Law Council
OF AUSTRALIA

Patent Amendment (Human Genes and Biological Material) Bill 2010

Submission to the Senate Standing Committees on Legal and Constitutional Affairs

by

Intellectual Property Committee, Business Law Section, Law Council of Australia

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In April 2009, the Intellectual Property Committee of the Business Law Section of the Law Council of Australia (IPC) made a submission to the Senate Community Affairs Committee in response to it's Inquiry into Gene Patents. This response to the Patent Amendment (Human Genes and Biological Material) Bill 2010 (the Bill) is consistent with the approach taken by the Committee in the earlier submission.

IPC has also had the advantage of reading the submission of the Institute of Patent and Trade Mark Attorneys of Australia (IPTA) to the Committees and the report of the Advisory Council on Intellectual Property on "Patentable Subject Matter" which was released on 17 February, 2011. IPC fully supports the comprehensive submission of IPTA in relation to the Bill and the recommendations of ACIP against any exclusion of human genes and genetic products from patentability.

1. General Comment

IPC submits that biological materials including gene technology should not be the subject of exception from the *Patents Act 1990* (Cth) (**the Act**).

The separate treatment of a specific field of technology such as biological materials or gene technology is likely to lead to legislative complexity, the use of loopholes, inconsistency, breach of Australia's international obligations and the need for judicial intervention to resolve issues, and therefore should not be implemented.

Further, the definition of biological materials to include DNA, RNA, proteins, cells and fluids and their respective components and derivatives, is extremely broad. The proposed exclusion covers a far greater field than merely human genes or gene sequences. Furthermore, excluding the possibility of patents for biological materials which fall within the scope of the Bill, may be an unjustifiable discrimination against a field of technology that is offensive to TRIPS-defined international patent norms[i] and other treaties or agreements to which Australia is a party.

Finally, it is of particular note that the Bill would not affect the patentability of the diagnostic method which originally sparked the current debate: the Myriad BRAC1 and BRAC2 tests. In that respect the Bill is misconceived.

Against that background, IPC notes that the basis for the opposition to the patenting of gene technology (notably not biological material as defined in the Bill generally about which the same concern has not been expressed) falls into four broad categories:

- concern that patented gene technology products have a high cost to the consumer;
- concern that an excessively low inventive threshold and an excessively wide scope of protection is applied to gene technology patents;
- concern that gene technology patents place restrictions on the ability of researchers to carry out pure research; and
- concern that the patenting of gene technology is unethical.

IPC has prepared a brief commentary on these points. It would be happy to elaborate further it that would assist.

2. Cost

IPC has seen nothing to demonstrate that gene technology presents a case deserving of special treatment over other technologies whether concerned with medical treatment or

not. It follows that IPC would not support a ban on the patenting of the broader class of "biological materials". Members of IPC have observed that, in relation to products such as pharmaceuticals, which require clinical trials and marketing approval, patent protection is a necessary prerequisite to a product being brought onto the market in Australia. Manufacturers would not have the incentive to incur the extremely high costs necessary to develop products, conduct trials and obtain marketing approvals unless they had an opportunity to recover those costs. Recovery of costs is normally achieved through a period of exclusivity as provided for under the Act.

Patent protection can be expected to result in increased cost to allow for the recovery of the research, development and commercialisation costs during some part of the period of exclusivity. It may not be for the whole period of exclusivity as other competitive products may be developed, and competitive conduct reduce pricing. This perceived disadvantage of higher pricing to the consumer is to be compared with the alternative option, which, in practice, may be that the product is not made available to the consumer in Australia or may not be developed at all. In this context, IPC notes that the commercialisation of many products of gene technology may require regulatory approval — for example, by the Therapeutic Goods Administration,[ii] the Australian Pesticides and Veterinary Medicine Authority[iii] or the Office of the Gene Technology Regulator.[iv]

Furthermore, the publication of the details of a patented pharmaceutical invention adds to the stock of knowledge available to the public. The ideas inherent in this body of knowledge can be used to stimulate other ideas often leading to the introduction of new "protected" pharmaceutical products which are in competition with existing "protected" pharmaceutical products.

It is also to be noted that cost is not all one way. Australian researchers who obtain patents in this area stand to benefit from any period of exclusivity under the Act. There are many examples of this phenomenon. An example relates to the development in Australia of the vaccine for womens cervical cancer, Gardasil. This has produced significant financial and other benefits flowing to the Australian community.

3. Low inventive threshold and wide scope of protection

In relation to inventive threshold and scope of protection, it has been contended in public debate that some granted gene technology patents have not met the required level of inventiveness or novelty, have been too broad or are not useful.

Whether or not this is the case, the argument now being mounted in respect of patents claiming genes and gene sequences is many years after the priority date of the particular patent at which point the criteria for patentability were considered. In the area of gene technology, what was patentable 20 years ago is likely not to be patentable today (ignoring the invention in question) given the rapid development of the technology area in the meantime. In particular, as IPTA points out, the conclusion of the human genome project has had a significant effect on what is and what is not now patentable.

However, there have in fact been very few challenges to the validity of granted gene patents, an observation which is inconsistent with there being substantial problems with invalid patents of commercial concern. The related issue of whether the Commissioner of Patents should exercise more rigour in the process of granting patents is an issue of general application relevant not only to gene technology. It is presently the subject of a separate enquiry by IP Australia.[v] The issue should not, in IPC's submission, drive a decision to exclude biological materials, including genes and genetic material from the Act.

