The Senate

Legal and Constitutional Affairs Legislation Committee

Patent Amendment (Human Genes and Biological Materials) Bill 2010

September 2011

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Suite S1.61	Telephone:	(02) 6277 3560
Parliament House	Fax:	(02) 6277 5794
CANBERRA ACT 2600	Email: legcon.sen@aph.gov.au	

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ABBREVIATIONS

ACIP	Advisory Council on Intellectual Property
ACIP Report	Advisory Council on Intellectual Property, *Patentable Subject Matter*, Final Report, December 2010
ALRC	Australian Law Reform Commission
ALRC Report	Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004
AUSFTA	Australia-United States Free Trade Agreement
CCA/COSA	Cancer Council Australia/Clinical Oncological Society
DIISR	Department of Innovation, Industry, Science and Research
EM	Explanatory Memorandum
GM	genetically modified
GMIA	Generic Medicines Industry Association
IPTA	Institute of Patent and Trade Mark Attorneys
NHMRC	National Health and Medical Research Council
NRDC case	*National Research Development Corporation v Commissioner of Patents (1959)* 102 CLR 252
Patents Act	*Patents Act 1990*
Raising the Bar Bill	Intellectual Property Laws Amendment (Raising the Bar) Bill 2011
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

RECOMMENDATIONS

Recommendation 1

5.27 The committee recommends that the Senate should not pass the Bill.

CHAPTER 1

INTRODUCTION

Background

1.1 On 26 November 2010, the Senate referred the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Bill) to the Senate Legal and Constitutional Affairs Legislation Committee (committee) for inquiry and report by 16 June 2011. On 15 June 2011, the Senate granted an extension of time for reporting until 25 August 2011. On 23 August 2011, the granted another extension of time for reporting to 21 September 2011. The Bill was introduced into the Senate on 24 November 2010 by Senators Coonan, Heffernan, Siewert and Xenophon.[1] The purpose of the Bill is to amend the *Patents Act 1990* (Patents Act) to prevent the patenting of human genes and biological materials existing in nature.

1.2 The introduction of the Bill into the Senate followed a lengthy inquiry into the impact of gene patents by the Senate Community Affairs References Committee, which tabled its report, *Gene Patents*, on 26 November 2010. That report included a recommendation that the Senate refer the Bill 'to the relevant Senate committee for inquiry and report'.[2]

Conduct of the inquiry

1.3 The committee advertised the inquiry in *The Australian* newspaper, and details of the inquiry, the Bill and associated documents were placed on the committee's website. The committee also wrote to a number of organisations and individuals, inviting submissions by 25 February 2011.

1.4 The committee received 122 submissions, which are listed at Appendix 1. Public submissions were published on the committee's website.

1.5 The committee held two public hearings for the inquiry, which took place on 28 and 29 April 2011 at Parliament House in Canberra. A list of witnesses who appeared at the hearing is at Appendix 2, and copies of the *Hansard* transcript are available online at http://www.aph.gov.au/hansard.

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1 A private members' Bill with the same title and similar provisions as the Bill before the committee was introduced into the House of Representatives on 21 February 2011, sponsored by the Hon Peter Dutton MP, the Hon Malcolm Turnbull MP, Mr John Forrest MP and Mr Rob Oakeshott MP.

2 Senate Community Affairs References Committee, *Gene Patents*, November 2010, Recommendation 3.

Acknowledgement

1.6 The committee thanks those organisations and individuals who made submissions and gave evidence at the public hearings.

Scope of the report

1.7 The structure of this report is as follows:

- Chapter 2 provides a brief background to the introduction of the Bill;
- Chapter 3 outlines the key provisions of the Bill;
- Chapter 4 discusses the key issues raised in submissions and evidence; and
- Chapter 5 provides the committee's conclusions and recommendations.

Note on references

1.8 References in this report are to individual submissions as received by the committee, not to a bound volume. References to the committee *Hansard* are to the proof *Hansard*. Page numbers may vary between the proof and the official *Hansard* transcript.

Terminology

1.9 The committee notes that patent law, genetic science and health research are areas which rely on specific and technical vocabularies. The committee's report seeks to avoid unnecessary use of technical terms wherever possible.

CHAPTER 2

BACKGROUND

Australia's patent system

2.1 In Australia, the patent system is governed by the Patents Act. Patents are granted by a statutory officer, the Commissioner of Patents, and IP Australia is the government agency with responsibility for administering the patent system. 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. A patent grants exclusive rights to the patent holder, allowing them to prevent others from exploiting the invention without a licence and to maximise the commercial potential of the invention.

2.2 Most granted patents are standard patents which offer a period of patent protection to inventions for 20 years. Innovation patents, which were introduced in 2001, offer protection to inventions which do not meet the inventive threshold required for standard patents and, correspondingly, have a more limited period of protection (eight years).

2.3 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. The patent system also promotes innovation through encouraging the diffusion of knowledge, as it is a condition of the grant of a patent that the inventor publicly discloses details of their invention.[1]

2.4 The Patents Act contains a number of requirements for the patentability of an invention. In particular, an invention will be patentable if:

- it is a 'manner of manufacture';
- it is novel and involves an inventive step (as judged against previous knowledge and practice, also known as the 'prior art');
- it is useful;
- the details of the invention are sufficiently well disclosed or described; and
- it is not the subject of one of the specific exclusions.[2]

2.5 The 'manner of manufacture' requirement and the specific exclusions are of particular relevance to the Bill.

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1 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 8-19.

2 *Patents Act 1990*, sections 18 and 40. The requirements outlined here are not exhaustive and focus on aspects of patent law most relevant to the Bill.

Manner of manufacture and specific exclusions

2.6 The Patents Act requires a patentable invention to be a 'manner of manufacture within the meaning of section 6 of the Statute of Monopolies'.[3] The English Statute of Monopolies of 1623 is the historical predecessor of Australian patent law, including the current Patents Act. The original purpose of the Statute was to abolish monopolies which had been granted by the Crown on trades and industries. However, section 6 of the Statute made an exception for new inventions. Section 6 provided for a term of exclusive exploitation rights 'to the true and first inventor' who introduced 'any manner of new manufacture' to the jurisdiction, provided it met certain conditions.[4] As the Explanatory Memorandum (EM) to the current Bill notes:

> Section 6 of the Statute of Monopolies, being one of the express exceptions, provided that 'manners of new manufacture' could be the subject of 'Letters Patent and Grants of Privilege' provided they were 'not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient'.[5]

2.7 The basis of the current legal conception of the term 'manner of manufacture' was established by the High Court of Australia in the case of *National Research Development Corporation v The Commissioner of Patents* (NRDC case).[6] In that case, the court endorsed a more expansive definition of 'manner of manufacture', whereby patentability is determined by reference to the policy intent of the Patents Act rather than by application of a strict definition. The Court stated:

> The right question is: "Is this a proper subject of letters patent according to the principles which have been developed for the application of s. 6 of the Statute of Monopolies?"[7]

2.8 An invention will meet this requirement if it is an 'artificially created state of affairs' which belongs to the 'useful arts' rather than 'fine arts', and it must provide a material advantage in a field of economic endeavour. Judicial interpretation has also recognised a number of categories of subject matter that fail to satisfy the requirement. These include mere discoveries, ideas, scientific theories and laws of nature.[8]

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3 *Patents Act 1990*, paragraph 18(1)(a).

4 William van Caenegem, *Intellectual and Industrial Property in Australia*, 2009, p. 155.

5 EM, p. 2.

6 (1959) 102 CLR 252.

7 *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 at 269.

8 Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 118.

2.9 The Patents Act also provides that 'human beings, and the biological processes for their generation, are not patentable inventions'.[9] For the purposes of an innovation patent, another exception to patentability exists for plants and animals, and the biological processes for the generation of plants and animals (but this does not apply if the invention is a microbiological process or a product of such a process).[10]

2.10 Judicial and academic commentary indicates that the absence of further express statutory exclusions in the Patents Act has been influential in the willingness of courts to accept a broad range of subject matter as a 'manner of manufacture'.[11] The mainstream view has been that the NRDC case, and the lack of other express exclusions on patentability in the Patents 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 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.[12]

Generally inconvenient

2.11 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'. However, under Australian law it is currently unclear whether inventions can be excluded from patenting on public policy grounds, such as for being 'generally inconvenient'.[13]

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9 This exclusion was an amendment moved by Senator Brian Harradine when the Patents Act was passed. Senator Brian Harradine, *Senate Hansard*, 20 September 1990, p. 2654.

10 *Patents Act 1990*, subsections 18(2), (3) and (4).

11 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 12-13.

12 Mark Davison, Anne Monotti and Leanne Wiseman, *Australian Intellectual Property Law*, 2008, p. 410.

13 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 14; Advisory Council on Intellectual Property, *Patentable Subject Matter*, Final Report, December 2010, p.11.

Limitations on granted patents

2.12 Under the Patents Act, the grant of a patent by the Commissioner of Patents does not guarantee or necessarily imply that the patent is legally valid. There are four opportunities for the validity of a patent to be tested under the Patents 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 a 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).[14]

2.13 In practice, the grant of a patent does not give an absolute right to exploit an invention in any way the inventor chooses. A patent holder may still need to satisfy regulatory or legal requirements in order to exploit a patented product or process.

2.14 The Patents Act also contains certain safeguards which allow patent rights to be altered in some circumstances. For example, the Crown Use provisions of the Patent Act (sections 163-170) permit certain government entities to use, and to authorise others to use, patented inventions without the permission of the patent owner in certain circumstances. Such use is only permissible where the use is for the proper provision of services of the Commonwealth, or of a state, or a territory. The relevant government must give the patent owner remuneration for the use of their patent.[15]

2.15 The compulsory licensing provisions of the Patents Act (sections 133-140) provide that a compulsory licence can be sought where the patent holder fails to meet the reasonable requirements of the public. These provisions set 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 taken not to have been satisfied.[16]

2.16 These circumstances 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 to:

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14 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 15.

15 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 120.

16 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 122.

- manufacture the patented product to an adequate extent and supply it on reasonable terms; or
- grant licences on reasonable terms.[17]

International treaties

2.17 Australia is party to a number of multilateral and bilateral treaties which relate to the patent system, reflecting efforts to harmonise international intellectual property rules. Further details of two of these treaties, the Agreement on Trade-Related Aspects of Intellectual Property Rights and the Australia-United States Free Trade Agreement, are outlined below.

Agreement on Trade-Related Aspects of Intellectual Property Rights 1994

2.18 The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS Agreement) established, among other things, the minimum standard of patent protection that each member of the World Trade Organisation (WTO) must provide under its national laws. In particular, Article 27(1) of the TRIPS Agreement requires member countries, such as Australia, to make patents available to all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

2.19 Article 27(2) provides exceptions for the patentability of inventions 'the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment'. Article 27(3) provides that members may also exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans and animals', as well as 'plants and animals other than micro-organisms'.

Australia-United States Free Trade Agreement

2.20 The Australia-United States Free Trade Agreement (AUSFTA) entered into force on 18 May 2004 and contains a number of provisions relating to the patent system. According to Article 17.9 of the AUSFTA:

> 1. Each Party shall make patents available for any invention, whether product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application. The Parties confirm that patents shall be available for any uses or methods of using a known product.
>
> 2. Each Party may only exclude from patentability:
>
> (a) inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal, or plant life or health or to avoid

17 *Patents Act 1990*, section 135.

serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law; and

(b) diagnostic, therapeutic, and surgical methods for the treatment of humans and animals.

BRCA gene patents

2.21 The Senate Community Affairs References Committee gene patents inquiry was initiated in response to concerns arising from attempts in 2002-03 and 2008 by Genetic Technologies Ltd (Genetic Technologies), a genetic testing company, to enforce its patent rights over the BRCA1 and BRCA2 genes (BRCA gene patents) in Australia. The BRCA gene patents relate to methods and materials used to isolate and detect mutations in two genes which may indicate a predisposition to certain cancers, particularly ovarian and breast cancer. Myriad Genetics Ltd (Myriad), a company based in the United States, granted Genetic Technologies exclusive rights to BRCA gene testing in Australia.

2.22 In 2002-03 and 2008, Genetic Technologies sent 'cease and desist' letters to public laboratories, research bodies and other entities seeking to prevent these organisations from engaging in any further testing for the BRCA genes. However, in both cases, Genetic Technologies ultimately dropped legal demands in relation to testing for the BRCA genes. In a report to shareholders on 9 July 2003, Genetics Technologies stated 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'.[18] Similarly, following its attempt to enforce its patent rights in 2008, Genetic Technologies announced that it had reviewed its decision and 'resolved to immediately revert to its original decision to allow other laboratories in Australia to freely perform BRCA testing'.[19]

2.23 The Senate Community Affairs References Committee indicated that its understanding was that, in relation to the 2008 demands, state health departments had negotiated with Genetic Technologies following the issuing of the 'cease and desist' letters.[20] A number of reasons were suggested for Genetic Technologies' change of position in relation to the BRCA patents. These included: public and professional criticism of the decision to enforce the patents; the previous purported 'gift' of the BRCA genes to the Australian people would have created difficulties for enforcement; negotiations with state health departments may have indicated that the demands or the patents could be legally contested; and the Australian Competition and Consumer Commission was considering, or had instituted an investigation into, whether enforcement of the BRCA gene patents raised issues of anti-competitive behaviour.[21]

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18 Genetic Technologies Ltd, 'A report to shareholders', 9 July 2003, p. 1.

19 Genetic Technologies Ltd, 'New position re BRCA testing', 2 December 2008, p. 1.

20 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 6-7.

21 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 6-7.

Public reviews

2.24 The introduction of the Bill follows a number of public inquiries and reviews of the law relating to gene patents and their potential impacts.

Australian Law Reform Commission – Genes and Ingenuity (ALRC Report)

2.25 On 29 June 2004, the ALRC presented its extensive report on gene patenting and human health, which included 50 recommendations. While outlining a number of its concerns relating to gene patents, the ALRC concluded that inventions involving genetic materials and technologies should be assessed according to the same legislative criteria as other inventions:

> In the ALRC's view, concerns about the patenting of inventions involving genetic materials and technologies should not be addressed by the introduction of legislative requirements that would relate only to the patentability of this type of invention. Such an approach may set an undesirable precedent for the way in which the patent system should accommodate new technologies in the future. The current requirements for patentability are technology-neutral and are able to adapt to new technologies as they arise. Introducing specific rules for inventions involving genetic materials and technologies may suggest that special requirements for patentability should be implemented for future technologies that raise a different set of issues. Such an approach would unnecessarily fragment and complicate Australian patent law.[22]

Senate Community Affairs References Committee – Gene Patents

2.26 The Senate Community Affairs References Committee's report made 16 recommendations regarding gene patents, genetic testing and the patent system. Several of these recommendations supported or restated the recommendations in the ALRC Report. However, the Senate Community Affairs References Committee determined that 'it would not recommend at this stage the *Patents Act 1990* be amended to include an express prohibition on human genes and genetic products'. It concluded that 'there would need to be a very clear case and significant social and political consensus on the need for such a change' as the 'evidence to the inquiry shows there are legitimate and sometimes finely balanced arguments on both sides of the debate'.[23] The committee's decision not to recommend an express prohibition on gene patents was based on recent international and national legal developments relating to the patentability of genes, and the announcement of the current Bill 'which contains an express prohibition in specific terms'.[24]

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22 ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 119.

23 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 99-100.

24 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 100.

2.27 The Senate Community Affairs References Committee stated:

> 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...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.[25]

2.28 In its comments, the Senate Community Affairs References Committee also noted 'the 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'.[26]

Advisory Council of Intellectual Property – Review of Patentable Subject Matter (ACIP Report)

2.29 The Advisory Council on Intellectual Property (ACIP) is an independent body appointed by the Australian Government. ACIP advises the Minister for Innovation, Industry, Science and Research on intellectual property matters and the strategic administration of IP Australia. Adopting one of the recommendations made in the ALRC Report, the Minister, Senator the Hon Kim Carr, requested that ACIP conduct a review of patentable subject matter. The review included 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'. Following wide consultation, ACIP provided its final report on the review of patentable subject matter (ACIP Report) to the Minister in December 2010 and the final report was publicly released on 6 February 2011.[27]

2.30 The ACIP Report made 11 recommendations, including several recommendations for amendments to the Patents Act, namely:

- a recommendation to define patentable subject matter 'using clear and contemporary language' that embodies the principles of inherent patentability as developed in the case law of Australian courts;

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25 Senate Community Affairs References Committee, *Gene Patents*, November 2010, pp 100-101.

26 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 100.

27 ACIP, *Patentable Subject Matter – Options Paper*, September 2009; ACIP, *Patentable Subject Matter*, Final Report, December 2010.

- a recommendation that the specific exclusions which currently exist in the Patents Act should be maintained, but other specific exclusions, including 'to prevent the patenting of human genes and genetic products' should not be introduced; and
- a recommendation that a general exclusion on ethical grounds should be added to the Patents Act, as permitted under Australia's international obligations, 'to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'.[28]

IP Australia – public consultation and proposed legislation

2.31 In 2009, IP Australia released several consultation papers, and sought submissions from interested parties, as part of a proposed broad package of intellectual property reforms.[29] On 3 March 2011, IP Australia released a public exposure draft of the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Raising the Bar Bill), and an associated explanatory memorandum, and sought submissions from interested stakeholders. On 22 June 2011, the Raising the Bar Bill was introduced into the Senate.[30]

2.32 As currently drafted, the Raising the Bar Bill will amend a number of pieces of intellectual property legislation including the Patents Act. The amendments to the Patents Act incorporate changes intended to raise the quality of granted patents, and allow free access to patented inventions for research and regulatory activities. In particular, the Raising the Bar Bill will:

- amend the Patents Act to remove restrictions on the information and background knowledge taken into account when assessing whether an application is sufficiently inventive to justify a patent;
- strengthen the requirements that a patented invention be useful: that is, that the invention works in the way that the patent says it does and that the specification explains how the invention works;
- raise the standards set for disclosure of an invention, to ensure that granted patents are no broader than the invention which has been disclosed;
- increase certainty in the validity of granted patents by expanding the grounds which the Commissioner of Patents can consider; and applying a consistent

28 ACIP, *Patentable Subject Matter*, Final Report, December 2010, pp 2-20.

29 For example, see IP Australia, *Getting the Balance Right*, Consultation Paper, March 2009; IP Australia, *Exemptions to Patent Infringement*, Consultation Paper, March 2009; IP Australia, *Towards a Stronger and More Efficient IP Rights System*, Consultation Paper, November 2009.

30 *Journals of the Senate*, 22 June 2011, p. 1068.

standard of proof across all grounds, so that the Commissioner is not obliged to grant patents which would not pass scrutiny in a court challenge.[31]

2.33 In relation to access to patented inventions for research and regulatory activities, the Raising the Bar Bill will amend the Patents Act 'to draw a line between research and commercial activities, leaving researchers free to conduct their experiments without worrying about the patent system'. The amendments clarify that research and experimental activities relating to patented inventions are exempt from infringement, whereas commercial activities are not. The Raising the Bar Bill will also introduce an exemption for 'activities undertaken solely for the purpose of gaining regulatory approval to market or manufacture a patented technology'.[32]

Legal cases

2.34 Legal cases in the United States and Australia regarding the patentability of genes and genetic material are also relevant in providing background and context to the current Bill.

United States

2.35 On 29 March 2010, a legal challenge to the validity of the BRCA gene patents was decided in the US District Court for the Southern District of New York: *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others* (Myriad case). Judge Robert Sweet found in favour of the parties challenging the US Patent and Trademark Office's (USPTO) approach to granting patents over genetic material. 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.[33]

2.36 As part of its inquiry, the Senate Community Affairs References Committee received advice from the USPTO that the decision in the Myriad case was not at that 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'. The USPTO advised in the event that a final decision is delivered on the case in a higher court, such as the US Court of Appeals for

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31 *Intellectual Property Law Amendment (Raising the Bar) Bill 2011, Explanatory Memorandum*, pp 8-9.

32 *Intellectual Property Law Amendment (Raising the Bar) Bill 2011, Explanatory Memorandum*, pp 9-10.

33 *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others*, 09 Civ. 4515, S.D.N.Y, 29 March 2010, 4, available at http://www.genomicslawreport.com/wp-content/uploads/2010/03/Myriad-SJ-Opinion.pdf, accessed 2 August 2011.

the Federal Circuit or the US Supreme Court, it would 'conform its policy to that decision'.[34]

2.37 Following the decision, Myriad Genetics appealed to the Court of Appeals of the Federal Circuit. On 29 October 2010, the United States Department of Justice filed an *amicus curiae* brief[35] with the court which outlined disagreement with some of the positions taken in Judge Sweet's decision, and agreement with others. In particular, the brief agreed that genomic DNA that is simply isolated should not be patentable:

> The boundary between eligible and non-eligible subject matter is defined, in significant part, by the settled principle that the patent laws do not embrace laws of nature, physical phenomena, or abstract ideas...In attempting to apply that principle here, the district court erroneously cast doubt on the patent-eligibility of a broad range of manmade compositions of matter whose value derives from the information encoding capacity of DNA. Such compositions - e.g., cDNAs [complementary DNA], vectors, recombinant plasmids, and chimeric proteins, as well as countless industrial products, such as vaccines and genetically modified crops created with the aid of such molecules — are in every meaningful sense the fruits of human ingenuity and thus qualify as "human-made inventions" eligible for patent protection...The district court correctly held, however, that genomic DNA that has merely been isolated from the human body, without further alteration or manipulation, is not patent-eligible.[36]

2.38 On 29 July 2011, the Court of Appeals for the Federal Circuit overturned much of Judge Sweet's original decision. In particular, it reversed by 2-1 Judge Sweet's finding 'that Myriad's composition claims to "isolated" DNA molecules cover patent-ineligible products of nature under [US patent law] since the molecules as claimed do not exist in nature'.[37] The plaintiffs have indicated they will consider requesting the entire appellate court rehear the gene patenting aspects of the case or appealing the decision to the United States Supreme Court.[38]

Australia

2.39 On 8 June 2010, Maurice Blackburn Lawyers, representing Cancer Voices Australia and Ms Yvonne D'Arcy, commenced proceedings in the Federal Court of

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34 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 74.

35 An *amicus curiae*, or 'friend of the court', is a person not a party to a case who volunteers information to assist a court in deciding a matter before it.

36 United States Department of Justice, *Brief for the United States as amicus curiae in support of neither party*, 29 October 2010, pp 9-11.

37 *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others*, 2010-1406, 29 July 2011, 8, available at http://www.cafc.uscourts.gov/images/stories/opinions-orders/10-1406.pdf, accessed 2 August 2011.

38 Andrew Pollack, 'Ruling Upholds Gene Patent in Cancer Test', *New York Times*, 30 July 2011, p. B1.

Australia, seeking to invalidate the BRCA patents in Australia. Court dates for hearings are provisionally set for 20 February 2012 onwards.[39]

39 *Cancer Voices Australia & Anor v Myriad Genetics Inc & Ors*, Federal Court of Australia, NSD643/2010, available at http://www.comcourts.gov.au/file/Federal/P/NSD643/2010/actions, accessed 8 June 2011.

CHAPTER 3

OVERVIEW OF THE BILL

Key provisions of the Bill

3.1 The key provisions of the Bill amend the Patents Act.[1] In particular, the Bill amends section 18 which sets out the substantive requirements of a valid patentable invention for the purposes of a standard patent and innovation patent. Items 1 and 2 amend the 'manner of manufacture' test of patentability. Item 3 adds a new specific exclusion to patentability for 'biological materials', and Item 4 adds a new definition related to that exclusion.

3.2 The EM states that the Bill '(a) reinforces the applicability of the proviso in section 6 of the Statute of Monopolies within the meaning of section 18(1)(a) and section 18(1A)(a), (b) reinforces the applicability of the distinction between discovery and invention and (c) applies that distinction by expressly excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature, however made'.[2]

3.3 Item 1 of Schedule 1 of the Bill repeals existing paragraph 18(1)(a) of the Patents Act and substitutes '(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and'. In effect, this inserts the phrase 'within the full meaning, including the proviso' into the requirements of a patentable invention for the purposes of a standard patent.

3.4 Item 2 of Schedule 1 repeats this amendment of the requirements of a patentable invention for the purposes of an innovation patent. It repeals existing paragraph 18(1A)(a) and again substitutes 'a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and'.

3.5 Item 3 of Schedule 1 repeals subsection 18(2) and substitutes:

> (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.

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1 Possible amendments to the Bill were also proposed during the inquiry. These are addressed in chapter 4.

2 EM, p. 2.

3.6 In effect, this adds new paragraph (b) to existing subsection 18(2) which currently provides that human beings, and the biological processes for their generation, are not patentable inventions.

3.7 Finally Item 4 of Schedule 1 inserts new subsection 18(5). It provides '**biological materials**, in section 18, includes DNA, RNA, proteins, cells and fluids' [bold in original]. The abbreviation DNA presumably refers to deoxyribonucleic acid and is currently used elsewhere in the Patents Act without further definition. The abbreviation RNA presumably refers to ribonucleic acid and is not currently used or defined in the Patents Act.

Amended section 18

3.8 For convenience, the following extract indicates the proposed additions and deletions of the Bill's amendments to section 18 of the Patents Act. Underlined words are those added by the amendments in the Bill, while those words crossed out would be deleted.

Section 18 Patentable inventions

Patentable inventions for the purposes of a standard patent

(1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Patentable inventions for the purposes of an innovation patent

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

(b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an innovative step; and

(c) is useful; and

(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) The following are not patentable inventions:

(a) ~~H~~human beings, and the biological processes for their generation; and~~, are not patentable inventions.~~

(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.

Certain inventions not patentable inventions for the purposes of an innovation patent

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

(5) In this section:

biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids.

