Parliament of Australia
Department of Parliamentary Services

PARLIAMENTARY LIBRARY
INFORMATION ANALYSIS ADVICE

BILLS DIGEST NO. 107, 2010–11 11 May 2011

Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2]

Roger Beckmann
Science, Technology, Environment and Resources Section

Sharon Scully
Law and Bills Digest Section

This Digest replaces an earlier version dated 10 May 2011.

Contents

ISSN 1328-8091

Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2]

Date introduced: 24 November 2010

House: Senate

Portfolio: Senators Coonan, Heffernan, Siewert and Xenophon

Commencement: on the day after Royal Assent

Links: The links to the Bill, its Explanatory Memorandum and second reading speech can be found on the Bills home page, or through http://www.aph.gov.au/bills/. When Bills have been passed and have received Royal Assent, they become Acts, which can be found at the ComLaw website at http://www.comlaw.gov.au/.

Purpose

The stated aim of the Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2] (the Senate Bill) is to amend the *Patents Act 1990* (the Patents Act) by:

> expressly excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature, however made.[1]

The proposed amendments in the Senate Bill aim to enable doctors, clinicians, and medical and scientific researchers to gain unfettered access to biological materials, including genes, that are identical or substantially identical to those materials existing in nature, irrespective of how those materials are made. By doing so, it is hoped that the proposed amendments will advance the diagnosis and treatment of human illness and disease as well as scientific and medical research.[2]

Background information

Introductory comments

The title of the Senate Bill is ambiguous in that it is unclear from reading it whether the Bill applies to human biological materials or to both human and non-human biological materials.

However, it appears that according to **items 3** and **4** of the Senate Bill, the Bill would apply to both human and non-human biological materials. Consequently, the proposed amendments would

1. Explanatory Memorandum, Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No. 2], p. 2.
2. Ibid.

potentially affect a broad range of industries, such as biotechnological and pharmaceutical industries, as well as agricultural and animal protection industries, and bio-prospecting.

It should also be noted that by applying to non-human biological materials, the Senate Bill goes much further than the preceding debates about gene patents.

Genes and patents

Biotechnology has advanced rapidly in the last two decades. Knowledge of what constitutes a gene, and how genes work, has grown considerably.

Genes hold the information for the construction and operation of all living organisms. As a result, knowledge of human genes is of increasing medical and commercial importance. Debate continues vigorously in Australia and elsewhere over whether genes can be patented and, if so, whether such patenting represents, on the whole, a good or bad thing for society. This particularly applies to human genes.

Genes are made of the chemical deoxyribonucleic acid (DNA). Different versions of a gene are known as alleles. Further smaller differences, called single nucleotide polymorphisms (SNPs), also exist. Certain alleles or polymorphisms are associated with increased susceptibility to various diseases. Corporations may be interested not only in patenting genes, but also in acquiring and patenting information related to polymorphisms, because it is these small differences that are crucial in distinguishing the susceptibilities of one individual from another. For example, the Australian patent application to IP Australia by Myriad Genetics concerns the 'in vivo mutations and polymorphisms' of a gene associated with increased susceptibility to breast and ovarian cancer.[3]

Debates about gene patenting

The argument has been made that genes are merely chemicals isolated from living things. Following their isolation, these chemicals are not in the same form as they were within the organism. Therefore, the process for identifying and extracting the gene is patentable, and possibly the extracted, isolated DNA itself should also be, because following extraction it is no longer in exactly the same form in which it occurred in vivo. However, the information that a gene carries—which is the matter of interest—seems to remain a product of nature even after a gene is extracted, unless this information is altered.

The debate about 'gene patenting' thus turns not only on definitions of patents and of genes, but also on the degree of modification that turns a product of nature into a product of human invention. An isolated stretch or sequence of DNA that codes for a biological product can be modified from the

3 . IP Australia: AusPat Application Details, as stored by Genomics Law Report, viewed 19 April 2011, http://www.genomicslawreport.com/wp-content/uploads/2010/09/Myriad-AUS-Patent-686004.pdf

naturally occurring form without substantially changing the functional effect of the product that it encodes. This would create a gene that does not exist in nature but is functionally the same. Alternatively, the sequence could be modified to produce a different product. In both cases, the gene as it exists in nature has been chemically altered. The key point is the information that is written within the DNA.

The international Human Genome Project completed the mapping and sequencing of the human genome in 2003, with the information freely available to all researchers. Much of the commercial work in this area has occurred in the United States of America (the US). The practice of the US Patent and Trademark Office was that 'isolation and purification' of a gene was sufficient to warrant a patent. It was estimated in 2005 that about 20 per cent of all known human genes were involved in patents in the USA.[4] This position appears to be changing, following the announcement by the US Department of Justice in October 2010 that 'human and other genes should not be eligible for patents because they are part of nature.'[5]

However, the question still remains - will all the genes composing the entire human genome eventually be involved in patents? If a single corporation in the future were to acquire all patents pertaining to human genes, would that entity hold too much power over medical advances and, down the track, over putative modifications to the human genome? The Patents Act, in its existing form, prevents any patenting of human beings. Biologically speaking, the entire genome of an organism represents the distillation of the organism (all the information necessary for it to come into existence), so holding patents over each of the individual parts that make up the entire human genome would come close to patenting people.

Subject matter of patent claims

It should be pointed out that companies may not necessarily try to patent a human gene itself. They may argue that they are patenting a modification of this gene (that is, something that does not exist in nature), or part of the gene. They may take out a patent on a means of testing for whether a gene is defective. Such a test relies on knowledge of the different alleles (forms of the gene) that can occur in humans, and hence rests on the knowledge that the researchers have elucidated. However, the actual alleles themselves are not patented.

It is argued by some stakeholders that the isolation of a gene—its release from its natural surrounds and it being made available for the first time—could be an invention rather than discovery, as long

4. K Jensen and F Murray, 'Intellectual property landscape of the human genome', *Science*, vol. 310, 14 October 2005; JF Merz and MK Cho, 'What are gene patents and why are people worried about them?', *Community Genetics,* vol. 8, no. 4, 2005, pp.203-208, viewed 18 April 2011, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2220018/
5. A Pollack, 'U.S. says genes should not be eligible for patents', *New York Times* website, 29 October 2010, viewed 19 April 2011, http://www.nytimes.com/2010/10/30/business/30drug.html

as the requirements for patentability are met.[6] However, a counter-argument is that this is analogous to the situation of purifying iron from iron ore. The ore is naturally occurring; iron ingots are not, but they are derived from ore which has been identified in nature, extracted from nature, and then processed.

Biological materials and patents

The following information has been obtained from the joint submission to the Legal and Constitutional Committee's inquiry by the Department of Innovation, Industry, Science and Research and IP Australia.

As they occur in their natural state, biological materials are not eligible for patenting.[7]

However, isolated and purified biological materials are patentable if the requirements for patentability under the Patents Act, as described later in the Digest, are satisfied.[8]

Biological materials isolated from animals, plants and micro-organisms have been and continue to be important sources of many types of medicines including anti-cancer treatment, anti-bacterial and anti-viral agents.[9] It is also noted that isolated biological materials are also often used as templates for synthetic modifications to produce improved versions of therapeutic goods, such as insulin to treat diabetes.[10]

Discovery or invention?

The amendments proposed in this Bill use the phrase 'identical or substantially identical' to biological materials found in nature. However, the degree of change required to a naturally occurring DNA sequence to make it a novel product is not spelt out in the Senate Bill.

It is unclear how synthetic DNA, inspired by a natural sequence, will be regarded. There has recently been discussion about 'open source' biology, which parallels the situation with open source software (see, for example, *Biology is technology*, Robert H. Carlson, Harvard University Press, 2010). In this analogy, DNA sequences are like software code. Enthusiasts call for both to be made freely available, as this will stimulate more innovation. The crucial difference, of course, is that software code has been created, whereas DNA sequences exist in nature. However, the analogy becomes more valid

6. See, for example, the joint submission to the Legal and Constitutional Committee's inquiry by the Department of Innovation, Industry, Science and Research and IP Australia, pp. 7, 10–11, viewed 4 May 2011, http://www.aph.gov.au/senate/committee/legcon_ctte/patent_amendment/submissions.htm
As for patentability requirements, see the 'Validity of patents' section below in this Digest.
7. See, the joint submission to the Legal and Constitutional Committee's inquiry by the Department of Innovation, Industry, Science and Research and IP Australia, op. cit., p. 3.
8. Ibid.
9. Ibid., p. 18.
10. Ibid.

when considering synthetic sequences of DNA. In this case, the actual molecules of DNA created are not naturally occurring, even though DNA itself is a naturally occurring substance. If scientists modify a DNA sequence that has come from nature, the new product may be patentable.

Another analogy is to the use of the English language or the Roman alphabet. Neither English words nor the letters of the alphabet are owned or patented. They are 'naturally occurring.' However, a particular sequence of words – ranging from a couple of words in a slogan to an entire novel – can be copyrighted and owned by their creator.

A transgenic organism, which does not exist in nature, is clearly an invention and not a discovery. However, all the chemical components of the organism (apart from some altered DNA sequences) are 'substantially identical' to those occurring in nature, which would prevent the patenting of GMOs in areas such as agriculture.

