# CHAPTER 4

# EXPRESS PROHIBITION OF GENE PATENTS

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

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

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

## INTRODUCTION

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

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

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

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

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

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

## Types of gene patents

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

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

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

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

4.9 Typical method claims include:

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

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

- a gene therapy using the sequence.

## Extension of patent law to human genes and genetic materials

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

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

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

### *Judicial interpretation of the Act regarding non-patentable subject matter*

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

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

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

4 (1959) 102 CLR 252.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### *International and national developments*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## Discovery v invention

### *Genes and genetic materials as 'inventions'*

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

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20 Draft Explanatory Memorandum, p. 3.

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

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

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

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

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

*Isolated or purified substances/gene sequences*

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

> …the discovery of a microorganism, protein, enatiomer or antibiotic in nature can be claimed in its isolated form or as substantially free of (perhaps, specified) impurities. Also, a gene can be claimed as the gene per se (as long as the claim does not include within its scope the native chromosome of which the gene forms part) or as the recombinant or isolated or purified gene.[25]

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

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

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

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

4.33 With particular reference to genetic materials:

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

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

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

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

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

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

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

### *Objections to genes and genetic materials as 'inventions'*

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

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

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

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

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

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

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

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

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

4.39 Similarly, Professor Olver observed:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## Ethical objections to gene patents

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

4.49 Similarly, Ms Sally Crossing, Chair of Cancer Voices NSW, stated that, 'as an ethical principle, we do not believe that genes, as natural parts of the human body, should be patentable'.[46]

4.50 Dr Graeme Suthers, Chair of the Genetic Advisory Committee at the Royal College of Pathologists of Australasia (RCPA), described gene patenting as being wrong in both principle and practice.[47]

4.51 IP Australia responded to ethical concerns over the patenting of genes by observing that Australia's patent system is 'technology neutral'. Accordingly, the courts and patent examiners do not generally apply or interpret the law as mandating ethical considerations in relation to the granting of patents in respect of any particular subject technology:

> Gene related inventions are not made unlawful under any existing Australian regulations, and courts have been reluctant to refuse patentability

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

44 See for example, Senator the Hon. Bill Heffernan, *Submission 76*, pp 6-27; *Committee Hansard*, 15 June 2010, pp 1-8; and IP Australia, *Response to Senator the Hon. Bill Heffernan's submission no 76*, pp 1-3.

45 Dr Gillian Mitchell, Peter MacCallum Cancer Centre, *Committee Hansard*, 4 August 2009, p. 105.

46 Ms Sally Crossing, Cancer Voices NSW, *Committee Hansard*, 5 August 2009, p. 2.

47 Dr Graeme Suthers, Royal College of Pathologists of Australasia, *Committee Hansard*, 4 August 2009, pp 40-41.

> on the ground of generally inconvenient, believing it is best left to parliament to decide whether matters of ethics or social policy are to have any impact on what is patentable.[48]

4.52 The National Health and Medical Research Council (NHMRC) expressed the view that there is no need to introduce express exemptions for genetic material into the Act based on ethical considerations.[49]

4.53 To the extent that ethical objections were implicitly or explicitly grounded in the view that the granting of gene patents equates to the granting of ownership or control of an individual's genes, IP Australia stressed that, given the requirements of patentability, human genes and genetic materials occurring in their natural state—that is, in the body—are not patentable. It stated that '[a patent is not granted]…over a human gene. It is [granted] over the isolated human gene sequence for which a practical use has been identified'.[50]

4.54 Further, IP Australia noted that the grant of a patent does not confer any right of ownership or control of an individual's genes:

> A patent over a gene sequence does not equate to ownership of that sequence. A patent is a right to restrain others from using or exploiting the claimed invention without the patentee's permission; it does not confer ownership of the physical material as it exists in the body. A patent on an isolated gene sequence does not impinge on the freedom of the individual to use their own DNA.[51]

4.55 The Intellectual Property Committee of the Law Council of Australia supported the position of IP Australia:

> The ethical issues which have been raised appear to the Committee to be based largely on misconceptions as to the nature of patent protection. For example, the assertion that a patent gives the patentee 'ownership' of a gene is incorrect as a matter of law: there is a fundamental distinction between a patent which protects an invention as a form of intellectual property and the physical property in genetic material.
>
> Similarly, the concern that someone can patent something which is 'part of nature' misconceives a basic principle of patent protection. Patent protection can only validly extend to that which is new and non-obvious.[52]

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

49 National Health and Medical Research Council, *Submission 12*, p. 19.

50 Mrs Fatima Beattie, IP Australia, *Committee Hansard,* 20 August 2009, p. 35.

51 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19,* p. 23.

52 Law Council of Australia, *Submission 57,* p. 2.

## Impacts of express prohibition on gene patents

4.56 In general terms, supporters of an express prohibition on gene patents proposed that the prohibition should apply to human genes and genetic materials per se, and not to downstream uses involving such materials. Dr Gerard Cudmore from the Department of Industry and Investment (New South Wales), commented:

> …downstream uses of sequence data should remain open to the possibility of patenting…[We] believe there is a need, particularly in the context of medical research, to clarify what can and cannot be patented clearly through IP Australia to minimise any confusion and that there should be adequate training of patent officers to ensure that downstream patents are appropriately narrowly defined.[53]

4.57 Similarly, Dr Anna Ronan, a clinical geneticist from the Hunter Genetics Unit, commented:

> …the [testing] technology is improving all the time, and the technology is subject to patent and that is subject to competition…[Testing] has gotten much better obviously, and much quicker. That is how it should be. I just do not see why they need to actually patent the description of the human component that the test is based on.[54]

4.58 More specifically, some groups called for a prohibition covering 'biological materials'. Dr Palombi (and Cancer Council Australia) suggested that 'the *Patents Act 1990* be amended to…ban the patenting of biological materials that are identical or substantially identical to those that exist in nature.'[55]

4.59 Senator the Hon. Bill Heffernan also called for an express prohibition:

> I urge the Committee to consider, as an option, the express prohibition of the patenting of isolated biological materials which are identical or substantially identical to those that exist in nature.
>
> Furthermore, I urge it to consider the possibility of an express prohibition of diagnostic, therapeutic and surgical methods for the treatment of humans.[56]

4.60 DIISR and IP Australia warned that an express prohibition on patentability of 'isolated nucleic acid molecules from humans' would have 'far-reaching consequences'.[57] The supplementary submission from these bodies was particularly critical of the calls for the broader prohibition on 'biological materials' or on 'all

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53 Dr Gerard Cudmore, Department of Industry and Investment (NSW), *Committee Hansard*, 5 August 2009, p. 88.

