Piper Alderman

25 February 2011

Ms Julie Dennett
Committee Secretary
Senate Standing Committee on Legal and Constitutional Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Ms Dennett

Submission to Senate Standing Committee on Legal and Constitutional Affairs - Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Bill)

We wish to provide the **attached** submission to the Senate Standing Committee on Legal and Constitutional Affairs (Committee) in its inquiry on the Bill.

We ask the Committee to consider our submission in the context of the adverse impact that the Bill (if passed in its current form) would have on the Australian biotechnology and pharmaceutical industries.

For the reasons outlined in the attached submission, we strongly urge the Committee to reject the proposed amendments to the Patents Act 1990 (Cth).

As an alternative, we urge the Committee to review and consider the recommendations of the Australian Law Reform Commission's report on gene patenting and human health from 2004.

Yours faithfully
Piper Alderman

Dr Teresa Schafer
Partner

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Submission to Senate Standing Committee on Legal and Constitutional Affairs Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

Background

The patentability of genes and genetic material has been a controversial issue since at least 1990, when the bill which introduced the *Patents Act 1990* (Act) was considered before Parliament. At that time, an exclusion directed specifically to genetic inventions was proposed, but was rejected by the Senate Standing Committee on Industry, Science and Technology. A similar amendment to the Act was proposed in 1996 and 2001 by Senator Stott Despoja, and re-tabled in 2002 without subsequent consideration. The proposed amendment provided that naturally occurring genes, gene sequences, or descriptions of the base sequence of a naturally occurring gene or gene sequence, would not be regarded as novel or inventive for the purposes of section 18 of the Act.

More recently, on 8 June 2010, proceedings were commenced in the Federal Court of Australia by Cancer Voices Australia and breast cancer patient Yvonne D'Arcy. The case centres on patents relating to the BRCA1 gene, which is linked to an increased risk of breast and ovarian cancer. The general basis of the case is that certain claims of patents relating to the BRCA1 gene held by US-based Myriad Genetics, Inc and Melbourne-based Genetic Technologies Ltd are invalid. It follows a decision in March 2010 in the US, where the Federal District Court in New York found that certain claims of the patents relating to the BRCA1 and BRCA2 genes had been improperly granted to Myriad Genetics.

For more than two years, the issue of gene patenting has been the subject of a Senate Inquiry. On 26 November 2010, the Senate Community Affairs Committee tabled a report in relation to its inquiry into the *"impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form".* The report took into account more than 80 submissions from interested stakeholders.

Coinciding with the Senate's report, on 24 November 2010, the Patent Amendment *(Human Genes and Biological Materials) Bill 2010* (**Bill**) was introduced into the Senate by Senators Coonan, Heffernan, Siewert and Xenophon as a Private Member's Bill *"to amend the Patents Act 1990 to prevent the patenting of human genes and biological materials existing in nature*".

On 26 November 2010, the Senate's Selection of Bills Committee referred the Bill to the Legal and Constitutional Affairs Legislation Committee for inquiry and report.

The Proposed Bill

According to the Explanatory Memorandum to the Bill, the purpose of the Bill is *"to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological medicines, however made that are identical or substantially identical to such materials as they exist in nature*".

The Bill proposes to insert a provision into section 18(2) of the Patents Act 1990 (**Act**) that "*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*" are not patentable inventions. The term "*biological materials*" is defined in a proposed new section 18(5) and includes "*DNA, RNA, proteins, cells and fluids*". However, the terms "*components and their*

derivatives" and "*substantially identical*" are not defined.

The Explanatory Memorandum states that the Bill is intended to reinforce the applicability of the distinction between a discovery and an 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. It thereby gives effect, according to the Explanatory Memorandum, to the proposition that biological materials which are found in nature are not inventions, even if they are isolated, purified or synthetically made.

Does the Bill contravene international trade agreements?

Australia is a signatory to the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Australia-United States Free Trade Agreement (AUSFTA). Both the TRIPS Agreement and the AUSFTA set out minimum standards of intellectual property protection which signatories must adhere to, and provide that patents may be granted only for inventions, which are novel, inventive and have a practical application. Relevantly, Article 27(1) of the TRIPS Agreement provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application." Article 17.9 of the AUSFTA is couched in essentially similar terms. Article 27(2) of the TRIPS Agreement does provide for exclusions to made from patentability for "inventions, the prevention of 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 …"

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

In this regard, processes or methods involved in the isolation, purification and synthesis of biological materials should be patentable as long as they meet the threshold patentability criteria of novelty, inventive step and have a practical application. Inventions which make use of biological materials to derive new and inventive diagnostics, medicines and treatments should continue to be afforded patent protection, just as they are now.

Whilst the Explanatory Memorandum to the Bill states that the purpose of the Bill is to enable "doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological medicines", there is a lack of clear evidence as to how the proposed amendments to the Act are necessary or sufficient to achieve this object and that such an object must be achieved to protect *ordre public* or morality. In those circumstances, there is a real risk that the changes to the Act would be contrary to Australia's international obligations.

