Australia due to concerns about the potential cost-exposure of the legal proceedings. Dr Palombi observed that 'the whole system is stacked against anyone other than the patentee'. [39]

2.53 The submission of the South Australian Government also pointed to the apparent under-use of the legal system to challenge patents, even in cases where patents are of questionable quality. This is probably attributable to the complexity and high cost of the system. The submission also pointed to other factors, noting in particular that patent insurance is available to patent holders to cover the costs of defending a challenge to a patent's validity. In relation to revocation proceedings, the patent system therefore contains significant disincentives to potential challengers of patents.[40]

2.54 Mr Richard Hamer, Member, Business Law Section, Law Council of Australia (LCA), observed that legal challenges to patents are more common where large commercial interests are at stake. In the case of pharmaceutical patents, for example, generic-drug companies are proactive in challenging patents thought to contain any weaknesses. While smaller companies are unlikely to mount challenges, industry associations or other concerned groups have funded patent challenges. However, the LCA was not aware of any specific challenges to gene patents.[41] Mr Hamer noted that in many cases it is uneconomic, given the potential costs and risks of litigation, for patent holders to undertake legal action, even where they are aware of certain patent infringements.[42]

2.55 Some evidence suggested that, in many cases, threat of legal action is secondary to intentions to enter into licence agreements—that is, the threat of legal action is used strategically to persuade another party to negotiate a licence agreement in order to avoid expensive and time-consuming legal battles.[43] However, this raises the prospect that such threats could lead to such agreements being entered into even when based on unmeritorious claims, simply because a party cannot risk the expense of court proceedings.

2.56 Professor Peter Drahos advised that in practice very few patents are challenged in the courts:

> …it is important to remember that very few patents are ever litigated. The litigation rates in the United States are less than two per cent; that is the most active litigation system in the world. In most other countries, it is less

39 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 17.

40 South Australian Government, *Submission 16*, p. 5.

41 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, pp 83-84.

42 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 87.

43 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 87.

> than one per cent. So relying on courts to reform the patent system is fairly futile, actually.[44]

2.57 Given the expense of challenging patents through the courts, some submitters and witnesses suggested that the Government should consider funding a public interest litigation to challenge the validity of gene patents, particularly in relation to the question of whether human genes and genetic material should be regarded as patentable subject matter. Dr Palombi advised:

> If a test case were to be brought I think that it would be completely appropriate for the Commonwealth to fund the litigation to resolve what is going to happen to the patents that have already been granted. We are probably going to need a court decision to make it clear as to whether or not these patents are valid or whether the claims over isolated biological materials are valid.[45]

2.58 The Committee notes that, on 8 June 2010, Maurice Blackburn Lawyers representing Cancer Voices Australia and Ms Yvonne D'Arcy commenced proceedings in the Federal Court of Australia, seeking to invalidate the BRCA patents in Australia.[46] This is discussed further in Chapter 4.

Re-examination of patents

2.59 The Act provides a discretion to the Commissioner to re-examine an application and a granted patent on an own-motion basis.[47] A third party may not initiate any such re-examination until a patent has been granted. However, once granted, re-examination of a patent must be conducted if a request is received from the patentee or a member of the public (unless there are other proceedings pending);[48] or by a court (section 97(3)).

2.60 On re-examination of a patent specification, the Commissioner must report on whether the claim, when compared with the prior art base:

- is not novel; and
- does not involve an inventive step.[49]

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44 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 16.

45 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 13.

46 Cancer Voices Australia & Anor v Myriad Genetics Inc & Ors, Federal Court of Australia, NSD643/2010, available at https://www.comcourts.gov.au/file/Federal/P/NSD643/2010/actions.

47 Mark J Davison, Anne L Monotti and Leanne Wiseman, *Australian intellectual property law*, Cambridge University Press, Melbourne, 2008, p. 399.

48 See *Patents Act 1990*, sections 97, 97(2) and 97(4).

49 *Patents Act 1990*, sections 98(1) and (2). This effectively means that the only grounds available for refusing to grant or revoking the grant of a patent on re-examination are lack of novelty and/or inventive step.

2.61 Following requirements for informing an applicant of any adverse decision, the Commissioner may refuse to grant or revoke a patent. Any such decision by the Commissioner may be appealed to the Federal Court.[50]

2.62 Dr Matthew Rimmer suggested that the re-examination process could provide a more affordable and thus accessible means of challenging the validity of patents:

> Once the patent is granted, it then becomes very difficult to challenge the validity of the patent in terms of the costs and expenses associated with that. The United States regime has been making much greater use of re-examination of patents once they are granted. The Public Patent Foundation, which is a civil society organisation, has been particularly good of late in bringing re-examination requests against critically important patents such as, for instance, the BRCA1 and BRCA2 patents and some of the Wisconsin Alumni Research Foundation's stem cell patents. So some are keen on re-examination as a less expensive means of assessing the validity of patents. Some are interested in postgrant opposition proceedings in relation to the validity of patents. It is a big problem at the moment, because the current environment really allows patent trolls to flourish, because parties in most instances will be willing to pay a licence fee rather than necessarily take legal action.[51]

International patent system

2.63 The Committee heard that the patent system is relatively uniform across a number of countries, following many years of efforts to harmonise intellectual property systems. This has occurred as an aspect of international cooperation in the areas of economic and trade development.

2.64 A number of submissions to the inquiry raised issues related to the international system of patent law. In particular, a number of stakeholders contended that certain reforms to Australia's patent system could place Australia in breach of its international obligations. The potential for reform of Australia's domestic patent system to create breaches of its international obligations was identified in the ALRC report, which observed:

> …[Proposed reforms to the patent system] 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.[52]

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50 *Patents Act 1990*, sections 100(3) and 101(4).

51 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 16.

52 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 87, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

2.65 Australia is a party to a number of international legal instruments relating to intellectual property, which together reflect the ongoing harmonisation of the systems of the signatories. Australian domestic law has given effect to significant provisions of these agreements, including:[53]

Paris Convention

2.66 The Paris Convention for the Protection of Industrial Property 1883 is the principal international agreement on intellectual property. In relation to patents it provides, inter alia, for mutual recognition of the rights of the nationals of signatory states.

Patent Cooperation Treaty

2.67 The Patent Cooperation Treaty 1970 allows a patent to be filed simultaneously in multiple jurisdictions by filing a single international application in one country. Determining the validity of the patent remains the responsibility of each national patent office.

Budapest Treaty

2.68 The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977 establishes an international system for the deposit of microorganisms relating to patent applications.

TRIPS Agreement

2.69 The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS Agreement) establishes, inter alia, the minimum standard of patent protection that each member of the World Trade Organization (WTO) must provide under its national laws. Domestic law may augment any such standards as long as this does not affect the operation of other provisions of the TRIPS Agreement.

2.70 The TRIPS Agreement was the main focus of submissions to the inquiry on Australia's international obligations. A number of aspects of the Agreement were highlighted as being relevant to gene patents, and particularly the question of whether human genes and genetic materials should be expressly prohibited under the Act:

- a requirement that member states make patent protection available for any inventions, whether products or processes, in all fields of technology;
- provision for optional exclusions from patentability that may be adopted by member states; and

53 The following discussion of international agreements is largely based on Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, pp 88-93, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

- 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, and do not unreasonably prejudice a patent holder's rights.[54]

2.71 There was significant disagreement amongst some submitters and witnesses concerning the extent to which the TRIPS Agreement prevents Australia from expressly prohibiting or otherwise treating gene patents differently under the Act. This issue is discussed in more detail in Chapter 4.

Australia-United States Free Trade Agreement

2.72 In addition to the agreements outlined above, any reform of Australia's patent system may also have to take into account obligations or constraints arising from bilateral trade agreements with other countries. In particular, the Australia-United States Free Trade Agreement (AUSFTA), entered into on 18 May 2004, contained a number of provisions pertaining to aspects of the patent system, including:

- exclusions from patentability;
- revocation of patents;
- Crown use and compulsory licensing; and
- the requirement of 'usefulness' for patentability.[55]

2.73 The ALRC report notes that AUSFTA may be significant for any suggested reform of Australia's patent system: '[in cases where] the AUSFTA reflects existing Australian law or practice, the agreement may act as a constraint on future change'.[56]

Previous and current inquiries relevant to gene patents

Previous inquiries

2.74 The Committee notes that a number of previous inquiries have reported on both particular and general issues relevant to its inquiry into gene patents. The Committee acknowledges these efforts and was able to draw on this work to inform its own considerations. Notable completed inquiries include:

54 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, pp 88-93, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

55 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 94, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html. These amendments were passed in the *US Free Trade Agreement Implementation Act 2004*.

56 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, June 2004, p. 94, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

IPAC review of Australia's patent system

2.75 The report *Patents, innovation and competition in Australia* was presented to the Government on 29 August 1984. It was produced by the Industrial Property Advisory Committee (IPAC), chaired by Mr John Stonier. This report was influential in informing the policy underlying the development of the *Patents Act 1990*.[57]

IPCRC report on competition and intellectual property law

2.76 The *Review of intellectual property legislation under the Competition Principles Agreement* (the Ergas Report) was presented to the Government on 30 September 2000. It was produced by the Intellectual Property and Competition Review Committee (IPCRC), chaired by Mr Henry Ergas.

2.77 The Ergas report concluded that intellectual property laws and competition policy are 'largely complementary' on the basis that the former promotes innovation, 'which is a key form of competition'. However, it acknowledged that a tension exists between the two because of the potential for exclusive rights to promote anti-competitive behaviour:

> It must also be recognised that the rights granted by the intellectual property laws can be used for anti-competitive ends. This occurs when the rights are used to claim for the creator not merely a share of the efficiency gains society obtains from the creation, but also super-normal profits that arise from market power unrelated to the creation.[58]

2.78 The Ergas report concluded that the threshold for obtaining a patent should be higher, on the basis that monopolistic rights can excessively affect competition if granted to inventions that are not truly innovative.[59] The recommendations of the Ergas report (and an earlier ACIP Review of the Enforcement of Industrial Property Rights (patent enforcement))[60] were partially implemented in the *Patents Amendment Act 2001*.[61]

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57 Industrial Property Advisory Committee, *Patents, Innovation and Competition in Australia*, August 1984, available at http://www.acip.gov.au/library/Patents,%20Innovation%20and%20Competition%20in%20Australia.pdf.

58 Intellectual Property and Competition Review Committee, *Review of intellectual property legislation under the Competition Principle Agreement*, September 2000, p. 6.

59 Parliamentary Library, 'Patents Amendment Bill 2001', Bill Digest No. 1 2001-02, available at http://www.aph.gov.au/library/pubs/BD/2001-02/02bd001.htm.

60 Available at http://www.acip.gov.au/reviews_completed.html#enforce.

61 Parliamentary Library, 'Patents Amendment Bill 2001', Bill Digest No. 1 2001-02, available at http://www.aph.gov.au/library/pubs/BD/2001-02/02bd001.htm.

Australian Law Reform Commission report on gene patenting and human health

2.79 The report *Genes and ingenuity: gene patenting and human health* (the ALRC report) was presented to the government on 29 June 2004. As per usual practice, a broad-based expert advisory committee was established to provide the ALRC with general advice and assistance with the report.

2.80 The ALRC report concluded that it was too difficult to expressly prohibit patents on genetic sequences due to the 'hard and inconvenient fact' of the number of patents that had been granted on genetic sequences since the 1980s.[62] Finding that there was no case for 'radical overhaul of the patents system', the ALRC's recommendations were based on the view that 'it was far preferable to focus on reforms that would directly address the existing problems and make the system work better'.[63]

2.81 The report contained 50 recommendations, which focussed on three areas. These were:

- to the extent that gene patents highlighted any deficiencies in the patenting system, correcting systemic weaknesses in the patent system;
- improving the patent system in general, including a suite of reforms directed at the practices of IP Australia; and
- ensuring the appropriate use and exploitation of gene patents, particularly in the three sectors on which the ALRC was instructed to focus: research, biotechnology and healthcare.

2.82 The recommendations of the ALRC report served as an important reference point for much of the evidence received by the present inquiry in submissions and testimony.[64]

ACIP reviews relating to patent law

2.83 ACIP has completed a number of reviews with particular reference to patent law, including:

- review of Crown use provisions for patents and designs (November 2005); and
- review of patents and experimental use (October 2005).[65]

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62 Australian Law Reform Commission, *Submission 18*, p. 2.

63 Australian Law Reform Commission, *Submission 18*, p. 2.

64 The full list of the ALRC's recommendations can be viewed via the ALRC web site at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

65 These reports are available from Advisory Council on Intellectual Property web site at http://www.acip.gov.au/reviews_completed.html#crownuse.

Current inquiries

2.84 At the time of writing, there are also relevant inquiries being conducted by ACIP and IP Australia.

ACIP review of patentable subject matter

2.85 ACIP is conducting a review of patentable subject matter. The review website notes that in recent years a variety of concerns have been raised about the sorts of things that can be patented in Australia, and draws attention to the findings of the ALRC report that the 'manner of manufacture' test is ambiguous and obscure. The review will include consideration of:

- the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law; and
- the historical requirement that an invention must not be 'generally inconvenient'.[66]

2.86 The review released an options paper in September 2009, with responses to be provided by 13 November 2009. The Committee understands that the final report will be provided to Government in late 2010.

IP Australia review of the patent system

2.87 IP Australia advised that it is conducting a review of the patent system, which is being undertaken in the context of the innovation review the Government initiated late in 2008.[67] A number of consultation papers identifying areas of proposed reform have been released as part of this process.

2.88 The purpose of the review is to:

- reduce barriers in the innovation landscape for researchers and inventors;
- improve certainty about the validity of granted patents; and
- allow patent claims to be resolved faster.[68]

2.89 Department of Innovation, Industry, Science and Research and IP Australia advised:

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66 Advisory Council on Intellectual Property web site, http://www.acip.gov.au/reviews.html#subject (accessed 29 September 2009).

67 For information on the innovation review see http://www.innovation.gov.au/innovationreview/Pages/home.aspx.

68 IP Australia, 'Getting the Balance Right', Consultation Paper March 2009, available at http://www.ipaustralia.gov.au/pdfs/news/ip_reforms_balance.pdf; IP Australia, 'Exemptions to Patent Infringement', Consultation Paper, March 2009, available at http://www.ipaustralia.gov.au/pdfs/news/ip_reforms_exemptions.pdf.

IP Australia is progressing a package of reforms to the Australian patent system. The package is comprehensive, covering a range of proposals that would result in increased thresholds for patentability and to bring Australia into alignment with other jurisdictions.[69]

69 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 3.

CHAPTER 3

THE IMPACT OF GENE PATENTS

INTRODUCTION

3.1 This chapter addresses terms of reference (a)(i) to (iv), which direct the Committee to consider the impact that the granting of patent monopolies over genes and genetic materials has had, is having, and may have had on:

- the provision and costs of healthcare;
- the provision of training and accreditation for healthcare professionals;
- the progress in medical research; and
- the health and wellbeing of the Australian people.

Patents granted over genes and genetic material

Classes and numbers of patents relating to human genes

3.2 One of the difficulties in assessing the impact of gene patents concerned the number and character of patents being granted in Australia relating to genes and genetic materials. At filing all patent applications are classified according to the technical matter which they concern using the International Patent Classification (IPC) system.[1]

3.3 IP Australia noted that there are a number of IPC marks which cover biotechnology; however, IPC subclasses C12N and C12Q are relevant to gene patents as they cover most inventions relating to genes and genetic engineering.[2] Of the two subclasses C12N is most likely to contain applications that claim a human gene sequence per se, derivatives of the sequence such as probes and primers, and their use in diagnostic or therapeutic methods. C12Q is more likely to contain applications directed to processes and methods that use gene sequences, rather than claiming the gene sequence per se. In particular IPC subgroups C12N15/12 to C12N15/28 are 'a good but not absolute indicator of patents that claim a human gene sequence'.[3]

3.4 There was particular concern expressed during the inquiry that patents which grant exclusive rights to genetic testing are negatively impacting on the areas covered

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1 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 37.

2 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 37.

3 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, pp 26-27.

in the terms of reference. IP Australia noted that gene patent claims generally fall into two categories: product claims (such as isolated gene sequences per se) and method claims (such as the use of a gene sequence to diagnose diseases or disorders associated with the gene).[4] Similarly, the United States Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) final report on gene patents and access to genetic tests identified several categories of patent claims which can serve as the basis for exclusive rights to a genetic test. These included patents claims on isolated nucleic acid molecules as well as patent claims on 'processes for the detection of particular nucleic acid sequences or mutations' and 'processes involving simply associating a genotype with a phenotype' (for example associating a particular genetic sequence with the predisposition to a disease).[5]

3.5 A patent claim on an isolated gene sequence can give the patent holder exclusive rights to a genetic test because typical methods of testing the gene in question require the production of the patented sequences. The patent holder's capacity to exclude others from using the sequence gives them exclusive rights to testing. A similar situation occurs where there is a patent on the process or method involving testing for a particular genetic sequence and then associating that sequence with a disease or condition. The SACGHS report states:

> A significant distinction between composition of matter/manufacture claims to isolated nucleic acid molecules and method claims is that claims to molecules cover all uses of the molecule, including uses outside of diagnostics, while a claim to a method of using a molecule would not prohibit one from using that molecule for another method.[6]

3.6 IP Australia estimated there are 202 patents claiming an isolated human nucleic acid molecule which remain current, most of which have a priority date before the completion of the Human Genome Project in 2003.[7] There is no discrete IPC mark for human gene sequences, so the data provided by IP Australia was inclusive of animal genes. However, IP Australia commented that in their experience the majority of patents on gene sequences relate to human genes. The Department of Innovation, Industry, Science and Research and IP Australia joint submission stated that 'the

4 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 7.

5 Secretary's Advisory Committee on Genetics, Health and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, April 2010, pp 13-14.

6 Secretary's Advisory Committee on Genetics, Health and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, April 2010, p. 14.

7 Ms Lexie Press, IP Australia, *Committee Hansard*, 20 August 2009, p. 34; IP Australia, clarification of evidence, 7 September 2009, p. 1. The 'priority date' is the date on which a patent application was first filed.

inability to separate applications covering human DNA instead of animal DNA is not unique to IP Australia'.[8]

3.7 IP Australia also made the point that, since the first publication of the Human Genome Project in 2001, the filing numbers for methods or processes (sometimes referred to as 'downstream applications') have surged compared to filings for patents for gene sequences per se. IP Australia argued that this situation is unsurprising because, as knowledge of the human genome increases, patentability requirements (for example, the requirements that an invention is 'novel' and involves an inventive step) become more difficult to satisfy.[9] IP Australia submitted that the number of patents on gene sequences—and thus any adverse impacts that may have flowed from these patents—is diminishing. Mrs Fatima Beattie, Deputy Director General of IP Australia, stated:

> Concerns about the breadth of patents granted to the first inventor is common in any new area of technology. As the technology develops the scope of patent rights afforded get narrower and narrower and it becomes harder to satisfy the threshold patentability requirements of novelty and inventive step. This is due to the cumulative growth of prior art and skill of persons working in the technology area…IP Australia's data shows the number of patents claiming isolated human nucleic acid molecules steadily declining since the publication of the Human Genome Project. We expect only a small probability of additional such patents. [10]

3.8 However, Dr Luigi Palombi submitted that IP Australia's assessment of the number and character of gene patents did not fully encompass the scope of the inquiry's terms of reference. He provided an alternative analysis of the number of gene patents in Australia:

> …when I examined IP Australia's database in February this year I found that there were over 15,000 patents and patent applications that concerned both human and microbial genes and non-coding sequences, proteins, and their derivatives. This is not an insignificant number.[11]

3.9 In discussing the number of gene patents, Dr Hazel Moir focused on IPC class C12N15, noting it was not the only class in which gene and related patents may be found, but was the largest. Her submission outlined that there had been 42,326 patent applications in subclass C12N15, with 14,306 patents granted and a cumulative total of 8,352 patents being current as at 12 February 2009.[12]

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8 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, pp 25-26.

9 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 26.

10 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 28.

11 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 2.

12 Dr Hazel Moir, *Submission 20*, p. 37.

3.10 IP Australia noted that Dr Moir's assessment examined the whole C12N subclass which includes biotechnological inventions that:

> …although related to genetic engineering technology, are unlikely to include claims to isolated gene sequences per se or diagnostic methods based on the use of isolated gene sequences.[13]

3.11 IP Australia argued that a more accurate way of estimating the number of gene patents likely to claim an isolated sequence per se is by analysing the CN15/12 subgroup. Patents claiming methods of using an isolated gene sequence per se are likely to be given a class mark of C12Q 1/68.[14]

3.12 The table of data Dr Moir provided was broadly consistent with the argument by IP Australia that patent applications relating to gene sequences peaked around the time the Human Genome Project was published and completed. However, Dr Moir also noted that reasons for the fall in applications 'could include a genuine fall in the volume of 'inventions' being produced, or applicants [may] now be trying to avoid this class'.[15]

Difficulties assessing the impact of gene patents

3.13 Considerable time was devoted during the inquiry to discussing the actual and potential impacts of granting patents on genes and genetic material. While arguments were made for both the positive and negative impact of patents over genes and genetic material, others argued that there is insufficient evidence or research available to determine the issue. The lack of evidence regarding the impact of gene patents was also a feature of the Australian Law Reform Commission's (ALRC) inquiry in 2004. The ALRC noted that concerns about the impact of gene patents 'were anecdotal or hypothetical, and evidence of problems in practice—outside that small number of well-known examples—was more difficult to verify'.[16]

3.14 The Intellectual Property Research Institute of Australia (IPRIA) argued that:

> …[there is] as yet no empirical work available that carefully examines the relationship between gene patenting and the costs of providing healthcare, the training and accreditation of healthcare professionals, and progress in medical research.[17]

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13 IP Australia, *IP Australia response to Senator the Hon Heffernan's submission*, p. 5 (and see IP Australia, *Correction to IP Australia response to Senator the Hon Heffernan's submission*, p. 1).

14 IP Australia, *IP Australia response to Senator the Hon Heffernan's submission*, p. 5 (and see IP Australia, *Correction to IP Australia response to Senator the Hon Heffernan's submission*, p. 1).

15 Dr Hazel Moir, *Submission 20*, p. 37.

16 Australian Law Reform Commission, *Submission 18*, p. 2.

17 Intellectual Property Research Institute of Australia, *Submission 36*, p. 6.

3.15 Dr Kwanghui Lim, Associate Director of IPRIA, stated:

> We are not saying that the policy should not be changed; what we are saying is that, if you are going to base your arguments on fact and prior work, there is not enough of it. It is too new a technology…There are a lot of logical arguments that have been put in place, and they are valid ones, but there is not enough actual data…[18]

3.16 Dr Moir also considered that there is a lack of systematic evidence relating to the impact of gene patents. She suggested that there are empirical difficulties in assessing the impact of gene patents, including identifying all the relevant patent monopolies granted; assessing each patent and the benefit of innovation provided by the grant; and identifying whether there are competing products available which provide effectively the same result.[19] Dr Moir also argued that the issue of gene patents is essentially one of competition policy, as patent protection is a regulatory intervention into the innovation market.[20] Dr Moir observed that the Competition Principles Agreement between the Commonwealth, states and territories requires justification for any interference in a market with the effect of reducing competition. However:

> No such data…has been put in front of this committee in regard to patenting genes. There has been a claim that there is no evidence of any harm, but that is a completely different thing from demonstrating that there is any good.[21]

Improving the collection of data on the patent system and its impacts

3.17 Dr Moir argued that 'the lack of information on the ways in which granted monopolies are used in Australia is a major problem for the development of sound policy'. She suggested that 'the government might now consider heeding the advice of the Industrial Property Advisory Committee in 1984 relating to the regular collection of information on how the monopolies it grants are used'.[22] This recommendation stated:

> …that the Patent Office introduce procedures to collect more data from applicants and patentees, particularly concerning the use of patents, in a form which facilitates analysis for statistical and general policy assessment purposes, the information so collected being treated as received and held in confidence and subject to privilege.[23]

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18 Dr Kwanghui Lim, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, p. 4.

19 Dr Hazel Moir, *Submission 20*, p.35.

20 Dr Hazel Moir, *Submission 20*, p.45.

21 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 2.

22 Dr Hazel Moir, *Submission 20*, p. 39.

23 Industrial Property Advisory Committee, *Patents, Innovations and Competition in Australia*, 1984, Recommendation 46.

3.18 Professor Peter Drahos noted that, while information about patents is publicly available, it is not available in useful ways. He has suggested that patent offices need to proactively promote the transparency and diffusion of patented invention information, and should 'track and publish the patent portfolios of patent owners, especially those with large patent holdings.'[24]

3.19 Professor Drahos suggested that one way to deal with the complexity and uncertainty generated by 'gaming behaviour' within the patent system would be for regulatory agencies to establish 'patent transparency registers in areas of technology where there were serious risk management issues'. Registers could target specific areas, and companies would be required to use the registers to make a full disclosure of the patents and patent applications surrounding the targeted technology, if they wished to enforce their patent right. Registers could also include disclosure of information relating to ownership and licensing of patents, which is difficult to track. Other users of the patent systems would be able to rely on the information in the register to make informed decisions as to use of technology, innovation and research.[25]

3.20 Senator the Hon. Bill Heffernan's submission to the inquiry also recommended the establishment of a patent transparency register that would track and publish patent portfolios and:

> …develop databases in co-operation with user groups or other interested government agencies so that the degree of concentration of ownership of crucial technologies associated with that portfolio, and information about the licensing and assignment of those technologies are easily and publicly available.[26]

Provision and costs of healthcare

3.21 During the inquiry there was general agreement that patients, health professionals, researchers and governments are increasingly reliant on medical knowledge concerning the human genome to make decisions about healthcare, and that this reliance is likely to increase in the future. The main issues raised in relation to gene patents and the provision and costs of healthcare were:

- restrictive patent licensing and access to genetic testing services;
- innovation and healthcare;
- the importance of genetic counselling services; and
- the future of genetic testing.

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24 Professor Peter Drahos, *Submission 60*, p. 448.

25 Professor Peter Drahos, *Submission 60*, pp 451-456.

26 Senator the Hon. Bill Heffernan, *Submission 76*, p. 72.

Genetic testing services

3.22 As with the Australian Law Reform Commission's 2004 inquiry, the evidence received by the Committee concerning the impact of gene patents on healthcare focussed predominantly on genetic testing. However, it should be remembered that patents on genes and genetic material may also impact on the provision and costs of other types of healthcare, including gene therapy and the use of stem cells.[27]

3.23 Genetic tests are commonly used in a number of ways in healthcare. These include:

- preventative testing or screening of a patient for genetic variations that may increase the likelihood they will develop a disorder or illness;
- diagnostic testing performed to identify the cause of a patient's symptoms; and
- testing to target specific treatment to a patient.[28]

3.24 While the Medicare Benefits Scheme funds a limited number of genetic tests, state and territory governments fund and provide the bulk of genetic testing and related clinical services in Australia. Many genetic tests are arranged by clinical genetic services and carried out in public laboratories attached to public hospitals. The Commonwealth Government contributes to the funding of these genetic tests and services indirectly through the National Healthcare Agreements. The Department of Health and Ageing also noted that the Pharmaceutical Benefits Scheme funds pharmaceuticals, vaccines and other treatments developed from genes, proteins and other related biological materials, 'assessed to be both effective and value for money.'[29]

3.25 The results of the *Australian Genetic Testing Survey 2006* were highlighted by a number of submissions. The survey found that 437 different genetic tests were available across Australia in 2006. Of these, more than half (55 per cent) were offered by only one laboratory and only five per cent of genetic tests were provided by more than five laboratories. A total of 41,497 molecular genetic tests were rebated by Medicare in 2006. Genetic tests were only a small part of the approximately 60 million pathology tests funded by Medicare that year. A further 119,354 molecular genetic tests were provided by laboratories using non-Medicare funding, presumably through state governments and privately-paying patients.[30]

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27 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, 2004, pp 465 and 489.

28 Royal Society of Pathologists of Australasia, *Submission 49*, p. 3.

29 Department of Health and Ageing, *Submission 62*, p. 2.

30 Royal College of Pathologists of Australasia, *Submission 49, Report of the Australian Genetic Testing Survey 2006*, pp 15 -17; Medical Technology Association of Australia, *Submission 43*, p. 1.

3.26 The Peter MacCallum Cancer Centre (PMCC) noted comments by the President of the Royal College of Pathologists of Australasia (RCPA), Dr Bev Rowbotham, describing genetic testing in Australia as 'uncoordinated, inequitable and inefficient', predominantly due to the current funding mechanism. Dr Rowbotham commented that most genetic services see their role as the 'rationer' of access to genetic testing, mainly because of the expense of the tests and funding limitations.[31]

3.27 Cancer Council Australia (CCA) highlighted the potential cost burden of genetic testing on patients. They noted that state health departments and family cancer centres provide limited funds for genetic testing from their budget allocations for non-Medicare items. Where this funding is not available, patients may be required to pay for their own tests.

3.28 The Committee heard that the costs for testing can vary considerably depending on the type of test—from just over $100 to more than $2500 per test. Specialised genetic testing is a characteristically complex process with low throughput, and can take up to six months or longer. In some cases, samples are sent overseas for analysis at additional cost.

3.29 CCA noted that, under the current arrangements, there is no adequate legal protection to ensure that genetic testing for cancer risk remains freely accessible at reasonable cost to the health system and consumers.[32] Many submitters and witnesses were concerned that the burden of increased costs due to gene patents will be borne by patients, making access to genetic testing less equitable.

3.30 A number of other groups commented on affordability and accessibility. The NSW Government noted that the number of patients requiring or benefiting from genetic testing is rising, and observed that 'there is a significant concern that access to clinically appropriate testing may be reduced if prices exceed the currently available budgets'.[33]

3.31 The Medical Technology Association of Australia argued that access to genetic testing in Australia 'may be impeded where there is no payment for the test through Medicare' and highlighted that only a small number of tests are covered by the Medicare Benefits Schedule.[34]

3.32 However, Mrs Fatima Beattie, Deputy Director-General of IP Australia, suggested the issue was more '[an issue of] the health funding arrangements for those sorts of tests rather than an issue of the gene patent'. She stated:

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31 Peter MacCallum Cancer Centre, *Submission 28,* p. 5.

32 Cancer Council Australia, *Submission 50*, pp 5-6.

33 NSW Government, *Submission 54*, p. 5.

34 Medical Technology Association of Australia, *Submission 43,* p. 4.

> …the price of the BRCA test, in particular, provided by the exclusive Australian licensee, is on par with the cost of the test performed by the publicly funded clinics. The only difference is about who pays that price, whether it is the Australian government, through the health budget, or whether it is the actual patient.[35]

Patent licensing and access to genetic testing

3.33 The relationship between gene patents and the costs and provision of healthcare was disputed during the inquiry. There were concerns expressed that patent licensing over genetic testing could lead to restrictions on the number of laboratories conducting genetic tests. This could potentially restrict access to testing, delay results, influence the quality of test results and cause costs to rise for patients and the community. For example Dr Palombi commented:

> A patent monopoly over an isolated gene and its genetic information means that anyone that does anything that comes within the scope of that patent monopoly has infringed the patent and is liable to the patentee for damages or an account of profits and can be enjoined from continuing to infringe by the grant of an injunction.
>
> That kind of power, which a patentee possesses exclusively, is significant legally, economically and ethically. Legally because it provides the patentee with the right to sue with respect to the unauthorised use for damages, an account of profits and to seek an injunction. Economically because it enables the patentee to control access, use and price, in the exercise of their legal rights as a monopolist. Ethically because how the patentee exercises those rights can impact upon how society functions.[36]

3.34 The RCPA argued that the impact on the provision and costs of healthcare of a gene patent largely depends on the licensing approach taken by the patent owner. A number of models of licensing access were identified, including:

- the open access model, where no fee is charged by the patent owner for testing the relevant gene but royalties can be earned through producing and selling commercial test kits;
- the restricted access model, where the patent holder offers one of two options. The first option is that laboratories are licensed to perform their own in-house tests. This license consists of an up-front fee and ongoing royalties for each test performed. The second option is that laboratories must use a kit supplied (and method specified) by the patent holder (or sole licensee). This allows the patent holder to limit the number of tests that can be performed with each kit, and means the cost of the commercial kit may be significantly greater than an in-house test developed by the laboratory; and

35 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 15 June 2010, p. 37.

36 Dr Luigi Palombi, *Submission 4*; answer to question on notice, 2 April 2009, p. 5.

- the closed access model, where the patent holder does not offer licensing and mandates that all testing be completed at a nominated laboratory.[37]

3.35 The RCPA discussed the differences between these approaches and noted examples where the use of a restricted or closed model by a patent holder had influenced the provision and cost of genetic testing. In particular, where a laboratory is allowed to develop or refine its own in-house test, it is able, if required, to better meet the requirements of the local population, as variations in the frequency of genetic errors mean that a genetic test may not be accurate for all ethnic groups.

3.36 An example of the restricted model was IgH and TCR gene rearrangement tests performed on cancer tissue from patients with lymphoproliferative disorders or acute myeloid leukaemia. The United States based patent-holder, InVivoScribe Technologies, approached all Australian laboratories currently performing such tests and insisted they switch to the exclusive use of the company's kit and method or obtain a sub-license to use their own tests. The RCPA noted that the cost of the in-house test for laboratories was $28 per patient (excluding labour and other costs) while the cost of the provided kit was $292 per patient (excluding labour).[38]

3.37 The South Australian Government also outlined an example where a restricted approach by a patent holder has had an impact on health provision. In 2005, a company which claimed to be the exclusive licensee for genetic tests for cytochrome P450 mutations wrote to the Institute of Medical and Veterinary Science (now SA Pathology) and advised they would be exercising their exclusive right on the licence. The company sought a one-off fee of £20,000 and five per cent of any fees for tests performed. These additional costs were described as 'untenable' and the Institute ceased performing the test. The South Australian government noted that similar situations had occurred for other tests.[39]

3.38 The RCPA described Genetic Technologies's actions in seeking to enforce its licence rights against public laboratories in Australia performing BRCA1 and BRCA2 genetic tests as an example of the closed model of gene patent licensing. They considered this situation highlighted a number of problems with the closed approach to licensing. These included that having only a single provider of a genetic testing:

- limits opportunities for laboratory quality assurance;
- gives absolute control over the price of the test;
- allows the patent holder to develop an exclusive and private database of the genetic variation for that gene in the population; and
- exposes the delivery of health services to the risk of instability.[40]

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37 Royal College of Pathologists of Australasia, *Submission 49*, pp 8-11.