54 Dr Anna Ronan, *Committee Hansard*, 5 August 2009, p. 68.

55 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 12.

56 Senator the Hon. Bill Heffernan, *Submission 76*, p. 39.

57 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 30.

substances isolated from nature', given the likely effect of this on healthcare and medical research and innovation:[58]

> IP Australia does not support the broad exclusion proposed…to 'biological materials...which are identical or substantially identical to those that exist in nature'…Such a broad exclusion would capture a large proportion of healthcare inventions in the biotechnology and pharmaceutical industries as well as in other industries. Under the proposed exclusion these inventions, although novel, useful and involving an inventive step, would no longer benefit from patent protection. Such exclusion would adversely affect access to affordable future healthcare innovations, the competitiveness of Australia's biotechnology industry and reduce investment in Australian research and development. For example, under the proposed approach inventions such as Gardasil (the cervical cancer vaccine) would not be patentable in Australia but would be in other jurisdictions, which could have negative consequences for access and price in the Australian marketplace.[59]

4.61 In concluding that it did not support an express prohibition on gene patents, the ALRC's 2004 report also expressed concerns that this approach could adversely impact on investment in Australia's biotechnology industry:

> [A prohibition on patenting of genetic materials]…would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions, and may adversely affect investment in the Australian biotechnology industry.[60]

4.62 A number of groups expressed particular concern about the effect of an express prohibition on innovation more generally. Medicines Australia submitted:

> Medicines Australia believes that the formulation of proscriptive categories of subject matter which are to be excluded from patentability is a crude 'on/off' switch, which has the potential to stifle entire fields of innovation.[61]

4.63 Noting the broad range of materials described in the inquiry terms of reference, Xenome commented:

> This is an exceptionally broad scope…[which] encompasses facets of many industries within Australia—not only the medical and biotechnology fields but also the agricultural and brewing fields to name a few. Indeed, if the full spectrum of materials listed…were deemed to be non-patentable, it would have extremely negative effects on a large number of Australian companies

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58 Arguments about the impacts of gene patents on healthcare, medical research and human wellbeing are discussed in Chapter 3.

59 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 3.

60 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 130.

61 Medicines Australia, answer to question on notice, 25 September 2009, p. 1.

> and would drastically undermine emerging industries such as biotechnology.[62]

4.64 The ALRC concluded in its 2004 report that there are 'overwhelming practical impediments to expressly prohibiting gene patents', given the number of gene patents that have been granted. The report concluded that, 'if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed.[63]

4.65 Dr Palombi disagreed with these assessments of the scope and likely impacts of an express prohibition on gene patents on innovation:

> ...[Opponents of an express prohibition argue] that somehow the sky is going to fall in on the biotechnology industry or on medical and scientific progress if you make this incremental step. I say that actually it will do the exact opposite. By banning these sorts of patents on those very limited types of claims, these claims of these materials, you are actually opening up the door to further innovation because you are maximising the ability of scientists to freely use these materials…so that they can make an invention. That is what we want. We want them to make these sorts of massive leaps in technology, not grant patents over elementary processes and non-inventive applications such as diagnostics.[64]

4.66 Commenting on the effect of the suggested prohibition on existing patents, Dr Palombi observed:

> If you were to impose a ban on the isolated biological materials, it would not invalidate the entire patent; it would simply invalidate the claims to those types of materials. So you still leave it completely open for people to come along and develop new and inventive ways of using those materials.[65]

## Effectiveness of express prohibition on gene patents

4.67 A number of submitters and witnesses suggested that an express prohibition on isolated genetic materials would be ineffective.

### *Declining number of gene patents*

4.68 The Committee heard arguments from those opposed to an express prohibition on gene patents that this approach is unnecessary because, irrespective of the actual or potential adverse impacts of overly broad or inappropriate gene patents granted in the past, the quality of gene patents has improved such that similarly defective patents are not being granted today.

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62 Xenome Ltd, *Submission 70*, p. 2.

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

64 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 18.

65 Dr Luigi Palombi, *Committee Hansard*, 14 September 2009, p. 18.

4.69 The ALRC submission acknowledged that overly broad or inappropriate gene patents have previously been granted. However, it argued that the granting of such 'unfortunate' patents is characteristic of new fields of technology in general, and is not therefore a specific or unique feature of gene patents:

> …every new wave of scientific inventions places stress on the patent system as examiners try to come to grips with the new science and technology. Inevitably, some inappropriate and overly broad patents are granted in the first flush of applications, but then the system settles down as examiners become more expert in understanding the nature, complexities and boundaries of the new field.[66]

4.70 Pointing to the limited duration of patent monopolies (in most cases 20 years), the ALRC considered that problems arising from overly broad or inappropriate patents are 'transient' in nature. Given that many of the 'unfortunate' patents granted in the 1980s and 1990s are coming to an end, the ALRC considered a proposal to ban gene patents as being effectively 'yesterday's battle'.[67]

4.71 The submission from Pfizer Australia supported the ALRC's view:

> …as patent offices worldwide have gained experience with genetic technologies, the patents now granted are much more specific than the early gene patents…Since the patent term is 20 years from the date when the priority application is filed, many of the early, broad patents are nearing the end of their patent life.[68]

