SENATE LEGAL AND CONSTITUTIONAL AFFAIRS COMMITTEE

INQUIRY INTO THE PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

JOINT SUBMISSION BY THE DEPARTMENT OF INNOVATION, INDUSTRY, SCIENCE AND RESEARCH AND IP AUSTRALIA

CONTENTS

EXECUTIVE SUMMARY

This is a joint submission from the Department of Innovation, Industry, Science and Research (DIISR) and IP Australia which is a prescribed agency within the Innovation, Industry, Science and Research portfolio. DIISR and IP Australia welcome the opportunity to provide comments to the Senate Committee on Legal and Constitutional Affairs Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill).

The purpose of this submission is to inform the Committee on the patenting of biological material, including human genetic material, under section 18 of the *Patents Act 1990,* and the likely impact of enacting the changes to section 18 as proposed in the Bill.

Overall, the submission;

- provides a historical perspective of the patenting of biological material from the beginning of the federal patent system in 1903 to the present;
- describes why isolated biological material is considered to meet the requirements of section 18;
- outlines Australia's obligations with respect to patent subject matter eligibility under relevant international treaties and agreements;
- presents the findings and considerations of previous Inquiries and Parliamentary debates on patent subject matter eligibility and the patenting of gene sequences;
- describes current legal action on the patenting of gene sequences;
- identifies the subject matter that would be excluded from patentability if the amendment was enacted and the possible impact of such an exclusion on the relevant industries;
- comments on existing safeguards and reform measures that may address the issues the Bill seeks to overcome.

Biological material as it occurs in its natural state has never been eligible for patent protection. In contrast, isolated or purified biological material qualifies as patent eligible if two criteria are satisfied. Firstly, the material must be the result of human intervention, that is, a material product that results from an extraction, purification, isolation or synthesis process. Secondly, the material must have a specific use.

Since the early 1900s patents have been granted over biological material isolated from plants, animals and micro-organisms that are useful in industry and medicine. Modern biotechnology and molecular genetic methods has made possible the isolation and characterisation of an organism's genetic material. Isolated genes and proteins defined by their chemical structure (sequence) are considered as eligible for patent protection because they are useful chemical molecules after they are isolated from biological material.

Australia is consistent with most other nations in considering such material to be eligible matter for patent protection. Decades of debate has surrounded the patenting of isolated genetic materials. To date, no country which has granted patents over isolated gene sequences and other biological materials has changed its legislation to exclude genetic material from being eligible for patent protection.

The introduction of exclusions from patentability of specific products in the *Patents Act 1990* needs to be considered in light of Australia's international obligations to provide patents for certain subject matter. The international agreements most relevant to the Bill in this respect are the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Australia-United States Free Trade Agreement (AUSFTA). The amendment proposed by the Bill raises a number of issues with respect to Australia's compliance with these international agreements including whether the amendment:

- would exclude subject matter that are considered 'inventions' for which patents must be available for under TRIPS and AUSFTA;
- would be contrary to the TRIPS requirement that patents be available without discrimination as to the field of technology; and
- could be justified under the various exclusions from patent subject matter eligibility available under TRIPS and AUSFTA.

DIISR and IP Australia recommend that the Committee seeks the advice of the Department of Foreign Affairs and Trade on the Bill's consistency with Australia's international obligations.

The issues of patentable subject matter in general, and the patenting of biological materials specifically, have been considered on several occasions by various reviews and inquiries and by the Parliament of Australia. The main legislative criteria for patentable subject matter have not changed since the first patent legislation was enacted in Australia following Federation in 1903. All reviews initiated by the Government or Parliament that have considered these issues in the past have not recommended introducing specific exclusions for any categories of biological material including genetic material. There have been several previous proposals in Parliament to exclude certain categories of biological materials from patent eligibility (primarily related to genetic material). All of these proposals have been rejected by Parliament except for the proposal that resulted in the current exclusion under section 18(2) of the *Patents Act 1990* for human beings and the biological processes for their generation. This exclusion appears to fall within Article 27(2) of TRIPS which allows inventions to be excluded from patentability on the grounds that the commercial exploitation of the invention would offend *ordre public* or morality.

Judicial consideration of whether isolated genetic material is eligible for patent protection as a matter of law in Australia and the United States will occur for the first time in court actions currently on foot in both jurisdictions. The Australian court action is provisionally set for hearing from 19 September 2011. The US court action has already seen one lower court decision that ruled that such material was not eligible for patent protection. This decision has been appealed and is due to be heard in mid to late 2011.

The amendment is not limited to genetic material. It extends to all biological material. If enacted, the Bill will prohibit the grant of patents for biological material isolated from plants and animals and micro-organisms. Patents over biological material are fundamental to innovation and investment in the development of new and beneficial medical, industrial, environmental technologies and food.

The boundaries of the proposed exclusion are not clear. It is difficult to determine with reasonable certainty the type of inventions and subject matter which may be excluded by the Bill. There is no clear extrinsic guidance as to what 'derivative' or 'identical' or 'substantially identical' means in the context of the amendment. Many products that are produced through a biotechnological, genetic or bioengineering process might be considered a 'derivative' or an analogous counterpart of naturally occurring biological material.

Patenting has been particularly important for the biotechnology industry. Biotechnology inventions are expensive to produce, with a high risk of failure and a long time to market, but are comparatively inexpensive to reproduce, or reverse engineer. Current estimates of the full cost of bringing a new pharmaceutical (chemical or biological) entity to market are around US$1.2 to $1.3 billion.[1] Given the high cost of conducting research and development (R&D) before commercialisation, it is crucial for businesses, particularly small start-ups, to attract private investment.

The proposed exclusion may also have impacts outside the provision of healthcare, for example, on aspects of the burgeoning bioeconomy, including agricultural, industrial and environmental biotechnology, and the emerging area of synthetic biology. Absence of the patent incentive and attendant lack of access to capital could have significant consequences.

There is no evidence that access to diagnostic testing or medicines is restricted in Australia. If restrictive licensing practices did impede access to treatments or diagnostics, the Bill would not address such problems because methods of diagnosis and treatment are not excluded by the amendment. The Crown use and compulsory licenses provisions already existing in the patent system can be used to deal with such problems if the need arises.

There is no evidence that the present patentability of biological material is impacting adversely on research activities in Australia. Some concerns however have been expressed within the research community about the existence and scope of any common law research exemption. This is addressed in the Intellectual Property Laws (Raising the Bar) Amendment Bill 2011 (the Raising the Bar Bill) which proposes a statutory exemption from infringements for experimental and regulatory approval activities.

[1] IBISWorld Industry Report, *Global Pharmaceuticals and Medicine Manufacturing: C1933-GL*, April 2010, p. 21.

SUBMITTING AGENCIES

Department of Innovation, Industry, Science and Research

1.1. DIISR strives to encourage the sustainable growth of Australian industries, by developing a national innovation system that drives knowledge creation, cutting edge science and research, international competitiveness and greater productivity. The DIISR is committed to developing policies and delivering programs, in partnership with stakeholders, to provide lasting economic benefits ensuring Australia's competitive future.

1.2. In line with this aim, DIISR believes that Australia's intellectual property (IP) regime should abide by the following principles. It should:

- effectively encourage innovation to provide lasting economic benefits to Australia;
- enhance our competitiveness in a global environment; and
- be consistent with our international obligations.

IP Australia

1.3. IP Australia is the Australian Government agency responsible for:

- assessing and granting intellectual property (IP) rights in patents, trade marks, designs and plant breeder's rights ('registrable IP rights');
- promoting IP awareness;
- developing legislation to support Australia's IP system;
- contributing to bilateral and multilateral negotiations to improve IP protection internationally in accordance with Australia's interests; and
- administering the registration and discipline of patent and trade mark attorneys.

1.4. Both the DIISR and IP Australia are responsible for providing policy advice to government on registrable IP rights as part of the Innovation, Industry, Science and Research portfolio.

BACKGROUND

Patent protection for isolated or purified biological material pre-dates modern biotechnology

2.1. Products of nature such as animals, plants or micro-organisms as they exist in the natural environment have never been considered as eligible for patent protection in Australia or any other country. However, Australia's patent system has long regarded substances and chemicals isolated from natural sources and living organisms as inventions suitable for patent protection as long as all the requirements for patentability are satisfied. These include the threshold requirement of 'invention' and that the invention is new (that is, not published or previously used), and non-obvious and that the patent specification describes how to make and use the invention.

2.2. In assessing whether a biological material qualifies as patent eligible subject matter, two essential requirements must be met. First, the material must be the result of a man-made process (of human intervention), for example isolation, purification or synthesis process to yield the material in a useable form. Second, the material must have a specific use, for example, use in a specific industrial process or to treat or prevent a specific disease. The Australian patent system has applied these principles since the beginning of the federal patent system in 1903. For well over a century, Australia has granted patents over many isolated or purified biological materials that have medicinal or industrial uses.

2.3. An example of an early Australian patent granted to an industrial useful product, is the 1914 patent over improved peat and the process of preparing it by treating peat with solutions comprising micro-organisms.[2] In 1922 a patent was granted over a product consisting of the residue material remaining after distilling gum bearing parts of the *xanthorrhoea* tree, and various processes for obtaining the useful residue and oil fractions from the plant material.[3] The residue was found to be useful as a black varnish and 'harness maker's and shoemaker's wax'.[4]

2.4. In 1924 a medicinal substance isolated from the glands of fishes or mammalian pancreas useful for relieving diabetes was patented.[5] A herbal blood purifying product made from dried and powdered radiata pine needles was patented in 1938.[6]

2.5. Patents granted in the early 1900s often claimed isolated or processed biological material by the process of its manufacture or isolation. The science of the time was not so advanced so as to enable the material to be sufficiently characterised by its chemical structure or physical and chemical properties.