38 Royal College of Pathologists of Australasia, *Submission 49*, p. 9.

39 South Australian Government, *Submission 16*, p. 8.

40 Royal College of Pathologists of Australasia, *Submission 49*, p 11.

3.39 The RCPA also noted that there is a risk that patent monopolies on genetic testing may result in inappropriate standards of care, where they have the effect of blocking access to appropriate testing or promoting use of certain tests inappropriately.[41]

3.40 Other witnesses and submissions argued that gene patents negatively impact on equitable access to healthcare. For example, Dr Jennifer Leary argued that patents inevitably lead to a 'demand for profit', and licensing fees or lack of competition in the market will lead to increased testing costs. She also noted that a monopoly on service provision leading to increased costs means that those who cannot pay privately may not have access to genetic testing.[42] The Human Genetics Society of Australasia also stated that 'monopoly testing removes competition, which may result in excessive pricing and restricted access, particularly within the public health system which provides the majority of genetic testing'.[43]

3.41 The Society argued that such monopolies would create healthcare inequities between those who rely on public services and those who can afford to pay for tests privately.[44]

3.42 The Victorian, South Australian and New South Wales governments used the example of genetic testing for BRCA1 and BRCA2 to illustrate the negative impact a closed approach to licensing could have on healthcare, funding and access to genetic testing. The Victorian Government estimated that redirecting predictive gene testing for breast cancer to an exclusive provider would cost an additional $0.5 million per annum initially, an increase of 50 per cent on current funding for testing. Increased costs would require governments to either allocate additional funding to maintain service levels or reduce the number of funded tests, resulting in increased waiting times for public patients and reduced service equity as those able to pay would gain preferential access to private services. They noted that these cost implications would increase if this scenario were to occur across multiple genes and testing patents.[45]

3.43 Similarly the South Australian Government stated that, if Genetic Technologies had been successful in imposing a monopoly on testing for the BRCA genes, the cost of testing would have risen significantly, 'meaning additional cost to individuals, families and the South Australian Government'.[46] The New South Wales Government stated there is evidence the patent rights are 'adversely affecting medical care' and that healthcare providers feel that gene patents will decrease the integrity of gene tests and increase the cost of conducting genetic analyses. They noted 'there is a

41 Royal College of Pathologists of Australasia, *Submission 49*, p 14.

42 Dr Jennifer Leary, *Submission 39*, p. 4.

43 Human Genetics Society of Australasia, *Submission 33*, pp 1-2.

44 Human Genetics Society of Australasia, *Submission 33*, pp 1-2.

45 Victorian Government, *Submission 61*, p. 2.

46 South Australian Government, *Submission 16*, p. 8.

significant concern that access to clinically appropriate testing may be reduced if prices exceed the currently available budgets'.[47]

3.44 Some witnesses and submitters were concerned that patenting genes and genetic material could lead to commercial monopolies for gene testing associated with cancer and therefore increased costs for patients. The key concerns of the Cancer Council Australia related to the potential for monopolisation of genetic material through gene patents to reduce public access to predictive, diagnostic and therapeutic genetic technology in cancer control, and to increase their cost to both government and the community.[48] This view was shared by Breast Cancer Network Australia:

> In particular we are concerned that a private company holding a gene patent could limit access to genetic testing for women by insisting that tests are only conducted through specified laboratories, or that the cost of the test could be increased in order to increase the profitability of the testing process for the company.[49]

3.45 PMCC argued that restricted and closed approaches to licensing genetic tests could reduce the ability of public laboratories to offer genetic testing for other genes. PMCC stated that 'common gene tests provide a critical mass for laboratories, allowing them to undertake occasional testing for rarer mutations' that are not commercially attractive to large companies. These rarer mutations could become 'orphan diseases' with no genetic test available. PMCC also argued that losing 'core screening work' could result in some public laboratories closing, and that this would adversely affect clinical activity. PMCC noted that genetic tests are often not clear cut and require close consultation between the clinicians who manage the patients and the molecular pathology team performing the tests and interpreting results.[50] This type of close consultation could be inhibited where a restricted or closed approach to patent licensing is adopted.

3.46 There were also concerns raised about the misallocation of healthcare resources. Some feared that if genetic testing is not accessible, affordable and targeted to patients with high clinical need (because of the impact of gene patents) then healthcare costs will increase as a result of illnesses which may have been preventable.[51] For example, Dr Jennifer Leary considered that the health budget could be burdened 'through the development of disease that may have remained undetected without access to testing or through undergoing unnecessary surveillance and treatment procedures'.[52] Similarly, Associate Professor Judy Kirk advised:

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47 New South Wales Government, *Submission 54*, p. 5.

48 Cancer Council Australia, *Submission 50*, p. 6.

49 Breast Cancer Network Australia, *Submission 47*, p. 3.

50 Peter MacCallum Cancer Centre, *Submission 28*, p. 5; See also Dr Jennifer Leary, *Submission 39*, p. 4.

51 Breast Cancer Action Group NSW, *Submission 30*, p. 1.

52 Dr Jennifer Leary, *Submission 39*, p. 4.

> If genetic testing is not available to all appropriate families, it is likely that preventable cancers will occur in (unidentified) high risk individuals, leading to increased costs that could be avoided. In addition, if genetic testing is not available to all appropriate families, it is likely that (unidentified) low risk individuals will have inappropriately high levels of cancer surveillance, also increasing costs to the system.[53]

3.47 Ms Heather Drum, a member of Breast Cancer Network Australia, also highlighted the cost benefits for patients, the community and government of genetic testing which may facilitate preventative healthcare measures. She stated:

> Bypassing a diagnosis of cancer means bypassing the expensive costs of treatments such as chemotherapy and radiotherapy. My chemotherapy was somewhere in the vicinity of $2,000-plus per cycle, then include doctors appointments, hospital admissions, pathology tests, further drugs test treating side-effects and the time out of work. I spent nearly 18 months in treatment, working only sporadically—all unplanned.[54]

3.48 However, many other submissions rejected concerns about the impact of gene patents on access to genetic testing services. The Department of Health and Ageing (the Department) noted that the 2004 ALRC inquiry found little evidence that gene patents and licensing practices with respect to genetic testing have had any significant impact on the cost and provision of healthcare in Australia. The Department also highlighted that, since that report, neither the Australian Health Ministers' Advisory Group on Human Gene Patents and Genetic Testing nor the National Health and Medical Research Council's (NHMRC) Human Genetics Advisory Committee had been advised of any systemic concerns about the impact of gene patents on the cost of healthcare.[55]

3.49 IP Australia also noted the lack of empirical evidence identifying adverse impacts caused by gene patents. In particular, it observed that 'there has been no evidence that patents have resulted in any person being denied access to molecular genetic testing'. IP Australia suggested concerns about gene patents generally 'related to anecdotal evidence and what hypothetically could happen in future in terms of patentee licensing behaviour, costs and availability of genetic tests'.[56]

3.50 In response to particular concerns about the monopolisation of genetic testing by patent holders, IP Australia observed:

> On the issue of 'monopolisation' or single provider of tests, we note that over 55 [per cent] of the 437 genetic tests performed in 2006/07 in Australia were offered by one laboratory. Our understanding is that the

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53 Associate Professor Judy Kirk, *Submission 9*, p. 2.

54 Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, p. 89.

55 Department of Health and Ageing, *Submission 62*, p. 2.

56 IP Australia, *Submission 19*; and supplementary submission, 30 September 2009, p. 2.

> provision of a single provider for these tests did not seem to be subject to a patent in Australia…This statistic indicates that many market forces other than patents and exclusive licensing arrangement determine whether tests are provided by one laboratory and the prices charged for the tests. These factors include demand and market size.[57]

3.51 Genetic Technologies defended its role in providing BRCA genetic testing services, describing the company as a 'positive contributor to improving the health and well being of the Australian people'.[58] Genetic Technologies argued that, prior to its entry into the market, BRCA testing was 'performed [using] all manner of different test protocols among the state laboratories and many of these were slow and suboptimal in their specificity and accuracy'. Genetic Technologies stated that it had improved the accuracy, timeliness and efficiencies of the test process, and provided a benchmark against which many of the public laboratory services can be measured. Further, Genetic Technologies noted that it had never been requested to participate in an open and transparent tender for the provision of genetic testing services. According to the Genetic Technologies submission:[59]

> …we contend that our service has met a previously unfulfilled demand in the Australian health care sector. We do not force any customer to use our service and we charge a publicly published price. [Genetic Technologies] contends that it operates the most cost effective BRCA testing laboratory in the country and would welcome any subjective review of efficiencies and costs-charges incurred for such testing across all laboratories...[60]

3.52 Genetic Technologies also highlighted the United States SACGHS public consultation draft report on *Gene patents and licensing practices and their impact on patient access to genetic tests*. They noted that the draft report findings, which discussed gene patents and genetic testing in the context of the United States healthcare system, indicated that patents covering genetic tests and related licensing practices do not appear to be impeding patient or clinical access to tests.[61] The SACGHS draft report found that the evidence from the case studies examined during the inquiry:

> …did not reveal widespread overpricing for genetic diagnostic tests that were patented and exclusively licensed relative to tests that were either unpatented or non-exclusively licensed.[62]

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57 IP Australia, supplementary submission, 30 September 2009, p. 2.

58 Genetic Technologies Ltd, *Submission 24*, p. 6.

59 Genetic Technologies Ltd, *Submission 24*, p. 6.

60 Genetic Technologies Ltd, *Submission 24*, p. 6.

61 Genetic Technologies Ltd, *Submission 24*, p. 5.

62 Secretary's Advisory Committee on Genetics, Health, and Society, *Public consultation draft report on gene patents and licensing practices and their impact on patient access to genetic tests*, March 2009, p. 98.

3.53 The draft report concluded:

> Based on its review of the literature, case studies, and review of international policies regarding gene patents, SACGHS found little in the way of broad or consistent evidence that indicates either positive or negative effects of gene patents on patient access to diagnostic tests.[63]

3.54 The SACGHS draft report also stated that instances in which patient access to genetic tests may have been impeded were often caused not by the patent itself but by the way it was licensed or used.[64] However, the SACGHS final report, released in April 2010, noted that, where patents and licensing practices have created a sole provider of a genetic test, patient access to testing had suffered in cases where:

- the sole provider did not accept the patient's health insurance and the patient could not otherwise afford the test;
- patients wished to have a second-opinion from an independent laboratory; and/or
- patent enforcement disputes delay or prevent testings.[65]

3.55 The Johnson & Johnson Family of Companies (JJFC) noted that, while many thousands of gene patents have been granted in Australia, only a small few have raised concerns about the ability of public institutions to provide testing. Furthermore, where there have been concerns, such as with the BRCA2 test, the parties 'have reached an amicable resolution that has not hindered the effective screening of the gene'. JJFC argued:

> …costs pressures can be more effectively regulated by the market than by legislation governing the inventions themselves. Once again the BRCA-2 case can be used as an example. The pricing for tests utilising the BRCA-2 patent are varied in different countries, reflecting each environment's individual market dynamics. Additionally, the recent announcement in Australia that the tests could be conducted in public hospitals was brought about by general market forces.[66]

3.56 The Institute of Patent and Trade Mark Attorneys of Australia suggested that some of the opposition to patents on genes and genetic materials was due to a philosophical objection to gene patents. They also stated that:

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63 Secretary's Advisory Committee on Genetics, Health, and Society, *Public consultation draft report on gene patents and licensing practices and their impact on patient access to genetic tests*, March 2009, p. 98.

64 Secretary's Advisory Committee on Genetics, Health, and Society, *Public consultation draft report on gene patents and licensing practices and their impact on patient access to genetic tests*, March 2009, p. 108.

65 Secretary's Advisory Committee on Genetics, Health, and Society, G*ene patents and licensing practices and their impact on patient access to genetic tests*, April 2010, pp 3-4.

66 Johnson & Johnson Family of Companies Australia, *Submission 44*, p. 11.

> Other groups opposed to gene patenting may be self serving in that they wish to provide commercial services in the area of gene testing and healthcare without having to pay royalties or legitimate fees to patent owners and innovators.[67]

3.57 The Committee received evidence from Professor Dianne Nicol and Dr Jane Nielsen regarding their research in 2002-03 involving surveys and interviews with Australian researchers, biomedical companies and genetic testing laboratories. The research found that, while there was a great deal of concern about gene and related patents, there was little evidence that such patents were actively being enforced against genetic testing laboratories in Australia at that time.[68]

Innovation and healthcare

3.58 Submitters and witnesses also discussed the impact of gene patents on the provision and costs of healthcare more broadly, with many focusing on the extent to which gene patents promote or discourage research and innovation in medicine.

3.59 IP Australia commented that the access and cost issues related to gene patents are not limited to the prices incurred by individual patients. For example, it argued that the patent system promotes innovation in healthcare and, without this strong incentive to companies and researchers, 'there may be no or much slower access to newer and better tests'.[69] IP Australia also noted that innovations in human genetic research had benefited society through the availability of new and better healthcare products and services, such as the Gardasil vaccine against cervical cancer.[70]

3.60 This line of reasoning was supported by a number of other submissions, which emphasised the positive impacts of gene patents on the costs and provision of healthcare. The Institute of Patent and Trade Mark Attorneys of Australia, for example, stated that significant innovation in biotechnology had resulted 'in numerous new treatments, prevention, diagnostics and health guidance'.[71] The Victorian Government acknowledged that, while genetic tests are a cost pressure for governments, 'gene technologies may ultimately reduce healthcare costs through earlier and more accurate diagnoses and the ability to determine the suitability of individuals to therapeutic interventions'.[72] Similarly, the Law Council of Australia suggested:

> While patent protection can be expected to result in increased cost to the consumer during the period of exclusivity, this perceived disadvantage is to

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67 Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 5.

68 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 7.

69 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 29.

70 IP Australia, *Submission 19*, p. 8.

71 Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 12.

72 Victorian Government, *Submission 61*, p. 2.

> be compared with the alternative option, which, in practice, may be that the product is not available to the consumer at all.[73]

3.61 However, others argued the impact of gene patents was likely to be negative on healthcare innovation. This was particularly the case because 'once the gene sequence for a particular disease related gene has been identified and isolated, the development of a diagnostic test is not particularly onerous'.[74]

3.62 Senator the Hon. Bill Heffernan's submission to the inquiry outlined the adverse impacts of four patents on the cost and access to healthcare in Australia and overseas. In relation to the polypeptides of erythropoietin patent he stated the 'most immediate and significant impact of this patent monopoly was on the cost of provision of healthcare in Australia'. The patent had other impacts including that 'Australian scientists and researchers were directly inhibited for research purposes'.[75]

3.63 CCA commented that the monopolisation of genetic testing eliminates competition and carries the risk of sole providers having no incentive to find more efficient and affordable ways to undertake tests and make other use of the genetic information they control.[76]

3.64 The RCPA stated that patent holders can block further development of a genetic test, either by restricting analysis to one laboratory or by requiring laboratories to use a commercial kit. The RCPA described a situation where patent rights over a genetic test effectively blocked the delivery of supplementary testing which would have increased the accuracy and usefulness of the test for patients. While the supplementary method had been described by research scientists, other laboratories could not offer the test because they were not licensed to analyse the relevant genes.[77]

3.65 PMCC recognised that patents have played an important role in protecting and facilitating 'the transfer of novel intellectual property for the benefit of the community at large and the creators of that property', but considered genes to be a special case which should not be subject to patents. They argued that permitting gene patenting meant that there is no incentive for the gene patent holder to continue to improve their commercially available genetic test and particularly not to reduce the cost or improve the efficiency of the test. They highlighted variable pricing of the BRCA1 and BRCA2 genetic tests in different countries and noted that the cost of this test has not reduced appreciably in the United States despite the continuing reduction in the cost of genetic sequencing over time.[78]

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73 Law Council of Australia, *Submission 57*, p. 1.

74 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 5.

75 Senator the Hon. Bill Heffernan, *Submission 76*, p. 8

76 Cancer Council Australia, *Submission 50*, p. 7.

77 Royal College of Pathologists of Australasia, *Submission 49*, p. 13.

78 Peter MacCallum Cancer Centre, *Submission 28*, pp 2-3.

Genetic counselling and family cancer centres

3.66 There was considerable support expressed for the current approach to genetic testing in the public sector where 'patients receive their results and advice through a structured and considered clinical service with a holistic view to their healthcare'.[79] In particular there was support for family cancer centres, especially from patient groups associated with this disease.[80] In general, family (or familial) cancer centres provide genetic testing, medical advice, genetic counselling and psychological support to patients and their families who have health issues associated with cancer. Some feared that this comprehensive and supportive approach to genetic testing for cancer and other conditions could be at risk if patents restrict genetic testing to a limited number of laboratories.

3.67 The NSW Government noted that the impact of genetic test results on patients can be challenging and complex. Test results can indicate risk but do not indicate if and when symptoms will develop. Certain results can impact on a person's ability to obtain life insurance or employment and can have implications for health decisions. The NSW Government argued that it was therefore 'vital that supportive clinical processes, including provision of information and counselling, are provided to assist individuals with informed decision-making'.[81] The Victorian Government also commented on the benefits of an integrated approach to genetic testing:

> For human genetics services, there are risks in separating diagnostic testing from expert interpretation, counselling and support. All of these functions are critical in ensuring that individuals are accurately and fully informed of the implications of their test results.[82]

3.68 Genetic counselling was also seen as important because of the wide implications of genetic testing for family members.[83] Associate Professor Judy Kirk commented on some of the challenges facing those undertaking genetic testing:

> …before a family goes ahead with testing, they need to understand what the implications would be for the men and the women of the family. They need to understand the health implications, what it might mean for their children and what it might mean in terms of accessing insurance. They need to think about what sort of screening and prevention measures we would have in the event of a positive genetic test which shows a high risk and how they would communicate that to the rest of the family, and notify at-risk family members.[84]

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79 Dr Jennifer Leary, *Submission 39*, p. 7.

80 For example Cancer Voice NSW, *Submission 47*, p. 2.

81 NSW Government, *Submission 54*, p. 5.

82 Victorian Government, *Submission 61*, p. 3.

83 Professor Ian Olver, Cancer Council Australia, *Committee Hansard*, 5 August 2009, p. 29.

84 Associate Professor Judy Kirk, *Committee Hansard*, 5 August 2009, p. 79.

3.69 The importance of genetic counselling was highlighted by witnesses from Breast Cancer Network Australia (BCNA), who described their experiences of obtaining genetic test results and the impact it had on their subsequent healthcare decisions. These decisions could include preventative surgery such as prophylactic mastectomies intended to reduce the risk of cancer.[85] The BCNA representatives noted that, without adequate communication, information and support, the results of a genetic test can be highly distressing and confronting for patients. They were concerned that, if gene patent rights were used restrictively, the genetic counselling component of current genetic testing processes could be lost and replaced by a commercially cheaper approach, where, for example, relevant samples are sent to external laboratories for testing and test results are then sent directly to the patient.[86]

3.70 Similarly, the Country Women's Association of NSW was concerned that gene patent monopolies may threaten the ability of healthcare authorities in Australia to deliver high-quality genetic testing services. In particular, the Association was concerned that:

> …one-on-one friendly counselling would be lost if public hospitals lost their right to do testing on a privately patented gene and the entire nation's testing done through one commercial centre'.[87]

3.71 Misgivings about the potential for gene patents to alter the current public sector approach to genetic testing were also expressed by the Human Genetics Society of Australasia (HGSA). Under the current model, access to testing in the public sector is targeted to individuals assessed as being at high risk. Testing is conducted through specialist genetics and associated medical services in conjunction with appropriate genetic counselling. The HGSA noted that this approach limits unnecessary testing and ensures patient consent to testing is well informed and valid. The HGSA was concerned that:

> Exclusive intellectual property rights may encourage commercialisation and direct marketing [of genetic tests] to the wider, generally low risk, community, and thus may exploit anxiety, have questionable clinical utility and be costly to individuals.
>
> Genetic tests with health implications should not be available in direct to consumer form but through request by a qualified health care professional in an appropriate clinical setting, in order to provide the person with the relevant information and counselling so that consent to testing is well informed and valid. This is especially the case with patented tests, where

85 Mrs Kristi Smith, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, pp 84-85; Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, pp 85-89.

86 Breast Cancer Network Australia, *Submission 48*, p. 5.

87 Country Women's Association of NSW, *Submission 35*, p. 4.

> lay individuals may have unrealistic expectations of the potential of such tests. Patenting does not guarantee efficacy or clinical utility in all cases.[88]

3.72 Dr Jennifer Leary also warned that patent monopolies 'have the potential to result in an increase in 'direct to market' advertising of genetic tests'. Dr Leary stated:

> The U.S and Canadian experience of 'direct to market' advertising has resulted in the exploitation of breast cancer anxiety and increased private testing of those for whom the clinical utility of the test is questionable. Market driven access to testing also has the potential to reduce the spectrum of tests available.[89]

The future of genetic testing and treatment

3.73 While the Committee's terms of reference were directed at the impact that the granting of gene patents 'has had, is having and may have had', many submissions and witnesses were more concerned about future impacts, particularly on the cost and provision of healthcare. There was a general consensus that the trend in genetic testing and treatment would move toward testing multiple genes or whole patient genomes as testing techniques improve and the cost of testing decreases. The results of these tests would then be used to personalise treatment for each patient and effectively target treatments.[90]

3.74 Professor Ron Trent argued that the focus should be on genomics rather than genetics, noting the possibility that in five to ten years whole genome sequence tests may be completed for $1000. He highlighted that tests involving multiple genes were more likely to encounter problems with gene patents. Professor Trent stated:

> We are now in the genomics era…We have had a discussion today about single genes, yet we know that there are tests that will test 20, 30 or 40 genes at once. Goodness knows what sorts of patent issues are involved in 30 or 40 genes in one test.[91]

3.75 The United States Secretary's Advisory Committee on Genetics, Health and Society final report on gene patents also dealt with this issue. It noted that developing whole-genome sequencing will likely depend on acquiring multiple rights. Negotiating licences to all the relevant patents could be expensive and the cumulative cost of these licenses could make these products unmarketable. It stated:

> These concerns are more than hypothetical. Patents are already hindering the development of multiplex tests [which test multiple genes]. Laboratories

88 Human Genetics Society of Australasia, *Submission 33*, p. 3.

89 Dr Jennifer Leary, *Submission 39*, p. 7.

90 For example, Dr Gillian Mitchell, *Committee Hansard*, 4 August 2009, p. 104.

91 Professor Ron Trent, *Committee Hansard*, 5 August 2009, p. 76.

> utilizing multiplex tests are already choosing not to report medically significant results that pertain to patented genes for fear of liability.[92]

Training and accreditation for healthcare professionals

3.76 While the use of genetic testing was described as increasingly common in a broad range of healthcare areas, the health professionals most closely involved in genetic testing and services were identified as being:

- clinical geneticists (specialist medical practitioners);
- genetic pathologists;
- geneticists (specialist medical laboratory scientists); and
- genetic counsellors.

3.77 The Department of Health and Ageing noted that the training and accreditation of healthcare professions is a responsibility shared between the university sector and a range of professional bodies, such as the Australian Medical Council, specialist medical colleges, nursing registration boards, and the Australian Psychology Accreditation Council. Specialist medical education is delivered by specialist colleges, faculties and chapters. A National Registration and Accreditation Scheme for a number of professions including medical practitioners, nurses and psychologists commenced on 1 July 2010. The Division of Paediatrics and Child Health in the Royal Australasian College of Physicians and the Royal College of Pathologists of Australasia are particularly involved in genetic testing and services.[93]

3.78 The Medical Technology Association of Australia highlighted that tests not covered by Medicare—which represent the majority of genetic tests conducted—have not been subject to significant regulatory oversight in Australia, and laboratories performing these tests have not necessarily been accredited by the National Association of Testing Authorities. However, it noted that this lack of certainty about genetic testing quality will change with the arrival of regulatory oversight of genetic testing through the in vitro diagnostic regulatory framework to be administered by the Therapeutic Goods Administration.[94]

3.79 The Department of Health and Ageing commented that the new framework would 'ensure the quality of all therapeutic devices, including in vitro diagnostic kits used for genetic testing, and reduce the risk of test kits producing unreliable results'.[95] The new framework commenced on 1 July 2010. The Department's submission stated:

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92 Secretary's Advisory Committee on Genetics, Health, and Society, *Gene patents and licensing practices and their impact on patient access to genetic tests*, April 2010, p. 3.

93 Department of Health and Ageing, *Submission 62*, p. 3.

94 Medical Technology Association of Australia, *Submission 43*, p. 4; Department of Health and Ageing, *Submission 62*, p. 4.

95 Department of Health and Ageing, *Submission 62*, p. 4.

> The framework is being introduced to address concerns that many of these technologies are available on the Australian market with no regulatory oversight and no certainty that they perform as intended. Of key concern is genetic self-testing whereby people may order tests via the internet or direct from a provider, without essential information, counselling and support needed to deal with the results.[96]

3.80 Several submitters to the inquiry did not consider that the granting of patents for genetic materials could have an adverse impact on the provision of training and accreditation of healthcare professionals.[97] The Walter and Eliza Hall Institute of Medical Research (WEHI) noted there was a current shortage of molecular pathologists in Australia. However they considered this was due to a lack of funding and career attraction, and the rapid growth in molecular diagnostics, rather than gene patents. The WEHI did not believe that expressly prohibiting gene patents would have a positive impact on Australia's skill base, and pointed out that the most skilled countries in this area are those that allow the patenting of human genes.[98]

3.81 Others considered that, if gene patents caused genetic testing to be limited to private laboratories, or led to samples being sent overseas for testing, this could negatively impact the training and accreditation of healthcare professionals in Australia. For example, the Human Genetics Society of Australasia stated:

> Enforcement of patents may take testing off-shore or to a sole licenser resulting in the loss or lack of development of local expertise and opportunities for training…
>
> Monopoly rights may create disenfranchisement of other laboratories, usually public hospital/research laboratories, through loss of expertise and trained staff, which may further negatively impact on skill and scientific developments transferable across the range of laboratory tests.[99]

3.82 The Victorian Government stated that the current genetics workforce is predicted to be insufficient to meet future demand. It was concerned that a concentration of genetic testing in private laboratories could reduce the opportunities for student training and professional accreditation. It also noted that higher licensing costs on public laboratories could translate into fewer enrolments and increased course fees for genetics courses.[100] CCA also noted the importance of academic institutions maintaining internationally competitive standards, 'particularly at a time of medical

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96 Department of Health and Ageing, *Submission 62*, p. 4.

97 Davies Collison Cave, *Submission 27*, p.7; Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 9.

98 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, p. 13.

99 Human Genetics Society of Australasia, *Submission 33*, p. 3.

100 Victorian Government, *Submission 61*, p. 3.

workforce pressure and when the scope of genetic medicine is on the threshold of significantly widening'.[101]

3.83 A number of submissions commented on the potential risks for training and accreditation in the event that restrictive licensing approaches by patent owners cause public laboratories to reduce the number and variety of genetic testing services offered. The National Coalition of Public Pathology argued that patenting a process that provides exclusive access to a gene will hinder 'the transfer of knowledge and expertise among health professionals in new areas of knowledge and professional development'.[102] Similarly, the RCPA argued:

> By restricting testing to one laboratory, the training of the next generation of pathologists and laboratory scientists in the area covered by the patent will be impaired. Further it will limit the number of knowledgeable and trained individuals who can assist in the diagnosis and management of at-risk patients.[103]

3.84 The importance of laboratories sharing testing results and expertise to improve professional development was emphasised in several submissions.[104] Associate Professor Judy Kirk described data exchange amongst professional peers, benchmarking and continuous improvement as 'fundamental to the optimal training and accreditation of healthcare professionals'.[105] Dr Jennifer Leary observed:

> Training and subsequent accreditation of scientists in the molecular genetic discipline depends on access to the experience of others, availability of DNA and clinical resources to expand knowledge and the sharing of scientific information. The granting of patents will have a negative impact on the ability to train molecular genetic scientists and clinical trainees specialising in molecular pathology…
>
> …[if] DNA resources for testing become concentrated in laboratories with the monopoly rights to test, scientific skills will degrade through a lack of opportunity to undertake such training across the broad range of tests required.[106]

3.85 The RCPA noted that long complex genetic testing, such as for the BRCA1 and BRCA2 genes, allows professionals performing this work to gain skills that are applicable in other areas of genetic testing. The RCPA submitted that, if such testing were done in a single laboratory 'the loss of volume, complexity and training

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101 Cancer Council Australia, *Submission 50,* p. 7.

102 National Coalition of Public Pathology, *Submission 40,* pp 2-3.

103 Royal College of Pathologists of Australasia, *Submission 49,* p. 12.

104 For example, NSW Government, *Submission 54,* p. 5.

105 Associate Professor Judy Kirk, *Submission 9,* p. 2.

106 Dr Jennifer Leary, *Submission 39,* p. 5.

opportunities would significantly compromise the operation and sustainability of the public sector laboratories'.[107]

3.86 Further, the RCPA felt that testing in multiple laboratories assists the assessment of diagnostic tests by benchmarking performance against peers and having independent assessment of external quality assurance.[108]

Progress in medical research

3.87 As outlined in Chapter 2, the main policy rationale for the patent system is to provide incentives for individuals and organisations to invest in research, development and innovation.[109] In order to receive protection, patent applicants must publicly release details of their inventions, allowing other researchers to utilise and build on the knowledge which has been disclosed. However, patents can also act as a brake on innovation where patent monopoly rights are used to impede the research of later innovators.[110] During the inquiry the Committee heard arguments highlighting these conflicting perspectives on the impacts of gene patents on medical research.

Incentives for medical research

Patent system driving innovation and research

3.88 A number of submissions noted that Australia's intellectual property system has supported innovation and research in medicine, and claimed that patents act as an incentive for investment, development and innovation in medical research.[111] This was seen as being true in the particular case of patents relating to genes and genetic material.[112]

3.89 The close relationship between intellectual property protection and funding for medical research was outlined by a number of companies and publicly funded research institutions. The Association of Australian Medical Research Institutes noted:

> For medical research institutes, a significant proportion of the income derived from the licensing of these innovations flows directly back to the institutes which fostered them, thus perpetuating a cycle of research and innovation.[113]

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107 Royal College of Pathologists of Australasia, *Submission 49*, p. 12.

108 Royal College of Pathologists of Australasia, *Submission 49*, p. 12.

109 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 7.

110 Professor Andrew Christie, *Submission 38*, p. 6.

111 FB Rice & Co., *Submission 34*, p. 1.

112 For example, Genetic Technologies, *Submission 24*, p. 4.

113 Association of Australian Medical Research Institutes, *Submission 72*, p. 2.

3.90 WEHI outlined the importance of intellectual property to its ongoing research and commercialisation program. Three of approximately 300 patents held by WEHI generate significant revenue. WEHI receives around $2.6 million in royalty income from patents annually, with $1.3 million of this being derived from patents on human gene sequences. This income supplements the substantial public funding provided by the Australian Government (approximately $48.1 million per annum) and overseas funding.[114]

3.91 WEHI advised that it had filed 30 patent applications in Australia claiming gene sequences, with 21 of these being commercialised through licensing. WEHI highlighted a number of inventions derived from their genetic research which would not have 'been progressed to their current stage within the pipeline leading to clinical adoption' without patent protection.[115]

3.92 The role of patent protection in offsetting the large investment costs of medical research for investors was seen as particularly important by some submitters.[116] Medicines Australia argued that guaranteeing a period of market exclusivity through the patent system was necessary to mitigate the extraordinary risks for companies in investing in research and development and bringing new therapies to market.[117] It was noted that many start-up companies relied on patent protection as a means of attracting capital, including direct foreign investment.[118] The Johnson & Johnson Family of Companies emphasised the high costs associated with developing genetic medical research:

> Patent protection provides investors with a high level of assurance that they will be able to recover the cost of development. This is particularly crucial in the biotechnology sector…[In order to] ensure return on investment a high level of importance is placed on eliminating unpredictability.[119]

3.93 Genetic Technologies also emphasised the positive impact of patents in the biotechnology area. They noted that products in this area generally take about ten years of research and development to bring to market. They argued that patents provided certainty for innovators and investors over these timeframes:

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114 Dr Julian Clark, Walter and Eliza Hall Medical Research Institute, *Committee Hansard*, 3 August 2009, p. 56; Walter and Eliza Hall Medical Research Institute, answer to question on notice, received 3 August *2009*, p. 1.

115 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, pp 3-5.

116 See, for example, Biotechnology Industry Organisation, *Submission 28*, pp 1-2.

117 Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 5 August 2009, p. 32.

118 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 8.

119 Johnson & Johnson Family of Companies Australia, *Submission 45*, p. 10.

> Inventors and investors need an appropriate system under which they have faith that the product that they plan to market will justify the cost of the research and development they are required to commit to in advance…[120]

3.94 The importance of the patent system in providing a stable framework which protects the intellectual property of innovators and facilitates technology transfers was also emphasised.[121] For example, IPRIA highlighted research showing how intellectual property protection assists 'upstream' biotechnology firms to sell or licence technology to 'downstream' pharmaceutical companies, who are then able to develop these technologies through the commercialisation process.[122]

Patent system hindering innovation and research

3.95 However, some stakeholders did not consider that the relationship between patents and incentives for progress in medical research in genetics was clear-cut.