4.72 The Committee heard that the declining number of gene patents is also a function of the way in which the requirements for patentability such as 'inventiveness' apply to claimed inventions. Dr Trevor Davies, from the Institute of Patent and Trade Mark Attorneys of Australia (IPTMAA), noted that it is important to keep in mind that patents are granted according to the standards of knowledge and technical ability at a given time. Thus the threshold of inventiveness is subject to change as knowledge and technology advance in a given subject area, and what is considered to be an inventive step at one point in time may not necessarily be regarded as such at a later point in time (notwithstanding that the patent continues to be in force). Dr Davies observed that '[as] technology evolves, then what is considered to be inventive now might be quite different from what was considered inventive five or 10 years ago'.[69]

4.73 Pfizer Australia also considered that the thresholds for patentability are increasingly a barrier to the grant of gene patents:

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

67 Australian Law Reform Commission, *Submission 18*, p. 4.

68 Pfizer Australia, *Submission 51*, p. 3.

69 Dr Trevor Davies, Institute of Patent and Trade Mark Attorneys of Australia, *Committee Hansard*, 4 August 2009, p. 8.

> As knowledge of genetics has grown—particularly with the publication of the Human Genome in 2001—the number of patents on individual genes has dropped sharply. This is because the threshold for 'novelty' and 'inventiveness' at the heart of the patent system is now very much higher than it was when the first gene patents were issued...[70]

4.74 On this issue, IP Australia submitted:

> With the successful completion of the Human Genome Project and further rapid advances in sequencing technology, it is increasingly unlikely that a competent patent examiner would now approve an application for patent rights over a pure gene sequence. As Dr Ségolène Aymé of the (French) National Institute for Health and Medical Research Institute stated last year, when the European Parliament was considering this matter:
>
> 'Nowadays, identifying new genes is very obvious, and all the methods are well-established, so it should not be patentable anymore. What is patentable is the inventive process—if you can describe how to use a gene for a specific purpose—but not the gene itself'.[71]

4.75 Mrs Beattie also noted that, due to the increase of knowledge in the field of genetic science, a claim relating to isolated gene sequences may fail on the basis that it lacks novelty. She observed that 'because the genome has been published, for example, the gene sequences per se are now published, therefore they would not necessarily pass the novelty requirements'.[72]

4.76 However, despite the increasing threshold of inventiveness in relation to gene patents, Mr John Slattery, a consultant with Davies Collison Cave, observed that it was still possible that an isolated nucleotide sequence would justify the grant of a patent through meeting the requirements for patentability in terms of novelty, inventive step and usefulness.[73]

4.77 Finally, it was suggested that the number of patents on isolated or purified genetic materials per se is declining because claims are increasingly related to downstream uses of genetic information. Pfizer, for example, noted that gene patents 'are increasingly granted to biotechnologies rather than on isolated genes themselves'.[74] In more general terms, Dr Chris Dent, a senior research fellow with the Intellectual Property Research Institute of Australia (IPRIA), noted that '[recent] research suggests that…the patenting of genetic inventions may be on the decrease'.[75]

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70 Pfizer Australia, *Submission 51*, p. 3.

71 IP Australia, *Submission 18*, p. 4.

72 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 20 August 2009, p. 31.

73 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 9.

74 Pfizer Australia, *Submission 51*, p. 3.

75 Dr Chris Dent, Intellectual Property Research Institute of Australia, *Committee Hansard*, 3 August 2009, p. 7.

### *Definitional issues*

4.78 Professor Andrew Christie noted that a specific exclusion on genes was an alternative for the Committee to consider; however, he did not feel that such an approach would be successful.[76] Dr Moir felt that an express prohibition would continue to be undermined by the expansive approach of the courts on the question of patentable subject matter, and that further exclusions and strategies would need to be employed.[77]

4.79 The ALRC concluded in its 2004 report that a specific exclusion may fail to prevent patenting of genetic materials because 'many pure and isolated genetic sequences do not exist in exactly the same form in nature'.[78] The Committee notes that this would be a relevant consideration in determining whether a substance was 'identical or substantially similar to those that occur in nature' according to the terms of the express prohibition as recommended by some submitters.

### *Potential complexity*

4.80 Mr Hamer advised that the LCA disagreed with the proposal for an express prohibition, on the grounds that this approach would be likely to increase the level of legal disputes and therefore uncertainty in the patent system:

> To the extent that [an express prohibition]…is proposed we disagree with it…The reasons are that having exceptions or special treatment of particular forms of intellectual property…creates disputes, it results in people trying to find loopholes, it creates inconsistencies and it is unfair. Despite the fact that as lawyers you might say we like disputes, in this capacity we are trying to avoid it.[79]

4.81 DIISR and IP Australia also expressed concerns about the effect of the suggested prohibition on the administration of the patent system, arguing that Australia should maintain a 'technology neutral' patent system:

> This technology neutral approach contributes to reduced complexity and cost of providing a national patent system and has inherent flexibility to accommodate patenting of new and emerging areas of technology.[80]

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76 Professor Andrew Christie, private capacity, *Committee Hansard*, 4 August 2009, p. 68.

77 Dr Hazel Moir, *Committee Hansard*, 20 August 2009, p. 4.

78 Australian Law Reform Commission, *Genes and Ingenuity*, June 2004, p. 130.

79 Mr Richard Hamer, Law Council of Australia, *Committee Hansard*, 4 August 2009, p. 75.

80 Department of Innovation, Industry, Science and Research and IP Australia , *Submission 19*, p. 10.

## Barriers to express prohibition on gene patents

### *Consistency with international patent systems*

4.82 As noted in Chapter 2, the patent system is relatively uniform across a number of countries, following many years of efforts to harmonise intellectual property systems. Mr Slattery was concerned that the prohibition of gene patents 'would constitute a move away from harmonisation of Australia's patent laws with the patent laws of other major jurisdictions, particularly the US and Europe'.[81]

4.83 In terms of international practice relating to biological materials and isolated gene sequences in particular, IP Australia advised:

