

The patentability of biological material

– Summary of public submissions to Senate inquiry

The patentability of biological material is a highly contentious issue within the scientific community and a Bill currently before a Senate committee has generated further debate. Dr Teresa Schafer discusses the Bill and the reaction to date.

In the last edition of Legal Rx, we explored the legal issues surrounding the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (the Bill), which proposed to remove genetic and biological materials from patentability. As we stated in our previous article, on 26 November 2010 the Senate referred the Bill for inquiry and report. The Senate Legal and Constitutional Affairs Legislation Committee's report is expected to be published on 16 June 2011.

A total of 111 public submissions were received in response to the inquiry, comprising various stakeholders from different sectors of the industry, including submissions from industry bodies, pharmaceutical companies, medical device companies, research institutions, universities, law firms and interested individuals.

In this article, we discuss the key issues raised in the public submissions in this complex area of debate.

Ethics of owning genes

The issue of 'ownership' of genes has sparked intense public moral discourse. Many dissidents of the Bill argue that the proposed legislation is misconceived and that the existing legislation already excludes "human beings" and the "biological processes for their generation" from patent protection.¹ In a joint submission, research based universities in NSW² argued that patent law has always excluded human gene sequences as they exist in the human body from patentability. However, proponents of the Bill argue that genes, natural parts of the human body and other forms of life should not be patentable, and that there is no evidence that patentability is necessary to encourage the identification or isolation of human genes.

Although biological material as it occurs in its natural state has never been eligible for patent protection, isolated or purified biological material has been patentable **if** the material has been created as result of human intervention (ie. through extraction, purification, isolation or synthesis) **and** the material has commercial application. The inclusion of human gene sequences in a patent does not give the patentee rights of ownership in relation to the genes as they exist in the human body. Patents are granted once a gene sequence is isolated by human ingenuity and an "artificial state of affairs"³ is created which has some novel function and utility.

Effect of gene patents on current research

There are two opposing industry views as to the effect of patents on biological research. Some submissions argued that biological research would be impeded if gene patents were enforceable. However, submissions from key research facilities argued that the existence of gene patents (and patents more generally) has had no significant impact on their research activities, and the proposed legislative changes are not necessary to encourage biological research. Similarly, IP Australia, in its joint submission with the Department of Innovation, found no evidence that the present patentability of biological material hindered research activities, and there were no recent examples in Australia of lawsuits relating to research activities infringing upon patent rights.

Current access to public health

The public debate concerning gene patents ignited when the Peter Macallum Institute was forced, in 2008, to suspend testing for the BRCA1 and BRCA2 genes because of alleged violation of Genetic Technologies' intellectual property rights. In the highly publicised dispute, Genetic Technologies insisted that all future BRCA diagnostic testing be conducted "in-house" or be subject to excessive licence fees as part of the exercise of their intellectual property rights.

Following widespread public disapproval, however, Genetic Technologies backed down on its stance, but the issue prompted public debate regarding the grant of exclusive licences for gene patents and the adverse effect of restricted access to genetic testing on the delivery of healthcare.

Critics of the Bill argue that there was no evidence that patents negatively impact access to diagnostic testing or medicines in Australia or overseas. Relevantly, AusBiotech noted that there has never been any risk that some patients might not have access to testing. Rather, the issues concern the manner in which patent rights are exercised.

The Bill does not fit with its intended purpose

It has been widely submitted that the Bill is misaligned with its intended purpose to “*advance medical and scientific research and 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.*”⁴ Given that the public debate around access to diagnostic testing and ownership of genes sparked the inception of this Bill, the proposal to then exclude biological materials will, paradoxically, not exclude therapeutic or diagnostic tests from patentability even if such methods involve the use of biological materials. Hence, there is a view that the Bill will not improve consumer access to diagnostic testing (if this is really an issue) as method patents for these will still be available.

However, is the availability of method patents sufficient to secure investment into research? There is a danger that investors will make decisions not to invest in a new technology if the only intellectual property protection is by means of a method patent. Biotechnological research requires enormous financial investment due to the large number of drugs and treatments that fail the journey from bench to clinic, complex regulatory issues and high production costs. Understandably, a method patent without the base patent is riskier and can discourage crucial investment support.

Of particular concern is the effect that the Bill will have on research and incoming investment in research and development. If this Bill is enacted, the exclusion of biological materials from patentability could lead to a reduced ability to attract funding and investment into biological research and clinical trials, which will possibly lead to Australian patients losing early access to innovative therapies. Such a Bill can potentially have a negative impact on the global image of Australia as a destination for research and development investment. Innovative pharmaceutical companies have threatened to take their research and development activities overseas, where there is greater ability to protect the results of their research.

It has also been submitted that the medical research and biotechnology community (including investigators and hospitals) will risk losing resources (including funding) and jobs as much of the research will move offshore. NSW research universities argued that patents are essential at the value proposition stage for investment decision-making. In the absence of patent protection, a lot of high cost research may not be undertaken in Australia, because venture capitalists are likely to go elsewhere. Currently, the lack of funding is a more significant impediment to scientific research than patent litigation. In this regard, the Australian Institute of Innovation has argued that the concept that “patents should be restricted so that researchers are unrestricted is undesirable.”

A more minor-held view is that the Bill will make the biotechnology industry in Australia more competitive as more researchers will have access to essential biological materials. Proponents of this view support the proposed Bill and argue that it “fosters investment in research and development.” However, to this view, one should then ask how long can this be sustained if research and development investment moves offshore?

A further unintended consequence of the Bill in its current form is that it shifts the focus of the threshold inquiry for patentability from novelty, inventive step and utility of biological inventions to its similarities with a product of nature. The threshold test for patentability of an invention should be determined by its novelty, inventive step and utility, which the Bill intended to enforce, not whether the material is identical or substantially identical to that which exists in nature.