CHAPTER 4

KEY ISSUES RAISED IN EVIDENCE

Introduction

4.1 Key issues were raised in evidence in relation to a number of topics. These included:

- the drafting of the Bill;
- the efficacy of the Bill;
- the need for the Bill;
- the nature of discovery and invention;
- the impact of the Bill on healthcare;
- the impact of the Bill on investment;
- the impact of the Bill on research and development;
- the impact of the Bill on access to products;
- the impact of the Bill on access to knowledge;
- ethical issues related to the Bill;
- Australia's international obligations;
- support for the Raising the Bar Bill; and
- support for other policy approaches.

Drafting of the Bill

4.2 A number of concerns were raised regarding the terminology used in the Bill. These concerns related to both the proposed amendments to current paragraphs 18(1)(a) and 18(1A)(a) as well as the proposed exclusion of 'biological materials' from patentability. In particular, several individuals and organisations noted that unclear or ambiguous provisions would result in uncertainty for patent applicants and investors in research, and could result in unnecessary and costly litigation.[1]

Title of the Bill

4.3 Some submissions and witnesses considered that the title of the Bill does not accurately reflect the content of its provisions. For example Professor Dianne Nicol

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1 For example, Group of Eight, *Submission 28*, p. 2; AusBiotech, *Submission 97*, p. 5; Professor Douglas Hilton, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 4; Dr Brendan Shaw, Medicines Australia, *Committee Hansard*, 28 April 2011, p. 45.

was concerned that there is confusion about the Bill in the biotechnology sector, with some companies assuming it only applies to 'human genes'.[2] FB Rice & Co described the title of the Bill as 'misleading' as it implies that the Bill relates to 'human' biological material, while the proposed amendments in the Bill encompass biological material from any source.[3] Similarly, Griffith Hack and Griffith Hack Lawyers highlighted that '[d]espite the title of the Bill purporting to be for 'human genes and biological materials', nowhere within the Bill is there any limitation on the exclusion of patentability to biological materials derived from humans'.[4]

Manner of manufacture

4.4 Dr Luigi Palombi, the 'principal drafter of the Bill and Explanatory Memorandum',[5] outlined that the amendments to paragraph 18(1)(a) are intended to overturn 'two longstanding but, problematic' Full Federal Court of Australia decisions: *Anaesthetic Supplies Pty Ltd v Rescare Ltd* and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*.[6] Dr Palombi argued:

> In so doing the Bill restores the original intent of the *Patents Act, 1990*, and one that goes to the heart of Australian patent law, by preventing the grant of patents over subject matter which would be "contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient". This aspect of the Bill is designed to re-impose on the courts an obligation to inquire into the suitability, for the grant of a patent monopoly, subject matter that may be illegal, immoral, disreputable or otherwise injurious to Australian society or the economy and reinstate their power to strike these down *ab initio*, as if they had never existed.[7]

4.5 However, other submissions did not agree that this effect is clear in the proposed amendment. ResMed considered the amendment which inserts the phrase 'including the proviso' may reflect 'a concern that the "generally inconvenient" proviso is not currently law'. However in its opinion, while there may be doubt over how the 'generally inconvenient' proviso may operate, it is clear that it does in fact operate.[8]

4.6 Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow considered the amendment to modify reference to the Statute of Monopolies in

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2 *Committee Hansard*, 28 April 2011, p. 57.

3 *Submission 77*, p. 1.

4 *Submission 47*, p. 1 [underlining in original].

5 *Submission 103*, p. 1.

6 *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065 and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524. These decisions relate to the patentability of human medical treatments.

7 *Submission 103*, p. 1.

8 *Submission 80*, p. 12.

section 18 of the Patents Act to be 'superfluous'.[9] Similarly, Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee considered that the change would 'add nothing to the development or state of the law relating to 'manner of manufacture' and would not achieve any paradigm shift in the relevance of social and ethical dimensions to determinations of patentability'. In their view, it is clear from the case law that the proviso to section 6, including the question of whether the invention would be 'generally inconvenient', is already incorporated into the 'manner of manufacture' test.[10] Professor Nicol added 'if we want to have some sort of public policy or morality provision then it would be better to state that explicitly rather than reaffirming an old provision from way back in 1623'.[11]

4.7 La Trobe University questioned the clarity of the amendments to paragraphs 18(1)(a) and 18(1A)(a):

> The introduction of the proviso of the Statute of Monopolies provides no clarity or certainty that the resultant interpretation will in fact be to exclude discoveries from patentability. Moreover, the Bill does not link the introduction of the proviso with the restriction of biological materials. The applicability of the proviso to the other branches of science and engineering is therefore uncertain and should be clarified. Discoveries and inventions are not restricted to the field of biology.
>
> Unclear legislation should be avoided at all costs. In its current form, the Bill would result in uncertainty for patent applicants and investors in scientific research and ultimately cause unnecessary litigation.[12]

4.8 Davies Collison Cave could not perceive a difference between the current term 'within the meaning' and the Bill's proposed amendment 'within the full meaning'. It cautioned that the effect of the change 'will be to simply introduce an unnecessary ambiguity into the legislation'. Similarly to ResMed, Davies Collison Cave considered that it is not apparent what is meant by the proposed term 'including the proviso', arguing that the addition of the term 'including the proviso' to the current wording of section 18 of the Patents Act would also introduce unnecessary ambiguity.[13]

4.9 Dr Charles Lawson observed that it is '[p]erhaps surprising, [that] a law directed to high technology in 2011 reaches back nearly 400 years to 1623 to a concept of "manner of manufacture" as a way of drawing a distinction between what is, and what is not, patentable'. While he considered that the Patents Act should be subject to a thorough review (particularly in relation to competition policy), his view

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9 *Submission 18*, p. 4.

10 *Submission 39*, pp 32-33.

11 *Committee Hansard*, 28 April 2011, p. 61.

12 *Submission 41*, p. 3.

13 *Submission 17*, pp 6-7.

was that 'the formulation in section 6 of the Statute of Monopolies...is probably not appropriate to the modern Australian economy'.[14]

4.10 In their joint submission, the Department of Innovation, Industry, Science and Research (DIISR) and IP Australia highlighted that the recent Advisory Council on Intellectual Property (ACIP) report on the 'manner of manufacture' had recommended amending the Patents Act to codify the legal principles established by the NRDC case. DIISR and IP Australia considered that 'any recommendations for change to subject matter eligibility should follow from consideration of the ACIP recommendations'.[15]

4.11 The ACIP Report noted:

> Over time, the focus of the 'generally inconvenient' proviso has changed. The courts have imbued it with different functions – sometimes ethical, sometimes economic. The Australian High Court has referred to 'general inconvenience' a number of times as a possible ground of invalidity, but has neither applied that proviso to revoke a patent nor extinguished the concept.[16]

4.12 The ACIP Report supported the removal of the 'general inconvenience' proviso in favour of a general exclusion 'so as to exclude from patentability an invention the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'.[17]

Exclusion of biological materials

4.13 A number of submitters and witnesses expressed their concerns regarding the undefined use of the terms 'derivatives', 'components' and 'substantially identical' in the proposed exclusion of biological materials. For example, Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee stated:

> There are terms in the Bill that are not defined. Depending on the way they are interpreted, they could have far-reaching or limited effect. It is not at all clear what is intended by the use of these terms, nor whether they will be interpreted in a way that corresponds with the original intention.[18]

4.14 Davies Collison Cave also argued that the proposed prohibition from patentability for 'biological materials' and the associated definition of 'biological materials' 'would introduce substantial and wide ranging uncertainty in the Patents Act 1990 arising principally from the scope and potential impact of these

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14 *Submission 1*, pp 1-2.

15 *Submission 94*, p. 17.

16 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 11.

17 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 18.

18 *Submission 39*, p. 7.

proposed amendments, particularly in relation to the ambiguity, or lack of clarity which exists in relation to most of the terminology to be introduced'.[19]

4.15 The use of the term 'substantially identical' was viewed by some submitters and witnesses as particularly problematic.[20] Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow argued:

> ...the term "substantially identical" is ambiguous. It is unclear as to what quantum or character a lack of identity with a naturally occurring substance would be required before a synthetic molecule would be considered patentable. The use of this language introduces further ambiguity rather than clarifying the definition of patentable subject matter.[21]

4.16 Professor Andrew Christie argued that the focus on identicality 'runs the risk of precluding the potential for reward of a patent where it should be granted'. He noted that submitters to the inquiry had provided examples of biological materials 'which are changed but changed as little as possible to achieve the effect'. In these examples, inventions which meet the other requirements of patentability (novelty, inventiveness and utility) could be 'wrongly taken out of consideration for patentability' because they are substantially identical to material existing in nature.[22]

4.17 The National Health and Medical Research Council (NHMRC) was concerned about the proposed open definition for 'biological materials'. In particular, the NHMRC highlighted the lack of definition of 'substantially identical' which 'has the potential to obstruct and suppress innovation and translation of the outcomes of biomedical research into products and/or treatments to improve the health and wellbeing of Australians and people around the world'. As an example, the NHMRC noted a product of synthetic biology, while not a biological material, is modelled on biological material and would appear to be excluded under the Bill.[23] Similarly, the ALRC noted that it would be difficult to effectively define an exclusion relating to genetic materials. In relation to the formulation used in the Bill 'it is unclear...whether cDNA [complementary DNA] is "substantially identical" to genomic DNA'.[24]

4.18 However, Dr Luigi Palombi argued that the term 'substantially identical' is not new to intellectual property law, noting its extensive use in trade mark law. He stated that 'it is open for an Australian court to interpret the term "substantially identical" in the context of section 18(2)(b) by drawing a distinction between a naturally occurring

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19 *Submission 17*, pp 7-9.

20 For example, Institute of Patent and Trade Mark Attorneys, *Submission 49*, p. 7; Professor Ian Frazer, *Submission 92*, p.1; Professor Douglas Hilton, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 10.

21 *Submission 18*, p. 10.

22 *Committee Hansard*, 29 April 2011, pp 27-28.

23 *Submission 46*, p. 1.

24 *Submission 30*, p. 4.

biological material and one that has been modified so that it can no longer be said to be a product of nature but, instead, be a product of humankind'.[25] Further:

> While it may be argued that absent a statutory definition of 'substantially identical' there is some uncertainty in how the Australian courts will interpret and apply section 18(2)(b), the counter to that argument is that there already exists a body of law, albeit foreign, which provides guidance on point...[26]

4.19 Dr Palombi also considered that the term 'substantially identical' is necessary as an 'anti-avoidance provision' in order to 'avoid the wordplay that patent attorneys constantly apply to these sorts of claims'.[27]

Increased possibility of litigation

4.20 Unclear provisions in the Bill were seen to potentially create uncertainty, which would discourage investment in research and encourage unnecessary litigation. For example, AusBiotech predicted 'a frenzy of legal activity' would be necessary to interpret the language of the Bill.[28] The Institute of Patent and Trade Mark Attorneys (IPTA) highlighted the risks that the unclear language in the Bill would have, meaning that the community would be reliant on the courts to define the Bill's boundaries. This could result in long and costly litigation:

> It should also be remembered that when a biotechnology case is litigated, the clarification which it provides is limited to the scope of the issue which has been brought before the court...The community would be, therefore, reliant on the handing down of multiple decisions to bring clarity across the scope of the Bill. Whether or not this would occur is entirely dependent on the willingness of parties to both initiate and then follow through (i.e. not settle) their litigation. Realistically, this process is beyond anyone's control and would likely take decades to resolve, at enormous cost.[29]

4.21 Similarly, Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee noted that these uncertainties in terminology could result in patents claiming innovations with respect to biological materials in Australia being subject to 'protracted and expensive litigation'.[30] Griffith Hack and Griffith Hack Lawyers suggested that if the Bill were implemented 'there will be many millions of dollars wasted on patent attorney and lawyers' fees debating the interpretation of the exclusion, money that would be better spent on research and commercialisation'.[31]

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25 *Submission 103*, p. 2.

26 *Submission 103*, p. 3.

27 *Committee Hansard*, 29 April 2011, p. 17.

28 *Submission 97*, p. 5.

29 *Submission 49*, p. 9 [underline in original].

30 *Submission 39*, p. 13.

31 *Submission 47*, p. 4.

Possible amendments to clarify meaning

4.22 Possible amendments to the exclusion for biological materials were also suggested (and subsequently supported by Dr Luigi Palombi).[32] For example, the Cancer Council Australia and the Clinical Oncological Society of Australia (CCA/COSA) proposed that the exclusion on patentability in the Bill (Item 3) should be replaced with:

> (b) biological materials whether isolated or purified or not and however made which are identical to such materials as they exist in nature.[33]

4.23 CCA/COSA considered that this would clarify the distinction between invention and discovery. The amendment would replace several terms considered problematic in other submissions, including 'substantially', 'components' and 'derivatives'.

4.24 Further, CCA/COSA recommended that the provision of the Bill which defines 'biological materials' (Item 4) should also be replaced to read:

> (5) In this section:
>
> **biological materials**, in section 18, includes DNA, RNA, proteins, cells and fluids including their components
>
> **identical**, in section 18, means a biological material which is structurally and functionally identical and where any structural change or difference is immaterial to its function.

4.25 CCA/COSA considered that these suggested amendments to the Bill would add clarity, would ensure biological materials which have been structurally and functionally altered continue to be patentable, and 'should assure competitive researchers and investors that the patentability of biological materials adapted inventively for industrial use remains a commercial incentive'.[34]

4.26 At the public hearing on 28 April 2011, Senator Heffernan tabled a document with the committee which outlined similar proposed amendments to the Bill. Senator Heffernan's proposed amendments differ from the CCA/COSA amendments by proposing a more concise definition of 'identical':

> **identical**, in section 18, means a biological material which is structurally and functionally identical.[35]

4.27 Some witnesses considered that the proposed amendments would address their concerns in relation to the scope of the Bill.[36] However, others did not consider

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32 *Submission 103, Supplementary Submission*, pp 5-6.

33 *Submission 72*, p. 2.

34 *Submission 72*, pp 2-3.

35 Amendment to the Bill tabled by Senator the Hon Bill Heffernan on 28 April 2011.

these amendments to the Bill would address their concerns.[37] For example, Professor Dianne Nicol and Mr Johnathon Liddicoat asserted that the amendment would not resolve the questions they raised regarding the Bill's lack of clarity, broad scope and potential for unintended consequences.[38]

Support for the Bill's approach

4.28 However, Professor Peter Drahos did not consider the language of the Bill to be too broad. In relation to the term 'biological materials', he noted that other jurisdictions had also used general language in this area and '[t]o refer to some subset of biological materials...sets up a dangerous inference that other naturally occurring materials that have been isolated are patentable'. In relation to the term 'substantially identical', he noted that this concept is used in other areas of intellectual property law and the concept is important to prevent applicants introducing minor variations to defeat the purpose of the Bill.[39] In a similar vein, Ms Anna George considered the approach taken in the Bill to be 'simple, clear and unambiguous'.[40]

4.29 In contrast to many of those who expressed apprehensions about the breadth of biological materials covered by the language in the Bill, the National Coalition of Public Pathology was concerned that the inclusion of specific examples in the definition of 'biological materials' would limit the range of biological materials covered. Further, it considered that the list was not complete and may change over time in light of new knowledge and discoveries.[41]

Efficacy of the Bill

4.30 Many submissions and witnesses expressed their concern that the drafting of the provisions of the Bill would not achieve the Bill's intent, as outlined in the EM. The EM states:

> The purpose of this Bill is to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature.[42]

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36 For example, Dr Martin Cross, Generic Medicines Industry Association, *Committee Hansard*, 28 April 2011, p. 53.

37 For example, Dr Trevor Davies, Institute of Patent and Trade Mark Attorneys, *Committee Hansard*, 28 April 2011, p. 31; Mr Matthew Cossey, Croplife Australia, *Committee Hansard*, 29 April 2011, p. 12.

38 Answer to question on notice, provided 12 May 2011.

39 *Submission 25*, p. 2.

40 *Submission 55*, p. 6.

41 *Submission 33*, p. 2.

42 EM, p. 2.

Method claims

4.31 Some submitters and witnesses noted that the Bill's exclusion on biological materials would not exclude from patentability therapeutic or diagnostic methods, even if these methods involve the use of biological material.[43] Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow commented that both therapeutic and diagnostic methods are patentable under current Australian law. An exclusion from patenting the substance used would not prevent these methods or formulations from being patented.[44] Similarly, the Law Council of Australia considered the Bill 'misconceived' as 'the Bill would not affect the patentability of the diagnostic method which originally sparked the current debate: the Myriad BRAC1 and BRAC2 tests'.[45]

4.32 Dr Tania Obranovich from the Institute of Patent and Trade Mark Attorneys believed that, as diagnostic methods would remain patentable under the Bill, it 'would do very little to alleviate the very real concerns of the community' and could 'unintentionally create a range of new problems'.[46] Unintended consequences were also predicted by FB Rice & Co, should the Bill cause a shift from product claims to method claims in patent applications. It noted that the 'well known principle of the patent system is that product claims are easier to enforce than method claims'. If product claims for patented inventions are excluded by the Bill, 'patentees may have to spend more time and money to prove that their rights are being infringed'.[47]

4.33 Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee also argued that the Bill was too narrow in this respect:

> While the Bill seeks to exclude biological materials it does not exclude methods of using those materials. Hence, some of the most controversial aspects of patenting in the field of biotechnology are not fully addressed by this Bill, particularly methods of diagnostic testing and non-commercial research methods. The Bill also does not address problems created by broad downstream patent claims. Moreover, experience in Europe suggest[s] that specific exclusions of this nature tend to be worked around by creative drafting.[48]

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43 For example, see Institute of Patent and Trade Mark Attorneys, *Submission 49*, p. 8; CSIRO, *Submission 78*, pp 6-7.

44 *Submission 18*, p. 10.

45 *Submission 48*, p.2.

46 *Committee Hansard*, 28 April 2011, p. 30.

47 *Submission 77*, p. 5.

48 *Submission 39*, p. 3.

Timing of legislative intervention

4.34 During the inquiry, an argument was made that that the Bill may be too late to address the problems it seeks to solve.[49] This argument reflects the conclusion in the ALRC Report in 2004 that 'if there had been a time to recommend that gene patents should not be patentable, that time has long since passed'.[50] For example, La Trobe University suggested that, because of the completion of the Human Genome Sequencing Project in 2003, '[i]t is likely that the effect of the Bill would be to shut the gate after the horse has bolted, since the genes discovered by the project are already either patented or in the public domain and therefore not able to be patented'.[51] Similarly, the Law Council of Australia submitted:

> ...the argument now being mounted in respect of patents claiming genes and gene sequences is many years after the priority date of the particular patent at which point the criteria for patentability were considered. In the area of gene technology, what was patentable 20 years ago is likely not to be patentable today...given the rapid development of the technology area in the meantime...[T]he conclusion of the human genome project has had a significant effect on what is and what is not now patentable.[52]

4.35 The Association of Australian Medical Research Institutes noted that most patents only have a 20-year duration and many of the early gene sequence patents with overly broad claims were issued in the late 1980s and early 1990s. It concluded that many of these patents have now either expired or are nearing expiration; and with each new field of technology, as patent examiners have become more expert in understanding the nature of a new field, the scope of patent claims has over time become more appropriate.[53]

4.36 However, IVD Australia suggested that the Bill could affect existing patents, noting there are no transitional provisions included that would limit its application only to patents applied for after the Bill passes.[54] The Department of Health and Ageing also noted that the Bill does not include transitional provisions and does not provide clarity over the effect on patent applications currently being examined by IP Australia.[55] DIISR and IP Australia commented that effects on existing patents

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49 See, for example, ALRC, *Submission 30*, p. 2; Professor Dianne Nicol, Mr Johnathan Liddicoat, Dr Jane Neilsen and Mr Ben Mee, *Submission 39*, p. 41; AusBiotech, *Submission 97*, p. 2.

50 ALRC, *Genes and Ingenuity*, Report 99, June 2004, p. 13.

51 *Submission 41*, p. 3.

52 *Submission 48*, p. 3.

53 *Submission 63*, p. 3.

54 *Submission 57*, pp 7-9; see also CSIRO, *Submission 78*, p. 2.

55 *Submission 68*, p. 2.

could raise constitutional issues regarding the compensation of acquisition of property by the Commonwealth.[56]

Support for passage of the Bill

4.37 Others supported the passage of the Bill. The Australian Reproductive Health Alliance argued that the Bill would clarify and reinforce the existing provisions of the Patents Act 'to give the clear message that "scientific discoveries" should not be the subject of patents'.[57] Similarly, Ms Stephanie Gleeson argued:

> As biotechnology has potentially many economic, social, environmental and health consequences, the best course of action would be for the Parliament to pass this current amendment as a safeguard against ad hoc developments by the courts. Passing this amendment will provide clarity for the law and encourage cooperation between researchers to reward scientific endeavour whilst ensuring public access to publically owned biological materials.[58]

4.38 Dr Luigi Palombi acknowledged that the Bill is only one of several measures which need to be taken in order to improve patient access to genetic tests. However, '[w]hile other policy and legislative changes are required this Bill is an integral part of the solution'.[59] He described the Bill as follows:

> It is a nuanced, controlled and expertly crafted response to a specific problem in Australia's patent system. It is like a surgeon's scalpel removing a festering boil. That it prevents the patenting of biological materials which exist in nature is an achievement in itself. It puts to an end, once and for all, any suggestion that the mere isolation of a biological material from its natural environment transforms that material from a product of nature into a product of invention. But it does more. It also prevents the patenting of modified biological materials when those modifications are so minor, insignificant or immaterial that they cannot be said to transform the biological material into being an 'invention'.[60]

Scope of the Bill

4.39 The Second Reading Speech characterises the Bill as 'very narrow' and only seeking 'to clarify and apply existing patent law'.[61] Dr Luigi Palombi considered a narrow scope of exclusion was contemplated by the Bill. He noted the following matters would fall outside of the proposed prohibition:

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56 *Submission 94*, p. 23.

57 *Submission 27*, p. 1.

58 *Submission 37*, p. 5.

59 *Submission 103*, p. 6.

60 *Submission 103*, p. 8.

61 *Senate Hansard*, 24 November 2010, p. 2100.

> (a) products, process or methods that make use of, or include as a component or components, naturally occurring biological materials, even if identical or substantially identical to any that exist in nature, in such things as diagnostics, pharmaceuticals, therapeutic products or methods, treatments and cures; and
>
> (b) biological materials derived from naturally occurring biological materials provided such derivatives are not (a) identical or (b) substantially identical to any that exist in nature; and
>
> (c) naturally occurring biological materials which have been modified, genetically or otherwise, so that in their modified form the way they function is so changed when compared to their premodification state that they can no longer be considered to be identical or substantially identical to any that exist in nature.[62]

Concerns regarding the Bill's scope

4.40 However, a large number of submitters and witnesses raised concerns regarding the broad range of areas which could be affected by the exclusion on patentability of 'biological materials' in the Bill.[63] AusBiotech found the scope of the Bill 'broad and seemingly without limits'. It believed the Bill would encompass:

> [G]enes, DNA, RNA, cDNAs, oligonucleotide primers, proteins, peptides and amino acids, lipids, carbohydrates, vaccines, bacteria, viruses, antibiotics, enzymes, hormones, immunoglobulins and other blood products, stem cells, anti-toxins, antivenoms, skin and other tissues, allergenics, probiotics, antibodies, epitopes, monoclonal Abs, recombinant therapeutics and other personalised medicines.[64]

4.41 If the Bill were to pass, AusBiotech foreshadowed profound negative impacts across diverse sectors of the Australian economy and community, including those focused on: agriculture; animal production; diagnostics; vaccines; and biopharmaceuticals to treat major diseases such as arthritis, cancer and multiple sclerosis.[65]

4.42 Several submissions which opposed the Bill noted that the origin of the public debate was in relation to patents on human gene sequences. They argued that the broad exclusion in the Bill for 'biological materials' was therefore unjustified. For example, Professor Ian Frazer commented that the 'Bill is intended to prevent the

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62 *Submission 103*, p. 2.

63 For example, see CSIRO, *Submission 78*, p. 6; Australian Academy of Science, *Submission 100*, p. 2; Biotechnology Industry Organisation, *Submission 86*, p. 4; Prima BioMed, *Submission 73*, pp 2-3.

64 *Submission 97*, p. 5.

65 *Submission 97*, p. 5.

patenting of human genes and biological materials...[T]his intent is much broader than would be necessary to obviate my concerns with the Myriad genetics patents'.[66]

4.43 FB Rice & Co argued:

> There are many Australian companies whose existence relies upon the patenting of biological materials such as antibodies and stem cells. In our opinion, these companies can rightly feel aggrieved by their technology seemingly being encompassed by the Bill because until now the public debate has essentially been limited to human genes and genetic testing.[67]

4.44 Others emphasised the importance of the patents over biological material which may be affected by the amendments proposed in the Bill. DIISR and IP Australia stated that '[p]atents over biological material are fundamental to innovation and investment in the development of new and beneficial medical, industrial, environmental technologies and food'.[68]

4.45 Eli Lilly Australia used the example of therapeutic antibodies to illustrate the potential impact of the Bill, noting that such antibodies are being developed as treatments for a wide range of diseases, including various infectious diseases, cancers, autoimmune diseases, Alzheimer's disease, diabetes, cardiovascular disease and various musculoskeletal diseases:

> [M]any of these antibodies are fully human in structure, meaning they are derived from human antibody genes...[B]ecause they are derived from human genes, therapeutic human antibodies or the DNA that encodes them could be viewed as substantially identical to materials as they exist in nature'.[69]

4.46 The Walter and Eliza Hall Institute of Medical Research (WEHI) asserted that the Bill 'goes far beyond human gene patents, therapeutics and diagnostics...[I]t relates to all biological material and would impact negatively on many other areas such as the veterinary, agriculture, aquaculture, biofuel, brewing and biomaterials sectors'. Without evidence-based analysis, WEHI suggested that the risks of unintended negative economic and social consequences could be considerable.[70] The Peter MacCallum Cancer Centre held a similar position:

> The amendments, if accepted, may have profound implications not only in the field of medicine (antibiotics, antibodies, synthetic hormones), but also veterinary science, agriculture, industry and the rapidly expanding field of green and renewable energy...There has been insufficient discussion or

66 *Submission 92*, p. 1.