3.96 Cancer Voices NSW (CVNSW) argued that there is no evidence 'that offering patents is necessary to encourage the identification or isolation of human genes', given the potential outcomes of other models for promoting innovation. As an example it pointed to Australia's funding contribution to the International Cancer Genome Consortium (ICGC), a voluntary scientific organisation which aims to create a catalogue of genomic abnormalities in tumours of different cancer types. Countries in the ICGC share information, allowing the comparison of different cancers. The NHMRC, which has contributed to the ICGC, describes it as one of the most ambitious biomedical research efforts since the Human Genome Project.[123] CVNSW was concerned that such approaches could in fact be undermined by the patenting of genes and genetic material:

> We are concerned that if genes and genetic material can be patented and if those patents are enforced this vital area of medical research will be more costly, slower and less translatable to the end beneficiaries: us.[124]

3.97 The SACGHS final report on gene patents found that the prospect of patent protection does not play a significant role in motivating scientists to conduct genetic research. While the report found that patent protection does stimulate some private investment in genetic research, it also found that patents could harm genetic research. It states:

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120 Genetic Technologies Ltd, *Submission 24*, p. 4.

121 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 9.

122 Intellectual Property Research Institute of Australia, *Submission 36*, p. 5; Joshua Gans and Scott Stern, 'The Product Market and the Market for "Ideas": Commercialization Strategies for Technology Entrepreneurs', 2003, vol. 32, *Research Policy*, p. 333.

123 National Health and Medical Research Council, *Report on the operations of the NHNRC: Strategic Plan 2007-2009*, p. 77.

124 Ms Sally Crossing, Cancer Voice NSW, *Committee Hansard*, 5 August 2009, pp 2-3.

> Although the patent law requirement of disclosure and description of a claimed invention is meant to expand the public storehouse of knowledge and stimulate follow-on research, there is evidence to suggest that patents on genes discourage follow-on research[125]

3.98 Senator the Hon. Bill Heffernan using the example of a patent on associated with the hepatitis C virus (HCV) stated that evidence received proved that 'Chiron's patent monopoly over the HCV biological materials impeded the development of diagnostic tests that were necessary for the continued health and wellbeing of the Australian people'. He argued that 'gene patents can so easily overreach, with unintended consequences on medical and scientific research'.[126]

3.99 The significant role of public and charitable funding of medical research was highlighted in relation to this issue. Dr Lim of IPRIA noted that one of the arguments made against gene patents was that much of the research in the area is publicly funded through government grants or completed at universities. Where this is the case, the granting of gene patents could be perceived as privatising a public good.[127]

3.100 Dr Hazel Moir also noted that a large part of the funding for the basic medical research on which patented products are based is often provided by governments or non-profit foundations. Dr Moir pointed to the apparent inequity of granting patents derived from research funded in this way, commenting that '[it seems harsh that] health departments should then have to pay monopoly prices for products whose development was largely funded by taxpayers or philanthropists'.[128]

3.101 Furthermore, Dr Moir observed that the patent system pre-dates the widespread use of publicly funded incentives for medical research—such as public financing of research and taxpayer subsidies for private investment in research. However, the scope of the monopolies rights granted by the patent system has not been reassessed to take these forms of public funding into account.[129]

3.102 Professor Ian Olver argued that competition is in fact the driving force for commercial medical research, and that allowing patent monopolies on genetic products or sequences actually hinders this competition. Professor Olver also noted that 'a lot of the great discoveries in the past have not relied on commercial interests', citing the achievements of the Human Genome Project as an example.[130] Similarly, Dr Anne Ronan stated that medical research is 'not always driven by profit', and that

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125 Secretary's Advisory Committee on Genetics, Health, and Society, G*ene patents and licensing practices and their impact on patient access to genetic tests,* April 2010, p. 3.

126 Senator the Hon. Bill Heffernan, *Submission 76*, p. 16.

127 Dr Kwanghui Lim, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, p. 3.

128 Dr Hazel Moir, *Submission 20*, pp 43-44.

129 Dr Hazel Moir, *Submission 20*, pp 43-44.

130 Professor Ian Olver, *Committee Hansard*, 5 August 2009, p. 8.

the research breakthroughs in medical knowledge can provide other benefits to companies 'in terms of status, staff development and publicity'.[131] Dr Ronan observed that:

> The absence of patents in other areas of medical research has not hampered medical research development. Most medical research is carried out because people have started off caring for patients and they desperately want to find answers.[132]

The anti-commons

3.103 The Committee also heard many concerns that patents on genes and related materials are detrimental to innovation and medical research. In particular, submissions referred to the 'tragedy of the anti-commons', which describes situations where the existence of numerous rights holders prevents socially desirable outcomes. In the case of gene patents, this can occur where the number and scope of patent rights inhibits research and innovation because of concerns about infringing patents or the difficulties of obtaining licences to use patented materials.[133]

3.104 Professor Nicol and Dr Nielsen commented that gene patents may have a greater impact on medical research because genes and related inventions are 'particularly powerful tools in biomedical research and product development'. Professor Nicol and Dr Nielsen argued that, where access to basic research is restricted, there is likely to be a detrimental effect on subsequent downstream research and development.[134] Despite the continuing advances in biomedical research and development, there remains potential for the scope and number of gene patents to adversely impact on this area:

> Owners of patents claiming broadly applicable foundational technology could refuse to license or license on a restrictive basis, blocking off whole areas of downstream innovation. And if the patent landscape is too cluttered, necessitating entry into licence negotiations over multiple patents, innovation could be further impeded or delayed, creating what has become known as a tragedy of the anticommons. Such negative impacts on innovation would be likely to have flow on effects in terms of consumer access, and could extend to basic upstream research as well...[135]

3.105 A number of submitters pointed to concerns about the fragmentation of ownership of patent rights in genes, and the potential for this to frustrate medical research. In particular, this could create uncertainty and impose additional transaction

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131 Dr Anne Ronan, *Submission 3*, p. 2.

132 Dr Anne Ronan, *Committee Hansard*, 5 August 2009, p. 64.

133 Michael Heller, 'Can patents deter innovation? The anticommons in biomedical research', 1998, vol. 280, *Science*, p. 698.

134 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 8.

135 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 10.

costs on researchers attempting to negotiate access to patented genetic inventions. Dr Graeme Suthers of the RCPA commented:

> …many genes that are patented currently have multiple patents on the one gene. If you track the ownership of each individual patent applying to this gene, you end up with a dense thicket of arrows [patents].[136]

3.106 The fragmentation of patent rights over genes and genetic material could lead to situations where a researcher, for example, will need to secure the consent of multiple rights holders in order to undertake research on a number of genes. In such cases, the refusal of any single one of those rights holders can effectively prevent the entire research project. Associate Professor Webster of IPRIA commented that there is 'little evidence that the anti-commons exists in Australia'. However, she noted that the state of empirical knowledge on this issue is poor, and the law may well need to account for the potential for the anti-commons to arise.[137]

3.107 WEHI did not consider that the available data supports the view that there is an anti-commons effect relating to gene patents in Australia. WEHI pointed to research in the US in which only one per cent of biomedical researchers reported having had to delay, and none had to abandon, a project as a result of patents. Conversely, the research found that 25 per cent of pathology laboratories had abandoned a genetic test as a result of patents. WEHI suggested that this was probably due to a lack of willingness to accept the market price and access terms. WEHI concluded:

> These observations suggest neither the anti-commons nor restrictions on access are seriously limiting academic research – despite the fact that biomedical researchers operate in a patent-dense environment, without the benefit of a clear research exemption. Fears of widespread anti-commons effects blocking the use of upstream discoveries have largely not materialised.[138]

3.108 IP Australia also commented that available data shows 'a rise in patents claiming downstream uses of isolated human nucleic acid molecules'. Mrs Fatima Beattie stated:

> This indicates to us that basic research and innovation are not being stifled by patents. The evidence so far is that licensing issues are often resolved in the market through commercial negotiations, except for isolated instances like BRCA.[139]

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136 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 40.

137 Associate Professor Beth Webster, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, pp 9-10.

138 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, pp 8-9.

139 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 28.

3.109 Professor Peter Drahos argued that the patent system has 'increasingly generated tremendous amounts of uncertainty' for medical researchers because of the volume of patent applications and new patents being granted. This uncertainty about breaching patent rights could cause medical researchers to become 'risk adverse'.[140] Professor Drahos's research found:

> Companies are often not sure that they have found all the patents relevant to a product on which they are working. They frequently have doubts about the scope of the patents they have found. Patents, unlike blocks of land, do not come with settled boundaries. These kinds of uncertainty are especially dangerous from the point of view of the public management of risk…[141]

3.110 However, Mr Hamer of the Law Council of Australia observed that, in his experience, research scientists are generally well informed about the patent system. Mr Hamer noted it was standard practice for researchers to '[conduct] searches before they engage in their research to ensure that they are not reinventing the wheel and to ensure that there is freedom to operate'. [142]

3.111 The Committee heard that patent attorneys regarded freedom-to-operate searches as a common practice to identify what patents may exist in relation to a given field. Such searches are commonly undertaken in the early stages of a research program.[143] Davies Collison Cave suggested that apprehensions about the adverse impacts of patent protection on genetic research 'to large extent [arise] from a lack of understanding by researchers of the patenting process as well as a lack of experience and expertise to commercial exploit research'.[144]

3.112 In contrast, the Committee also received a submission from Ms Naomi Hawkins, a UK researcher with an interest in patent issues, who described the main legal challenge of gene patents as being the difficulties of effectively conducting due diligence and the associated problem of a potentially crowded patent landscape. Despite this, Ms Hawkins suggested that patents in fact have a minimal impact on researchers. This is not because patents are being appropriately managed but because 'patents are essentially ignored by those who develop genetic tests in the public sector, and patent holders do not tend to take any enforcement action'.[145]

3.113 Dr Luigi Palombi commented that, in his experience, restrictions caused by gene patents can interfere with the ability of scientists to undertake research. While

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140 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 18.

141 Professor Peter Drahos, *Submission 60*, p. 450.

142 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 87.

143 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 10; Mr Richard Jarvis, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 88.

144 Davies Collison Cave, *Submission 27*, p. 7.

145 Ms Naomi Hawkins, *Submission 22*, p. 3.

most scientists ignore these restrictions, Dr Palombi noted that '[when] someone does decide to enforce those patents, all hell breaks loose'.[146]

3.114 CCA observed that there is significant investment in cancer research in Australia, and was concerned that gene patents might in fact be acting as a disincentive to cancer researchers. This is because:

> …[patents] give a patentee the ability to impose conditions on the use of these materials in the conduct of that research, including a requirement to share ownership of intellectual property that may result from that research.[147]

3.115 The 2004 ALRC report discussed such far-reaching or 'reach-through' license conditions, in which patent holders retain rights over future discoveries made by licensed researchers. The report noted that, while reach-through licence agreements may offer some advantages—for example, by permitting researchers to defer payment until research yields valuable results—they are perceived by researchers as benefiting patent holders disproportionately.[148]

3.116 The ALRC report stated that there is 'little evidence' that gene patents have had any significant adverse impact on the conduct of genetic research in Australia. It cited international studies which suggested that patent holders and researchers are capable of developing working solutions for dealing with problems. These solutions 'sometimes take time to work out, and may not be optimal, but research generally moves forward'. However, the report also noted that 'the current position may change, particularly if patent holders become more active in enforcing patent rights'.[149]

3.117 An example of a situation where restrictive licensing approaches have had significant impacts on medical research was described by PMCC. PMCC had planned to conduct tests on a large cohort of women to determine the frequency of BRCA1 and BRCA2 mutations. The study was being conducted in collaboration with a commercial partner, Myriad Genetics, who was to conduct the testing. However, it became apparent that Myriad Genetics would be in breach of a licensing agreement with Genetic Technologies if it did in fact conduct the tests. Professor Bowtell explained:

> We went to [Genetic Technologies] and told them this was a research study and it had implications for understanding the frequency of these mutations in the population and could actually be good for their business in the end. We asked whether we could go ahead and do this [BRCA testing] with

146 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, pp 15-16.

147 Cancer Council Australia, *Submission 50*, p. 7.

148 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, Report 99, 2004, pp 305 & 309.

149 Australian Law Reform Commission, *Genes and ingenuity: gene patenting and human health*, Report 99, 2004, p. 307.

> Myriad. It was an extraordinarily hostile reaction and…[Genetic Technologies] shut it down. Myriad was unable to move and that avenue completely collapsed.[150]

3.118 IP Australia noted that many comparable industries, such as 'software, electronics, organic chemistry and pharmaceuticals', have managed to deal with cross-licensing issues; there was no reason the biotechnology industry would not be able to deal with these issues in a similar way.[151] Professor Nicol noted that research results suggested that practical strategies to work around patents are being found in biomedical research and other areas that are impacted by gene patents. These strategies included:

- licensing and other collaborative arrangements;
- ignoring patents;
- working around patents; and
- challenging the validity of patents.

3.119 Professor Nicol stated that there 'are many reasons' driving the type and nature of the strategies being employed, including the difficulty for patent holders in pursuing infringers, the practical benefits of cooperative strategies and the uncertain validity of certain patents.[152]

3.120 The view that 'working solutions' had been developed to mitigate the negative impacts of patents on genetic medical research appeared to be supported by Pfizer Australia. Pfizer Australia advised that it licensed use of gene patents in the development of new medicines, and regarded licensing fees as part of normal business costs. These costs had not been a barrier to the development of new medicines.[153] Pfizer Australia stated that their own policy was explicit that gene patents must not impede research. The quoted policy stated:

> …gene inventions and, in particular, research tools should be readily available for non-commercial purposes consistent with the advancement of biomedical research. This may be achieved through scientific publications or patent licensing. In the latter case, patents should be available for licensing on a voluntary basis for non-commercial purposes. Such licenses should be available on a non-exclusive and non-discriminatory basis and under fair terms consistent with the advancement of biomedical research.[154]

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150 Professor David Bowtell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, pp 114-115.

151 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 29.

152 Professor Dianne Nicol, *Committee Hansard*, 3 August 2009, p. 28.

153 Pfizer Australia, *Submission 51*, p. 10.

154 Pfizer Australia, *Submission 51*, p. 10.

Research tools and databases

3.121 A number of submitters and witnesses expressed concern that gene patents would restrict the development of genetic medical research by preventing researchers from accessing genetic materials, samples and data held by companies.[155] For example, the BCNA saw a risk that:

> …gene patent holders may choose to charge a fee for access to data and samples, which could be prohibitive for publicly funded researchers, or which could place considerable additional burdens on their research budgets.[156]

3.122 There were also concerns that monopoly testing may create restricted knowledge bases and remove opportunities for shared knowledge in research and improved result interpretation.[157] Dr Jennifer Leary warned that the monopolisation of testing due to gene patents could result in information on genetic variants being 'locked up' by companies, which would treat such data as a valuable commercial asset. Dr Leary also highlighted the importance of information sharing for genetic research and clinical care:

> Sharing knowledge of mutations is essential to understanding the clinical significance of the rare variants that can be observed in genes. Access to unpublished experimental data, knowledge of the frequency of observations, knowledge of instances of co-occurrence with other variants in addition to robust exchange of ideas amongst a variety of scientists can all help to unravel the complexity faced in the interpretation of the variants.[158]

3.123 With particular reference to the BRCA genes, Dr Luigi Palombi argued that the cost of allowing gene patents to be enforced includes 'the opportunity cost for Australian laboratories to gather important scientific data'. Dr Palombi described this data as vitally important to improve the reliability of BRCA gene testing. This is because the genes are complex and lack universally applicable genetic markers, which means there is a need for the data to be shared among laboratories.[159] The importance of accessible databases of genetic testing was also raised by the RCPA, who argued patents on genetic materials could create exclusive databases of genetic variants. The RCPA submission explained:

> If genetic testing is provided by multiple laboratories, they will often pool their records of genetic variants in public databases. As more data accumulate about the frequency of variants and their association with

155 Ms Janet Green, Breast Cancer Action Group, *Committee Hansard*, 5 August 2009, p. 3.

156 Breast Cancer Network Australia, *Submission 48*, p. 4.

157 Human Genetics Society of Australasia, *Submission 33*, p. 2; NSW Government, *Submission 54*, p. 5.

158 Dr Jennifer Leary, *Submission 39*, p. 4.

159 Dr Luigi Palombi, *Submission 4, Part 2*, p. 42.

> disease, this information will help laboratories to interpret variants and provide useful information to requesting clinicians and patients. These databases are in the public domain and are a resource for other laboratories, researchers, companies, and policy makers.
>
> If testing of a gene is provided by a single laboratory, there is no incentive to create a public database of variants. In effect, the information about genetic variants becomes the property of the patent-holder, with no opportunity for this information to be reviewed by independent researchers, or made available for public analysis.[160]

3.124 Other stakeholders were concerned that gene patents could jeopardise successful relationships established between clinical care and medical research entities. HGSA argued that gene patents may limit the further investigation that currently occurs in public hospital laboratories as new variants are identified, and stressed that 'the line between service and research is not always clear'.[161]

3.125 HGSA also emphasised the importance of the relationships between patients, healthcare professionals and medical researchers. In many cases, samples taken from patients for genetic testing are held by laboratories to enable further research. As new medical data becomes available, laboratories can return to stored samples for further testing. The results of new tests can then assist the healthcare of patients and feed back into ongoing medical research.

3.126 Ms Heather Drum, a member of BCNA, was concerned that there is potential for patent holders to enforce their rights over the BRCA genes and affect the ability of researchers to continue to conduct research on tissues and samples donated by individuals and families.[162] Ms Drum commented:

> We have been confident to donate various tissues from the surgeries, secure in the knowledge that it will be used in research by Peter Mac. We have been assured our tissues will continue to be used in research and even retested for the BRCA1 and 2, should further discoveries be made.
>
> …we are one of those families where the tissue is really important to the researchers. I would feel really devastated if the tissues my sisters and I have donated were used to make money out of patenting thereby excluding other women from being treated appropriately on the basis of future breast cancer research.[163]

3.127 The South Australian Government stated that private sector research is published much less frequently than research done in the public sector. The South

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160 Royal College of Pathologists of Australasia, *Submission 49*, p. 13.

161 Human Genetics Society of Australasia, *Submission 33*, p. 2.

162 Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, p. 89.

163 Ms Heather Drum, Breast Cancer Network Australia, *Committee Hansard*, 3 August 2009, p. 89.

Australian Government submission suggested that if genetic testing is concentrated in the private sector 'there is a risk of genetic data residing with this sector, making it difficult for staff with the public health system to access data for population health studies'.[164]

3.128 However, WEHI noted that it had not experienced any restrictive licence requirements that have prevented it from conducting further research. Nor had it experienced any infringement or enforcement challenges. Further, WEHI's patents have not impeded rapid publication in the public domain.[165] The WEHI submission commented that:

> …gene patents have had no negative impact on WEHI's research activities and ability to innovate. Furthermore, we believe that rather than hindering dissemination of research results, patents actually reduce the possibility of information being kept as trade secrets.[166]

The general research exemption

3.129 Patents confer monopoly rights that exclude others from using the invention, including those who wish to use the invention for research (unless they obtain a licence from the patentee). There is no specific exemption for research or experimental use in the *Patents Act 1990*, and it is unclear whether a defence of research or experimental use is available under Australian law (because it has not been tested in the courts).

3.130 However, the committee heard that there is a widespread belief in research institutions that a general research exemption exists in Australia, which allows research to be conducted on patented materials.[167] Many institutions rely on this belief to conduct research or to experiment on patented materials, despite being unsure as to the scope and limits of any such assumed exemption.[168]

3.131 The Committee heard that IP Australia is in the process of public consultation over a proposed statutory experimental use exemption.[169] This issue is discussed further in Chapter 5.

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164 South Australian Government, *Submission 16*, p. 10.

165 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, p. 5.

166 Walter and Eliza Hall Institute of Medical Research, *Submission 26*, p. 8.

167 Intellectual Property Research Institute of Australia, *Submission 36*, p. 7.

168 See, for example, Mr John Slattery, Davies Collison Cave, 4 August 2009, *Committee Hansard*, p. 10.

169 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 31.

Health and wellbeing of the Australian people

3.132 The broad scope of the term of reference relating to the 'health and wellbeing of the Australian people' invited evidence covering a number of issues. Much of this evidence repeated or elaborated on the matters discussed above relating to the provision and costs of healthcare, training and accreditation of healthcare professionals and the progress of medical research. A number of submitters and witnesses felt that the granting of patent protection in respect of genetic materials has not had any direct impact on the health and wellbeing of the Australian people.[170]

3.133 Several submissions focussed on the economic and employment benefits of the fields of biotechnology and medical research which are supported by patent protection. For example, the Tasmanian Government noted that healthcare issues need to be balanced against the economic benefits of the 'biotechnology and pharmaceutical industry, which can produce highly successful companies'.[171]

3.134 IP Australia commented that, while it is difficult to isolate the contribution of gene patents, the Australian pharmaceutical industry employs 40,000 people and was Australia's second largest exporter of manufactured goods in 2008.[172] IP Australia submitted research which attempted to calculate the 'patent premium' in Australia—the implicit subsidy provided to innovators through the patent system. Although this did not address the specific impact of gene patents, the overall patent premium was estimated to be $12 billion, which is 'much larger than the support to innovators via direct transfers from the government or fiscal incentives'.[173]

3.135 The Institute of Patent and Trade Mark Attorneys of Australia (IPTMAA) highlighted the number of patent applications filed in the area of biotechnology by Australian research institutes. IPTMAA argued that, without the possibility of obtaining patent protection, a number of well-known Australian biotechnology innovations may not have achieved commercial success. IPTMAA also noted that 33 of the 90 companies listed on the Australian Securities Exchange (ASX) in the Pharmaceuticals, Biotechnology and Life Sciences Industry Group had applied for, or obtained, patents in the area of biotechnology.[174]

3.136 Genetic Technologies identified itself as an Australian company 'built on so-called gene patents' that employs 61 people in Australia and generated $16 million revenue in 2008. Genetic Technologies argued that it is a significant contributor to the

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170 Davies Collison Cave, *Submission 27*, p. 8.

171 Tasmanian Government, *Submission 53*, p. 1.

172 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 8.

173 Paul Jensen et al, *Estimating the Patent Premium: Evidence from the Australia Inventor Survey*, Intellectual Property Research Institute of Australia, Working Paper 11/09, May 2009, p. 25.

174 Institute of Patent and Trade Mark Attorneys of Australia, *Submission 31*, p. 12.

Australian economy and has made a positive contribution (in the order of $60 million) to Australia's balance of payments.[175]

3.137 The Committee also heard about the emotional and financial stress experienced by patients and their families undergoing genetic testing. For example, Dr Belinda Coyte advised that there was a considerable financial burden in obtaining complicated genetic testing for her son, including tests which were only available overseas and subject to considerable delay.[176] Ms Trish Carey, whose daughter died of a complication of Marfan Syndrome, explained genetic testing for her granddaughter in relation to this condition could cost approximately $3000. The point was made that restrictive enforcement of patent rights in relation to genetic testing could add to the stress and the costs incurred by patients and their families.[177]

3.138 Others noted that the impacts of gene patents are potentially very broad, and extend beyond the realm of healthcare to other industries, including agriculture and conservation. For example, Dr Rimmer noted the potential of current gene research in the field of energy and global warming:

> J Craig Venter, who did shotgun sequencing of the human genome, is now applying that same technology to shot gun sequencing the world's micro-organisms in the oceans under the Sorcerer II Expedition. His synthetic genomics project is very much focused on developing novel minimal genomes to address certain concerns about biofuels, partly funded by the department of energy.[178]

3.139 The privacy of genetic test results and the potential for discrimination based on those results, particularly in the area of healthcare and life insurance, were also issues raised with the Committee. Reference was made to decisions made by the European Patent Office, which upheld the rights of Myriad Genetics over particular mutations in BRCA2 associated with a predisposition to breast cancer among the Ashkenazi Jewish community. Consequently, in certain overseas jurisdictions patients with this ethnic background were likely to pay more for this type of genetic testing.[179]

3.140 The BCNA argued that strict rules need to be put in place to ensure that genetic data is not treated as a commodity and that the privacy of patients using genetic testing services is ensured. The BCNA observed:

> …the granting of gene patents could increase the risk of discrimination against women and men who test positive to a genetic mutation such as the

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175 Genetic Technologies Ltd, *Submission 24*, p. 6.

176 Dr Belinda Coyte, *Submission 55*, p. 2; Dr Belinda Coyte, *Committee Hansard*, 4 August 2009, pp 93-96.

177 Ms Trish Carey, *Submission 56*, p. 1.

178 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 23.

179 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 47.

> BRCA 1 or BRCA 2 gene mutation. We are concerned that a company that holds the sole right to test for the presence of a gene or gene mutation would also hold a significant amount of personal genetic information.[180]

3.141 The Department of Health and Ageing noted that the management of privacy issues in healthcare has been challenged by the implications arising from genetic technologies. It commented that insurers are currently not able to ask, or indirectly coerce, applicants for insurance to undertake genetic testing. However, the Department also noted:

> Currently, the position is that an insured person's duty of disclosure to his or her insurer includes an obligation to disclose knowledge which that person has acquired through genetic testing Moreover, insurers are not prevented from requesting family history and genetic testing results, from which they can make decisions about whether to insure individuals or not, and if so, upon what terms.[181]

CONCLUSION

3.142 While scientific understanding of genetics has progressed over the years since the report by the ALRC into gene patents, the indications concerning the impacts of gene patents in Australia appear to have remained largely the same. The actions of Genetic Technologies in relation to BRCA1 and BRCA2 have renewed many of the concerns about gene patents held by government officials, healthcare professionals, researchers and patient groups. However, the evidence the Committee received concerned only isolated examples of impacts from gene patents on healthcare, training and accreditation of healthcare professionals, medical research and the health and wellbeing of the Australian people.

3.143 Although evidence of negative impacts caused by gene patents was relatively sparse, significant potential impacts were highlighted during the inquiry. The Committee was concerned that there do not appear to be strong mechanisms in place to effectively monitor the impacts of gene patents. Without this information it is difficult for policy makers and regulators to respond to the potential impacts of gene patents, should they occur.

3.144 Despite such concerns, the Committee could not therefore conclude that gene patents have caused significant impacts on the provision and costs of healthcare in Australia to date. The Committee also acknowledges that it is possible that patent protection has, at least in some cases, encouraged innovation and thus had positive impacts on the delivery of health services through the development of better testing and treatments. This may have led to lower healthcare costs, for example, by introducing genetic testing to target expensive treatments.

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180 Breast Cancer Network Australia, *Submission 48*, p. 6.

181 Department of Health and Ageing, *Submission 62*, p. 4.

3.145 The granting of patent monopolies has been associated with some accessibility and affordability issues for patients. However, it is difficult to determine the contribution gene patents have made to these issues, which are also subject to other factors such as the rapid development of, and increased demand for, genetic testing and treatment, and the level and structure of public funding.

3.146 The evidence received clearly identified the use of closed, restrictive or exclusive licensing models by gene patent holders as a key potential risk to the accessibility, affordability, accuracy and timeliness of genetic testing services. While there is theoretically no limit to what a patent holder might seek to charge for a licence, commercial realities mean that the more usual outcome is that negotiated licence agreements will result in a level of charge that reflects what potential licence holders can afford and are willing to pay.[182] However, the Committee notes that patent regulators and regulation should be robust enough to ensure that they can respond to instances where commercial influences fail to ensure broad licensing of patents which are important to the health and wellbeing of Australians. These licensing issues are considered further in Chapter 5.

3.147 The potential impact of gene patents on the current integrated public sector approach to genetic testing was highlighted by a number of submissions and witnesses. It was clear to the Committee that this poses risks in several areas which will need to be closely monitored by IP Australia and health departments around Australia. The possible affected areas include the number and capacity of public laboratories conducting genetic testing, the relationship between genetic testing and standards of clinical care, and the provision of medical advice and genetic counselling to patients using genetic testing services.

3.148 The Committee received little evidence concerning the impacts of gene patents on the training and accreditation of healthcare professionals. However, restrictive approaches to licensing by gene patent owners were again identified as a key potential risk. Genetic testing being conducted in a restricted number of laboratories, or samples required to be sent overseas for testing as a consequence of patent rights, would clearly reduce opportunities for training and limit the development of expertise for Australian healthcare professionals.

3.149 The evidence presented to the inquiry revealed that there are few instances in Australia where enforcement of a patent has restricted medical research. However, examples where gene patent licensing has impeded research, including the incident described by the Peter MacCallum Cancer Centre, indicated this could be a problem area in the future. The lack of impacts on medical research may be due to researchers ignoring patent rights or assuming that an exemption exists for medical research and experimental use. Patent protection was seen by many as an important incentive for the encouragement of research and to offset the large investments required to undertake research and development. Again, restrictive licensing approaches by patent

182 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 29.

owners were perceived as a key potential risk through reducing access to research tools and databases, contributing to anti-commons scenarios which restricted research, and by creating uncertainty for medical researchers.

3.150 Evidence to the inquiry indicated that there is a lack of accessible data in relation to gene patents. The Committee notes that many witnesses and submitters argued that policy in relation to gene patents should be based on evidence and research rather than apprehensions regarding circumstances which may occur in the future. Others highlighted the lack of research and empirical evidence available concerning the impacts of gene patents.

3.151 The *Australian Genetic Testing Survey 2006* was undertaken in response to the lack of available data on the level of demand and supply of genetic testing. The RCPA undertook the survey in consultation with the Human Genetics Society of Australia and with funding from the Department of Health and Ageing. This collaborative approach to data collection and analysis in relation to genetic testing and healthcare should be encouraged, expanded and regularly updated. The debate over gene patents would benefit from increased empirical evidence and research concerning the costs and provision of genetic testing and treatment.

3.152 The ALRC's report considered that the impact of genetic technologies needed to be closely monitored by health policy makers in Australia. The ALRC recommended that the Australian Health Ministers' Advisory Council 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.[183] The Committee agrees that better information in relation to the use of gene patents in Australia is needed.

3.153 Professor Drahos and others have also suggested the establishment of a patent transparency register, whereby companies would be required to disclose patent holdings in designated subject matter areas. The system would be intended to promote transparency and to overcome some of the issues relating to accessibility of information regarding gene patents, which may act as barriers to research and innovation. A proposal was also made by Dr Moir to include a requirement in the patent renewal process to regularly require patent owners to disclose the use of their monopoly rights.[184] This would be an additional administrative burden on patent owners but would allow policy makers to track the use and enforcement of patents. While the Committee considers these suggestions to have merit, it notes that other submissions, particularly those from research institutes and relevant companies, have not highlighted this as an area of reform.

3.154 Given the lack of comprehensive, systematic and accessible data and information on the impact of patents generally, and of the impacts of gene patents on

183 Australian Law Reform Commission, *Genes and Ingenuity*, 2004, pp 470-472.

184 Dr Hazel Moir, *Submission 20*, p. 39.

healthcare and medical research in particular, the Committee considers that the Government should support the development and maintenance of better systems to collect patent data and information as per Recommendation 19-1 of the 2004 ALRC report, which states:

> **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.[185]

This information will facilitate assessments regarding the costs and benefits of gene patents in relation to healthcare and medical research in Australia.

3.155 The Committee also endorses the need to establish a patent transparency register. The Committee considers that these initiatives will also support the activities of an external oversight body for the patent system in Australia (see Recommendation 15 and related discussion in Chapter 5).

Collection of patent data and information

Recommendation 1

3.156 The Committee recommends that the Government support and expand on the collection of data, research and analysis concerning genetic testing and treatment in Australia, in line with recommendation 19-1 of the 2004 Australia Law Reform Commission report *Genes and ingenuity*.

Establishing a patent transparency register

Recommendation 2

3.157 The Committee recommends that the Government conduct a public consultation and feasibility study regarding establishing a transparency register for patent applications and other measures to track the use of patents dealing with genes and genetic materials.

185 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 472.

CHAPTER 4

EXPRESS PROHIBITION OF GENE PATENTS

4.1 This chapter addresses term of reference (c), which directs the Committee to consider whether the *Patents Act 1990* (the Act) should be amended so as to expressly prohibit the grant of patent monopolies over human genes and genetic materials.

4.2 The focus of this chapter is on arguments that, notwithstanding the current practice of granting patents claiming human genes and genetic material in Australia, gene patents do not satisfy the requirements of patentability under the Act, and so should be expressly prohibited. It also considers issues around the effectiveness of, and possible alternatives to, this approach.

4.3 The analysis in the previous chapter of impacts arising from gene patents is also relevant to arguments for an express prohibition on gene patents, and to the conclusions at the end of this chapter.

INTRODUCTION

4.4 As noted in Chapter 2, the Act provides a specific exclusion for human beings and the methods of their reproduction; a number of general grounds of exclusion, such as 'contrary to law' and 'generally inconvenient; and a discretion granted to the Commissioner of Patents to refuse a patent application for other types of inventions. However, the Act does not specifically exclude the patenting of genetic materials.

4.5 An express exclusion on gene patents in Australia has been considered previously. It was considered in relation to the Patents Bill 1990, but not supported by the Senate Standing Committee on Industry, Science and Technology. The amendment would have excluded genes, genetic material and genetically modified organisms from patentability.[1] An amendment to the Act of similar effect was proposed by the Democrats' Senator Natasha Stott-Despoja in 1996 and 2001; and re-tabled in 2002 without any subsequent consideration. 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 section 18 [of the Act]'.[2]

4.6 A number of submitters and witnesses supported a recommendation that the Act be amended to expressly prohibit the grant of monopolies over human genes and gene patents. These groups generally represented stakeholders in the research, healthcare, health advocacy and public health sectors. In contrast, other groups did not support any such recommendation. These groups generally represented stakeholders in

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1 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 170.