For more on the scientific background and terminology around genes and biotechnology, see Appendix 1 to this Digest.

Patent law in Australia

Only a summary of laws relating to what is a patent and the validity thereof will be given in this Digest, as a comprehensive outline of the law is set out in the reports by the Australian Law Reform Commission (the ALRC) and the Senate Standing Committee for Community Affairs (the Community Affairs Reference Committee).[11]

Domestic legal framework

The Commonwealth Parliament's power to make laws relating to patents derives from section 51(xviii) of the *Commonwealth of Australia Constitution Act* (the Constitution).

The Patents Act and Patents Regulations 1991 (the Patents Regulations) are the primary legislation regulating the patents regime in Australia.

What is a patent?

A patent is an intellectual property[12] right granted for 'any device, substance, method or process which is new, inventive and useful'[13], as well as being legally enforceable, giving the owner exclusive

11. See Australian Law Reform Commission (ALRC), *Genes and ingenuity*, Report 99, June 2004, Chapters 4 and 5, viewed 8 April 2011, http://www.alrc.gov.au/publications/report-99 (international and domestic legal frameworks); Community Affairs References Committee, *Gene patents*, November 2010, Chapter 2, viewed 8 April 2011, http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/index.htm (Australia's patent system).
12. As for the meaning of 'intellectual property', see IP Australia, *What is intellectual property?*, viewed 8 April 2011, http://www.ipaustralia.gov.au/ip/index.shtml

right to commercially exploit the invention in a patent area[14], for a specified time.[15] In other words, a patent grants a monopoly to the patent holder to exploit the invention for a limited period of time.[16] However, this right is not absolute as patent holders may have to satisfy other legal requirements to commercially exploit the invention.[17]

There are two types of patents:

- standard patent – protection and control for up to 20 years and
- innovation patent – protection and control for up to 8 years.[18]

An innovation patent is not available for plants or animals, or the biological processes for the generation thereof.[19]

Human beings, and the biological processes for the generation thereof, are not considered to be patentable inventions for the purposes of both standard and innovation patents.[20]

The Patent Office of IP Australia administers the patents regime in Australia.[21]

Validity of patents

Patents are granted for patentable inventions not discoveries.

In particular, section 18 of the Patents Act provides that:

> 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 meaning 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:

13. IP Australia, 'What is a patent?', viewed 8 April 2011, http://www.ipaustralia.gov.au/patents/what_index.shtml
14. As to the meaning of 'patent area', see also *Patents Act 1990*, Schedule 1 Dictionary. For the meaning of 'exploit', see, for example, ibid., section 119A(5) and Schedule 1 Dictionary.
15. IP Australia, 'What is a patent?', op. cit. See also *Patents Act 1990*, section 13. Patent rights may also be assigned: *Patents Act 1990*, section 14. Patent protection overseas is also available: see IP Australia, *The Patents Guide*, pp. 24–26, viewed 8 April 2011, http://www.ipaustralia.gov.au/pdfs/patents/patentsguide.pdf
16. See Community Affairs References Committee, op. cit., p. 8; ALRC, op. cit., [2.11].
17. An example of such other legal requirements is approval under the *Therapeutic Goods Act 1989* for a pharmaceutical compound: ALRC, *Genes and ingenuity*, op. cit., [2.11].
18. IP Australia, 'What is a patent?', op. cit. See also *Patents Act 1990*, sections 67 and 68, Schedule 1 Dictionary.
19. *Patents Act 1990*, subsection 18(3). See also IP Australia, 'Australian patents for biological inventions', pp. 5-6, viewed 8 April 2011, http://www.ipaustralia.gov.au/pdfs/patents/specific/biotech.pdf
20. *Patents Act 1990*, subsection 18(2). See also IP Australia, *Patent Manual of Practice and Procedures*, vol. 2, 2.9.5, viewed 8 April 2011, http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm
21. ALRC, op. cit., [5.7].

> (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 patent holder or nominated person or the patent holder's or nominated person's predecessor in title to the invention.[22]

This is subject to subsection 18(2) of the Patents Act, which states that human beings, and the biological processes for their generation, are not patentable inventions.

Importantly, 'manner of manufacture' directly relates to the subject matter of a patent—a patent must relate to something created artificially.[23] However, the Patents Act does not define 'manner of manufacture', but gives this term the meaning which is set out in section 6 of the *Statute of Monopolies (1623)* (the Statute of Monopolies). The Statute of Monopolies abolished all monopolies except where:

- the patent is granted to the first inventor
- the invention is new
- the patent neither hurts trade nor increases prices of the commodity and
- the patent is not 'generally inconvenient'.

In Australia, 'manner of manufacture' has generally been interpreted more broadly by the courts.[24] The High Court of Australia has stated that:

> The point is that a process, to fall within the limits of patentability which the context of the Statute of Monopolies has supplied, must be one that offers some advantage which is material, in the sense that the

22. For the meaning of 'invention', see *Patents Act 1990*, Schedule 1 Dictionary.
'Novel' means that the invention must not have been publicly disclosed in any form, anywhere: see IP Australia, *The Patents Guide*, op. cit., p. 4. See also *Patents Act 1990*, subsection 7(1).
'Inventive step' means the invention must not be obvious to anyone with knowledge and experience in the technological field of the invention: see IP Australia, *The Patents Guide*, op. cit., p. 4; IP Australia, *Patent Manual of Practice and Procedures*, op. cit., vol. 2, 2.5.1.1. See also *Patents Act 1990*, subsections 7(2) and (3).
For the meaning of 'prior art base', see *Patents Act 1990*, Schedule 1 Dictionary.
'Priority date' means the date on which the patent application is initially filed or as otherwise prescribed by the regulations: *Patents Act 1990*, subsection 43(2). See also IP Australia, *Patent Manual of Practice and Procedures*, op. cit., vol. 2, 2.12. The filing date is determined under the Patent Regulations 1991 regulations 3.5 and 3.5A.
For the meaning of 'useful', see IP Australia, 'Australian patents for biological inventions', op. cit., p. 2.
As to secret use, see *Patents Act 1990*, section 9.
23. Community Affairs References Committee, *Gene patents*, op. cit., pp. 10–11.
24. See *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252. See also, for example, ALRC, *Genes and ingenuity*, op. cit., [6.22]; Community Affairs References Committee, *Gene patents*, op. cit., pp. 11–12.

> process belongs to a useful art as distinct from a fine art ... that its value to the country is in the field of economic endeavour.[25]

In addition, as noted by the Community Affairs References Committee:

> A number of judicial comments have indicated that the absence of express statutory exclusions has been influential in the willingness of courts to accept broader subject matter as a manner of manufacture.[26]

International legal framework

Australian patent law and practice also operate within an international legal framework. There are several international legal instruments to which Australia is a party, which include:

- *Paris Convention for the Protection of Industrial Property* (the Paris Convention)
- *Patent Cooperation Treaty* (PCT)
- *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977* (the Budapest Treaty) and
- *World Trade Organization Agreement on Free Trade-related Aspects of Intellectual Property Rights* (the TRIPS Agreement).[27]

In addition, Australia may adopt international obligations relating to patents as part of bilateral free trade agreements with other countries, such as the A*ustralia-United States Free Trade Agreement* (AUSFTA), which came into effect on 1 January 2005.[28]

TRIPS Agreement

Particularly relevant to arguments surrounding the prohibition of gene patents, paragraph (1) of Article 27 of the TRIPS Agreement provides:

> Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and

25. *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 at [22].
26. See Community Affairs References Committee, *Gene patents*, op. cit., [2.30]. See also *Rescare Ltd v Anaesthetic Supplies Pty Ltd* (1992) 25 IPR 119 at 151 (Gummow J) and *Bristol-Myers Squibb Co v F H Faulding & Company Ltd* (2000) 97 FCR 524.
27. For information about these instruments, see IP Australia, 'Multilateral agreements', viewed 8 April 2011, http://www.ipaustralia.gov.au/resources/international_agreements.shtml
    Copies of the Budapest Treaty and regulations made in relation to that treaty, as well as the PCT, are contained in Patents Regulations 1991 Schedules 1, 1A and 2.
28. See Austrade, 'A*ustralia-United States Free Trade Agreement* (AUSFTA)', viewed 8 April 2011, http://www.austrade.gov.au/AUSFTA/default.aspx
    For further information about other bilateral free trade agreements that Australia has entered or proposes to enter into, see IP Australia, 'Bilateral agreements and arrangements', viewed 8 April 2011, http://www.ipaustralia.gov.au/resources/international_bilateral.shtml

> are capable of industrial application.[29] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

AUSFTA

AUSFTA is said to replicate the TRIPS Agreement requirements for non-discrimination of technologies and exclusions of patentable subject matters. Article 17.9 of AUSFTA relates to patents. Paragraphs 1 and 2 of Article 17.9 state:

> 1. Each Party shall make patents available for any invention, whether a 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 new uses or methods of using a known product. For the purposes of this Article, a Party may treat the terms "inventive step" and "capable of industrial application" as synonymous with the terms "non-obvious" and "useful", respectively.
>
> 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 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.