4. Impact on Research

Proponents of the Bill argue that the ability to conduct research is adversely impacted upon by the ability to patent genes and genetic material. Whilst IPC doubts this assertion as a general proposition and particularly where research is directed to an investigation of particular genetic material, the appropriate response comes in the form of an experimental use exemption or the compulsory licence provisions of the Patents Act. Experimental use has been the subject of reports by the Australian Law Reform Commission[vi] and ACIP[vii] which have both recommended the Act be amended to include an experimental use exception. IP Australia has since set out a proposal for a specific exemption covering particular experimental activities.[viii] It is submitted that the issue of experimental use should be dealt with by a general approach and not by excluding biological materials, including genes and genetic materials from patentability under the Act.

As the Patents Act stands at the moment, a person may apply for a compulsory licence in circumstances where the reasonable requirements of the public are not being satisfied in relation to the working of a patented invention. Whilst IPC notes that this provision has been seldom used, the provision is nonetheless available.

5. Ethical issues

The ethical issues which have been raised appear to IPC to be based largely on misconceptions as to the nature of patent protection. For example, the assertion that a patent gives the patentee 'ownership' of a gene is incorrect as a matter of law: there is a fundamental distinction between a patent which protects an invention as a form of intellectual property and the physical property in genetic material.

Similarly, the concern that someone can patent something which is 'part of nature' misconceives a basic principle of patent protection. Patent protection can only validly extend to that which is new and non-obvious.

6. Manner of Manufacture

The Bill also proposes to amend sections 18(1)(a) and 18(1A)(a) by replacing the existing words with the following:

> *"…is a manner of manufacture within the full meaning, including the proviso, of section 6 of the Statute of Monopolies;…"*

Whilst noting that ACIP has recommended the removal of the reference to "manner of manufacture" contrary to this Committee's recommendation, IPC opposes the amendment proposed in the Bill. IPC believes that the proposed amendment is unclear and will only lead to further debate and uncertainty in the light of judicial decisions over the years which have dealt with the issue.

7. Conclusion/Recommendation

IPC does not consider there are any substantial problems with the current language of the statute or the body of case law that has been developed. The terms of the Act require that the thresholds of inventive step, novelty and utility be met prior to grant of registration, which excludes claims that merely 'claim rights over the sequence information',[ix] and could therefore be characterised as nothing more than discoveries. Therefore, IPC considers that the application of the principles and tests ensures that any rights awarded to an applicant fall within the policy underpinning the current Australian law. If a party considers that a grant is too broad, or that otherwise mistakes have been made, there are mechanisms to mount a challenge.

IPC submits therefore that no reasons are demonstrated for gene technology and biological material to be excluded from the Act.

Attachment A: Profile of the Law Council of Australia

The Law Council of Australia is the peak national representative body of the Australian legal profession. The Law Council was established in 1933. It is the federal organisation representing approximately 50,000 Australian lawyers, through their representative bar associations and law societies (the "constituent bodies" of the Law Council).

The constituent bodies of the Law Council are, in alphabetical order:

- Australian Capital Territory Bar Association
- Bar Association of Queensland Inc
- Law Institute of Victoria
- Law Society of New South Wales
- Law Society of South Australia
- Law Society of Tasmania
- Law Society of the Australian Capital Territory
- Law Society of the Northern Territory
- Law Society of Western Australia
- New South Wales Bar Association
- Northern Territory Bar Association
- Queensland Law Society
- South Australian Bar Association
- Tasmanian Bar Association
- The Victorian Bar Inc
- Western Australian Bar Association
- LLFG Limited (a corporation with large law firm members)

The Law Council speaks for the Australian legal profession on the legal aspects of national and international issues, on federal law and on the operation of federal courts and tribunals. It works for the improvement of the law and of the administration of justice.

The Law Council is the most inclusive, on both geographical and professional bases, of all Australian legal professional organisations.

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[i] TRIPS article 27 and Australia-United States Free Trade Agreement article 17.9.2.

[ii] Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, *Regulation of Therapeutic Products in Australia* <http://www.tga.gov.au/subject/index.htm> at 2 April 2009.

[iii] Australian Government, Australian Pesticides and Veterinary Medicines Authority, *Registration Requirements* <http://www.apvma.gov.au/registration/registering.shtml> at 3 April 2009.

[iv] Australian Government, Department of Health and Ageing, Office of the Gene Technology Regulator, *Licence Applications & Assessment Process* <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/process-1> at 3 April 2009.

[v] Australian Government, IP Australia, *What's New: Public Consultation on IP Rights Reforms - Call for submissions on proposed reforms to the IP system*, 27 March 2009 <http://www.ipaustralia.gov.au/resources/news_new.shtml#21> at 6 April 2009.

[vi] Australian Law Reform Commission, *ALRC 99 Genes and Ingenuity: Gene Patenting and Human Health* <http://www.austlii.edu.au/au/other/alrc/publications/reports/99/> at 3 April 2009.

[vii] Australian Government, *Advisory Council on Intellectual Property, Patents and Experimental Use* (2005) Recommendation 1, 5, <http://www.acip.gov.au/library/ACIP%20Patents%20&%20Experimental%20Use%20final%20report%20FINAL.pdf> at 3 April 2009.

[viii] IP Australia has proposed amendments to the *Patents Act 1990* (1990) Part 1 Chapter 11 'to include a statutory exemption that covers research, experimentation aimed at determining freedom to operate and experimental activities to obtain the information required for regulatory approval of a patented invention.' See IP Australia, 'Exemptions to Patent Infringement: Toward a Stronger and More Efficient IP Rights System' (IP Australia Consultation Paper March 2009) 5.

[ix] Dianne Nicol, 'On the Legality of Gene Patents' (2005) 29(3) *Melbourne University Law Review* 1, 5.