2 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 170.

the intellectual property (IP) sector, such as IP regulators and patent attorneys, and commercial entities such as biotechnology and pharmaceutical companies.

Types of gene patents

4.7 An isolated or purified genetic sequence for which a use has been identified may be regarded as an invention for the purposes of the Act, and may therefore be patentable (providing all other requirements for patentability are met). The Department of Innovation, Industry, Science and Research (DIISR) and IP Australia submission noted:

> Australia's current patents law does not give IP Australia any basis in law to refuse to patent genes, nucleic acid or protein sequences defined by their corresponding DNA sequence solely because the patent relates to these areas of technology. As such, IP Australia has granted patents over isolated and purified gene sequences, when other requirements for patentability under the *Patents Act* are met.[3]

4.8 IP Australia advised that it has granted patents over a wide range of human genes and genetic material, and noted that patent claims may relate to a product, a process for making a product and to a method of making or using a product. In relation to gene patents, typical product claims include:

- an isolated gene sequence per se;
- an isolated protein encoded by the gene sequence;
- vectors harbouring the isolated gene sequence;
- cell lines transformed with the vectors or sequence;
- recombinant protein expressed from the cell lines;
- antibodies produced using the sequence or fragments of the sequence;
- probes comprising the sequences or fragments;
- vaccines and compositions comprising the sequence or protein; and
- kits comprising the sequence or specific primers or fragments of the sequence.

4.9 Typical method claims include:

- use of the gene or protein sequence to diagnose or prognose disease or disorders associated with the gene;
- use of the sequence and/or protein as a therapeutic to treat a disease or disorder associated with the gene
- methods of identifying molecules that modulate or interact with the gene wherein the methods are directly based on the use of the sequence; and

3 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 3.

- a gene therapy using the sequence.

Extension of patent law to human genes and genetic materials

4.10 As described in Chapter 2, the principles for determining the patentability of any given subject matter under the Act were laid down in 1959 in *National Research Development Corporation v The Commissioner of Patents* (the NRDC case).[4] A patent may only be granted for an 'invention', which is defined as 'any manner of new manufacture'. A 'policy-oriented approach' is adopted in considering whether a particular invention is a manner of new manufacture. In summary, for an invention to be a manner of manufacture:

- it must belong to the useful arts (as opposed to the fine arts);
- it must provide a material advantage; and
- its value to the country must be in the field of economic endeavour.[5]

4.11 The precedents in the NRDC case have established a 'flexible and permissive approach to patenting new technologies in Australia',[6] which has allowed the extension of patent protection to subject matter that has historically been excluded from such protection, including methods of medical treatment, living organisms, computer software, and biological and human genes and genetic materials. The Advisory Council on Intellectual Property (ACIP) options paper on patentable subject matter observes that 'patenting in each of these fields has been controversial'.[7]

Judicial interpretation of the Act regarding non-patentable subject matter

4.12 In addition to the NRDC case principles, Australian courts have expressed a general reluctance to 'read in' further exclusions to patentable subject matter on the basis of ethical or policy considerations.

4.13 Dr Hazel Moir pointed to historical and legal factors as the basis of this reluctance of courts to exclude certain subject matter from patentability. Dr Moir explained that, at the time the Act was drafted and presented to parliament, it was agreed that the Act would not list specific exclusions on patentable subject matter, despite awareness and acknowledgment of traditional classes of unpatentable subject matter. Dr Moir explained:

> The *Patents Act 1990* resulted from a review of the patents act that was commissioned by the Fraser government and reported to the Hawke government. The Intellectual Property Advisory Committee put forward

4 (1959) 102 CLR 252.

5 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 120.

6 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 2.

7 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 2.

> this report, which had a number of recommendations in it [as to whether or not certain subject matter should be patentable. However, the committee]…recommended against adopting a European type system that listed exclusions—things that could not be patented. [At] no point in the parliamentary debate was there any disagreement between the major parties over the legislation that the government brought, and the legislation the government brought specified no exclusions. They accepted the recommendation of the committee that it was not useful to go down the European track and list the exclusions.[8]

4.14 Dr Moir explained that, despite the agreement that the Act would not contain specific exclusions, in negotiating the passage of the Act through the Senate a specific exclusion on human beings and the methods for their reproduction was included to win the support of the then balance of power holder, Senator Brian Harradine.

4.15 The Committee heard that the inclusion of the specific exclusion on human beings and the methods for their reproduction has had a significant and unintended impact on the interpretation of the Act in the courts. On the basis of this single exclusion, courts have reasoned that parliament did not therefore intend that any other subject matter, such as human genes and genetic materials, should be excluded (that is, should be non-patentable).[9] Given the history of the development and passage of the Act as outlined above, Dr Moir considered that this interpretation of the Act was out of keeping with the intent of parliament at the time the Act was passed:

> Today's patent system has emerged from a series of decisions by judges, often in settling disputes between private parties, and with no input on the public impact. Since 1990 a view seems to have developed among Australian judges that if something is not expressly excluded from the *Patents Act 1990*, then parliament did not intend to exclude it…[10]
>
> …
>
> Parliament did not say that they wanted to throw out long-standing presumptions that you cannot patent maths and you cannot patent methods of medical treatment. But our courts have done that.[11]

4.16 In addition to the factors outlined above, Professor Peter Drahos submitted that restrictions on patentable material in the Act were also prone to erosion by the 'development of patent claim drafting techniques to overcome publicly mandated restrictions on patentability'.[12]

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8 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 3.

9 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, pp 3-4.

10 Dr Hazel Moir, *Submission 20*, p. 7.

11 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 9.

12 Professor Peter Drahos, *Submission 60*, p. 428.

4.17 The Committee heard that, notwithstanding the allowing of gene patents by IP Australia, the validity of the patenting of human genes and genetic material has not been considered by Australian courts:

> Despite the long judicial history, to date no court decision in Australia has considered specifically whether isolated and purified gene sequences are proper subject-matter for patents.[13]

4.18 Professor Ian Olver, the Chief Executive Officer of Cancer Council Australia, also observed that there was no definitive legal statement on gene patents from the courts:

> The difficulty is that there are a lot of precedent cases overseas but to date they have only been resolved on technicalities and not on this very basic issue of whether patent law was ever meant to apply to discoveries of natural substances rather than inventions and protecting the inventor.[14]

International and national developments

Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others (USA)

4.19 The Committee notes that, since the inception of its inquiry into gene patents (11 November 2008), a legal challenge to the validity of the BRCA gene patents has been decided in the US District Court for the Southern District of New York, *Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others* (the MPO case). The MPO case directly considered the question of whether genetic materials in an isolated form are patentable as 'inventions', or are in fact mere 'discoveries' over which patents cannot as a matter of law be granted. This was a central issue in evidence submitted to the inquiry regarding the inherent patentability of genes and genetic material.

4.20 The MPO case was filed on 12 May 2009; the final judgement was handed down on 29 March 2010. Judge Robert Sweet found in favour of the parties challenging the US Patent and Trademark Office (USPTO) approach to granting patents over genetic material. In simple terms, the court ruled that Myriad's patents claiming (a) isolated BRCA gene sequences and (b) methods for comparing or analysing BRCA gene sequences to diagnose a predisposition for breast cancer were invalid.[15]

4.21 In relation to isolated gene sequences, Judge Sweet found that:

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13 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 13.

14 Professor Ian Olver, *Committee Hansard*, 5 August 2009, p. 1.

15 Genomics Law Report website, 'Pigs fly: Federal Court invalidates Myriad's patent claims', 30 March 2010, http://www.genomicslawreport.com/index.php/2010/03/30/pigs-fly-federal-court-invalidates-myriads-patent-claims/ (accessed 20 August 2010).

> DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter…[16]

4.22 In relation to the method claims, Judge Sweet found that the claimed comparisons of DNA sequences were unpatentable because they were in fact 'abstract mental processes'.[17]

4.23 The Committee notes that the outcome in the MPO case is significant for the Australian patent system, given that it considered the same BRCA gene patents as are currently valid in Australia. More generally, the case was centred upon elements of patent law and practice that are significantly comparable across the two jurisdictions.[18]

4.24 However, the Committee received advice from the USPTO that the decision in the MPO case is not at this stage binding on the USPTO, and that its examination policy has not changed in response to the decision. Accordingly, the USPTO 'continues to issue patents directed to isolated genes, proteins and their derivatives that meet patentability requirements under the United States patents laws'. In the event that a final decision is delivered on the case in a higher court, such as the US Court of Appeals for the Federal Circuit or the US Supreme Court, the USPTO advised that it would 'conform its policy to that decision'.[19]

4.25 On 29 October 2010, in an appeal to the MPO decision being heard in the US Court of Appeals for the Federal Circuit, the US Department of Justice indicated, in an *amicus curiae* submission to the court, that the US Government had altered its policy to reflect the US District Court's finding that isolated genetic materials are a product of nature and not an 'invention'. It was not clear whether and, if so, when the USPTO would implement the revised policy.

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16 *Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others*, pp 3-4.

17 *Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others*, p. 4.

18 For example, central to the question of patentability under Australian law is whether an invention may be said to be a 'manner of manufacture'. Similarly, section 101 of the US Patent Act, which sets out the categories of patentable subject matter, states that any 'useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof' may be patented. In both jurisdictions, natural phenomena and abstract mental process (such as theories) per se are not patentable subject matter.

19 US Patent and Trademark Office, *Correspondence to Senate Community Affairs References Committee*, 8 July 2010.

4.26 On 17 November 2010, a group of members of the House of Representatives and senators announced that they would be introducing a private member's Bill into the federal Parliament, intended to prevent the patenting of human genes and biological materials existing in nature. The Bill, the Patent Amendment (Human Genes and Biological Materials) Bill 2010, would amend the Act to 'reinforce the distinction between discovery and invention and…apply that distinction by expressly excluding from patentability biological materials which are identical or substantially identical to those existing in nature, however made'.[20] Accordingly, Item 3 of the Bill would, inter alia, repeal existing subsection 18(2) of the Act and substitute the following provision:

> (2) The following are not patentable inventions:
>
> > (a) human beings, and the biological processes for their generation; and
> >
> > (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.

4.27 The Committee notes that, due to the timing of the Bill's introduction, the inquiry did not explicitly consider the specific formulation of the proposed amendment. However, it did consider in broad terms the proposal for an express prohibition relating to 'biological materials that are identical to those that are identical or substantially identical to those that exist in nature' (see paragraph 4.58).

Should the *Patents Act 1990* be amended so as to expressly prohibit the grant of patent monopolies over human genes and genetic materials?

4.28 Many individuals and groups that supported an amendment to the Act to expressly prohibit gene patents did so on the basis that inventions involving genes and genetic materials do not satisfy the requirements for patentability under the Act. In particular, it was claimed that human genes and genetic materials are not patentable subject matter because they are discoveries, and not capable of being an invention (that is, a 'manner of manufacture').

Discovery v invention

Genes and genetic materials as 'inventions'

4.29 As noted in Chapter 2, patent law traditionally holds that, whereas an invention may be patentable, a 'mere' discovery is not patentable, 'because no knowledge or ingenuity has been applied to produce a new and useful thing'.[21] The IP Australia *Patent examiners manual* explains:

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20 Draft Explanatory Memorandum, p. 3.

21 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 122.

> Discoveries having no way of…[being carried] into effect…have traditionally been regarded as not per se patentable, because they do not exhibit the requirements of a manner of manufacture.[22]

4.30 The majority of the objections to the granting of gene patents on the grounds that they do not satisfy the requirements of patentability were based on the view that human genes and genetic materials are 'discoveries' rather than 'inventions'. It was claimed that, being discoveries, human genes and genetic materials in fact fall outside the scope of patentable subject matter.

4.31 However, the Committee heard that the distinction between an invention and a discovery in law was recognised as being both imprecise and potentially misleading.[23] Mrs Fatima Beattie, Deputy Director-General, IP Australia, explained that the application of human ingenuity to a discovery could result in an 'invention' for the purposes of Australia's patent law:

> The courts have…recognised that the distinction between discoveries, which are not patentable, and inventions can be extremely fine. However, if ingenuity has been applied to a discovery to produce a new and useful result, it is an invention and may be patentable. A practical application of information to a useful end translates a discovery into an invention because a step is taken from [merely] knowing to being able.[24]

Isolated or purified substances/gene sequences

4.32 This reasoning takes on a particular significance in the context of patents involving human genes and genetic materials, and indeed other naturally occurring substances or chemicals. Whereas a naturally occurring substance or chemical is not patentable, a claim to the isolated or purified substance or chemical may be an invention because it is considered to involve an artificially created state of affairs. The IP Australia *Patent examiners manual* explains:

> …the discovery of a microorganism, protein, enatiomer 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.[25]

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22 IP Australia, *Patent examiners manual*, 2.9.2.5, http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm (accessed 6 October 2009).

23 *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 264.

24 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 19 March 2009, p. 4.

25 IP Australia, *Patent examiners manual*, 2.9.2.5, http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm (accessed 6 October 2009).

4.33 With particular reference to genetic materials:

> …DNA or genes in the human body are not patentable, however, a DNA or gene sequence which has been isolated from the human may be patentable.[26]

4.34 Ms Lexie Press, a Senior Examiner of Patents with IP Australia, expanded on the distinction between naturally occurring genes and isolated or purified gene sequences:

> Genes do not exist as discrete entities in the human body or in nature...[but] are part of our entire complement of genomic DNA. In isolating a gene sequence, it becomes a discrete entity usually maintained in a vector, where it can be replicated easily and manipulated easily. So, in a sense, it may be analogous to what we have in our human body, but it is something quite different when it is in an isolated form.[27]

4.35 Mr Richard Hamer, Member, Business Law Section, Law Council of Australia (LCA), also commented on how an isolated or purified gene sequence or chemical compound is distinguishable from one found in its naturally occurring state:

> As a principle you can get a patent for isolating something which has never been isolated before. The isolated compound is something that you can do something with—something that you cannot do when it is in the body. For example, you can use an isolated gene sequence in a test kit. You cannot use it in a test kit when it is in the patient's body. It is capable of uses that are not there in the body and that is because it has been isolated. It is also different chemically because it is separated from the other components.[28]

4.36 IP Australia also stressed that the isolation or purification of a genetic sequence is not of itself sufficient for it to be capable of being adjudged an invention. Mrs Beattie advised that a specific use for the isolated sequence must also be identified:

> …for a patent to be [potentially] granted over a gene sequence, the applicant must disclose a new and practical use for the sequence. Typically, this will include evidence of the association of the sequence with a particular disease and its use as a diagnostic or therapeutic.[29]

Objections to genes and genetic materials as 'inventions'

4.37 Dr Luigi Palombi strongly rejected IP Australia's contention that there is no basis in Australian law for it to refuse to grant a patent over human genes and genetic

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26 IP Australia, 'Australian patents for biological inventions', http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf (accessed 6 October 2009).

27 Ms Lexie Press, IP Australia, *Committee Hansard*, 19 March 2009, p. 15.

28 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 79.

29 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 19 March 2009, p. 4.

materials, on the grounds that the recognition of isolated or purified gene sequences potentially as inventions was an improper application of the law:

> …Australian patent law does give IP Australia a clear basis to refuse to grant a patent on gene sequences because gene sequences…are not inventions but are discoveries. Patents are only about inventions. The problem is that IP Australia have for 20 years deliberately ignored the law so that now we are faced with an enormous problem and requiring the parliament to impose an express ban on this illicit practice.[30]

4.38 Dr Moir observed that a great deal relied on the semantics of the invention/discovery distinction, in that if it were not accepted that the isolation or purification of a gene sequence allowed it to be classified as an 'invention' then it would clearly not be patentable under Australian law.[31] Dr Palombi pointed to the opinions of many scientists rejecting as 'semantics' or 'absurd' the contention that an isolated or purified gene sequence could be regarded as an invention.[32] For example, he cited the view of Professor Ian Frazer:

> …there is no more invention in isolating and characterising biological material that exists in our bodies, using existing research techniques, than in collecting and arranging a set of postage stamps.[33]

4.39 Similarly, Professor Olver observed:

> Natural genes are part of your body. There is no invention in genes that are taken out of your body but that have the same look and the same function as when they were in your body.[34]

4.40 Professor David Bowtell, Director of Research for the Peter MacCallum Cancer Centre (PMCC), also stressed that an isolated gene sequence is the same as that which occurs in the body:

> The isolated gene is still DNA and it still has the same sequence [as the gene occurring in the body]…It is just another piece of DNA in a tube.[35]

4.41 In his submission to the inquiry, Senator the Hon. Bill Heffernan also rejected the view that isolated gene sequences could as a matter of law constitute an invention.

> The Committee has been advised that the BRCA 1 human gene is natural. It exists in all humans. That some people have mutations in this gene that predispose them to breast and ovarian cancer is also natural. Accordingly, it

30 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 7.

31 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 2.

32 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, pp 10-11.

33 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 9.

34 Professor Ian Olver, Cancer Council Australia, *Committee Hansard*, 5 August 2009, p. 18.

35 Professor David Bowtell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, p. 105.

> must be the case that neither the BRCA 1 human gene nor the mutations to this gene nor the genetic sequence of the gene or the amino acid sequence of the proteins that are coded for by the gene (including any mutations) can be patentable. I ask the Committee to accept that a naturally occurring phenomenon cannot be patented in Australia as the law stands at present. As Justice Heerey said in *Rescare*: '[taxol] is a naturally-occurring compound and thus is itself unpatentable'.
>
> The Committee should understand that the isolation of the BRCA 1 human gene does not change what it is or the genetic information it contains. It merely changes its physical state by removing it from the human body.
>
> …
>
> …an isolated or purified biological material which is identical or substantially identical to what exists in nature is not an invention. The characterisation of a naturally occurring biological material is a mere discovery.[36]

4.42 Dr Moir argued that to classify a gene sequence as an invention simply on the basis that it has been isolated or purified is an inherently artificial and spurious form of reasoning:

> Yes, the distinction between a discovery and an invention can be very fine. [However, it]…does not appear to be fine in this case; it merely seems to be a matter of spin. If you add the words 'isolated' and 'purified' then information that is no different to information occurring in nature suddenly shifts from being a discovery to an invention…
>
> …[The question is:] do the words 'isolated' and 'purified' suddenly convert the information that exists in the gene that is there in nature from a discovery into an invention? I would argue that they do not.[37]

4.43 In addition, Dr Moir observed that the terms 'isolated' and 'purified' were historically derived from the patenting of chemicals. She suggested there is little evidence that any such refining of genetic materials is taking place, and that the importing of these terms from a different field of technology is:

> …credited with a number of oddities in the way in which genes are now treated in the patent system, including the reliance on structural elements rather than the essential function or 'information' nature of gene sequences.[38]

4.44 In answer to criticisms of treating isolated genetic materials as inventions, Medicines Australia submitted:

> Medicines Australia believes that statements such as, 'the fiction argued by proponents of gene patents is that once they remove a gene from its natural

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36 Senate the Hon. Bill Heffernan, *Submission 76*, p. 36.

37 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 1.

38 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 8.

> environment…they have a [patentable] invention', highlight a troubling confusion among some policy makers about how, and on what types of subject matter patents are granted in Australia.
>
> Such confusion is always unhelpful. However, when it becomes the basis for changes to existing law, confusion can be disastrous.[39]

4.45 IP Australia defended and attempted to clarify the distinction between naturally occurring substances and isolated and purified substances and its application to gene patents. It acknowledged that gene patents are treated in an analogous way to chemical patents, observing that 'in the absence of Australian precedents IP Australia has turned for guidance to decisions and practice relating to chemical compounds'.[40] Mrs Beattie explained:

> Patent claims take two primary forms—to the product or method. In the case of chemicals the claim to the product is to the chemical molecule or combination of molecules. Gene patents take the same form. In the gene patent a claim to an isolated gene sequence, per se, for which a practical use is identified is a claim to a chemical molecule; a nucleic acid molecule to be precise. Patents claiming chemical products have been the subject of national sensitivity for hundreds of years as they tend to relate to medicines and food and, until [the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)], were treated differently by different countries.[41]

4.46 Further, IP Australia observed that Australia's patent system has evolved over time in keeping with international developments, statutory and court-made law and scientific and technological developments, and that patent protection has been extended to 'substances and materials isolated from nature since at least 1924'.[42] Mrs Beattie offered a number of historical examples:

> …Australia's patent system has [long] regarded as inventions substances isolated from nature, both flora and fauna, for which a practical use has been identified. By way of actual examples I provide in evidence: a patent granted in 1920 for substances isolated from Australian flora for use in dyeing wool, cotton et cetera; and a patent granted in 1924 for a substance isolated from mammalian pancreas or glands of fishes and other sources which relieves the cardinal symptoms and signs of diabetes. In both of these examples a patent was granted over the isolated substance and the method of isolation…
>
> Chemical inventions such as isolated human gene sequences for which a practical use is identified have not been treated differently because they are derived from the human body. IP Australia has applied over 100 years of

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39 Medicines Australia, *Submission 21*, p. 1.

40 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 13.

41 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, pp 27-28.

42 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 19 March 2009, p. 4.

> patenting practice and precedent to its examination of applications for gene patents.[43]

4.47 At the hearings in Canberra on 18 May 2010 and 15 June 2010, IP Australia addressed numerous individual patents which were identified by Senator the Hon. Bill Heffernan both in his submission and questioning directed to IP Australia representatives.[44] IP Australia's responses to these individual patents indicated that it considered its current approach to the granting of gene patents over isolated genetic materials for which a novel use has been identified as being consistent with the body of Australian patent case law.

Ethical objections to gene patents

4.48 Beyond semantic and legal questions concerning the invention/discovery distinction, a number of submitters and witnesses expressed more fundamental or ethical concerns about the patenting of genes, on the basis of their being natural substances and/or parts of the human body. Dr Gillian Mitchell, Director of the Familial Cancer Centre at the Peter MacCallum Cancer Centre (PMCC), commented that 'the DNA is part of what we are. The basis of our submission is that we cannot understand how we can patent something that is part of us'.[45]

4.49 Similarly, Ms Sally Crossing, Chair of Cancer Voices NSW, stated that, 'as an ethical principle, we do not believe that genes, as natural parts of the human body, should be patentable'.[46]

4.50 Dr Graeme Suthers, Chair of the Genetic Advisory Committee at the Royal College of Pathologists of Australasia (RCPA), described gene patenting as being wrong in both principle and practice.[47]

4.51 IP Australia responded to ethical concerns over the patenting of genes by observing that Australia's patent system is 'technology neutral'. Accordingly, the courts and patent examiners do not generally apply or interpret the law as mandating ethical considerations in relation to the granting of patents in respect of any particular subject technology:

> Gene related inventions are not made unlawful under any existing Australian regulations, and courts have been reluctant to refuse patentability

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43 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, pp 27-28.

44 See for example, Senator the Hon. Bill Heffernan, *Submission 76*, pp 6-27; *Committee Hansard*, 15 June 2010, pp 1-8; and IP Australia, *Response to Senator the Hon. Bill Heffernan's submission no 76*, pp 1-3.

45 Dr Gillian Mitchell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, p. 105.

46 Ms Sally Crossing, Cancer Voices NSW, *Committee Hansard*, 5 August 2009, p. 2.

47 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, pp 40-41.

> on the ground of generally inconvenient, believing it is best left to parliament to decide whether matters of ethics or social policy are to have any impact on what is patentable.[48]

4.52 The National Health and Medical Research Council (NHMRC) expressed the view that there is no need to introduce express exemptions for genetic material into the Act based on ethical considerations.[49]

4.53 To the extent that ethical objections were implicitly or explicitly grounded in the view that the granting of gene patents equates to the granting of ownership or control of an individual's genes, IP Australia stressed that, given the requirements of patentability, human genes and genetic materials occurring in their natural state—that is, in the body—are not patentable. It stated that '[a patent is not granted]…over a human gene. It is [granted] over the isolated human gene sequence for which a practical use has been identified'.[50]

4.54 Further, IP Australia noted that the grant of a patent does not confer any right of ownership or control of an individual's genes:

> A patent over a gene sequence does not equate to ownership of that sequence. A patent is a right to restrain others from using or exploiting the claimed invention without the patentee's permission; it does not confer ownership of the physical material as it exists in the body. A patent on an isolated gene sequence does not impinge on the freedom of the individual to use their own DNA.[51]

4.55 The Intellectual Property Committee of the Law Council of Australia supported the position of IP Australia:

> The ethical issues which have been raised appear to the Committee to be based largely on misconceptions as to the nature of patent protection. For example, the assertion that a patent gives the patentee 'ownership' of a gene is incorrect as a matter of law: there is a fundamental distinction between a patent which protects an invention as a form of intellectual property and the physical property in genetic material.
>
> Similarly, the concern that someone can patent something which is 'part of nature' misconceives a basic principle of patent protection. Patent protection can only validly extend to that which is new and non-obvious.[52]

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48 Mrs Fatima Beattie, IP Australia, *Committee Hansard,* 19 March 2009, p. 4.

49 National Health and Medical Research Council, *Submission 12*, p. 19.

50 Mrs Fatima Beattie, IP Australia, *Committee Hansard,* 20 August 2009, p. 35.

51 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19,* p. 23.

52 Law Council of Australia, *Submission 57,* p. 2.

Impacts of express prohibition on gene patents

4.56 In general terms, supporters of an express prohibition on gene patents proposed that the prohibition should apply to human genes and genetic materials per se, and not to downstream uses involving such materials. Dr Gerard Cudmore from the Department of Industry and Investment (New South Wales), commented:

> …downstream uses of sequence data should remain open to the possibility of patenting…[We] believe there is a need, particularly in the context of medical research, to clarify what can and cannot be patented clearly through IP Australia to minimise any confusion and that there should be adequate training of patent officers to ensure that downstream patents are appropriately narrowly defined.[53]

4.57 Similarly, Dr Anna Ronan, a clinical geneticist from the Hunter Genetics Unit, commented:

> …the [testing] technology is improving all the time, and the technology is subject to patent and that is subject to competition…[Testing] has gotten much better obviously, and much quicker. That is how it should be. I just do not see why they need to actually patent the description of the human component that the test is based on.[54]

4.58 More specifically, some groups called for a prohibition covering 'biological materials'. Dr Palombi (and Cancer Council Australia) suggested that 'the *Patents Act 1990* be amended to…ban the patenting of biological materials that are identical or substantially identical to those that exist in nature.'[55]

4.59 Senator the Hon. Bill Heffernan also called for an express prohibition:

> I urge the Committee to consider, as an option, the express prohibition of the patenting of isolated biological materials which are identical or substantially identical to those that exist in nature.
>
> Furthermore, I urge it to consider the possibility of an express prohibition of diagnostic, therapeutic and surgical methods for the treatment of humans.[56]

4.60 DIISR and IP Australia warned that an express prohibition on patentability of 'isolated nucleic acid molecules from humans' would have 'far-reaching consequences'.[57] The supplementary submission from these bodies was particularly critical of the calls for the broader prohibition on 'biological materials' or on 'all

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53 Dr Gerard Cudmore, Department of Industry and Investment (NSW), *Committee Hansard*, 5 August 2009, p. 88.

54 Dr Anna Ronan, *Committee Hansard*, 5 August 2009, p. 68.

55 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 12.

56 Senator the Hon. Bill Heffernan, *Submission 76*, p. 39.

57 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 30.

substances isolated from nature', given the likely effect of this on healthcare and medical research and innovation:[58]

> IP Australia does not support the broad exclusion proposed…to 'biological materials...which are identical or substantially identical to those that exist in nature'…Such a broad exclusion would capture a large proportion of healthcare inventions in the biotechnology and pharmaceutical industries as well as in other industries. Under the proposed exclusion these inventions, although novel, useful and involving an inventive step, would no longer benefit from patent protection. Such exclusion would adversely affect access to affordable future healthcare innovations, the competitiveness of Australia's biotechnology industry and reduce investment in Australian research and development. For example, under the proposed approach inventions such as Gardasil (the cervical cancer vaccine) would not be patentable in Australia but would be in other jurisdictions, which could have negative consequences for access and price in the Australian marketplace.[59]

4.61 In concluding that it did not support an express prohibition on gene patents, the ALRC's 2004 report also expressed concerns that this approach could adversely impact on investment in Australia's biotechnology industry:

> [A prohibition on patenting of genetic materials]…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.[60]

4.62 A number of groups expressed particular concern about the effect of an express prohibition on innovation more generally. Medicines Australia submitted:

> Medicines Australia believes that the formulation of proscriptive categories of subject matter which are to be excluded from patentability is a crude 'on/off' switch, which has the potential to stifle entire fields of innovation.[61]

4.63 Noting the broad range of materials described in the inquiry terms of reference, Xenome commented:

> This is an exceptionally broad scope…[which] encompasses facets of many industries within Australia—not only the medical and biotechnology fields but also the agricultural and brewing fields to name a few. Indeed, if the full spectrum of materials listed…were deemed to be non-patentable, it would have extremely negative effects on a large number of Australian companies

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58 Arguments about the impacts of gene patents on healthcare, medical research and human wellbeing are discussed in Chapter 3.

59 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 3.

60 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 130.

61 Medicines Australia, answer to question on notice, 25 September 2009, p. 1.

> and would drastically undermine emerging industries such as biotechnology.[62]

4.64 The ALRC concluded in its 2004 report that there are 'overwhelming practical impediments to expressly prohibiting gene patents', given the number of gene patents that have been granted. The report concluded that, 'if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed.[63]

4.65 Dr Palombi disagreed with these assessments of the scope and likely impacts of an express prohibition on gene patents on innovation:

> ...[Opponents of an express prohibition argue] that somehow the sky is going to fall in on the biotechnology industry or on medical and scientific progress if you make this incremental step. I say that actually it will do the exact opposite. By banning these sorts of patents on those very limited types of claims, these claims of these materials, you are actually opening up the door to further innovation because you are maximising the ability of scientists to freely use these materials…so that they can make an invention. That is what we want. We want them to make these sorts of massive leaps in technology, not grant patents over elementary processes and non-inventive applications such as diagnostics.[64]

4.66 Commenting on the effect of the suggested prohibition on existing patents, Dr Palombi observed:

> If you were to impose a ban on the isolated biological materials, it would not invalidate the entire patent; it would simply invalidate the claims to those types of materials. So you still leave it completely open for people to come along and develop new and inventive ways of using those materials.[65]

Effectiveness of express prohibition on gene patents

4.67 A number of submitters and witnesses suggested that an express prohibition on isolated genetic materials would be ineffective.

Declining number of gene patents

4.68 The Committee heard arguments from those opposed to an express prohibition on gene patents that this approach is unnecessary because, irrespective of the actual or potential adverse impacts of overly broad or inappropriate gene patents granted in the past, the quality of gene patents has improved such that similarly defective patents are not being granted today.

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62 Xenome Ltd, *Submission 70*, p. 2.

63 Australian Law Reform Commission, *Submission 18*, p. 2.

64 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 18.

65 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 18.

4.69 The ALRC submission acknowledged that overly broad or inappropriate gene patents have previously been granted. However, it argued that the granting of such 'unfortunate' patents is characteristic of new fields of technology in general, and is not therefore a specific or unique feature of gene patents:

> …every new wave of scientific inventions places stress on the patent system as examiners try to come to grips with the new science and technology. Inevitably, some inappropriate and overly broad patents are granted in the first flush of applications, but then the system settles down as examiners become more expert in understanding the nature, complexities and boundaries of the new field.[66]

4.70 Pointing to the limited duration of patent monopolies (in most cases 20 years), the ALRC considered that problems arising from overly broad or inappropriate patents are 'transient' in nature. Given that many of the 'unfortunate' patents granted in the 1980s and 1990s are coming to an end, the ALRC considered a proposal to ban gene patents as being effectively 'yesterday's battle'.[67]

4.71 The submission from Pfizer Australia supported the ALRC's view:

> …as patent offices worldwide have gained experience with genetic technologies, the patents now granted are much more specific than the early gene patents…Since the patent term is 20 years from the date when the priority application is filed, many of the early, broad patents are nearing the end of their patent life.[68]

4.72 The Committee heard that the declining number of gene patents is also a function of the way in which the requirements for patentability such as 'inventiveness' apply to claimed inventions. Dr Trevor Davies, from the Institute of Patent and Trade Mark Attorneys of Australia (IPTMAA), noted that it is important to keep in mind that patents are granted according to the standards of knowledge and technical ability at a given time. Thus the threshold of inventiveness is subject to change as knowledge and technology advance in a given subject area, and what is considered to be an inventive step at one point in time may not necessarily be regarded as such at a later point in time (notwithstanding that the patent continues to be in force). Dr Davies observed that '[as] technology evolves, then what is considered to be inventive now might be quite different from what was considered inventive five or 10 years ago'.[69]

4.73 Pfizer Australia also considered that the thresholds for patentability are increasingly a barrier to the grant of gene patents:

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66 Australian Law Reform Commission, *Submission 18*, p. 2.

67 Australian Law Reform Commission, *Submission 18*, p. 4.

68 Pfizer Australia, *Submission 51*, p. 3.

69 Dr Trevor Davies, Institute of Patent and Trade Mark Attorneys of Australia, *Committee Hansard*, 4 August 2009, p. 8.