In addition, Article 17.9.14 of AUSFTA states:

> Each Party shall endeavour to reduce differences in law and practice between their respective systems, including in respect of differences in determining the rights to an invention, the prior art effect of applications for patents, and the division of an application containing multiple inventions. In addition, each Party shall endeavour to participate in international patent harmonisation efforts, including the WIPO for addressing reform and development of the international patent system.

Previous attempts to prohibit gene patents

In Australia, there have been previous attempts to prohibit gene patents. These include the following.

On 28 August 1990, Senator Coulter requested that the Patents Bill 1990 be amended to include an express exclusion from patentability of genetic material generally.[30] Senator Coulter's proposed amendments were not agreed to.[31]

---

29. 'For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.': TRIPS Agreement note 5.
30. See Senator Coulter, 'Second reading speech: Patents Bill 1990', Senate, *Debates,* 22 August 1990, p. 1910.
31. Senate, 'Patents Bill 1990 - Division', *Hansard*, Senate, 20 September 1990, p. 2653.

On 27 June 1996, the Patents Amendment Bill 1996 was introduced in the Senate by Senator Natasha Scott Despoja to prohibit the patenting of naturally occurring genes or genetic sequences. However, the Bill lapsed at the end of Parliament. Senator Scott Despoja proposed similar amendment to the Patents Act in 2001, which also were not incorporated.

Myriad Genetics and BRCA gene patents

Myriad Genetics (Myriad) is a molecular diagnostic company, focusing on developing and marketing new predictive and prognostic medical products to assess a person's risk of developing disease and guide treatment decisions.[32]

Myriad is the holder of various patents, including patents over the BRCA1 and BRCA2 genes (and naturally occurring variations to them) and diagnostic methods for testing mutations in these genes, which are associated with an increased predisposition to breast and ovarian cancers.

In March 2010, a United States District Court judge found that several claims in Myriad's BRCA patents were invalid—ruling that isolated BRCA genes are not patentable subject matter under section 101 of the United States Patent Act, as they are not markedly different from what occurs in nature. An appeal against the decision in this case has been lodged in the Court of Appeals for the Federal Circuit and oral arguments were expected to commence on 4 April 2011.[33]

It is noted that proceedings were also commenced in the Federal Court of Australia on 8 June 2010, challenging a BRCA1 patent held by Myriad and it is stated that a provisional date has been set for hearing this matter on 19 September 2011.[34]

Myriad has now offered to 'gift' one of its patents to the Australian people, and has filed with the Australian Official Journal of Patents an offer to surrender Australian Patent No 686004 (known as the '004 Patent).[35]

Recent inquiries into genes and the subject matter of patents

Several inquiries have been conducted in recent times into the impacts of gene patents on access to healthcare, as well as genetic and biomedical research.

---

32. See Myriad Genetics Inc., 'Fact sheet', viewed 1 April 2011, http://files.shareholder.com/downloads/MYGN/1209888423x0x337525/553a046d-64ce-4218-8431-36e0e2515287/Fact_Sheet_V3___12-6-09.pdf
33. M Murphy, 'United States weighs in on the Myriad Genetics case', *National Law Review*, 7 November 2010, viewed 1 April 2011, http://www.natlawreview.com/article/united-states-weighs-myriad-genetics-case
34. Submission to the Legal and Constitutional Committee's inquiry by Department of Innovation, Industry, Science and Research and IP Australia, p. 4 (see also note 45 below).
35. Australian Official Journal of Patents, 2 September 2010, viewed 19 April 2011, http://www.genomicslawreport.com/wp-content/uploads/2010/09/Myriad-AUS-Patent-Surrender.pdf

Australian Law Reform Commission (2004)

In December 2002, the federal Attorney-General at the time requested that the Australian Law Reform Commission (the ALRC) inquire into 'the laws and practices governing intellectual property rights over genetic materials and related technologies, with a particular focus on human health issues'.[36]

It is noted that one of many recommendations made by the ALRC in its report was that the Patents Act not be amended to exclude genetic materials or technologies from being patented, but that patent applications relating to such materials and technologies should be assessed according to the same legislative criteria for patentability applying to patent applications that relate to any other type of technology. [37]

At the time of writing, the Government had not yet formally responded to the ALRC's report.

Senate Standing Committee for Community Affairs (2010)

On 30 September 2010, the Senate requested that the Community Affairs References Committee inquire into the impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form.[38]

---

36. Australian Law Reform Commission, 'Gene patenting', viewed 31 March 2011, http://www.alrc.gov.au/inquiries/gene-patenting
For Terms of Reference, see Australian Law Reform Commission, 'Terms of Reference - intellectual property rights over genetic materials and genetic and related technologies', viewed 31 March 2011, http://www.alrc.gov.au/inquiries/gene-patenting/terms-of-reference
37. ALRC, *Genes and ingenuity*, op. cit., Recommendations 6-1 and 7-1.
38. The Committee were asked to inquire into and report on:

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

Following the federal election in 2010, the Senate re-referred this inquiry with the same terms of reference as the Community Affairs References Committee's previous inquiry during the 42nd Parliament so that the Committee could complete and table its report.[39]

It is noted that, among its many recommendations, the Community Affairs References Committee did not recommend that the Patents Act be amended to include an express prohibition on human genes and genetic products.[40]

Australian Council for Intellectual Property (2010)

Following the ALRC's recommendation in its report on gene patents that the manner of manufacture test be reviewed, the then Minister for Innovation, Industry, Science and Research requested that the Advisory Council on Intellectual Property (ACIP) conduct the review.[41]

ACIP's report was released on 19 February 2011.[42] In its report, ACIP concluded that no persuasive case had been made to specifically exclude the patenting of human genes and genetic products.[43]

IP Australia draft Bill (2011)

On 3 March 2011, IP Australia announced that, following previous consultations in 2009 and 2010, it has completed an exposure draft version of the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Raising the Bar Bill), with the aim of raising intellectual property standards across all technologies.[44]

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

(c) whether the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent monopolies over such materials: Community Affairs References Committee, 'Terms of Reference', *Inquiry into gene patents*, viewed 31 March 2011, http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents_43/tor.htm

39. For a copy of the report, see Community Affairs References Committee, *Gene patents*, op. cit.
40. Ibid., [4.129].
41. ALRC, op. cit., Recommendation 6-2; Advisory Council on Intellectual Property (ACIP), 'Review of patentable subject matter', viewed 31 March 2011, http://www.acip.gov.au/reviews_completed.html
42. For a copy of ACIP's report, see ACIP, *Patentable subject matter*, Final report, December 2010 (released 16 February 2011), viewed 8 April 2011, http://www.acip.gov.au/library/ACIP%20PSM%20final%20report%204%20Feb%202011.pdf
43. Ibid., p. 14.
44. IP Australia, 'Third Round of Public Consultation on IP Rights Reforms', in W*hat's new*, 3 March 2011, viewed 5 April 2011, http://www.ipaustralia.gov.au/resources/news_new.shtml

In particular, Schedule 2 of the Raising the Bar Bill proposes to amend the Patents Act so as to expressly provide for an experimental purposes exemption (see comments relating to research use exemption in relation to patents in Appendix 3). Proposed section 119C provides:

> (1) A person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention.
>
> (2) For the purposes of this section, ***experimental purposes*** relating to the subject matter of the invention include, but are not limited to, the following:
>
> (a) determining the properties of the invention;
>
> (b) determining the scope of a claim relating to the invention;
>
> (c) improving or modifying the invention;
>
> (d) determining the validity of the patent or of a claim relating to the invention;
>
> (e) determining whether the patent for the invention has been infringed.

Recent debate relating to gene patents

As mentioned above, the subject of gene patents has been the subject of debate for several years and there have been recent court challenges to gene patents, both here and in the US.[45]

In 2010, Melissa Parke MP sought to move that the Patents Act be amended 'to ensure that patents cannot be granted over any biological materials which are identical or substantially identical to what exists in nature.'[46] According to Ms Parke, 'I'm certainly hoping that this will be a Government bill and I will continue to advocate within the caucus and to the relevant ministers for this'.[47]

45. See ABC, 'US judge rules cancer gene patent invalid', *PM*, 30 March 2010, viewed 8 April 2011, http://www.abc.net.au/pm/content/2010/s2860484.htm; LifeScientist, *BRCA1 gene patent challenged in Australian court*, 8 June 2010, viewed 8 April 2011, http://www.lifescientist.com.au/article/349307/brca1_gene_patent_challenged_australian_court/
46. See House of Representatives, *Notice Paper*, 30 September 2010, pp. 6–7, viewed 8 April 2011, http://parlinfo.aph.gov.au/parlInfo/download/chamber/noticer/20100930_RNP002/toc_pdf/rnp002.pdf;fileType=application/pdf#search=%22parke%22
    Ms Parke's Notice of Motion continues to be listed for subsequent sitting days in 2011: see, for example, House of Representatives, *Notice Paper*, 10 February 2011, pp. 26–27, viewed 8 April 2011, http://parlinfo.aph.gov.au/parlInfo/download/chamber/noticer/20110210_RNP021/toc_pdf/rnp021.pdf;fileType=application/pdf#search=%22parke%20gene%22
47. ABC, 'Motion to ban gene patenting', *The World Today*, 30 September 2010, viewed 8 April 2011, http://www.abc.net.au/worldtoday/content/2010/s3025990.htm?site=canberra

The House of Representatives Bill

The Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the House of Representatives Bill) was introduced into Parliament on 21 February 2011 by P Dutton, R Oakeshott, J Forrest and M Turnbull.