> Internationally all developed countries and our major trading partners, including the European Union, the US, UK, Japan, Korea and emerging economies of India and China, allow patenting of isolated biological materials, including isolated human gene sequences for which a practical use is identified. This is reflective of a principle underpinning the Australian federal patent system since its inception in 1904—that patents should be available for all products and processes that have a practical use.[82]

4.84 Ms Deborah Monk, from Medicines Australia, advised that a prohibition on gene patents in Australia could affect its competitiveness in relation to the pharmaceutical industry:

> …at the moment we are facing enormous challenges in continuing to bring clinical research to Australia. Our near neighbours India and China, and other countries such as Brazil and those in Eastern Europe, are able to do that research as well as we can and have been able to for many years. They can start their clinical research faster. They have large patient populations that they can get into clinical trials, so they can complete the research faster. They can do it cheaper. We are losing our competitive edge. If we have a situation where our intellectual property protection in Australia is eroded in some way or is less robust than it is in other markets then that will be another reason why the headquarters of pharmaceutical companies will not send the research to Australia. There is a very strong view that we need to maintain consistency with other developed markets around the world with respect to our intellectual property protection.[83]

4.85 However, the ACIP options paper on patentable subject matter notes that, despite a fairly high degree of conformity in the approach of various countries to defining patentable subject matter, there are observable differences in the approaches of those countries to interpreting such definitions:

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81 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 2.

82 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, supplementary submission, 30 September 2009, p. 1.

83 Ms Deborah Monk, Medicines Australia, *Committee Hansard*, 5 August 2009, p. 35.

> These outcomes suggest that courts account for national interests when interpreting 'invention', beyond the literal wording of any test. The varying definitions of invention, together with explicitly legislated exclusions create considerable variation in patentable subject matter in different countries.[84]

### *Compliance with international agreements*

4.86 A common objection to an express prohibition on gene patents was that this would place Australia in breach of its international obligations. Two international agreements were identified as being of particular relevance:

- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement); and
- Australia-United States Free Trade Agreement (AUSFTA).[85]

*TRIPS*

4.87 Article 27(1) of the TRIPS Agreement provides that patents shall be available for any inventions and that the patent rights shall be enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'.[86] IP Australia advised that this required Australia to maintain a 'technology neutral' patent system:

> A key feature of patent systems worldwide is that they must be technology neutral in compliance with the TRIPS Agreement…In particular, the TRIPS Agreement requires patents to be made available in all fields of technology without discrimination. IP Australia therefore assesses applications for gene patents by applying the same patentability requirements as for all other applications, irrespective of their technological field.[87]

4.88 Objectors to an express prohibition on gene patents were concerned that:

> …excluding the possibility of patents for gene technology may comprise unjustifiable discrimination against a field of technology that is offensive to TRIPS-defined international patent norms.'[88]

4.89 In contrast, the ALRC's 2004 report noted that, although TRIPS prohibits discrimination, it is possible to differentiate between fields of technology. The allowable extent of any such differential treatment is, however, uncertain:

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84 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', p. 29.

85 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 23. See also Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 2.

86 TRIPS Agreement, article 27(1).

87 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 10.

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

> The non-discrimination provision places constraints on the degree to which gene patents may be singled out for special treatment—for example, through new exclusions from patentability or defences to claims of infringement. However, the extent of these constraints is not clear.[89]

4.90 Dr Matthew Rimmer noted that the possibility for differentiation under TRIPS could potentially support an express prohibition on gene patents:

> …I would disagree with the interpretation that [DIISR and IP Australia]…place upon article 27[(1)] of the TRIPS Agreement. There has been one big WTO decision on the interpretation of article 27, which …says that one cannot discriminate against technologies but one can differentiate between technologies.[90]

4.91 The Committee also heard debate on whether Australia could legislate an express prohibition on gene patents on the basis of certain grounds on which TRIPS allows exclusions to patentability. The ACIP options paper on patentability notes:

> The TRIPS Agreement thus provides a general principle that inventions in a field of technology are eligible for patent protection. Excluding an invention from patentability is an exception to that rule and must fall into one of the exceptions allowed for by the TRIPS Agreement.[91]

4.92 The exceptions with apparent relevance to gene patents include:

- an exclusion to protect public order (*ordre public*) or morality as a result of commercial exploitation in a member's territory (Art. 27(2)); this article is replicated in AUSFTA Article 17.9.1; and
- an exclusion from patentability for methods of diagnostic, therapeutic and surgical treatment of humans (Article 27(3)(a)); this article is replicated in AUSFTA Article 17.9.2(b).

4.93 In relation to the public order exemption, IP Australia advised that in overseas jurisdictions this has been 'narrowly interpreted' and would not in its view 'be able to be used to limit patentability of genetic materials'.[92]

4.94 In relation to the exclusion for methods of diagnostic, therapeutic and surgical treatment of humans, IP Australia advised that Australia does not currently rely on this article to exclude any subject matter from patentability. However, it believed that any changes to Australia's patent law to implement this exclusion 'would require careful

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89 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 91, available at http://www.alrc.gov.au/inquiries/title/alrc99/index.html.

90 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

91 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 26.

92 Department of Innovation, Industry, Science and Research and IP Australia *Submission 19*, p. 24.

consideration of the full impact on innovation in Australia, trade with overseas countries, and transfer and access to medical technologies'.[93]

4.95 Further, DIISR and IP Australia regarded the application of the exclusion to isolated genetic materials as problematic, insofar as it applies only to methods and not products:

> [These Articles]…give Australia the ability to exclude certain subject matter from patentability should it wish to exercise that right. The exclusion is confined to 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'. Therefore, Australia could, should it wish to do so, exclude such methods from patentability, but it could not rely on those Articles to exclude products such as isolated human gene sequences from patentability. It is also not clear whether the Articles could be relied on to exclude a diagnostic method to treat humans if the method contains a product as an integral component.[94]

4.96 In response to IP Australia's views, Dr Rimmer commented:

> IP Australia and the department of industry may speculate on the scope of the exemptions under articles 27(2) and 27(3), but I do not necessarily share their conclusions. I think article 27(2) could be read quite broadly to include gene patents as a kind of exclusion of genes from the scope of patentable subject matter. Indeed, the Canadian position in not allowing patents on higher life forms suggests that that is a possibility with the regime.[95]