---

[2] Australian patent No. 9824/13 'Improved treatment of peat for manurial and other purposes'.
[3] Australian patent No. 530/21 'Improvements relating to the treatment of the gum of the *xanthorrhoea* tree and to the recovery of oils and the manufacture of a stain and other products therefrom'.
[4] Ibid, column 1.
[5] Australian patent 113, 427/23 'A product obtainable from the mammalian pancreas, the related glands of fishes, and other sources, useful in the treatment of diabetes mellitus, and a method of preparing it.'
[6] Australian patent No. 105, 958 'A herbal blood purifying remedy'.

2.6. Patents have also been granted for micro-organisms. Micro-organisms have uses in many industrial and fermentation processes and are an important source of antibiotic compounds. An inoculum of a new *Clostridium* micro-organism, obtained from potato or cereal plants, was patented in 1936.[7] The bacterium improved fermentation of plant material for the manufacture of alcohol solvents. Novobiocin, an antibiotic patented in 1958, is produced by fermenting *Streptomyces spheroids,* a micro-organism found in soil.[8]

Patent protection for isolated genetic material is a logical extension of the protection afforded to other biological material derived from natural sources

2.7. Modern scientific advances have enabled many biological derivatives of natural products to be defined by their chemical structure or composition. By the late 1970s techniques were available for isolating genetic material and determining its chemical sequence (the exact order of nucleotide bases or amino acids). Genetic engineering methods were also available for using isolated genetic material to produce important biochemical proteins, such as blood clotting factors and hormones, in bacterial hosts. By the early 1990s the biotechnology community was actively engaged in isolating and characterising genes from organisms of interest. The advent of automated sequencing technologies facilitated the Human Genome Project, a large scale, collaborative undertaking to map (identify the specific chromosomal location) and sequence the entire human genome. These activities were accompanied by the filing of patent applications over isolated deoxyribonucleic acid (DNA),[9] gene sequences and proteins, and methods of isolating, detecting, manipulating and using the isolated genes and proteins. These 'gene patents' underpinned the development of new pharmaceuticals, diagnostics, research tools and new animal and plant varieties.

2.8. Patent protection for isolated genetic materials and proteins defined by their chemical structure (sequence) represents a logical extension of the patent rights afforded to other kinds of biological material and chemicals isolated from natural sources. Australia and most other countries take the position that isolated genes, DNA and proteins are chemical molecules[10] and therefore eligible for patent protection on the same basis as other isolated or purified substances and chemicals.

2.9. Gene patents are not based on finding a gene in nature or confirming a gene exists alone. Merely isolating and describing the chemical sequence of a gene is insufficient. A useful purpose for the isolated gene must also be demonstrated, for example, a specific therapeutic use or as the basis of a specific diagnostic test.

2.10. The other standard requirements for patentability must also be met. The isolated and useful gene sequence must be new, useful and non-obvious over what was previously known and the patent application must disclose how to obtain and use the isolated DNA molecule or gene. Newness in respect of a patented gene sequence (or any material isolated from a natural biological source) means that the gene sequence/material was not previously known and

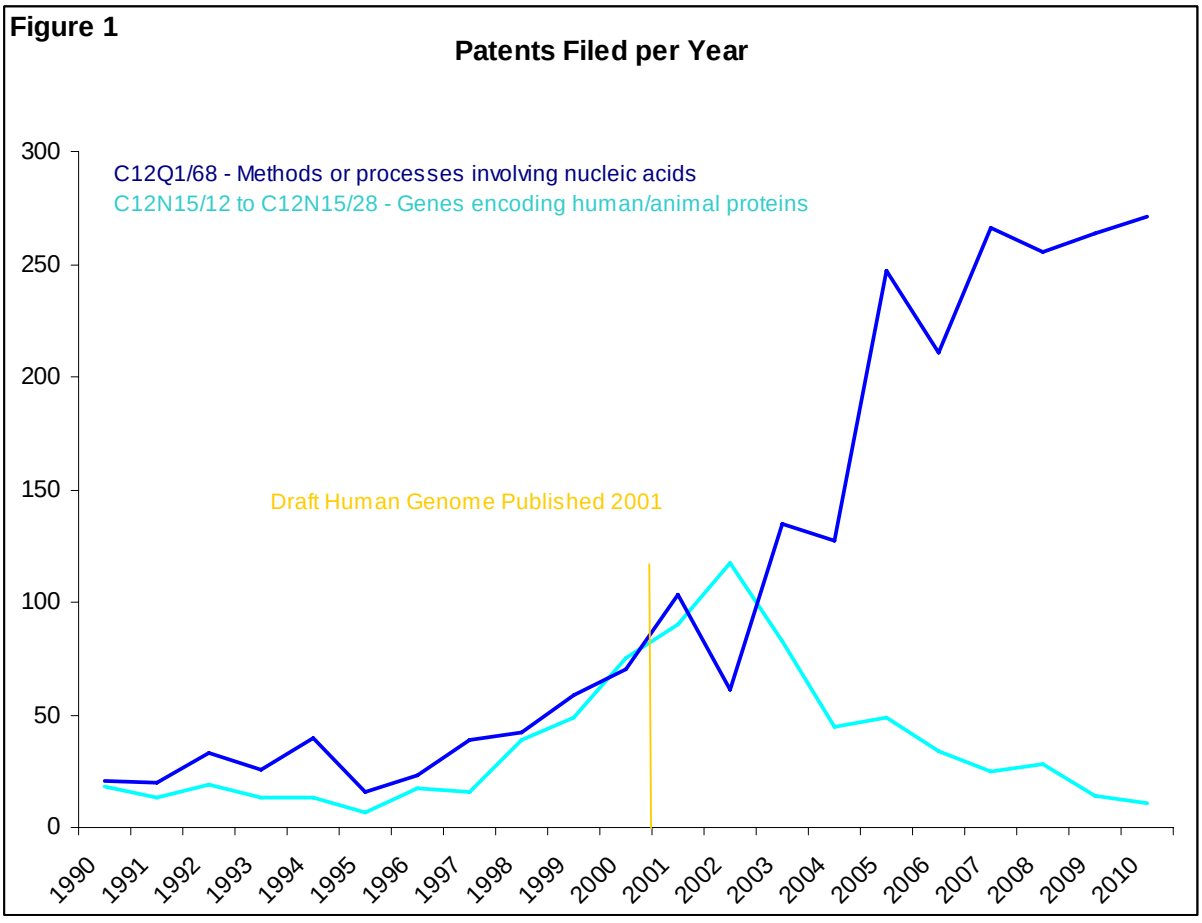
---

[7] Australian patent No. 22, 388/35 'Improvements in or relating to manufacture of solvents by fermentation'.
[8] Australian patent No. 213, 841 'Novobiocin and the preparation thereof'.
[9] DNA is a very large linear molecule which acts as the store of genetic information in all cells: Lawrence, E (ed.) 2005, *Henderson's Dictionary of Biology*, 13th edn, Pearson Education Limited, England.
[10] In US litigation *Amgen Inc. v. Chugai Pharm. Co*., 927 F.2d 1200, 1206 (Fed. Cir. 1991) 'A gene is a chemical compound, albeit a complex one…'.

available to the public in an isolated or purified form. Gene sequences do not exist in nature in an isolated or purified form.

2.11. As advances are made in a technology, and the related common general knowledge increases, it becomes harder for an invention to satisfy the criteria of newness (novelty) and non-obviousness (inventive step). Consequently, there is a narrowing of the monopoly rights in subsequent patents. Since the publication of the draft sequence of the entire human genome in 2001, a claim to an isolated human gene sequence is unlikely to satisfy the novelty requirement unless it is a previously unknown variant form of the gene sequence. Even if it satisfies the novelty requirements, it may well not satisfy the requirement that it be non-obvious, because related variants of the gene sequence are known. The effect of the increasing knowledge in the art on gene patent filing trends is provided in Figure 1. A full explanation of the International Patent Classification System (IPC) as it relates to gene patents and used in the Figure can be found in the joint DIISR and IP Australia submission to the Senate Community Affairs Committee's Inquiry into gene patents (the Senate Gene Patent Inquiry) at Attachment A. Figure 1 is an update of Figure 2 of the Senate Gene Patent Inquiry submission. In the course of the Senate Gene Patent Inquiry the trend has continued to move to downstream applications and decrease in respect of gene sequences *per se*. An example of a downstream invention is a method of using a known gene to diagnose predisposition to a disease, not previously known to be associated with that gene sequence.

Figure 1



2.12. A common feature of public patent debates is the application of contemporary knowledge and understanding of the state of the art to patents which were filed years ago. Patent applications are assessed from the point of view of a person skilled in the art and the common general knowledge in the art at the time of the application filing (its priority date) and not at when it is examined or at the time the patent is granted or commercially exploited, which can be some years later.

Australia's position on the patenting of isolated biological material is consistent with most other countries

2.13. Debate and controversy surrounding the patenting of genetic materials, has persisted for decades, however, all but a few countries now consider genetic and biological material to be eligible for patent protection.

2.14. In Europe, the patentability of genes was controversial. Following a ten year debate, the European Commission adopted a directive in 1988 (The EU Biotechnology Directive on the Legal Protection of Biotechnological inventions 98/44/EC) mandating that biotechnological inventions should be treated no differently to inventions in other technologies.[11]

2.15. Contracting states were required to align their national laws with the Directive by July 2000 but it was not until January 2007 that all contracting states finally implemented the Directive. Articles of particular relevance include:

> Article 3 (2)
>
> Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

2.16. Article 5 (1) to (3) addresses the distinction between 'discovery' and 'invention' in respect of genes and matter isolated from humans:

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

2.17. Article 5 (2) clarifies that an isolated gene sequence *per se* can be protected. That is, patent protection is not limited to practical uses of the isolated gene sequence.