The House of Representatives Bill is virtually identical to the Senate Bill. The only difference is in relation to **item 4** of both Bills. **Item 4** of the Senate Bill provides:

> Insert:
>
> (5) In this section:
>
> ***biological materials***, in section 18, includes DNA, RNA, proteins, cells and fluids.

Item 4 of the House of Representatives Bill does not include 'in section 18'.

Committee consideration

The Senate Bill has been referred to the Senate Standing Committee on Legal and Constitutional Affairs (the Legal and Constitutional Committee) for inquiry and report by 16 June 2011.[48]

In addition, the Senate Standing Committee for the Scrutiny of Bills reviewed the Senate Bill and did not make any comment on it.[49]

Position of major interest groups

The various inquiries into gene patenting, including the current inquiry into the Senate Bill by the Legal and Constitutional Committee, have stimulated a large number of comments by major interest groups.[50]

Comments in submissions available as at 31 March 2011 will be addressed wherever relevant in the Key provisions section of this Digest.

48. Details of the inquiry are at http://www.aph.gov.au/senate/committee/legcon_ctte/patent_amendment/info.htm
49. See Senate Standing Committee for the Scrutiny of Bills, *Alert Digest*, No. 1 of 2011, 9 February 2011, p. 31, viewed 8 April 2011, http://www.aph.gov.au/senate/committee/scrutiny/alerts/2011/d01.pdf
50. Submissions are available at: http://www.aph.gov.au/senate/committee/legcon_ctte/patent_amendment/submissions.htm

Key/important issues

Uncertain effect of the proposed amendments

It is stated in the Explanatory Memorandum that:

> 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.[51]

It is then explained that the legislation has been expanded to ensure that 'biological materials', '[including DNA, RNA, proteins, cells and fluids]', and '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' are expressly excluded from patentability to ensure that natural phenomena are not patentable inventions and thus subject to restricted use.[52]

The application of the proposed amendments is uncertain and is likely to significantly expand the scope of subsection 18(2) of the Patents Act with respect to what would not be patentable inventions under the Act.

Should genes be excluded from patenting?

In the various inquiries mentioned above, those arguing that genes should not be patentable base their argument on several grounds. These grounds include that:

- the commercial exploitation of gene patents has the potential to:
  - adversely affect matters such as incentives to conduct genetic and biotechnological research; as well as costs of and access to genetic testing, and
  - reduce competition, and
- genes are discoveries not inventions and, consequently, are not patentable.[53]

On the other hand, those arguing that genes should be patentable argue that:

- prohibiting gene patents may result in:
  - creating a situation where Australia breaches its international law obligations

51. Explanatory Memorandum, op. cit., p. 2.
52. See subsections 18(2) and (3) of the Senate Bill.
53. See, for example, ALRC, *Genes and ingenuity*, op. cit., Chapters 12, 19 and 20; Community Affairs References Committee, *Gene patents*, op. cit., pp.35–39. See also discussion on pp. 6–7 of this Digest.

  - creating a situation incompatible with global obligations to harmonise patent laws
  - adverse impacts on domestic and international investment in Australian genetic and biomedical research and development

- the distinction between discoveries and inventions is not clear cut, and
- there is insufficient empirical evidence to prove that gene patents adversely affect matters such as costs and access to genetic testing.[54]

Alternatives to prohibiting gene patents

It has been suggested that, perhaps, the concerns about gene patents have more to do with how these patents are exploited commercially, instead of their mere existence.[55] Consequently, both the ALRC and Community Affairs References Committee explored alternative means of addressing those problems.[56] These include, but are not limited to:

- Crown use provisions
- compulsory licensing
- research exemption, and
- competition laws.[57]

Financial implications

The Explanatory Memorandum is silent about any financial implications of the Senate Bill.

Key provisions

Items 1 and 2

Items 1 and **2** of the Senate Bill propose to **amend paragraphs 18(1)(a)** and **18(1A)(a)** in the Patents Act.

54. See, for example, ALRC, *Genes and ingenuity*, op. cit., [4.31], [6.19], [6.31], [6.33], [12.78]–[12.81], [20.72]–[20.74]; Community Affairs References Committee, *Gene patents*, op. cit., pp. 64–66, [4.31], [4.32], [4.34], [4.87], [4.99]–[4.100].
55. ALRC, *Genes and ingenuity*, op. cit., [20.76].
56. See, for example, ibid., Chapters 22–27 and Community Affairs References Committee, *Gene patents*, op. cit., pp. 120–140.
57. For further discussion about these alternatives, please see Appendix 2 of this Digest.

Currently, these paragraphs provide that an invention is a *patentable invention*, for the purposes of a standard or innovation patent, if the invention:

> is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
>
> ...

Proposed paragraphs 18(1)(a) and **18(1A)(a)** would provide:

> is a manner of manufacture within the *full* meaning*, including the proviso,* of section 6 of the Statute of Monopolies; and ...

Comments

The Explanatory Memorandum states that the Senate Bill reinforces the applicability of the proviso in section 6 of the Statute of Monopolies and reinforces the distinction between discovery and invention.[58]

Professor Luigi Palombi, proponent and author of the Senate Bill, further explains that this amendment strengthens 'the prerequisite of patentable subject matter' and that:

> ... the amendment to section 18(1)(a) overturns two longstanding but, problematic, Full Federal Court decisions. They are *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065 and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* (2000) FCR 524. 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.[59]

The *Statute of Monopolies 1624* (the Statute of Monopolies) is an old English Act, described as England's first legislative expression of patent law, which generally made void past and future patents except for the exceptions as set out the subsequent sections, such as section 6. Section 6, as referred to earlier in this Digest, does not simply contain a proviso but is itself a proviso to that general rule.

At the conclusion of their respective inquiries, both the ALRC and ACIP stated that the wording of section 6 of the Statute of Monopolies is obscure.[60]

---

58. Explanatory Memorandum, op. cit., p. 2.
59. See submission to the Legal and Constitutional Committee's inquiry by L Palombi, 24 February 2011, p. 1. See also *Anaesthetic Supplies Pty Ltd v Rescare Ltd* [1994] FCA 1065 at [76] and *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316 at [12] and [13]. See also ibid., [162] per Finklestein, J in agreement.
60. See ALRC, *Genes and ingenuity*, op. cit., [6.56]; ACIP, *Patentable subject matter*, op. cit., pp. 8–9.

In addition, as mentioned earlier, the concept of invention has not, to date, been limited to the literal meaning of the term 'manner of new manufacture' in the Statute of Monopolies. ACIP has noted that:

> The principles of inherent patentability used by the High Court in the *National Research Development Corporation v Commissioner of Patents* (*NRDC)* decision of 1959, and subsequently followed, are that an invention should be an artificially created state of affairs in the field of economic endeavour. These principles have been consistently applied ever since, and there is now a large body of Australian case law illustrating their operation.[61]

The proposed amendments have been criticised on various grounds by several major interest groups.

First, rather than taking the opportunity to modernise the meaning of 'manner of manufacture', as recommended during inquiries by the ALRC, Community Affairs References Committee and ACIP, the proposed amendments continue to rely on the old-English language of the Statute of Monopolies, which arguably has less relevance to the practice of modern economies.[62]

Second, the proposed amendments have been criticised as being 'superfluous', changing nothing.[63]

Third, the proposed amendments are said to contribute to further ambiguity in the Patents Act.[64]

It is noted that ACIP recommended the following changes:

> • replacing the words 'is a patentable invention' in subsections 18(1) and 18(1A) with the words 'is patentable';
>
> • replacing the words 'if the invention, so far as claimed in any claim' in subsections 18(1) and 18(1A) with the words 'if it';
>
> • replacing the current words of paragraphs 18(1)(a) and 18(1A)(a) with the words 'an artificially created state of affairs in the field of economic endeavour';
>
> • changing the definition of 'invention' in Schedule 1 to be 'the subject matter of any claim'; and
>
> • deleting the definition of 'patentable invention' in Schedule 1.[65]

---

61 ACIP, *Review of patentable subject*-matter, op. cit., p. 9.

62. See submissions to the Legal and Constitutional Committee's inquiry by: Dr Charles Lawson, 5 January 2011, p. 2; D Calhoun, 24 February 2011, p. 2.

63. See submissions to the Legal and Constitutional Committee's inquiry by: Davies Collison Cave, 23 February 2011, pp. 6–7; A Kurts, M Lutherborrow and N Stoianoff, 23 February 2011, p. 4; D Nicol et al, February 2011, pp. 4, 32–34.

64. See submissions to the Legal and Constitutional Committee's inquiry by: Davies Collison Cave, 23 February 2011, pp. 6–7; C Dent, February 2011, p. 7. Both the Law Council of Australia and Griffith Hack Lawyers (IP Lawyers) comment that the proposed wording, resulting in further ambiguity, would result in costly legal debates to clarify ambiguities: see submissions to the Legal and Constitutional Committee's inquiry by: Law Council of Australia, 25 February 2011, p. 4; Griffith Hack Lawyers, 25 February 2011, p. 1.