4.97 Professor Drahos also did not agree that TRIPS would necessarily act as a barrier to excluding gene patents. He noted that it had not prevented other countries excluding certain subject matter:

> …it has not stopped countries like India, for example, from inserting specific exclusions in relation to the patenting of pharmaceutical compounds…it certainly has not stopped other countries.[96]

4.98 The RCPA noted that the exception for diagnostic tests had been narrowly construed, and called for the interpretation of this exclusion to be reviewed:

> It appears this has generally been interpreted by IP officers to refer to diagnostic tests performed on a person's body, but not to diagnostic procedures where a sample is removed from the body and tested in a

93 Department of Innovation, Industry, Science and Research and IP Australia *Submission 19*, p. 24.

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

95 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 22.

96 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 22.

> laboratory…The RCPA considers that the interpretation of what constitutes a diagnostic test should be revisited.[97]

*AUSFTA*

4.99 As indicated above, AUSFTA replicates the TRIPS requirements for non-discrimination and grounds for exclusion of patentable subject matter. IP Australia advised that, in addition, AUSFTA imposes an obligation on Australia and the US to pursue harmonisation of their patent systems:

> The agreement does require both parties to seek to reduce differences in law and practices between their respective systems and participate in international patent harmonisation efforts. [However, there is]…flexibility to implement the agreement in a way that reflects the interests of our domestic interest groups and Australia's legal and regulatory environment.[98]

4.100 Given this obligation, IP Australia commented that any proposed changes to Australia's patent system, such as an express prohibition on gene patents, would require 'consideration of Australia's obligations under the USFTA' and an assessment of potential impacts on:

- Australia's exports to the US;
- inward technology transfer from the US; and
- trade with the US more generally.[99]

## Alternatives to express prohibition on gene patents

4.101 The Committee notes there was strong support among submitters and witnesses—generally but not exclusively from those who did not support an express prohibition on gene patents—for a broader suite of measures to address any actual or potential adverse impacts of gene patents.

4.102 Many submitters observed that reforms to the patent system generally would improve outcomes in relation to gene patents and the areas of concern to the inquiry. The submission of Professor Diane Nicol and Dr Jane Nielsen urged the Committee to avoid 'focussing on the single issue [of express prohibition of gene patents]'. Instead:

> …the Community Affairs Committee…should take a more expansive approach, both with regard to the issue of how patentable subject matter should be dealt with in the *Patents Act 1990* and also with regard to the exploration of other legal and policy options for dealing with any potential

97 Royal College of Pathologists of Australasia, *Submission 49*, p. 7.

98 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, p. 24.

99 Department of Innovation, Industry, Science and Research and IP Australia, *Submission 19*, pp 24-25.

> adverse consequences resulting from gene and related patents on healthcare, research, innovation and the health and wellbeing of Australians.[100]

4.103 Dr Graeme Suthers observed that the ethical issues in relation to gene patents are also relevant to the patent system in general:

> Genetics is the hot potato for the moment, but the issues that are captured in the ethics story are not peculiar to genetics. If indeed there is a case for having some broader consultation about patenting issues, then it should apply to other patents and not just genetic patents.[101]

4.104 The ACIP options paper on patentable subject matter comments:

> Many of the issues raised in submissions to the Senate reflect concerns cited generally across the patent system. Stakeholders expressed concerns over the width of patents, access to technology, use of patented inventions in research, and the ability of the system to distinguish between patentable and unpatentable subject matter. The context of the gene patent inquiry is important. It concerns the health and wellbeing of Australians. Patents in that field present some unique challenges. However, many of these issues apply to the patenting of other technologies as well.[102]

4.105 Dr Kwanghui Lim, from IPRIA, noted that it would be desirable to ensure that changes to the patent system are done 'in a way that is coherent and consistent with [the patent system as a whole]'.[103] The ALRC also supported a systemic approach in its 2004 report on genetic technology:

> The ALRC was not directed to undertake a general review of the patent system in Australia. Nevertheless, it became apparent that often it was neither possible nor appropriate to suggest amendments directed exclusively at the patenting of genetic materials and technologies in legislation of general application…To the extent that gene patents highlighted any deficiencies in the patenting system generally, the ALRC considered it preferable to craft solutions aimed at correcting systemic weaknesses, in order to ensure that the system remains sufficiently robust to anticipate and respond to future challenges.[104]

4.106 The necessity for such an approach was emphasised by Professor Drahos:

> If I have one message for the committee it is that thinking about improving patent quality, whether it is in the area of biotechnology or any other area, requires an integrated strategy. You do not fix the problem of tax evasion

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100 Professor Dianne Nicol and Dr Jane Nielsen, *Submission 23*, p. 3.

101 Dr Graeme Suthers, Royal College of Pathologist of Australasia, *Committee Hansard*, 4 August 2009, p. 50.

102 Advisory Council on Intellectual Property, 'Patentable subject matter: options paper', September 2009, p. 3.

103 Dr Kwanghui Lim, *Committee Hansard*, 3 August 2009, p. 5.

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

> with a single amendment to the Tax Act, and you are not going to fix the problem of patent quality with a single amendment to the *Patents Act*.[105]

4.107 The submission of the Swedish National Council on Medical Ethics outlined how discrete elements of the patent system can operate to restrict the nature and breadth of patents claiming human genes and genetic material in relation to a product or a process:

> …product protection of genetic diagnostic tests would only be approved on rare occasions if the criterion inventiveness were to be strictly implemented. A strict implementation of the criterion usefulness would counteract patents on DNA sequences as research tools. Product protection would not be possible to apply to the use of DNA sequences in gene therapy since the link between gene and disease is already known [ie is obvious].[106]