> As knowledge of genetics has grown—particularly with the publication of the Human Genome in 2001—the number of patents on individual genes has dropped sharply. This is because the threshold for 'novelty' and 'inventiveness' at the heart of the patent system is now very much higher than it was when the first gene patents were issued...[70]

4.74 On this issue, IP Australia submitted:

> With the successful completion of the Human Genome Project and further rapid advances in sequencing technology, it is increasingly unlikely that a competent patent examiner would now approve an application for patent rights over a pure gene sequence. As Dr Ségolène Aymé of the (French) National Institute for Health and Medical Research Institute stated last year, when the European Parliament was considering this matter:
>
> 'Nowadays, identifying new genes is very obvious, and all the methods are well-established, so it should not be patentable anymore. What is patentable is the inventive process—if you can describe how to use a gene for a specific purpose—but not the gene itself'.[71]

4.75 Mrs Beattie also noted that, due to the increase of knowledge in the field of genetic science, a claim relating to isolated gene sequences may fail on the basis that it lacks novelty. She observed that 'because the genome has been published, for example, the gene sequences per se are now published, therefore they would not necessarily pass the novelty requirements'.[72]

4.76 However, despite the increasing threshold of inventiveness in relation to gene patents, Mr John Slattery, a consultant with Davies Collison Cave, observed that it was still possible that an isolated nucleotide sequence would justify the grant of a patent through meeting the requirements for patentability in terms of novelty, inventive step and usefulness.[73]

4.77 Finally, it was suggested that the number of patents on isolated or purified genetic materials per se is declining because claims are increasingly related to downstream uses of genetic information. Pfizer, for example, noted that gene patents 'are increasingly granted to biotechnologies rather than on isolated genes themselves'.[74] In more general terms, Dr Chris Dent, a senior research fellow with the Intellectual Property Research Institute of Australia (IPRIA), noted that '[recent] research suggests that…the patenting of genetic inventions may be on the decrease'.[75]

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70 Pfizer Australia, *Submission 51*, p. 3.

71 IP Australia, *Submission 18*, p. 4.

72 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 31.

73 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 9.

74 Pfizer Australia, *Submission 51*, p. 3.

75 Dr Chris Dent, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, p. 7.

Definitional issues

4.78 Professor Andrew Christie noted that a specific exclusion on genes was an alternative for the Committee to consider; however, he did not feel that such an approach would be successful.[76] Dr Moir felt that an express prohibition would continue to be undermined by the expansive approach of the courts on the question of patentable subject matter, and that further exclusions and strategies would need to be employed.[77]

4.79 The ALRC concluded in its 2004 report that a specific exclusion may fail to prevent patenting of genetic materials because 'many pure and isolated genetic sequences do not exist in exactly the same form in nature'.[78] The Committee notes that this would be a relevant consideration in determining whether a substance was 'identical or substantially similar to those that occur in nature' according to the terms of the express prohibition as recommended by some submitters.

Potential complexity

4.80 Mr Hamer advised that the LCA disagreed with the proposal for an express prohibition, on the grounds that this approach would be likely to increase the level of legal disputes and therefore uncertainty in the patent system:

> To the extent that [an express prohibition]…is proposed we disagree with it…The reasons are that having exceptions or special treatment of particular forms of intellectual property…creates disputes, it results in people trying to find loopholes, it creates inconsistencies and it is unfair. Despite the fact that as lawyers you might say we like disputes, in this capacity we are trying to avoid it.[79]

4.81 DIISR and IP Australia also expressed concerns about the effect of the suggested prohibition on the administration of the patent system, arguing that Australia should maintain a 'technology neutral' patent system:

> This technology neutral approach contributes to reduced complexity and cost of providing a national patent system and has inherent flexibility to accommodate patenting of new and emerging areas of technology.[80]

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76 Professor Andrew Christie, private capacity, *Committee Hansard*, 4 August 2009, p. 68.

77 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 4.

78 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 130.

79 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 75.

80 Department of Innovation, Industry, Science and Research and IP Australia , *Submission 19*, p. 10.

Barriers to express prohibition on gene patents

Consistency with international patent systems

4.82 As noted in Chapter 2, the patent system is relatively uniform across a number of countries, following many years of efforts to harmonise intellectual property systems. Mr Slattery was concerned that the prohibition of gene patents 'would constitute a move away from harmonisation of Australia's patent laws with the patent laws of other major jurisdictions, particularly the US and Europe'.[81]

4.83 In terms of international practice relating to biological materials and isolated gene sequences in particular, IP Australia advised:

> Internationally all developed countries and our major trading partners, including the European Union, the US, UK, Japan, Korea and emerging economies of India and China, allow patenting of isolated biological materials, including isolated human gene sequences for which a practical use is identified. This is reflective of a principle underpinning the Australian federal patent system since its inception in 1904—that patents should be available for all products and processes that have a practical use.[82]

4.84 Ms Deborah Monk, from Medicines Australia, advised that a prohibition on gene patents in Australia could affect its competitiveness in relation to the pharmaceutical industry:

> …at the moment we are facing enormous challenges in continuing to bring clinical research to Australia. Our near neighbours India and China, and other countries such as Brazil and those in Eastern Europe, are able to do that research as well as we can and have been able to for many years. They can start their clinical research faster. They have large patient populations that they can get into clinical trials, so they can complete the research faster. They can do it cheaper. We are losing our competitive edge. If we have a situation where our intellectual property protection in Australia is eroded in some way or is less robust than it is in other markets then that will be another reason why the headquarters of pharmaceutical companies will not send the research to Australia. There is a very strong view that we need to maintain consistency with other developed markets around the world with respect to our intellectual property protection.[83]

4.85 However, the ACIP options paper on patentable subject matter notes that, despite a fairly high degree of conformity in the approach of various countries to defining patentable subject matter, there are observable differences in the approaches of those countries to interpreting such definitions:

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81 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 2.

82 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 1.

83 Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 5 August 2009, p. 35.

> These outcomes suggest that courts account for national interests when interpreting 'invention', beyond the literal wording of any test. The varying definitions of invention, together with explicitly legislated exclusions create considerable variation in patentable subject matter in different countries.[84]

Compliance with international agreements

4.86 A common objection to an express prohibition on gene patents was that this would place Australia in breach of its international obligations. Two international agreements were identified as being of particular relevance:

- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement); and
- Australia-United States Free Trade Agreement (AUSFTA).[85]

TRIPS

4.87 Article 27(1) of the TRIPS Agreement provides that patents shall be available for any inventions and that the 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'.[86] IP Australia advised that this required Australia to maintain a 'technology neutral' patent system:

> A key feature of patent systems worldwide is that they must be technology neutral in compliance with the TRIPS Agreement…In particular, the TRIPS Agreement requires patents to be made available in all fields of technology without discrimination. IP Australia therefore assesses applications for gene patents by applying the same patentability requirements as for all other applications, irrespective of their technological field.[87]

4.88 Objectors to an express prohibition on gene patents were concerned that:

> …excluding the possibility of patents for gene technology may comprise unjustifiable discrimination against a field of technology that is offensive to TRIPS-defined international patent norms.'[88]

4.89 In contrast, the ALRC's 2004 report noted that, although TRIPS prohibits discrimination, it is possible to differentiate between fields of technology. The allowable extent of any such differential treatment is, however, uncertain:

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84 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', p. 29.

85 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 23. See also Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 2.

86 TRIPS Agreement, article 27(1).

87 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 10.

88 Law Council of Australia, *Submission 57*, p. 1.

> 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.[89]

4.90 Dr Matthew Rimmer noted that the possibility for differentiation under TRIPS could potentially support an express prohibition on gene patents:

> …I would disagree with the interpretation that [DIISR and IP Australia]…place upon article 27[(1)] of the TRIPS Agreement. There has been one big WTO decision on the interpretation of article 27, which …says that one cannot discriminate against technologies but one can differentiate between technologies.[90]

4.91 The Committee also heard debate on whether Australia could legislate an express prohibition on gene patents on the basis of certain grounds on which TRIPS allows exclusions to patentability. The ACIP options paper on patentability notes:

> The TRIPS Agreement thus provides a general principle that inventions in a field of technology are eligible for patent protection. Excluding an invention from patentability is an exception to that rule and must fall into one of the exceptions allowed for by the TRIPS Agreement.[91]

4.92 The exceptions with apparent relevance to gene patents include:

- an exclusion to protect public order (*ordre public*) or morality as a result of commercial exploitation in a member's territory (Art. 27(2)); this article is replicated in AUSFTA Article 17.9.1; and
- an exclusion from patentability for methods of diagnostic, therapeutic and surgical treatment of humans (Article 27(3)(a)); this article is replicated in AUSFTA Article 17.9.2(b).

4.93 In relation to the public order exemption, IP Australia advised that in overseas jurisdictions this has been 'narrowly interpreted' and would not in its view 'be able to be used to limit patentability of genetic materials'.[92]

4.94 In relation to the exclusion for methods of diagnostic, therapeutic and surgical treatment of humans, IP Australia advised that Australia does not currently rely on this article to exclude any subject matter from patentability. However, it believed that any changes to Australia's patent law to implement this exclusion 'would require careful

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89 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 91, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

90 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

91 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 26.

92 Department of Innovation, Industry, Science and Research and IP Australia *Submission 19*, p. 24.

consideration of the full impact on innovation in Australia, trade with overseas countries, and transfer and access to medical technologies'.[93]

4.95 Further, DIISR and IP Australia regarded the application of the exclusion to isolated genetic materials as problematic, insofar as it applies only to methods and not products:

> [These Articles]…give Australia the ability to exclude certain subject matter from patentability should it wish to exercise that right. The exclusion is confined to 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. Therefore, Australia could, should it wish to do so, exclude such methods from patentability, but it could not rely on those Articles to exclude products such as isolated human gene sequences from patentability. It is also not clear whether the Articles could be relied on to exclude a diagnostic method to treat humans if the method contains a product as an integral component.[94]

4.96 In response to IP Australia's views, Dr Rimmer commented:

> IP Australia and the department of industry may speculate on the scope of the exemptions under articles 27(2) and 27(3), but I do not necessarily share their conclusions. I think article 27(2) could be read quite broadly to include gene patents as a kind of exclusion of genes from the scope of patentable subject matter. Indeed, the Canadian position in not allowing patents on higher life forms suggests that that is a possibility with the regime.[95]

4.97 Professor Drahos also did not agree that TRIPS would necessarily act as a barrier to excluding gene patents. He noted that it had not prevented other countries excluding certain subject matter:

> …it has not stopped countries like India, for example, from inserting specific exclusions in relation to the patenting of pharmaceutical compounds…it certainly has not stopped other countries.[96]

4.98 The RCPA noted that the exception for diagnostic tests had been narrowly construed, and called for the interpretation of this exclusion to be reviewed:

> It appears this has generally been interpreted by IP officers to refer to diagnostic tests performed on a person's body, but not to diagnostic procedures where a sample is removed from the body and tested in a

93 Department of Innovation, Industry, Science and Research and IP Australia *Submission 19*, p. 24.

94 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 2.

95 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

96 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 22.

> laboratory…The RCPA considers that the interpretation of what constitutes a diagnostic test should be revisited.[97]

AUSFTA

4.99 As indicated above, AUSFTA replicates the TRIPS requirements for non-discrimination and grounds for exclusion of patentable subject matter. IP Australia advised that, in addition, AUSFTA imposes an obligation on Australia and the US to pursue harmonisation of their patent systems:

> The agreement does require both parties to seek to reduce differences in law and practices between their respective systems and participate in international patent harmonisation efforts. [However, there is]…flexibility to implement the agreement in a way that reflects the interests of our domestic interest groups and Australia's legal and regulatory environment.[98]

4.100 Given this obligation, IP Australia commented that any proposed changes to Australia's patent system, such as an express prohibition on gene patents, would require 'consideration of Australia's obligations under the USFTA' and an assessment of potential impacts on:

- Australia's exports to the US;
- inward technology transfer from the US; and
- trade with the US more generally.[99]

Alternatives to express prohibition on gene patents

4.101 The Committee notes there was strong support among submitters and witnesses—generally but not exclusively from those who did not support an express prohibition on gene patents—for a broader suite of measures to address any actual or potential adverse impacts of gene patents.

4.102 Many submitters observed that reforms to the patent system generally would improve outcomes in relation to gene patents and the areas of concern to the inquiry. The submission of Professor Diane Nicol and Dr Jane Nielsen urged the Committee to avoid 'focussing on the single issue [of express prohibition of gene patents]'. Instead:

> …the Community Affairs Committee…should take a more expansive approach, both with regard to the issue of how patentable subject matter should be dealt with in the *Patents Act 1990* and also with regard to the exploration of other legal and policy options for dealing with any potential

97 Royal College of Pathologists of Australasia, *Submission 49*, p. 7.

98 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 24.

99 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, pp 24-25.

> adverse consequences resulting from gene and related patents on healthcare, research, innovation and the health and wellbeing of Australians.[100]

4.103 Dr Graeme Suthers observed that the ethical issues in relation to gene patents are also relevant to the patent system in general:

> Genetics is the hot potato for the moment, but the issues that are captured in the ethics story are not peculiar to genetics. If indeed there is a case for having some broader consultation about patenting issues, then it should apply to other patents and not just genetic patents.[101]

4.104 The ACIP options paper on patentable subject matter comments:

> Many of the issues raised in submissions to the Senate reflect concerns cited generally across the patent system. Stakeholders expressed concerns over the width of patents, access to technology, use of patented inventions in research, and the ability of the system to distinguish between patentable and unpatentable subject matter. The context of the gene patent inquiry is important. It concerns the health and wellbeing of Australians. Patents in that field present some unique challenges. However, many of these issues apply to the patenting of other technologies as well.[102]

4.105 Dr Kwanghui Lim, from IPRIA, noted that it would be desirable to ensure that changes to the patent system are done 'in a way that is coherent and consistent with [the patent system as a whole]'.[103] The ALRC also supported a systemic approach in its 2004 report on genetic technology:

> The ALRC 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 amendments directed exclusively at the patenting of genetic materials and technologies in legislation of general application…To the extent that gene patents highlighted any deficiencies in the patenting system generally, the ALRC considered it preferable to craft solutions aimed at correcting systemic weaknesses, in order to ensure that the system remains sufficiently robust to anticipate and respond to future challenges.[104]

4.106 The necessity for such an approach was emphasised by Professor Drahos:

> If I have one message for the committee it is that thinking about improving patent quality, whether it is in the area of biotechnology or any other area, requires an integrated strategy. You do not fix the problem of tax evasion

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100 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 3.

101 Dr Graeme Suthers, Royal College of Pathologist of Australasia, *Committee Hansard*, 4 August 2009, p. 50.

102 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 3.

103 Dr Kwanghui Lim, *Committee Hansard*, 3 August 2009, p. 5.

104 Australian Law Reform Commission, *Submission 18*, p. 2.

> with a single amendment to the Tax Act, and you are not going to fix the problem of patent quality with a single amendment to the *Patents Act*.[105]

4.107 The submission of the Swedish National Council on Medical Ethics outlined how discrete elements of the patent system can operate to restrict the nature and breadth of patents claiming human genes and genetic material in relation to a product or a process:

> …product protection of genetic diagnostic tests would only be approved on rare occasions if the criterion inventiveness were to be strictly implemented. A strict implementation of the criterion usefulness would counteract patents on DNA sequences as research tools. Product protection would not be possible to apply to the use of DNA sequences in gene therapy since the link between gene and disease is already known [ie is obvious].[106]

4.108 Dr Rimmer noted that there was a 'great consensus' across a number of submissions to the inquiry, concerning the 'need for modernisation and reform of the patent regime'.[107] Professor Drahos noted that many countries are interested in and undertaking patent reform processes, suggesting that the issues examined by the inquiry are of global relevance.[108] DIISR and IP Australia also referred to reform efforts in other jurisdictions, and to the nature and range of measures being considered:

> There are solutions proposed in other jurisdictions to address community concerns about gene patents that strike a balance between the need for genetic research, prosperity of the biotechnology industry and access to innovations in health care. Such measures include strong patentability criteria, public education, a research exemption, access to compulsory licensing, and guidelines for the licensing of genetic inventions.[109]

4.109 IP Australia advised that it was currently pursuing a 'patent reform package' to strengthen Australia's patentability criteria. Beyond this, it felt that existing provisions of the Act—notably the crown use and compulsory licensing provisions—are also generally sufficient and available to deal with any adverse impacts on healthcare or medical research arising from gene patents.[110]

4.110 Submitters and witnesses in favour of implementing a suite of reforms to address the issues of concern to the inquiry often referred the Committee to the

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105 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 14.

106 Swedish National Council on Medical Ethics, *Submission 37*, p. 2.

107 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 12.

108 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 15.

109 Department of Innovation, Industry, Science and Research and IP Australia *Submission 19*, p. 4.

110 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 19 March 2009, p. 5.

conclusions and recommendations of previous inquiries relevant to the patent system and/or to gene patents in particular (these were listed in Chapter 2, and include the ALRC inquiry into gene patents and the current ACIP review of patentable subject matter). Mr Slattery submitted:

> …the implementation of the recommendations of these reports is appropriate and important, and will go a long way towards addressing many of the concerns which the general public seem to have in relation to the matters raised in the terms of reference.[111]

4.111 Similarly, Professor Christie noted:

> Many of the concerns expressed by stakeholders to this Inquiry about patents for genetic inventions are valid and significant. What is important for this Committee to recognise is that a number of other inquiries have addressed, or are addressing, the issues at the heart of these concerns. Furthermore, those other inquiries have identified, or will identify, the changes needed to remedy these concerns. Thus, the appropriate action for the government is to implement the recommendations of those inquiries as soon as possible.[112]

CONCLUSION

4.112 The Committee notes that the question of whether there should be an express prohibition on gene patents requires the weighing of a number of factors to determine how to achieve the best possible outcomes for healthcare, medical research and the health and wellbeing of Australians more broadly.

4.113 The Committee first considered whether the purported benefits of patent protection in relation to gene patents are outweighed by the actual and potential adverse impacts on healthcare and medical research. As indicated in the conclusions set out in Chapter 3, the poor quality and scope of available evidence did not allow the Committee to come to a definitive conclusion in relation to this question. Much of the evidence on adverse impacts was restricted to generalised and/or anecdotal accounts. However, there were clearly some significant cases of adverse impacts arising from gene patents in Australia and overseas, and the Committee also noted that there is obvious and significant potential for adverse impacts arising from gene patents in the future, given the way in which genetic science continues to develop. The difficulty of assessing the purported benefits and adverse impacts of gene patents regarding the question of whether the Act should contain an express exemption underlies the importance of the Committee's recommendations in Chapter 3, concerning improved data collection on, and transparency of, the patent system.

4.114 In relation to the issues considered in this chapter, much of the evidence received in submissions and hearings went to the question of the distinction between

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111 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 1.

112 Professor Andrew Christie, *Submission 38*, p. 8.

inventions and discoveries under patent law. This distinction is critical because the law does not allow a 'mere discovery' to be patented. The Committee heard that, for the purposes of the Act, isolated or purified genetic materials for which a use has been identified may be recognised as inventions. This approach was defended by IP Australia as being consistent with the principles of Australian patent law laid down by the High Court, international practice and the application of patent law principles in analogous fields of technology.

4.115 The Committee heard strong criticisms of this current approach on the basis of what might be termed literal or common-sense objections. A number of submitters and witnesses characterised the recognition of isolated genes and genetic materials as 'inventions' as being a purely semantic rather than substantial distinction, given the fact that a gene sequence in an isolated or purified form is apparently often, if not usually, identical to the same sequence occurring in its natural state.

4.116 The Committee recognises that the argument against the recognition of genetic materials as inventions is forceful in that it employs a common-sense application of language, and also connects to some of the broader ethical concerns that apply to the patenting of naturally-derived products, be they human or otherwise. In a similar way, the ALRC 2004 report conceded that 'there are attractive arguments for the view that such materials should not have been treated as a patentable subject matter'.[113] However, the Committee recognises also that technical or legal distinctions may be and commonly are valid, despite not reflecting the everyday or common meaning of the language they employ.

4.117 Despite this, in the Committee's opinion, there is substantial doubt that IP Australia's approach to the granting of patents over genes conforms with the general prohibition in law on the patenting of a discovery or product of nature. While the Committee acknowledges IP Australia's defence of the current approach as being analogous to other classes of patents, such as chemical products, the Committee strongly rejects the reasoning which says that, for the purposes of the *Patents Act 1990* (the Act), genetic information that is isolated from its naturally occurring state in the human body may be classed as an invention, and therefore properly be the subject of a patent (where the other requirements of patentability are satisfied). The Committee considered this objection to be the strongest justification for recommending that the Act be amended to include an express prohibition.

4.118 In terms of the impacts of an express prohibition on gene patents, the Committee notes that virtually all submitters and witnesses supported the maintenance of patent protection for so-called downstream uses of genetic information. That is, supporters of an express prohibition wanted it to apply only to genetic information per se. In some cases, a broader prohibition on biological materials was proposed. It was claimed that this approach would not unduly disrupt existing patents, and would promote research and innovation in the healthcare and medical research sectors by

113 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 124.

removing the disincentives and barriers associated with the existence of gene patents (as outlined in the Chapter 3).

4.119 Conversely, opponents of express prohibition emphasised concerns that this approach would have far-reaching impacts on existing patents and on research and innovation across many different fields of technology. In relation to the healthcare and medical research sectors in particular, it was said that an express prohibition on gene patents would remove important incentives for research and innovation in fields such as biotechnology and pharmaceuticals (as outlined in Chapter 3).

4.120 The Committee notes that the consequences of an express prohibition on gene patents would be undoubtedly complex. Some groups argued that the nature and extent of potential impacts of this approach would be relatively uncertain in relation to healthcare and medical research. This is because, for example, while research institutions may experience added expense, delay and/or uncertainty arising from the existence of the patent system, many such institutions also rely on income from the patent system to fund their work; and for others patent protection provides an incentive for investment in research and innovation.

4.121 In addition to the uncertainty of how an express prohibition might affect the healthcare and medical research sectors, the Committee notes arguments relating to how effective such a prohibition would be in a legal sense. First, it was argued that there is potential for this approach to lead to higher levels of litigation, cost, uncertainty and possibly unfairness as patent system actors seek to promote and/or protect their interests on the terms of any new exclusion introduced into the Act. Second, it was argued that the history of patent law has been characterised by the incremental expansion of the scope of patentable subject matter, and an express prohibition could be undermined by creative patent drafting and such practices. The Committee therefore remained unsure as to the extent to which an express prohibition could by itself achieve sufficient certainty in terms of future development of the law through the courts and IP Australia.

4.122 The Committee also heard arguments that an express prohibition on gene patents is unnecessary due to the declining number of gene patents. Arguments about the number of gene patents granted in the past, and likely to be granted into the future, were considered in detail in the previous chapter.

4.123 Opponents of an express prohibition on gene patents contended that the occurrence of overly broad or inappropriate patents is a common phenomenon in relation to new and emerging technologies, and that such low-quality patents are less likely to occur today given the greater experience and expertise of patent offices. It was also argued that gene patents are less likely to be granted today because the thresholds of patentability in relation to the elements of novelty and inventiveness are more difficult to achieve, given the maturing of knowledge and technology in the field of genetics.

4.124 The Committee notes its previous conclusions that it was not convinced of a substantial decline in the number of gene patents, or that future developments in genetic science will not continue to form the basis of substantial numbers of patent claims relating to human genes and genetic materials into the future. However, the Committee does accept that some of the poor quality patents issued in the past were likely due to patent offices' relative inexperience with genetic technologies, and certain recommendations in the following chapter are relevant to this issue.

4.125 In relation to the thresholds of patentability, the Committee accepts that the thresholds of patentability for novelty and inventiveness—being relative to the state of knowledge and technology at the time a patent application is made—would today possibly prevent claims that were in the past sufficiently novel and innovative to deserve patent protection. However, the Committee was not convinced that patentability thresholds are otherwise operating sufficiently well to ensure that overly broad or inappropriate patents are not being granted in relation to human genes and genetic products. These issues are discussed in detail in Chapter 5, and a number of recommendations are made to address these issues around patent quality.

4.126 In relation to potential barriers to creating an express prohibition on gene patents, despite the possible difficulty of fashioning legislative provisions that would be sufficiently precise, effective and of enduring effect, the Committee does not agree with the view that it is not feasible or necessarily possible to expressly prohibit gene patents, as the ALRC concluded in its 2004 report. Nor did the Committee regard the need for compliance with international agreements such as TRIPS to be insurmountable if Australia were to seek to enact a prudent exclusion for gene patents. The Committee believes that Government should not feel prevented from enacting express exemptions of certain subject matter in future where this is justified by sufficient evidence. In the event that the Government decided to pursue an express prohibition, the Committee considers that it would be appropriate to discuss and promote this reform in relevant international forums relating to trade and the patent system.

4.127 However, the Committee concluded that there would need to be a very clear case and significant social and political consensus on the need for such a change. The totality of the submissions and evidence to the inquiry shows that there are legitimate and sometimes finely balanced arguments on both sides of the debate. Given this, the Committee believes it is critical to improve the extent and quality of interaction with the patent system by Government, as well as its understanding of the principles underpinning the operation of the patent system. As noted in the previous chapter, this is critical to ensuring that governments are aware of how effectively the patent system is operating and delivering the benefits expected in return for the grant of patent monopolies. In addition to the recommendations in Chapter 3 going to better accumulation of data on patents, a number of recommendations in the following chapter are intended to ensure that governments are informed about and engaged with the patent system, particularly in relation to the challenges thrown up by new and emerging technologies.

4.128 Finally, the Committee notes a strong consensus among opponents of an express prohibition on gene patents that the concerns which formed the basis of the Committee's inquiry can be more effectively addressed through a range of responses directed not at gene patents per se but at improving the operation of the patent system more generally. The Committee was encouraged to consider the conclusions and recommendations of a number of previous inquiries into gene patents or the patent system as the basis for its own conclusions and recommendations in this report.

4.129 In light of the factors and analysis outlined above, and despite its concern with the current practices of IP Australia around application of the invention-discovery distinction to isolated genetic materials, the Committee determined that it would not recommend at this stage that the *Patents Act 1990* be amended to include an express prohibition on human genes and genetic products.

4.130 The Committee's decision was based, first, on recent international and national legal developments relating to the patentability of genes. In the US, the courts have rejected the patenting of isolated genes on the basis that they are in fact products of nature or 'mere discoveries', and this policy has been confirmed by the US Department of Justice (see below paragraphs 4.132 and 4.133). In Australia, a similar challenge to the BRCA gene patents has commenced. If the court were to find, as in the US, that isolated genetic materials are 'mere discoveries' and therefore not patentable subject matter, there may be less need for an express prohibition on gene patents, as was considered under term of reference (c); particularly if the recommendations of this report are also implemented.

4.131 Second, the Committee's decision not to recommend an express prohibition on gene patents at this stage recognises the announcement that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill) would be introduced to the Senate in late November 2010 (see below paragraphs 4.134 and 4.135), which contains an express prohibition in specific terms. While the Committee would support an amendment to the Act to ensure that isolated genetic materials are not classed as an invention and therefore patentable, the Committee acknowledges that there are many issues which require further investigation in relation to the Bill, such as the likely impacts, effectiveness and scope of an express prohibition relating to 'biological materials' as is proposed.

4.132 As noted above, the Committee's decision not to recommend an express prohibition at this stage was influenced by international and national developments relating to the invention-discovery distinction and its application to isolated genetic materials. Since the inception of its inquiry, this very issue has been considered in the MPO case in the US.[114] The judgement in the MPO case ruled that Myriad's BRCA gene patents were invalid, largely on the basis that the claims to isolated genetic

114 *The Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others*, US District Court for the Southern District of New York, 09 Civ. 4515, p. 83.

sequences did not constitute an invention as a matter of law. On 29 October 2010, the US Department of Justice indicated that the US federal government had altered its policy to reflect the US District Court's finding on this issue (although it was not clear whether the USPTO would implement the revised policy). The Committee understands that, in the event that this ruling is mirrored in the judgement of a higher court, it will become binding on the practices of the USPTO. In such circumstances, and assuming there was no change to the Act in the meantime, the Committee would expect that the Government and IP Australia will act quickly to update Australian patent law and practice to conform with the US approach, particularly given evidence concerning the importance that IP Australia places on international harmonisation of patent systems and Australia's obligations under AUSFTA.

4.133 The Committee notes also that, on 8 June 2010, a challenge to the validity of the BRCA patents in Australia was launched in the Federal Court by Maurice Blackburn Lawyers, Cancer Voices Australia, and a Brisbane woman with breast cancer, Yvonne D'Arcy.[115] The Committee understands that, as with the US MPO case, the Australian case will focus on the fundamental question of whether or not an isolated gene sequence is an 'invention' as a matter of law and therefore patentable in the Australian jurisdiction. In the event that the Federal Court decision follows the MPO case, and assuming there was no change to the Act in the meantime, IP Australia will be required to adjust its approach to conform to that decision.

4.134 The Committee further notes that, on 17 November 2010, a group of members of the House of Representatives and senators announced that they would be introducing a private member's Bill into the federal Parliament, intended to prevent the patenting of human genes and biological materials existing in nature. The Committee notes that, if the Patent Amendment (Human Genes and Biological Materials) Bill 2010 were passed, this would effectively override the significance of the abovementioned cases in relation to the invention-discovery distinction and the granting of patents over human genes and genetic materials (assuming, of course, that the amendment was effective in terms of its intended scope and impacts).

4.135 The Committee believes that the introduction of the Bill to the Senate will provide a further, and much-needed, opportunity for the arguments and questions around the impacts and effectiveness of an express prohibition on gene patents to be considered. The Committee agreed that a Senate inquiry into the Bill should be undertaken, with a focus on the specific terms of the proposed amendments and the implications of their implementation for human health and other potentially affected fields of innovation. The Committee notes that its inquiry has served a valuable purpose in bringing the issue of gene patenting to the light of public interest and

115 Maurice Blackburn Lawyers website, 'Biotech monopoly on cancer genes is unlawful: Australian test case over patents', 8 June 2010, available at http://www.mauriceblackburn.com.au/news/press-releases--announcements/biotech-company-monopoly-on-cancer-genes-is-unlawful-australian-test-case-over-patents.aspx (accessed 20 August 2010).

attention, and provides a sound basis on which a targeted inquiry into the Bill can build. In recognition of the seriousness and complexity of the issues around the issue of expressly prohibiting gene patents, as outlined in this report, the Committee would expect that the Senate will ensure the time allowed for an inquiry into the Bill is sufficient to ensure due consideration of relevant issues and the arguments of potentially affected interests.

4.136 In consideration of the developments outlined above, the Committee intends to maintain a watching brief over the area of gene patents. As part of this watching brief, the Committee will continue to monitor the progress and outcomes of the US and Australian cases relating to the patenting of isolated genetic materials, as well as the progress of the Patent Amendment (Human Genes and Biological Materials) Bill 2010 through the federal Parliament.

Recommendation 3

4.137 The Committee recommends that the Senate refer the Patent Amendment (Human Genes and Biological Materials) Bill 2010 to the relevant Senate committee for inquiry and report.

4.138 Despite the Committee's decision not to recommend an express prohibition on gene patents at this point, the next chapter makes a number of recommendations for measures to ameliorate any adverse impacts arising from gene patents. The rationale behind many of these is to raise the thresholds of patentability such that, despite there being no direct prohibition on gene patents, the number of gene patents being granted would necessarily be reduced, and the quality of those that are granted will be greatly improved. Yet other recommendations seek to ensure that the Government utilises existing options under the Act to ameliorate the impacts of gene patents on healthcare, where these arise; to ensure that research is not impeded by the patent system; and to institute a mechanism for external and objective assessment of the patent system and the performance of IP Australia.

4.139 The Committee notes that the recommendations in the next chapter (as well as those elsewhere in this report), would not be rendered obsolete or less effective in the event that the express prohibition contained in the Patent Amendment (Human Genes and Biological Materials) Bill 2010 became law. The Committee's recommendations are not directed at gene patents per se, but at patents and the patent system more generally, and many of these are based on patent reform recommendations for which there has been widespread and longstanding support. Indeed, the Committee notes that, in the event that Parliament agrees to legislate an express prohibition on biological materials as proposed, the recommendations in this report relating to information and data collection could be critical to ensuring that the intended effects and benefits of the prohibition on gene patents are able to be assessed into the future. The recommendations in this report would also ensure that gene patents relating to isolated genes (if these continue to be granted) or to the downstream uses of genes (to which the Committee believes gene patents should and would be restricted if the invention-discovery distinction were being properly applied) are of high quality, and thus clearly justified in both social and economic terms.

CHAPTER 5

MEASURES TO AMELIORATE ANY ADVERSE IMPACTS OF GENE PATENTS

5.1 This chapter addresses term of reference (b), which directs the Committee to identify measures that would ameliorate any adverse impacts arising from the granting of patents over human genes and genetic materials, including whether the *Patents Act 1990* (the Act) should be amended, in light of the matters identified by the inquiry.

INTRODUCTION

5.2 As noted in the previous chapter, many stakeholders disagreed with any proposal for an express prohibition on gene patents, but instead supported measures to improve the quality of patents and reform the operation of the patent system more broadly. IP Australia, for example, argued that a range of reforms and strategies could preserve an appropriate balance between the incentives and benefits that flow from gene patents and their potential for adverse impacts on healthcare and medical research. Medicines Australia expressed a typical view about the goal of such reforms to the patent system:

> …any reform of the Australian patent system must embody the following guiding principles: the system must uphold the globally accepted balance between the incentive to innovation and a society's right to access innovative products at a fair and affordable price…[1]

5.3 The Committee notes that, while the recommendations in this chapter are posited in the particular context of gene patents, the measures identified are in fact general measures that would apply equally to all patent applications. In taking this approach the Committee acknowledges that, despite the inquiry's relatively narrow terms of reference, many of the actual and potential problems relating to gene patents that were identified arise in relation to the patent system more broadly.

5.4 The Committee notes that the recommendations contained in this chapter are to be understood implicitly or explicitly as being made in the context of the many previous and current inquiries into the issues raised by the inquiry's terms of reference.