65. ACIP, *Patentable subject matter*, op. cit., p. 13.

Items 3 and 4

Item 3 of the Senate Bill proposes to **replace subsection 18(2)** in the Patents Act. Currently, subsection 18(2) provides that human beings and the biological processes for their generation are not patentable inventions.

Proposed subsection 18(2) would add an additional exception—biological materials however made (including their components and derivatives), irrespective of whether they are isolated or purified or not, which are identical or substantially identical to such materials as existing in nature—would also not be patentable inventions. This would have the effect of excluding such materials from being patented.

Item 4 of the Senate Bill proposes to define biological materials as 'including DNA, RNA, proteins, cells and fluids'.

Comments

It is noted that, at the conclusion of their respective inquiries, neither the ALRC, Community Affairs References Committee nor ACIP recommended that human genes, let alone all biological materials, be exempted from patenting.[66]

As mentioned earlier, the proposed amendments are ambiguous and do not provide certainty as to what would not be a patentable invention under the Patents Act.

Importantly, and as mentioned earlier, the proposed application of the Patents Act to both human and non-human biological materials would greatly expand the scope of subsection 18(2) of the Patents Act with respect to what would not be patentable inventions under the Act. This is likely to have implications for a broad range of industries.

The broad scope of these amendments means it is not just genetic material that would be rendered ineligible for patenting. For example, a naturally occurring potentially therapeutic compound from a plant could be covered by this exclusion if it is a protein or, if not, if it is deemed to be a 'fluid'. As all the chemical reactions that constitute life take place in water, it could be argued that any substance (even if crystallised post-extraction) is 'a fluid' when *in vivo*. The cytoplasm (internal content) of any living cell from any organism is a viscous 'fluid' when fully hydrated.

The question then turns on whether an extracted compound, if slightly chemically modified, would be counted as being 'substantially identical' (to use the proposed words of the Senate Bill) to the natural material. For example, salicylic acid and methyl salicylate ($C_8H_8O_{3)}$ acid both occur widely in many plants, especially willow and birch trees, whose barks were used traditionally to treat fever

66. See ALRC, *Genes and ingenuity*, op. cit., [7.28]; Community Affairs References Committee, *Gene patents*, op. cit., [4.113]; ACIP, *Patentable subject matter*, op. cit., p. 14.

and pain. The compound acetyl salicylic acid ($C_9H_8O_4$) differs by only two atoms from the naturally occurring substance, and is marketed as Aspirin. Under the Senate Bill, would this count as 'substantially identical' to a material existing in nature? Chemically it is very similar, but in terms of pharmaceutical activity in humans it is less toxic and more useful than the naturally occurring compounds. If such materials are excluded in future from patents, it could restrict the development of new pharmaceuticals derived from nature. Thus, the proposed amendments appear to cover far more than genes.

Essentially, **proposed subsection 18(2)** of the Senate Bill would appear to prevent patenting not only all genomic material, but also any components of the proteome.

The proposed amendments in **items 3** and **4** attracted a range of comments from major interest groups.

On the one hand, some interest groups express support for excluding human genes and biological materials from patenting per se.[67] Reasons for this support have included:

- protecting access to testing and treatments[68]
- not hindering genetic and biological research[69] and
- arguments that genes are not inventions but discoveries under the Patents Act and are, consequently, not patentable.[70]

On the other hand, these specific amendments proposed in the Senate Bill have been criticised by other interest groups for several reasons, which include the following.

First, it is argued that, as mentioned previously, the proposed amendments go much further than simply excluding human genetic materials, as the proposed wording could apply to *all* biological materials, thereby potentially affecting a broad range of industries, such as biotechnological and

67. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Cancer Voices NSW, 19 February 2011, p. 1; Human Genetics Society of Australasia, 8 February 2011; Professor Peter Drahos, 9 February 2011; Gene Ethics, February 2011, p. 2; Breast Cancer Action Group (NSW), p. 1; Cancer Council (Australia), February 2011, p. 1; Generic Medicines Industry Association, 25 February 2011, p. 2; Mylan, 23 February 2011, p. 3; Alphapharm, 25 February 2011, p. 2; G Burton, p. 1; J Leary, 25 February 2011, p. 1 and Attachment 1.
68. See, for example, ALRC, *Genes and ingenuity*, op. cit., Chapter 19, [20.8] and [20.38]–[20.39]. See also Community Affairs References Committee, *Gene patents*, op. cit., pp. 37–39.
69. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Generic Medicines Industry Association, 25 February 2011, p. 2; Mylan, 23 February 2011, p. 3; Alphapharm 25 February 2011, p. 2; and Gene Ethics, February 2011, Appendix 1 (Introduction to Gene Ethics submission 07/10). See also, for example, ALRC, *Genes and ingenuity*, op. cit., Chapter 12; Community Affairs References Committee, *Gene patents*, op. cit., pp. 43 (potential to negatively affect research), 52–61.
70. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Gene Ethics, February 2011, Appendix 1 (Introduction to Gene Ethics submission 07/10); Mylan, 23 February 2011, p. 3; G Burton, pp. 2–3; J Leary, 25 February 2011, Attachment 1; and Alphapharm 25 February 2011, p. 2. See also, for example, ALRC, *Genes and ingenuity*, op. cit., [6.11]–[6.19]; Community Affairs References Committee, *Gene patents*, op. cit., pp. 75–79. See also further discussion about the distinction between discovery and invention earlier in this Digest.

pharmaceutical industries, as well as agricultural and animal protection industries, and bio-prospecting.[71]

Second, as mentioned earlier, it is argued that terms in **item 3** of the Senate Bill are unclear with no guidance given as to their intended meaning. Such terms include 'components and derivatives', as well as 'identical or substantially identical'.[72] In addition, some interest groups have argued that this ambiguity would require judicial interpretation of terms resulting in increased litigation costs.[73]

It is noted, however, that in a supplementary submission to the Legal and Constitutional Committee's inquiry, Professor Luigi Palombi suggested amending **items 3** and **4** of the Senate Bill.[74]

---

71. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Bayer Crop Science, 21 February 2011, p. 2; Abbott Australasia, February 2011, p. 4; Peter MacCallum Cancer Centre, 24 February 2011, p. 3; Griffith Hack Lawyers, 25 February 2011, pp. 2–3; Medicines Australia, 25 February 2011, p. 3; Grains, Research and Development Corporation, 28 February 2011, p. 5; Department of Innovation, Industry, Science and Research and IP Australia, pp. 4 and 20–21; Licensing Executives Society (Australia and New Zealand), 25 February 2011, p. 3; AusBiotech, 25 February 2011, p. 5; Australian Academy of Science, p. 2; Burnet Institute, 20 February 2011, p. 3; American Intellectual Property Law Association, 15 March 2011, pp. 3–4; FB Rice & Co, 25 February 2011, pp. 1–2; Department of Health and Ageing, p. 2; BioMelbourne Network, 25 February 2011, p. 2; Sydnovate, 25 February 2011, p. 2; Garvan Institute, 24 February 2011, p. 2; Association of Australian Medical Research Institutes, 25 February 2011, pp. 1–2; Merck, Sharp and Dohme, 25 February 2011, p. 1; Genetic Technologies, p. 1; ResMed, 25 February 2011, p. 1; CSIRO, February 2011, p. 6.
72. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Davis Collison Cave, 23 February 2011, pp. 7–8; ALRC, p. 3; D Nicol et al, February 2011, pp. 3, 7–10; Griffith Hack Lawyers, 25 February 2011, p. 3; Department of Innovation, Industry, Science and Research and IP Australia, p. 18; ATSE, February 2011, p. 10; American Intellectual Property Law Association, 15 March 2011, p. 3; FB Rice & Co, 25 February 2011, pp. 1–2, 5.
73. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Shelston IP, 25 February 2011, pp. 2–3; ATSE, February 2011, p. 10; FB Rice & Co, 25 February 2011, p. 5 (such costs will be passed on to consumers).
74. Professor Luigi's proposed amendment is as follows:

    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 purified or not and however made, which are identical to such materials as they exist in nature.

    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 and where any structural change or difference is immaterial to its function.

Senator Heffernan has also tabled similarly worded amendments to **items 3** and **4** with the Legal and Constitutional Committee inquiry.[75] The effect of these amendments is to remove the word 'derivatives', so that the Senate Bill covers biological materials (and their components) as they exist in nature. It could be argued that an isolated gene is a 'derivative' of a gene in its natural state—for example, an isolated gene is stripped of its histones (surrounding, protective proteins), and may have a few nucleotides excised or inserted at one of its ends. Hence, without the word 'derivatives' being present, such a gene may be patentable because it is different from the natural form, unless the counter-argument of 'substantially identical' is used and applied to the information content residing in the gene rather than its precise chemical nature.

In terms of non-gene biological materials, further difficulties may arise if a novel and synthetic chemical compound is patented and this substance is later found to be present in nature. Consider the following example: substance A, in nature, is extracted from a plant and modified to create a novel, synthetic derivative, substance B, which is of commercial value. A short while later, other researchers discover by chance that substance B does, in fact, occur naturally in some species—for example, within bacteria. Substance B has now changed status to become a 'biological material identical to that which occurs in nature.' Given the enormous biochemical diversity at the microbial level, and also among plants, it is impossible to know which compounds occur in nature until a biochemical index of all life has been completed.