67 *Submission 77*, p .2.

68 *Submission 94*, p. 4.

69 *Submission 52*, p. 2.

70 *Submission 59*, pp 16 & 20.

> evidence available to make any changes to patent law that are so profound in their potential impact at this stage.[71]

4.47 Evidence to the committee highlighted that, because the previous public discussion had focused on patents on human gene sequences, the impact on the biotechnology sector of an exclusion on patenting biological materials has not been adequately considered. For example, Professor Natalie Stoianoff, Dr Ann Kurts and Dr Mark Lutherborrow noted that the previous Senate inquiry had been directed to the impact of gene patenting on human health and '[t]o date there has been no [i]nquiry or any other basis for asserting that biological materials in general should be excluded from patent protection'.[72]

4.48 CropLife Australia argued that there were potential impacts for the agriculture sector in Australia which had not been considered, and had not been dealt with during the previous inquires into gene patents. In particular, it noted the lengthy regulatory hurdles for new genetically modified (GM) crops, the need for patent protection to prevent 'free-riders', and the importance of GM crops for Australian farmers to remain viable in an international marketplace:

> This Bill would effectively stop the commercialisation of future GM crops in Australia because companies would refuse to risk their intellectual property by releasing it here. This would undermine hundreds of millions of dollars in private and public investment in this research and would have major implications for how Australian science is viewed globally. In addition to these effects, the competitiveness of Australian agriculture would be greatly reduced.[73]

4.49 Additionally, CropLife Australia highlighted the importance of agricultural chemicals, such as pesticides, and outlined a number of pesticides isolated from naturally occurring compounds:

> Overall, the proposed Bill would lead to a reduction in newer softer chemicals being used in agriculture and an increased reliance on older, more synthetic chemicals, many of which are currently subject to regulatory review.[74]

4.50 Agrifood Awareness Australia agreed that, while the initial focus of the Bill was on medical applications, the Bill would 'impact all areas of biotechnology research and development, including Australian agriculture'. This would 'have negative consequences for the agriculture sector, leading to a decline in the global

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71 *Submission 24*, p. 4.

72 *Submission 18*, p. 11.

73 *Submission 65*, p. 7.

74 *Submission 65*, p. 9.

competitiveness of our agriculture sectors with flow-on impacts to rural and regional communities'.[75]

4.51 The Institute of Patent and Trade Mark Attorneys (IPTA) was concerned that the Bill 'arguably encompasses virtually all biological materials even where they are structurally different from their native counterparts'. It noted that the 'active agents of many of the pharmaceutical products we take for granted are in fact biological materials isolated from natural sources or their derivatives'.[76] Dr Tanya Obranovich from the IPTA elaborated on this point in evidence:

> The bill proposes to exclude from patentability all biological materials which are identical or substantially identical to materials as they exist in nature. Since the ban extends to all organisms, the bill would adversely impact not only health care but also sectors as diverse as agriculture, animal husbandry and food technology. The breadth of biological materials which the exclusion would encompass is enormous. Therefore, the potential impact of the functioning of all of these sectors would be significantly impacted.[77]

4.52 However, the Cancer Council Australia and the Clinical Oncological Society (CCA/COSA) supported a broader approach:

> ...genes are not the only natural biological materials fundamental to medical research and healthcare services that can be locked up by commercial monopolisation. There is a valid view that excluding only genetic products from patentability would not protect from monopoly other biological materials integral to competitive medical research, such as proteins and peptides.[78]

4.53 While he maintained reservations regarding the provisions of the Bill, Dr Graeme Suthers from the Royal College of Pathologists also noted that there are advantages in phrasing an exclusion in general terms, such as 'biological materials', because 'there are lots of diagnostic chemicals that we want to analyse and that we need to analyse in the delivery of health care...[T]hey are not just genetic ones'.[79] Similarly, Professor Peter Drahos stated:

> [T]he phrase 'biological materials' is used for the purposes of exclusion because what you are trying to do is to ensure that the law excludes those things that are naturally occurring. To confine it to some subset sets up the dangerous inference that other naturally occurring biological materials are patentable.[80]

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75 *Submission 51*, p. 1.

76 *Submission 49*, pp 6-7.

77 *Committee Hansard*, 28 April 2011, pp 29-30.

78 *Submission 72*, p. 6.

79 *Committee Hansard*, 28 April 2011, p. 16.

80 *Committee Hansard*, 28 April 2011, p. 23.

Need for the Bill

4.54 Conflicting evidence was received regarding the need for the Bill.

No necessity for the Bill

4.55 Many of the submitters and witnesses opposed to the passage of the Bill highlighted that its proposed amendments are not supported by the findings of the three most recent public inquiries examining this area: the ALRC Report; the Senate Community Affairs References Committee report; and the ACIP Report.[81] For example, IVD Australia argued that there is 'little evidence to support claims that gene patents restrict research or that Australian scientists lack free access to biological materials because of issues with pre-existing patents'. It noted that the finding in the Senate Community Affairs References Committee report that 'the evidence does not show that gene patents are systematically leading to adverse impacts [in the areas of healthcare and medical research]' is 'at odds with the policy behind the Bill'.[82] Similarly, in the view of DIISR and IP Australia, there was no evidence that access to diagnostic testing or medicines is restricted or that present patentability of biological material is impacting adversely on research activities in Australia.[83]

4.56 Others emphasised their own experiences in relation to patents. The Walter and Eliza Hall Institute of Medical Research (WEHI) asserted that in its experience, 'patents have minimal or no negative impact on research and the effects predicted by proponents of the "anti-commons issue" are not borne out in the available data, and fears of [patents] blocking the use of upstream discoveries are largely unfounded'. Using the example of the BRCA1 patent, WEHI highlighted that the grant of that patent had not impeded subsequent research or patent applications.[84] This point was also emphasised by AusBiotech, which noted that the grant of the BRCA1 patent had not prevented 'over 5,500 BRCA1 primary sequence publications...[w]ith no fewer than 49 Australian research organisations having contributed to this total'.[85]

4.57 This position was endorsed by GlaxoSmithKline:

> There is no coherent body of evidence establishing that patents have had a negative impact on access to healthcare or have impeded research to any significant degree in Australia or elsewhere.[86]

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81 For example, Walter and Eliza Hall Institute for Medical Research, *Submission 59*, p. 3; Pfizer Australia, *Submission 60*, p. 2; CropLife Australia, *Submission 65*, p. 4.

82 *Submission 57*, p. 8.

83 *Submission 94*, p. 5.

84 *Submission 59*, pp 9-13.

85 *Submission 97*, p. 6.

86 *Submission 69*, p. 2.

Necessity for the Bill

4.58 However, other evidence to the committee emphasised the problems with the current patent system which the Bill aims to solve or alleviate. In particular, the Generic Medicines Industry Association (GMIA) had the view that innovation, research, and market competition have been unnecessarily stymied in the Australian pharmaceutical and biopharmaceutical industries because of the increasing reach of patent rights:

> Patent monopolies regarding critical pharmaceuticals and biopharmaceuticals which have been invalidated elsewhere have either remained unchallenged in Australia (due to the relatively small size of the Australian market) or have been held to be valid in Australia (due to significant differences in Australian law). Australian industry and the Australian public have been disadvantaged and will continue to be disadvantaged if these issues are not rectified.[87]

4.59 GMIA argued that case law in Australia has drifted away from global trends in relation to standards of patentability, resulting in patents being easier to obtain and harder to revoke than in the rest of the world. It claimed the threshold for 'inventive step' is easier to meet in Australia and patent examinations are less robust:

> Patents that were not granted or have been invalidated in other jurisdictions continue to deliver royalties and profits to the owners and licensees of equivalent patents in Australia, resulting in higher prices to the Australian public.[88]

4.60 GMIA perceived that policy positions are changing in Europe and the United States in relation to patenting biological materials. For these reasons, GMIA supported legislative intervention in Australia:

> GMIA acknowledges that Australia will be "ahead of the curve" if the Gene Patenting Bill is implemented without amendment, but supports Australia aligning its position with global trends, and taking the global lead in this important area.[89]

4.61 GMIA also highlighted the difficulties in challenging inappropriate patents and obtaining access to some patented substances:

> When we go to challenge a patent, we normally expect—especially when we go through the appeals—that we are going to be delayed anywhere between 2½ to three years to get through all the appeals and the legal system, and it will normally cost somewhere in the region of $2 million to

87 *Submission 71*, p. 1.

88 Answer to question on notice, provided 12 May 2011, p. 3.

89 *Submission 71*, pp 3-6.

> $3 million. That is what you are up against when you have to challenge a patent even if the patent is non-valid.[90]

4.62 Mylan, a large generic pharmaceutical company, echoed several of GMIA's concerns:

> The patenting of naturally occurring biological materials is stifling medical and scientific research as well as the diagnosis, treatment and cure of human illness and disease. Such patenting prevents doctors, clinicians and medical and scientific researchers from gaining free and unfettered access to these materials...[T]hese monopolies go well beyond the traditional scope of patent protection and are unfairly hampering free competition in the development of biogeneric medicines.[91]

4.63 The increasing importance of genetic testing and biological materials was also highlighted by those supporting legislative change. For example, Dr Graeme Suthers from the Royal College of Pathologists noted that greater understanding of human genetics is leading to 'more and more genetic testing' and the type of therapeutics being developed are shifting 'more and more [to] biological [treatments] rather than straight chemicals'.[92] However, others considered the increasing importance of genetic and biological materials in healthcare was an argument against the excluding these materials from the patent system. Dr Anna Lavelle from AusBiotech stated:

> In the modern world, the new age of medicines will be based on biologics and that is what makes this bill so potentially dangerous in terms of thwarting new medicines, therapies and technologies that are coming through, and that is based on the last 30-odd years of genetic and biological research.[93]

4.64 The Cancer Council Australia and the Clinical Oncological Society of Australia (CCA/COSA) had the view that problems with the gene patent legal framework are 'well-documented'. They noted that attempts to monopolise genetic tests for breast and ovarian cancer risk through the enforcement of a patent licence have been withdrawn, following a sustained public outcry. However, 'there was nothing in the law that could have protected Australian women's access to testing in public laboratories'.[94]

4.65 Professor Peter Drahos argued that the significant pressures on national patent offices, including in Australia, are negatively affecting the quality of patent examination being undertaken. He suggested that creating 'exemption[s] in certain

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90 Dr Martin Cross, Generic Medicines Industry Association, *Committee Hansard*, 28 April 2011, p. 51.

91 *Submission 70*, p. 3.

92 *Committee Hansard*, 28 April 2011, p. 16.

93 *Committee Hansard*, 29 April 2011, p. 5.

94 *Submission 72*, p. 6.

areas' is one of a series of 'regulatory adjustments' which could be taken to address this issue.[95]

Discovery and invention

4.66 A number of submitters and witnesses focused on the distinction between discovery and invention in the granting of patents over biological materials. This evidence highlighted both the complexity of the subject and the variety of views held regarding it.

4.67 The EM states that the Bill 'reinforces the applicability of the distinction between discovery and invention' in the Patents Act. Further:

> It has long been accepted that natural phenomena are not patentable inventions. This is because the elucidation of a natural phenomenon such as the discovery of a naturally occurring thing, while adding to the storehouse of human knowledge, does not transform it into a product of humankind...This distinction between invention and discovery has thus been an accepted part of English patent law for hundreds of years and was received law by the Australian colonies. After Federation the Australian parliament maintained that distinction in the Patents Act, 1903. Likewise, successive Australian parliaments followed suit in the Patents Act, 1952 and the Patents Act, 1990.[96]

4.68 However, Dr Chris Dent provided the committee with his research, which focuses on the complex historical underpinnings of the Statute of Monopolies. He argued that there 'is no evidence that there was a clear distinction between invention and discovery in the early 17th century' and it is therefore not correct for the EM to claim that such a distinction 'is in keeping with the original intent of the English Parliament'. He concluded that 'to import the whole of s.6 of the Statute of Monopolies would only make the issue of interpretation more challenging'.[97]

4.69 Submitters and witnesses in support of the Bill emphasised the distinction between discoveries and inventions. For example, Mylan stated:

> Biological materials that are identical or substantially identical to any that exist in nature should not be patentable because they are a product of nature and have not been transformed into a product of humankind, historically regarded as a prerequisite for patentability. Simply put, they are not 'inventions'. Just as a cotton ball removed from a cotton plant is not an invention, neither is a human gene mutation linked to, say, breast or ovarian cancer.[98]

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95 *Committee Hansard*, 28 April 2011, pp 25-26.

96 EM, p. 1.

97 *Submission 40*, p. 8.

98 *Submission 70*, p. 3.

4.70 However, the Group of Eight universities considered the Bill to be 'unnecessary' as, in their view, the distinction is clear in the current wording of the Patents Act:

> While the requirement to be a manner of manufacture...can be open to a wide interpretation, the requirement for an inventive step should be sufficient to ensure that discoveries cannot be the subject of granted patents.[99]

4.71 Professor Andrew Christie argued that the Bill uses the wrong criterion for drawing the distinction between discovery and invention:

> The distinction between a non-patentable discovery and a patentable invention is not determined by whether or not the material is identical or substantially identical to that which exists in nature. Rather, the distinction is determined by whether or not the material is an artificially created state of affairs...The 'artificially created state of affairs' criterion has been recognised as the appropriate test for distinguishing between a discovery and an invention since at least the 1959 decision of the Australian High Court in [the NRDC case]. In adopting this form of words, the High Court sought to make it clear that the key determinant of whether subject matter is an invention is the extent to which the alleged inventor has 'created' (as distinct from 'discovered') the material.[100]

4.72 Similarly, Dr Tania Obranovich from the Institute of Patent and Trade Mark Attorneys noted that 'across the entire developed world isolated biological materials are regarded as patentable, on the basis that they represent an artificially created state of affairs'. However, she pointed out that the fact that isolated biological materials can form patentable subject matter does not mean they will be patented, as new inventions must also meet the other requirements of patentability.[101]

4.73 Conversely, Dr Luigi Palombi argued that the intent of the Bill is supported by judicial decisions going back more than 150 years:

> [P]atent law and the judicial interpretation of patent law in the United States, the United Kingdom and Australia is that you cannot patent a composition of matter or substance if that substance is a natural phenomenon. It matters not how the substance is made; it matters not what the substance does. If the substance is identical to a natural phenomenon then, regardless of how much time, sweat, blood and money it has taken to make it or develop a process of making it, the substance itself cannot be the subject of a valid patent monopoly.[102]

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99 *Submission 28*, p. 1.

100 *Submission 19*, p. 3.

101 *Committee Hansard*, 28 April 2011, p. 30.

102 *Committee Hansard*, 29 April 2011, p. 14.

4.74 In considering the Raising the Bar Bill, the Royal College of Pathologists of Australasia put its view that the distinction between a discovery and an invention with utility lies at the heart of the test for patentable subject matter, and should not be incorporated into flexible concepts of manner of manufacture. It considered that there should be an explicit, proscriptive, plain language test for patentable subject-matters 'which precludes discoveries from consideration, irrespective of the utility of those discoveries'.[103]

4.75 Others supported the intention of the Bill to provide clarity regarding the distinction between discoveries and inventions for biological materials, but did not support the specific provisions of the Bill itself.[104] For example, while it maintained concerns about the Bill's breadth and effectiveness, the Department of Health and Ageing supported the Bill's intention to clarify the distinction between a discovery and an invention:

> It is the Department's view that isolated gene sequences that are homologous to those that occur naturally are discoveries, and we have concerns about these being considered patentable subject matter eligible for the grant of a patent monopoly. Despite the energy and ingenuity expended to identify the natural function of a particular gene, its mere isolation from the larger human genome and extraneous cellular material does not give rise to an invention where the isolated gene sequence remains identical to the sequence of its native homologue.[105]

4.76 However, Ms Fatima Beattie from IP Australia noted that new inventions can be created 'by deconstructing' existing material:

> [Y]ou can take a large molecule and you can create a new invention out of that large molecule by deconstructing it, by creating a smaller molecule which has a different functionality, a different structure and a different application from that large molecule...Isolated genetic sequences are, in fact, molecules that have been created by deconstructing a larger molecule. An isolated gene sequence is created by breaking covalent bonds from a molecule and finding a practical use for that molecule. That is what makes them eligible for consideration of a patent grant.[106]

4.77 James & Wells Intellectual Property also highlighted the aspect of 'isolation' which was viewed as the key criterion in considering the patentability of biological materials. It argued that 'it is not the ability to isolate the gene that makes it inventive and patentable...it is most often the intensive research which results in the identification of advantages and commercial uses of the isolated gene which is inventive'. In that context, it noted that the purpose of the Bill is to give doctors and

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103 Answer to question on notice, provided 3 May 2011.

104 For example, see Department of Health and Ageing, *Submission 68*, p. 2; Tasmanian Government, *Submission 96*, p. 1.

105 *Submission 68*, *Supplementary submission*, pp 1-2.

106 *Committee Hansard*, 29 April 2011, p. 36.

researchers unfettered access to biological materials 'as they exist in nature' but that isolated forms of biological material do not exist in nature.[107] Similarly GlaxoSmithKline stressed that isolated genes on their own, with no known utility, are not sufficient for a patent to be granted under the current system.[108]

4.78 Referring to the NRDC case, Mr Matthew Cossey from Croplife Australia noted that there is a need for 'clear parameters, principles and a guiding framework' capable of allowing patent law to 'evolve as technology evolves'. In this regard, he stated that 'for more than half a century...there have been recognition that it is very hard in statute to define to the point of differentiations on a specific level between innovation and discovery'.[109]

Impact on healthcare

4.79 Concerns which were previously expressed during the Senate Community Affairs References Committee's inquiry regarding the potential impact of gene patents on healthcare, medical research and the training and accreditation of healthcare professionals, were repeated in several submissions to the current inquiry.[110] For example, Clinical Associate Professor Judy Kirk, Director of the Familial Cancer Service at Westmead Hospital, emphasised the importance of genetic testing for the treatment of cancer. She was concerned that patenting could cause limitations on the use of the human DNA sequence which may hamper clinical services and stifle ongoing research in this rapidly changing field:

> [C]ommercial monopolisation of genes and other biological material has the potential to impact negatively on health outcomes in Australia, by reducing access to diagnostic and therapeutic procedures, stifling research and development and reducing the effectiveness of professional training and development.[111]

4.80 While the Royal College of Pathologists did not support the specific amendments proposed in the Bill, it nonetheless argued:

> [Gene patent] [m]onopolies have serious consequences for the training, delivery, quality and reliability for medical testing. They also have the potential to compromise research into better genetic tests...[G]ene patents can and do compromise the equitable delivery of health care. We do not accept that the care of some patients...should be compromised at the whim

107 *Submission 53*, pp 1 & 3.

108 *Submission 69*, p. 5.

109 *Committee Hansard*, 29 April 2011, p. 4.

110 For example, see Human Genetics Society of Australasia, *Submission 5*, pp 1-4; South Australian Government, *Submission 15*, pp 2-4.

111 *Submission 2*, pp 1-2.

> of a patent holder who may legally restrict a doctor's freedom to make a diagnosis.[112]

4.81 Cancer Voices NSW strongly supported the Bill, based on the likelihood that gene patents will increase healthcare costs and discourage medical research. It noted the important role of genes in the treatment of cancer, and submitted that it did not wish to see 'patent monopolies over human genes, badly limiting needed opportunities in diagnosis, prognosis and treatment of cancer'.[113] Similarly Dr Jennifer Leary, Laboratory Director at the Familial Cancer Service of Westmead Hospital asserted:

> A goal of any society must be to strive for equitable access to the healthcare benefits that arise from the unhindered access to genetic and biological information as it is discovered. A patent that restricts access to this information potentially prevents this equity. Use of the discovery in an invented procedure, product, process etc might then be rewarded by patent protection. Any changes to the Patent Act must be in keeping with the advancement of healthcare and medical research for the benefit of all Australians.[114]

4.82 Dr Luigi Palombi argued that the Bill would improve patient access to genetic tests by preventing 'the monopolisation for 20 years (a very significant period of time) of the fundamental raw ingredients of these genetic tests'. Further:

> This frees up other scientists and doctors to use these biological materials to make new and inventive medical and scientific products, processes and methods using these materials in laboratories and for clinical use...[T]he Bill enhances access to genetic testing by ensuring that genetic information is not controlled by any one individual, company or organisation.[115]

4.83 Alphapharm, part of generic pharmaceutical company Mylan, argued:

> The patenting of biological materials – as found in nature or if modified in ways that produce no material change in function – must not be allowed to continue. The practice threatens to severely inhibit medical and scientific research because the patent monopoly that these kinds of patents provide means that the biological materials are quarantined to the exclusive benefit of the patent holder. Such broad and unjustified patent monopolies reduce innovative competition in the development of new and inventive medicines. More importantly, they will interfere with the right of every Australian citizen to have future access to cost-effective, lifesaving medicines.[116]

4.84 However, the Consumer Health Forum of Australia considered that 'calls to ban the patenting of genes will not improve consumer access to services such as

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112 *Submission 4*, p. 2.

113 *Submission 8*, p. 2.

114 *Submission 61*, p. 2.

115 *Submission 103*, p. 6.

116 *Submission 75*, p. 2.

diagnostic tests', and noted that the Bill would not 'prevent patenting of therapeutic methods and non-biological products such as chemotherapy'.[117]

4.85 Others argued that, without patent protection to encourage investment and innovation, new medicines and diagnostic methods may never be developed or made available in Australia. Thus the Bill could have a detrimental effect on healthcare in Australia.[118] For example, DIISR and IP Australia suggested that, if patent protection is not available in Australia for some products developed overseas, 'it is possible the Australian public could not access many important medicines'.[119]

4.86 Similarly, Medicines Australia listed a large number of medicines and vaccines with active ingredients which could be defined as 'biological materials' (extracted overleaf) and noted that 'some half a million Australians were treated using these medicines and vaccines'. Medicines Australia argued:

> Had a ban on patents on biological materials been in place ten years ago, Australian patients today would likely not have access to many of the medicines and vaccines listed...These medicines and vaccines would have been ineligible for patent protection, and the companies which developed them would, in many cases, not have sought to market them in Australia.
>
> Passage of this Bill, or a variant of it, would lead to enormous uncertainty around the patent status of many current and future life-saving medicines. This would have serious effects on patient access to medicines in Australia.[120]

4.87 Dr Brendan Shaw for Medicines Australia continued:

> Right now, there are over 400 biological medicines in development globally, targeting diseases such as diabetes, cancer, AIDS, arthritis and Alzheimer's. It is uncertain whether these medicines would be eligible for patents in Australia if this bill becomes law. If even part of this global development cycle were threatened as a result of our decisions here, it would be Australian patients who, along with Australian industry, would pay the price. That is, if companies are forced to cease research and development into new products, or even if some of them choose not to bring patented products to Australia for fear of exposing their intellectual property to free riders, Australian patients would have to settle for older, less effective medicines.[121]

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117 *Submission 16*, pp 1-2.

118 For example, see Dr Malcolm Lyons, *Submission 20*, p. 1; Dr Brendan Shaw, Medicines Australia, *Committee Hansard*, 28 April 2011, p. 36.

119 *Submission 94*, p. 23.

120 Medicines Australia, *Submission 89*, pp 5-6.

121 *Committee Hansard*, 28 April 2011, p. 36.

Table 1. Extract from Medicines Australia submission.[122]

Major Indications[12]	Generic Name	Brand Name
rheumatoid arthritis	Anakinra	Kineret®
rheumatoid arthritis	Adalimumab	Humira®
Diabetes mellitus	Insulin aspart	NovoRapid®
multiple sclerosis	Natalizumab	Tysabri®
rheumatoid arthritis	Abatacept	Orencia®
Anticoagulant	Bivalirudin	Angiomax®
fertility treatment	Choriogonadotropin α	Ovidrel®
Anaemia	Darbepoetin alfa	Aranesp®
severe sepsis	Drotrecogin alfa	Xigris®
osteoporosis	Teriparatide	Forteo®
anaemia	Epoetin beta	NeoRecormon®
cardiac ischemia	Eptifibatide	Integrilin®
rheumatoid arthritis	Etanercept	Enbrel®
prostate cancer	Triptorelin embonate	Diphereline®
multiple sclerosis	Glatiramer acetate	Copaxone®
Crohn's Disease	Infliximab	Remicade®
anaemia	Epoetin alfa	Eprex 2000®
colorectal cancer	Cetuximab	Erbitux®
fertility treatment	Follitropin alfa	Gonal-F 75®
macular degeneration	Ranibizumab	Lucentis®
neutropenia	Pegfilgrastim	Neulasta®
hepatitis C	Peginterferon alfa-2b	PEG-Intron®
HIV	Enfuvirtide	Fuzeon®
heart attack	Reteplase	Rapilysin 10 U®
leukaemia	Rituximab	Mabthera®
myocardial infraction	Tenecteplase	Metalyse®
thyroid cancer	Thyrotropin alfa	Thyrogen®
breast cancer	Trastuzumab	Herceptin®

4.88 A similar point was made by Industry and Investment NSW which argued that the inability to patent certain inventions based on biological materials, such as vaccines and biological therapeutics could be 'a disincentive to companies to provide their new products to the Australian market' and ' may have an impact on the cost and availability of new medicines'. The loss of these newly developed products could also lead to 'a reduction of healthcare standards' and 'reduce economic productivity and capacity associated with advances in human health'.[123]

4.89 Pfizer Australia also commented:

> We fear a ban on the patenting of all genetic material and derivatives in Australia would halt commercial development and supply and access to a wide range of innovative medicines and health technologies in Australia...The Bill will reduce research and development in Australia; it will reduce the chances of further medical discoveries particularly in the promising fields of biologics and vaccines; it will reduce Australians' access to new medicines available elsewhere in the world.[124]

122 Medicines Australia, *Submission 89*, p. 5.

123 *Submission 105*, p. 2.