Raising the thresholds of patentability

5.5 Recommendations going to the raising of the thresholds of patentability are concerned with the first element of patent quality: that is, the legislative requirements

1 Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 5 August 2009, p. 31.

of patentability. The Committee considered evidence going to the following requirements:

- manner of manufacture;
- inventive step; and
- usefulness.

5.6 Many submitters and witnesses observed that the thresholds of patentability in Australia have been eroded through judicial and administrative decision-making. Dr Matthew Rimmer commented that there is a 'general consensus that there needs to be something done in relation to patent quality'.[2]

5.7 The Advisory Council on Intellectual Property (ACIP) options paper observes:

> …there are concerns that decision makers have extended the reach of patents on legal rather than economic grounds. The boundaries of patentable subject matter have expanded through administrative and judicial decisions...Venturous Australia (the Review of the National Innovation System) found the ease with which patents are granted in areas such as software and business methods may be hampering innovation.[3]

5.8 DIISR and IP Australia acknowledged the incremental changes to patentability thresholds as a result of decisions by Australian courts, and observed that, as a result, Australia has lower patentability thresholds than other jurisdictions.[4] The DIISR and IP Australia submission suggested that this carries broad implications for the operation of the patent system in the international context:

> For countries that are a net importer of technology, like Australia, it is advantageous to have patent thresholds set at least as high as thresholds set for countries with which we conduct the majority of our technology trade. Strong and aligned thresholds give Australian innovators confidence that having satisfied those [thresholds] in Australia they are likely to satisfy the requirements in their export markets. Aligned thresholds are also likely to reduce costs for Australian applicants seeking patent protection overseas. Conversely, differences that make Australia's patent law out of step with major jurisdictions may adversely affect Australian businesses wanting to develop their inventions and prosper in a global market place.[5]

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2 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

3 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 2.

4 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 3.

5 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 9.

Manner of manufacture

5.9 The Australian Law Reform Commission (ALRC) in its 2004 report on gene patents, *Genes and ingenuity* (the ALRC report), concluded that aspects of the manner of manufacture test are ambiguous. It recommended:

> The responsible Minister should initiate a 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]

5.10 As noted in Chapter 2, ACIP is currently undertaking a review of patentable subject matter which encompasses the issues outlined in the ALRC's recommendation above. The ACIP review website notes that in recent years a variety of concerns have been raised about the sorts of things that can be patented in Australia, and draws attention to the findings of the ALRC report that the 'manner of manufacture' test is ambiguous and obscure. The review includes consideration of:

- the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian law; and
- the historical requirement that an invention must not be 'generally inconvenient'.[7]

5.11 The submission of Professor Andrew Christie noted that those who object to the patentability of genetic inventions do so on either economic or social (non-economic) reasons. The submission stated that economic concerns are usually based on the view that these patents are overly broad and therefore anti-competitive, or impact adversely on healthcare and medical research. Concerns about overly broad patents are able to be addressed through the requirement of usefulness (discussed below); and concerns about impacts on healthcare and medical research are able to be addressed through Crown use provisions and development of a research exemption (also discussed below).[8]

5.12 However, in relation to socially based objections to gene patenting, Professor Christie observed that the 'manner of manufacture' test is the 'main mechanism' by which Australia's patent system is able to take account of social or non-economic considerations in relation to the granting of patents. The question of how well the current test accommodates or achieves social objectives, such as those based on moral or ethical concerns, is an important aspect of the current ACIP review.[9]

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6 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 132.

7 Advisory Council on Intellectual Property web site, http://www.acip.gov.au/reviews.html#subject (accessed 29 September 2009).

8 Professor Andrew Christie, *Submission 38*, p. 7.

9 Professor Andrew Christie, *Submission 38*, p. 8. Professor Christie is the Chair of the Advisory Council on Intellectual Property review of patentable subject matter. Professor Christie appeared before the inquiry in a private capacity.

5.13 The ACIP options paper on patentable subject matter notes that the threshold requirements for patentability—manner of manufacture, novelty, inventive step et cetera—have been described as being a 'rough proxy' for the benefits of a claimed invention. That is, 'these tests advance the economic goals of the system'.[10]

5.14 In contrast, the Act contains a number of express exclusions and discretions to refuse a patent. Human beings and the biological processes for their generation are not patentable inventions, and the Commissioner of Patents may refuse a patent where:

- the use of the invention would be contrary to law;
- a substance is capable of being used as a food or medicine and it is a mere mixture of known ingredients; or
- the name of a person is used as the name of the invention in a claim.[11]

5.15 The exclusions and discretions contained in the Act may be considered as acting to '[filter] out some subject matters where patents may be undesirable, taking social concerns into account'. Thus 'the threshold tests can be viewed as chiefly economic in nature, while the filters or exclusions for undesirable subject matter are predominantly social in nature'.[12]

5.16 In putting forward a number of specific options for reform of the manner of manufacture test, the ACIP options paper concluded:

> …our view is that the legislation must be able to regulate what can and cannot be patented, as determined both economically and socially. In addition, the legislation must be logical, compliant and practical. It must be logical in that it is internally consistent. It must be compliant in that it is not inconsistent with Australia's international obligations. And, it must be practical in that administration of the law is effective and transparent.[13]

5.17 In relation to the options being considered by ACIP:

> The options we have devised follow a similar approach, of economic tests and social filters, to define the field of patentable subject matter. In addition, there are a number of changes that could enhance the operation and administration of the law.[14]

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10 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 5.

11 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 5.

12 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 5

13 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 7.

14 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 7.

5.18 The ACIP options paper offers four mutually exclusive options for reform of the manner of manufacture test:

> A. Retain the manner of manufacture test. This option retains the requirement that an invention must be a 'manner of manufacture within the meaning of section 6 of the *Statute of Monopolies*'.
>
> B. Clarify the language of the definition of an invention, for example by using the NRDC requirements that an invention must be an artificially created state of affairs in a field of economic endeavour.
>
> C. Replace the manner of manufacture test with an alternative test, such as the TRIPS Agreement language that patents are available for any inventions in a field of technology.
>
> D. Delete the requirement for an invention. Under this option, the objective tests of novelty, inventive step and usefulness would do the economic work of limiting patentable subject matter.[15]

5.19 A number of submitters supported changes to the Act that fall within the scope of the ACIP options for reform of the 'manner of manufacture' test, such as by clarifying the current test or developing a new definition of invention. For example, Dr Graeme Suthers, from the Royal College of Pathologists of Australasia, submitted:

> The current patent legislation should be implemented using a rational interpretation of words such as 'invention' and 'discovery'. The problem principally has been with the interpretation of the law and the amendment required is one to ensure that this distinction between inventions and discoveries is made explicit…We must address the anomaly of patenting a discovery.[16]

5.20 Dr Hazel Moir submitted:

> If the *Patents Act 1990* were to be amended to provide guidance to the courts and IP Australia on when a discovery is not an invention, I would recommend an amendment focusing on these combined characteristics. This would not only prevent patenting of genetic information identical to that found in nature, but would also provide sound principles for future contentious areas.
>
> …[The] policy the Committee might consider for adoption could be that…to be patentable an invention must be *substantially different* from anything found in nature and the *differences must contribute sufficient utility to provide a benefit* to the nation.[17]

5.21 Dr Rimmer noted:

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15 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 11.

16 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 41.

17 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 3.

> …it would be much more worthwhile thinking about some of the issues in relation to manner of manufacture that need clarification, like stem cell patent…[The] Metabolite Laboratories case and the Australian case of Grant against the Commissioner of Patents shows that there are certain areas that do need clarification, particularly distinguishing between scientific discoveries and inventions and the scope of abstract ideas and products of nature. So I think there is a kind of in between position between the extremes of 'anything under the sun is patentable' and 'we should have broad prohibitions or exclusions of patentable subject matter'.[18]

5.22 In relation to specific exclusions and discretions to refuse, the ACIP paper offers three non mutually exclusive options for reform of the Act's 'social filters':

> E. Retain the current exceptions and filters;
>
> F. Add specific exclusions, such as a list of specific subject matters that are not patentable;[19] and
>
> G. Add general social filters, such as excluding inventions that are 'generally inconvenient' and/or 'contrary to *ordre public* or morality'.[20]

5.23 The ACIP paper notes that under Option F above it would be possible to have an exclusion for 'a mere discovery'. In relation to concerns about gene patents in particular, the Committee notes that this option would allow the excluding of specific subject matter of this type:

> This option…provides a list of things that are not patentable because they do not benefit society, regardless of whether they are inventions. Any exceptions would need to comply with Australia's international obligations.[21]

5.24 Further, the ACIP paper notes that this approach could 'promote greater certainty' in the patent system, provided interpretation issues can be properly managed'.[22]

5.25 Given the scope of the ACIP review and its relevance to the issue of gene patents, Professor Christie submitted:

> The appropriate response to the concern about the inherent patentability of genetic inventions is to determine whether—and, if so, how—the manner of

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18 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 20.

19 Chapter 4 considers the specific issue of whether the Act should contain a specific exclusion, or express prohibition, on gene patents.

20 The options paper notes, however, that the 'meaning and ongoing application of 'generally inconvenient' is unclear' (p. 16).

21 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 18.

22 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 18.

> manufacture test should be reformed. That is the topic of the ACIP review of Patentable Subject Matter. The appropriate action for the government, therefore, is to await, to consider and, if in agreement, to implement the recommendations resulting from that review.[23]

Inventive step

How inventive step is determined in Australia

5.26 As noted in Chapter 2, the requirement that an invention involve an inventive step is fundamental to the patent system, as it ensures that a monopoly is not awarded for knowledge that was obvious or that would have been available at the time of the patent application.

5.27 In Australia, whether an invention involves an inventive step is judged by a comparison with the state of knowledge in the field relevant to the invention, referred to as the 'prior art base'. Section 7(2) of the Act provides:

> For the purposes of this Act, an invention is to be taken to involve an inventive step when compared with the prior art base unless the invention would have been obvious to a person skilled in the relevant art in the light of the common general knowledge as it existed in the patent area [ie in Australia] before the priority date of the relevant claim, whether that knowledge is considered separately or together with the information mentioned in subsection (3).

5.28 The Act defines 'prior art base' as including:

- information in a document that is publicly available, whether in or out of the patent area (ie anywhere in the world); and
- information made publicly available through doing an act, whether in or out of the patent area (ie anywhere in the world).

5.29 Section 7(3) of the Act then provides that the information for the purposes of Section 7(2) is (a) any single piece of prior art information; or (b) a combination of any two or more pieces of prior art information:

> …being information that the skilled person mentioned in subsection (2) could, before the priority date of the claim, be reasonably expected to have ascertained, understood, regarded as relevant and, in the case of information mentioned in paragraph (b), combined as mentioned in that paragraph.

Criticisms of current approach

5.30 Many submitters and witnesses objected to the grant of certain gene patents for the reason that they did not contain sufficient inventiveness to warrant the grant of monopoly. However, the Law Council of Australia questioned whether the level of

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23 Professor Andrew Christie, *Submission 38*, p. 8.

inventiveness required for the granting of a patent is too low, observing that there have been 'very few challenges to the validity of granted gene patents'.[24]

5.31 With particular reference to the inquiry's terms of reference, Dr Palombi called on the patent system to be adjusted to:

> …increase the inventive step threshold so that uses of such materials in applications that are routine and standard, such as in diagnostics, will no longer be patentable.[25]

5.32 However, IP Australia submitted that a number of common misconceptions operate in respect of the requirement of inventive step. In particular, it emphasised that inventive step is determined against the state of knowledge or prior art base at the time a patent claim was lodged:

> Some researchers query the validity of patents for isolating and determining the function of particular genes, as techniques to accomplish this are now quite routine and well-known. However, a misconception can arise from the application of hindsight and taking into account the knowledge base that exists now compared to when the patent application was assessed. Although isolating the gene sequence might be routine now, Inventive Step is assessed as at the 'priority date' of the patent claims, which could be many years in the past.[26]

5.33 IP Australia also pointed to a common misconception that patents are granted only for 'ground-breaking inventions':

> This misunderstanding is most often voiced by researchers. That belief is inconsistent with recent High Court authority which affirms that only the smallest level of inventiveness (i.e. a scintilla of inventiveness) is needed for the grant of a patent. Inventions as defined by patent law can be, and often are, incremental advancements over what has been done before.[27]

5.34 Despite any prevailing misconceptions, IP Australia supported changes to raise the threshold for inventive step. It noted:

> …lower inventive threshold requirements in Australia raise the question whether Australian law strikes the correct balance between the scope of monopolies and access to innovation and new technology.[28]

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24 Law Council of Australia, *Submission 57*, p. 2.

25 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 12.

26 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 22.

27 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 22.

28 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 13.

5.35 An IP Australia consultation paper on reforms to the IP system noted that too low a threshold for inventive step could also involve a greater potential for the development of 'patent thickets', whereby overlapping sets of patent rights act as a barrier or disincentive to innovation.

5.36 IP Australia also pointed to trends in overseas jurisdictions towards the raising of inventive step thresholds. Similarly, Dr Rimmer noted:

> The approach of the United States Supreme Court…has been very interesting in terms of raising the standard of novelty and inventive step in applying a slightly higher threshold in terms of what is required. That is being applied in terms of biotechnological inventions…[and] I think that has been a very productive approach...[29]

Potential reforms affecting inventive step

5.37 In a recent discussion paper on possible reforms to the patent system, IP Australia identified three particular elements of the requirements of inventive step which are 'set at a lower level than those of other jurisdictions or of international norms':

- common general knowledge;
- prior art; and
- threshold test for inventive step.[30]

Common general knowledge

5.38 The IP Australia consultation paper on possible reforms to the patent system observes that the restriction of the prior art base to 'common general knowledge in the relevant art in Australia' is out of step with international approaches:

> [Australia's approach]…restricts common general knowledge in a way that it is not restricted in our major trading partners and under the PCT, where when assessing inventive step, common general knowledge anywhere in the world can be taken into account. Such a restriction is also at odds with deliberations in international forums…where there has been a consistent move to global concepts of prior art and validity on the basis that information that invalidates a patent in one jurisdiction should also invalidate patents in others. It also does not take account of the global research, information and innovation environment that exists today.[31]

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29 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

30 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 9.

31 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 10.

5.39 Accordingly, IP Australia has proposed that the Act be amended to remove the limitation that common general knowledge be confined to that existing in Australia at the time a patent application is lodged.

5.40 The Committee notes that previous inquiries have considered this issue. The Ergas Report recommended that the prior art base for determining inventive step be expanded to include all information, including common general knowledge, anywhere in the world.

5.41 However, Dr Moir commented:

> Personally I consider that using a global standard for 'common general knowledge' would have almost no impact on the quantum of inventiveness required for a patent monopoly. The many rules and procedures about decisions on patent grant are each slanted in favour of the applicant. As the US Federal Trade Commission said in respect of the USA, a 'plethora of presumptions and procedures tip the scales in favor of the ultimate issuance of a patent, once an application has been filed' (US FTC 2003: 8). Australia uses many of the same rules, but excludes even more existing knowledge from decisions on inventiveness. In my view far more radical proposals are needed to set the patent system back on a path where it delivers benefits to the nation.[32]

Prior art

5.42 As noted above, the 'prior art base' against which inventive step is assessed is defined as including:

- information in a document that is publicly available, whether in or out of the patent area (ie anywhere in the world); and
- information made publicly available through doing an act, whether in or out of the patent area (ie anywhere in the world).

5.43 Such information may be considered as part of the prior art base if it is information that a skilled person in the relevant art could be 'reasonably expected to have ascertained, understood, regarded as relevant and…[if involving a combination of any two or more pieces of prior art information] combined'.[33]

5.44 The IP Australia consultation paper on reform of the patent system notes that Australia's approach places limitations on how prior art information can be considered that 'do not exist elsewhere':

> In Australia prior art information must be such that a skilled person in the art could be reasonably expected to have ascertained, understood and regarded [it] as relevant. This approach has led to circumstances where the

32 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 2.

33 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

> Federal Court has found that information in US patents, although highly relevant and readily understood, would not have been ascertained in certain circumstances.[34]

5.45 In comparison, other jurisdictions did not have a requirement that the skilled person would have ascertained, or 'looked for and found the [relevant] prior art' information. IP Australia considered that this approach 'is more aligned with the global innovation environment that exists today where there is more ready access to information via the internet and electronic means'.[35]

5.46 Further, the need to establish that a skilled person would have found a relevant citation was not a feature of patent systems in other major countries. Parties seeking to challenge an Australian patent would need to carry the evidentiary burden on this question, which could increase the uncertainty and costs of patent litigation:

> The Federal Court also noted that when the ability of the skilled person to ascertain relevant prior art is in doubt it is necessary to have evidence to resolve the dispute. This has the potential to introduce significant additional costs to litigating patent disputes.[36]

5.47 IP Australia advised that it was currently considering changes to the Act to remove the requirement that prior art information for the purposes of inventive step must be that which could be reasonably expected to be 'ascertained'.[37]

Threshold test for inventive step

5.48 Dr Rimmer advised the Committee that there were concerns with the level of inventiveness credited to the person skilled in the art when assessing inventive step:

> A lot of commentators have…emphasised the role of a person skilled in the art. A great problem in terms of the judgments in relation to novelty and inventive step has been that a person skilled in the art is credited too little creativity. Some commentators…argue that [for] the reasonable person test, the person skilled in the art, you must attribute a greater level of creativity to them.[38]

5.49 In Australia, the threshold test for inventive step is formulated as an inquiry as to whether an invention lacks an inventive step, or in other words is obvious. IP

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34 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

35 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

36 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

37 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 11.

38 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

Australia's consultation paper on reform of the patent system notes that the test for obviousness is to ask whether or not the skilled person in the relevant art would be led directly as a matter of course to try a particular approach with a reasonable expectation of success.[39]

5.50 IP Australia was proposing that Australia adopt a test for obviousness similar to that which is employed by the European patent community, where the test is to ask: Would the invention have been obvious to try with a reasonable expectation of success? Specifically, IP Australia proposed that the inventive step test be revised so that a claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.[40]

5.51 IP Australia argued that under such a test it would be easier to argue obviousness than under current Australian law, as it would account for 'situations where it is routine to conduct testing or combine particular approaches in order to solve a problem or find a better way of doing things'.[41]

5.52 In relation to such an approach, the ACIP options paper on patentable subject matter observes:

> The US Supreme Court has recently reinstated a similar test in that country. A submission to the Senate Gene Patent Inquiry by several US Law Professors has suggested that these developments in the US law are likely to call the validity of many patents for gene sequences into question, now that the methods of DNA isolation are conventional.[42]

Usefulness

5.53 The Committee heard that the usefulness of an invention is assessed both explicitly and implicitly under the Act.[43]

5.54 First, section 18(1)(c) of the Act requires that an invention be 'useful'. However, IP Australia advised that this requires only that an invention produce the result or effect that the patentee claims it can achieve:

> To satisfy the patentability criteria an invention must be useful. This does not mean the invention has some usefulness to society or that it is

39 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 12.

40 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 13.

41 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', IP Australia Consultation Paper, March 2009, p. 12.

42 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 51.

43 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 21.

> commercially viable or successful. Rather Usefulness under patent law requires that the claimed invention be capable of achieving the result(s) that the patentee promises it can achieve.[44]

5.55 The ALRC report explains:

> …the usefulness criterion does not require that an invention be useful in the sense that it is worthwhile or commercially viable; only that if a particular result is claimed, it must be achievable.[45]

5.56 Professor Andrew Christie observed that this interpretation of usefulness was more limited than that which is applied in other jurisdictions:

> …the concept of 'useful' in Australian patent law is quite different from – and, in particular, is much more limited than – the concept of 'utility' in US patent law and the concept of 'industrial application' under the European Patent Convention.[46]

5.57 Second, along with the explicit requirement that an invention be 'useful' under section 18 of the Act, the 'manner of manufacture' requirement is also understood as containing an implicit requirement that an invention be useful. The ALRC report observes:

> 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'.[47]

5.58 Third, the usefulness of an invention is also considered indirectly pursuant to the requirement in section 40 of the Act that a complete specification fully describe the use of the invention and how the result claimed can be achieved. The ALRC report explains that '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'.[48]

5.59 Despite the various ways in which usefulness is currently considered under Australian patent law, the usefulness of an invention does not operate as an express requirement for examination of an Australian patent application. The ALRC report explains:

> 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

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44 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 20.

45 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 143.

46 Professor Andrew Christie, *Submission 38*, p. 5.

47 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 143.i

48 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 144.

> useful under s 18(1)(c) before accepting a patent application. 'Lack of utility' (as the objection is phrased) can be raised as an express objection only in revocation proceedings. It is not a separate basis upon which a patent may be opposed or re-examined. 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.[49]

5.60 IP Australia advised that it was proposing reforms which would introduce usefulness as an express requirement for examination, beyond the limited sense in which it is currently considered:

> IP Australia is proposing a number of changes to the Usefulness requirement under the Patents Act…Under the proposals, Usefulness would become a ground for consideration in examination and it would be clarified that the claimed invention would have to demonstrate 'specific, substantial and credible utility' similar to requirements in the United States. These changes are the same as those proposed by ALRC Report 99, recommendations 6-3 (a) - (c).[50]

5.61 The Committee notes that the proposal for the inclusion of usefulness as a requirement in patent examination was recommended by the ALRC in its 2004 report. The report also recommended that an invention only satisfy the usefulness requirement where a patent application discloses a 'specific, substantial and credible use'; that the question of usefulness be decided on the balance of probabilities; and that 'lack of usefulness' be available as a basis upon which a patent application may be opposed.[51]

5.62 This approach was endorsed in the ACIP options paper on patentable subject matter, which noted that the requirement that an invention have a specific, substantial and credible utility 'will provide additional clarity to the law'.[52] The paper described how these elements might apply to a patent application:

> [A requirement that an invention have a specific, substantial and credible utility would mean that]…an invention would need to be:
>
> - specific – the use is specific to the subject matter of the invention and not a generic use;
> - substantial – no further research is required to identify a real or specific use;

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49 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 144.

50 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 20.

51 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendation 6-3, p. 157.

52 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 21.

- credible – the use is logical and consistent with the state of the art.[53]

5.63 IP Australia also commented on the expected scope of the new usefulness requirement:

> Concerning [stricter] requirements to prove an invention's usefulness at examination and require experimental results showing that the patented invention has utility…These changes to utility will not go so far as requiring applicants to demonstrate their invention's efficacy in humans (as has been suggested by some comments to the Inquiry) as that level of experimental evidence is unrealistic at the early stage of seeking patent protection.[54]

5.64 Professor Christie observed that the requirement of usefulness was connected with the question of overly broad patent claims, which were specifically identified as an issue in relation to gene patents.[55] He explained:

> Some stakeholders are of the view that patents are being granted for genetic inventions that are 'too wide', in the sense that the claims of the patent cover subject matter that goes beyond the actual invention made by the patentee. Because the exclusive rights of a patent apply to the subject matter of the claims of the patent, if the claims are too wide then the exclusive rights granted by the patent will also be too wide. [The requirements that a claimed invention is useful are] primary mechanisms for ensuring that the claims of a patent are not too wide…
>
> The appropriate response to the concern about the width of the exclusive rights provided by patents for genetic inventions is to require that the claims of the patent do not go beyond the actual invention made and disclosed by the patentee.[56]

5.65 Mrs Beattie acknowledged that the proposed usefulness requirement could operate to limit overly broad patent claims:

> …some of the initial patents did have broad claims that may not have been supported as well as they could have been, but patent reforms that we are proposing would limit the scope of those claims to the extent that you would have to demonstrate utility. So we would be examining for specific utility and it would have to be specific, substantial and credible. To that effect you would not be able to say that a particular nucleic acid has a therapeutic effect, full stop. You would have to be very specific about the nature of the therapeutic effect that you expected this to have and provide

53 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 23.

54 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 5.

55 See, for example, Professor Ian Olver, Chief Executive Officer, Cancer Council Australia, *Committee Hansard*, 5 August 2009, p. 10.

56 Professor Andrew Christie, *Submission 38*, p. 5.

> some support for those claims. So, yes, I think some of the original patents that were broader may have been granted…[57]

5.66 Mrs Beattie noted that some patents granted in the past may have been refused if subject to the proposed new test:

> In terms of what we are proposing with the patent reforms some of those [overly broad] patents may have failed. If we were able to, for example, examine on utility, they may have failed on specific, substantial and credible.[58]

5.67 The ACIP options paper observes that the usefulness requirement also bears on the issue of distinguishing between inventions and discoveries in determining patentability of subject matter:

> Both the ALRC and IPCRC considered that the requirement for usefulness has taken on greater importance in some new technologies, where the dividing line between mere discovery and invention has become difficult to define. This option would also require patent examiners to assess, and report on, the usefulness of an invention as a separate requirement.[59]

5.68 In relation to gene patents in particular, the paper noted the view of the IPCRC that the requirement of a specific, substantial and credible utility 'would exclude the mere identification of a gene sequence from patentability'.[60]

5.69 Dr Rimmer noted that the proposed usefulness requirement had effectively operated to exclude certain gene patents in the US:

> The other very important thing on questions of patent quality is introducing the US standards in relation to utility, for there to be a substantial specific and credible utility. There is a big biotechnology case in the United States in re Fisher dealing with the patentability of expressed sequence tags in relation to maize. The Court of Appeals for the Federal Circuit rejected the particular patent application by Monsanto…on the grounds of utility.[61]

Full description and fair basis

5.70 IP Australia advised that it was considering reforms to section 40 of the Act which could also help to address concerns about the granting of overly broad patents. Section 40 requires that a patent specification provide sufficient detail to describe an

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57 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 30.

58 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 32.

59 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 23.

60 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 36.

61 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

invention, and that a claim is 'fairly based on the matter described in the specification'. IP Australia's consultation paper on patentability standards explains:

> It is a fundamental basis of the patent system that the patentee describe their invention fully and that the scope of protection obtained does not go substantially beyond what has been described [in the patent specification] (ie is 'fairly based').
>
> This is the *quid pro quo* that forms the basis of the patent system: the patentee is given a time limited monopoly in exchange for public disclosure of their invention and detailed information about how to make and use the invention.[62]

5.71 The IP Australia consultation paper notes that 'there is a notable difference between full description and fair basis requirements in Australia and requirements in the US, Europe and Japan'. In these jurisdictions a patent specification must provide 'sufficient details of the invention to enable the reader to produce anything across the full scope of the invention claimed'. In contrast, the requirement in Australia is 'simply that there is sufficient detail to produce something, potentially only one thing, within the scope of the claim'. In relation to 'fair basis' requirements:

> This fair basis requirement has come to be understood as one of consistency between the specification and the claims. It is not a test [of] whether the description of the invention and technical detail in the body of the specification is sufficient to support the scope of the invention that is claimed...[63]

5.72 The consultation paper concludes that the lower Australian requirements in relation to full description and fair basis 'allows a patentee to monopolise a greater field than they have disclosed to the public', raising issues as to 'whether an invention may be afforded substantially broader protection in Australia than could be obtained in other jurisdictions'.[64]

5.73 IP Australia was proposing that section 40 of the Act be amended to:

> …introduce descriptive support requirements analogous to those applied in other jurisdictions including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.[65]

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62 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, p. 6.

63 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, p. 7.

64 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, pp 7-8.

65 IP Australia, 'Getting the balance right: toward a stronger and more efficient IP rights system', March 2009, p. 8.

5.74 IP Australia expected that raising the threshold for disclosure requirements in this way would 'limit the reach of claims so that the protection given to an inventor is not disproportionate with what has been described'.[66]

OTHER MEASURES

5.75 Apart from suggestions for reform of the patent system that went to the legal requirements for patentability, the Committee received numerous suggestions for reform going to other aspects of the Act, such as the Crown use and compulsory licensing provisions, and the lack of an explicit research exemption. Yet other suggested reforms went to what might be termed external measures or strategies to improve the operation of the patent system more generally, and in this way address particular concerns around gene patents and their actual and potential impacts.

Crown use provisions

5.76 A number of submitters and witnesses suggested that the existing Crown use provisions in the Act (ss 163-170) could be employed to ameliorate any potentially adverse impacts of gene patents on the healthcare and medical research sectors. Regarding the scope and operation of the Crown use provisions IP Australia advised:

> The Crown Use provisions of the Patents Act permit certain government entities to use, and to authorise others to use, patented inventions, without permission from the patent owner in certain circumstances. The use is only permissible where such use is for the [proper provision of] services of the Commonwealth, the State or a Territory. The government would have to pay the patent owner or exclusive licensee remuneration for that use, in accordance with the Patents Act.[67]

5.77 A 2005 ACIP report on the Crown use provisions notes:

> The ultimate purpose of the provisions is to ensure that governments in Australia can balance the grant of exclusive patent and design rights to IP owners, with the needs of the Australian public.[68]

5.78 Professor Christie noted that the Crown use provisions had potential to address concerns about the effect of gene patents—notably that in some situations a patent for a genetic invention has been, or will be, used to preclude wide public access to that invention, such as in the case of the BRCA genes and the attempt by Genetic Technologies to enforce its exclusive right to conduct BRCA testing in Australia. Professor Christie submitted:

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66 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 5.

67 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 30.

68 Advisory Council on Intellectual Property, *Review of Crown use provisions for patents and designs*, November 2005, p. 1.

> It must be noted…that the Australian patent legislation contains a mechanism by which the government can compulsorily acquire a right of access to an invention: the Crown use provisions.[69]

5.79 IP Australia submitted that :

> These provisions might be able to assist government bodies where they can establish that such use is necessary for the proper provision of government services within Australia.[70]

5.80 However, Dr Palombi submitted that there was 'no evidence of the exercise of Crown use [provisions]', and questioned whether these provisions would be effective to address issues around exclusive patent rights:

> There is no evidence that...Crown use provisions—which would be useful in ameliorating some of the worst excesses of the patent system in this instance—have [ever] been effectively used. So we are unfortunately in a situation where, as with the BRCA1, we have an Australian company that, had it acted within its rights, could have actually sought injunctions to close down all of the public testing in this country for breast and ovarian cancer.[71]

5.81 IP Australia acknowledged that there was some uncertainty around the operation of the Crown use provisions, commenting that, 'to IP Australia's knowledge, these provisions have been rarely litigated and interpreted by the courts'.[72]

5.82 The Committee notes that in its 2004 report the ALRC made a number of recommendations to ensure that the Crown use provisions are sufficient to specifically address health issues, and that the circumstances justifying their use are sufficiently well defined. The ALRC recommended:

- that the Australian Health Ministers' Advisory Council 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 for the purposes of promoting human health;
- that the Department of Health and Ageing 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;
- that the 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

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69 Professor Andrew Christie, *Submission 38*, p. 6.

70 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 30.

71 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 22.

72 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 30.

authority (or by an authorised person) is for the provision of healthcare services or products to members of the public; and

- that the Act be amended 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 the Act be amended to ensure that remuneration for an acquired patent is paid promptly, and is just and reasonable.[73]

5.83 In relation to the ALRC's recommendations, Dr Rimmer observed:

> I think they [the ALRC] need to go further and pick up the requirements under the TRIPS Agreement to adequately have domestic and export mechanisms to deal with essential medicines.[74]

5.84 Professor Christie noted that ACIP had also conducted a review of the Crown use provisions:

> The scope and operation of the Crown use provisions was the subject of a review by the ACIP in 2004-2005. That review concluded that entitlement of the Crown to access an invention in the public benefit should be maintained, but that the provisions should be amended to ensure a more transparent and accountable process for their utilisation. The government has not, as yet, implemented these recommendations.[75]

Compulsory licensing

5.85 IP Australia advised that 'a compulsory licence can be sought where the patent holder fails to meet the reasonable requirements of the public or where they engage in anticompetitive conduct (ss 133-140)'.[76] The Act sets out the circumstances where, for the purposes of granting a compulsory licence, the 'reasonable requirements of the public with respect to a patented invention' are to be taken not to have been met. These include:

- where an existing trade or industry in Australia, or the establishment of a new trade or industry, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:

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73 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 34.

74 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

75 Professor Andrew Christie, *Submission 38*, pp 5-6.

76 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 29. As well as showing the reasonable requirements of the public have not been met the applicant must show that the patentee has no satisfactory reason for failing to exploit the patent; and that the applicant has tried unsuccessfully to obtain a licence from the patentee (see section 133(2)(a)(i)-(iii)).

- to manufacture the patented product to an adequate extent and supply it on reasonable terms; or
- to grant licences on reasonable terms.[77]

5.86 Dr Charles Lawson noted that the purpose of the compulsory licensing of patents is 'to encourage the licensing and working of inventions sooner, serving as an effective incentive for patent holders to grant a licence voluntarily and on their own terms'.[78]

5.87 Dr Lawson observed that:

> …compulsory licensing is one of the very few avenues available to limit patent abuse and misuse, and has become (potentially) increasingly important with the lowering of the patent threshold standards of subject matter and obviousness.[79]

5.88 Many submitters and witnesses identified the compulsory licensing provisions of the Act as having the potential to ameliorate any adverse impacts of gene patents on healthcare and medical research. The ALRC submitted:

> …the key factor in ensuring both the accessibility of quality health care and the facilitation of further research is the smooth functioning of the system regulating licensing and use.[80]

5.89 Professor Ron Trent, University of Sydney, noted that he had not witnessed significant problems arising from gene patents per se, but identified exclusive licences as having the potential to adversely impact on the availability and quality of healthcare:

> To me, [exclusive licensing] is the real key issue in terms of the sorts of patents that we have. In the breast cancer example, if an exclusive licence is given to one company…I have concerns that this will impact negatively on both the availability of the test as well as the quality of the test.[81]

5.90 Similarly, Dr Suthers submitted:

> For existing gene patents, our principal concerns would be addressed by ensuring that the patents do not provide a monopoly on medical testing. Gene patents must be broadly licensed so that laboratories are free to

77 *Patents Act 1990*, section 135(1)(a)(i) and (iv).