Third, it is argued that the definition in **item 4** of the Senate Bill, which is set out as an inclusive list of specific matters, results in the definition being both broad and indeterminate, raising the question of what is not covered by that definition.[76] For example, the Royal College of Pathologists of Australia stated:

> First, the list is by no means complete. There are many naturally-occurring substances in humans which do not fall into the five categories listed, including fats, cholesterol, vitamins etc. it is essential that these naturally·occurring substances are not deemed patentable by implication because they are not included in this list.
>
> Second, each of the items on this list can be synthesised or manufactured *de novo*, without being naturally occurring. This possibility is addressed in the third amendment proposed above which only excludes biological materials which are -identical to such materials as they exist in nature". In other words, this list provides no additional definition beyond that already included in the third amendment.[77]

Fourth, it is argued that these proposed amendments would not address the crux of concerns regarding gene patents—the situation involving Myriad Genetics as previously mentioned. In

75. A copy of Senator Heffernan's amendments is available at: http://www.aph.gov.au/senate/committee/legcon_ctte/patent_amendment/submissions.htm
76. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Law Council of Australia, 25 February 2011, p. 2; Royal College of Pathologists of Australia, 10 February 2011, p. 4; A Kurts et al, February 2011, pp. 10–11; Department of Innovation, Industry, Science and Research and IP Australia, p. 18.
77. Royal College of Pathologists of Australia, 10 February 2011, p. 4.

particular, the proposed amendments do not exclude diagnostic or treating *methods* relating to biological materials.[78]

Fifth, it is argued that these proposed amendments may result in unintended adverse consequences, such as damaging investment in Australian genetic and biotechnological research and development, which may in fact restrict availability of certain forms of treatment to consumers in Australia.[79]

Sixth, it is argued that these proposed amendments would make Australia out of step with, if not contravene:

- its international obligations under TRIPS and AUSFTA, as previously discussed,[80] and
- global attempts to harmonise patent laws.[81]

In addition, those interest groups not supporting the Senate Bill point out that:

- under the current patent system in Australia, naturally occurring genetic and biological materials are not patentable[82]
- the existence of a patent over genetic or biological material does not constitute 'ownership' of such material[83]
- the time for amending the Patents Act to prohibit such patents has passed as a consequence of changes in patents examination processes; and advances in scientific knowledge and technologies[84]

78. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: D Nicol et al, February 2011, p. 3; Griffith Hack Lawyers, 25 February 2011, p. 2; Law Council of Australia, 25 February 2011, p. 2; Department of Innovation, Industry, Science and Research and IP Australia, pp. 5 and 24; American Intellectual Property Law Association, 15 March 2011, p. 5; CSIRO, February 2011, pp. 6–7.
79. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: A Kurts et al, February 2011, p. 1; Perth Bone and Tissue Bank Inc, 21 February 2011. p. 1; Amgen Australia, 21 February 2011, p. 6; Consumers' Health Forum of Australia, 24 February 2011, p. 2; Piper Alderman, 25 February 2011, p. 5; Medicines Australia, 25 February 2011, pp. 1, 4–6; Department of Innovation, Industry, Science and Research and IP Australia, pp. 5, 19 and 23; CSIRO, February 2011, pp. 2 and 5; FB Rice & Co, 25 February 2011, p. 4; AusBiotech, 25 February 2011, p. 7; ATSE, February 2011, pp. 4, 8 and 9; MGroup, pp. 1 and 2; Janssen, 25 February 2011, pp. 8 and 9; BioMelbourne Network, 25 February 2011, p. 2; Prima Biomed Ltd, 25 February 2011, pp. 2–3.
80. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Davis Collison Cave, 23 February 2011, pp. 9–10; Kurts et al, 23 February 2011, pp. 13–15; International Federation of Intellectual Property Attorneys, 24 February 2011, pp. 2–6; D Nicol et al, February 2011, pp. 37–41; Griffith Hack Lawyers, 25 February 2011, p. 3; IPTA, February 2011, pp. 12 and 15–16; Piper Alderman, 25 February 2011, p. 2; American Intellectual Property Law Association, 15 March 2011, p. 6.
81. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Davis Collison Cave, 23 February 2011, pp. 10–11; International Federation of Intellectual Property Attorneys, 24 February 2011, pp. 7–9; D Nicol et al, February 2011, pp. 37–41; Griffith Hack Lawyers, 25 February 2011, p. 3; IPTA, February 2011, pp. 13–16; Piper Alderman, 25 February 2011, p. 3; American Intellectual Property Law Association, 15 March 2011, p. 6.
82. For further detail, see submissions to the Legal and Constitutional Committee's inquiry by: Department of Innovation, Industry, Science and Research and IP Australia, pp. 7 and 8; ATSE, February 2011, p. 5; Biotechnology Industry Organisation, 25 February 2011, p. 3.
83. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: American Intellectual Property Law Association, 15 March 2011, pp. 4–5; Biotechnology Industry Organisation, 25 February 2011, p. 3.

- there are alternative methods of dealing with problems that arise, in relation to concerns of various interest groups, warranting consideration,[85] and
- there is insufficient empirical evidence that the existence of patents over genetic or biological materials adversely affects matters such as costs and access to genetic and biomedical testing.[86]

Lastly, it is noted that the Senate Bill is silent as to how it would apply to existing patents over genetic or biological materials.

Concluding comments

The amendments proposed in the Senate Bill go much further than the longstanding debate as to whether to prohibit gene patents.

The proposal to exclude particular subject matter from the Patents Act would effectively extend to all naturally occurring biological materials per se, not simply *human* genes and *human* biological materials as the title of the Senate Bill suggests. As mentioned in several submissions, this would have the potential to affect a wider cross-section of biotechnological industries other than simply the medical industry.

Comments made by major interest groups in relation to the Senate Bill reflect evidence already provided at the various inquiries on the impacts of human gene patents, and in particular, those conducted by the ALRC and the Community Affairs References Committee discussed earlier. These have been referred to elsewhere in this Digest and will not be repeated here.

Parliament may wish to keep in mind the arguments and counter-arguments for and against the Senate Bill as previously outlined. These are summarised as follows.

---

84. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Department of Innovation, Industry, Science and Research and IP Australia, p. 9 (patents moving towards downstream applications); AusBiotech, 25 February 2011, p. 3; ATSE, February 2011, p. 5; Association of Australian Medical Research Institutes, 25 February 2011, p. 3.
85. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: Medicines Australia, 25 February 2011, pp. 7–9 (research use exemption, improving threshold test for granting patents, Crown use and compulsory licensing provisions); Department of Innovation, Industry, Science and Research and IP Australia, p. 5 (Crown use and compulsory licensing provisions); Licensing Executives Society (Australia and New Zealand), 25 February 2011, pp. 5–7 (Crown use and compulsory licensing provisions, Commonwealth acquisition, competition laws); AusBiotech, 25 February 2011, pp. 6, 7–8 (research use exemption, review of Crown use and compulsory licensing provisions); ATSE, February 2011, pp. 4–5 (research use exemption); Burnet Institute, 20 February 2011, p. 5 (research use exemption); American Intellectual Property Law Association, 15 March 2011, p. 5 (research use exemption); FB Rice & Co, 25 February 2011, p. 4 (research use exemption); CSIRO, February 2011, pp. 2 and 8.
86. See, for example, submissions to the Legal and Constitutional Committee's inquiry by: AusBiotech, 25 February 2011, p. 4; ATSE, February 2011, p. 4; American Intellectual Property Law Association, 15 March 2011, p. 2; Sydnovate, 25 February 2011, p. 1.

Arguments

Arguments supporting the Senate Bill include:

- genes are discoveries not inventions—consequently, should not be patentable
- gene patents hinder genetic and biological research, and
- gene patents hinder access to genetic and biomedical testing and treatments.

Counter-arguments

Counter-arguments not supporting the Senate Bill include:

- under the current patent system in Australia, genetic and biological materials in their natural form are not patentable
- the existence of a patent over genetic or biological material does not constitute 'ownership' of such material
- concerns relating to gene patents, and the subject matter of patents generally, have already been extensively reviewed with a similar conclusion—there is insufficient empirical evidence of adverse effects resulting from gene patents to warrant prohibiting the patenting of genes and biological materials
- at this stage in any case, the nature and scope of patent applications relating to human genes have changed over time with changes in examination practices and, in the words of the ALRC:

> the time for taking this approach to the patenting of products and materials has long since passed[87]

- the proposed amendments go much further than simply excluding human genetic materials—the proposed wording could apply to *all* biological materials, thereby potentially affecting a broad range of industries, such as biotechnological and pharmaceutical industries; agricultural and animal protection industries; and bio-prospecting
- the proposed amendments may result in unintended adverse consequences to that broad range of industries, such as making it more difficult to patent novel genetically modified organisms in areas unconnected with human genes (for example—agricultural plants)
- prohibiting the patenting of genes and biological materials may represent a significant departure from international practice with respect to genetic inventions in many developed countries and may adversely affect investment in the Australian biotechnology industry, and
- alternative methods—such as Crown use and compulsory licensing provisions, as well as a research use exemption and competition laws—have been proposed to address concerns regarding any monopoly arising from the existence of gene patents; and the development of and access to genetic and biomedical testing.