Even if, it were held that the changes to the Act are not contrary to Australia's international obligations, there is a risk that Australia would be perceived as being "out of step" with other major industrialised countries in relation to protection of inventions relating to the biotechnology and pharmaceutical industries. This may prejudice both Australian and international investment in Australian research and development and Australian biotechnology and pharmaceutical companies. In particular, multinational pharmaceutical companies may be relatively less likely to invest in research activity in Australia (thus depriving the Australian community of the consequent benefits in terms of local employment and tax revenue) if they perceive their interests are not being protected in Australia in line with other countries.

What is the international position?

In the US, it was ruled in March 2010 that 15 claims of seven US patents granted to Myriad relating to the BRCA1 and BRCA2 genes were invalid because they were not inventions. In October 2010, this view found support from the US Government when the US Department of Justice filed an amicus curiae brief in the appeal to that case, adopting a position against the patenting of isolated genomic DNA, which it acknowledged was "contrary to the longstanding practice of the Patent and Trademark Office, as well as the practice of the National Institutes of Health and other government agencies that have in the past sought and obtained patents for isolated genomic DNA". It remains to be seen, of course, how the appeal to the Myriad case proceeds in the US courts. On the other hand, EU laws currently provide that isolated biological materials are patentable. Directive 98/44 EC provides for the legal protection of biotechnological inventions. Article 3 of the Directive provides:

"Article 3

1. *For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.*

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."* [1]

A distinction has to be drawn between a discovery of something that is naturally-occurring and an invention which results subsequent to that discovery. The inclusion of the word "may" in the second paragraph makes it clear that not all biological material which is isolated from its natural environment will, as a matter of course, be patentable, and that patentability will depend (as it does for all types of inventions) on whether the threshold tests of novelty, inventive step and industrial application are satisfied.

Article 5 of the Directive sets out the EU position with respect to patentability of genetic material:

"Article 5

1. *The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*

2. *An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*

3. *The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."*

Article 5 thus provides that, as long as an "element" of the human body (eg DNA) is in its natural environment, it is not patentable. However, once it has been isolated from that environment or otherwise produced by means of a technical process, it becomes potentially patentable subject matter. Further, paragraph 3 of Article 5 makes it clear that, in order for a patent to be granted in respect of a gene sequence, the patent application must disclose the specific industrial application of that gene sequence. It is not enough that the gene sequence has been merely isolated or produced by a means of a technical process.

What is the position under Australian law?

Under current Australian law, an invention is patentable if it is "a manner of manufacture" within the meaning of section 6 of the Statute of Monopolies, is novel and inventive, and is useful. The High Court considered the term "manner of manufacture" in the case of National Research Development Corporation v Commissioner of Patents[2] and held that for an invention to be patentable, it "must be one that offers some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art - that its value to the country is in the field of economic endeavour."

More specifically, the patentability of gene sequences was considered in *Kirin-Amgen Incorporated v Board of Regents or the University of Washington and Genetics Institute, Inc*[3]. In this case, the Commissioner of Patents considered the distinction between a discovery and an invention, and held that the "*purified and isolated*" DNA sequences were patentable because they claimed "*an artificially created state of affairs*". The Commissioner further held that "*a claim directed to naturally occurring DNA characterised by specifying the DNA coding for a portion of that molecule would likely be claiming no more than a discovery per se and not be a manner of manufacture*".

In essence, the case law in Australia makes it clear that genes or gene sequences in the form in which they exist in nature are not patentable because they will not satisfy the "*manner of manufacture*" requirement. For genetic material to be patentable, there must be an "*artificially created state of affairs*", such that genetic material which has been isolated or synthetically produced is capable of being patented, provided the tests of novelty, inventive step and utility are also satisfied.

For example, isolated DNA is not in the same form as DNA as it exists in the human body. An isolated DNA molecule must be chemically changed to break the covalent bonds that link it to other nucleotides in the human body, which results in an "*artificially created state of affairs*".

Thus, the mere discovery or isolation of a new gene, without knowledge of its function and practical application, will not satisfy the requirements for patentability. To be patentable, the gene or gene sequence must:

- be isolated from its naturally occurring environment (or synthetically produced), AND
- its function must not have been previously known and must be described in detail in the patent claim, AND
- the requirements of novelty, inventiveness and utility must be satisfied.

Protecting the public interest

That then leaves the question of the possible social, ethical and moral issues raised by the patenting of inventions such as a diagnostic test which detects increased susceptibility to cancer.

Fundamentally, inventors should have the right to benefit from and exploit inventions in which they have invested considerable resources to create. In this regard, the right to exploit an invention which detects increased susceptibility to cancer is no less significant than, say, the right to exploit an invention which is used to treat cancer. A public interest element arises in relation to both inventions, and yet there have been many therapies in the treatment of cancer which have been patented, without the same public controversy which has arisen in the case of the BRCA genes.