124 *Submission 60*, p. 3.

4.90 While AusBiotech considered that improved patient access to novel tests and therapies was essential, it did not agree that the Bill would have that effect:

> The claimed purpose of the Bill, to deliver free and unfettered access to biological materials, is not sufficient on its own to deliver new medicines and tests to Australians. Arguably the opposite is a more likely outcome with fewer innovative products and technologies reaching the community since the absence of patents for biological materials will be a serious disincentive for foreign and domestic private investors and others interested in commercialising innovation in Australia.[125]

4.91 Roche, the world's largest biotechnology company, stated that, if the Bill were passed, pharmaceutical and biotechnology companies 'would be extremely unlikely to undertake clinical trials in Australia if their medications in development could not be patents here'. Roche noted that, annually, over 18,000 Australians participate in clinical trials which provide them with access to medicines in development.[126]

Impact on investment

4.92 A large number of submissions, mainly from pharmaceutical and biotechnology companies and research institutes, highlighted the potential risks to investment in research and development, and the possible negative impacts on their operations, if the Bill were to be passed.[127] For example, Chemskill described the commercial impact of the Bill on the biotechnology industry as 'devastating':

> The removal of the current patent law will undeniably discourage a vast number of businesses to invest at the research point. This will [translate] into job losses for research scientists and a reduction in the number of graduate placements in the scientific sector which our universities so heavily rely on...[W]e will be absolutely and negatively affected by the passing of this Bill in its current form.[128]

4.93 Many submitters and witnesses noted that the development of new products in these areas involve a high level of investment and a high degree of risk.[129] For example, Sanofi Aventis submitted that '[t]he research and development of new medicines, particularly biologic medicines, is a complex, expensive and protracted endeavour, taking over a decade and costing over $1 billion for each successful new medicine'.[130]

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125 *Submission 97*, pp 6-7.

126 *Submission 42*, p. 8.

127 For example, Chemskill, *Submission 31*, p. 1; Metabolic Pharmaceuticals, *Submission 38*, p. 2; Grasslanz Technology, *Submission 45*, pp 5-6; Hexima, *Submission 58*, p. 1; Pfizer Australia, *Submission 60*, p. 1; Prima BioMed, *Submission 73*, p. 3.

128 *Submission 31*, p. 1.

129 For example, Australian Institute of Innovation, *Submission 34*, p. 1.

130 *Submission 32*, p. 1.

4.94 DIISR and IP Australia highlighted that patenting is particularly important for the biotechnology industry:

> Biotechnology inventions are expensive to produce, with a high risk of failure and a long time to market, but are comparatively inexpensive to reproduce, or reverse engineer. Current estimates of the full cost of bringing a new pharmaceutical (chemical or biological) entity to market are around US$1.2 to $1.3 billion. Given the high cost of conducting research and development (R&D) before commercialisation, it is crucial for businesses, particularly small start-ups, to attract private investment.[131]

4.95 The intellectual property protection of the patent system was seen as critical to mitigating the risks of developing new products and allowing researchers to attract investment. Medicines Australia explained the important role of patent protection in researching new medicines:

> By guaranteeing a clearly defined period of market exclusivity, patents (and other forms of intellectual property rights such as data exclusivity) act to mitigate the extraordinary risk of bringing new medicines to market, making it significantly more likely for private enterprises to continue to invest in research and development.[132]

4.96 Any uncertainty regarding the ability or capacity to secure patents over inventions related to biological materials was perceived as discouraging investment. For example, Mr Johnathon Liddicoat told the committee that Australian medical biotechnology companies have indicated that 'they need strong, unfettered, clear patent protection to raise tens of millions of dollars from investors to take products through rigorous clinical trials'.[133] Professor Dianne Nicol expanded on this point:

> [P]atents are often used as a tool to get venture capital and to negotiate with downstream pharmaceutical companies and partners, and they are all looking for robust intellectual property protection. So if there is any uncertainty about the scope of protection then it could well deter investment, deter downstream partnering opportunities.[134]

4.97 The Bill was also perceived as potentially discouraging foreign investment in Australia. CropLife Australia argued that a ban on biological patents would increase the level of disparity between intellectual property law in Australia and in other jurisdictions, and this would 'further stifle foreign investment in Australian biotechnology and reduce, or significantly delay, technology transfer from overseas'.[135] It noted the ALRC Report into gene patents had commented:

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131 *Submission 94*, p. 5.

132 *Submission 89*, p. 4.

133 *Committee Hansard*, 28 April 2011, p. 57.

134 *Committee Hansard*, 28 April 2011, p. 60.

135 *Submission 65*, p. 16.

> Australia's adoption of a position that diverges from the general international consensus would likely have adverse implications for Australia's participation in the global biotechnology market and might adversely affect the extent to which foreign entities participate in, and provide capital investment for, research and commercialisation of genetic materials and technologies in Australia.[136]

4.98 In contrast, comparisons were also made to approaches taken in other countries to patenting human genes and biological material, and the influence of patents on investment. For example, Dr Luigi Palombi noted recent large investments by international companies, such as Amgen and GlaxoSmithKline, in Brazil despite local restrictions on patenting biological materials.[137] Similarly, Professor Drahos stated:

> Countries which have moved down the path of regulating gene patents – for example, Brazil – have suffered no adverse impact on investment; to the contrary, investment continues to rise in those countries in the biotech sector.[138]

4.99 However, it was also suggested that there could be other reasons for investments into developing countries, such as Brazil, including the pursuit of market growth in countries which previously may not have been perceived as territories with the highest level of patent protection.[139]

Impact on research and development

4.100 As outlined above, the effect of the Bill on investment was identified as a key impact on research and development in Australia. However a number of other research and development issues were also raised, particularly in relation research and development moving offshore, the impact on specific research and development organisations and the effect on publicly funded research.

4.101 There was significant concern expressed that the Bill may cause investment in research, research companies and researchers to move to jurisdictions with clearer or more stable patent protection. In particular a number of submissions took the view that the amendments in the Bill would inhibit research and investment in pharmaceuticals

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136 Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 173.

137 *Committee Hansard*, 29 April 2011, p. 23.

138 *Committee Hansard*, 28 April 2011, p. 22.

139 Dr Julian Clarke, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 6; Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 28 April 2011, p. 39.

and biotechnology in Australia, and could potentially cause it to move offshore.[140] The Institute of Patent and Trade Mark Attorneys commented:

> Australia risks becoming a pariah (and a backwater) within the international biotechnology community of the developed world... Since research is often conveniently centred where development and investment occur, Australia runs the risk that Australian scientists and their research programs will move overseas to where the patenting and commercialisation becomes centred. We also open ourselves to cherry picking of promising Australian research programs by overseas research institutes, companies and investors.[141]

4.102 Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee noted that the exclusion in the Bill would not prevent patenting of these materials in other jurisdictions. This created a risk that 'Australian innovations in biotechnology will be developed offshore'.[142]

4.103 A number of research and development companies and institutes in Australia highlighted the potential adverse consequences of the Bill for them. These organisations emphasised that patents were considered key assets and the passage of the Bill in its current form 'may have serious consequences for their operations'.[143] For example, the Perth Bone & Tissue Bank noted the significant expenditure on developmental research work that it has undertaken, and stated that, if the Bill prevented several of their pending patent applications, it would mean that clinical studies for their research products would not be financially possible.[144]

4.104 The potential impact of the Bill on publicly funded research was also outlined. A joint submission on behalf of six universities in the Sydney Basin emphasised the link between research funding and patents. The submission noted that university research is increasing reliant on external funding through partnerships with corporate and venture capital entities. The cornerstone of the ability of universities to attract commercial partnerships to increase research funding is through providing tangible value through patents and other intellectual property. In their view, universities benefit from the intellectual property system because patents:

- inform and advance research programs through associated [re]searches;
- provide a vital platform for collaboration with industry;

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140 For example, see Group of Eight, *Submission 28*, p. 2; Roche, *Submission 42*, p. 8; Dr Teresa Schafer, Mr Tim Clark and Mr George Raitt (partners in Piper Alderman), *Submission 50*, p. 5.

141 *Submission 49*, pp 10-11.

142 *Submission 39*, p.13.

143 For example, see Amgen Australia, *Submission 12*, p. 1; Garvan Institute of Medical Research, *Submission 64*, p. 1; Baxter Healthcare, *Submission 91*, p. 1.

144 *Submission 13*, p. 1.

- enable secure investment and income streams from technology licensing deals, which provide growth in research and rewards for inventors;
- define rights and ownership over materials and inventions, enabling the attraction of funds and world class staff and students;
- support academic career progression; and
- underpin the translation of research innovation.[145]

4.105 Sydnovate, the Technology Transfer Office of the University of Sydney, considered that a broad interpretation of the Bill could negatively affect the patentability of many inventions generated from researchers in their science and medicine faculties. It estimated 25 per cent of the University of Sydney's 221 active patent families could be adversely affected by the proposed change in legislation.[146]

4.106 Others emphasised the large contribution of public funding to research and development activities in Australia and overseas. For example Dr Graeme Suthers from the Royal College of Pathologists noted that a large amount of the funding for research regarding biological materials 'both national and internationally, is coming from the public purse for the benefit of the public'.[147] In this context, Dr Hazel Moir highlighted the lack of reliable data regarding the impact of patents on research and investment:

> Despite the overwhelming evidence that patent systems, including that in Australia, largely benefit a fairly small number of foreign firms, there are frequent loud voices from patent owners, and others earning income from patent monopolies, arguing that if any changes are made all industrial innovation and scientific research will cease. There is no substantive evidence for this position – only the subjective views of those benefiting financially from the current system.[148]

Access to products

4.107 Many companies highlighted that the Bill could inhibit the development of new products in Australia. For example, AusBiotech emphasised the important role of private sector investment and partnerships to 'translate' or develop new research and products from 'bench to bedside':

> Australia must rely on companies and financiers to take the risks and invest in the commercialisation of novel medicines and diagnostic technologies. This Bill is a tragedy in the making for a 'smart country' like Australia;

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145 University of Western Sydney, University of Sydney, University of New South Wales, Macquarie University, University of Wollongong and Newcastle University, *Submission 54*, p. 2.

146 *Submission 66*, p. 2.

147 *Committee Hansard*, 28 April 2011, p. 19.

148 *Submission 29*, p. 3.

> Australian innovations will be lost as they follow the funding to the US, Europe and Asia. Global pharmaceutical companies may not include Australia in their market launch plans and ultimately Australians will have delayed access to new medicines and tests.[149]

4.108 Similarly, Croplife Australia outlined that it typically took 8-10 years and $80-$100 million to develop a biotech crop trait from the discovery phase to the point where it has received all the regulatory approvals for commercialisation.[150] It emphasised the importance of patent protection (in conjunction with plant breeder rights) to allow developers to recoup the investment made to bring the trait into the marketplace. It stated:

> If the Bill were to ban patents on these gene sequences, then there would be nothing stopping a competitor from cross breeding the GM trait into a different variety and claiming plant breeder rights. This process would take one growing season and would completely undermine the original technology provider's investment. With such a significant "free rider" effect, no company would invest in developing the technology in the first place.[151]

4.109 Grasslanz Technology, an agricultural research and development company, highlighted its considerable investment 'in research and development of endophyte innovations suited to temperate pasture grasses'. It stated that should the Bill pass 'then investments in Australia by Grasslanz Technology in related technologies (endophytes, GMOs, etc) will cease' and new technologies will not be developed and commercialised for Australian industries to use.[152]

4.110 FB Rice & Co referred to research which estimated that the development of a single molecular diagnostic test could cost US$40 million. It commented that if 'genetic diagnostics are not afforded patent protection it is difficult to see who is going to bother developing them'.[153] The Australian Institute of Innovation also argued that restricting the scope of patents is also likely to lead to higher costs for new products:

> If constraints are imposed on the investment opportunity set, a response will occur, either in the form of a withdrawal of investment capital generally or a requirement for higher returns on the remaining opportunity set.[154]

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149 *Submission 97*, p. 7.

150 *Submission 65*, p. 5.

151 *Submission 65*, p. 6.

152 *Submission 45*, pp 5-8.

153 *Submission 77*, p. 6.

154 *Submission 34*, p. 2.

Access to knowledge

4.111 Others highlighted that the patent system encourages researchers and companies undertaking research to publish their results in order to claim patent protection.[155] For example, the Garvan Institute of Medical Research had a positive view of the influence of patents on research:

> At the Garvan, the existence of patents [has] not at all impeded our research activities. In fact, at times, patents are often considered in a similar light to journal publications in providing access to new information and technology that promotes progress in the research community. It often prevents researchers from "reinventing the wheel" and facilitates most effective use of scarce resources.[156]

4.112 If patent protection for new inventions did not exist, new research could remain undisclosed. For example, SciVentures commented that '[i]f the types of subject matter that can be patented is reduced, then logically one way for a company to protect their investment is to keep the scientific advances [they have made] a secret as long as possible'.[157] The Peter MacCallum Cancer Centre agreed that there is a risk that, without the possibility of patent protection, 'biotechnology and pharmaceutical companies may shift to a model of trade secrets, for which there are no time limits and no statutory limitations'.[158]

Ethical issues

4.113 Ethical issues were often raised by those who supported the Bill, and also by those who were sympathetic to the intent of Bill, but did not support its specific provisions. For example, Ms Elizabeth Gleeson considered the granting of patents for human genes and biological materials to be 'ethically reprehensible', and stated that '[h]uman genes belong to each of us as individuals and have not been invented or manufactured by anyone'. While noting its serious concerns with the provisions of the Bill, the National Health and Medical Research Centre submitted that 'widespread community concern regarding the patenting of naturally occurring gene sequences indicates a need for clarity'.[159]

4.114 Ethical objections to the patenting of human genes and biological materials were expressed in a number of ways. In relation to patenting biological materials, Mr Craig Patterson stated that 'an imperialist attitude where discovery means

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155 For example, Prima BioMed, *Submission 73*, p. 1; Dr Anna Lavelle, AusBiotech, *Committee Hansard*, 29 April 2011, p. 4.

156 *Submission 64*, p. 2; see also Sydnovate, *Submission 66*, p. 1.

157 *Submission 23*, p. 3.

158 *Submission 24*, p. 4.

159 *Submission 46*, p. 2.

ownership...is a philosophy now repudiated in our society'.[160] Similarly, Greenpeace Australia Pacific considered that '[l]iving organisms should not be placed on the same level as human technical inventions'.[161] Dr Luigi Palombi argued that the Bill would prevent 'privatisation of genetic sequence information – information which belongs to humanity and is not the product of human ingenuity but is the product of human evolutionary and natural processes'.[162]

4.115 The Breast Cancer Action Group NSW commented:

> As an ethical and philosophical principle, we do not believe that genes as natural parts of the human body should be patentable. We strongly recommend that Australian patent law be amended so that no part of a living thing can be patented.[163]

4.116 However, the Law Council of Australia considered that the ethical issues raised appear to be 'based largely on misconceptions as to the nature of patent protection' and noted that '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'.[164]

4.117 The ACIP inquiry into patentable subject-matter also considered the issue of patents on genetic material. It acknowledged the concerns of people regarding patents over 'undesirable, unethical or offensive inventions'. Consequently, ACIP proposed a general exclusion to preclude the patenting of inventions the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public.[165]

Australia's international obligations and other jurisdictions

4.118 Many submitters held the view that an amendment of the Patents Act to expressly exclude patent protection for biological materials would conflict with Australia's international obligations, particularly the TRIPS Agreement and the AUSFTA. However, others considered that the exclusions in those treaties, or their interpretation, would allow the exclusion for 'biological materials' proposed in the Bill.

4.119 Several submitters and witnesses noted the requirement in Article 27 of the TRIPS Agreement that patent protection should be available 'for any inventions,

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160 *Submission 79*, p. 1.

161 *Submission 122*, p. 1.

162 *Submission 103*, p. 6.

163 *Submission 84*, p. 1.

164 *Submission 48*, p. 4.

165 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 1.

whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. Additionally, they argued that the Bill would be in conflict with the requirement that 'patents shall be available and patent rights enjoyable without discrimination as to…the field of technology'.[166]

4.120 A number of submitters also argued that the exclusion for 'biological materials' in the Bill would not be permitted under the allowed exclusions from patentability in the TRIPS Agreement and the AUSFTA. For example, the International Federation of Intellectual Property Attorneys highlighted that the exclusion for biological materials in the Bill does not fall within the permitted exclusion in the AUSFTA 'to protect *ordre public* or morality' or 'diagnostic, therapeutic, and surgical methods for the treatment of humans and animals'. Therefore, the exclusion in the Bill would be in violation of the AUSFTA.[167]

4.121 Dr Teresa Schafer, Mr Tim Clark and Mr George Raitt (partners in Piper Alderman) argued:

> The introduction of legislation which specifically seeks to restrict the patentability of biotechnological inventions would appear, in the absence of reasons why commercial exploitation is necessary to be prevented to protect *ordre public* or morality, to be contrary to the TRIPS Agreement and AUSFTA, both of which provide that patents should be available "in all fields of technology".[168]

4.122 However, Professor Peter Drahos considered that the Bill would not breach Australia's treaty obligations. He noted that neither the TRIPS Agreement, or the AUSFTA, define 'invention':

> The international framework allows states to exclude subject matter from the meaning of invention. All states take advantage of the open meaning of invention in this framework.[169]

4.123 Professor Drahos also argued that the Bill would not mean Australia was 'out of step with other countries' and listed examples of other jurisdictions which have taken a different approach to the patenting of biological materials.[170] Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee also noted that jurisdictions such as Brazil, Mexico, Argentina and the Andean Community have

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166 *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Article 27 (1); for example see Davies Collison Cave, *Submission 17*, pp 9-10; Dr Ann Kurts, Dr Mark Lutherborrow and Professor Natalie Stoianoff, *Submission 18*, p. 13; International Federation of Intellectual Property Attorneys, *Submission 35*, pp 2-5.

167 *Submission 35*, p. 6.

168 *Submission 50*, p. 2.

169 *Submission 25*, p. 1.

170 *Submission 25*, p. 1.

provisions which prohibit patenting of biological materials, but suggested these exclusions may result from a response to 'the threat of biopiracy'. They suggested that an emerging norm of excluding biological materials from patentability in developing countries 'does not necessarily provide guidance to Australia'.[171] Similarly, the Institute of Patent and Trade Mark Attorneys commented that 'it is not desirable to effectively model the future of the Australian patent system on that of undeveloped or developing countries with entirely different economic and Governmental structures to Australia'.[172]

4.124 Others compared the approach of the Bill to the approaches taken in the United States, Europe, Japan, China and other major trading partners of Australia.[173] DIISR and IP Australia commented that Australia's current position is consistent with most other countries and that presently the United States, China and Japan 'all consider isolated biological material, including gene sequences, to be eligible for patent protection' where the other substantive requirements of patentability are met.[174] Ms Fatima Beattie from IP Australia noted that if the Bill were enacted, Australia would be out of step with patenting activities 'in all the developed and most of the developing countries'.[175]

4.125 Several submitters and witnesses referred to the European Biotechnology Directive which expressly states that biological material which is isolated from its natural environment, or produced by technical processes, may be the subject of a patentable invention even if it previously occurred in nature.[176] Article 5 of that directive clarifies the distinction between invention and discovery in relation to genes and material isolated from humans:

> Article 5
>
> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
>
> 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
>
> 3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

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171 *Submission 39*, p. 40.

172 *Submission 49*, p. 16.

173 For example, Institute of Patent and Trade Mark Attorneys, *Submission 49*, pp 12-14; Professor Peter Drahos, *Committee Hansard*, 28 April 2011, pp 23-24.

174 *Submission 94*, p. 11.

175 *Committee Hansard*, 29 April 2011, p. 34.

176 *Directive on the legal protection of biotechnological inventions*, Directive 98/44/EC, Article 3(2).

4.126 Dr Tania Obranovich from the Institute of Patent and Trade Mark Attorneys argued that, as Europe expressly enshrines the patentability of biological materials, the enactment of the Bill would put Australian patent law 'directly at odds with Europe'.[177]

4.127 Mr Doug Calhoun also commented that the patentability of biological materials, internationally and in Australia, was recognised by the enactment of the Budapest Treaty.[178] The treaty provided for the establishment and maintenance of depositories of cultures of micro-organisations and other biological materials in support of patents. He argued that the consequential amendments to the Patents Act following Australia becoming a signatory to the Budapest Treaty, 'implicitly acknowledged that biological materials are patentable inventions'.[179]

4.128 Those opposed to the Bill often emphasised the importance of maintaining Australian intellectual property rules which are in harmony with international standards and with those of Australia's major trading partners.[180] Bayer CropScience believed that 'the current Bill, by concentrating on "biological materials" almost certainly infringes on Australia's international obligations under TRIPS...and AUSFTA treaties and would reverse decades of work aimed at harmonising Australian and international approaches to patents'.[181] In contrast, the Cancer Council Australia/Clinical Oncological Society of Australia (CCA/COSA) argued that 'Australia is not beholden to any international obligations in relation to domestic gene patent policy; the public interest, particularly public health and access to healthcare, should be the priority'.[182]

Support for the Raising the Bar Bill

4.129 A number of submitters and witnesses recommended that the Bill should be rejected in favour of the Raising the Bar Bill.[183] For example, Medicines Australia

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177 *Committee Hansard*, 28 April 2011, p. 30; see also Ms Fatima Beattie, IP Australia, *Committee Hansard*, 29 April 2011, p. 34.

178 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, (Budapest 1977), http://www.wipo.int/treaties/en/registration/budapest/trtdocs_wo002.html, accessed 18 April 2011. Australia became a treaty country in 1987.

179 *Submission 21*, pp 7-8.

180 For example, Foursight Associates, *Submission 36*, pp 1-2; CSL, *Submission 56*, p. 2; Croplife Australia, *Submission 65*, p. 13; Ms Fatima Beattie, IP Australia, *Committee Hansard*, 29 April 2011, p. 34

181 *Submission 7*, p. 2.

182 *Submission 72*, p. 7.

183 For example, Institute of Patent and Trade Mark Attorneys, *Submission 49*, p. 20; CSL, *Submission 56*, p. 3; AusBiotech, *Submission 97*, p. 8; Industry and Investment NSW, *Submission 105*, p. 3; Dr Julian Clark, Walter and Eliza Hall Institute of Medical Research, *Committee Hansard*, 28 April 2011, p. 13; Mr Johnathon Liddicoat, *Committee Hansard*, 28 April 2011, p. 58.

stated that the government's proposed legislation is 'likely to clarify and strengthen the conditions required to be met in order for a technology to become patented...[T]his will help ensure the distinction between 'discovery' and 'invention' is clear'. According to Medicines Australia, the Raising the Bar Bill would 'in all likelihood raise the threshold for granting a patent without the adverse unintended consequences' anticipated from possible introduction of the Bill before the committee.[184] Amgen Australia also considered that any concerns regarding access to biological materials for research would be addressed by the amendments in the Raising the Bar Bill 'which contains a statutory provision clarifying researchers' freedom to conduct experiments without infringing patents'.[185]

Support for other policies approaches

4.130 Other policy approaches to address the potential adverse impacts of patents on human genes and biological materials were also highlighted. In particular, many submitters and witnesses preferred policy approaches which were 'technology neutral'.[186] These include: better use of the existing provisions of the Patents Act, such as the 'compulsory licensing' and 'crown use' provisions; an express research exception; and other options canvassed in the ALRC Report, the Senate Community Affairs References Committee report and the ACIP Report.[187] For example, Griffith Hack and Griffith Hack Lawyers stated:

> There are alternatives to the proposed Bill, using technology neutral language...[T]hese include the introduction of a provision to exempt patent infringement for experimental use of patented technology and clarification of the Crown Use and compulsory licensing provisions of the Patents Act.[188]

4.131 AusBiotech also argued that the interests and needs of the Australian public can be protected via the safeguard mechanisms that already exist in the law. In relation to the crown use and compulsory licensing provisions of the Patents Act, it commented that while these provisions had never been invoked in relation to healthcare in Australia 'it may be that the spectre of these provisions within the patent system offer a degree of protection to the Australian community from undesirable behaviour in relation to the exercise of patent rights'.[189] However CCA/COSA did not view the Crown use provisions of the Patents Act as an effective mechanism in this

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184 *Submission 89*, p. 8.

185 *Submission 12*, p. 7.

186 For example, CSL, *Submission 56*, p. 3; Dr Tania Obranovich, Institute of Patent and Trade Mark Attorneys, *Committee Hansard*, 28 April 2011, p. 30; Dr Anna Lavelle, AusBiotech, *Committee Hansard*, 29 April 2011, p. 9.

187 For example, Group of Eight, *Submission 28*, p. 2; IVD Australia, *Submission 57*, p. 10; Hexima, *Submission 58*, p. 2; CSIRO, *Submission 78*, p. 2.

188 *Submission 47*, p. 2. See also Prima BioMed, *Submission 73*, p. 1.