87. ALRC, *Genes and ingenuity*, op. cit., [6.52].

Appendix 1

Definitions

The following material may help the non-specialist understand the scientific areas referred to in the Amendments. The explanations are not written in scientific language, but are merely simplified summaries of highly technical concepts. The material is offered for general assistance only, and is not referenced. **The definitions should not be used for scientific purposes.**

Allele: A gene can exist in various different versions, referred to as alleles. Within a population of individuals, there can be many different alleles of a gene. Humans and many other organisms have two copies of each gene, one inherited from the mother and one from the father. Only one parental allele is usually expressed. Knowing the full spread of possible alleles for any gene within the human species is important in realising the scientific potential of the human genome sequence, and for therapeutic applications of genetics.

Amino acid: The building block of all proteins. Proteins consist of long chains of amino acids joined together. There are about 20 different types of naturally occurring amino acids. Proteins consist of anywhere from tens to millions of amino acids joined together. The sequence in which these subunits are arranged will determine the specificity and hence function of the protein. This sequence is controlled by and encoded within the sequence of nucleotide bases in the DNA and RNA.

Bioinformatics: the developing field of computational biology; in other words, the application of high-powered computing and statistical methods to biology, mainly molecular biology. The information within DNA molecules is so vast and potentially complex that the task of dealing with requires the use of information science and its tools. There can be genomic and post-genomic bioinformatics, depending on whether the information comes from the genome or from proteome. Australia maintains an ARC Centre of Excellence in Bioinformatics.

DNA: Deoxyribonucleic acid. DNA is the naturally occurring chemical used to encode biological information. In almost all organisms – animals, plants, fungi, bacteria – genes are made of DNA. DNA is a type of nucleic acid (so-called because these acidic chemicals were first found in the nucleus of cells). Nucleic acids are polymers: long, thin molecules consisting of many sub-units strung together like beads on a necklace. Each sub-unit is called a nucleotide, and each nucleotide contains an important component called a base. The sequence in which the bases are placed in the nucleic acid is crucial, because it spells out information and instructions, like words on a page.

Exon: See gene

Gene: The definition of gene has changed rapidly in the last few decades, and the term is now used in various different ways. A simple definition of gene is a segment of nucleic acid that codes for a specific trait in an organism. However, certain genes may not code for an obvious trait, but may code for important functional molecules that may have effects on the operation of other genes. A

definition that reflects this is that a gene is a segment of nucleic acid that contributes to phenotype (the physical organism) or to function.

All genes are mediated through RNA transcripts, which are mainly used to provide the information necessary to assemble polypeptide molecules. In some cases, however, the RNA may have a direct regulatory function itself.

It must be understood that, in most organisms, much of the DNA does not appear to code for the construction of protein molecules. This DNA is sometimes called 'junk DNA'; a more precise name is non-coding DNA. The non-coding sequences (also called non-coding regions) of DNA may be transcribed into RNA, but then their information is often edited out. Put simply, therefore, a non-coding sequence is a stretch of DNA that does contain instructions for making proteins.

These non-functional sequences are called introns. A stretch of DNA that used to be designated a gene is now known to consider of coding regions (called exons) and non-coding regions (introns). The introns are usually edited out after transcription, and the exons are spliced together. Therefore a further definition of a gene takes into account the fact that a gene is not necessarily a single uninterrupted stretch of DNA. A gene can therefore be defined as a union of genomic sequences encoding a coherent product. The US genomics company Celera describes a gene as "a locus of co-transcribed exons."

Exons can be spliced in different ways, giving rise to different protein varieties from one gene. In some translated versions, one or more exons may be excluded from the final product, resulting in a very different protein. It is thought that possibly some genetic disorders and other diseases may result from problems with splicing or unwanted variation in it. The complexities of splicing are one of the reasons that knowledge of genetic sequences is not, by itself, sufficient to predict all the products that may result, or the metabolic behaviour consequent to that.

It is now apparent that only about 2% of the human genome codes for proteins or useful RNA products. In other words, 98% of our DNA is 'junk' or, at least, non-coding. It seems that, in humans and probably many other mammals, exons are separated by long stretches of introns. The function – if any – of such sequences is a hot topic in molecular biology. Evidence is starting to accumulate suggesting that removal of or damage to non-coding regions will result in difficulties for the cell. Some non-coding DNA may function as genetic switches, affecting the activation of nearby genes. It has also been suggested that non-coding regions serve as physical spacing that may be necessary for genes to be read. In addition, large amounts of junk DNA could be useful as a reservoir of sequences that evolution could draw on in the creation of new genes.

Another suggested definition of genes in all organisms other than bacteria and viruses is a combination of DNA segments that together constitute an expressible unit (Maxime Singer and Paul Berg).

Many genes are not expressed. Most cells silence the majority of their genes during the course of their development. Unexpressed genes that become expressed can cause unregulated cell growth and activity, and this can result in diseases such as cancer.

Genome: All the genes of an individual organism (or larger taxonomic unit, such as species). The genome includes non-coding sequences. The genome of a species includes all the possible alleles occurring in the population.

Germplasm: the genetic resources of a species.

Intron: See gene

In vivo: in a living thing.

In vitro: literally 'in glass.' This means in a laboratory and outside a living system.

Mutations: Mutations are changes in the DNA sequence of an organism. Depending on where in the DNA these changes occur, consequences may range from undetectable to fatal. Mutations occur naturally, but can be induced. Laboratory-controlled mutagenesis (the creation of mutations) can be a useful tool in exploring ways of changing genetic sequences.

mRNA: messenger RNA. See RNA.

Proteins: Proteins are a class of biological molecule. They occur in all organisms, and life cannot exist without protein molecules. Proteins are very large and complex polymers, made of sub-units called amino acids. The amino acids are attached one to another to form a line, being arranged in a particular sequence (like the bases in DNA and RNA). The long line of amino acids joined together is called a polypeptide. A protein can be defined as one or more polypeptides, which may be elaborately folded or intertwined.

The sequence of amino acids determines the nature, shape and function of the protein that they compose. There are literally millions of different protein molecules – each performing specific functions that are essential to life. The most significant role of proteins is to work as enzymes, which catalyse the many chemical reactions upon which life depends. However, not all proteins are enzymes. Some are specialised for particular work (e.g., haemoglobin to carry oxygen); a large family (called immunoglobulins) work as antibodies in the immune system. Some proteins function to regulate the entry and exit of substances from cells; others work to copy the DNA, so that genes can be passed on. Still others act as genetic switches, determining whether a gene within the DNA will be 'read' (i.e. transcribed to RNA), ignored, or partially expressed. Many hormones (for example, insulin) are small polypeptides, and thus qualify as proteins. The range of biological functions performed by proteins is immense, and so proteins are highly significant therapeutically and in research.

Protein Derivatives: The term is used to refer to proteins extracted from a particular tissue (e.g. blood) or from a particular organism (e.g., soya). In vivo, proteins are present in conjunction with many other complex biological compounds. Separation and purification is necessary to obtain a single protein product. Blood protein derivatives are widely used and would include, for example, clotting factors (necessary for haemophiliacs) and immunoglobulins.

Proteome: The proteome is the entire complement of proteins produced by a cell or organism (or system or taxonomic unit under study). The Human Proteome Project (analogous to the Human Genome Project) was officially launched in Sydney in September 2010. The proteome is considered the next great frontier of molecular biology, but is more complex than the genome because it is ever-changing and larger (there are more proteins than genes because of post-translational modifications and gene splicing effects). However, it is at the level of the proteome that gene instructions are given effect and controlled.

Polymorphisms: Nucleotide polymorphisms refer to slight changes in DNA bases (or nucleotides) between different individuals. It is similar to having several copies of the same document, but each copy having a sprinkling of typographical errors in different places. Often, a change to just one nucleotide will have no effect, but occasionally such a change may give rise to a different gene product. These differences account for much of the genetic variation between individuals.

RNA: There are two main forms of nucleic acid: DNA and RNA, which is ribonucleic acid. Chemically, RNA differs only slightly from DNA. However, it has a different function. DNA is a more stable molecule, and is used for the long term storage of genetic information in all organisms (apart from in a few viruses). RNA is used as a temporary copy of a section of the DNA molecule. When a gene is 'read', the information within it is converted into a coded segment of RNA. This process is called transcription. RNA contains bases like DNA. The RNA transcript (called messenger RNA or mRNA) is formed by copying the DNA, and it then diffuses away from the DNA and into the rest of the cell. The sequence of the bases in the mRNA reflects the sequence in the stretch of DNA that it was transcribed from. The bases are complementary to the original.

The mRNA transcript may then be 'edited' within the cell, with certain pieces removed and the remaining portions spliced together. The mRNA is usually then translated, which means the information it encodes is used to construct a specific protein product. The amount of product finally synthesised may differ according to the state of the cell and the nature of the product. A protein can be further modified after it is first formed (referred to as post-translational modification).

Splicing: Gene splicing can mean removing introns (non-coding sequences), and sticking together the exons to make a continuous strip of coding DNA. It can also refer to cutting out a DNA sequence that constitutes a gene from one position and inserting it (pasting it) into another position. This position could be within the genome of another species, thus creating a transgenic organism.