4.108 Dr Rimmer noted that there was a 'great consensus' across a number of submissions to the inquiry, concerning the 'need for modernisation and reform of the patent regime'.[107] Professor Drahos noted that many countries are interested in and undertaking patent reform processes, suggesting that the issues examined by the inquiry are of global relevance.[108] DIISR and IP Australia also referred to reform efforts in other jurisdictions, and to the nature and range of measures being considered:

> There are solutions proposed in other jurisdictions to address community concerns about gene patents that strike a balance between the need for genetic research, prosperity of the biotechnology industry and access to innovations in health care. Such measures include strong patentability criteria, public education, a research exemption, access to compulsory licensing, and guidelines for the licensing of genetic inventions.[109]

4.109 IP Australia advised that it was currently pursuing a 'patent reform package' to strengthen Australia's patentability criteria. Beyond this, it felt that existing provisions of the Act—notably the crown use and compulsory licensing provisions—are also generally sufficient and available to deal with any adverse impacts on healthcare or medical research arising from gene patents.[110]

4.110 Submitters and witnesses in favour of implementing a suite of reforms to address the issues of concern to the inquiry often referred the Committee to the

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105 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 14.

106 Swedish National Council on Medical Ethics, *Submission 37*, p. 2.

107 Dr Matthew Rimmer, *Committee Hansard*, 20 August 2009, p. 12.

108 Professor Peter Drahos, *Committee Hansard*, 20 August 2009, p. 15.

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

110 Mrs Fatima Beattie, IP Australia, *Committee Hansard*, 19 March 2009, p. 5.

conclusions and recommendations of previous inquiries relevant to the patent system and/or to gene patents in particular (these were listed in Chapter 2, and include the ALRC inquiry into gene patents and the current ACIP review of patentable subject matter). Mr Slattery submitted:

> …the implementation of the recommendations of these reports is appropriate and important, and will go a long way towards addressing many of the concerns which the general public seem to have in relation to the matters raised in the terms of reference.[111]

4.111 Similarly, Professor Christie noted:

> Many of the concerns expressed by stakeholders to this Inquiry about patents for genetic inventions are valid and significant. What is important for this Committee to recognise is that a number of other inquiries have addressed, or are addressing, the issues at the heart of these concerns. Furthermore, those other inquiries have identified, or will identify, the changes needed to remedy these concerns. Thus, the appropriate action for the government is to implement the recommendations of those inquiries as soon as possible.[112]

## CONCLUSION

4.112 The Committee notes that the question of whether there should be an express prohibition on gene patents requires the weighing of a number of factors to determine how to achieve the best possible outcomes for healthcare, medical research and the health and wellbeing of Australians more broadly.

4.113 The Committee first considered whether the purported benefits of patent protection in relation to gene patents are outweighed by the actual and potential adverse impacts on healthcare and medical research. As indicated in the conclusions set out in Chapter 3, the poor quality and scope of available evidence did not allow the Committee to come to a definitive conclusion in relation to this question. Much of the evidence on adverse impacts was restricted to generalised and/or anecdotal accounts. However, there were clearly some significant cases of adverse impacts arising from gene patents in Australia and overseas, and the Committee also noted that there is obvious and significant potential for adverse impacts arising from gene patents in the future, given the way in which genetic science continues to develop. The difficulty of assessing the purported benefits and adverse impacts of gene patents regarding the question of whether the Act should contain an express exemption underlies the importance of the Committee's recommendations in Chapter 3, concerning improved data collection on, and transparency of, the patent system.

4.114 In relation to the issues considered in this chapter, much of the evidence received in submissions and hearings went to the question of the distinction between

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111 Mr John Slattery, Davies Collison Cave, *Committee Hansard*, 4 August 2009, p. 1.

112 Professor Andrew Christie, *Submission 38*, p. 8.

inventions and discoveries under patent law. This distinction is critical because the law does not allow a 'mere discovery' to be patented. The Committee heard that, for the purposes of the Act, isolated or purified genetic materials for which a use has been identified may be recognised as inventions. This approach was defended by IP Australia as being consistent with the principles of Australian patent law laid down by the High Court, international practice and the application of patent law principles in analogous fields of technology.

4.115 The Committee heard strong criticisms of this current approach on the basis of what might be termed literal or common-sense objections. A number of submitters and witnesses characterised the recognition of isolated genes and genetic materials as 'inventions' as being a purely semantic rather than substantial distinction, given the fact that a gene sequence in an isolated or purified form is apparently often, if not usually, identical to the same sequence occurring in its natural state.

4.116 The Committee recognises that the argument against the recognition of genetic materials as inventions is forceful in that it employs a common-sense application of language, and also connects to some of the broader ethical concerns that apply to the patenting of naturally-derived products, be they human or otherwise. In a similar way, the ALRC 2004 report conceded that 'there are attractive arguments for the view that such materials should not have been treated as a patentable subject matter'.[113] However, the Committee recognises also that technical or legal distinctions may be and commonly are valid, despite not reflecting the everyday or common meaning of the language they employ.

4.117 Despite this, in the Committee's opinion, there is substantial doubt that IP Australia's approach to the granting of patents over genes conforms with the general prohibition in law on the patenting of a discovery or product of nature. While the Committee acknowledges IP Australia's defence of the current approach as being analogous to other classes of patents, such as chemical products, the Committee strongly rejects the reasoning which says that, for the purposes of the *Patents Act 1990* (the Act), genetic information that is isolated from its naturally occurring state in the human body may be classed as an invention, and therefore properly be the subject of a patent (where the other requirements of patentability are satisfied). The Committee considered this objection to be the strongest justification for recommending that the Act be amended to include an express prohibition.

4.118 In terms of the impacts of an express prohibition on gene patents, the Committee notes that virtually all submitters and witnesses supported the maintenance of patent protection for so-called downstream uses of genetic information. That is, supporters of an express prohibition wanted it to apply only to genetic information per se. In some cases, a broader prohibition on biological materials was proposed. It was claimed that this approach would not unduly disrupt existing patents, and would promote research and innovation in the healthcare and medical research sectors by

113 Australian Law Reform Commission, *Genes and ingenuity*, June 2004, p. 124.

removing the disincentives and barriers associated with the existence of gene patents (as outlined in the Chapter 3).