[11] Directive on the Legal Protection of Biotechnological inventions 98/44/EC available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF, accessed 11 February 2011.

2.18. The United States[12], China and Japan all consider isolated biological material, including gene sequences, to be eligible for patent protection, on the pre-condition that all the substantive requirements for patentability are met. In these countries, the patent legislation does not expressly mandate patent protection for biological material. Eligibility is based on the recognition that 'isolated' or 'purified' biological material with a practical use is distinct from biological material in its natural state.

2.19. In 2001 the United States Patent and Trademark Office (USPTO) issued Utility Examination Guidelines addressing compliance with the utility aspect of 35 U.S.C. 101 which relates to patent subject matter eligibility.[13] The guidelines specify that the utility of an invention such as a gene sequence must be specific, substantial and credible. The guidelines also provide a detailed response to public concerns around gene patenting that prevailed at that time.

2.20. The Chinese examination guidelines also stipulate that finding a gene in nature, or a DNA fragment in its natural state, is a discovery and not for patent protection. In contrast, a gene or a fragment of a gene isolated or extracted from its natural state, is eligible for patent protection if it has an industrial application, and the chemical sequence of the material has not been previously known.[14]

2.21. Some WTO Members (e.g. Brazil, Andean Community (Bolivia, Colombia, Ecuador and Peru), Argentina) exclude patents for biological materials isolated from nature in their national law. For example, Brazil's Industrial Property Law 1996, Article 10 states that:

> The following are not considered to be inventions or utility models:
> …
> IX. all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.

INTERNATIONAL OBLIGATIONS AND PRACTICE

3.1. The introduction of exclusions from patentability of specific products in the *Patents Act 1990* needs to be considered in light of Australia's obligations under various international treaties and bilateral and multilateral trade agreements. The international treaties and agreements most relevant to the Bill are the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Australia-United States Free Trade Agreement (AUSFTA). This section is not a formal legal advice; rather it identifies some of the possible issues with the Bill in respect of our international obligations. It also provides examples of the practice of some countries that have international obligations under TRIPS. DIISR and IP Australia recommend that the Committee seeks the advice of the

---

[12] The *amicus curiae* brief submitted by the United States Department of Justice (DOJ) in respect of, *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others, US District Court for the Southern District of New York*, 09 Civ. 4515., suggests a shift in this position. See Attachment B to this submission.

[13] See http://www.uspto.gov/web/patents/patog/week53/OG/TOCCN/item-160.htm, accessed 10 February 2011.

[14] See 'Patent Protection of New Technologies', State Intellectual Property Office of China, available at http://www.sipo.gov.cn/sipo_English/news/official/200904/t20090417_453512.html, accessed 10 February 2011.

Department of Foreign Affairs and Trade on the Bill's consistency with Australia's international obligations.

TRIPS

3.2. Australia has been a member of the WTO since 1 January 1995. As such, Australia is obliged to apply TRIPS in its domestic legislation.

3.3. In particular, Article 27(1) of TRIPS requires patents to be made available for inventions in all fields of technology, without discrimination, provided that they are new, involve an inventive step and are capable of industrial application. IP Australia assesses patent applications that claim biological materials by applying the same patentability requirements as for all other applications. Introducing a general exclusion specifically for a category of biological materials may breach Australia's obligations under TRIPS.

3.4. During the second reading for the Bill, Senator the Hon. Bill Heffernan addressed the compatibility of the proposed amendment of the *Patents Act 1990* with Australia's international obligations. He stated that:

> 'Biological materials which are identical or substantially identical to what exists in nature are not inventions. They are discoveries and therefore incapable of being inventions. The Bill merely seeks to apply the law as it is and this law is compliant with both [TRIPS and AUSFTA].'[15]

3.5. The explanatory memorandum for the Bill also states that it:

> …reinforces the applicability of the distinction between discovery and invention and … applies that distinction by expressly excluding from patentability, biological materials which are identical or substantially identical to such materials as they exist in nature, however made.

3.6. In short, the reasoning put forward appears to be that such biological materials are not 'inventions' for the purpose of TRIPS and AUSFTA. Therefore, the obligations of these international agreements do not apply to patents for such biological materials. TRIPS and AUSFTA do not provide a definition of 'invention'. Later sections in this submission address the scope of subject matter that is likely to fall within the scope of the exclusion prescribed by this amendment which may assist the Committee in considering this reasoning. If this exclusion did cover subject matter that was an 'invention' under TRIPS, it would be necessary to consider whether this exclusion resulted in discrimination as to a field of technology under the second sentence of Article 27(1) of TRIPS.

3.7. There are some limited exclusions from patentability available under TRIPS that can be used even where subject matter meets the requirements of Article 27(1).

3.8. Article 27(2) of TRIPS permits the exclusion from patentability of inventions:

> the *prevention* within their territory of the *commercial exploitation* of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.' (emphasis added)

[15] Commonwealth of Australia, *Parliamentary Debates*, Senate, 24 November 2010, p. 2100.

3.9. Article 53(a)[16] of the European Patent Convention (EPC) is an example of a regulation which provides for the exclusion of European inventions which by way of publication or exploitation, would be contrary to *ordre public* or morality.

3.10. In practice the European Patent Office (EPO) interprets this morality exclusion narrowly.[17] For example, in Europe in 1992 the 'Relaxin' gene patent EP 112149 was granted to the Howard Florey Institute of Australia. This patent comprises claims to gene sequences *per se*[18] and was subject to opposition on many grounds[19], including that the patent contravened morality or *ordre public*. This view was dismissed by the EPO Opposition Division in 1995 which concluded that:

> [o]nly in those very limited cases in which there appears to be an **overwhelming** [public] **consensus** that the exploitation or publication of an invention would be immoral may an invention be excluded from patentability under Article 53(a) (emphasis in original).[20]

3.11. More recently, the EPO Technical Board of Appeal also reaffirmed their approach to gene patents in view of Article 53(a) by deciding that the claimed diagnostic methods relating to the BRCA genes[21] did not offend morality or *ordre public.*[22]

3.12. It would appear that this European exclusion would not in practice limit the patentability of the subject matter covered by the amendment proposed in the Bill.

3.13. Article 27(3)(a) of TRIPS permits the exclusion from patentability of:

> diagnostic, therapeutic and surgical *methods* for the treatment of humans or animals (emphasis added).

3.14. In Europe, surgical, diagnostic and therapeutic methods practiced on the human or animal body are excluded from patentability according to Article 53(c) of the EPC. In practice, and according to the law, only methods practiced on the living human body are excluded from patentability. Diagnostic methods performed on isolated tissues and specimens are not excluded.[23]

3.15. Australia could, should it wish to do so, exclude such *methods* from patentability, but it could not rely on this Article to exclude products such as isolated biological material from patentability. It is also not clear whether this Article could be relied on to exclude a diagnostic method to treat humans or animals if the method contains a product (e.g. a gene sequence *per se*) as an integral component. Figure 2 provides a more detailed representation of IP Australia's

---

[16] Article 53(a) states that 'European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States'.
[17] Journal of Intellectual Property Law & Practice, 2007, Vol. 2, No. 2, pp. 61-62.
[18] For example, claim 1 was for 'A DNA fragment encoding Human H2-preprorelaxin, said H2-having the amino acid sequence depicted set out in figure 2.'
[19] See *Bioethics and Patent Law: The Relaxin Case*, WIPO Magazine, April 2006. Available online at http://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html.
[20] Official Journal of the EPO, 6/1995, p. 403.
[21] BRCA genes are associated with a predisposition to certain types of breast and ovarian cancers.
[22] See decisions T 1213/05 and T 0080/05.
[23] See Guidelines for Examination in the EPO, 4.8.1 Limitations of exception under Art. 53(c). Available online at http://www.epo.org/patents/law/legal-texts/html/guiex/e/c_iv_4_8_1.htm.

understanding of such an exclusion with respect to gene patents. The figure is a reproduction of the figure provided in response to a Question on Notice stemming from the public hearing on 19 March 2009 (Hansard reference CA22) of the Senate Gene Patent Inquiry.

Figure 2: Gene Patent

Typical Product Claims	**Effect of Articles**
• Isolated gene sequence *per se* • 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 • Kits comprising the sequence or specific primers or fragments of the sequence	None of these would be excludable
Typical Method Claims	
• Use of the gene or protein sequence to diagnose or prognose disease or disorders associated with the gene	Ability to exclude **uncertain** because use of the isolated gene/protein (i.e. product) *per se* is necessary for the diagnosis (i.e. integral to the method)
• Use of the sequence and/or protein as a therapeutic to treat a disease or disorder associated with the gene	Ability to exclude **uncertain** because the use of the isolated gene/protein *per se* is necessary in the treatment (i.e. integral to the method)
• Methods of identifying molecules that modulate or interact with the gene wherein the methods are directly based on the use of the sequence	Not excludable because this is not a diagnostic or therapeutic method to treat human/s as required under the Articles
• Gene therapy using the sequence	Ability to exclude **uncertain** because the isolated gene *per se* is necessary in the therapy (i.e. integral to the method).

3.16. As noted earlier, some WTO Members (e.g. Brazil, Andean Community (Bolivia, Colombia, Ecuador and Peru), Argentina) exclude patents for biological materials isolated from nature in their national law. WTO Members have their IP legislation reviewed by the TRIPS Council, which provides an opportunity for other WTO Members to ask questions about how that WTO Member has implemented TRIPS.

3.17. In the review of its IP legislation, Brazil was asked a number of questions about the above provision in terms of its justification and compliance with TRIPS.[24] In short, Brazil justified excluding these materials on the basis that 'they are not considered new since they already exist in nature.'[25]

3.18. In the review of its IP legislation, Australia was asked whether 'non naturally occurring micro-organisms, plants or animals produced through some act of human intervention' were eligible to be patented in Australia. Australia confirmed that they were eligible.[26]

3.19. These reviews do not result in a determination by the WTO on whether a WTO Member's legislation complies with TRIPS. Such a determination would result from a WTO Member taking a dispute against another WTO Member at the WTO. No dispute has been taken against a WTO member in relation to their definition of invention under TRIPS.