Sequencing: Determining the order (sequence) of nucleotide bases that make up a molecule of DNA or RNA. The sequence of the bases contains the genetic information, rather like the sequence of letters on a page can form words and sentences and spell out information. Equally, letters on a page can be random and spell out no meaningful words at all. This can also be the case with nucleotide sequences. Such non-coding regions of DNA are called exons.

Transgenic organism: Any organism containing one or more genes from a different species, created by genetic engineering.

Appendix 2

Alternatives to prohibiting gene patents

Crown use provisions

It has been suggested that existing Crown Use provisions in the Patents Act could be used to address any potentially adverse affects of gene patents on genetic and biomedical research, as well as access to medical treatment.[88]

Chapter 17 of the Patents Act sets out provisions relating to the Crown and in particular, section 163 provides:

> (1) Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement:
>
> (a) if the application is pending—of the nominated person's rights in the invention; or
>
> (b) if a patent has been granted for the invention—of the patent.
>
> (2) A person may be authorised for the purposes of subsection (1):
>
> (a) before or after any act for which the authorisation is given has been done; and
>
> (b) before or after a patent has been granted for the invention; and
>
> (c) even if the person is directly or indirectly authorised by the nominated person or patentee to exploit the invention.
>
> (3) Subject to section 168, an invention is taken for the purposes of this Part to be exploited for services of the Commonwealth or of a State if the exploitation of the invention is necessary for the proper provision of those services within Australia.

In short, where exploitation of an invention is necessary for the provision of services in Australia, Crown Use provisions allow the Commonwealth or a State to either:

- exploit the invention (whether patented or the subject of a patent application) without infringement or
- authorise someone to do so,

88. See ALRC, *Genes and ingenuity*, op. cit., Chapter 26 and Community Affairs References Committee, *Gene patents*, op. cit., [5.76].

for the services of the Commonwealth or State, as the case may be.

Research exemption

The Patents Act does not explicitly provide for a research exemption (also referred to as 'experimental use').

At the time of its inquiry into experimental use in 2005, ACIP generally noted that in Australia, industry convention had been to regard experimental use of patented inventions as 'non-infringing activity'.[89] In its conclusion, ACIP recommended that, among other things:

> The Patents Act be amended to establish the following provision:
>
> The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.
>
> Acts done for experimental purposes relating to the subject matter of the invention include:
>
> - determining how the invention works;
>
> - determining the scope of the invention;
>
> - determining the validity of the claims;
>
> - seeking an improvement to the invention.[90]

During its own inquiry, the Community Affairs References Committee noted widespread support to amend the Patents Act so as to have an explicit research exemption provision.[91]

However, such support was not unanimous. For example, the Cancer Council was quoted as stating:

> While we commend the Advisory Council on Intellectual Property and the Australian Law Reform Commission for proposing an experimental use exemption for patented genes in some medical research, in our view the recommendations are not sufficiently extensive. For example, exemption should also apply to research on the patented tests for identifying certain genes, to encourage continuous improvement; just because a commercial interest discovered a particularly gene or developed a test for its isolation does not mean that the test could not be improved (e.g. made more accessible and affordable) by a separate research entity. There are numerous other examples where exemption for experimental use would not be sufficient. Applying for the exemption could also impose administrative burden for not-for-profit and academic institutions involved in medical research.[92]

---

89. ACIP, *Patents and experimental use*, Report, October 2005, p. 32, viewed 8 April 2011, http://www.acip.gov.au/library/ACIP%20Patents%20&%20Experimental%20Use%20final%20report%20FINAL.pdf
90. Ibid., Recommendation 1. This wording is very similar to that proposed by IP Australia in its Raising the Bar Bill referred to earlier in this Digest.
91. See Community Affairs References Committee, *Gene patents*, op. cit., [5.110]–[5.113]. Other inquiries into gene patents also supported such provision: see, for example, ALRC, *Genes and ingenuity*, op. cit., Recommendation 13-1.
92. See in Community Affairs References Committee, *Gene patents*, op. cit., [5.120].

The wording of such provision was also debated, with some support for ACIP's recommendation above.[93]

It is noted that the Government response to ACIP's report was that it would amend the Patents Act to introduce an experimental use or research provision as recommended by ACIP.[94]

Compulsory licensing

A compulsory licence is an authorisation for a patented product or process to be exploited, which is given by a national authority without the patent holder's consent.[95]

Submissions to the Community Affairs References Committee's inquiry identified compulsory licensing provisions of the Patents Act as potentially being able to address adverse impacts of gene patents on genetic testing and medical treatment.[96]

Section 133 of the Patents Act provides:

> Subject to subsection (1A), a person may apply to the Federal Court, after the end of the prescribed period, for an order requiring the patentee to grant the applicant a licence to work the patented invention.
>
> ...
>
> (2) After hearing the application, the court may, subject to this section, make the order if satisfied that:
>
> (a) all the following conditions exist:
>
> (i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;
>
> (ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;[97]
>
> (iii) the patentee has given no satisfactory reason for failing to exploit the patent; or
>
> (b) the patentee has contravened, or is contravening, Part IV of the *Competition and Consumer Act 2010* or an application law (as defined in section 150A of that Act) in connection with the patent.

93. Ibid., [5.121]–[5.125].
94. Australian Government, *Response to the Advisory Council on intellectual property report—patents and experimental use*, 6 August 2007, viewed 8 April 2011, http://www.acip.gov.au/library/Government%20Response%20to%20ACIP%20Report%20on%20Patents%20&%20Experimental%20Use_Final.pdf
See also IP Australia's Raising the Bar Bill referred to above.
95. ALRC, *Genes and ingenuity*, op. cit., [27.2].
96. Community Affairs References Committee, *Gene patents*, op. cit., [5.88].
97. Section 135 of the Patents Act explains when the 'reasonable requirements of the public' are not satisfied. Note that the ALRC had proposed certain amendments to this provision in its report: see ALRC, *Genes and ingenuity*, op. cit., [27.51]–[27.59].

> (3) An order must direct that the licence:
>
> (a) is not to give the licensee, or a person authorised by the licensee, the exclusive right to work the patented invention; and
>
> (b) is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;
>
> and may direct that the licence is to be granted on any other terms specified in the order.

There are various reasons why a compulsory licence may be sought to use a patented genetic invention in conducting genetic and biomedical research; or providing medical treatment. According to the ALRC, these include:

> a researcher or research organisation might need access to an upstream genetic invention to develop a downstream product, such as a pharmaceutical drug;
>
> a researcher or research organisation that has developed an improvement on a patented research tool might require a licence over the primary tool in order to exploit the patented improvement;
>
> a pharmaceutical company, a private laboratory, or other private organisation might wish to provide a patented medical genetic test, or other healthcare service to the Australian community where demand is not being met; or
>
> a public sector health authority might wish to provide a patented medical genetic test or other healthcare service where demand is not being met; or where the patent holder has not licensed the patent widely, and this is having an injurious effect on the provision of services, the development of skills and the conduct of further research within Australia.[98]

Section 136 of the Patents Act provides that compulsory licensing orders must be consistent with international agreements that the Commonwealth enters into with a foreign country. Article 31 of the TRIPS Agreement sets out the procedures and certain procedural requirements that Member states must follow when granting compulsory licences.[99] In addition, Article 17.9.7 of AUSFTA permits the unauthorised use of a patented invention only:

> (a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices;[17] or
>
> (b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:
>
> (i) the Party shall limit such use to use by the government or third persons authorised by the government;
>
> (ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and

98. ALRC, *Genes and ingenuity*, op. cit., [27.23].
99. Likewise for Crown use as mentioned above.

(iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.

Competition laws

It has been argued that major concerns of competition policy in relation to patent rights are:

- the market power that may result from granting such rights, and
- the effect of the anti-competitive exercise of these rights.[100]

The way in which a patent holder exploits rights in genetic materials or technologies may affect competition, as well as access to and the pricing of genetic and biomedical research tools; and medical services.[101] The ALRC, during its inquiry into gene patents, noted tension between intellectual property and competition laws in the ways that they try to support innovation.[102]

Part IV of the *Trade Practices Act 1974* (the TP Act) prohibits certain anti-competitive conduct. For example, such conduct includes:

- contracts, arrangements or understandings which have the purpose or effect of substantially lessening competition, or contain 'exclusionary provisions';
- exclusive dealing and resale price maintenance;
- the misuse of market power; and
- anti-competitive mergers or acquisitions.[103]

These provisions could arguably apply to patent holders who engage in such anti-competitive conduct in relation to patents over genetic materials and technologies.

In particular, subsection 51(3) of the TP Act exempts conditions in licenses and assignments from Part IV to the extent that they 'relate to' the subject matter of an intellectual property right, but does not extend other matters such as the misuse of market power. The ALRC noted that there was some uncertainty as to the scope of this provision, due to ambiguity regarding the term 'relates to' and recommended that subsection 51(3) be amended to clarify the ambiguity.[104]

100. ALRC, *Genes and ingenuity*, op. cit., [24.1].
101. Ibid.
102. Ibid., [24.4].
103. See ibid., [24.7].
104. Ibid., [24.52]–[24.53] and Recommendation 24–1.