4.119 Conversely, opponents of express prohibition emphasised concerns that this approach would have far-reaching impacts on existing patents and on research and innovation across many different fields of technology. In relation to the healthcare and medical research sectors in particular, it was said that an express prohibition on gene patents would remove important incentives for research and innovation in fields such as biotechnology and pharmaceuticals (as outlined in Chapter 3).

4.120 The Committee notes that the consequences of an express prohibition on gene patents would be undoubtedly complex. Some groups argued that the nature and extent of potential impacts of this approach would be relatively uncertain in relation to healthcare and medical research. This is because, for example, while research institutions may experience added expense, delay and/or uncertainty arising from the existence of the patent system, many such institutions also rely on income from the patent system to fund their work; and for others patent protection provides an incentive for investment in research and innovation.

4.121 In addition to the uncertainty of how an express prohibition might affect the healthcare and medical research sectors, the Committee notes arguments relating to how effective such a prohibition would be in a legal sense. First, it was argued that there is potential for this approach to lead to higher levels of litigation, cost, uncertainty and possibly unfairness as patent system actors seek to promote and/or protect their interests on the terms of any new exclusion introduced into the Act. Second, it was argued that the history of patent law has been characterised by the incremental expansion of the scope of patentable subject matter, and an express prohibition could be undermined by creative patent drafting and such practices. The Committee therefore remained unsure as to the extent to which an express prohibition could by itself achieve sufficient certainty in terms of future development of the law through the courts and IP Australia.

4.122 The Committee also heard arguments that an express prohibition on gene patents is unnecessary due to the declining number of gene patents. Arguments about the number of gene patents granted in the past, and likely to be granted into the future, were considered in detail in the previous chapter.

4.123 Opponents of an express prohibition on gene patents contended that the occurrence of overly broad or inappropriate patents is a common phenomenon in relation to new and emerging technologies, and that such low-quality patents are less likely to occur today given the greater experience and expertise of patent offices. It was also argued that gene patents are less likely to be granted today because the thresholds of patentability in relation to the elements of novelty and inventiveness are more difficult to achieve, given the maturing of knowledge and technology in the field of genetics.

4.124 The Committee notes its previous conclusions that it was not convinced of a substantial decline in the number of gene patents, or that future developments in genetic science will not continue to form the basis of substantial numbers of patent claims relating to human genes and genetic materials into the future. However, the Committee does accept that some of the poor quality patents issued in the past were likely due to patent offices' relative inexperience with genetic technologies, and certain recommendations in the following chapter are relevant to this issue.

4.125 In relation to the thresholds of patentability, the Committee accepts that the thresholds of patentability for novelty and inventiveness—being relative to the state of knowledge and technology at the time a patent application is made—would today possibly prevent claims that were in the past sufficiently novel and innovative to deserve patent protection. However, the Committee was not convinced that patentability thresholds are otherwise operating sufficiently well to ensure that overly broad or inappropriate patents are not being granted in relation to human genes and genetic products. These issues are discussed in detail in Chapter 5, and a number of recommendations are made to address these issues around patent quality.

4.126 In relation to potential barriers to creating an express prohibition on gene patents, despite the possible difficulty of fashioning legislative provisions that would be sufficiently precise, effective and of enduring effect, the Committee does not agree with the view that it is not feasible or necessarily possible to expressly prohibit gene patents, as the ALRC concluded in its 2004 report. Nor did the Committee regard the need for compliance with international agreements such as TRIPS to be insurmountable if Australia were to seek to enact a prudent exclusion for gene patents. The Committee believes that Government should not feel prevented from enacting express exemptions of certain subject matter in future where this is justified by sufficient evidence. In the event that the Government decided to pursue an express prohibition, the Committee considers that it would be appropriate to discuss and promote this reform in relevant international forums relating to trade and the patent system.

4.127 However, the Committee concluded that there would need to be a very clear case and significant social and political consensus on the need for such a change. The totality of the submissions and evidence to the inquiry shows that there are legitimate and sometimes finely balanced arguments on both sides of the debate. Given this, the Committee believes it is critical to improve the extent and quality of interaction with the patent system by Government, as well as its understanding of the principles underpinning the operation of the patent system. As noted in the previous chapter, this is critical to ensuring that governments are aware of how effectively the patent system is operating and delivering the benefits expected in return for the grant of patent monopolies. In addition to the recommendations in Chapter 3 going to better accumulation of data on patents, a number of recommendations in the following chapter are intended to ensure that governments are informed about and engaged with the patent system, particularly in relation to the challenges thrown up by new and emerging technologies.

4.128 Finally, the Committee notes a strong consensus among opponents of an express prohibition on gene patents that the concerns which formed the basis of the Committee's inquiry can be more effectively addressed through a range of responses directed not at gene patents per se but at improving the operation of the patent system more generally. The Committee was encouraged to consider the conclusions and recommendations of a number of previous inquiries into gene patents or the patent system as the basis for its own conclusions and recommendations in this report.

4.129 In light of the factors and analysis outlined above, and despite its concern with the current practices of IP Australia around application of the invention-discovery distinction to isolated genetic materials, the Committee determined that it would not recommend at this stage that the *Patents Act 1990* be amended to include an express prohibition on human genes and genetic products.

4.130 The Committee's decision was based, first, on recent international and national legal developments relating to the patentability of genes. In the US, the courts have rejected the patenting of isolated genes on the basis that they are in fact products of nature or 'mere discoveries', and this policy has been confirmed by the US Department of Justice (see below paragraphs 4.132 and 4.133). In Australia, a similar challenge to the BRCA gene patents has commenced. If the court were to find, as in the US, that isolated genetic materials are 'mere discoveries' and therefore not patentable subject matter, there may be less need for an express prohibition on gene patents, as was considered under term of reference (c); particularly if the recommendations of this report are also implemented.