AUSFTA

3.20. AUSFTA is a major bilateral trade agreement with the United States that Australia entered into in 2004. Chapter 17 of AUSFTA deals with IP rights including patents.

3.21. AUSFTA removes the availability of Article 27(3)(b) of TRIPS, which permitted the exclusion from patentability of plants and animals (other than micro-organisms), and biological processes for their generation.

3.22. Article 17.9.14 of the AUSFTA requires both parties to endeavour to reduce differences in law and practices between their respective systems and to participate in international patent harmonisation efforts. Australian and US law and practice with respect to the patenting of biological materials are currently quite similar. In this regard, the Committee may like to consider the ongoing court action in the US described in Attachment B to this submission.

3.23. There is flexibility to implement AUSFTA in a way that reflects domestic interests and Australia's legal and regulatory environment.[27] Any changes to Australian patent law would require consideration of Australia's obligations under AUSFTA, and an assessment of:

- the full impact on Australia's exports to the US;

---

[24] See Council for Trade-Related Aspects of Intellectual Property Rights - Review of Legislation – Brazil, IP/Q3/BRA/1, 24 February 2004.
[25] Ibid, p. 17.
[26] See Council For Trade-Related Aspects Of Intellectual Property Rights - Review Of Legislation In The Fields Of Patents, Layout-Designs (Topographies) Of Integrated Circuits, Protection Of Undisclosed Information And Control Of Anti-Competitive Practices In Contractual Licences – Australia, IP/Q3/AUS/1, 22 October 1997, p. 12.
[27] Department of Foreign Affairs and Trade's Fact Sheet 8 Intellectual Property, http://www.dfat.gov.au/trade/negotiations/us_fta/outcomes/08_intellectual_property.html.

- inward technology transfer from the US; and
- trade with the US more generally.

HISTORY OF AUSTRALIAN PATENT LAW AND THE GENE PATENT DEBATE

4.1. Attachment B sets out the history of:

- previous inquiries and parliamentary consideration of Australian patent law regarding patentable subject matter in general, and the patenting of biological materials; and
- current legal challenges to BRCA gene patents which cover isolated BRCA gene sequences, isolated mutated BRCA sequences associated with an increased risk of breast and ovarian cancer, and methods of diagnosing breast or ovarian cancer using these sequences.

PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

4.2. This submission now considers the Bill with a focus on the scope and issues likely to arise from enacting the proposed changes to section 18 of the *Patents Act 1990*.

4.3. It should be noted that the changes proposed in the Bill are far broader ranging than those considered in the Senate Gene Patent Inquiry and the other reviews discussed in Attachment B. In contrast to those inquiries, which primarily considered gene patents, the Bill proposes changes encompassing all biological material.

What the amendment to 18(1)(a) and (1A)(a) proposes and its potential impact

4.4. Paragraphs 18(1)(a) and (1A)(a) define subject matter that can be patented, by reference to the *Statute of Monopolies 1623*. A patentable invention is an invention that:

> (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies.

4.5. Section 6 of the Statute of Monopolies sets out the criteria that must be met for grant of a patent. It provides that 'manners of manufacture' could be the subject of a patent, with the proviso that they were not 'contrary to the Law, nor mischievous to the State, by raising the Prices of Commodities at home, or Hurt of Trade, or generally inconvenient'.

4.6. The concept of 'manner of manufacture' has a long history of legal interpretation, resulting over time in an expansion of the types of products and processes that can be regarded as a manner of manufacture.[28] The requirements for manner of manufacture in the modern age

[28] The Australian Council on Intellectual Property (ACIP) has been reviewing the 'manner of manufacture' and has in the course of the review produced 'Patentable Subject Matter, Issue Paper' 2008, which sets out the history of evolution of the 'manner of manufacture' test in Australia.

were considered by the High Court of Australia in *National Research and Development Corporation v Commissioner of Patents* (NRDC).[29] The key principle articulated in NRDC was that an invention is patentable if it gives rise to 'an artificially created state of affairs' in a 'field of economic endeavour'.[30] The view of the High Court was that the manner of manufacture test should be flexible to accommodate and encourage national development in 'excitingly unpredictable fields'.[31]

4.7. The Bill proposes to amend sections 18(1)(a) &18(1A)(a) of *Patents Act 1990* to:

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

4.8. The explanatory memorandum to the Bill indicates the change would be in '*keeping with the original intent of the English Parliament, which in 1623 passed the Statute of Monopolies*'.

4.9. The 'manner of manufacture' test has recently been considered by the Advisory Council on Intellectual Property (ACIP) as part of a comprehensive review of patentable subject matter. Its report on this was released in February 2010. IP Australia considers that ACIP's review offers a comprehensive analysis of the issue and that any recommendations for change to subject matter eligibility should follow from consideration of the ACIP recommendations. The recommendations include changing the Act to codify the legal principles established by NRDC.[32]

What the amendment to subsection 18(2) and inclusion of subsection (5) proposes and their potential impact

4.10. Subsection 18(2) of the *Patents Act 1990* defines subject matter which cannot be patented. Currently, human beings are the only matter expressly excluded:

> (2) Human beings, and the biological processes for their generation, are not patentable inventions.

4.11. Parliament introduced the exclusion in response to ethical concerns raised in the Senate during consideration of the Patents Bill 1990. [33]

4.12. The proposed amendment seeks to extend the express exclusion from patentability to an additional category of subject matter, namely:

> (2)(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.

4.13. A second subsection is also proposed for inclusion. Subsection 18(5) would be a non-exhaustive statement specifying:

> (5) biological materials, in section 18 includes DNA, RNA, proteins cells and fluids.

---

[29] [1959] HCA 67.
[30] *CCOM Pty Ltd v Jiejing Pty Ltd* (1994) 51 FCR 260.
[31] [1959] HCA 67 at [15].
[32] Advisory Council on Intellectual Property (ACIP) Final Report Patentable Subject Matter, February 2011, p. 1.
[33] Advisory Council on Intellectual Property (ACIP) Issues paper on Patentable Subject Matter, July 2008, p. 29.

4.14. As noted previously, in Australia and most other countries, material which is isolated, purified or derived from natural and living sources through human effort, is considered eligible for patent protection. In contrast, patents are not granted for biological and living material as it occurs in the natural environment.

4.15. Many patented pharmaceuticals and industrial and nutritional products relate to isolated natural products. In particular, biological materials isolated from animals, plants and micro-organisms continue to be an important source of new anti-cancer drugs and antibacterial and antiviral agents as well as many other medicines. Isolated biological materials often also serve as templates for synthetic modifications to produce improved and more efficacious therapeutics.

4.16. Examples of such types of materials are: proteins such as insulin, used to treat diabetes; enzymes such as amylases, used in textile dying; and chemical derivatives of taxol which are used in the treatment of breast and uterine cancers and antibiotics isolated from bacteria and fungi.

4.17. Without clear extrinsic guidance, as to the meaning of 'derivatives', 'identical' and 'substantially identical', the patent eligibility of man made products such as antibodies and recombinant proteins is equivocal since a biological 'derivative' is defined as a chemical substance derived from another chemical substance either directly, or by modification or partial substitution.[34] Many man made, second generation therapeutics and molecules might reasonably be considered to be substantially *structurally* identical derivatives of naturally occurring molecules, yet possess markedly different *functional* properties relative to the naturally occurring counterpart. It is not clear if such derivative molecules would also be excluded.

4.18. It is also not clear if the definition of 'biological materials' proposed includes 'biological entities' such as micro-organisms and sometimes even 'biomaterials'. Micro-organisms would be considered biological material in view of a standard dictionary definition of 'biological'.[35] Specialist dictionaries differ, however, in the expansiveness of their definitions.[36] Item 4 of the Bill does not clarify the boundaries of non-patentable 'biological material'.

4.19. Since the development of techniques for isolating and manipulating DNA and emergence of the biotechnology industry, patents have also been sought and granted for genetic material. The rationale for this has been that isolated DNA is a chemical, and thus eligible for patent protection on the same basis as other isolated or purified chemicals and biological materials. A wide range of patents include claims to 'isolated DNA'.

4.20. Many patents claiming isolated DNA or genetic material relate to human and veterinary health products. For example, many vaccines are based on DNA isolated from an organism. A patent protecting such a vaccine typically claims the 'isolated DNA' in addition to 'a vaccine' comprising the isolated material. An example is Merck & Co's Australian patent to Gardasil®, the cervical cancer vaccine, which claims the isolated DNA encoding the protein which is essential for the active component of the vaccine.[37] The University of Queensland and CSL

[34] http://www.biology-online.org/dictionary/Derivative (viewed 28 January 2011).
[35] See Macquarie Dictionary, fifth edition, p. 166.
[36] Compare http://dictionary.babylon.com/biological%20material/, accessed 28 January 2011 with http://becker.wustl.edu/impact/assessment/research/biomat.html, accessed 28 January 2011.
[37] See Australian patent AU 714533 titled 'DNA encoding human papilloma virus type 18'.

Limited's IP relating to the vaccine also claims probes, primers and sera[38] and modified viral DNA and protein derivatives that would be excluded if the Bill was enacted. [39] Another example, Australian patent 614503 covers a vaccine for cattle ticks, and claims isolated immunogenic polypeptides and the isolated DNA encoding the polypeptides.