The Bill could also be viewed as logically paradoxical as it is not inconceivable that in a lot of cases of biological research, the objective is to create a substance that is similar or identical to a naturally occurring substance for successful interaction in physiological processes. It should be noted that patents granted in new emerging fields of technology naturally evolve, starting from early broader patents to more narrow patents as patent examiners grapple with ongoing technological development. Such processes are a natural progression of new technologies, and are not just limited to genetic technologies.

Some stakeholders have argued that the Bill may be superfluous in light of the completion of the Human Genome Project. The Association of Australian Medical Research Institutes submitted that broad gene sequence patents from the late 1980s and early 1990s have or will soon be expiring if they are not already invalidated. In fact, future patent claims over actual gene sequences will be unlikely or will be rejected for lack of novelty. Coupled with the fact that this Bill cannot retrospectively act on existing gene patents, some see the enactment of this Bill as unnecessary.

Scope of the Bill

One of the main public criticisms is that the language used in the Bill will have far-reaching consequences. Contrary to the narrowness of the Bill as described by Senator Heffernan, opponents have submitted that the wording is too broad. More specifically, the Bill couches the amendments to section 18 of the *Patents Act 1990* to exclude patents on all 'biological materials' and also bans patents on compounds that are 'components' and 'derivatives' that are considered to be 'substantially identical' to naturally occurring biological materials. It is the opinion of many stakeholders that such amendments will result in ambiguity and uncertainty.

The practical effect of such wording of the legislation will be to exclude much more than human genes, potentially extending to other biological substances such as material derived from plants, animals, insects, microorganisms, yeasts, moulds and fungi. The proposed changes to the legislation will have potentially far-reaching consequences on our agricultural, chemical, veterinary, pharmaceutical and biotechnological sectors.

Australia's international obligations

A number of submissions to the Senate inquiry argued that Australia would be moving away from global intellectual property law trends, and would be breaching certain international obligations if the Bill is enacted. The proposed amendments to exclude patent protection in respect of biological materials would conflict with the requirement of Article 27 Paragraph 3 of the Agreement on Trade Related Aspects of Intellectual Property Rights that patent protection should be available for inventions "without discrimination as to ... the field of technology". Most submissions that raised this fact further noted that this same issue could also cause Australia to potentially violate the Australia–United States Free Trade Agreement.

Even though the global trend is to move away from the patentability of certain biological materials, no region has yet felt it necessary to legislate to facilitate that change. Rather than singling out specific technologies and specific exclusions, the ALRC's *Genes and Ingenuity: Gene patenting and human health report* in 2004 (ALRC Report 99) recommended that no patents be granted on inappropriate subject matter. This is sensible, because the exclusion of specific subject areas would not be good policy in the face of ever-changing technology.

Current patent system is adequate

Many industry stakeholders believe that the current patent system is adequate in ensuring that patents are granted on appropriate subject matter that demonstrates appropriate levels of novelty, inventive step and utility.

It is well accepted that discoveries are not patentable and this is clear from the current wording of the patent law. The predominantly shared industry view is that the current patent law is operating well for the Australian community and for investors in balancing the need to encourage innovation, promote disclosure of information and promote access to technologies in the public interest.

There exist mechanisms in the current patent system for patent oppositions, crown use⁵ and compulsory licensing⁶, however it appears that the latter two methods to deal with inappropriate patents or inappropriate exercise of intellectual property rights are rarely utilised, though nonetheless available.

Submissions argued that the better, technology-neutral method of reforming the patent system would be to clarify and utilise the existing provisions relating to compulsory licenses and crown use, in addition to introducing a research use exemption which can be invoked where the public interest is not being served through restrictive practices.

Research institutes have voiced the need to have more certain and defined rights in relation to research so that they can be confident of avoiding the threat of litigation. Most stakeholders support a research use exemption from patent infringement for experimental and regulatory approval activities and this has been introduced in the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*. This Bill might be more effective in promoting 'unfettered access' to research rather than excluding specific subject areas. The *Raising the Bar Bill* seems to have wider industry support due to its technology-neutral applications and higher standards for patentability.

Conclusion

There has been a lot of criticism in relation to the Bill as it currently stands. No previous review of intellectual property concerning gene patents⁷ has recommended that gene patents should be excluded under the *Patents Act 1990*.

Perhaps a more fitting way to amend the patent law is to focus on the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* rather than the *Patent Amendment (Human Genes & Biological Materials) Bill 2010*. Given the natural progression of research and development, the grant of broad patents seems inevitable in the early stages of a new field of technology. The only safeguard a patent system can have is a robust test for patentability. The *Raising the Bar Bill*, which introduces higher standards for patentability and a research use exemption, might just be the answer.

We will report further following the release of the Senate Legal and Constitutional Affairs Legislation Committee's report in June 2011.

Endnotes

1. Section 18(2) *Patents Act 1990*
2. University of Western Sydney, University of Sydney, University of New South Wales, Macquarie University, University of Wollongong and Newcastle University.
3. *Kirin-Amgen Incorporated v Board of Regents or the University of Washington and Genetics Institute, Inc* [1995] APO 61; (1996) AIPC 91-231; 33 IPR 557 (19 October 1995).
4. *Patent Amendment (Human Genes and Biological Materials) Bill 2010 Explanatory Memorandum*
5. Chapters 12 and 17 of the *Patents Act 1990*
6. Section 133 *Patents Act 1990*
7. ALRC Report 99, the Senate Community Affairs References Committee Report on Gene Patents (released 26 November 2010) and the Australian Council on Intellectual Property's Review of Patentable Subject Matter (released 16 February 2011)

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