189 *Submission 97*, p. 8.

regard, as the 'inability or reluctance of jurisdictions to invoke the provisions underscored their limitations as a feasible legal instrument to protect the public interest from gene patent exploitation'.[190]

4.132 Alternative options to address the potential problems created by patents were also raised in evidence. La Trobe University noted that the 'Pharmaceutical Benefits Scheme provides Australia with a robust and flexible mechanism by which the public may gain affordable access to otherwise expensive patented pharmaceutical and biological medication while maintaining a viable pharmaceutical research and development industry'.[191] This reflects the ALRC Report into gene patents in 2004 which recommended that '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' should be examined.[192]

4.133 AusBiotech supported a tribunal-like model or the appointment of a 'Patents Ombudsman' with whom the public, clinicians, researchers and industry could raise grievances.[193] Professor Peter Drahos noted his proposal for patent transparency registers to assist the tracking of granted patents.[194] DIISR and IP Australia also advised that other approaches, such as patent pools, have been used successfully in industries such as software and consumer electronics:

> 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.[195]

4.134 Dr Graeme Suthers of the Royal College of Pathologists supported a proposal by the United States Secretary's Advisory Committee on Genetics, Health and Society to create 'a statutory exemption from liability for medical tests that have been developed under a patent'.[196]

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190 *Submission 72*, p. 5.

191 *Submission 41*, p. 4.

192 ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99, June 2004, p. 474.

193 *Submission 97*, p. 2. Dr Anna Lavelle, AusBiotech, *Committee Hansard*, 29 April 2011, pp 5-6.

194 *Committee Hansard*, 28 April 2011, p. 25.

195 *Submission 94*, p. 24.

196 *Committee Hansard*, 28 April 2011, p. 14; see also, 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. 94, http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf, accessed 6 June 2011.

4.135 Finally, a number of submissions, such as CCA/COSA, supported both an amendment to the Patents Act to exclude human genes and/or biological materials from patentability (in the case of CCA/COSA with some amendments), along with corresponding implementation of recommendations made in previous public reviews, such as the ALRC Report.[197]

197 Cancer Council Australia and Clinical Oncological Society, *Submission 72*, p. 6; Human Genetics Society of Australasia, *Submission 5*, p. 4.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

Introduction

5.1 The committee notes that the Bill has been introduced in the context of a number of other reviews and other ongoing processes. IP Australia has recently finalised over two years of consultation in relation to the reforms which have been introduced as part of the Raising the Bar Bill. Legal cases related to the patentability of human genes are also currently being undertaken, both in Australia and overseas. Australian Government responses are also anticipated in relation to:

- the report of the ALRC inquiry on gene patenting and human health;
- the report of the Senate Community Affairs Committee inquiry on gene patents; and
- the report of the ACIP inquiry on patentable subject matter.

5.2 These events will be relevant to the broader issues identified in the EM as being affected by the Bill.

Key issues

5.3 In the view of the committee, the key issues to be addressed regarding the provisions of the Bill and the issue of the patenting of human genes and biological materials are:

- the distinction between discoveries and inventions;
- the scope of the Bill's exclusion for biological materials;
- access to treatments, diagnostics and methods for healthcare;
- the freedom to conduct research;
- investment in research and development;
- access to new products and knowledge;
- ethical issues with respect to the patenting of human genes and biological materials;
- the crown use and compulsory licensing provisions of the Patents Act; and
- international considerations.

Discovery and invention

5.4 The Bill before the committee attempts to make amendments to the Patents Act in order to clarify the distinction between invention and discovery in the patents system. However, it is evident from the inquiry that there is not wide

agreement that the amendments proposed facilitate this clarification. In the view of the committee, the amendments proposed in the Bill will, at best, not assist to clarify the distinction between discovery and invention in the patent system and, at worst, make the distinction more obscure.

5.5 The inquiry touched on several of the difficult policy questions regarding the appropriate distinction between discovery and invention in relation to patents over human genes and biological materials. However, these difficult policy questions are not limited to these particular subject matters. Other controversial areas include the grants of patents over computer software and business methods. Further, there are likely to be new fields of technology in the future where the issue of the appropriate distinction between discovery and invention will need to be carefully considered. This indicates to the committee that a technology neutral approach to this issue is preferable to an approach which will focus on one category of inventions only.

5.6 ACIP has recently completed an extensive inquiry into patentable subject matter. ACIP concluded that:

> The current test for patentable subject matter as applied by the courts in Australia is the best one available to us. It has the flexibility to cope with a variety of concepts and to adapt to new technologies.[1]

5.7 ACIP has proposed codifying the 'principles of inherent patentability (as developed by the High Court in the NRDC case and in subsequent Australian court decisions)'. In the view of the committee, this is an approach that is likely to add clarity to the Patents Act. In contrast, the amendments proposed in the Bill to alter the 'manner of manufacture' test in section 18 of the Patents Act are not likely to generate certainty within the patent system.

5.8 The proposed amendments contained in the Raising the Bar Bill also illustrate that other technology neutral changes to requirements in the Patents Act are viable. These amendments would tighten the requirements for the grant of patents in all fields of technology through proposals to raise the standards for inventive step, usefulness and disclosure of inventions. In the view of the committee, these proposals should contribute to improving the quality of inventions which are granted patents.

Scope of the Bill

5.9 While previous inquiries and public discussions have focused on the patenting of human genes, the Bill goes further and proposes a specific exclusion for biological materials which are identical or substantially identical to such materials 'as they exist in nature'. The evidence received during the inquiry indicates that this exclusion is likely to have significant implications for a broad range of sectors and industries in Australia, including healthcare, pharmaceuticals, agriculture, food manufacturing and biotechnology. Extensive inquiries by the ALRC, the Senate Community Affairs

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1 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 42.

Committee and ACIP have not revealed any persuasive evidence that would justify this type of broad exclusion from patentability for all biological materials.

5.10 The broad scope of the Bill, and the imprecise language of its provisions, was perceived by many as being potentially detrimental to Australia's patent system, the research sector and the many industries reliant on a stable patent system. The committee agrees that this ambiguity in the language of the Bill could discourage investment in research and development, and encourage litigation by those seeking to clarify patent rights.

5.11 The use of the term 'substantially identical' highlights many of these issues, particularly in view of the examples provided of current patented products, and those in development, which included inventive elements designed to mimic biological materials 'as they exist in nature'. The uncertain scope of the exclusion proposed for biological materials creates a risk that worthy inventions, which meet all the other requirements of patentability, will be unable to claim patent protection. Some amendments to the Bill were suggested during the inquiry to clarify the scope of the biological materials exclusion. However, in the view of the committee, these suggestions do not resolve the key deficiency of the Bill in seeking to carve out a broad category of subject matter from patentability.

Access to healthcare

5.12 The context for the debate over patents granted in relation to human genes and biological materials is the increasing scientific understanding of these materials and their increasing application to healthcare. As Dr Graeme Suthers from the Royal College of Pathologists noted, the relationship between genetic tests and clinical care 'is in a state of rapid flux at the moment'.[2]

5.13 Like the Senate Community Affairs Committee, the committee received commentary which was concerning in relation to the potential impacts of the patents system on equitable access to healthcare. However, there was no evidence received by the committee that patents on human genes or biological materials are systematically leading to adverse impacts in the provision of healthcare in Australia. Further, as a number of submissions and witnesses highlighted, the enactment of the Bill would not resolve the issue which focused public attention on the patenting of human genes in Australia in the first place: the claims of Genetic Technologies over BRCA1 and BRCA2 genetic testing.

5.14 The evidence the committee received suggests that the key measure proposed by the Bill, the exclusion from patentability of biological materials which exist in nature, would also have significant adverse consequences for healthcare in Australia. This could potentially include:

2 *Committee Hansard*, 28 April 2011, p. 20.

- long delays for Australian patients to access new diagnostic tests, medicines and treatments;
- reduced access for Australian patients to clinical trials; and
- a reduction in investment for medical research and development in Australia.

Freedom to research

5.15 It is clear that legal uncertainty in relation to patents can cause anxiety for researchers and delays for research. In the BRCA example, legal claims by Genetic Technologies caused the research of the Peter MacCallum Cancer Centre to be delayed for a significant period. Currently, there is no provision in the Patents Act which clarifies the rights of researchers to freely conduct experiments. To ensure certainty exists for researchers, there was considerable support expressed during the inquiry for an explicit research exemption in the Patents Act. The amendments proposed in the Raising the Bar Bill clarify that research and experimental activities relating to patented inventions are exempt from infringement. In the view of the committee, a clear research exemption is the preferable approach to provide certainty for researchers. The Bill's proposed exclusion for biological materials would not provide this certainty for researchers.

Investment in research and development

5.16 The evidence the committee received indicates that patents over human genes and biological materials have not hindered research, particularly medical research, in Australia. In contrast, there was clear evidence from submitters and witnesses that these patents have encouraged and contributed to research and development activities. Patents allow researchers to attract investment to pursue the development of new inventions and allow companies to mitigate the risks associated with developing costly new products, such as medicines.

5.17 The committee agrees that the significant amendments proposed in the Bill risk creating uncertainty regarding the stability of Australia's patent system. A broad range of research organisations and companies highlighted their concerns that the ambiguous nature of the Bill's provisions could negatively affect investment in research and development in Australia. Uncertainty regarding the capacity to secure patent protection for new inventions, caused by the enactment of the Bill, is likely to discourage investment in research and development and potentially drive investment funding and research activities overseas.

Access to new products and knowledge

5.18 In the view of the committee there is a clear risk that, without certainty in relation patent protection for biological materials, companies will have less incentive to develop and commercialise new products for the Australian market. This could negatively impact these companies, and their employees and shareholders, but also Australian industries and consumers who would lose access to these new products. Additionally, there is a risk that without clear patent protection for inventions related

to biological materials, there will be less incentive for researchers to publicly disclose recently developed knowledge and inventions in this area. Other researchers would then be unable to utilise and build on this new knowledge in their own endeavours.

Ethical considerations

5.19 In addition to social, economic and policy considerations, there are clearly ethical dimensions to the issue of patenting human genes and biological materials. Particularly in the case of patents over human gene sequences, many in the community feel uncomfortable that the patent system may allow applicants to claim a degree of ownership over material which already exists, in another form, in nature.

5.20 The recent ACIP report on patentable subject matter (ACIP Report) included significant discussion in relation to these ethical concerns. It noted that it was important that the social contract of the patent system should able to take into account both economic and ethical matters when regulating the subject matter eligible to be patented. The report proposed maintaining the current specific exclusions, including for 'human beings, and the biological processes for their generation' as well as amending the Patents Act to insert a general ethical exclusion. This general exclusion would exclude from patentability inventions 'the commercial exploitation of which would be wholly offensive to the ordinary reasonable and fully informed member of the Australian public'.[3]

5.21 The ACIP Report recognised the benefit in having a flexible approach to this issue through creating an arrangement which considers Australian values as they exist at the relevant time. In the view of the committee, the ACIP proposal for a general ethical exclusion has merit and is a preferable approach to prevent the grant of patents which would be perceived as unethical by the community.

International considerations

5.22 In the view of the committee, the enactment of the Bill could breach Australia's international obligations under the TRIPS Agreement and the AUSFTA to allow for the patenting of inventions in 'all fields of technology' without discrimination. While there is explicit scope in these international agreements for other relevant exceptions, such as to protect *ordre public* or morality and for human healthcare, the provisions of the Bill are not framed in these terms.

5.23 Examples of restrictions on the patenting of biological materials in some developing countries were raised during the inquiry. However, in the view of the committee, the factors driving these sorts of exclusions in developing countries do not necessarily translate to an advanced research jurisdiction such as Australia. The international legal position may, or may not, be in the process of evolution, but it is too early to be certain how these issues will be resolved. The committee's view is that, until a clear approach exists in comparable jurisdictions, significant advantages

3 ACIP, *Patentable Subject Matter*, Final Report, December 2010, p. 17.

remain for Australia in maintaining the harmonisation of its intellectual property regime with international standards and those of its major trading partners.

Crown use and compulsory licensing

5.24 The committee does not agree with the characterisation, made during the inquiry, that the Crown Use and compulsory licensing provisions in the Patents Act are not effective because they are rarely, if ever, utilised. The existence of legislative mechanisms can effectively influence patent-holder behaviour. For example, it can be argued that these provisions were an important contributing factor in the decision of Genetic Technologies to abandon its legal claims in relation to BRCA1 and BRCA2 genetic testing. However, the committee was also concerned to hear that there may be some complexity with the operation of the crown use provisions, depending on whether they were exercised in the right of the Commonwealth or in the right of the states.[4] This subject may be an appropriate topic of future inquiry by ACIP.

Conclusion

5.25 During the inquiry, the Bill was described as 'well-intentioned' and the committee agrees with this characterisation. However, the committee does not agree that the Bill represents an effective solution to the problems which may be caused by patents over human genes and biological materials. In particular, the committee is concerned that proposed amendments in the Bill, which are focused on addressing a specific issue, could have a large number of unintended consequences across the entire patent system with indeterminate impacts on a range of industries and sectors.

5.26 Like many of those who gave evidence, the committee prefers the solutions offered in the proposed amendments of the Raising the Bar Bill. However, the committee does not consider that the amendments in the Raising the Bar Bill will resolve all of the issues in the patent system. In the opinion of the committee, serious consideration should also be given to the proposals for legislative enactment of the patentable subject matter test and the general 'ethical' exclusion made in the ACIP report on patentable subject matter. Other reforms may also be necessary in the future, particularly in relation to ensuring equitable access to healthcare. In this context, the committee recognises that the Senate Community Affairs References Committee has indicated it will maintain a 'watching brief' in relation to the impact of gene patents in Australia.[5] Despite the need for further reform to the patent system, the committee agrees that removing an area of patentable subject matter, as proposed by the Bill, is not an appropriate solution to this complex set of issues.

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4 Mr Chris Reid, Department of Health and Ageing, *Committee Hansard*, 29 April 2011, p. 36.

5 Senate Community Affairs References Committee, *Gene Patents*, November 2010, p. 102.

Recommendation 1

5.27 The committee recommends that the Senate should not pass the Bill.

Senator Trish Crossin
Chair

DISSENTING REPORT BY SENATOR THE HON BILL HEFFERNAN, SENATOR RACHEL SIEWERT AND SENATOR NICK XENOPHON

EXECUTIVE SUMMARY

The Australian patent system has been in operation since 1903.

In 1990 the current Patents Act came into operation. It was the result of an extensive process of consultation, commenced in 1979 by the then Minister Productivity, the Hon. Ian Macphee. In 1984 the Industrial Property Advisory Council handed its report to the then Minister for Science and Technology, the Hon. Barry Jones MP. The IPAC Report was then reviewed and examined by stakeholders. In 1989 the Patents Bill was introduced into Parliament.

However, during the ten years of consultation no economic study assessed whether and how the Australian patent system maximises the social benefits and minimises the social costs to Australians; yet this is the principal objective.

With Australia joining the World Trade Organization in 1995, amendments were made to comply with the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). Again after the signing of the Australia and United States Free Trade Agreement (AUSFTA), the Act was further amended. And yet again, no economic study was conducted into how these changes to Australia's patent system would impact on Australians.

Amid claims that Australia's patent system is important to fostering Australian innovation, the available anecdotal and statistical evidence seriously undermines these claims. Not only does Australia grant around 90% of patents to foreigners, but the percentage of resident-inventors of granted patents places Australia between Brazil and Israel. More recently IP Australia has admitted that Australia's patentability standards are too low compared with its major trading partners. So they were in 1990 when Mr Jones promised the Australian Parliament that the new Patents Act would make Australia a more innovative country. But the evidence shows that since 1990 Australian innovation, at least as measured by the number of granted patents, has not improved. According to IP Australia the consequences of an imbalance in the system is a reduction in "access to follow-on innovation for Australian innovators and the advantages that flow to Australian consumers from access to information about new technology and competition in the Australia marketplace."

And the grant of patents over biological materials which are identical or substantially identical to those existing in nature only contributes further to the imbalance and makes the consequences which IP Australia refers to only more severe. The grant of a

patent according to TRIPS must be for an invention, yet many thousands of patents have been granted, mainly to foreigners, over things that no one invented. Human genes carrying identical genetic information to that contained in the human genome have been patented on the pretext of being isolated from the human body. Human proteins have likewise been patented. The result has been to impose burdens and restraints on those that are striving to find new diagnostics, medicines, treatments and cures for human illness and disease. Rather than contributing to Australia's capacity to innovate these patents have retarded that capacity.

This Bill provides the Australian Parliament with a unique opportunity to address a very serious issue by recalibrating Australia's patent system in one specific respect. And while the Bill does not address all of the issues that must be addressed if the Australian patent system is to continue to be relevant in the 21st century, the passage of this Bill will make a significant contribution to the betterment of the Australian people by ensuring through legislation that things which no one invented cannot be monopolised and commoditised.

As the U.S. Supreme Court has said time and again, natural phenomena are not patentable subject matter, not because their discovery is obvious or does not involve risk and ingenuity but because they "manifestations of … nature, free to all men and reserved exclusively to none".

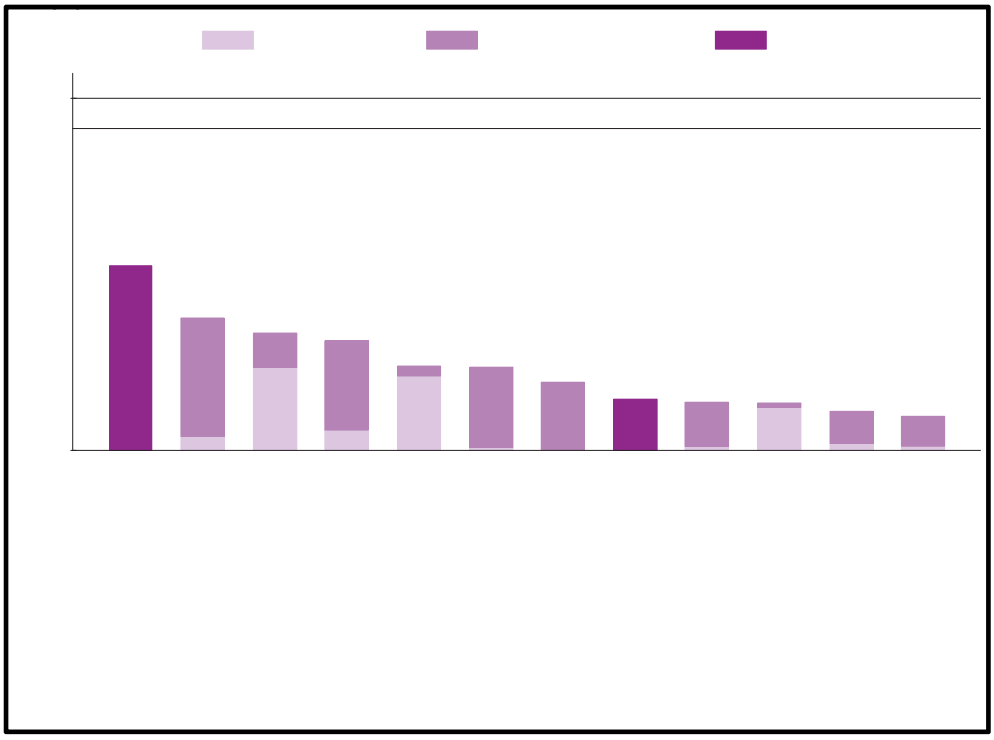
That IP Australia has, through an errant policy, permitted the patenting of natural phenomena in violation of this basic principle of patent law requires legislative intervention. This Bill sets out that legislative intervention.

INTRODUCTION

1.1 On 29 August 1984 the Industrial Property Advisory Committee (IPAC), the predecessor to the Advisory Committee on Intellectual Property (ACIP), provided its report to the then Minister for Science and Technology, the Hon. Barry Jones MP. The IPAC report was the end result of a five year review of Australia's patent system and the operating legislation, the *Patents Act, 1952*. The report was not unanimous. The dissenter, Prof. Donald Lamberton, an economist from the University of Queensland, wrote:

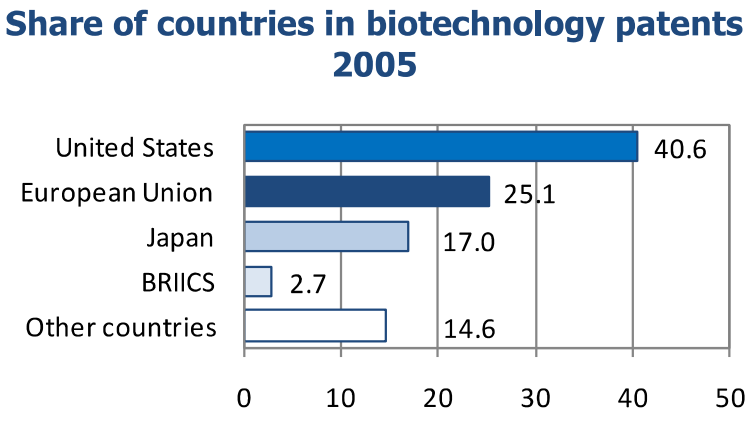
> This Report does not live up to its claim to have adopted an economic perspective and to have applied economic criteria. It has not consistently applied economic criteria; it has not made full use of available empirical evidence; and the concept of social cost, so frequently mentioned, has never really been fully grasped. The underlying idea of the process of innovation is little more than faith that more patent protection will ensure more innovation. The sensible objective is rightly declared to be "to modify the Australian patent laws, adjusting the length, strength and breadth of patent rights" to maximize the net benefit. It is unfortunate that the Report soon strays from this path.
>
> No amount of talk about individual patent successes nor about a future in which the Australian economy has magically become progressive, innovation-oriented, and competitive on the world scene, can hide the facts that Australia exports little in the way of manufactured goods and has few inventions for sale. Mast patents are granted to overseas firms. To make the most of this situation, Australia needs to reduce social costs to the extent possible without inhibiting innovation and without provoking international retaliation. As a small nation, there is scope for such action. The constraints of the Convention are largely myth.

1.2 Other than the fact that today Australia manufactures less than it did in 1984, we understand on the basis of the evidence provided to this Committee that Prof Lamberton's comments are as relevant today as they were then. According to IP Australia's own statistics Australian innovation, as measured by the number of Australian patents applied by and granted to Australian residents, has not improved in 30 years. Patent statistics provided by the World Intellectual Property Office (WIPO) are corroborative. The percentage of Australian patents granted to non-Australian residents in 2008 was 89.3%. By way of contrast the same figure for Japan was 15.6%; Germany, 21.1%; Korean Republic, 25.5%; China, 32.9%, Russian Federation, 33.8% and the U.S., 49.2%. WIPO also confirms that today the only two countries that come anywhere near the U.S., the E.U. and Japan, the three dominant patent filing countries or regions in 1985, are China and the Korean Republic. What these statistics demonstrate is that if the number of foreign owned Australian patents are removed from the total number of patents granted by IP Australia, this country lags between Brazil and Israel. Only Thailand, Singapore, Mexico and Hong Kong have even lower resident-inventors.



Source: WIPO, World Intellectual Property Indicators, 2010.

1.3 To put Australia's biotechnology industry into a global perspective it needs to be understood that the three dominant countries are the United States with 40.6% (of all biotech patents); E.U., 25.1% and Japan, 17%. These three countries alone produced 82.6% of all biotechnology patents in 2005. The remaining 17.4% is produced by 150 countries (WTO membership is 153 countries) and of that figure, 2.7% is attributable to Brazil, India and China. Australia is, therefore, a most insignificant player in this market.



Source: OECD Compendium of Patent Statistics, 2008

1.4 According to the Productivity Commission's 2007 report, *Public Support for Science and Innovation*, venture capital plays an important role in providing funding

to expansion phase businesses but not to start-up and early stage businesses in Australia. The Productivity Commission's Report stated:

> Venture capital brings with it not only access to finance but management expertise and contacts as well. Firms can also benefit from being able to tap into the established network of relationships that venture capitalists have built up over time. In these ways, venture capitalists may significantly improve the probability that start-up and early stage firms succeed in commercialising their IP.

However, the enormous size of the venture capital markets in the U.S., the E.U. and Japan, when compared to that of Australia, even if Australia's venture capital market is expanding, helps only partially to explain why Australia lags significantly behind these countries in the biotechnology sector. The Productivity Commission was advised in submissions of other factors impeding funding of start-ups and early stage businesses, such as:

(a) "Australian private equity market tend to be skewed towards later stage development" as opposed to start-ups (which disadvantages "commercial opportunities in academia" because venture capital consortia "necessarily take a very short term approach to liquidity and therefore identify only late stage projects") and early stage firms;

(b) "… limited access to venture capital seriously constrains the ability of start-ups and early firms to commercialise knowledge and technology;

(c) "seeking to license their knowledge and technology relatively early (which can mean that the value of the IP is heavily discounted)"; and

(d) "adopting a cautious approach to patenting because of the difficulty of covering the cost of protecting their IP."

1.5 The Productivity Commission summed up as follows:

> A well functioning and self-sustaining venture capital market potentially provides a relatively efficient mechanism for identifying, screening and funding the most promising early stage commercialisation ventures. However, the general consensus appears to be that Australia still has some way to go in achieving this goal. The most significant impediments to the development of the venture capital sector in Australia are considered to be the scale of the existing venture capital industry, the relatively small pool of investment managers and the lack of a strong track record in delivering the kind of returns needed to attract major institutional investors to this high risk market.

1.6 The Productivity Commission's report, however, did not adequately explain how Biota, an Australian biopharma company that was spun-out of the C.S.I.R.O.'s development of the anti-flu vaccine (zanamivir) or Relenza as it is better known, failed to maximise the value of the product after licensing it to GlaxoSmithKline in 1990. According to Mr. Peter Cook, Biota's CEO and managing director, "the worry

for small biotech companies is that Big Pharma will acquire a product and then 'park it'." In 2004 Biota sued GlaxoSmithKline in the Victorian Supreme Court seeking $700 million in damages for allegedly not adequately promoting the medicines. The law suit was settled in 2008 for $20 million.