4.21. Patenting has been particularly important for the biotechnology industry. Biotechnology inventions are expensive to produce, with a high risk of failure and a long time to market, but comparatively inexpensive to reproduce or reverse engineer. Current estimates of the full cost of bringing a new pharmaceutical (chemical or biological) entity to market are around US$1.2 to $1.3 billion.[40] The time taken to develop a product can take up to 15 years.[41] Longer development and approval times, larger and more complex clinical trials, increased expenditures on new technologies, and shifts in product portfolios towards riskier, more expensive therapeutic categories have contributed to a real increase in the development costs. Further, the industry is experiencing falling R&D productivity. According to the Pharmaceuticals Industry Strategy Group's final report, the number of new products approved in 2006 was lower than in 1995, despite the industry spending three times as much on R&D in 2006 as in 1995.[42]

4.22. Given the high cost of conducting R&D before commercialisation, it is crucial for businesses, particularly small start-ups, to attract private investment. Patents, as a component of a business's value, can be a deciding factor in whether to invest in a particular business, particularly for international investors who have little incentive to examine all the issues in detail. Patents are also often the sole assets of small and medium biotechnology companies. Most of these companies have no revenue from product sales to fund research. As such, strong and predictable patent protection enables the flow of risk capital that is vital to achieving biotechnology's promise. The prospect of exclusive rights is a critical consideration for investors who invariably look to the patents covering such work as a way to protect and harvest their investment. The significance of patents to such investments are incontrovertible after the events of 2000. In announcing publication of the Human Genome mapping initiative a White House spokesman erroneously suggested that the United States and Great Britain would restrict gene patents. Due to that statement, stock of two relevant companies dropped 25 to 30 per cent.[43] Even after President Clinton and Prime Minister Blair sought to correct the incorrect report, the NASDAQ plunged to its second steepest dive ever.[44]

4.23. As an indication of the value of medicines potentially affected, three of the 50 highest cost items on the Pharmaceutical Benefits Scheme (PBS) for 2009-10 were monoclonal antibodies: Ranibizumab (anti-angiogenic - 89,753 volume; $187,650,894 cost to Government); Adalimumab (anti-inflammatory - 23,892 volume; $41,985,024 cost to Government); and Rituximab (treatment for non-Hodgkin's lymphomas - 11,674 volume; $28,473,667 cost to Government).[45] The PBS determines the cost effective price to the Government of each medication for the benefit of those Australians suffering from significant diseases. Monoclonal

---

[38] See Australian patent 651727 'Papilloma virus vaccine'.
[39] See Australian patent 682092 'Modified papilloma virus L2 protein and VLPs formed therefrom'.
[40] IBISWorld Industry Report, *Global Pharmaceuticals and Medicine Manufacturing: C1933-GL,* April 2010, p. 21.
[41] Ibid.
[42] Pharmaceuticals Industry Strategy Group (2009), *Pharmaceuticals Industry Strategy Group Report*, Commonwealth of Australia.
[43] *Clinton/Blair Gene Patent Announcement Draws Reaction,* BIOTEC Patent News (1 Mar 2000), available at http://www.allbusiness.com/business-finance/equity-funding-stock/497481-1.html.
[44] Tom Reynolds, *Genome Data Announcement Fuels Stock Plunge, Misunderstanding,* 92(8) J. National Cancer Institute, 594, 594-97 (2000).
[45] Pharmaceutical Benefits Pricing Authority Annual Report 2009-10.

antibodies have revolutionised the treatment of many previously untreatable diseases like rheumatoid arthritis and certain cancers. The availability of these drugs could be directly affected by a ban because although most recombinant monoclonal antibodies themselves would still be eligible for patent protection, the isolated antigen critical for the development of a specific monoclonal antibody would be excluded.

4.24. The proposed exclusion may also have impacts outside the provision of healthcare, for example, on aspects of the burgeoning bioeconomy, including agricultural, industrial and environmental biotechnology, the emerging area of synthetic biology, and food manufacturing. Absence of the patent incentive and attendant lack of access to capital could have significant consequences. Examples of potential industrial and agricultural biotech that may not have been developed due to lack of investment include:

- Bio-based materials manufactured from renewable biological feedstocks, rather than petrochemicals. These products have significant potential to mitigate the effects of climate change by reducing greenhouse gas emissions, and promoting clean and sustainable manufacturing practices. Examples of biobased products include:
    - Biofuels – e.g. algal or other biomass based biodiesel and bioethanol.

      Recently accepted Australian patent application AU 2005252266 by MicroBioGen covers a non-genetically engineered yeast strain that grows on xylose. This strain reportedly enables efficient second-generation fuel ethanol production from xylose rich non-food plant materials such as wood and grass.[46] Another example is AU 2004253603 granted to the University of Queensland in 2010. This patent covers photosynthetic algae that are useful for the production of clean, sustainable, hydrogen energy from water.

- Environmental benefits from transgenic plants:
    - Pesticide resistant cotton has reduced pesticide use by 80 per cent compared with conventional varieties, improving the environmental sustainability and profitability of this billion dollar industry in regional Australia.[47]

    - Herbicide resistance in crops such as cotton and canola has resulted in farmers moving to more sustainable reduced-till or no-till farming techniques giving rise to benefits such as reduced soil erosion, water loss, and the emission of greenhouse gases. In 2008 reduced-till or no-till practices are estimated to have had the equivalent of 15.6 billion kg of carbon dioxide being removed from the atmosphere or equal to removing 6.9 million cars from the road for one year.[48]

- Bioremediation using enzymes:
    - Languard – an enzyme-based product that can rapidly degrade pesticide residues, developed jointly by CSIRO Entomology and Orica Watercare. It reduces organophosphate levels in cotton irrigation wastewater by 90 per cent within 10 minutes and in used sheep dip by 99 per cent within 30 minutes. [49]

[46] IP Australia AusPat database; MicroBioGen website (www.microbiogen.com).
[47] www.csiro.au/files/files/puyo.pdf.
[48] Graham Books and Peter Barfoot, *Global Impact of Biotech Crops: Environmental Effects, 1996-2008,* 13 J. Agrobiotech, Managmeent and Economics, 1, 76 (2010), p. 87.
[49] www.csiro.au/files/files/pn0v.pdf.

- Chemicals extracted from natural sources with beneficial properties:
    - Termilone® – a naturally occurring oil extracted from the Australian native tree *Eremophila mitchellii* with low toxicity to animals, being commercialised to control termites.[50]

4.25. The lengthy development times and rigorous testing required for these kinds of products, including seeking regulatory approval, means that companies would be unlikely to invest in their development without patent protection.

4.26. Table 1 identifies general categories of biotechnological inventions that would no longer be patentable if the amendment is implemented. Currently all the products and methods in Table 1 are eligible for patent protection. The proposed exclusion would deny protection for many products which were previously patent eligible, and only afford protection for methods of isolating or using those products. The table also includes inventions whose patentability status would be uncertain (as noted in preceding discussion) due to lack of clarity of the proposed amendments and further guidance in the explanatory memorandum.

[50] http://www.asx.com.au/asxpdf/20100521/pdf/31qg0gj9q9w0lq.pdf.

TABLE 1: IP Australia interpretation of non-patentable matter arising from the Patent Amendment (Human Genes and Biological Materials) Bill 2010

Not patentable	Patentable
• Any material or substance including DNA, RNA, protein, enzyme, antibody, cell, or fluid isolated from any organism, including mutated or variant DNA, RNA, protein that has a naturally occurring counterpart • Isolated chemicals, compounds, extracts, and mixtures obtained from any organism • Synthetic DNA and complementary DNA (cDNA)[51] obtained from a naturally occurring RNA template • Recombinant proteins	• Methods of isolating or purifying compositions and matter, including DNA, RNA, proteins, chemicals, etc from any biological source • Methods of using any isolated DNA, RNA, protein, primer or probe etc o In diagnostics o In gene therapy o In a method of manufacturing a recombinant protein o As a therapeutic medicine • Methods of isolating micro-organisms and their use • Vaccines comprising virus like particles but not the gene sequences necessary for producing the virus like particles • An array of probes and primers
Equivocal Patentability Status[52]	
• Attenuated virus vaccines, subunit vaccines • Probes and primers, including modified probes and primers • Any isolated or cultured micro-organism, including bacteria, virus, fungus, algae • Vectors and cells comprising introduced DNA • Isolated plasmids and phage • Polyclonal antibodies • Monoclonal antibodies[53] • Genetically engineered micro-organisms, plants and animals[54] • New plant and animal varieties obtained from traditional breeding methods • Man made biological tissues (e.g. corneal tissue or veins or heart valves engineered from isolated cells)	

[51] cDNA is an artificially created form of DNA: Lawrence, E (editor), *Henderson's Dictionary of Biology* (13th ed, 2005), Pearson Education Limited, England.

[52] Without clear guidance as to the meaning of 'derivative', 'identical' and 'substantially identical', the patent eligibility of isolated chemicals and substances is difficult to determine.

[53] Recombinant monoclonal antibodies would likely not be excluded, in contrast to naturally occurring monoclonal antibodies found in plasma. Antigens necessary for the production of recombinant monoclonal antibodies would be excluded.

4.28. A ban on patenting biological material could severely affect the ability of industries in Australia to deliver on other government objectives, such as:

- access to affordable health outcomes – companies may not make medicines available in Australia;
- innovation and R&D productivity – it sends the wrong message about innovation and productivity in the Australian economy;
- clean green technologies – the ban could impact on the profitability and therefore emergence of new industrial sectors that have the potential to replace petrochemical-based feedstocks with renewable feedstocks such as biomass; and
- climate change mitigation strategies – the ban could affect the use of biotechnologies to increase crop tolerance in marginal lands and increasing agricultural yields.

CONSTITUTIONAL ISSUES

5.1. It is not clear whether the amendments proposed in the Bill are intended to apply to patents currently in force or only to patents applied for or granted after enactment.

5.2. If it is the former, the amendments would result in many patents or patent claims currently in force being rendered invalid. The Committee may want to consider whether this raises any issues under section 51(xxxi) of the Constitution in terms of there being an acquisition of property that may give rise to claims for compensation against the Commonwealth.

