

Via email: community.affairs.sen@aph.gov.au

Mr Elton Humphery
Committee Secretary
Senate Standing Committee on Community Affairs
P O Box 6100
Parliament House
Canberra ACT 2600

Dear Mr Humphery,

Inquiry into Gene Patents

I have pleasure in enclosing a submission in response to the Senate Standing Committee on Community Affairs' Inquiry into Gene Patents.

The submission has been prepared by the Intellectual Property Committee of the Business Law Section of the Law Council of Australia. The submission has been endorsed by the Business Law Section. Owing to time constraints, it has not been reviewed by the Directors of the Law Council of Australia Limited.

Thank you for giving us the opportunity to comment. If you have any questions in relation to the submission, in the first instance please contact the Committee Chair, Ian Pascarl, by phone on [03] 9254 2567 or by email: ipascarl@davies.com.au

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Bill Grant', with a stylized flourish at the end.

Bill Grant
Secretary-General

15 April 2009

Enc.

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

Submission to the Senate Community Affairs Committee — Inquiry into Gene Patents

1. General Comment

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (“the Committee”) submits that gene technology should not be the subject of exception from the *Patents Act 1990* (Cth) (**the Act**).

The Committee considers that separate treatment of a specific field of technology such as gene technology is likely to lead to legislative complexity, use of loopholes, inconsistency, unfairness of application and disputes, and should not be implemented without good reason. Furthermore, excluding the possibility of patents for gene technology may comprise unjustifiable discrimination against a field of technology that is offensive to TRIPS-defined international patent norms.¹

In that context, the Committee notes that opposition to patenting gene technology 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 ability of experimenters to carry out pure research; and
- concern that patenting of gene technology is unethical.

The Committee has prepared a brief commentary on these points. The Committee would be happy to elaborate further if that would assist.

2. Cost

The Committee is not an economic committee, and does not wish to comment on issues of cost, beyond indicating that it has seen nothing to demonstrate that gene technology presents a special economic case. Members of the Committee have observed that, in relation to products such as pharmaceuticals, which require clinical trials and marketing approval, patent protection is a practical prerequisite to the product being brought onto the market in Australia. It appears that manufacturers will not incur the high costs necessary to conduct trials and obtain marketing approval unless they can recover those costs. Recovery of costs is normally achieved through a period of exclusivity as provided for under the Act.

While patent protection can be expected to result in increased cost to the consumer during the period of exclusivity, this perceived disadvantage is to be compared with the alternative option, which, in practice, may be that the product is not available to the consumer in Australia at all. In this context, IPC notes that the commercialisation of many of the most valuable aspects of gene technology will require regulatory approval — for example, by the Therapeutic Goods

Administration,² the Australian Pesticides and Veterinary Medicine Authority³ or the Office of the Gene Technology Regulator.⁴

It is also to be noted that cost is not all one way. Australian researchers who file patents in this area stand to benefit from any period of exclusivity under the Act.

3. Low inventive threshold and wide scope of protection

In relation to inventive threshold and scope of protection, the Committee notes that 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. 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.⁵ The issue should not, in the Committee's submission, drive a decision to exclude gene technology from the Act.

4. Experimental use

Experimental use has been the subject of reports by the Australian Law Reform Commission⁶ and ACIP⁷ 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.⁸ It is submitted that the issue of experimental use should be dealt with by a general approach and not by excluding gene technology from the Act.

5. Ethical issues

The ethical issues which have been raised appear to the Committee 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. Conclusion/Recommendation

The Committee 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',⁹ and could therefore be characterised as nothing more than discoveries. Therefore, the Committee 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.

The Committee submits therefore that no reasons are demonstrated for gene technology to be excluded from the Act.

If you have any questions in relation to the submission, in the first instance please contact the Committee Chair, Ian Pascarl, by phone on [03] 9254 2567 or by email: ipascarl@davies.com.au

¹ TRIPS article 27 and Australia-United States Free Trade Agreement article 17.9(1).

² 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.

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

⁴ 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.

⁵ 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.

⁶ 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.

⁷ 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.

⁸ 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.

⁹ Dianne Nicol, 'On the Legality of Gene Patents' (2005) 29(3) *Melbourne University Law Review* 1, 5.

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