1.7 Despite Prof. Lamberton's dissent, the then Minister relied on the IPAC report in drafting, what was to become, the *Patents Act, 1990*. Nonetheless, in light of Prof. Lamberton's concerns an important question which needs to be answered, in our opinion, is: has Australia's patent system produced a net economic and social benefit to Australia in the past 30 years? On the basis of statements like: "the patent system … promotes innovation through encouraging the diffusion of knowledge" contained in the majority report, it would seem that the majority believe that it has. But we are not convinced. Where is the data to support this statement? Certainly, none was provided to this Committee by those that subscribed to it.

1.8 During the second reading of the *Patents Bill, 1989* on 1 June 1989, the then Minister told the Parliament that it was a "complete redraft of the Patents Act 1952, which it repeals and replaces." He also explained that starting in 1979, when the then Minister for Productivity, the Hon. Ian Macphee announced the IPAC review of the Australian patent system, that Mr. Macphee had been "faced … with criticisms of that complex legal and economic policy instrument which is the Patents Act."

1.9 According to Mr. Jones, one of the major reforms ushered in by the *Patents Bill, 1989* was its "language and structure", which he said was "down to earth, so that mere mortals without law degrees have some chance of understanding what it is all about, at least in general terms."

1.10 Mr. Jones also acknowledged that the IPAC report did not "wholeheartedly embrace the patent system". And while the Australian government eventually made the decision to retain the patent system, Mr. Jones said that it was not be treated as "some kind of mysterious sacrament which has to be observed if we are to proceed along the path to economic heaven", rather, it had to earn its way by "maximis[ing] the social benefits and minimis[ing] the social costs to Australians", the very point made by Prof. Lamberton.

1.11 Next, Mr Jones told the Parliament that the patent system was "out of kilter" with those of its major trading partners.

1.12 Mr. Jones said that "by strengthening Australia's patent law and by incorporating more universal standards within that law", the *Patents Bill, 1989* would place Australia "in a sounder position in relation to the negotiations in both GATT and WIPO". He also said that "an adjustment of the standards of novelty and inventiveness" would require testing patent applications "against disclosures in documentary form anywhere in the world" and this was a desirable outcome in that it would "make it harder to get a … standard patent" in Australia.

1.13 However, a mere 22 years later, in a report entitled, 'Getting the Balance Right', IP Australia has acknowledged that "Australia's patentability standards are set

at a level that is lower than the standards set in countries who are our major trading partners" particularly in regards to the standards "for full description of inventions" and "inventive step". The consequences, according to IP Australia are significant.

> These differences potentially upset the balance between the patent system and competition. They allow the grant of broader patents in Australian than elsewhere, and they allow the grant of patents that may disclose less information about the inventions that they claim than is disclosed elsewhere. This reduces access to follow-on innovation for Australian innovators and the advantages that flow to Australian consumers from access to information about new technology and competition in the Australia marketplace.

1.14 So in much the same way as Mr Jones did in 1989 with the *Patents Bill*, the present Minister for Industry, Innovation, Science and Research, Senator the Hon Kim Carr, has done with the *Raising the Bar Bill, 2011*.

1.15 And while the *Raising the Bar Bill, 2011* has been referred to in the majority report, we question its relevance in the context of this inquiry particularly when the email that accompanied the Bill's release to stakeholders stated that the Bill did "not deal with gene specific issues" but was seeking to "raise [specific] standards across all technologies". The problem is, the word 'technologies' is something of etymological stretch.

1.16 The Oxford Dictionary defines 'technology' to mean "the application of scientific knowledge for practical purposes". But genes and proteins are not technologies. They are natural phenomena. For example claim 1 of Australian Patent 686004 entitled, *In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene* is a claim to genetic mutations that are causative of breast cancer in humans. How is that a 'technology'?

> Claim 1: An isolated nucleic acid coding for a mutant or polymorphic BRCA 1 polypeptide, said nucleic acid containing in comparison to the BRCA 1 polypeptide encoding sequences set forth in SEQ.ID No: 1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

1.17 A closer inspection of the Tables referred to in this claim demonstrate that the source of the "isolated nucleic acid" of claim 1 are people with breast cancer. Table 12, at page 89 of the patent specification, specifically refers to 'patients' and identifies them by way of a number that provides public anonymity while enabling the researchers to know the exact physical source of the genetic "mutations or polymorphisms" linked to breast cancer. That it does so is beyond argument given that another column is headed "Age of Onset". The information contained in the table also specifies the nucleic and amino acid sequences linked to the same "mutations or polymorphisms". Moreover, the claim itself makes no reference to, nor is it qualified by, any practical application to which the biological material may be put. It is a claim,

pure and simple, to the biological material, that is, that part of the human genome linked to breast cancer.

1.18 Our confidence in our view is fortified by the position adopted by the U.S. government, as argued by the U.S. Department of Justice in its amicus curiae brief filed with the U.S. Court of Appeals for the Federal Circuit (CAFC) in October 2010.

1.19 The brief said:

> The mere fact that genes do not occur in "isolated" form in nature does not provide a principled basis for patent-eligibility. See Intervet, 617 F.3d at 1294-95 (Dyk, J., concurring in part). Many natural products — coal beneath the earth, cotton fibers mixed with cotton seeds, the stigmas of the saffron flower — must be physically separated, i.e., "isolated," from their natural environments before becoming useful to mankind, but few would doubt that coal, cotton, and saffron are products of nature and not patent-eligible. Likewise, the unique nucleotide sequence that induces human cells to express the BRCA1 protein is no more an invention of appellants or NIH when captured in a test tube than in its natural context in the human body. The process of applying restriction enzymes to select and extract a naturally occurring segment of DNA in the human genome from its chromosomal environment (now well understood in the art) was undoubtedly patent-eligible when it was first conceived, and an improved process for doing so may be the subject of a patent in the future. But the isolated DNA segment itself remains, in structure and function, what it was in the human body.

1.20 Just as 'coal', 'cotton fibres' and the 'stigmas of saffron flowers' are not *technologies*, nether is a biological material that has been isolated, removed or extracted from the natural world *if it is identical or substantially identical to how it exists in nature*. Furthermore, if the biological material is also new or unknown, its elucidation is an act of discovery, not an act of invention. Therefore, the discovery of a hitherto unknown microbe, plant or animal or any component of each of these things, even if there is a new and practical application to which they can be put to, is not an act of invention in regard to the biological material *per se*. More is required. The U.S. Supreme Court in *Diamond v Chakrabarty* 100 S. Ct. 2204 (1980) established the requisite legal threshold for the purposes of U.S. patent law in 1980. The Supreme Court held that in genetically modifying a naturally occurring bacterium so that it would degrade crude oil, Dr. Chakrabarty had produced a new bacterium with *markedly different characteristics from any found in nature* and which had the potential for significant utility.

1.21 The fact that the process of discovery can also be expensive, risky and time consuming does not justify patenting the end result. Again, support comes from the U.S. Supreme Court. Justices Breyer, Souter and Stevens in *Laboratory Corporation of America Holdings v Metabolite Laboratories Inc* 126 S. Ct. 2921 (2006) held that a principle which "finds its roots in both English and American law" prevents patent protection extending to "laws of nature, natural phenomena and abstract ideas" not because "'laws of nature' are obvious, or that their discovery is easy, or that they are not useful [for] such matters [even though they] may be costly and time consuming;

monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race … [but because] sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts'".

1.22 In other words, while an invention can be the subject of a patent monopoly, a discovery cannot be. The deep seated principle which Justices Breyer, Souter and Stevens refer is so fundamental to the proper and legitimate function of the patent system that undermining it not only threatens the legitimacy of the patent system, but threatens our economic system, which is foremost based on free competition.

1.23 Sixteen years after IPAC's report, the Intellectual Property and Competition Review Committee (IPCRC) examined the impact of intellectual property on Australia's economic system. In its report, presented to both Senator the Hon. Nicholas Minchin, then Minister for Industry, Science and Resources and the Hon. Daryl Williams AM QC MP, then Attorney-General, in September 2000 IPCRC reinforced the importance of maintaining a clear division between discovery and invention. The IPCRC report stated:

> The Committee considers that the goals underpinning the National Competition Policy are well served by a patent policy that rigorously distinguishes between *discoveries* that advance our understanding of the nature, structure and properties of matter, and *inventions* that apply this understanding to useful products and processes. **Within such a policy, only the latter should qualify for patent protection.** (bolding added, italics original)

1.24 While IPRCR's report took into account the approach taken by the High Court of Australia in *The Commissioner of Patents v National Research Development Corporation* (*NRDC*) (1959) 102 CLR 252, it did not rely *solely* on the *NRDC* decision. Importantly, IPCRC went beyond *NRDC* because "other considerations reinforce the need to distinguish between discovery and invention". This contrasts sharply with the more limited analysis applied by ACIP in its Patentable Subject Matter Report. The IPCRC's report explained the serious economic consequences of blurring the line between discovery and invention:

> It is important that patent rights are clearly defined in a way that the difficulty and costs for the public or a competitor to determine the scope of a patent right are kept within reasonable limits. This result would not hold were the patent right extended to discovery. In particular, although 'discovery' is a heterogeneous category, it seems reasonable to suppose that it can be far more difficult to define and enforce the scope of a patent claim relating to, say, a law of nature than to a particular useful application of scientific and technological principles. Moreover, with the passage of time, it becomes ever more difficult to identify the uses in which a particular principle is embodied. ***Property rights in discoveries would therefore be costly to define and implement and could give rise to unreasonable barriers to potential competitors or to those who wished to use the 'discovery' in other fields of endeavour. It may also add very significant burdens on scientific communication***. (emphasis added)

1.25 As regards the ACIP Patentable Subject Matter Report, which itself sprang from one of the recommendation in the Australian Law Reform Commission's Inquiry into the patenting of human genes, ACIP's recommendation to abandon the 'manner of manufacture' test is, in view of both the IPAC and IPCRC reports, concerning.

1.26 Not only did the IPAC report specifically consider the 'manner of manufacture' test, but, having done so recommended its retention in the *Patents Act, 1990* in spite of the fact that one of the key objectives of the legislation was the use of plain, modern and, relatively, simple language. The fact that IPAC was determined, in view of this Ministerial mandate, to retain the reference to s.6 of the *Statute of Monopolies, 1623* suggests that the 'manner of manufacture' test cannot be as easily overlooked as ACIP has done. The IPAC report said this:

> We consider that the existing concept operates quite satisfactorily. It has the advantage of being underpinned by an extensive body of decided case law which facilitates its application in particular circumstances. At the same time it has, in the past, exhibited a capacity to respond to new developments.

1.27 Furthermore, the IPCRC Report took the same approach 16 years later and after taking into account the operation of the *Patents Act, 1990*, over a 10 year period. IPCRC stated:

> The Committee believes that Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the 'manner of manufacture' test. As a result, we recommend that this test be retained.

1.28 Specifically, in the context of gene patenting, the IPCRC looked at the 'manner of manufacture' test and examined how an initiative taken by the U.S. Patent and Trade Mark Office (USPTO) could be applied in Australia to deal with the issues that gene patenting was then raising. The USPTO had proposed the implementation of 'utility' guideline for use by U.S. patent examiners in their assessment of patentability, in an attempt to reinforce the distinction between discovery and invention under U.S. patent law. That guideline has since been implemented in the U.S. The IPCRC report described the effect of this guideline as follows:

> The implementation of these guidelines would preclude the patenting of discoveries for which a specific, substantial and credible use has not been defined [in the claim].

1.29 That said, in ACIP's Patentable Subject Matter Report, none of ACIP's 11 recommendations adopted the IPCRC recommendation. To the contrary, at page 13 of the ACIP report, ACIP recommended that the *Patents Act, 1990* be amended by simply repealing the 'manner of manufacture' test entirely and replacing it with a test based *solely* on the following words:

> "an artificially created state of affairs in the field of economic endeavour".

1.30 What is relevant, in our opinion, is to contrast the approach of the IPCRC with that of ACIP. The IPCRC report made it clear that "a specific, substantial and credible use" of a naturally occurring biological material, such as a gene, was essential to be

part of the definition of the invention as defined in the patent claims. It was not, as ACIP recommend, a matter for the "specific, substantial and credible use" to be described in the patent specification only.

1.31 The problem with ACIP's recommendation is that absent a causal link between a naturally occurring biological material and "a specific, substantial and credible use" in the patent claims, the scope of patentable subject matter is broadened beyond the present 'manner of manufacture' test. Artificiality effectively becomes the only criterion to be satisfied in order to meet ACIP's patentable subject matter threshold since the criterion of 'economic endeavour' can be assumed to apply even to an isolated DNA sequence.

1.32 In other words, should ACIP's recommendation be adopted, literally anything artificial, including a human gene that has been isolated from the human genome, will be patentable subject matter if the patentee can attribute "a specific, substantial and credible use" in the patent specification as opposed to the patent claims. This means it will be possible to claim an isolated biological material as one invention and claim the specific, substantial and credible uses of those materials as other inventions. The net effect of ACIP's recommendation is to legitimise IP Australia's policy.

1.33 We are of the opinion, however, that IPCRC's approach is to be preferred over ACIP's approach. The IPCRC report stated:

> … mere discoveries - that is, the identification and specification of the nature, structure and properties of existing matter and its interaction - should continue to be excluded from the class of patentable subject matter. We consider that this principle should exclude from the scope of patent protection the mere identification of a gene sequence, much as it would preclude the granting of a patent over, say, Mendel's law.

1.34 The point being that regardless of which test is applied, whether it be the current 'manner of manufacture' test or the one proposed by ACIP, the Bill which is the subject of this Inquiry seeks to impose a *per se* prohibition so that, consistent with the IPCRC's position, the Australian patent system "should continue" to exclude from "the *class* of patentable subject matter" any subject matter that comes within the new amended s.18(2)(b) that was tabled by Senator Heffernan during the Committee hearings, namely:

> biological materials whether isolated or purified or not and however made, *which are identical or substantially identical to such materials as they exist in nature*. (emphasis added)

The new amended s.18(5) which accompanied Senator Heffernan's proposal provided new definitions:

> ***biological materials***, in section 18, includes DNA, RNA, proteins, cells and fluids and their components.
>
> ***identical***, in section 18, means a biological material which is structurally and functionally identical.

The reason being that these things are not the product of invention, but the product of discovery.

The new amendment in full is attached to this dissenting report as 'Appendix A'

1.35 Artificiality should not be the sole criterion of patentable subject matter and it is incorrect, in our opinion, for ACIP to assert that the central principle of the *NRDC* decision is accurately reflected in its key recommendation particularly when this passage in *NRDC* is taken into consideration:

> The statement was that fruit and other growing crops, although the assistance of man may be invoked for their planting and cultivation, do not result from a process which is a "manner of manufacture". This may be agreed. However advantageously man may alter the conditions of growth, the fruit is still not produced by his action.

1.36 The High Court in *NRDC* draws a distinction between processes that can be used in the production of naturally occurring things, such as fruit, and the naturally occurring things themselves. According to the High Court, a new process to grow fruit may be patentable subject matter, but the fruit itself is not. This is completely consistent with the Bill.

1.37 *NRDC* is often portrayed as the definitive case on patentable subject matter. However, it is important to appreciate three relevant facts about *NRDC*. First, it was decided in 1959. Next, the invention in that case had nothing to do with a naturally occurring biological material, rather it was about a horticultural process. Finally, legal controversy was whether the *effect* produced by the horticultural process, which involved the use of known herbicides to kill weeds without killing the crops over which the herbicide was sprayed, was itself capable of being patented. And while *NRDC* is an important decision with respect to the 'manner of manufacture' test, it must be applied in context taking into account, what IPRCR described as, "other considerations[which] reinforce the need to distinguish between discovery and invention".

1.38 Thus, the Bill seeks to both clarify the existing patent law and overturn a policy which IP Australia adopted in 1988 and which we believe to be inconsistent with that law.

1.39 IP Australia's policy, first developed by the USPTO in concert with the European Patent Office and the Japanese Patent Office in June 1988, has not been judicially reviewed in Australia. As a result, IP Australia has perused a policy based on an internally generated and untested interpretation of *NRDC*, an interpretation apparently shared by ACIP, which ignores the concerns expressed by IPCRC that *NRDC* was not definitive on its own and that "other considerations reinforce the need to distinguish between discovery and invention".

1.40 Once again, our opinion is backed up by the U.S. Department of Justice which, representing the U.S. government, has criticised the very policy which the USPTO adopted in 1988. The U.S. Department of Justice states:

> Methods of identifying, isolating, and using such DNA molecules may be patented, as may any new and useful alteration of those molecules through human intervention. Genomic DNA itself, however, is a product of nature that is ineligible for patent protection, whether or not claimed in "isolated" form. *We acknowledge that this conclusion is contrary to the longstanding practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA.* The district court's judgment in this case, however, prompted the United States to reevaluate the relationship between such patents and the settled principle under Supreme Court precedent that the patent laws do not extend to products of nature. For the reasons below, the United States has concluded that isolated but otherwise unaltered genomic DNA is not patent-eligible subject matter under 35 U.S.C. § 101. (italics added)

1.41 And while the recent Myriad CAFC decision brought down on 29 July 2011 disagreed with the U.S. government, the 2:1 decision is now under appeal. We also take into account that judicial opinion in the U.S. is evenly divided on the issue once the original decision is taken into account. Consequently, a definitive ruling on the legality of the policy under U.S. patent law is not likely to occur any time soon.

1.42 The question for this Parliament is: should it wait for the controversy to be resolved in the U.S. or Australian courts or should it resolve the issue now by way of legislative amendment to the *Patents Act, 1990*?

1.43 A relevant consideration for the Parliament are the circumstances described in the attached media article whereby Myriad was under no compunction because of its patent rights to manufacture or provide or allow others to provide a genetic test that improved its reliability or accuracy. (see Appendix B)

THE SUBMISSIONS

2.1 The Bill is the subject of much criticism. The criticism, however, has come mainly from sectorial interests associated with the biotechnology, pharmaceutical and agri-biotech industry. Along with Ausbiotech, the peak biotech industry association in Australia, the critics include patent attorneys, patent lawyers, research scientists, patent and legal professional associations, medical and scientific research institutes and their representative professional bodies and Australian universities who are either the holders of patents which contain claims to biological materials that are identical or substantially identical to those that exist in nature or who have acted for, procured, or benefited directly or indirectly from such patents and their procurement.

2.2 The Bill, however, is supported, as written or in principle, by a more representative section of the Australian community that includes Cancer Council Australia, Department of Health and Ageing, the South Australian government, the Human Genetics Society of Australasia, the Australian Medical Association, Meat and Livestock Ltd, Cancer Voices Australia, Cancer Voices New South Wales, the Royal College of Physicians, The Royal College of Pathologists of Australasia, the Tasmanian government, Breast Cancer Action Group NSW and the Generic Medicines Industry Association.

2.3 The Royal College of Pathologists of Australasia (RCPA), which declared in its submission that it does not "depend on revenue from gene patents" supports the intent of the Bill because:

(a) it holds "grave reservations" over policy adopted by IP Australia.

(b) "a person with a patent over a gene sequence can restrain another person from using that sequence to make a medical diagnosis."

(c) "The patent holder did not create the gene, the mutation, or the disease - but the patent holder can restrict a doctor's freedom to make a diagnosis. This restriction is not based on the machine or process by which the doctor might make the diagnosis, but is focused on the biological basis of the disease itself."

(d) "The power of the patent holder in this situation compromises the very foundation of health care in this country. Such a restriction should have no place in our society."

(e) "biological materials which are 'identical or substantially identical to such materials as they exist in nature' should not be patentable. *We would go further, arguing that any substance which is identical to that found in nature should not be patentable. Such substances are discoveries, not inventions*." (emphasis added)

2.4 On the other hand the Human Genetics Society of Australasia (HGSA) unequivocally supports the Bill because:

(a) "of serious concerns relating to the current operation of the patent system in relation to patenting of genes and the balance of commercial benefits of patent protection versus social, community and health impacts."

(b) "identifying naturally occurring genetic material and its function is not an invention but a discovery."

(c) "gene sequences are not of themselves a new 'manner of manufacture' and that they have more of a collaborative genesis than other inventions."

2.5 The HGSA submission is adopted by The Royal College of Physicians in full.

2.6 The South Australian government unequivocally supports the Bill as proposed because:

(a) "broad patent claims specifically related to human genes and biological materials, as they exist in nature, have been shown to have an adverse impact on the provision of health care, including medical research, the scope of the provision of training and accreditation of health care professionals and the cost of performing certain genetic tests within South Australia."

(b) it provides "greater clarity … by ensuring that the discovery of naturally existing biological material is not patentable."

2.7 The Department of Health and Ageing supports the "intention" of the Bill because:

(a) "genes (or portions of genes) and biological materials that have a natural homologue (i.e. are identical to those that are 'naturally-occurring') are not inventions and hence should not be considered patentable subject matter."

(b) "The intrinsic nature and function of a gene is not altered when it is isolated, purified or cleaved to remove the regions that do not code for the formation of proteins."

(c) "Free access to genetic material, including the normal genome and its mutations (as well as information relating to the association of genes with disease), is essential to promote continued innovation in the prevention, diagnosis, prognosis and treatment of disease."

2.8 Cancer Council Australia supports the intent of the Bill because it has "the potential to prevent monopolisation of genetic sequences and other biological substances that should be freely available for competitive research and to help ensure equitable access to healthcare."

2.9 The Generic Medicines Industry Association supports the intent of the Bill because:

(a) "the Australian pharmaceutical and biopharmaceutical industries, innovation, research, and market competition have been unnecessarily stymied because of the increasing reach of patent rights."

(b) "Patent monopolies regarding critical pharmaceuticals and biopharmaceuticals which have been invalidated elsewhere have either remained unchallenged in Australia (due to the relatively small size of the Australian market) or have been held to be valid in Australia (due to significant differences in Australian law). Australian industry and the Australian public have been disadvantaged and will continue to be disadvantaged if these issues are not rectified."

2.10 Mylan, Inc a U.S. company and the world's third largest producer of generic medicines that operates in Australia via its fully owned subsidiary, Alphapharm, supports the Bill because:

(a) The Bill "aims to redress the imbalance in the patent framework in Australia by raising the bar for what is considered to be patentable material.

(b) "The Bill merely seeks to clarify and apply the true intent of patent law and amend that part of the Patents Act that provides the patentability criteria for the grant of a valid patent monopoly."

(c) "Biological materials that are identical or substantially identical to any that exist in nature should not be patentable because they are a product of nature and have not been transformed into a product of humankind, historically regarded as a prerequisite for patentability."

(d) "The patenting of naturally occurring biological materials is stifling medical and scientific research as well as the diagnosis, treatment and cure of human illness and disease. Such patenting prevents doctors, clinicians and medical and scientific researchers from gaining free and unfettered access to these materials, however made, that are identical or substantially identical to such materials as they exist in nature."

2.11 The Australian Medical Association supports the Bill because:

> Allowing doctors, clinicians, and researchers free and unfettered access to such biological materials has the very real potential to facilitate greater, more competitive research into the development of genetic technologies. This would benefit patients, health care professionals, and the broader health care system by allowing more equitable access to a wider range of genetic tests and related technologies.

2.12 Meat and Livestock Limited, a producer-owned company investing $47 million annually on meat and livestock research and development on behalf of 47,000 cattle, sheep and goat producers, supports the Bill because:

(a) "MLA's genetic and genomic improvement programs are encountering many of the same issues currently being debated in humans, as these same problems

also apply to gene discovery in animals and plants. More and more, we are seeing that general discoveries of nature have sought to be patented. This patenting is hampering the evolution of our research and our understanding of the underlying causes for genetic variation in animals and plants, and improvement in our national genetic improvement programs."

(b) "If the protection of genes and gene markers continues, it will be imperative for MLA and the research organisations involved to reassess their current strategy and investment in genetic and genomic research, development and implementation. At this point in time there are no obvious ways to avoid the loss of research effectiveness or the substantially higher transaction costs. This has the potential to stifle our ability to continually improve the productivity and sustainability of the Australian meat and livestock industry."

ANSWERING THE CRITICISMS

3.1 The Bill seeks to achieve two outcomes which we maintain are vitally important to the credibility of Australia's patent system. The first is to restore the full scope of the 'manner of manufacture' test as it was understood and applied in Australian patent law prior to 1994. It was this test which both the IPAC and IPCRC reports recommended be retained. The critics of this aspect of Bill have failed to address this point. The second, is to reinforce the distinction between discovery and invention in respect of one specific context. The IPCRC report made specific reference to the importance of the maintenance of this distinction only a decade ago and after TRIPS was in operation. The critics of the Bill have raised a plethora of excuses as to why this Bill should not be passed but none of them have addressed the plain simple fact that a gene and a protein which are identical to what exists in nature, regardless of its state or how it is made, is not something that anyone invented. And if there is no inventor, how can there be an invention?

Overruling Anaesthetic Supplies Pty Ltd v Rescare Ltd (1994) FCA 1065 *and Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524

3.2 Before *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1992) 25 IPR 119 the scope of the 'manner of manufacture' test was broader in that the proviso in s.6 of the *Statute of Monopolies, 1623* was understood to empower the courts to invalidate, on the grounds of public policy, patents that failed to meet the social, economic, ethical or moral norms of Australian society. Specifically, the issue in that case was whether a method for the treatment of sleep apnoea in a human being was patentable subject matter. The *Statute* provides that a patent is invalid if the subject matter is "contrary to the Law, … mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient".