WHAT PROBLEM DOES THE BILL AIM TO OVERCOME?

6.1. The explanatory memorandum states the objective of the Bill as being to 'advance medical and scientific research and the diagnosis, treatment and cure of human illness …'.

6.2. There is a significant risk that the Bill will have an opposite effect. The development of health care products is a high risk and expensive enterprise. Patent rights provide an incentive for capital investment in such activities. Although the amendments would not preclude the grant of patents for the therapeutic or diagnostic use of a gene or biological material, a patent for the use of a compound gives a narrower scope of protection than a patent to the compound *per se*. The inventor of the compound would not be able to benefit from any potential licensing of the drug for subsequent new uses. Erosion of the potential for a patentee or investor to make a return on investment is likely to curtail investment in the development of new diagnostics and drugs especially since the main sources of venture capital are markets where patents are currently available over biological materials.

6.3. If patent protection is not available in Australia for a product developed overseas, it is possible the Australian public could not access many important medicines. While it may be possible for a manufacturer to produce a generic counterpart in Australia, there is a risk that the prospect of relatively small profits, from the relatively small Australian market, may not be an adequate incentive for local manufacture.

---

[54] The patentability status may depend on the type and function of genetic material introduced into a host organism.

Is there a problem of freedom to research?

6.4. No Australian review or evidence has provided that patents over biological material systemically hinder research activity and subsequently impact adversely on the availability of health products and services to Australians. Concerns have however been expressed about the adverse impact of uncertainty in the research community concerning the existence or scope of any common law research exemption. These concerns are addressed by amendments proposed in the Raising the Bar Bill. The amendments would introduce a statutory exemption from infringements for experimental and regulatory approval activities relating to a patented invention. An exposure draft of the Raising the Bar Bill was released in December 2010 and IP Australia hopes to have it introduced into the Winter 2011 Parliamentary sitting.

Will monopolies over diagnostic methods be prevented by the proposed amendment?

6.5. The exclusion in the proposed amendment does not extend to methods of diagnosis and treatment. Therefore, the Bill will not prevent grant of patents for diagnostic tests, and thus monopolisation of a diagnostic test, such as the breast cancer test (the BRCA test) that is the subject of Myriad Genetics' patents discussed in Attachment B.

6.6. The Australian Government and society can continue to rely on the existing powerful safeguards within the patent system. These are Crown use and compulsory licenses, which can be invoked where the public interest is not served through restrictive licensing practices that block access to important medical or other technologies.

Will development of personalised medicine and diagnostics be less encumbered?

6.7. The presence of patent thickets and their potential to increase the cost of personalised medicine innovations is often put forward as a reason to ban gene patents.[55] The Bill will not alleviate thickets because patents on diagnostic methods will not be excluded by the Bill.

6.8. One reason given for the development of patent thickets is low patentability thresholds, particularly low thresholds for inventive step. The Raising the Bar Bill also includes amendments to raise the patentability criteria overall including that of inventive step in Australia and thereby reduce the likelihood of patent thickets developing.

6.9. Another measure available which has been used successfully in the software and consumer electronics industries is patent pools. Patent pools can be defined as an agreement between two or more patent owners to license one or more of their patents to one another and/or third parties. The key benefit of patent pools is in reducing transaction costs for users having to identify relevant patents and then seek cross licensing arrangements with multiple individual patent holders. A successful example of such arrangements is the MPEG-2 patent pool relating to a digital video compression standard which includes more than 425 essential

[55] See for example Chandrasekharan S. & Cook-Deegan R., 'Gene Patents and personalized medicine – what lies ahead', 2009, Genome Medicine., vol 1. pp. x1-x.4.

patents owned by more than 20 patent holders.[56] The World Health Organization has also been encouraging creation of patent pools in cases where there is significant public interest. For example, it is developing a patent pool relating to patent rights over gene sequences for the SARS virus. Patent pools may be of benefit in reducing cross-licensing costs for developers of multi gene diagnostics.

CONCLUSION

7.1. The proposed amendment to the definition of 'invention' shifts the focus of the threshold inquiry from the innovative aspects of biological inventions – that result from human ingenuity – to the properties they share with a product of nature.

7.2. Our observation is that the current system appears to be functioning effectively in achieving its concurrent objectives of encouraging innovation, promoting diffusion of information, and providing access to and transfer of technologies, in balance with the public interest. Existing provisions within the patent system can be used to deal with any impacts associated with the cost of, and access to patents on biological material should problems arise.

7.3. That is not to say that Australia's patent system does not need fine-tuning. IP Australia's current patent reform package, contained in the Raising the Bar Bill, seeks to strengthen patentability criteria and in doing so remove the potential for broader patents to be granted here than in other international jurisdictions. IP Australia will also continue to monitor through its policy development and stakeholder engagement processes, any other issues relating to Australia's patent system that require legislative reform.

[56] Futa in Overwalle G.V, et al (2007), *Dealing with Patent Fragmenation in ICT and Genetics: Patent Pools and Clearing Houses*, p. 3. The article is available at http://outrach.lib.uic.edu/www/issues/issue12_6/vanoverwalle/.

ATTACHMENT A

ATTACHMENT B

PREVIOUS INQUIRIES AND PARLIAMENTARY CONSIDERATIONS

The issues of patentable subject matter in general, and the patenting of biological materials specifically, have been considered on several occasions by various reviews and inquiries and by the Parliament of Australia. The following is a non comprehensive summary of those considerations which may be of use to the Committee in its inquiry.

Patents Act 1903

Australia's first patent legislation following Federation was the *Patents Act 1903*. The Bill for this Act was based on a report of a conference of state patent officers that occurred in April 1901. This Act defined a patentable 'invention' to mean:

> any manner of new manufacture the subject of letters patent and grant of privilege within section six of the Statute of Monopolies (that is the Act of the twenty-first year of the reign of King James the First, chapter three, intituled 'an Act concerning monopolies and dispensations, with penal laws and the forfeiture thereof'), and includes an alleged invention.[57]

The Act also provided that the 'Commissioner may refuse to grant a patent for an invention of which the use would in his opinion be contrary to law or morality.'[58]

These elements were effectively the same as existed in the *Patents, Designs & Trade Marks Act 1883* (UK). During the second reading of the Patents Bill, the Government explained that 'following the lines of legislation passed in England … shall have the advantage of a long series of decisions which have been given upon patents law to guide us in the application of our own measure.'[59]

Patents Act 1952

The *Patents Act 1952* was influenced by the recommendations of reports by the Knowles Committee (in 1939) and the Dean Committee (in 1952). These Committees were appointed by the Attorney-General to consider desirable alterations to Australia's patent law.

Neither Committee considered the scope of patentable subject matter in general and did not recommend changing the definition of 'invention' as it was in the *Patents Act 1903*.

However, the Knowles Committee did consider whether to adopt a provision similar to that in the *Patents and Designs Act 1907* (UK) preventing the patenting of chemical substances, foods and medicines *per se*. [60] This provision limited patent protection to only such substances *when produced* by a special method or process (or obvious chemical equivalent). However, the onus

[57] *Patents Act 1903* (Cth), Definitions.
[58] Ibid, s118.
[59] Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 17 September 1903 (E Barton).
[60] Section 38A(1).

was put on the defendant in a patent infringement action to prove that any substance at issue was not produced by that special method or process.

The Knowles Committee recommended that this provision not be adopted in Australian law. They considered, in respect of this specific provision, that the:

> English provisions are very complicated and highly illogical. For the most part they are declaratory of existing law, and for the rest we cannot see any reason why patents for human medicines and foodstuffs should be placed on a different basis from patents for other substances. The English provisions have not met with unqualified approval and we think they should not be adopted here. It would be difficult to devise any satisfactory set of provisions.[61]

Notably, this provision was repealed in the *Patents and Designs Act 1949* (UK).
A UK Governmental report[62] had recommended that it not be retained from the 1907 Act. Reasons put forward in that report for this recommendation included that:

- '[i]t has been argued that the real invention lies in the discovery of a new substance, with new and useful properties, and that the process of manufacture often involves little novelty in itself'[63];
- the provision 'merely encourages the drafting of a specification to cover all conceivable methods of manufacture, so that, in effect, it is the substance itself and not the process of manufacture which is protected by the patent'[64]; and
- other types of substances were not prevented from being claimed *per se.*

However, the *Patents Act 1952* did follow the UK Act in introducing a provision giving the Commissioner discretion to refuse a patent application that claimed:

> (i) a substance which is capable of being used as food or medicine, whether for human beings or for animals and whether for internal or external use, and is a mere mixture of known ingredients; or
> (ii) a process producing such a substance by mere admixture.

During the second reading of the Patents Bill 1952, the Government explained that:

> [m]any of the provisions of the 1949 British act have been adopted, in substance, in the bill. In matters of patents for inventions it is particularly important that legislation in Australia and the United Kingdom should correspond, as closely as possible, in the interests alike of British and Australian inventors and their advisers.[65]

For reasons that are not apparent, the discretion in the *Patents Act 1903* to refuse applications that were contrary to morality was not retained in the *Patents Act 1952*.

Patents Act 1990

The *Patents Act 1990* was influenced by the recommendations of the 1984 report of the Industrial Property Advisory Committee (IPAC) entitled *Patents, Innovation and Competition in Australia*. This report was initiated by the Minister for Productivity.

---

[61] Paragraph 214.
[62] Patents and Designs Acts: Final Report of the Departmental Committee (Cmd. 7206, September 1947).
[63] Ibid, para 93.
[64] Ibid.
[65] Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 3 June 1952, p. 1241 (H Beale).

In relation to patentable subject matter, IPAC recommended that 'the present threshold test of patentability by reference to section 6 of the Statute of Monopolies and to the expression 'manner of new manufacture' be retained, without specific legislative inclusions or exclusions.'[66] This recommendation was reflected in the drafting of the Patents Bill 1989 and Patents Bill 1990.