If there is a real need to safeguard the public interest, there are a number of other options already available under the Act. The Act provides for Crown use and acquisition of a patented invention.[4] In addition, the Act provides that the Federal Court may grant a compulsory licence to a patent if *"the reasonable requirements of the public with respect to the patented invention have not been satisfied"*.[5]

Whilst there is little precedence for either of these provisions having been invoked, if there is perceived a need to protect the public interest, they could potentially be applied in circumstances in which the patentee has not provided reasonable access to the patented invention.

Does the current law stifle research?

There is no empirical evidence which demonstrates that the current law is stifling research. In relation to the BRCA genes, for example, which are currently patent-protected but are the subject of validity proceedings in the US and Australia, there have been more than 5,500 scientific papers published from independent researchers, despite the existence of patents in respect of the genes.

However, one of the proposals to address the specific concerns expressed by the research community is to introduce a research exemption into the Act, which would provide an exemption to infringement if a patented invention was used for certain specified research or experimental purposes. There appears to be broad support for such an exemption from researchers, patent owners and IP Australia, which would ensure that the public interest in advancing scientific and medical research is safeguarded.

What are the potential adverse consequences of the proposed changes to the Act in the Bill?

As discussed above, there is potential for prejudicial effects of the propose law on both Australian and international investment in Australian research and development and Australian biotechnology and pharmaceutical companies if Australia is perceived to be "out of step" with other industrialised nations in relation to the protection of biological inventions. In particular, multinational pharmaceutical companies may be relatively less likely to invest in research, development and commercialisation activity in Australia (with the consequent economic detriment to Australia) if they perceive their interests are not being protected in Australia in line with other countries.

There is also a risk to Australian biotechnology industry in that investment in companies in the biotechnology industry are sometimes made on the basis that commercialisation of the technology will occur first in Australia to provide a foundation for expansion into international markets through licensing or marketing of products using the technology. From our experience, this is particularly relevant to segments of the biotechnology industry such as diagnostics and medical devices where Australian biotechnology companies will seek to commercialise their technology in Australia first to fund further activities and international expansion. There is a real risk that if patent protection for some biological inventions is excluded, these companies will not have sufficient protection to exploit their technology in Australia and will be forced to enter international markets sooner. This may deter, or force offshore, the initial investment in research, development and commercialisation in Australia or, for existing Australian biotechnology companies, force them to move their operations offshore to take advantage of stronger foreign patent protection (with a consequent detrimental effect on Australian employment) or force them to license or sell their technology to overseas partners earlier (and usually at lower valuations) than otherwise (with a consequent adverse effect on the value being created in Australian companies).

There is also a risk that some types of biotechnology and pharmaceutical products will not be made available to the Australian public as a result of the proposed changes to the Act. One of the major issues with the development of "orphan drugs" (that is, pharmaceuticals or other therapies for rare diseases) is providing sufficient incentive for research, development and marketing of these drugs given the small potential commercial return to the developer of the drugs. Depending on the nature of the therapy involved, a narrowing of protection of inventions relating to biological materials in Australia may lead to developers of some therapies for rare diseases not to seek approval for marketing of these therapies in Australia since they may not have adequate patent protection in Australia to protect the already small potential commercial return. This could lead to a further reduction in the availability

of therapies for rare diseases being available in Australia.

Options for moving forward

An express prohibition on the patenting of biological material would appear to be unwarranted. There is a real danger that legislation which expressly prohibits the patentability of "*human genes and biological materials existing in nature*" will be improperly applied to prevent the patenting of important diagnostics, medicines and therapies based on antibodies, antibiotics, hormones, metabolites and proteins which have been essentially "*isolated from nature*". The proposed legislation would have arguably prevented the patenting of inventions relating to insulin, erythropoietin, human growth hormone and other "natural" therapies which have been of great importance to the community.

The Australian patent system is designed to ensure that only patents which properly satisfy the threshold tests for patentability are granted, through tight examination of patent applications to ensure the threshold tests of novelty, inventive step and utility are satisfied before a patent is granted. Provided this occurs, the current system already contains appropriate safeguards which address the concerns raised during the Senate Inquiry.

However, to alleviate concerns with respect to the application of the current legal system, a research exemption introduced into the legislation would provide an exemption to infringement for certain research or experimental use, and would thereby safeguard the interests of advancing medical and scientific research. Infringement would only arise if a patented invention was exploited for commercial benefit.

For the reasons outlined above, we strongly urge the Committee to reject the proposed amendments to the Patents Act 1990.

As an alternative, we urge the Committee to review and consider the recommendations of the Australian Law Reform Commission's report on gene patenting and human health from 2004.

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Endnotes:

1. Article 2(1)(a) of the Directive defines "biological material" as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system".
2. [1959] HCA 67; (1959) 102 CLR 252 (16 December 1959).
3. [1995] APO 61; (1996) AIPC 91-231; 33 IPR 557 (19 October 1995).
4. Chapters 12 and 17 of the Act.
5. Section 133(2)(a)(ii) of the Act.

Note: The views expressed in this submission are those of the above authors personally and do not necessarily reflect the views of the firm.