3.3 In *Rescare*, Justice Sheppard, in dissent, held that it was not. He held that even though the Parliament had not in the *Patents Act, 1990* expressly banned patents over medical methods, as it had done with regards to process for human cloning (s.18(2)), it did not mean that the courts were not empowered to rely on the proviso to do so. In his opinion, it was "not going too far" in circumstances where the exercise of a patent owner's exclusive patent rights over the use of an invention "might mean the death or unnecessary suffering of countless people", to rely on the proviso to invalidate the patent. In his view the technology in issue and the human disease itself, which he believed to be "life-threatening", meant that a patent that sought to monopolise this method of human treatment was not 'manner of manufacture'.

3.4 Justices Lockhart and Wilcox, however, disagreed. Wilcox J. explained "that, in the face of apparently deliberate decisions by Parliament not to build this particular exclusion into its legislation, courts should be hesitant to introduce the exclusion by reference to those very general principles."

3.5 Six years later in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* the Full Federal Court followed *Rescare*. In doing so, the Court overruled the decision of

Justice Heerey who, in attempting to apply the proviso, invalidated a patent over a method for the administration of taxol on the ground that it was not a 'manner of manufacture'. Taxol was a well known chemotherapeutic, first discovered in 1977, but which was not approved for use in the treatment of breast cancer until 1994. It is important to appreciate that there was nothing new in taxol *per se* nor in its use as a chemotherapeutic drug.

3.6 Claim 1 was as follows:

> A method for treating cancer in a patient suffering therefrom including infusing from 135 to 175 mg/m2 of taxol over a duration less than 6 hours wherein said method results in a reduction of hematological toxicity and neurotoxicity compared with infusing greater than 170 mg/m2 of taxol over a duration of 24 hours.

3.7 The claim was to a method of human treatment defined by (a) the length of time over which taxol was administered and (b) the actual dosage. Apparently, the new dosage regime provided some benefits to patients but it was, at best, an incremental advance not a medical breakthrough.

3.8 The trial judge, Heerey J., made that very point in deciding that it was not a 'manner of manufacture':

> At the priority date the material (taxol) had been known for many years. *It is a naturally-occurring compound and thus in itself unpatentable*. In the words of the specification, taxol had "shown great promise as an anticancer drug" and "been found to be an active agent against drug-refractory ovarian cancer" ... . The properties which made taxol effective against cancer, that is to say its biological mechanism, were well known. They had been discussed in the articles referred to in the specification which were "incorporated by reference as if reproduced in full below" ... . Thus the specification is not merely a claim of a "new use of an old substance" ... but a claim for the same use of an old substance. (italics added)

3.9 It is important to note that the trial judge had made findings of fact based on the evidence presented at the trial that the patent sought to monopolise, via a method claim rather than a product claim, a substance (which was derived from a biological material found in the bark of a Pacific Yew tree) that was neither new nor inventive if the *use* of that substance was directed to a specific form of human treatment. In other words the trial judge had formed the view that there was no merit in the patent sufficient to warrant the grant of a patent monopoly.

3.10 The Full Court, however, disagreed. According to Black C.J. and Lehane J., "drawing a logical distinction which would justify allowing patentability for a product for treating the human body, but deny patentability for a method of treatment was an insurmountable problem". Finklestein J. merely took the view that it was "not the function of a court [to adjudicate] on an issue such as this … [and] if public policy requires a different result, it is for the Parliament to amend the 1990 Act".

3.11 As a consequence of *Rescare* and *Bristol-Myer* decisions the Federal Court effectively repealed the proviso in s.6 of the *Statute of Monopolies, 1623* thereby negating an important check and balance in the patent system that had been a part of the 'manner of manufacture' test for nearly 400 years.

3.12 This result, however, was inconsistent with the Parliament's intent. As the then Minister, the Hon Barry Jones MP, said during the second reading speech, one of the main objectives of the *Patents Bill, 1989* was to "make it harder" to get a patent. Another was to "maximise the *social* benefits and minimise the *social* costs to Australians". (emphasis added) The fact that s.18(2) expressly banned patents over human cloning, introduced into what became the *Patents Act, 1990* by an amendment moved by Senator Harradine, did not, with respect, override these two central objectives nor provide the courts with a mandate to ignore the full scope of the 'manner of manufacture' test.

3.13 These two decisions did the exact opposite by first making it easier to get a patent and second by ignoring the net social impact on the Australian people.

3.14 Far from being "superfluous", a charge made by Prof. Natalie Stoianoff, Dr. Ann Kurts and Dr. Mark Lutherborrow from the University of Technology, Sydney and relied on by the committee as a point of criticism, the passage of this aspect of the Bill will restore both the original intent of s.18(1)(a) *Patents Act, 1990* and full scope and operation of the 'manner of manufacture' test.

3.15 The committee in the report stated:

> "Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee considered that the change would "add nothing to the development or state of the law relating to 'manner of manufacture' and would not achieve any paradigm shift in the relevance of social and ethical dimensions to determinations of patentability'."

3.16 But this criticism, respectfully, misses the point because this aspect of the Bill is not seeking to "add" something new or revolutionary to the operation of the *Patents Act, 1990*, rather it is merely seeking to restore an important check and balance and one that was never intended to be removed in the first place. Once it is restored this check and balance will, once again, be available to the courts and to apply the law, this time, with the benefit of an amendment that overrules these two Federal Court decisions.

3.17 In regards to the committee's reference to the joint submission by the DIISR and IP Australia and to the ACIP Patentable Subject Matter Report, we are of the view for the reasons already provided that the IPAC and IPCRC reports and recommendations on this issue are to be preferred.

Exclusion of biological materials

3.18 The central criticism of the second or principle aspect of the Bill, which is contained in the proposed s.18(2)(b) to the Patents Act, 1990, is that the terms

'derivatives', components' and 'substantially identical' are undefined and thereby open to a variety of judicial interpretations that could, according to Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee "have far-reaching or limited effect".

3.19 Related to that criticism is that the term 'biological materials', which is defined, would "introduce substantial and wide ranging uncertainty in the Patents Act 1990 arising principally from the scope and potential impact of these proposed amendments, particularly in relation to the ambiguity, or lack of clarity which exists in relation to most of the terminology to be introduced".

3.20 We are, however, of the opinion that while the Bill provides the courts with scope to interpret and apply these terms in the context of the *Patents Act, 1990*, these criticisms are exaggerated. Every day in the Parliament legislation is passed that is open to judicial scrutiny and interpretation. The fact that there is no iron clad guarantee that the courts will necessarily apply the law as intended or proposed does not mean that Parliament does not pass legislation. Nor that it passes legislation that is so prescriptive so as to leave the courts with no ability to do their job. It is frankly absurd to suggest that the courts will not be able to, with the benefit of submissions from learned counsel, come to a workable definition of these terms that is also consistent with Parliament's intention. Indeed, it does so happen, as we explain in the case of *Rescare* and *Bristol-Myers* decisions, that sometimes the courts do get it wrong. But when they do Parliament is always there to right that wrong if the Parliament deems it necessary to do so.

3.21 As Dr. Palombi explained, the term 'substantially identical' is undefined in the *Trade Marks Act, 1995* but that was not a reason not to pass that legislation, nor has the lack of a definition created legal uncertainty in the courts.

3.22 Regardless of the fact that we believe the Bill as originally introduced meets the criticisms, it was decided to reformulate s.18(2)(b) and the relevant definitions in s.18(5) in a new amendment. This amended version of the Bill is, as already stated, attached to this dissenting report.

3.23 In so doing the terms 'derivatives', 'components' and 'substantially identical' are deleted from s.18(2)(b) and a definition of 'identical' is inserted in s.18(5) so as to make it clear that the scope of the express exclusion is directed to only those biological materials that are structurally and functionally identical.

3.24 Accordingly, a biological material that is structurally identical to one that exists in nature but is functionally different will fall outside of the scope of the express prohibition. This means that if a biological material can be made to function in a way that it did not function in nature that biological material with its new function will be patent eligible.

3.25 This is the kind of outcome which we expect would have resulted with the original Bill had an Australian court been given the opportunity to interpret the term 'substantially identical'.

Increased possibility of litigation

3.26 It follows, respectfully, that litigation goes hand-in-glove with legislation. Everyday the courts are called upon to adjudicate disputes involving litigants who take different approaches to the same legislation and invite the courts to prefer one interpretation over another. For this committee to take seriously the assertion by Ausbiotech that the Bill will lead to a "frenzy of legal activity" and use that to criticise the Bill is to ignore this fact.

3.27 In any event, patent litigation is not new. In fact the patent system heavily relies on patent litigation to filter out patents that may be invalid. The *Patents Act, 1990* in s. 20(1) expressly denies any guarantee of validity in regard to a granted patent so as to encourage the use of the courts as a filtering process.

3.28 The claim by Prof. Dianne Nicol, Mr. Johnathon Liddicoat, Dr. Jane Nielsen and Mr. Ben Mee that the Bill will be the subject of "protracted and expensive litigation" appears to ignore the fact that nearly all patent litigation is protracted and expensive. The criticism by the patent attorney and law firm Griffith Hack, that "there will be many millions of dollars wasted on patent attorney and lawyers' fees debating the interpretation of the exclusion, money that would be better spent on research and commercialisation", appears to ignore the significant costs already inherent within the patent system.

3.29 Millions and millions of dollars each year are spent by litigants embroiled in patent litigation, yet this is probably the first time that the cost of patent litigation has been seriously advanced as an excuse not to pass patent-related legislation.

Efficacy of the Bill

3.30 What are the Bill's objectives? First to restore the 'manner of manufacture' test to how it was originally intended by overturning *Rescare* and *Bristol-Myers*. Second, to prohibit the patenting of any biological material that is identical or substantially identical to what exists in nature. In our opinion, the Bill achieves both of these objectives.

Need for the Bill

3.31 Since 1988 IP Australia has pursued a policy leading to the grant of thousands of patents over biological materials that no one invented. These materials have been isolated from their natural environments or have been synthetically duplicated through some biotechnological process. Either way, in these states the biological materials are identical or substantially identical to those that exist in nature either structurally or functionally.

3.32 The submissions referred to earlier (paras 2.3 – 2.14) provide evidence of the problems caused by these patents. In addition evidence provided to the Senate Community Affairs References Committee also showed specifically how patents of

this kind have delayed or interfered with medical and scientific research into BRCA 1 and BRCA 2 genetic testing. The majority report simply ignores this evidence and prefers the submissions of Ausbiotech and GlaxoSmithKline. We, however, do not. In our opinion, there is ample evidence to show that patents of the kind in issue have been and continue to be problematic particularly when they interfere with the provision of medical services.

3.33 The majority report did not appear to take account the evidence that clearly pointed to serious and fundamentally important health security concerns. For example, Dr. Palombi, in submissions made to the Senate Community Affairs References Committee and to this Committee, gave evidence of a number of instances of how patents of this kind have interfered with or restricted access to diagnostic tests or medical treatment going back to the early 1990s when Chiron Corporation was granted patents over the hepatitis C virus (HCV). In this case the Australian patent over HCV prevented Australia doctors and clinicians from developing their own diagnostics. The patentee simply refused to permit anyone other than its licensing partners from making HCV diagnostics, but there was a serious issue of the reliability of the Chiron licensed HCV tests. In fact, so serious was the issue that the Ass. Prof. Locarnini, the then Director of the Fairfield Infectious Diseases Hospital, said at the time (1995):

> Blood banks in Australia and elsewhere are losing blood donors permanently. This means that the source of blood needed on a daily basis by the Australian community and other communities, is being seriously threatened. Once a blood donor is labelled as an HCV-indeterminate or HCV positive, their blood is excluded from the blood supply, even though they maybe truly negative for HCV. In other words, blood donors are being falsely labelled as 'HCV positive' when in fact they are not because of the inadequacies of the present anti-HCV test kits.
>
> The fact that third generation anti-HCV test kits are giving such results is really saying something: it means in a low risk group such as blood donors, the present generation anti-HCV tests are detecting something other than HCV and giving false positive results in up to 75% of cases. It has been five years since the first anti-HCV test kits were first used in Australia and the manufacturers of these kits have not yet produced a kit which is as sensitive and specific as the test kits for HIV. This is clearly unsatisfactory.

3.34 In another example, Dr. Palombi provided evidence about the denial of medical services to infants at Westmead Hospital, western-Sydney's main public hospital. In this case infants were denied access to a genetic test for Dravet syndrome, a severe form of epilepsy, because of a patent over the genetic mutations to the human SCN1A gene linked to the disease. The patent was granted by IP Australia to Bionomics, an Australian company, which in turn granted an exclusive license to Genetic Technologies, another Australian company. The denial of service occurred in spite of the fact that over $1 million of Australian taxpayer funds had been provided to both an Australian University in the research leading to the identification of the relevant genetic mutations and to Bionomics for the subsequent development of a genetic test. Part of the evidence provided by Dr. Palombi was an article published in the Sydney

Morning Herald on 29 November 2008. An excerpt from that article, entitled, 'Sick babies denied treatment in DNA row' is as follows:

> Specialists are sending blood samples to Scotland, and only babies whose seizure patterns closely resemble Dravet syndrome are tested. This means children with slightly different symptoms may be treated with the wrong medicines for months, potentially retarding their development. "It's frustrating that we can't get the test done readily," Dr. Gill said. "If we could include it as part of the work-up, we could identify them early." At present the diagnosis is often delayed until the child is 12 to 18 months old. This is after the optimum time for treatment with strong drugs that are unsuitable for most babies with epilepsy but are used for infants with Dravet's to control severe seizures that can damage the brain. Standard childhood epilepsy medications are ineffective with Dravet's and may worsen it, Dr. Gill said.
>
> SCN1A is the most important epilepsy gene discovered, Dr. Gill said, and is abnormal in about 70 per cent of children with Dravet syndrome, which affects about one in 30,000 babies - almost 10 per cent of infant epilepsy cases. About one in 20 children have a seizure when they develop a fever, though only a minority had epilepsy, Dr. Gill said.

3.35 Far from being a diminishing problem, Prof. Ian Olver OA, CEO of Cancer Council Australia, believes the problem is only going to get worse as medical treatments become tailored to an individual patient's genetic make up. In evidence he gave to the Senate Community Affairs References Committee in August 2010, Prof. Olver stated:

> The position of the Cancer Council of Australia and the Clinical Oncological Society of Australia is that … we need to change the law to reflect what we regard as a common sense approach. The timing of this is absolutely critical since genes and their products are increasingly going to become the targets of new treatments for a range of diseases. If I stick to cancer, we are seeing a paradigm shift in cancer treatments towards targeted therapies—and the targets are genes and gene products. We are going to see hundreds more of these over the next decade, so a change now would protect us before the floodgates open.

Investment in research and development in pharmaceuticals and biotechnology – the need for patent protection

3.36 The majority report relies heavily on evidence from DIISR, IP Australia, Ausbiotech, Medicines Australia, CropLife, Roche, Pfizer, Chemskill, the Institute of Patent and Trade Mark Attorneys and Prof. Dianne Nicol, Mr. Johnathon Liddicoat, Dr. Jane Nielsen and Mr. Ben Mee to criticise the Bill on the basis that it will have a negative impact on investment in research and development in the pharmaceutical and biotechnology industry in Australia.

3.37 Medicines Australia, for instance, produced a list of 28 medicines which it asserts would be threatened by the Bill.

3.38 Pfizer asserts that "a ban on the patenting of all genetic material and derivatives in Australia would halt commercial development and supply and access to a wide range of innovative medicines and health technologies in Australia".

3.39 Roche asserts that clinical trials would be threatened in Australia.

3.40 Ausbiotech asserts that "the absence of patents for biological materials will be a serious disincentive for foreign and domestic private investors and others interested in commercialising innovation in Australia."

3.41 However, these assertions are misleading, exaggerated and are made without any objective analysis of the scope of the Bill or the kinds of patents that which will be impacted by the Bill. And unfortunately the majority report has been led into drawing erroneous conclusions based on this evidence.

3.42 For example, the list of medicines provided by Medicines Australia (Table 1 at para 4.87, majority report) is supposed to back up the claim, made by Medicines Australia, that "it is uncertain whether these medicines would be eligible for patents in Australia if this bill becomes law". The assertion is, however, made without any explanation as to how precisely the Bill, if passed, would preclude these medicines from being be patent eligible. The language of the Bill in the proposed s.18(2)(b) is not directed to medicines. It does not say that a medicine which can treat a human being suffering from a specific disease or ailment is precluded from patentability. Rather the proposed s.18(2)(b) refers only to "biological materials … *which are identical or substantially identical to such materials as they exist in nature.*" The words in italics qualify and narrow the scope of the prohibition to only biological materials that meet that specific criteria. Accordingly, biological materials that are materially different to what exists in nature, or medicines that contain such biological materials, would not be excluded from patentability.

3.43 Indeed, neither would medicines that contain naturally occurring biological materials, even if identical or substantially identical to those that exist in nature as a component, because medicines used to treat a specific human disease or ailment do not exist in nature. The majority report appears not to have taken account of this information and has instead relied on many unsubstantiated claims or comments that have provided little substantive analysis.

3.44 In 1618 (before the genesis of the modern Anglo-American patent system in 1624) the London *Pharmacopoeia* taught that natural biological materials could be used as medicines when isolated (that is, when removed from their natural environment) and purified (subjected to a process of purification). Strychnine, morphine, atropine and colchicines were all developed during the 19th century applying this very idea. The active ingredient of Aspirin, the famous trade mark applied to a drug containing acetylsalicylic acid, is a derivative of salicin, a substance found naturally in the bark of a willow tree. Salicin-rich plants had been known for thousands of years to be useful in the treatment of fever, pain and inflammation. However, in 1838, the Italian organic chemist, Raffaele Piria, converted salicin into

salicylic acid and although more effective (as a medicinal ingredient) than salicin it produced unpleasant side effects. It was not until 1897, when Bayer chemist Felix Hoffmann converted salicylic acid into acetylsalicylic acid, that the side effects were eradicated. In 1898 Bayer applied for patents over acetylsalicylic acid and in February 1900 the United States Patent and Trade Mark Office (USPTO) granted Bayer US patent 644,077. In the Bayer patent Hoffmann did not claim to have invented salicin; indeed, no mention is made of salicin nor the natural source of salicin. Rather, Hoffmann describes his invention by distinguishing it from an earlier attempt by another German chemist, Karl Kraut, to produce acetylsalicylic acid. Hoffmann declared in the patent:

> According to my researches the body obtained by means of my new process is undoubtedly the real acetylsalicylic acid. Therefore the compound described by Kraut cannot be the real acetylsalicylic acid, but is another compound. In the following I point out specifically the principal differences between my new compound and the body described by Kraut.

It is important to note that Hoffmann was describing a new product that did not exist in nature. It was not merely a matter of isolating and purifying salicin from the bark of the willow tree. Apart from the fact that this kind of extraction had been done for thousands of years and therefore was not inventive, Hoffmann's claim to invention focused on the new process which when applied to salicylic acid (an artificial derivative of salicin) produced "the real acetylsalicylic acid". Thus the invention was a new artificial product produced by a new artificial process. The two were inseparable and Hoffmann's patent was to acetylsalicylic acid manufactured by the specific process he had invented and disclosed in his patent. It was not to acetylsalicylic acid *per se*. And, as already noted, it most certainly was not to salicin, that natural source of acetylsalicylic acid. This is an important point of distinction in the context of the patents in issue because the inventions which are claimed by these patents, and which the Bill is directed to, are to nothing more than isolated genes, proteins and other naturally occurring biological materials. The genes and the proteins which they code for are, apart from being in an artificial environment, substantially identical structurally and functionally from those from which they have been derived.

3.45 It is important to understand that patents of the kind in issue contain claims that cover not merely biological materials *per se* which have been isolated or purified or synthesised by some biotechnological process. These claims are merely the beginning. And it should be noted that the biological materials covered by these claims have no prophylactic, therapeutic or curative properties in themselves. They are claims to either to isolated or purified nucleic acids or amino acids that are identical or substantially identical to those that exist in nature.

3.46 For example, the claim at para 1.13 is reproduced to illustrate the point:

> Australian Patent 686004 entitled, *In vivo mutations and polymorphisms in the 17q-linked breast and ovarian cancer susceptibility gene*:

> Claim 1: An isolated nucleic acid coding for a mutant or polymorphic BRCA 1 polypeptide, said nucleic acid containing in comparison to the BRCA 1 polypeptide encoding sequences set forth in SEQ.ID No: 1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19.

This is not a claim to a medicine. In fact, the genetic sequence defined in the claim is linked to breast cancer. Essentially, this claim defines the invention to be a genetic trigger of breast cancer.

3.47 This claim, however, is only 1 of 30 claims. In addition to this claim are claims to the use of the biological material in genetic tests as well as other claims to methods and other biological materials which are not identical or substantially identical to those that exist in nature. These claims would not be affected by the Bill. In fact, if the Bill had been in operation at the time this patent was filed, 24 of the 30 claims would have been untouched by the Bill. (See Schedule A)

3.48 The 24 remaining claims enable Myriad Genetics, the patent owner, to exploit the invention as defined in each of these claims.

3.49 Neither will the Bill prevent the patenting of new, novel and inventive uses of naturally occurring biological materials in products, methods or processes. The freedom to operate and patent inventive medicines, therapeutics, diagnostics and cures remain untouched by the Bill.

3.50 Whatever incentive is provided by the Australian patent system in regards new and inventive medicines, therapeutics, diagnostics and cures remain open and available.

3.51 Further support for our view comes from the U.S. government's amicus brief (para 1.19) particularly as the United States is home to some of the world's largest biotechnology and pharmaceutical companies including Amgen, Genentech (owned by Roche), Novartis, Merck and Monsanto.

3.52 Despite the CAFC decision, handed down in the United States on 29 July 2011 reversing the earlier decision of Judge Sweet invalidating U.S. patents granted to Myriad Genetics over the mutant BRCA nucleic acids and proteins, the issue is far from being legally resolved.

3.53 On 25 August 2011 the American Civil Liberties Union (ACLU) acting for the plaintiffs in *Association for Molecular Pathology et al v Myriad Genetics and others* filed a Petition for Panel Rehearing with the CAFC. As a result the CAFC decision of 29 July is neither final nor definitive as a matter of U.S. law.

3.54 The Petition for Panel Rehearing summarises the grounds as follows:

> … the majority erred in analyzing the chemical structure of the patented genes and gene fragments without considering (1) that the language of the

> patents defines the function, not the structure of the patented genes and gene fragments; (2) that gene fragments with the altered chemical structure identified by the Court exist in nature.

3.55 The issues raised by the Petition for Panel Rehearing is precisely the issue that the Bill attempts to resolve through legislative means in Australia. And the U.S. government supports this position.

3.56 The U.S. government stated in the U.S. Department of Justice's Amicus Curiae Brief to the CAFC the following:

> The extent to which basic discoveries in genetics may be patented is *a question of great importance to the national economy, to medical science, and to the public health*. This appeal consequently implicates the expertise and responsibilities of a wide array of federal agencies and components, including the Patent and Trademark Office (PTO), the National Institutes of Health (NIH), the Antitrust Division of the Department of Justice, the Centers for Disease Control and Prevention, the Office of Science and Technology Policy, and the National Economic Council, among others. (emphasis added)

3.57 We believe that the U.S. government's concern that the resolution of this issue is a "matter of great importance", not just to the U.S. biotechnology industry and the legal, scientific and university communities that are associated with it, but to "the national economy, to medical science, and to the public health". This aspect has been brushed over or minimised in the majority report.

3.58 IP Australia's policy has, as the evidence presented to both to this committee and to the Senate Community Affairs References Committee shows, negatively and seriously impacted on Australia's national economy, medical science and public health. It is vitally important that the interest of the *entire* Australian community be balanced against the interests of one industry sector. This balancing act is critical to the future of this country, its people and cannot be resolved satisfactorily, as the majority report recommends, by ignoring the social and ethical problems it has caused on the basis of an unsubstantiated theory, that patents drive innovation, and the unfounded fear, that without patent protection the Australian biotechnology will ceased to be. Particularly when this policy has over the past 30 years permitted the grant of thousands of patents over naturally occurring biological materials, none of which have been invented, under the guise of untested legal reasoning

3.59 Moreover, as the U.S. government has argued, it is a matter of common sense that the biological materials which this Bill is directed to, are not patentable subject matter. The U.S. government's reasoning is summarised in the following passage from the Amicus Curiae Brief:

> The discovery of any number of basic natural phenomena could be recharacterized as the "invention" of an isolated "manufacture" or "composition of matter" under section 101. For example, many highly reactive elements on the periodic table, such as lithium, occur in nature only in chemical compounds (i.e., salts). Not until 1818 was lithium, which has

> innumerable industrial applications, first isolated in metallic form by Sir Humphry Davy and W.T. Brande. See Krebs, The History and Use of Our Earth's Chemical Elements: A Reference Guide 48 (2d ed. 2006). That accomplishment marked a significant achievement in chemistry, but it did not entitle Davy and Brande to claim a patent on the third element in the periodic table. Cf. Funk Brothers, 333 U.S. at 130 (the "qualities of metals" are "part of the storehouse of knowledge of all men"). Courts in the early part of the 20th century repeatedly rejected claims for isolated natural elements as new "manufactures." See Gen. Electric Co. v. De Forest Radio Co., 28 F.2d 641 (3d Cir. 1928) (pure ductile tungsten, though previously thought impossible to produce, held unpatentable as a product of nature); In re Marden, 47 F.2d 957 (CCPA 1931) (same, pure ductile uranium); In re Marden, 47 F.2d 958 (CCPA 1931) (same, pure ductile vanadium); cf. In re Seaborg, 328 F.2d 996 (CCPA 1964) (upholding patent for element 75, americium, which does not occur in nature). The unacceptable implication of appellants' argument is that these cases were wrongly decided.

3.60 The U.S. government's reasoning, once again, fortifies us in our dissent and should be a reminder to the majority that no matter how bleak a picture those opposed to this Bill have painted in terms of the potential negative impact on the biotechnology sector, which we believe is grossly exaggerated, this Parliament should be comforted by the position of the U.S. government on this issue.