78 Dr Charles Lawson, *Submission 5*, p. 1.

79 Dr Charles Lawson, *Submission 5*, Attachment 1, p. 3.

80 Australian Law Reform Commission, *Submission 18*, p. 2.

81 Professor Ron Trent, *Committee Hansard*, 5 August 2009, p. 53.

> perform the test and improve on it as required. However, unrestrictive licensing is not the whole solution.[82]

5.91 Dr Gillian Mitchell, Director, Familial Cancer Centre, Peter MacCallum Cancer Centre, also called for compulsory licence provisions to be used to ensure that patent holders did not use their rights in such a way as to slow the delivery of healthcare services, such as diagnostic tests, and the development of research.[83]

5.92 With particular reference to the BRCA gene patents, Dr Rimmer observed:

> …once patents are granted there will be some patents—for instance, the BRCA 1 patent—which might still be valid in some form but that you might think have some negative consequences in terms of…social impact. If you really want to better control the behaviour of patent holders, it is very important to have a strong, modern and efficient compulsory licensing regime.[84]

5.93 Dr Rimmer emphasised, however, that the compulsory licence provisions were important in a range of different contexts:

> Compulsory licensing…is very important in a range of different contexts—biotechnology patents for pharmaceutical drugs, especially in the context of access to essential medicines. Interestingly enough, in relation to clean technologies as well at the moment there is a great deal of debate in the lead-up to Copenhagen.[85]

Reasonable requirements provisions

5.94 Despite the apparent ability of the compulsory licence provisions to ameliorate any actual or potential adverse impacts of gene patents, the Committee heard that the reasonable requirements provisions have not been successfully used for the grant of a compulsory licence. IP Australia advised:

> IP Australia has only been able to identify three applications for compulsory licences in Australia since 1903; none under the *Patents Act 1903*, two under the *Patents Act 1952* and one under the *Patents Act 1990*…
>
> In each case a compulsory licence was sought to enable use of a patentee's invention in order to satisfy perceived unmet 'reasonable requirements of

82 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 41.

83 Dr Gillian Mitchell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, pp 116-117.

84 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

85 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

> the public' for the patented invention. No compulsory licenses were granted.[86]

5.95 However, IP Australia submitted that 'the mere availability of this option lends strength to prospective licensees in private negotiations'.[87] Similarly, the Law Council of Australia commented that the few or no cases of use of the compulsory licence provisions did not necessarily indicate that the provisions were ineffective, given the fact that their potential or threat did in some cases act as an incentive for patent holders to negotiate commercial arrangements providing access to a patent.[88]

5.96 In contrast, Dr Charles Lawson submitted that 'in [their] present form the compulsory licensing provisions in the [Act] are effectively a barrier to the working of inventions in Australia'.[89]

5.97 Dr Lawson provided a textual analysis which argued that the threshold criteria for the grant of a compulsory licence in s 133(2)(a)(i) to (iii) are 'practically uncertain and probably very limited' in meaning:[90]

> …it is apparent that the uncertain meanings impose significant thresholds for evidence (proof), qualifications, discretions, expense and uncertain access to the know-how necessary to actually exploit the invention. The conclusion…must be that the uncertain meanings, evidentiary requirements, and the likely considerable expense with little prospect of gauging the likely success of an application are unlikely to encourage a potential applicant. Rather, these thresholds appear as a likely barrier to a potential applicant and undermine any incentive the provision might hold for a patent holder to license and work the invention sooner.[91]

5.98 Dr Lawson concluded that significant reform of the compulsory licence provisions was required:

> …to satisfy its policy objectives the meaning of the compulsory licensing provisions should be clear, so that patent holders really are 'incentivised' to license and work their inventions earlier and potential compulsory license applicants can structure their affairs so as to avoid the unnecessary expense of pursuing uncertain license grants.[92]

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86 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19,* p. 10.

87 Mrs Fatima Beattie, IP Australia, *Committee Hansard,* 20 August 2009, p. 29.

88 Mr Richard Hamer, Law Council of Australia, *Committee Hansard,* 4 August 2009, p. 86.

89 Dr Charles Lawson, *Submission 5,* p. i.

90 Dr Charles Lawson, *Submission 5,* Attachment 1, p. 1.

91 Dr Charles Lawson, *Submission 5,* Attachment 1, pp 31-32.

92 Dr Charles Lawson, *Submission 5,* Attachment 1, p. 3.

5.99 Dr Rimmer noted that there was also potential for reform of the compulsory licensing provisions in relation to essential medicines:

> …the Joint Standing Committee on Treaties said two years ago that it would modernise the compulsory licensing regime in line with TRIPS to deal with the issues in relation to access to essential medicines, especially in relation to the export of essential medicines. I think it is very important that our compulsory licensing regime adequately deals with concerns about competition and public non-commercial use, but also about health concerns and health crises [such as SARS], which can cross over into the field of gene patents...[93]

5.100 The Committee notes that in its 2004 report the ALRC concluded there was significant potential for anti-competitive exploitation of biotechnology inventions due to their unique nature and 'possible lack of substitutability'. Accordingly, it proposed certain reforms to the compulsory licence provisions to 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'.[94] Specifically, the ALRC proposed that the Act be amended to clarify the scope of the 'reasonable requirements of the public test', in particular the circumstances in which the reasonable requirements of the public are taken not to have been satisfied.[95]

Competition based test

5.101 In addition, the ALRC recommended that the competition-based test recommended by the Intellectual Property and Competition Review Committee (IPCRC) be inserted into the Act as an additional ground for the grant of a compulsory licence.[96] This recommendation was based on the IPCRC's view that intellectual property laws and competition policy are 'largely complementary', because the former promotes innovation 'which is a key form of competition'.[97]

5.102 The IPCRC had originally recommended that the competition-based test replace the 'reasonable requirements of the public' test and 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;

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93 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 14.

94 Dr Matthew Rimmer, 'The alchemy of junk: patent law and non-coding DNA', *Intellectual property and biotechnology*, p. 234 (2008).

95 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 34.

96 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 34.

97 *Review of property legislation under the Competition Principles Agreement*, 30 September 2000, p. 6, cited in Parliamentary Library, 'Intellectual Property Laws Amendment Bill 2006', *Bills Digest No. 159 2005-06*, 19 June 2006, p. 9.

- 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.[98]

5.103 In response to the IPCRC report, the Government indicated in-principle support for making the compulsory licence regime subject to a competition test. However, it argued the competition based test should be additional to the existing reasonable requirements test, on the grounds that in some circumstances:

- the competition based test might not apply; or
- could be harder to satisfy than the existing test.[99]

5.104 In 2006, the *Intellectual Property Laws Amendment Act 2006* amended the Act to provide that a compulsory license may be granted where the patentee has been found guilty of any proscribed anti-competitive conduct under the *Trade Practices Act 1974*. Section 133(2)(b) now provides that a person may apply for a compulsory licence on the grounds that:

> …the patentee has contravened, or is contravening, Part IV of the *Trade Practices Act 1974* [to do with restrictive trade practices] or an application law (as defined in section 150A of that Act) in connection with the patent.

5.105 An analysis of this provision by Dr Lawson, however, suggests that in practice the competition based test may be of little effect:

> …[The analysis shows that] the discretion [to award the compulsory licence] may not be exercised for reasons that may be outside the knowledge of an applicant, that the scope of a compulsory license order is limited, that there are significant difficulties with treaty interpretation, and that there are particular difficulties with the restrictive terminology and other provisions in the *Patents Act* limiting the scope of any compulsory license order.[100]

5.106 Dr Lawson concludes:

> …the 'competition test' amendment is unlikely to be a practical remedy for contravention of Pt IV of the *Trade Practices Act* because of the limited scope of a compulsory license order under the *Patents Act*. These hurdles

98 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 619.

99 Parliamentary Library, 'Intellectual Property Laws Amendment Bill 2006', *Bills Digest No. 159 2005-06*, 19 June 2006, p. 12.

100 Dr Charles Lawson, *Submission 5*, Attachment 2, p. 25.

> seem unattractive when the same, or an arguably superior, remedy is already available under the *Trade Practices Act*.[101]

5.107 Dr Rimmer also observed that the competition amendments to the compulsory licensing regime 'are minor, and will do little to address the policy issues raised by the [ALRC]',[102] while noting that a competition based approach was still a potential strategy in relation to ameliorating the potential adverse impacts of certain patents:

> ..it would be useful to have a regulator who had a greater purview of some of the [competition] impacts of some applications of certain patents. Interestingly enough, in relation to non-coding DNA patents, Myriad Genetics accused GTG of anti-competitive conduct in their initial skirmish before they reached a settlement.[103]

Research exemption

5.108 Much of the evidence to the inquiry concerned the need for Australia's patent system to contain an explicit research exemption. A 2009 IP Australia consultation paper on exemptions to patent infringement provided the following summary of the present status of such an exemption in Australia:

> …the *Patents Act 1990* does not contain a specific research or experimental use exception and IP Australia is not aware of any legal cases in Australia where experimental use was argued as a defence against infringement litigation. As a consequence it is unclear whether an experimental use exemption exists in Australia, and if it does, the extent to which it applies. Experiences in other countries where there are no statutory experimental use provisions indicate that courts have struggled to ascertain the scope of the experimental use defence or have applied restrictive tests that are potentially detrimental to research.[104]

5.109 Many submitters and witnesses raised concerns about the impact of the uncertain status of the research exemption on research both in relation to human genes and genetic material and more broadly. With reference to gene patents, the Committee notes the conclusion of the ALRC that the uncertain status of the research exemption for patent infringement in Australia 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.[105]

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101 Dr Charles Lawson, *Submission 5*, Attachment 2, p. 5.

102 Dr Matthew Rimmer,'The alchemy of junk: patent law and non-coding DNA', *Intellectual property and biotechnology* (2008), p. 238.

103 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

104 IP Australia, 'Exemptions to patent infringement', Consultation paper, March 2009, p. 3.

105 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 331.

5.110 There was widespread support for an amendment to the Act to introduce an explicit research exemption into Australia's patent law. Dr Cudmore advised:

> …where possible, the intellectual property environment should operate such that researchers can conduct their research in good faith, with a minimum level of encumbrance from the law…
>
> The ability to conduct research on the gene sequence, without necessarily using a proprietary, therapeutic or diagnostic downstream development from that gene sequence, is something that we believe would significantly enhance researchers' comfort zones in the area that we are discussing, simply because they would have confidence that working on the gene itself does not give rise to legal liability.[106]

5.111 Professor Christie encouraged the Committee to consider 'making a recommendation in relation to a clear and express exemption for experimental and research purposes'.[107] He observed:

> The appropriate response to the concerns about patents for genetic inventions retarding innovation by precluding follow-on research is to ensure that Australian patent law recognises that acts done for experimental purposes do not infringe a patent. This requires that the patent legislation be amended, by introducing an express experimental use defence to infringement.[108]

5.112 The Law Council Australia also indicated that it supported a 'specific and express experimental use exception in the law'.[109]

5.113 Dr Cudmore suggested that any amendment to support a research exemption could take the form of a specific provision for academic licensing:

> …a specific provision for academic licensing in the law would more likely than not be a stimulant to desirable medical research activities. The way that we would see that provision being constructed is that it would allow activities in particular environments—NHMRC accredited environments or something similar to that—and would constitute a protection for research.[110]

5.114 The Committee notes that a number of inquiries into gene patents or aspects of the patent system have supported the introduction of a research exemption into

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106 Dr Gerard Cudmore, Department of Industry and Investment (NSW), *Committee Hansard*, 5 August 2009, p. 92.

107 Professor Andrew Christie, *Committee Hansard*, 4 August 2009, p. 69.

108 Professor Andrew Christie, *Submission 38*, pp 6-7.

109 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 80.

110 Dr Gerard Cudmore, Department of Industry and Investment (NSW), *Committee Hansard*, 5 August 2009, p. 93-94.

Australian patent law. In its 2004 report the ALRC recommended that a research exemption be incorporated into the Act:

> The Commonwealth should amend the [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.[111]

5.115 Dr Rimmer indicated that the ALRC's was the 'best' of the suggested approaches to implementing a research exemption in Australia.[112]

5.116 The Victorian government indicated that it supported a consideration of 'the feasibility of implementing the ALRC…[recommendation for a] statutory exemption for patent infringement in the case of non-commercial experimental use (as applies in some jurisdictions internationally).'[113]

5.117 ACIP has also recommended that the Act be amended to include an explicit experimental research exemption, following its inquiry into this issue in 2005. It suggested the following provision be introduced to the Act:

> The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent. Acts done for experimental purposes relating to the subject matter of the invention include:
>
> -determining how the invention works;
>
> -determining the scope of the invention;
>
> -determining the validity of the claims;
>
> -seeking an improvement to the invention.[114]

5.118 In addition, ACIP made a number of recommendations intended, inter alia, to clarify the interpretation and application of the research exemption by IP Australia and to harmonise the Australian exemption with international practice.

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111 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 335.

112 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

113 Victorian Government, *Submission 61*, p. 2.

114 Advisory Council on Intellectual Property, 'Patents and experimental use', October 2005, p. 5.

5.119 The NHMRC supported the ACIP proposal for a research exemption. Dr Clive Morris, Chief Knowledge and Development Officer, stated:

> The NHMRC, in its submissions to the Australian Law Reform Commission in 2003 and, I think, subsequently to this committee, has spoken about the researchers' exemption and the need for clarity which researchers have expressed. We have said recently that we support the position of the Advisory Council on Intellectual Property that this should be made more clear in legislation.[115]

5.120 In contrast, Cancer Council Australia, which supported an express prohibition on gene patents, argued that the recommendations of the ALRC and ACIP on a research exemption would not offer sufficient protection:

> While we commend the Advisory Council on Intellectual Property and the Australian Law Reform Commission for proposing an experimental use exemption for patented genes in some medical research, in our view the recommendations are not sufficiently extensive. For example, exemption should also apply to research on the patented tests for identifying certain genes, to encourage continuous improvement; just because a commercial interest discovered a particularly gene or developed a test for its isolation does not mean that the test could not be improved (e.g. made more accessible and affordable) by a separate research entity. There are numerous other examples where exemption for experimental use would not be sufficient. Applying for the exemption could also impose administrative burden for not-for-profit and academic institutions involved in medical research.[116]

5.121 In its recent consultation paper on exemptions to patent infringement, IP Australia has also set out the broad intent of the research exemption it is proposing:

> A person may, without infringing a patent, do any act on a patented invention which is solely for the purpose of:
>
> - determining how the invention works
> - seeking an improvement to the invention
> - testing the validity of a patent
> - determining the scope of the patent claims
> - determining whether an act or product infringes a patent
>
> or
>
> - obtaining the information required for regulatory approval under Australian law or the law of any other country that regulates the manufacture, construction, use or sale of the patented invention.

115 Dr Clive Morris, National Health and Medical Research Council, *Committee Hansard*, 20 August 2009, p. 48.

116 Cancer Council Australia, *Submission 50*, p. 8.

> The statutory exemption will not apply where the invention is used in, but is not the subject of, an experiment.[117]

5.122 IP Australia submitted that its suggested approach:

> …would clarify the current situation and clearly delineate that research on the patented invention is allowed, for example: to determine how the invention works; to seek improvements to the invention; to determine unknown and useful properties of the invention; and to undertake trials for the purposes of obtaining regulatory approval for its exploitation.[118]

5.123 However, Dr Moir criticised IP Australia's proposal as being overly narrow:

> IP Australia recently circulated their discussion paper on the research exemption and they framed it quite narrowly. They said the exemption should apply where the sole purpose was research. But purposes are very rarely sole. For example, a university undertaking research might also be undertaking education, and I can tell you that a patent lawyer would say, 'Well, that means that it is not solely for research and therefore you cannot claim the exemption.' So I would look very closely at propositions in regard to the long-awaited research exemption and make sure it is very tight and very broad, because it is that cumulative research that is very important.[119]

5.124 Dr Palombi also criticised the scope of the research exemption suggested by IP Australia:

> …the test that is proposed by IP Australia is completely unworkable. They use a sole purpose test. If the sole purpose of the experimentation is experimentation, non-commercial, then it is exempted. How many universities, how many people, these days actually do experimentation solely for the sake of experimenting? They don't. Everything is applied, everything has got a commercial link. It is so easy to get around that exemption that it is hardly worth the trouble of even making it legislation.[120]

5.125 Similarly, Dr Rimmer commented:

> I share…concerns about the very narrow way in which IP Australia has put forward their proposal in relation to a defence of experimental use. The sole purpose test I think is used in the Netherlands and has not proved to be a very effective way of dealing with that scope.[121]

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117 IP Australia, 'Exemptions to patent infringement', Consultation paper, March 2009, p. 5

118 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 30.

119 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 8.

120 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 18.

121 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 13.

Inclusion of anti-avoidance provisions in *Patents Act 1990*

5.126 A number of submitters and witnesses discussed the issue of patent drafting and the extent to which creative drafting of patent claims had contributed to the broadening scope of patentable subject matter in the past. Dr Moir offered the following example to indicate the prevalence and impact of creative legal drafting in the patent system:

> In my recent in-depth study of 72 Australian business method patents, 50 of the 72 applications were amended during negotiations with the examiner, and in many cases it was the amendment that was instrumental in allowing the grant…[The] triviality of these amendments indicates the problem of clever legal drafting.[122]

5.127 Professor Drahos indicated that the problem of creative legal drafting was widespread:

> …if you look at the effect of exclusions in the European Patent Convention you see that there are a number of exclusions to do with, for example, the patentability of computer programs, the patentability of plant varieties and so on. I can show you in the European Patent Office many thousands of patents—probably tens or hundreds of thousands of patents—on computer programs and on plant varieties.[123]

5.128 Professor Drahos noted that the problem arising from creative legal drafting would also be relevant in the event that specific exclusions of any sort were introduced into the Act in future. He explained:

> Unfortunately, I think it is unlikely that you will ever achieve very clear statutory language. Most patent attorneys will tell you that there is not an exclusion they cannot draft around. So essentially the patent attorney profession you should think of as a bunch of tax evaders. Tax evaders always think of new ways to get around our tax laws…Relying on the words of the statute alone probably will not be enough.[124]

5.129 Dr Moir commented:

> Legal semantics in patent law is the parallel of crafting financial products to avoid paying tax; it involves using words to provide a veneer of inventiveness to something that would not otherwise merit a patent monopoly.[125]

5.130 Professor Drahos suggested that the inclusion of anti-avoidance provisions in the Act could be a suitable remedy to the problem of creative legal drafting. In simple

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122 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 8.

123 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 21.

124 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 21.

125 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 7.

terms, anti-avoidance tax provisions operate to ensure that artificial or blatant schemes cannot be used to avoid paying tax, even where such a scheme might be otherwise in conformity with the legal requirements of the tax legislation. Professor Drahos explained:

> [Tax acts]…contain provisions that encourage courts to look at the substance of the particular tax scheme. Is it really a tax minimisation scheme or is it an anti-avoidance scheme? So what we need in our [patent] statute is language that encourages courts to look beyond the claiming format, because what we have to remember is that patent offices accept particular claiming formats…What they are worried about is the form of the words. They do not worry about effects.[126]

5.131 Dr Moir also supported this approach:

> …the patent system has been heavily under-mined by those using it. It is rife with legal pretence: that software is not software; that methods of medical treatment are patentable despite longstanding traditions that they are not; and that minimal difference equates with inventiveness even if that difference is in the words not the substance. Without a parallel to the anti-avoidance principles now used in the tax acts, legal drafters will simply work round this and any other amendments the Committee proposes.[127]

Inclusion of objects in *Patents Act 1990*

5.132 Some submitters and witnesses commented on the fact that the Act does not set out specific objects, as is common in much legislation. Dr Moir suggested that the inclusion of objects may be desirable to provide guidance to courts in interpreting the Act:

> It might also be useful to write an objective into the Patent Act, because there is no objective at present. I understand that lawyers are very much divided as to whether or not they think it is useful to write objectives into a statute. But it is not surprising that when there is not a stated objective the courts can misinterpret the parliamentary intent.[128]

5.133 The ACIP options paper on patentable subject matter also notes briefly that it 'may be desirable for an express statement of objectives to be included in the legislation'.[129]

5.134 The government of South Australia supported this approach to provide a guide to patent examiners.[130]

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126 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 21.

127 Dr Hazel Moir, answer to question on notice, 16 September 2009, p. 2.

128 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 4.

129 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 60.

130 South Australian Government, *Submission 16*, p. 4.

'PBS' style approach

5.135 With respect to the potential for gene patents to restrict the availability and affordability of healthcare, such as gene-dependent diagnostic tests or gene therapies, a number of submitters and witnesses suggested that such impacts could be effectively managed through regulatory measures. A common example was the Pharmaceutical Benefits Scheme (PBS), through which the Government subsidises the cost of medicines that would otherwise be unaffordable for many people. IP Australia submitted:

> The Committee may also wish to take advantage of non-patent policy levers. For example, healthcare and ethical issues respectively have been managed via the Pharmaceutical Benefits Scheme to ensure affordable access to cost-effective drugs, while stem cell research is currently regulated to uphold ethical and community standards in that area.[131]

5.136 Professor Christie noted that, in respect of the concerns raised about the BRCA patents' actual or potential impacts on the provision of healthcare, a pricing mechanism akin to the PBS or Medicare would be an effective and appropriate measure:

> The Australian government is rightly concerned to ensure that medical treatment is available to each individual who requires it, irrespective of the individual's financial means. This is the motivation behind the government's subsidisation of the cost of medical treatment, through the Medicare system. It is also the motivation behind the government's subsidisation of the cost of pharmaceuticals, through the Pharmaceutical Benefits Scheme (PBS). It is noteworthy that most of the top-selling pharmaceuticals subsidised by the PBS are pharmaceuticals in respect of which patents exists. Thus, the government has found a mechanism by which it can facilitate wide access to pharmaceuticals, while leaving in place the availability of patent protection for those pharmaceuticals.
>
> In the event that it is found that patents on genetic inventions are unduly restricting patient access to diagnostic tests or other medical treatment, the Australian experience with pharmaceuticals suggests that the remedy to the access problem lies with a pricing mechanism, not with removing patent protection for these inventions.[132]

5.137 Mrs Jennifer West, Secretary, Australian Marfan Foundation, was supportive of establishing a PBS-style arrangement for genetic testing, noting that availability of testing for a syndrome such as Marfan was essentially dictated by availability of funding, which was inconsistent:

> I would gladly welcome a system where people with Marfan syndrome, suspected Marfan syndrome or a known history of Marfan syndrome had

131 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 5.

132 Professor Andrew Christie, *Submission 38*, pp 5-6.

> access to that genetic screening like they do for other genetic abnormalities at the moment.[133]

5.138 Dr Suthers, however, cautioned that any such approach would likely need to be more responsive than the current PBS in order to adequately account for the development and management of gene patents:

> My big concern is that the PBAC [Pharmaceutical Benefits Advisory Committee, which assesses applications for listing of medicines on the PBS] has been a superb and innovative mechanism for Australian health, but it is slow. When we look at the rapidity with which gene tests are added, modified, improved, changed, et cetera, in Australia at the moment we find that no vehicle of that ilk would be able to respond quickly enough. When we did this national survey looking at genetic testing across Australia in 2006 with projections into 2007 we found that the diversity of genetic testing increased by seven per cent just in that period. This is a very rapidly moving field, and we would need to have a very responsive mechanism if that were to be successful.[134]

5.139 Professor Bowtell noted that public funding through PBS-style arrangements could see an increasing burden being placed on the taxpayer, given the level of public funding going to health and medical research.[135]

External accountability/patent quality mechanisms

5.140 A number of submitters and witnesses expressed the view that the IP system operates too far in favour of commercial interests, and that this is reflected in the low thresholds for patentability that have allowed human genes and genetic materials to be patented with relative ease in Australia. Dr Suthers commented:

> What is one-sided about [the IP system]…is that the framework has been set up principally as a commercial IP issue where the principal players involved in running those processes are members of the IP industry rather than professional service providers, such as ourselves, patient groups, ethicists, health economists and so on.[136]

5.141 The submission of Professor Peter Drahos also pointed to the dominance of commercial interests and patent industry 'insiders' in the patent system:

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133 Mrs Jennifer West, Australian Marfan Foundation, *Committee Hansard*, 4 August 2009, p. 99.

134 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 56.

135 Professor David Bowtell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, p. 130.

136 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, p. 41.

> Patent systems in their present form represent deep concentrations of power and dominance in which networks of big business, patent attorneys and patent offices co-operate to produce an insider governance of the system.[137]

5.142 Professor Drahos concluded that patent offices had 'abdicated their responsibilities to their respective publics under their respective national patent social contracts';[138] and that the 'densely technocratic' nature of the patent system was acting as a barrier to reform of the patent system to promote a proper balance between the economic and social interests which underpin the patent social contract:

> The patent system is so densely technocratic that politicians do not take the lead on patent policy unless an industry lobby dictates a clear direction…The real accountability of patent offices lies with the private governance network of the large businesses that dominate patent applications.[139]

5.143 In light of these issues, Professor Drahos called for the development of external accountability mechanisms to operate as a counterweight to the established interests in the patent system.[140] The rationale underlying the development of such bodies was that:

> General accountability mechanisms such as ministerial responsibility cannot provide the kind of close oversight that is needed of patent office decision-making. Instead, there has to be a long term strategy based on building a counter network to the private governance network that has absorbed patent offices. This counter network should be guided by the separation of powers principle...The basic idea is to contest the power of the private network at every point where key decisions are made and where possible to create veto rights or checks over patent office decisions.[141]

5.144 Professor Ian Olver, Chief Executive Officer, Cancer Council Australia, also called for a greater involvement of broader interests in the operation of the patent system:

> …one of the things that we would be encouraging in this whole debate is that, if there is going to be reform, the people who should be involved should be more than patent lawyers. We should look at the scientists, the clinicians and the consumers—the patients—who have a stake in that.[142]

5.145 Dr Palombi called for an extensive system of external oversight of IP Australia and the patent profession:

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137 Professor Peter Drahos, *Submission 60*, p. 427.

138 Professor Peter Drahos, *Submission 60*, p. 428.

139 Professor Peter Drahos, *Submission 60*, p. 429.

140 Professor Peter Drahos, *Submission 60*, p. 431.

141 Professor Peter Drahos, *Submission 60*, p. 431.

142 Professor Ian Olver, Cancer Council Australia, *Committee Hansard*, 5 August 2009, p. 6.

> Third, that there be the Office of the Regulator of Intellectual Property established to monitor, audit and ensure that IP Australia and patent attorneys and lawyers act lawfully.[143]

External patent audit committee

5.146 In specific terms, Professor Drahos proposed the establishment of an external patent audit committee. Such a body could act as a counterweight to commercial dominance of the patent system by providing to government an independent source of credible advice and information in relation to patents and the patent system:

> Legislators and ministers in many countries generally do not understand the extent of the regulatory capture of patent offices and tend to be excessively reliant on them for advice, advice that tends to be of a predictable kind. External audit mechanisms for patent offices would catalyse different information flows about patents to legislators, something needed in many, if not most, countries.[144]

5.147 Professor Drahos offered the following description of how such a body might be comprised, and the scope of its interests and activities:

> I hasten to add this committee would not have formal powers, it would not be a formal regulator; rather, it would be an information gathering body. It would be staffed by scientists of considerable stature, of independence, of integrity, who were concerned about the public interest dimensions of patents in particular areas. They would, on perhaps a yearly or biannual basis, with the assistance of members of the profession perhaps or legal expertise at any rate, conduct an independent audit of a selection of patents. …They would essentially conduct an independent audit of the quality of patents that were being granted in [a chosen area]…and then…report to whatever body was thought suitable. That would be one way in which we would have independent information about what was going on in patent offices.[145]

Advisory panel to Commissioner of Patents

5.148 The Committee notes that ACIP, as part of its current review of patentable subject matter, was considering recommending the establishment of an advisory panel to assist the Commissioner of Patents and patent examiners to decide on matters of

143 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 13.

144 Professor Peter Drahos, *Submission 60*, p. 439.

145 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 15.

social policy.[146] The ACIP paper notes that such a panel 'may be particularly valuable if a general social exclusion was introduced [to the Act]'.[147]

5.149 However, the ACIP paper also acknowledges potential problems with such an approach:

> Arguments advanced against having such a panel relate to difficulties of implementation and the potential for additional costs and delays to the processing of patent applications. There are also concerns about the composition of a panel and the possibility that inconsistent positions may be taken by differently constituted panels.[148]

5.150 The government of South Australia supported the use of expert advisory panels to assist with the assessment of gene patent applications.[149]

Patent pools

5.151 IP Australia identified the development of patent pools as a possible strategy to overcome problems arising from fragmented patent ownership. In relation to gene patents in particular it was suggested that the number of separately owned patents relating to human genes and genetic materials could act as a disincentive to research due to increased transaction costs and uncertainty (see Chapter 3). IP Australia advised:

> Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders. Patent pools are particularly beneficial in cases where the relevant technology is subject to fragmented patent ownership.[150]

5.152 Dr Trevor Davies, Councillor, Institute of Patent and Trade Mark Attorneys of Australia (IPTMAA) also suggested that patent pools could overcome some of the difficulties around patents relating to human genes and genetic material:

> In areas where there have been a large number of patent applications filed or patents granted, one way of moving forward is…patent pools…I would not be surprised going forward in the area of biotechnology that there will

146 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 21.

147 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 53.

148 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 53.

149 South Australian Government, *Submission 16*, p. 5.

150 IP Australia, supplementary submission, 30 September 2009, p. 3.

> be more examples of patent pools in which technology is cross-licensed so that ultimately it will made available to the public.[151]

5.153 IP Australia noted that, while the establishment of patent pools tended to be 'driven by industry on a voluntary basis', government could 'play an important role in incentivising the creation of patent pools', particularly through providing an 'appropriate institutional framework'. However, given the lack of government experience in this area, IP Australia suggested any action on this front 'should be contingent on further analysis'.[152]

CONCLUSION

5.154 The inquiry received a range of evidence going to term of reference (b), which asked the Committee to identify measures that would ameliorate any adverse impacts arising from the granting of patents over human genes and genetic materials. However, given the predominant focus of the inquiry on the question of whether gene patents should be expressly prohibited, and the relatively narrow focus of the inquiry on the impacts of gene patents on healthcare, medical research and the health and wellbeing of Australians, the Committee notes that it did not conduct an exhaustive consideration of potential reforms to the patent system. In relation to the measures discussed above, the Committee has focussed on those suggestions that appeared to have particular relevance to the issues of concern to the inquiry, that have been prominent in the reviews conducted in the past and currently, or which highlight areas of potential reform that in the Committee's view appeared to merit further consideration.

5.155 While there was in some cases a clear and broad consensus about the benefits of instituting a specific reform, such as in the case of the 'usefulness' requirement for patentability, in many cases there were differing views on the specific form, scope and effectiveness of a suggested reform. In yet other cases, the evidence presented concerning the specific form, scope and effectiveness of a suggested measure was limited, in that it was relatively brief or was not commented on by a range of stakeholders.

Ensuring that the Government responds to past and current inquiries

5.156 The Committee notes also that much of the evidence it received in relation to term of reference (b) referenced the work of past and current inquiries into the patent system and gene patents. In particular, many of the recommendations from the ALRC's 2004 review of gene patents, and of reviews of elements of the patent system conducted by ACIP, were identified as being capable, if implemented, of addressing

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151 Dr Trevor Davies, Institute of Patent and Trade Mark Attorneys, *Committee Hansard*, 4 August 2009, p. 35.

152 IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 4.

specific concerns with the impacts of gene patents on the specific areas of healthcare and medical research.

5.157 Further, the work of current reviews being conducted by ACIP, into patentable subject matter, and IP Australia, into the patent system more generally, was also identified as relevant to the concerns underpinning the inquiry's terms of reference. In both cases, these bodies have put forward proposals for reform of the patent system that it is claimed will improve the quality of patents and the operation of the patent system, and therefore address many of the specific concerns about the impacts of gene patents on healthcare and medical research. The Committee understands that the ACIP and IP Australia processes should be completed by the end of 2010.

5.158 The Committee notes in particular that the 2004 ALRC report on gene patents had not received any formal response from Government at the time of preparing this report. Given the importance of the issues addressed in that report, and the continuing relevance of much of its analysis and recommendations, the Committee considers the lack of a Government response to be a serious failure that must be addressed with particular urgency.

5.159 However, given the current reviews being conducted by ACIP and IP Australia, the Committee agreed that it would make sense for the Government to commit to a consolidated response addressing the three reports as well as the Committee's report, following the completion of the ACIP and IP Australia reviews. The fact that there is likely to be a high degree of overlap across the issues raised in these four inquiries and reviews will allow the Government to provide a single response addressing the multiple inquiries.

5.160 The Committee agreed that it will maintain a watching brief over the area of gene patents, particularly in light of its recommendations for improved systems of data collection and transparency, and national and international legal developments relating to the patentability of isolated genetic materials. The Committee intends that, by ensuring a comprehensive Government response to the reviews conducted in relation to gene patents and the patent system more generally, any future inquiry by the Committee will be informed by that response. Accordingly, the Committee agreed that, at an appropriate time following the publication of the review of ACIP and IP Australia, the Senate should require the Committee to inquire into the Government's response to and implementation of the recommendations arising from both those reviews and this report.

Recommendation 4

5.161 The Committee recommends that the Government provide a combined response addressing the Committee's inquiry into gene patents; the 2004 report on gene patents by the Australian Law Reform Commission; the review of patentable subject matter by the Australian Council on Intellectual Property (ACIP); and the review of Australia's patent system by IP Australia. The

Committee recommends that the response be provided not later than mid-2011 or three months after the release of the findings of all reviews.