The Patents Bill 1990 was referred to the Senate Standing Committee on Industry Science and Technology on 24 August 1990. During debate in this Committee, former Senator John Coulter proposed an amendment to that Bill that would have excluded the patenting of inventions relating to genes, genomes and genetically engineered organisms. The amendment was rejected by that Committee.[67]

During the second reading debate on the Patents Bill 1990 on 17 September 1990, Dr Coulter proposed a similar amendment with the addition that a patent for such an invention would not be excluded if a committee so recommended. It was suggested that 'a suitable committee might comprise people drawn from the areas of technical expertise, bioethics and consumer interests' who would make recommendations in 'the light of community standards and in the light of the expert knowledge of the people in these various areas'.[68]

This addition was apparently motivated in part to address concerns raised by the Minister for Science and Technology that the original amendment would prevent the patenting of some vaccines.[69] The Senate resolved against this amendment.[70]

During the same debate in the Senate Standing Committee on Industry Science and Technology, former Senator Brian Harradine proposed an amendment excluding the patenting of inventions relating to human life forms, genetic manipulations of the human species and trans-species procedures involving human cells.[71] A modified version of this proposal was later agreed to by Parliament and is now section 18(2) of the *Patents Act 1990*.

These proposals were later commented on during the second reading debate in the House of Representatives on 16 October 1990.

The Opposition made the following comments:

> I touch briefly upon an amendment which the Australian Democrats raised when this Bill was being considered in the Senate. The Democrats sought through their amendment to preclude all human life from being patentable. In doing this, they were precluding from the scope of patents all innovations based on genes, genetic material, animals and plants. The Democrats' amendment was rejected by both the Senate Standing Committee on Industry, Science and Technology and the Opposition. From our point of view, the amendment precluded the patenting of animal and plant life. Both of these play a fundamental role in the development of crucial vaccines and medicines.

---

[66] Industrial Property Advisory Committee, Patents, Innovation and Competition in Australia (1984), p. 41.
[67] Senate Standing Committee on Industry Science and Technology, *Report on the Consideration of the Patents Bill 1990* (1990), p. 3.
[68] Commonwealth of Australia, *Parliamentary Debates*, Senate, 17 September 1990, p. 2478.
[69] Ibid.
[70] Commonwealth of Australia, *Parliamentary Debates*, Senate, 20 September 1990, p. 2653.
[71] Commonwealth of Australia, *Parliamentary Debates*, Senate (In Committee), 12 September 1990, p. 17 (P Button).

> The amendment was also restrictive. As it stood, it would have prevented the patenting of sufficient numbers of vaccines and antibiotics which are based on live genetic material-for example, viral vaccines, live polio vaccines and one particular tuberculosis vaccine. The amendment would also have precluded the patenting of new medical techniques-for example, skin growth techniques, which are becoming increasingly widely used in burns cases.
>
> A flow-on effect from the Democrats' amendment would have been to substantially hinder research into and development of new technology. This would particularly apply to the medical and pharmaceutical fields. Effectively, the amendment would have stopped most research into life, genes and living organisms.
>
> If there is no incentive or award for an inventor, currently provided through the patent system, he or she will simply not undertake the research. To illustrate that, pharmaceutical industry research can cost hundreds of millions of dollars and is primarily motivated by the reward at the end.
>
> However, the Senate did agree to one amendment moved by Senator Harradine. His amendments modified those moved by the Democrats and precluded the patenting of human beings and their biological processes. This essentially precludes in-vitro fertilisation and cloning for reproduction purposes from being patentable.[72]

The Government made the following comments:

> Whilst this aspect is not opposed by the Opposition, it is important to remind the House that the Act has, for many years, allowed the patenting of life forms. Whilst we have accepted the amendment by Senator Harradine, in the other place, apart from Senator Harradine's amendment the Bill represents no change in policy in relation to the patentability of life forms. Effectively, Senator Harradine's amendment means that human beings and the biological processes for their generation would not be patentable inventions. As I say, we have taken the view that it is important to continue the practice that has existed for a very long time of allowing the patenting of life forms, subject to that qualification and amendment to which I have just alluded.
>
> The reason for our doing that is that it is impossible to foresee what inventions there will be in the future. Flexibility is required. Patent laws need to have that inherent flexibility to cope with the changing technology. In our view, a patents Act which is not flexible enough to deal with the unforeseen would not serve the inventors, the public or the Government. The Patents Act which was passed in 1952 did not prohibit the patenting of life forms; nor did it discriminate between biological and other technologies. The Patents Act 1903, the first Commonwealth Act in this area, was similar. The first Australian patent for an invention involving a living organism was granted as far back as 1921; this was for a tuberculosis vaccine containing a tuberculosis bacterium. The first Australian claims for micro-organisms themselves were allowed in 1976.[73]

Genetic Manipulation: the Threat or the Glory Report - 1992

In 1992, the House of Representatives Standing Committee on Industry, Science and Technology released a report entitled *Genetic Manipulation: the Threat or the Glory*. The Terms of Reference for that Report asked the Committee to:

---

[72] Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 16 October 1990, p. 2945 (G Prosser).
[73] Ibid, p. 2954, (S Crean).

> identify and report on any national issues unique to the contained development and use of genetically manipulated organisms and their release into the environment; and inquire into and report upon the adequacy of the current arrangements, and advise on future desirable legislative frameworks for the regulation of the contained development and use of genetically manipulated organisms, and their release into the environment, including imported material.[74]

In relation to patents, the Committee concluded that:

> there is no justification for denying the biotechnology industry the opportunity to use the Patents Act to seek a reward for effort.[75]

Patents Amendment Bill 1996

In 1996, former Senator Natasha Stott Despoja introduced the Patents Amendment Bill 1996 which would have amended section 18 of the *Patents Act 1990* to add:

> (3) The following are not to be regarded as possessing the quality of novelty or inventiveness for the purposes of this section:
>
> (a) naturally occurring genes; or
>
> (b) naturally occurring gene sequences; or
>
> (c) descriptions of the base sequence of a naturally occurring gene or a naturally occurring gene sequence.

A significant aspect of this Bill is that it limited its application to naturally occurring genes and gene sequences. In contrast, the amendment moved by Dr Coulter during debate on the Patents Bill 1990 would have applied to genes and genes sequences whether naturally occurring or not.

The second reading speech by Ms Stott Despoja including the following statements in this regard:

> The bill I move is both simple and self-evident. Two general principles involved in the patenting of something are that the item being patented should possess the properties of inventiveness and novelty. It would seem to follow from this that something that occurs spontaneously and naturally in nature cannot be patented.
>
> …
>
> The same could be said of the genes of other species. They are not novel; they do not possess the quality of novelty. Moreover these molecules occur in nature. Genes and gene sequences occur naturally; they are in every respect like other naturally occurring molecules.
>
> …
>
> The question of patenting should not logically arise. But it has and somehow some people have confused the process of extraction and use of the genes with the genes themselves—perhaps deliberately or perhaps because they did not understand the naturalness and the commonness of genes.

---

[74] House of Representatives Standing Committee on Industry Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (1992), xii.
[75] Ibid, [7.113].

> My bill seeks merely to make this point explicit so that there can be no confusion in future. If carried it would mean that genes or gene sequences could not themselves be patented. However the processes by which the genes are extracted from the cells, or the processes by which the extracted genes are manipulated or the specific uses to which the genes may be put, provided one or other of these showed the qualities of novelty and inventiveness in sufficient degree, would be patentable.
>
> ...
>
> It should be both morally repugnant and clearly dangerous to continue to allow the patenting of genes or gene sequences or the information contained in genes or gene sequences and I commend the Amending bill to the Senate.[76]

The Bill lapsed without further debate.

Intellectual Property Laws Amendment Bill 1997

This Bill did not specifically address the patenting of biological materials. However, the debate over this Bill is of interest in that Mr Martyn Evans, the former Member for Bonython, took the opportunity to express his view on the patenting of genetic material including naturally occurring genetic material:

> …There are those—and principally a few of them reside in the other chamber—who are very much opposed to the notion that we should patent anything to do with the human genome. They say that for anyone to have control or a patent over genes or gene related sequences of DNA would be inherently wrong, that it would be unethical and improper.
>
> …
>
> If one simply has a gene sequence, if one simply knows the sequence of amino acids or nucleotides which constitute the gene, one does not have an inventive step, one does not have a patentable thing, and that is a reality which many of those who argue on the other side of this debate have chosen to ignore. You cannot simply patent information which is readily available to anyone who wants to look, and although it is a tedious process chemically to sequence an area of DNA, the reality is that any competent laboratory technician can sequence a given length of DNA and tell you the code which makes up that sequence.
>
> There is no inventive step in that, so one cannot simply go to the Patent Office and say, `I have a sequence here; I wish to patent it.'
>
> …
>
> In order to have a patent it is essential that you have that inventive jump of faith as well. And of course once the patent has been gained, once you have identified not only the sequence but the way in which that sequence can be used, what that sequence does, what its functions are and how it can be applied for the benefit of humankind—once you understand that—then you are in a position to seek a patent for that material or for that sequence of DNA.
>
> But the reality is that that patent will not give you ownership of that DNA. It will not give you ownership of the processes of life; it will not give you a title, if you like, over nature itself.

[76] Commonwealth of Australia, *Parliamentary Debates*, Senate, 27 June 1996, p. 2331.

