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Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Australian Law Reform Commission (ALRC) welcomes the opportunity to make this submission to the Senate Standing Committee on Legal and Constitutional Affairs Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill).

The purpose of this private Senators' bill is to amend the *Patents Act 1990* (Cth) (Patents Act) to prevent the patenting of human genes and biological materials existing in nature.

ALRC gene patents inquiry

The desirability or otherwise of excluding genetic materials from patentability was a matter considered in detail by the ALRC in the course of its major inquiry into gene patenting, conducted in 2003–04.

This ALRC inquiry culminated in the report *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC Report 99) in June 2004.[1] The report, which made 50 recommendations for reform in relation to gene patenting, is available on the ALRC's website at < www.alrc.gov.au/publications/report-99>. This submission highlights the conclusions and recommendations relevant to the Standing Committee's consideration of the Bill. These conclusions and recommendations are set out more fully in ALRC Report 99 (especially Chapter 6 and 7).

Senate Community Affairs References Committee inquiry

The November 2010 report of the Senate Community Affairs References Committee inquiry into gene patents referred extensively to ALRC Report 99. It noted that the ALRC report 'served as an important reference point' for much of the evidence received by it.[2] The ALRC made a submission to the Community Affairs References Committee in March 2009, a copy of which is attached.

Despite holding concerns about the potential patentability of isolated genetic materials, the Community Affairs References Committee determined that it would not, at this stage, recommend that the Patents Act be amended to include an express prohibition on the patentability of human genes and genetic products.

The Committee said that this decision was based on recent international and national legal developments relating to the patentability of genes. These comprise a successful challenge against patents held by Myriad Genetics and relating to the breast cancer susceptibility genes known as BRCA1 and BRCA2 in the United States District Court (the Myriad Genetics case);[3] and a forthcoming Federal Court challenge concerning Australian patents over the same genes.[4]

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1 *Genes and Ingenuity: Gene Patenting and Human Health* (ALRC Report 99),

2 Senate Community Affairs References Committee, *Gene Patents* (November 2010), [2.82].

3 *Association for Molecular Pathology v United States Patent and Trademark Office*, United States District Court for the Southern District of New York, case no. 09-CV-4515 (29 March 2010).

4 The Federal Court is expected to be hear the case in September 2011: see Maurice Blackburn Lawyers Press Release 'Court Sets Down Timetable for Test Case-on-Breast-Cancer-Gene <www.mauriceblackburn.com.au> (accessed 12 January 2011).

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The Committee's decision not to recommend an express prohibition on gene patents also recognised the forthcoming introduction of the current Bill, which would provide a further opportunity for the arguments and questions 'around the impacts and effectiveness of an express prohibition on gene patents to be considered'.[5]

Excluding genetic material from patentability

In ALRC Report 99, the ALRC specifically recommended that the Patents Act should not be amended to exclude genetic materials and technologies from patentable subject matter.[6] The ALRC concluded that such a reform would pose a significant risk to Australia's biotechnology industry, raise problems for Australia's compliance with its international obligations under the *Agreement on Trade-Related Aspects of Intellectual Property Rights 1994* (TRIPS Agreement) and be difficult to implement effectively.[7]

During the extensive expert and community consultation undertaken as part of the ALRC inquiry, arguments were often made that claims over genetic sequences should not be patentable because the sequences—being naturally occurring—could only amount to 'discoveries', rather than 'inventions', as is required under intellectual property laws in Australia and overseas.

Whatever the merits of that argument, the fact is that since the 1980s, in Australia and internationally, many tens of thousands of patents have been granted on genetic sequences, provided they have been isolated from their natural state and otherwise satisfy the statutory requirements for patentability.

Had the ALRC had been conducting its inquiry 20 years earlier, it may have been in a position to influence law and practice in this area so as to expressly prohibit the patenting of genetic sequences or isolated genetic material. However, faced with the practicalities of the contemporary situation, the ALRC concluded in 2004 that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed.