4.131 Second, the Committee's decision not to recommend an express prohibition on gene patents at this stage recognises the announcement that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill) would be introduced to the Senate in late November 2010 (see below paragraphs 4.134 and 4.135), which contains an express prohibition in specific terms. While the Committee would support an amendment to the Act to ensure that isolated genetic materials are not classed as an invention and therefore patentable, the Committee acknowledges that there are many issues which require further investigation in relation to the Bill, such as the likely impacts, effectiveness and scope of an express prohibition relating to 'biological materials' as is proposed.

4.132 As noted above, the Committee's decision not to recommend an express prohibition at this stage was influenced by international and national developments relating to the invention-discovery distinction and its application to isolated genetic materials. Since the inception of its inquiry, this very issue has been considered in the MPO case in the US.[114] The judgement in the MPO case ruled that Myriad's BRCA gene patents were invalid, largely on the basis that the claims to isolated genetic

114 *The Association of Medical Pathology and Others v The United States Patent and Trademark Office and Myriad Genetics, Inc and Others*, US District Court for the Southern District of New York, 09 Civ. 4515, p. 83.

sequences did not constitute an invention as a matter of law. On 29 October 2010, the US Department of Justice indicated that the US federal government had altered its policy to reflect the US District Court's finding on this issue (although it was not clear whether the USPTO would implement the revised policy). The Committee understands that, in the event that this ruling is mirrored in the judgement of a higher court, it will become binding on the practices of the USPTO. In such circumstances, and assuming there was no change to the Act in the meantime, the Committee would expect that the Government and IP Australia will act quickly to update Australian patent law and practice to conform with the US approach, particularly given evidence concerning the importance that IP Australia places on international harmonisation of patent systems and Australia's obligations under AUSFTA.

4.133 The Committee notes also that, on 8 June 2010, a challenge to the validity of the BRCA patents in Australia was launched in the Federal Court by Maurice Blackburn Lawyers, Cancer Voices Australia, and a Brisbane woman with breast cancer, Yvonne D'Arcy.[115] The Committee understands that, as with the US MPO case, the Australian case will focus on the fundamental question of whether or not an isolated gene sequence is an 'invention' as a matter of law and therefore patentable in the Australian jurisdiction. In the event that the Federal Court decision follows the MPO case, and assuming there was no change to the Act in the meantime, IP Australia will be required to adjust its approach to conform to that decision.

4.134 The Committee further notes that, on 17 November 2010, a group of members of the House of Representatives and senators announced that they would be introducing a private member's Bill into the federal Parliament, intended to prevent the patenting of human genes and biological materials existing in nature. The Committee notes that, if the Patent Amendment (Human Genes and Biological Materials) Bill 2010 were passed, this would effectively override the significance of the abovementioned cases in relation to the invention-discovery distinction and the granting of patents over human genes and genetic materials (assuming, of course, that the amendment was effective in terms of its intended scope and impacts).

4.135 The Committee believes that the introduction of the Bill to the Senate will provide a further, and much-needed, opportunity for the arguments and questions around the impacts and effectiveness of an express prohibition on gene patents to be considered. The Committee agreed that a Senate inquiry into the Bill should be undertaken, with a focus on the specific terms of the proposed amendments and the implications of their implementation for human health and other potentially affected fields of innovation. The Committee notes that its inquiry has served a valuable purpose in bringing the issue of gene patenting to the light of public interest and

115 Maurice Blackburn Lawyers website, 'Biotech monopoly on cancer genes is unlawful: Australian test case over patents', 8 June 2010, available at http://www.mauriceblackburn.com.au/news/press-releases--announcements/biotech-company-monopoly-on-cancer-genes-is-unlawful-australian-test-case-over-patents.aspx (accessed 20 August 2010).

attention, and provides a sound basis on which a targeted inquiry into the Bill can build. In recognition of the seriousness and complexity of the issues around the issue of expressly prohibiting gene patents, as outlined in this report, the Committee would expect that the Senate will ensure the time allowed for an inquiry into the Bill is sufficient to ensure due consideration of relevant issues and the arguments of potentially affected interests.

4.136 In consideration of the developments outlined above, the Committee intends to maintain a watching brief over the area of gene patents. As part of this watching brief, the Committee will continue to monitor the progress and outcomes of the US and Australian cases relating to the patenting of isolated genetic materials, as well as the progress of the Patent Amendment (Human Genes and Biological Materials) Bill 2010 through the federal Parliament.

**Recommendation 3**

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

4.138 Despite the Committee's decision not to recommend an express prohibition on gene patents at this point, the next chapter makes a number of recommendations for measures to ameliorate any adverse impacts arising from gene patents. The rationale behind many of these is to raise the thresholds of patentability such that, despite there being no direct prohibition on gene patents, the number of gene patents being granted would necessarily be reduced, and the quality of those that are granted will be greatly improved. Yet other recommendations seek to ensure that the Government utilises existing options under the Act to ameliorate the impacts of gene patents on healthcare, where these arise; to ensure that research is not impeded by the patent system; and to institute a mechanism for external and objective assessment of the patent system and the performance of IP Australia.

4.139 The Committee notes that the recommendations in the next chapter (as well as those elsewhere in this report), would not be rendered obsolete or less effective in the event that the express prohibition contained in the Patent Amendment (Human Genes and Biological Materials) Bill 2010 became law. The Committee's recommendations are not directed at gene patents per se, but at patents and the patent system more generally, and many of these are based on patent reform recommendations for which there has been widespread and longstanding support. Indeed, the Committee notes that, in the event that Parliament agrees to legislate an express prohibition on biological materials as proposed, the recommendations in this report relating to information and data collection could be critical to ensuring that the intended effects and benefits of the prohibition on gene patents are able to be assessed into the future. The recommendations in this report would also ensure that gene patents relating to isolated genes (if these continue to be granted) or to the downstream uses of genes (to which the Committee believes gene patents should and would be restricted if the invention-discovery distinction were being properly applied) are of high quality, and thus clearly justified in both social and economic terms.