Recommendation 5

5.162 The Committee recommends that, at an appropriate time following the release of the ACIP review of patentable subject matter and the IP Australia review of the patent system, the Community Affairs References Committee be tasked with inquiring into the Government's response to, and implementation of, the recommendations of those reviews, as well as the recommendations of the Committee's report on gene patents.

Amendments relating to 'inventive step', 'full description' and 'fair basis'

5.163 In relation to measures going to the raising of the thresholds of patentability, the Committee considers that a comprehensive set of reforms to the patent system in this area could substantially address many of the concerns raised about the impacts of gene patents on healthcare and medical research, particularly in relation to inappropriate grants of patents over human genes and genetic material and the granting of overly broad patents in relation to such subject matter.

5.164 The Committee heard that social—that is, moral and ethical—concerns about the granting of gene patents could be addressed through reform of the 'manner of manufacture' test, which governs the scope of patentability; and reform of the specific exceptions contained in the Act, which may be used to 'filter out' certain subject matter on the basis of social objections. The Committee notes that the current test is regarded by some as 'ambiguous and obscure', and it was the view of some submitters and witnesses that the Act was not operating to exclude subject matter that should not be patentable, such as gene patents.

5.165 The Committee heard that these issues are currently under consideration as part of the ACIP review of patentable subject matter, which has proposed a number of different options for reform of the manner of manufacture test. Of the four options put forward (one of which is to retain the existing approach), the Committee considers that only the proposal to clarify the definition of 'invention' could act to prevent the patenting of human genes and genetic materials. However, this would require a definition that offered some guidance on the invention/discovery distinction in relation to materials isolated from nature. While such an approach is not apparently precluded by ACIP's proposal, it may also recommend just that 'invention' be defined to reflect the current requirements that an invention must be an artificially created state of affairs in a field of economic endeavour, which have not operated thus far to preclude the patenting of human genes and genetic materials in an isolated or purified form.

5.166 Of the three options put forward by ACIP in relation to reform of the express exceptions contained in the Act (one of which is to retain the existing approach), the Committee notes that one of these is to include specific exclusions to patentable subject matter in the Act. If this option were pursued, governments could in future consider an express exclusion relating to gene patents, provided that any such

exclusion could be sufficiently well crafted to avoid any adverse impacts on innovation in healthcare and research, as well as other fields of technology.

5.167 While the Committee acknowledges that some of ACIP's reform proposals could potentially exclude gene patents, and thus in theory ameliorate any actual or potential impacts of gene patents on healthcare and medical research, there was no indication given to the Committee as to which of these proposals ACIP is likely to endorse in its final report. Given the closeness of the issues under review to the question of whether the Act should expressly exclude gene patents, and the Committee's concerns about this approach as outlined in Chapter 4, the Committee considered that it would be prudent to make no recommendation in relation to reform of the manner of manufacture test and specific exceptions contained in the Act. However, given the longstanding nature of concerns about the operation of Act in relation to patentable subject matter, the Committee urges the Government to promptly consider and respond to the ACIP review, once the review has reported its findings.

5.168 In relation to the inventive step threshold, the Committee acknowledges that care must be taken not to apply current standards of knowledge and technology to assessing the objective inventiveness of a patent, as the inventive step requirement must be assessed as at the time of the patent application. Despite this, it is also clear that the inventive step threshold in Australia is lower than in comparable jurisdictions, which is in part due to the definitions of 'common general knowledge' and 'prior art base', and the lower threshold test for inventive step relating to the 'obviousness' of a claimed invention.

5.169 The Committee outlined above a number of reforms proposed by IP Australia intended to bring the elements of Australia's inventive step requirements into line with international settings, and in so doing increase the inventive step threshold. The proposed change to the test for inventive step in particular was identified as potentially making it harder to claim patents over gene sequences, given the current state of knowledge and technology in relation to the isolation of human genes and genetic materials. Reforms to the tests or standards associated with the assessment of inventive step were also suggested to ensure that patents are only granted where there is sufficient inventiveness, as judged by reasonable standards of 'common general knowledge' and 'prior art information'.

5.170 IP Australia's proposed reforms also include changes to the 'full description' and 'fair basis' requirements of the Act, which may address concerns about overly broad patents.

5.171 The Committee regards the reforms suggested by IP Australia as having the potential to improve the operation of the patent system in relation to the grant of patents for inventions that are not sufficiently inventive or contain overly broad claims, and notes that the proposed reforms will also serve to bring Australia's requirements for patentability into conformity with other patent jurisdictions. Given this, the Committee regarded the proposed reforms as uncontroversial and relatively

straightforward in terms of their intended and expected impact on the operation of Australia's patent system, and endorses their implementation.

Recommendation 6

5.172 The Committee recommends that the *Patents Act 1990* be amended so that the test for obviousness in determining inventive step is that a claimed invention is obvious if it was 'obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success'.

Recommendation 7

5.173 The Committee recommends that the *Patents Act 1990* be amended to remove the limitation that 'common general knowledge' be confined to that existing in Australia at the time a patent application is lodged (that is, that 'common general knowledge' anywhere in the world be considered).

Recommendation 8

5.174 The Committee recommends that the *Patents Act 1990* be amended to remove the requirement that 'prior art information' for the purposes of determining inventive step must be that which could reasonably have been expected to be 'ascertained' (that is, that the 'prior art base' against which inventive step is assessed not be restricted to information that a skilled person in the relevant field would have actually looked for and found (ascertained)).

Recommendation 9

5.175 The Committee recommends that the *Patents Act 1990* be amended to introduce descriptive support requirements, including that the whole scope of the claimed invention be enabled and that the description provide sufficient information to allow the skilled addressee to perform the invention without undue experimentation.

Raising the thresholds of patentability: 'usefulness'

5.176 In relation to the evidence received concerning the requirement of 'usefulness' under the Act, the Committee notes that there was widespread and consistent support for an amendment to the Act to introduce the concept of 'usefulness' as an express ground for consideration in patent examination; and that this require a claimed invention to demonstrate a 'specific, substantial and credible utility'.

5.177 The Committee notes that the suggested amendment could address concerns going to the granting of overly broad patent claims; and could be of greater importance in relation to gene patents or other technologies where the distinction between mere discovery and invention is less clear.

5.178 Given the broad support for the proposals going to 'usefulness' and their apparent effectiveness in other jurisdictions, the Committee supports the introduction of 'usefulness' as a requirement in the examination of a patent; and for this

requirement to be satisfied where an application discloses a 'specific, substantial and credible use'. The Committee notes and endorses the ALRC's comprehensive recommendations on this issue in its 2004 report, which also covered inclusion of 'usefulness' as a ground for examination of an innovation patent; inclusion of 'lack of usefulness' as a basis for opposing patents; defining the relevant standard of proof for establishing 'usefulness'; and the development of guidelines by IP Australia to assist patent examiners in applying the 'usefulness' requirement. Specifically, the Committee endorses Recommendations 6-3 and 6-4 of the ALRC report as follows:

> **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…
>
> **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…[153]

Recommendation 10

5.179 The Committee recommends that the *Patents Act 1990* be amended to provide that an invention will satisfy the requirement of 'usefulness' in section 18(1) only in such cases as a patent application discloses a 'specific, substantial and credible' use; the Committee recommends that such amendments incorporate the full set of recommendations on this issue from the Australian Law Reform Commission's 2004 report, *Genes and ingenuity* (Recommendations 6-3 to 6-4).

153 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendations 6-3 to 6-4, pp 130-157.

Strengthening Crown use provisions and government policy

5.180 In relation to the issue of Crown use provisions, a number of submitters and witnesses noted that the current provisions in the Act provide a means for governments to use, and to authorise others to use, patented inventions in certain circumstances—that is, governments may compulsorily acquire a right of access to an invention where such use is 'necessary for the proper provision of government services within Australia'.

5.181 However, the Committee heard that there were few if any cases of the Crown use provisions being exercised in relation to gene patents. Further, the provisions had been rarely litigated and interpreted by the courts, suggesting there may be some uncertainty about their scope and effectiveness.

5.182 The Committee notes that governments need access to a range of options to address potential impacts of not only gene patents but also patents more generally, particularly where patents impact on areas of critical importance to social and human welfare, such as healthcare. While the apparent under-use of the Crown use provisions, at least in relation to the areas of healthcare and medical research, may reflect a lack of suitable occasion for their use, the Committee notes that it may also be due to potential uncertainty around their application.

5.183 The Committee notes that in its 2004 report the ALRC produced a broad set of recommendations going to clarifying the application of the Crown use provisions in circumstances involving the provision of healthcare service or products to the public; establishing clear government policies regarding the circumstances in which it may be appropriate for governments to acquire a patent under the Crown use provisions for the purposes of promoting human health; and ensuring that just and reasonable remuneration is paid promptly where a patent is acquired under the Crown use provisions. The Committee endorses the ALRC's recommendations on clarifying the application and use of the Crown use provisions in relation to healthcare delivery, specifically Recommendations 26-1 to 26-3 as follows:

> **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.[154]

5.184 The Committee agrees that any guidelines or amendments to the Act in relation to the exercise of Crown use provisions should require the Government to consider, as a relevant factor, the extent to which public funding contributed to the invention that is the subject of the patent for which it is contemplated that the Crown use provisions will be exercised.

Recommendation 11

5.185 The Committee recommends that the *Patents Act 1990* be amended to clarify the circumstances in which the Crown use provisions may be employed; and that the Government develop clear policies for the use of the Crown use provisions. The Committee recommends that the Government adopt the Australian Law Reform Commission's recommendations on this issue from its 2004 report, *Genes and ingenuity* (Recommendations 26-1 to 26-3).

Clarifying the operation of compulsory licence provisions

5.186 In relation to compulsory licensing, there was significant support among submitters and witnesses for the use of compulsory licences to ameliorate potentially adverse impacts arising from certain patents.

5.187 The Committee heard that there have been few if any grants of compulsory licenses in Australia, which may suggest that the provisions are not operating effectively. In contrast, it was argued by some parties that this may be an indication of the effectiveness of the provisions as an incentive for parties to successfully negotiate license arrangements.

5.188 The Committee notes that the 2004 report of the ALRC into gene patents called for the Act to be amended to clarify the scope of the 'reasonable requirements of the public test' on which the grant of a compulsory licence may be based; and the introduction of a competition based test to make a compulsory licence also available

154 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendations 26-1 to 26-3, p 608.

where a patentee has engaged in anti-competitive conduct under the *Trade Practices Act 1974* (TPA). Specifically, recommendation 27-1 stated:

> **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.[155]

5.189 The Committee found that there remains considerable doubt as to the operation of the compulsory licence provisions. In particular, the threshold criteria for the grant of a compulsory licence relating to, inter alia, the 'reasonable requirements of the public' are uncertain and possibly limited in effect, and may in fact be operating as a barrier to applications under these provisions. Further, the Committee notes that the recently introduced competition based test requires review by the Government to ensure that it is working effectively, particularly in relation to its interaction with the TPA.

Recommendation 12

5.190 The Committee recommends that the Government amend the *Patents Act 1990* to clarify the scope of the 'reasonable requirements of the public' test, taking into account the recommendation of the Australian Law Reform Commission on this issue in its 2004 report, *Genes and ingenuity* (Recommendation 27-1); the Committee recommends that the Government review the operation of the competition based test for the grant of a compulsory licence, with particular reference to its interaction with the *Trade Practices Act 1974*.

Including a broad research exemption in the Act

5.191 In relation to a research exemption, the Committee heard that it is unclear whether there is any such common law exemption under Australian patent law; and there is no such exemption expressly provided for in the Act. Despite the apparent widespread reliance by Australian researchers on a research exemption, the Committee found that the existence and, if it does exist, scope of any such exemption is very uncertain; and that this uncertainty could be acting to hinder innovation and investment in research.

5.192 The Committee notes there was widespread support for the inclusion of an express research exemption in the Act; and that various bodies such as the ALRC, ACIP and IP Australia have previously examined, or are currently examining, this

155 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, Recommendations 26-1 to 27-1, p 625.

issue and have proposed particular approaches to formulating a research exemption. Concerning these suggested approaches, some submitters and witnesses objected strongly to formulations of a research exemption in which the exemption will apply only where the otherwise infringing act is for the *sole purpose* of research or experimentation. It was argued that the sole purpose test is overly restrictive, particularly in the modern environment where research is increasingly undertaken with commercial motives.

5.193 The Committee supported calls for the inclusion of an express research exemption in the Act. However, the Committee believes that any such exemption must be carefully designed to ensure that it is not overly restrictive. The Committee notes the terms of the exemption proposed by IP Australia in its March 2009 paper, 'Exemptions to patent infringement':

> A person may, without infringing a patent, do any act on a patented invention which is solely for the purpose of:
>
> - determining how the invention works;
> - seeking an improvement to the invention;
> - testing the validity of a patent;
> - determining the scope of the patent claims;
> - determining whether an act or product infringes a patent or
> - obtaining the information required for regulatory approval under Australian law or the law of any other country that regulates the manufacture, construction, use or sale of the patented invention.
>
> The statutory exemption will not apply where the invention is used in, but is not the subject of, an experiment.[156]

5.194 The Committee agreed that an appropriately generous and broad research exemption could be modelled on the words proposed by IP Australia, with the removal of the word 'solely' and, possibly, with the removal of the final paragraph.

Recommendation 13

5.195 The Committee recommends that the *Patents Act 1990* be amended to include a broad research exemption.

Inclusion of anti-avoidance and objects provisions in the Act

5.196 In relation to other potential amendments to the Act to ameliorate any actual or potential impacts of gene patents, the Committee was asked to consider the introduction of anti-avoidance provisions into the Act; and for the inclusion of specific objects. It was argued that both of these approaches would assist the courts and patent examiners in interpreting and applying the Act, and ensuring that the patent system

156 IP Australia, 'Exemptions to patent infringement', March 2009, p. 5.

achieves a proper balance between its economic and social objectives. The Committee believes that such approaches merit consideration by Government, as part of developing a suite of strategies to promote the effective operation of the patent system.

Recommendation 14

5.197 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the *Patents Act 1990*, the Government consider amending the Act to include anti-avoidance provisions.

Recommendation 15

5.198 The Committee recommends that, to assist courts and patent examiners with the interpretation and application of the *Patents Act 1990*, the Government consider amending the Act to include objects provisions.

Developing external accountability/patent quality mechanism

5.199 In relation to external measures to improve the operation of the patents system, the Committee received a number of notable suggestions which clearly would have potential to ameliorate any actual or potential impacts of gene patents. A number of submitters and witnesses endorsed consideration of a PBS or Medicare style approach to the funding of medicines, therapies or techniques that may rely on genetic inventions. The Committee notes that the ALRC considered these issues in some detail in its 2004 report on gene patents, and made a recommendation that the Australian Health Ministers' Advisory Council (AHMAC) conduct a broad examination of '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'.[157] Specifically, recommendation 19-2 stated:

> **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.[158]

5.200 The Committee offers in-principle support for a broad-ranging inquiry on such terms, and expects that the long-awaited Government response to the ALRC's recommendations will offer a considered response to this recommendation.

5.201 In relation to calls for the establishment of some form of external mechanism to provide oversight of the patent system, the Committee heard a variety of suggestions, ranging from an apparently comprehensive patent system regulator, in the form of an Office of the Patent Regulator, to a more limited patent audit committee

157 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, pp 473-474 (Recommendation 19-2).

158 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, pp 473-474.

with specific expertise and interests in issues of patent quality in emerging and challenging fields of technology. The Committee believes that the establishment of such a body would be an important step to address many of the concerns relating to gene patents and, indeed, the patent system more broadly, and to establish an objective source of advice and guidance for governments in relation to, for example, the impact of patents in emerging or complex fields of technology, patent quality and the exercise of Crown use and compulsory licence provisions. The Committee therefore agreed that the Government should establish a patent audit committee as described by Professor Drahos. Whether there is a need for a more comprehensive Office of the Patent Regulator is a question that could be re-examined at an appropriate time in the future, and the Committee acknowledges that such an approach would need to be fully examined in terms of its regulatory impacts.

Recommendation 16

5.202 The Committee recommends that the Government establish a patent audit committee.

Senator Rachel Siewert

Chair

ADDITIONAL COMMENTS

SENATORS COONAN AND HEFFERNAN.

While we agree with all of the Report's recommendations we are of the view that the Report, regrettably, does not contain a recommendation to the effect that the Patents Act, 1990 be amended to ban the grant of patents over biological materials which are identical or substantially identical to such materials as they exist in nature.

In short, the Report fails to address the very issue which triggered this inquiry in the first place – gene patents.

Unfortunately, while the Report states that the Bill introduced into the Senate to ban gene patents is providing a "much-needed opportunity for the arguments and questions around the impacts and effectiveness of an express prohibition on gene patents to be considered" (para 4.135), we are of the view that the evidence presented to this Committee is sufficient to support the call for the implementation of such a ban. The time has come, after more than two years, for action. More talk, which is what this Report suggests as "much-needed" we believe will simply delay necessary action to prohibit gene patents.

Senators Coonan and Heffernan therefore recommend that the Patents Act be amended to ban the grant of patents over biological materials which are identical or substantially identical to such materials as they exist in nature.

Senator the Hon. Bill Heffernan

Liberal Senator for New South Wales

Senator the Hon. Helen Coonan

Liberal Senator for New South Wales

ADDITIONAL COMMENTS

SENATOR BOYCE

1. I share the view of other Committee members that naturally occurring material, such as genes, should not be able to be patented.

2. However, I remain very concerned that any changes in one part of patent law may have unintended consequences across a system which has underpinned most technological and industrial advances for centuries.

3. No changes should be made to patent law without the expert advice of organisations such as IP Australia and the Australian Law Reform Commission.

Senator Sue Boyce

Liberal Senator for Queensland

APPENDIX 1

LIST OF PUBLIC SUBMISSIONS, TABLED DOCUMENTS AND ADDITIONAL INFORMATION AUTHORISED FOR PUBLICATION BY THE COMMITTEE

Submissions received

1 Partington, Mr Michael

2 Sutherland, Dr G K

3 Ronan, Dr Anne

4 Centre for Governance of Knowledge and Development (Dr Luigi Palombi)

5 Lawson, Dr Charles

6 Winfield, Ms Bee

7 Australian Medical Association

8 Hamblin, Dr John

9 Kirk, A/Professor Judy

10 Such MP, The Hon Bob

11 Haskell, Professor Dennis and Ms Rhonda

12 National Health and Medical Research Council

13 Wahlstrom, Emertius Professor Jan

14 Western Australian Government

15 Willcox, Professor Mark

16 South Australian Government

17 Sarnoff, Professor Joshua D
Kahn, A/Professor Jonathan
Andrews, Professor Lori B
- Supplementary submission received 24.04.09

18 Australian Law Reform Commission

19 Department of Innovation Industry, Science and Research and IP Australia
- Supplementary submission dated 30.09.09

20 Moir, Dr Hazel

21 Medicines Australia

22 Hawkins, Ms Naomi

23 Nicol, Professor Dianne and Nielsen, Dr Jane

24 Genetic Technologies Limited

25 Bath, Mr David
26 Walter and Eliza Hall Institute of Medical Research
27 Davies Collison Cave
28 Peter MacCallum Cancer Centre
29 Biotechnology Industry Organization
30 Breast Cancer Action Group NSW
31 Institute of Patent and Trade Mark Attorneys of Australia
- Supplementary submission dated 07.09.09
- Additional supplementary submission received 06.08.10

32 Office of the Gene Technology Regulator
33 Human Genetics Society of Australasia
34 FB Rice & Co
35 Country Women's Association of NSW
36 The Intellectual Property Research Institute of Australia
37 Swedish National Council on Medical Ethics
38 Christie, Professor Andrew
39 Leary, Professor Jennifer
40 National Coalition of Public Pathology
41 Royal Australasian College of Surgeons
42 George, Ms Anna
43 Medical Technology Association of Australia
44 Johnson & Johnson Family of Companies Australia
45 Rimmer, Dr Matthew
46 Saul, Dr Ben
47 Cancer Voices NSW
48 Breast Cancer Network Australia
49 Royal College of Pathologists of Australasia
50 Cancer Council Australia
51 Pfizer Australia
52 Australian Marfan Foundation
53 Tasmanian Government
54 New South Wales Government
55 Coyte, Dr Belinda
56 Carey, Ms Trish

57 Intellectual Property Committee of the Business Law Section of the Law Council of Australia

58 Royal Australian and New Zealand College of Obstetricians and Gynaecologists

59 Johnston, Mr Adam

60 Centre for Governance of Knowledge and Development (Professor Peter Drahos)

61 Victorian Government

62 Department of Health and Ageing

63 MADGE

64 Wylie, Ms Alison

65 Ninham, Ms Veronica

66 Skippings, Ms Tracy

67 Campbell, Dr M

68 Gill, Dr Deepak

69 Parke MP, Ms Melissa

70 Xenome Limited

71 CSL Limited

72 Association of Australian Medical Research Institutes

73 Bourne, Mr Paul

74 Chartered Institute of Patent Attorney's

75 AusBiotech

76 Heffernan, Senator the Hon Bill

77 Beardsell, Mr Harry

78 Rijk Zwaan Australia

Tabled Information

1 Breast Cancer Network Australia (Submission 48)

- 'The key issues for BCNA's members' tabled at hearing 03.08.09

2 Cancer Council Australia (Submission 50)

- Letter to Senator the Hon Humphries tabled at hearing 18.05.10

3 Cancer Voices NSW (Submission 47)

- Opening statement from hearing 05.08.09

4 Department of Innovation Industry, Science and Research and IP Australia (Submission 19)

- Opening statement for hearing 20.08.09
- Copy of Patent No. 13,427/23 application dated 19 July 1923, provided at hearing 20.08.09
- Copy of Patent No. 11,047/19 application dated 8 May 1919, provided at hearing 20.08.09
- 'Timesframes of ACIP Review and IP Australia's IP Reform Project', tabled at hearing 15.06.10

5 Heffernan, Senator the Hon Bill (Submission 76)

- Correspondence by Genetic Technologies referred to in questions, tabled at hearing 19.03.09
- Proposed amendments to the Patents Act, tabled at hearing 20.08.09

6 The Intellectual Property Research Institute of Australia (IPRIA) (Submission 36)

- Copy of overheads of presentation provided at hearing 03.08.09

7 Moir, Dr Hazel (Submission 20)

- Boldrin & Levine: Against Intellectual Monopoly, Chapter 9: The Pharmaceutical Industry, provided at hearing 20.08.09

8 Nicol, Professor Dianne and Nielsen, Dr Jane (Submission 23)

- Copy of articles they authored tabled at hearing 03.08.09:
- Whither patent use without authorisation in Australia? Federal Law Review, v36 no.3 2008, pp333-364
- Patents and Medical Biotechnology: An empirical analysis of issues facing the Australian industry, Centre for Law and Genetics, Occasional Paper No.6/2003

Additional Information

1 Australian Competition & Consumer Commission

- Comments on issues concerning competition law, exceptions from the TPA and Genetic Technologies Ltd's patent rights over BRCA1&2 testing, dated 16.10.09

2 Australian Marfan Foundation (Submission 52)

- Additional information dated 10.08.09

3 Breast Cancer Network Australia (Submission 48)

- Response to Senator the Hon. Heffernan submission, received 29.04.10

4 Cancer Council Australia (Submission 50)

- Response to questions on notice arising from the hearing 05.08.09, received 18.08.09
- Correspondence clarifying the Council's position on evidence received dated 15.12.09
- Response to Senator the Hon Heffernan submission, dated 22.04.10

5 Cancer Voices (Submission 47)

- Response to Senator the Hon Heffernan submission, dated 09.04.10

6 Centre for Governance of Knowledge and Development, (Dr Luigi Palombi) (Submission 4)

- Responses to questions on notice from hearing 19.03.09, dated 02.04.08 and received 06.05.09
- Copy of presentation at hearing 14.09.09

7 Christie, Professor Andrew (Submission 38)

- Response to question on notice arising from hearing 04.08.09, received 02.10.09

8 Coyte, Dr Belinda (Submission 55)

- Additional information concerning gene testing, received 19.08.09

9 Department of Innovation Industry, Science and Research and IP Australia (Submission 19)

- Response to questions arising from the preliminary briefing 19.03.09, dated 04.06.09
- Response to question regarding exclusions from patentability under TRIPS and AUSFTA, dated 29.07.09
- 'Estimating the Patent Premium: Evidence from the Australian Inventor Survey', P.H. Jensen, R. Thomson and J. Yong, May 2009, received 07.08.09

- Response to question on notice arising from hearing 20.08.09, received 31.08.09
- Response to question on notice arising from hearing 20.08.09 concerning copies of two patent applications, dated 01.09.09
- Clarification of evidence relating to the 202 Australian patents, dated 07.09.09
- Response to a question arising from the hearing 20.08.09 regarding ALRC recommendations, dated 07.09.09
- Response to question on notice arising from hearing 20.08.09, received 07.09.09
- Response to Senator the Hon. Heffernan submission, dated 08.04.10
- Correction to IP response to Senator the Hon. Heffernan's submission, received 03.05.10
- Clarification of evidence from hearing 18.05.10, received 07.06.10
- Response to questions on notice arising from public hearing 15.06.10, received 30.07.10

10 Genetic Technologies Limited (Submission 24)

- Web Link to articles relating to the granting of patents on human genes, received 31.03.09

11 The Intellectual Property Research Institute of Australia (IPRIA) (Submission 36)

- 'An Empirical Investigation into Patent Enforcement in Australian Courts', K. Weatherall and P.H. Jensen, received 03.08.09

12 Medicines Australia (Submission 21)

- Response to a question arising from the hearing on 05.08.09, dated 28.09.09

13 Moir, Dr Hazel (Submission 20)

- Response to two IP Discussion papers dated 06.05.09
- Submission to the ACIP Review of patentable subject matter 2008, received 15.09.09
- Response to a question on notice arising from the hearing 20.08.09, received 16.09.09
- Response to Senator the Hon. Heffernan submission, dated 02.05.10

14 National Health and Medical Research Council (Submission 12)

- Response to questions concerning SCNIA gene and its association with Dravet syndrome, dated 23.04.09

15 Nicol, Professor Dianne and Nielsen, Dr Jane (Submission 23)

- Additional information regarding patent pooling arrangements arising from hearing 03.08.09, received 31.08.09

16 Pfizer Australia (Submission 51)

- Additional information commenting on a ban on gene patenting, dated 30.04.09

17 Rimmer, Dr Matthew (Submission 45)

- Additional information relating to a US lawsuit which argues that patents on two human genes associated with breast and ovarian cancer are unconstitutional and invalid, received 13.05.09
- Additional information regarding higher threshold standards for patent validity arising from the hearing 20.08.09, received 21.08.09

18 Royal College of Pathologists of Australasia (Submission 49)

Documentation received following hearing 03.08.09:

- 'Genetic Testing in the 21st Century: Are we ready?', Royal College of Pathologists of Australasia
- 'Report of the Australian Genetic Testing Survey 2006', Royal College of Pathologists of Australasia
- Clarification of evidence and response to question arising from 04.08.09 hearing, received 16.08.09
- Copy of the presentation from the Chair of the US Secretary's Advisory on Genetics, Health and Society received 16.10.09
- Meeting summary of Secretary's Advisory Committee on Genetics, Health , and Society (SACGHS) October 8-9 2009, received 20.10.09
- "The Supreme Court, Process Patents, and Medical Innovation', A. Kesselheim, New England Medical Journal; 361:24
- 'Who Owns Science? The Manchester Manifesto', University of Manchester, Institute for Science Ethics and Innovation, November 2009

19 Walter and Eliza Hall Institute of Medical Research (Submission 26)

- Response to question arising from hearing 03.08.09, received 03.08.09

APPENDIX 2

WITNESSES WHO APPEARED BEFORE THE COMMITTEE AT PUBLIC HEARINGS

Thursday, 19 March 2009
Parliament House, Canberra

Committee Members in attendance

Senator Claire Moore (Chair)
Senator Catryna Bilyk
Senator Sue Boyce
Senator Mitch Fifield
Senator Mark Furner
Senator the Hon. Bill Heffernan
Senator Gary Humphries

Witnesses

Department of Health and Ageing

Ms Mary Murnane, Deputy Secretary
Mr Chris Reid, General Counsel

National Health and Medical Research Council

Professor Warwick Anderson, Chief Executive Officer

IP Australia

Mrs Fatima Beattie, Deputy Director General
Mr Leo O'Keeffe, Director, Domestic Policy
Ms Kristina Huynh, Policy Officer
Ms Lexie Press, Senior Examiner of Patents

Dr Luigi Palombi

Dr Hazel Moir

Monday, 3 August 2009
St James Court Conference Centre, West Melbourne

Committee Members in attendance

Senator Rachel Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator Judith Adams
Senator Sue Boyce
Senator the Hon. Bill Heffernan
Senator Gary Humphries
Senator John Williams

Witnesses

Intellectual Property Research Institute of Australia (IPRIA)

Associate Professor Beth Webster, Director
Dr Kwanghui Lim, Associate Director
Dr Chris Dent, Senior Research Fellow

Professor Diane Nicol and Dr Jane Nielsen

Human Genetics Society of Australasia

Associate Professor David Amor

Walter and Eliza Hall Institute of Medical Research

Mr Julian Clark, Head, Business Development

Ms Carmela Monger, Intellectual Property and Contracts Manager

Breast Cancer Network Australia

Ms Lyn Swinburne AM, Chief Executive Officer

Ms Michelle Marven, Policy Manager

Ms Heather Drum, Member

Ms Kristi Smith, Member

Tuesday, 4 August 2009
St James Court Conference Centre, West Melbourne

Committee Members in attendance

Senator Rachel Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator Judith Adams
Senator Sue Boyce
Senator the Hon. Bill Heffernan
Senator Gary Humphries
Senator John Williams

Witnesses

Institute of Patent and Trade Mark Attorneys of Australia

Dr Trevor Davies, Councillor

Davies Collison Cave

Mr John Slattery, Consultant

FB Rice & Co

Mr Ian Rourke, Partner

Royal College of Pathologists of Australasia

Dr Graeme Suthers, Chair, Genetics Advisory Committee

Mr Michael Ralston, Member, Genetics Advisory Committee

Dr Tamsin Waterhouse, Deputy Chief Executive Officer

Professor Andrew Christie

Law Council of Australia, Intellectual Property Committee

Mr Richard Hamer, Partner, Allens Arthur Robinson

Mr Richard Jarvis, Partner, Davies Collison Cave

Australian Marfan Foundation

Mrs Jennifer West, Secretary

Dr Belinda Coyte ***(via teleconference)***

Peter MacCallum Cancer Centre

Dr Gillian Mitchell, Director, Familial Cancer Centre

Professor Stephen Fox, Director of Pathology

Professor David Bowtell, Director of Research

Wednesday, 5 August 2009
Dixson Room, State Library of New South Wales, Sydney

Committee Members in attendance

Senator Rachel Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator Judith Adams
Senator Sue Boyce
Senator the Hon. Bill Heffernan
Senator Gary Humphries
Senator John Williams

Witnesses

Cancer Council Australia

Professor Ian Olver, Chief Executive Officer

Professor Bruce Mann, Specialist Breast Surgeon and Surgical Oncologist, Clinical Oncological Society of Australia

Breast Cancer Action Group

Ms Janet Green, Chair

Cancer Voices NSW

Ms Sally Crossing AM, Chair

Medicines Australia

Ms Deborah Monk, Director, Innovation and Industry Policy

Clinical Associate Professor Judy Kirk, Director Familial Cancer Service, Westmead Hospital

Dr Jennifer Leary, Laboratory Director, Familial Cancer Service, Westmead Hospital

Dr Anna Ronan, Clinical Geneticist, Hunter Genetics Unit

Professor Ron Trent, Professor of Molecular Genetics, University of Sydney

Department of Industry and Investment New South Wales

Dr Gerard Cudmore, Acting Director, Office for Science and Medical Research

Thursday, 20 August 2009
Parliament House, Canberra

Committee Members in attendance

Senator Rachel Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator Judith Adams
Senator the Hon. Bill Heffernan
Senator Gary Humphries
Senator John Williams

Witnesses

Dr Hazel Moir

Dr Matthew Rimmer

Professor Peter Drahos

IP Australia

Mrs Fatima Beattie, Deputy Director General

Mr Leo O'Keeffe, Director, Domestic Policy

Ms Kristina Huynh, Policy Officer

Ms Lexie Press, Senior Examiner of Patents

Department of Health and Ageing

Ms Mary McDonald, Acting First Assistant Secretary, Regulatory Policy and Governance Division

Mr Chris Reid, General Counsel

National Health and Medical Research Council

Dr Clive Morris, Chief Knowledge and Development Officer

Monday, 14 September 2009
Parliament House, Canberra

Committee Members in attendance

Senator Rachel Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator the Hon. Bill Heffernan
Senator John Williams

Witnesses

Dr Luigi Palombi

Tuesday 18 May 2010
Parliament House, Canberra

Committee Members in attendance

Senator Rachel Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator Judith Adams
Senator the Hon. Bill Heffernan
Senator Gary Humphries

Witnesses

IP Australia
Mrs Fatima Beattie, Deputy Director General
Mr Leo O'Keeffe, Director, Domestic Policy

Tuesday 15 June 2010
Parliament House, Canberra

Committee Members in attendance

Senator Rachel Siewert (Chair)
Senator Claire Moore (Deputy Chair)
Senator Judith Adams
Senator Sue Boyce
Senator the Hon. Bill Heffernan

Witnesses

IP Australia
Ms Terry Moore, Director, Office of the Director General
Mrs Fatima Beattie, Deputy Director General
Ms Lexie Press, Senior Examiner of Patents