In relation to future patent applications, there may now be no need to expressly exclude genetic materials from patentability. It is increasingly unlikely that patents will be granted over gene sequences or isolated genetic material under existing Patents Act requirements of novelty, inventiveness and usefulness. In particular, the simple identification and isolation of a genetic sequence may now be insufficient to satisfy the Patent Act requirements of an 'inventive step'.

Similar conclusions may soon be confirmed under United States law. The United States Department of Justice, in its brief as amicus curiae in the Myriad Genetics case before the United States Court of Appeals, has submitted that:

> Methods of identifying, isolating, and using such DNA molecules may be patented, as may any new and useful alteration of those molecules through human intervention. Genomic DNA itself, however, is a product of nature that is ineligible for patent protection, whether or not claimed in 'isolated' form.[8]

The brief acknowledges that this conclusion is contrary to the 'longstanding practice' of the USPTO, 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.

Excluding genetic materials from patent rights, in order to be effective, may require the retrospective invalidation of many tens of thousands of patents granted around the world—and whose recognition and enforcement is often guaranteed by international instruments, including TRIPS. That might cause considerable uncertainty, litigation and cost.

Concern about patents over genetic sequences may be characterised as 'yesterday's battle'. The monopoly exploitation rights granted by a patent extend (with some limited exceptions) for twenty years—which means that, by definition, many or most of the problems caused by patents granted over gene sequences, or overly broad patents, are transient ones.

The exclusion provided by the Bill

The Bill would exclude from patentability 'biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such

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5 ALRC Report 99, [4.135], rec 3.
6 Ibid, rec 7–1.
7 Ibid, [7.27].
8 *Association for Molecular Pathology v United States Patent and Trademark Office*, United States Court of Appeals for the Federal Circuit, Brief for the United States as Amicus Curiae in Support of Neither Party (29 October 2010), 17–18.

materials as they exist in nature'.[9] Biological materials are defined as including 'DNA, RNA, proteins, cells and fluids'.

ALRC Report 99 referred to some of the difficulties involved in defining the scope of any exclusion relating to genetic materials.[10] In the case of the formulation chosen in the Bill it may be unclear, for example, whether cDNA (complementary DNA) is 'substantially identical' to DNA existing in nature. As observed in the ALRC inquiry, cDNA is a copy of the genomic DNA but lacking the interspersed intron sequences. It does not generally occur naturally.[11]

The United States Department of Justice has submitted that engineered DNA Molecules, including cDNAs, are human-made inventions eligible for patent protection and that the District Court in the Myriad case erred in implying that 'any isolated DNA molecule whose value derives from the information-encoding capacity of DNA must be deemed an unpatentable product of nature'.[12]

The ALRC also observes that the exclusion from patentability provided by the Bill, in referring to all 'biological materials', may goes further than necessary to address concerns about gene patents, with uncertain effect for many other categories of patents—such as those involving blood products.

Other approaches

The experience of the ALRC in the gene patenting inquiry suggests that other changes to patent law and practice may be more effective in promoting the Bill's stated purpose to 'advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical or substantially identical to such materials as they exist in nature'.[13]

Rather than attempting to carve out an exclusion from patentability, it may be preferable to focus on reforms that would directly address existing problems and make the patent system work better. To this end, the recommendations in ALRC Report 99 focused on:

- improving patent law and practice concerning the patenting of genetic materials and technologies, including through amendments to the Patents Act and changes in the practices and procedures of IP Australia, patent examiners and the courts;
- improving patent law and practice concerning the exploitation of gene patents, including in relation to an experimental use exemption, Crown use, and compulsory licensing of gene patents;
- ensuring the appropriate use and exploitation of gene patents, particularly in research, biotechnology and healthcare provision.