Australia's international obligations

3.61 For the same reasons it is unlikely the U.S. government would have adopted the position it has on the issue, if there was any merit to the argument that its position would contravene either TRIPS or the AUSFTA.

3.62 Prof. Drahos and Dr. Palombi have explained to this Committee, both in submissions and in evidence, that TRIPS and the AUSFTA provide a minimum requirement that patents be granted for what is an 'invention' and then only if the invention is novel, involves an inventive step and is industrially applicable.

3.63 It is common sense, for the reasons stated earlier, that biological materials identical or substantially identical to what exists in nature, regardless of their physical state, are not inventions in themselves.

The European Biotechnology Directive

3.64 This Committee was referred the European Parliament's passage, in 1998, of the European Biotechnology Directive. The Directive mandated E.U. members to amend their patent laws so that an isolated but otherwise identical biological material or those synthesised through a "technical process", are to be deemed to be patentable subject matter under art. 52.1 of the European Patent Convention.

3.65 While it is a matter for the European Parliament to make laws as it sees fit for the E.U., it is a matter for the Australian Parliament to make laws as it sees fit for Australia, subject to meeting Australia's international obligations for Australia. We,

therefore, are cautious of arguments advanced to this Committee that the Directive is persuasive, or should be, on this Parliament given the U.S. government's stand on the issue.

3.66 Moreover, it must be appreciated that the Directive mandated a change of law in 1998, amid great controversy that was unresolved until 2006 and 10 years after the decision of the U.K. Court of Appeal in *Genentech v Wellcome* [1989] RPC 147, in this case the entire patent, granted to Genentech over a synthetic human protein, human tissue plasminogen activator (t-PA) and its process of manufacture, was wholly invalidated.

3.67 The principal product claim of Genentech's t-PA patent defined the invention to be "recombinant human tissue plasminogen activator essentially free of other protein of human origin". It was a claim to synthetic t-PA. And it clearly was a claim to both purified and isolated t-PA. Yet the Court held that synthetic T-PA was not something that could be patented under the European Patent Convention (as it was prior to the Directive). And, reinforcing the point, Lord Justice Mustill held that the word "recombinant" did not describe "the product itself, but its history". In his opinion, to differentiate t-PA produced by recombinant means from naturally occurring t-PA was misleading because it suggested that "[the] protein molecules with the amino acid sequences shown … and the functional characteristics set out in the [patent] specification" were new, when in fact they "have existed since far into the distant past". Neither was he convinced that the technical process used to mass produce purified t-PA resulted in a product that was any different from the t-PA produced by the human body, concluding: "[t]he t-PA which Genentech made [was] neither more nor less than t-PA".

3.68 The Appellate Committee House of Lords cited *Genentech v Wellcome* with approval in another biotechnology patent case, *Biogen v Medeva* [1997] RPC 1. Lord Mustill, as he then was, held as follows:

> Certainly, in the great majority of cases, there will be no need to complicate the enquiry by looking outside the four conditions. The traditional law of patents is, however, in the course of adapting itself to new technologies, beyond contemplation when the foundations of that law were established. This process is not without strain, and I believe that in some instances a close conceptual analysis of the nature of patentability will not be a waste of time. Such a case was *Genentech Inc's Patent where the claim was for a product already existing in nature*, a subject far distant from the mechanical and chemical inventions to which so much of traditional patent law relates. There may well be others in the future. (italics added)

3.69 Again, the Appellate Committee House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 169 held that a claim to a synthetic human protein, erythropoietin, was invalid because it was not new in that it already existed in the human body.

3.70 In regards to the structure of human protein erythropoietin, a 1989 decision of a U.S. Federal Court makes it unquestionably clear that the identity of the synthetic protein to the natural protein is exactly the same. The Court held:

> … the overwhelming evidence, including Amgen's own admissions, establishes that [natural erythropoietin] and [recombinant erythropoietin] are the same product. The [erythropoietin] gene used to produce [recombinant erythropoietin] is the same [erythropoietin] gene as the human body uses to produce [natural erythropoietin]. The amino acid sequences of human [natural erythropoietin] and [recombinant erythropoietin] are identical. … There are no known differences between the secondary structure of [recombinant erythropoietin] produced in a Chinese hamster cell and [erythropoietin] produced in a human kidney. Amgen's own scientists have concluded that by all criteria examined, [recombinant erythropoietin] is the "equivalent to the natural hormone."

3.71 In other words, the Directive was a legislative enactment of the joint USPTO, EPO and JPO policy – a policy that was not at the time it was formulated in accordance with the European Patent Convention as interpreted and applied by the U.K. Court of Appeal and the Appellate Committee of the House of Lords.

3.72 This suggests to us, absent a similar amendment to the *Patents Act, 1990*, as effected by the Directive in terms of European patent law, the Bill is consistent with current Australian patent law.

Crown use, compulsory licensing and experimental use – freedom to operate

3.73 Crown Use and Compulsory Licensing provisions have been contained in all three Australian patent legislations since Federation. The origin of the policy for these provisions is to be found in the patent laws of Great Britain – laws that provided the template for the *Patents Act, 1903* and the *Patents Act, 1952*. The legal connection between Australian and British law, however, was severed in 1977 when the British Parliament passed the *Patents Act, 1977 (U.K.)* as a result of Great Britain joining the European Community in 1973.

3.74 The *Patents Act, 1990* therefore represented a break from its legislative predecessors. Nonetheless, the Crown Use and Compulsory Licensing provisions were retained. In regards compulsory licensing the IPAC report stated the following:

> The next matter considered is the focus of compulsory licensing provisions in patent law on what are permissible or desirable ways in which a patent may be exploited, and in particular on local manufacture or "working" as against importation. *We conclude that the existing provisions should be retained, observing that they take account of both the possible desirability of local working and the fact that local demand may be met satisfactorily by importation*. In addition, a compulsory licence ought to be available notwithstanding that the prospective licensee wishes to exercise the licence by importation. The court should have a discretion to order transfer of related know-how as part of the reasonable terms on which a compulsory

> licence is granted. Compulsory licences should be made a remedy available in actions under the Trade Practices Act.

3.75 However, in 1995 Australia joined the World Trade Organization (WTO). Accordingly, Australia accepted TRIPS and since then has signed and ratified AUSFTA. Both of these international agreements have imposed stringent limitations on the scope of compulsory licensing.

3.76 Prof. Drahos, a recognised world leader on the subject of intellectual property and trade law advised the Committee as follows:

> Relying on crown use/compulsory licensing provisions is not a politically feasible strategy. The US has been a great critic of the use of these provisions and has brought trade pressure to bear on countries that have gone down this path (eg Thailand). It is true that China and Brazil have been prepared to confront the US in the WTO over trade disputes concerning intellectual property, but one wonders whether Australian political leaders would be prepared to tread this same confrontational path. By enacting the Bill, Australia would be taking an option that is supported by the US administration. It follows that it would also minimize the risks of a trade confrontation with the US over the patenting of biological materials.

3.77 We are of the opinion that Prof Drahos is correct in his assessment and, accordingly, the possibility that any Australian government will make use of crown use or compulsory licensing to ameliorate the worst effects of these kinds of patents is very low. While we accept that there may be exceptional circumstances where an Australian government may be persuaded to use these provisions, for example, in the event of a pandemic or military hostilities, the historical evidence does not support the majority report's conclusion that these provisions "can effectively influence patent-holder behavior".

CONCLUSION

The Australian patent system has operated since 1903. Since that time no Australian government has undertaken a thorough economic assessment of its net effects on the Australian economy. The latest iteration of the patent system, in the form of the *Patents Act, 1990*, came from a review that was criticised by the only economist on the panel of experts. Despite the concerns that he raised about the lack of any empirical data or analysis, the then Australian government decided to maintain the patent system. Since then there has been an explosion in the growth of intellectual property around the world and since 1995 intellectual property has been included in international trade talks. Throughout this Inquiry the Committee received many submissions about the Australian patent system, how it operates to encourage innovation and how patent protection is seen as vital to medical and scientific research. The problem, however, is that there is no data to substantiate any of these claims or counter-claims.

Regardless, patents are today recognised as a form of property, albeit with a 20 year sunset clause. And as a form of property can be valued, traded and transferred, it follows that they are legal instruments that provide their owners with the power to exclude all others from exploiting the property defined in the patent claims. That said, what can be made the subject of this form of property is limited to something that is an invention. Indeed, it is the act of invention that provides the justification for the grant of a property right.

But since 1988 that justification has been the subject of potential abuse. The patenting of naturally occurring biological materials on the pretext that they are in an artificial state or artificially made has stretched the credibility of the patent system and now poses a threat to its very existence. It is for this reason that this Bill is so important. It seeks to recalibrate the system in one specific way. In doing so it does not address many other issues that hang, unresolved, over the patent system. And it is not meant to. Ultimately whether the patent system continues and on what terms is a matter for decision after a thorough economic assessment has been undertaken and completed. However, until that assessment has occurred, we must work with what we have. Accordingly, to the extent that it is possible for this Parliament to put the Australian patent system back on track it should do so. It is for this reason that we dissent and recommend to the Parliament that it pass the Bill.

Recommendation: The Senate should pass the Bill with the attached amendment.

Senator the Hon Bill Heffernan
Liberal Senator for New South Wales

Senator Rachel Siewert
Greens Senator for Western Australia

Senator Nick Xenophon
Independent Senator for South Australia

Appendix A
Schedule 1— (New) Amendment of the Patents Act 1990

1 Paragraph 18(1)(a)

Repeal the paragraph, substitute:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

2 Paragraph 18(1A)(a)

Repeal the paragraph, substitute:

(a) is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies; and

3 Subsection 18(2)

Repeal the subsection, substitute:

(2) The following are not patentable inventions:

(a) human beings, and the biological processes for their generation; and

(b) biological materials ,whether isolated or not and however made, which are identical to such materials as they exist in nature.

4 After subsection 18(4)

Insert:

(5) In this section:

biological materials, in section 18, includes DNA, RNA, proteins, cells and fluids and their components.

identical, in section 18, means a biological material which is structurally and functionally identical

Appendix B

August 24, 2011

Despite Gene Patent Victory, Myriad Genetics Faces Challenges

By ANDREW POLLACK

http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?pagewanted=all

Myriad Genetics retained its monopoly on a lucrative genetic test for breast cancer risk when a federal appeals court recently upheld the company's patents on two human genes — and the validity of gene patents in general.

But it is only a matter of time before the company's business faces severe challenges, some experts say, because that $3,340 test is technologically outmoded, incomplete and too costly.

"Science has moved beyond what these folks do," said Mary-Claire King, a professor of genome sciences and medicine at the University of Washington. "It's not good for the science and it's not good for the patients and their clinicians if they cannot have the most complete, up-to-date information."

Myriad sequences the two patented genes, known as BRCA1 and BRCA2, for mutations that raise the risk of a woman getting breast and ovarian cancer.

But newer DNA-sequencing techniques are far faster and only a fraction of the cost of the 1990s technology that Myriad uses. Indeed, it will soon be possible to sequence a person's entire genome, all 22,000 or so genes, for less than Myriad charges for just two genes.

Executives at Myriad say they are preparing for changes. Although its major patents start expiring in 2014, the executives say the company's patent protection should last until at least 2018.

They say that will give the company time to adopt new technology and to diversify beyond the breast cancer test, which accounted for $353 million, or 88 percent, of Myriad's $402 million in revenue in the fiscal year that ended in June.

The company also plans to rely less on patents and more on trade secrets. Because it has done so much more testing than anyone else, Myriad has more information on

which of the thousands of possible mutations in the two genes actually raise the risk of getting cancer.

Myriad used to share such information with a public database maintained by the National Institutes of Health, and it cooperated with academic scientists trying to analyze the mutations. But a few years ago, the company quietly stopped contributing and cooperating, in favor of building its own database.

An academic consortium, relying on data from European labs or from individual patients, is trying to catch up, but "it's kind of slow going," said Sean Tavtigian, a former Myriad scientist who is now an associate professor of oncological sciences at the University of Utah and is involved in the consortium.

Myriad, which is based in Salt Lake City, is hoping to use that advantage first in Europe, where it will open a testing laboratory next year.

"If I had my druthers, I would not want to go into a new market in a heavy-handed fashion, trying to enforce patents," Peter D. Meldrum, Myriad's chief executive, told analysts in January. Instead, he said the company would exploit its quicker turnaround time for testing and its "vastly superior information."

Myriad executives have said that when a European laboratory finds a mutation in either of the two genes, 20 to 40 percent of the time it does not know if the mutation raises the cancer risk. They say that Myriad's rate of uncertain findings is just 3 percent.

Daniel B. Vorhaus, a New York lawyer and editor of the Genomics Law Report, a Web site, said there were ethical questions about whether Myriad should be withholding the mutation information, important for public health, that it has gathered by dint of its patents to essentially extend its monopoly beyond the life of the patents.

Mark C. Capone, the president of Myriad's laboratory division, said in an interview that the company had invested heavily in characterizing the various mutations. He said that the company became uncomfortable sharing its information with a public database when it realized the information might be used to compete against it.

Ever since Myriad and its partner, the University of Utah, beat other researchers, including Professor King of the University of Washington, in identifying the BRCA1 gene in 1994, Myriad has been the target of those opposed to the patenting of genes.

In 2009, the American Civil Liberties Union and the Public Patent Foundation filed a lawsuit challenging Myriad's patents on behalf of various medical researchers, medical societies and patients.

A federal district judge last year said genes could not be patented. But his decision was reversed in late July by a 2-1 decision from the Court of Appeals for the Federal Circuit. The plaintiffs are considering appealing to the Supreme Court.

The lawsuit contends that the patents, by giving Myriad a monopoly, have limited testing options for patients and led to lower-quality tests.

The latest controversy concerns a supplemental test that Myriad is offering.

In 2006, Professor King and colleagues published a paper showing that Myriad's test, known as the Comprehensive BRACAnalysis, actually failed to detect a significant number of genetic alterations in the two genes.

Myriad then developed a test for these alterations. But instead of incorporating it into its main product, it offered it as a supplemental test at a price of $700. Many insurers do not pay for it, and therefore many women do not get it.

Myriad's data shows that for Latina women in particular, 20 percent of all mutations found are detectable only by the supplemental test.

"The comprehensive testing they are advertising is not really comprehensive," said Ellen T. Matloff, director of cancer genetic counseling at Yale, who is also a plaintiff in the patent lawsuit. "This would not happen in a competitive market. It simply would be unacceptable."

More than 200 doctors, genetic counselors and other health care professionals have signed an open letter to Myriad urging it to incorporate the supplemental testing into the main test.

Kathleen Maxian says that if that had been done earlier, she might not be fighting for her life against ovarian cancer.

Her sister developed breast cancer at age 40 about five years ago, but tested negative for mutations on Myriad's main test. She was not offered the supplemental test.

Two years ago, Ms. Maxian developed ovarian cancer. It turned out that both she and her sister had genetic alterations that were detectable only by the supplemental test.

"If my sister had had that test and had gotten a positive result, I would have gone to a genetic counselor and have been tested," said Ms. Maxian, who is 49 and lives in Pendleton, N.Y., near Buffalo. She would then have had the option of having her ovaries removed to avoid getting ovarian cancer.

"I don't want to see this happen to anyone else," she said. "Women should have this test."

Mr. Capone of Myriad said the company kept the test separate because insurers would not pay for it. The company has now compiled the data necessary to arrange for reimbursement and is moving to incorporate that testing into its main product.

He said only 1 percent of women over all would have a mutation detected only by the supplemental test.

The future challenge for Myriad is from new sequencing machines and techniques. Last year, Professor King and colleagues published a paper on a technique that can test BRCA1 and BRCA2, as well as 20 other genes that contribute to breast cancer risk, and at a cost much lower than Myriad's.

Some companies like Knome already offer sequencing of a person's full genome. Prices are still high — Illumina, for instance, charges $9,500 — but are dropping rapidly. Others, like GenomeQuest, are developing software tools to analyze the genetic information.

Lawyers say it is not clear if sequencing a person's whole genome and then providing information on mutations in the BRCA genes would violate Myriad's patents on the isolated genes.

Mr. Capone said that full genome sequencing did not yet meet the requirements for accuracy required of a medical diagnostic test. And the reported cost of sequencing a human genome does not include the significant cost of analyzing the data.

“It will probably take four years or more before whole genome sequencing can be done clinically,” Mr. Capone said. By then, Myriad will have developed its test using new sequencers that will judge the risk of all hereditary cancers, not just hereditary breast and ovarian cancers.

Many analysts like the stock, though Isaac Ro of Goldman Sachs rates it a sell, saying the price of the breast-cancer risk test is unsustainable.

For now, sales of the breast cancer risk test continue to grow, rising 10 percent in the last fiscal year. Mr. Capone said that many women who were eligible for testing under medical guidelines were still not getting tested, leaving a large untapped market.

Myriad is also trying to diversify. It sells seven other tests, including one for the risk of inherited colon cancer and one that helps guide prostate cancer treatment by gauging a tumor’s aggressiveness.

It has at least 13 other tests in development and is moving into so-called companion diagnostics, which are tests to show whether a particular drug is appropriate for a particular patient.

But so far, the other tests pale beside the one for breast cancer. Professor Tavtigian said Myriad insiders refer to the company’s product portfolio as Snow White and the Seven Dwarfs. END

APPENDIX 1

SUBMISSIONS RECEIVED

Submission Number	Submitter
1	Dr Charles Lawson
2	Professor Judy Kirk
3	Mr Adam Johnston
4	The Royal College of Pathologists of Australia
5	Human Genetics Society of Australasia
6	Mr Christopher Aitchison
7	Bayer CropScience
8	Cancer Voices NSW
9	The Royal Australasian College of Physicians
10	Mr Paul McCormack
11	Cancer Voices Australia
12	Amgen Australia
13	Perth Bone and Tissue Bank
14	Abbott Australasia
15	South Australian Government
16	Consumers Health Forum of Australia
17	Davies Collison Cave
18	Dr Ann Kurts, Dr Mark Lutherborrow and Professor Natalie Stoianoff
19	Professor Andrew Christie
20	Dr Malcolm Lyons
21	Mr Doug Calhoun
22	Australian Medical Association
23	SciVentures
24	Peter MacCallum Cancer Centre
25	Professor Peter Drahos
26	Liberty Victoria
27	Australian Reproductive Health Alliance
28	Group of Eight
29	Dr Hazel Moir
30	Australian Law Reform Commission
31	ChemSkill
32	Sanofi-Aventis
33	National Coalition of Public Pathology
34	Australian Institute for Innovation
35	International Federation of Intellectual Property Attorneys
36	Foursight Associates
37	Ms Stephanie Gleeson
38	Metabolic Pharmaceuticals

39	Professor Dianne Nicol, Mr Johnathon Liddicoat, Dr Jane Nielsen and Mr Ben Mee
40	Dr Chris Dent
41	La Trobe University
42	Roche
43	Ms Elizabeth Gleeson
44	St Vincent's Institute of Medical Research
45	Grasslanz Technology Limited
46	National Health and Medical Research Council
47	Griffith Hack and Griffith Hack Lawyers
48	Law Council of Australia
49	Institute of Patent and Trade Mark Attorneys of Australia
50	Dr Teresa Schafer, Mr Tim Clark and Mr George Raitt (partners in Piper Alderman)
51	Agrifood Awareness Australia
52	Eli Lilly Australia
53	James and Wells Intellectual Property
54	University of Western Sydney, University of Sydney, University of New South Wales, Macquarie University, University of Wollongong and Newcastle University
55	Ms Anna George
56	CSL
57	IVD Australia
58	Hexima
59	Walter and Eliza Hall Institute of Medical Research
60	Pfizer Australia
61	Dr Jennifer Leary
62	Knowledge Commercialisation Australasia
63	Association of Australian Medical Research Institutes
64	Garvan Institute of Medical Research
65	CropLife Australia
66	Sydnovate
67	BioMelbourne Network
68	Department of Health and Ageing
69	GlaxoSmithKline Australia
70	Mylan
71	Generic Medicines Industry Association
72	Cancer Council Australia and Clinical Oncological Society of Australia
73	Prima BioMed
74	Mr Geoffrey Burton
75	Alphapharm
76	Merck Serono Australia
77	FB Rice and Co
78	CSIRO
79	Mr Craig Patterson

80	ResMed
81	Genetic Technologies
82	Merck Sharp and Dohme Australia
83	Dr Mark Summerfield
84	Breast Cancer Action Group NSW
85	Biomedical Consulting Services
86	Biotechnology Industry Organization
87	Shelston IP
88	Murdoch Childrens Research Institute
89	Medicines Australia
90	Grains Research and Development Corporation
91	Baxter Healthcare
92	Professor Ian Frazer
93	Bristol-Myers Squibb Australia
94	Department of Innovation, Industry, Science and Research and IP Australia
95	Licensing Executives Society of Australia and New Zealand
96	Tasmanian Government
97	AusBiotech
98	Australian Academy of Technological Sciences and Engineering
99	Mooroolbark Technology
100	Australian Academy of Science
101	Janssen, Pharmaceutical Companies of Johnson and Johnson
102	Meat and Livestock Australia
103	Dr Luigi Palombi
104	MS Research Australia
105	Industry and Investment NSW
106	Gene Ethics
107	Confidential
108	Confidential
109	The Burnet Institute
110	Amercian Intellectual Property Law Association
111	Dr Warwick Neville FM, Dr Luigi Palombi, Dr Buddhima Lokuge
112	Victorian Government
113	Ms Katrina Howard
114	Genzyme Australasia
115	Mr John Wood
116	Ms Joanne Mulcahy
117	Ms Lin Stuart
118	Mrs Emily Wallis
119	Ms Wilma Western
120	Name Withheld
121	Name Withheld
122	Greenpeace Australia Pacific

ADDITIONAL INFORMATION RECEIVED

1 Amendment to the Bill tabled by Senator the Hon Bill Heffernan on 28 April 2011

2 Answer to Question on Notice provided by the Royal College of Pathologists of Australasia on 3 May 2011

3 Answer to Question on Notice provided by Professor Dianne Nicol and Mr Johnathon Liddicoat on 12 May 2011

4 Answer to Question on Notice provided by Dr Luigi Palombi on 12 May 2011

5 Answer to Question on Notice provided by Generic Medicines Industry Association on 12 May 2011

6 Answer to Question on Notice provided by CropLife Australia on 13 May 2011

7 Answer to Question on Notice provided by Walter and Eliza Hall Institute of Medical Research on 13 May 2011

8 Answer to Question on Notice provided by Medicines Australia on 17 May 2011

9 Clarification of evidence provided by CropLife Australia on 31 May 2011

10 Correspondence received from Government of Brazil on 8 June 2011

APPENDIX 2

WITNESSES WHO APPEARED BEFORE THE COMMITTEE

Canberra, 28 April 2011

CLARK, Dr Julian, Head of Business Development, Walter and Eliza Hall Institute of Medical Research

CROSS, Dr Martin, Chairman, Generic Medicines Industry Association

DAVIES, Dr Trevor, Councillor, Institute of Patent and Trade Mark Attorneys

DRAHOS, Professor Peter, Director, Centre for Governance of Knowledge and Development, Australian National University

HAMER, Mr Richard, Deputy Chairman, Intellectual Property Committee, Business Law Section, Law Council of Australia

HANNAH, Mr Colin, Vice President, Australia and New Zealand, Hospira Pty Ltd; Board Member, Generic Medicines Industry Association

HILTON, Professor Douglas, Director, Walter and Eliza Hall Institute of Medical Research

JARVIS, Mr Richard, Member, Intellectual Property Committee, Law Council of Australia

LIDDICOAT, Mr Johnathon, Private capacity

LOFTHOUSE, Dr Shari, Manager of Intellectual Property and Development and Acting Director of Commercialisation, Peter MacCullum Cancer Centre

MITCHELL, Dr Gillian, Clinical Oncologist and Director, Familial Cancer Centre, Peter MacCallum Cancer Centre

MONK, Ms Deborah, Director, Innovation and Industry Policy, Medicines Australia

MURPHY, Mr Tim, Co-Chair, Innovation Strategic Committee, Medicines Australia; Head, Government Affairs and Policy, GlaxoSmithKline Australia

NICOL, Professor Dianne, Private capacity

OBRANOVICH, Dr Tania, Fellow, Institute of Patent and Trade Mark Attorneys

OLVER, Professor Ian, Chief Executive Officer, Cancer Council Australia

SHAW, Dr Brendan, Chief Executive, Medicines Australia

SUTHERS, Dr Graeme, Chair, Genetics Advisory Committee, Royal College of Pathologists of Australasia

Canberra, 29 April 2011

BEATTIE, Mrs Fatima, Deputy Director-General, IP Australia

CHRISTIE, Professor Andrew, Private capacity

COSSEY, Mr Matthew, Chief Executive Officer, CropLife Australia

HALTON, Ms Jane, Secretary, Department of Health and Ageing

LAVELLE, Dr Anna, Chief Executive Officer, AusBiotech

LUNN, Mr Peter, Manager, Pharmaceuticals and Health Technologies Section, Department of Innovation, Industry, Science and Research

McDONALD, Ms Mary, First Assistant Secretary, Regulatory Policy and Governance Division, Department of Health and Ageing

MOORE, Ms Terry, Director, Domestic Policy, IP Australia

PALOMBI, Dr Luigi, Private capacity

PETERS, Dr Kirrily, Manager, Pharmaceuticals Industry Strategy and Environment Section, Department of Innovation, Industry, Science and Research

PRESS, Ms Lexie, Examiner of Patents, IP Australia

QUINN, Mr Daniel, Policy Manager, Biotechnology, and Policy Manager, Minor Use, CropLife Australia

REID, Mr Chris, General Counsel, Department of Health and Ageing