…

> Another argument is that one should not grant a patent because something occurs in nature. Because our DNA is a naturally occurring thing, one should not permit something occurring in nature to be patented. But the reality is that many other natural things are patented and we have permitted that for a great length of time…[77]

Review of IP legislation under the Competition Principles Agreement by the Intellectual Property and Competition Review Committee (IPCRC) - 2000

This review by the IPCRC considered the issues of patentable subject matter and patenting of gene sequences with the following findings:

> The Committee believes that Australia has on the whole benefited from the adaptiveness and flexibility that has characterised the 'manner of manufacture' test. As a result, we recommend that this test be retained.[78]
>
> In the controversial area of patenting gene sequences, the Committee considers that the tests for granting a patent should be non-technologically specific. The Committee strongly believes that mere discoveries should continue to be excluded from patentable subject matter. It recommends the Patent Office help ensure this outcome by requiring that granted patents disclose specific, substantial and credible uses.[79]

Patents Amendment Bill 2001

The Democrats moved the same amendment from the 1996 Bill during debate over the Patents Amendment Bill 2001.[80] The amendment was not agreed to by the Senate.[81]

ALRC Genes and Ingenuity: Gene Patenting and Human Health Report - 2004

During the second reading debate on the Research Involving Embryos Bill 2002, the Democrats moved an amendment for the Senate to request 'the Attorney-General to provide a reference to the Australian Legal Reform Commission (ALRC) and the Australian Health Ethics Committee (AHEC) requesting that they investigate and prepare a report on the intellectual property and patent issues concerning stem cells and stem cell products…'[82]

---

[77] Commonwealth of Australia, *Parliamentary Debates*, House of Representatives, 11 March 1998, p. 1053.
[78] Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation under the Competition Principles Agreement* (2000), 149.
[79] Ibid, 10.
[80] Commonwealth of Australia, *Parliamentary Debates*, Senate (In Committee), 27 September 2001, p. 28195.
[81] Ibid, p. 28197.
[82] Commonwealth of Australia, *Parliamentary Debates*, Senate, 12 November 2002, p. 6134.

On 17 December 2002, the Attorney-General made a referral to the ALRC for a broader inquiry into current patenting laws and practices related to genes and genetic and related technologies.

In 2004, the ALRC released its report entitled *Genes and Ingenuity: Gene Patenting and Human Health*. In relation to the patenting of genetic material, the report made the following recommendation:

> 7-1 The Patents Act 1990 (Cth) should not be amended:
> (a) to exclude genetic materials and technologies from patentable subject matter;
> (b) to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter; or
> (c) to expand the existing circumstances in which social and ethical considerations may be taken into account in decisions about granting patents.
>
> Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of a patented invention.[83]

The report put forward the following reasons for this recommendation:

- It would represent a significant and undesirable departure from accepted international practice with respect to genetic inventions, and may adversely affect investment in the Australian biotechnology industry.
- It may fail to deliver the anticipated benefits because many pure and isolated genetic sequences do not exist in exactly the same form in nature—for example, patented sequences may not contain the introns that are found in the naturally occurring material.
- Claims to genetic materials in their natural form (that is, in situ) do not constitute patentable subject matter.
- Arguments that genetic materials are not patentable inventions do not always take adequate account of the fact that—in addition to the threshold requirement of 'patentable subject matter'—a number of statutory requirements must be satisfied for patent protection to be obtained. In particular, patent protection cannot be conferred over genetic materials unless a use for such materials has been identified and fully disclosed.
- It would be difficult, on any rational basis, to confine reform to genetic materials and technologies, yet the extension of the reform to other fields—where the patenting of pure and isolated chemicals that occur in nature is uncontroversial—may have unknown consequences.[84]

The Government had not yet responded to this report when, on 11 November 2008, the Senate referred matters relating to the patenting of human genes and genetic materials to the Senate Community Affairs Committee for inquiry and report.

[83] ALRC 99, 2004, p. 26.
[84] Ibid, [6.53].

Senate Community Affairs References Committee Gene Patents report - 2010

On 26 November 2010, the Senate Community Affairs References Committee released its *Gene Patents* report following some two years of consideration of the impacts of gene patents on the provision of healthcare and medical research.

The Senate Community Affairs Committee concluded in the *Gene Patents* report that there was a lack of evidence to support a conclusion that gene patents were having a widespread, adverse impact on the research or healthcare sectors. The Committee, however, doubted that genetic material isolated from natural sources qualified as an 'invention' in contrast to a 'discovery', at least within the common meaning of those terms, but did not recommend amending the *Patents Act 1990* to expressly exclude isolated genes and genetic material from patent eligibility.[85]

The rationale for not recommending an express exclusion is articulated in the report and is based in part on the Committee's support for referral of the Bill to the Senate Standing Committee on Legal and Constitutional Affairs Committee for consideration.[86]

CURRENT LEGAL CHALLENGES TO BRCA GENE PATENTS

Public concern about gene patenting continues. The spotlight is presently focused on the legal challenge to the validity of Myriad Genetics' BRCA patents in the United States and Australia.[87] In these actions, the issue of whether isolated genetic material is eligible for patent protection as a matter of law in these jurisdictions will be directly addressed for the first time in these actions.

United States - 2010

Myriad Genetics' portfolio of patents covers the isolated BRCA1 and BRCA2 genes and diagnostic methods for testing for mutations in the BRCA genes which are associated with an increased predisposition to breast cancer. Myriad Genetics is the sole commercial provider of the BRCA diagnostic testing service in the United States.

In March 2010, a US district court invalidated 15 claims contained in seven of Myriad's 23 patents relating to isolated BRCA1 and BRCA2 gene sequences and some diagnostic method claims which related to comparing isolated DNA to detect mutations in a patient's BRCA gene.

The district court judge ruled that isolated BRCA DNA was not patentable subject matter because it was not 'markedly different'[88] from the matter as it occurs in nature and that 'products of nature do not constitute patentable subject matter absent a change that results in the creation of a fundamentally new product'.[89] And further, 'purification' of a compound that occurs in

[85] Community Affairs References Committee, *Gene Patents*, 26 October 2010, p. 100.
[86] Ibid, p. 102.
[87] *The Association of Molecular Pathology and Others v The United States Trademark Office and Myriad Genetics, Inc and Others*, US District Court for the Southern District of New York, 09 Civ. 4515.
[88] Ibid.
[89] Ibid, 107.

nature, is insufficient to make that product of nature patentable.[90] In support of his decision he noted that it would be 'erroneous to view DNA as 'no different' than other chemicals previously the subject of patents…as DNA serves as the physical embodiment of laws of nature-those that define the construction of the human body'.[91]

The method claims were found invalid because they were considered to be merely directed to the mental action of comparing two gene sequences without specifying any particular method steps.

Myriad Genetics is appealing the district court decision in the Court of Appeals for the Federal Circuit (CAFC). The significance of the issue under appeal is highlighted by the numerous *amicus curiae* briefs filed.

Amicus briefs advocating reversal of the district court decision have been filed from a broad range of parties including life science corporations, industry associations, a non-profit health advocacy group, intellectual corporations, industry associations, intellectual property owners, law associations and legal academics support a reversal of the lower court decision.

All the briefs in support of reversal conclude that the district court had no legal basis to exclude isolated or purified DNA that has diagnostic or therapeutic uses, and associated methods, from patent eligibility.

The majority of the briefs also contend that a ban on the patentability of isolated DNA will have a significant negative impact on their business and innovation, and investment in the life sciences in general, resulting in reduced health benefits and effective treatments for the public, and for environmental sustainability and food security.

Amicus briefs have also been filed in full or partial support of the District Court decision.

Significantly, the US Department of Justice (DOJ) filed a brief supporting the lower court decision in part. The DOJ brief is in contradiction of the United States Patent and Trademark Office (USPTO) long standing practice of granting patents on both isolated genomic DNA and cDNA. The DOJ's perspective is that isolated genomic DNA is not an invention but rather a product of nature, whereas cDNA is necessarily man made and patent eligible, along with man made inventions such as vaccines and genetically modified crops.

Also, at issue is whether the plaintiffs have standing to pursue the legal action. If the CAFC decides otherwise, the court is unlikely to address the question of whether isolated DNA and gene sequences are eligible for patent protection in the United States.

The CAFC is expected to hear the matter around mid to late 2011. The USPTO has not changed its practice with respect to gene patents in light of the District Court decision or the DOJ *amicus curiae* brief. However, we understand, it will be bound to do so if the CAFC affirms the District Court decision, although once decided, an appeal against the CAFC decision by either party to the United States Supreme Court will delay resolution of the matter.

[90] Ibid, 110.
[91] Ibid, 123, 124.

Australia - 2010

Following the district court decision in the United States, in June 2010, a consortium initiated a similar legal action in Australia against 3 claims in Australian patent 686004, one of Myriad Genetics' three Australian patents relating to the BRCA1 gene.[92]

The challenge represents the first time that a court in Australia will directly consider the fundamental question of whether isolated gene sequences *per se* for which a practical use has been identified are a manner of manufacture within the meaning of section 18(1)(a) of the *Patents Act 1990*.

The legal challenge is mounted by Cancer Voices Australia, and Yvonne D'Arcy, who has breast cancer.

It is contested that three claims in AU 686004 to isolated DNA coding for mutant BRCA1 proteins are not a manner of manufacture within the meaning of section 18(1)(a) of the Patents Act because the isolation of such sequences is a discovery of a naturally occurring phenomenon that does not give rise to an invention.

In August 2010, Myriad Genetics offered to surrender AU 686004. As the patent is the subject of legal proceedings, the Commissioner of Patents could not accept the offer of surrender, without either leave of the court or consent of both parties. Neither was received and the case is proceeding before the Court. The matter is provisionally set for hearing from 19 September 2011.

A decision of the Federal Court of Australia is binding on IP Australia. Should the Federal Court decide that isolated gene sequences *per se*, for which a practical use has been identified, are not a manner of manufacture and therefore not eligible for patent protection, IP Australia would have to change its practices accordingly.

[92] Australian patents 686004, 691133 and 691956 relate to BRCA1; Australian patent 773601 relates to BRCA2.