A range of reforms recommended by the ALRC were subsequently endorsed by the report of the Community Affairs References Committee. These included recommendations to amend the Patents Act to:

- provide that an invention will satisfy the requirement of 'usefulness' only in such cases as a patent application discloses a 'specific, substantial and credible' use;[14]
- clarify the circumstances in which the Crown use provisions may be employed;[15]
- clarify the scope of the 'reasonable requirements of the public' test for the granting of compulsory licences;[16] and
- provide a broad research exemption.[17]

Similar conclusions have recently been reached in the United States by the Secretary of Health and Human Services' Advisory Committee on Genetics, Health and Society (SACGHS). SACGHS also rejected a ban on

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9 Patent Amendment (Human Genes and Biological Materials) Bill 2010, sch 1 cl 3.
10 ALRC Report 99, [7.26].
11 Ibid, [6.66].
12 *Association for Molecular Pathology v United States Patent and Trademark Office*, United States Court of Appeals for the Federal Circuit, Brief for the United States as Amicus Curiae in Support of Neither Party (29 October 2010), 14.
13 Explanatory Memorandum, Patent Amendment (Human Genes and Biological Materials) Bill 2010.
14 Senate Community Affairs References Committee, *Gene Patents* (November 2010), rec 10. See ALRC Report 99, recs 6–3, 6–4.
15 Ibid, rec 11. See ALRC Report 99, recs 26–1, 26–2, 26–3.
16 Ibid, rec 12. See ALRC Report 99, rec 27–1.
17 Ibid, rec 13. See ALRC Report 99, rec 13–1 (recommending an 'experimental use' exemption).

patenting genes and focused instead on developing recommendations narrowly tailored to improve genetic test development and patient access. SACGHS recommended, among other things, the creation of new exemptions from liability for patent infringement for clinical genetic testing and research, mechanisms to promote non-exclusive licensing of diagnostic genetic technologies and to enhance transparency in licensing, and provide additional expertise to the United States Patent office.[18]

The ALRC also recommended that the Government should initiate an independent review of the appropriateness and adequacy of the 'manner of manufacture' test—the threshold requirement for patentable subject matter under Australian law.[19] Such reform is currently being considered by the Advisory Council on Intellectual Property (ACIP). The Community Affairs References Committee noted that ACIP's recommendations in this area 'may also clarify the application of the invention-discovery distinction to isolated genetic materials'.[20]

Conclusion

Based on its experience in the gene patenting inquiry, the ALRC considers that the Bill is unlikely to be effective in its stated purpose of advancing medical and scientific research and the provision of healthcare services, for the following reasons.

First, there may now be no need expressly to exclude genetic materials from patentability, given that it is increasingly unlikely that patents will be granted over gene sequences or isolated genetic material under existing Patents Act requirements of novelty, inventiveness and usefulness.

Secondly, it will be difficult to define effectively the scope of any exclusion relating to genetic materials. In the case of the formulation chosen in the Bill it is unclear, for example, whether cDNA is 'substantially identical' to genomic DNA.

Thirdly, other changes to patent law and practice are likely to be more effective in promoting the Bill's stated purpose. These include possible changes to the 'manner of manufacture' test, the way in which usefulness is assessed during patent examination and in relation to an experimental use exemption, Crown use, and compulsory licensing of gene patents.

The ALRC's primary concern is that the introduction of an exclusion from patentability will detract from the prospects of implementing more useful reforms, as identified by the ALRC and endorsed by the Senate Community Affairs References Committee, to improve the scope and operation of gene patents and the patent system as a whole.

We trust that the Senate Standing Committee on Legal and Constitutional Affairs will find these comments of value, particularly taken together with the findings, recommendations and supporting research and commentary contained in ALRC Report 99.

Yours sincerely,

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18 Secretary's Advisory Committee on Genetics, Health, and Society, *Revised Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (2010), <oba.od.nih.gov/oba/SACGHS> at 14 January 2011.

19 ALRC Report 99, rec 6–2.

20 Senate Community Affairs References Committee, *Gene Patents* (November 2010), xiii.