

Department of Health and Ageing

Response to Advisory Council on Intellectual Property
Options Paper

“Patents and Experimental Use”

INTRODUCTION AND SUMMARY

The objective of the Department of Health and Ageing (hereafter 'Health') is for better health and healthier ageing for all Australians through the provision of world class health services that are responsive, accessible and sustainable. Its views on the application of intellectual property law flow directly from that objective.

Health confirms its view, as set out in its submission to the Inquiry's February 2004 Issues Paper, that the *Patents Act 1990* (Cth) (Patents Act) should be amended to make specific provision for a research exemption. It considers that such an exemption is in the best interests of health-related research.

Australia has a high level of competence in health and medical research¹ and needs to have an intellectual property framework that both encourages a free and open research environment and the exploitation of research outcomes. This is of particular importance because most of the world's medical and biotechnology research is undertaken in other countries. Health considers that the form of the research exemption should be defined so as to adequately balance the interests of research and the commercialisation of research. In this context, Health endorses the guiding principles set out in the Options Paper. It also notes that a number of experts on intellectual property issues have noted that the issues associated with encouragement of innovation are complex and that secondary innovation, as well as primary innovation, needs to be facilitated. This requires a balance of rights and freedom to undertake research, within constraints, on patented technologies.²

Health favours Option C8 of the options set out in the Options Paper. Health considers that this option will balance the interests of researchers with commercialisation of research. This option should provide certainty to researchers and patent holders because it is very similar to the exemption provided in many European countries.

Health considers that, while none of four options preferred in the Options Paper will completely eliminate uncertainty, Option B (no change) is the least satisfactory. This is in view of the uncertainty inherent in of the current law in the face of developing commercial pressures, particularly in the area of medical biotechnology.

RESPONSES TO QUESTIONS RAISED IN THE OPTIONS PAPER

1. Are there any new arguments for and against each of the options?

Health is not aware of any major developments since its submission in response to the Inquiry's Issues Paper. However, it draws attention to recent article by members of the Intellectual Property Rights Institute of Australia and to comments on the increasing pervasiveness of patents and dysfunctionality within the patent system internationally.^{3 4 5 6}

¹ Final Report of the Investment Review of Health and Medical Research, December 2004.

² For example, *Standing on the Shoulders of Giants: Protecting Cumulative Innovators*, Suzanne Scotchmer, University of California, <http://ist-socrates.berkeley.edu/~scotch/ch5.pdf>

³ *The Cost of Ideas*, The Economist, 11 November 2004.

⁴ *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Adam B. Jaffe and Josh Lerner, Princeton University Press, 2004

While many of these issues are beyond the scope of the current inquiry, they make resolution of a research exemption increasingly important.

2. What is the likely effect of each option on particular sectors of the economy?

Health is not in a position to provide a comprehensive assessment of each option. It agrees broadly with the ACIP assessment of the individual options. Briefly, it considers that:

- Option A (express exclusion of experimental use as an allowable activity) would have a negative impact on both private and public sector research and retard innovation.
- Option B (no change) would result in an unsatisfactory level of uncertainty about freedom to undertake research.
- Option C in its broadest formulation (introduce an express provision allowing experimental use) would provide a greater degree of clarity for researchers and encourage innovation. Health prefers Option C8.
- Option D (restricting the scope of patents on the basis of disclosed utility) has potential benefits for research and needs further analysis, particularly regarding its acceptability under international treaties. The recommendations contained in Chapter 6 of the Australian Law Reform Commission's Report 99, 'Genes and Ingenuity', may go some way to addressing these issues.

3. What is the likely effect of each option on the activities of the Department of Health and Ageing?

Health considers that Option C8 is likely to have the most beneficial outcomes for Australia's healthcare system. Brief comments on each option are as follows:

Option A: Expressly exclude experimental use from allowable activity

Expected impact would be higher costs for, and more restricted access to, patented knowledge necessary for medical research. Medical research would be impeded and the costs of patented products may be higher than would be the case with a more liberal approach to experimental use. Health notes that such an option is not broadly accepted internationally. For example, the Final Communiqué of the Meeting of the OECD Committee for Scientific and Technological Policy at Ministerial Level, 29-30 January 2004 'Science, Technology and Innovation for the 21st Century', included a statement that "Ministers further shared the view that IPR regimes need to protect researchers' access to fundamental inventions, such as through exemptions for research use of patented inventions".⁷

Option B: No change

The progressive increase in patenting of research outcomes would result in continued uncertainty for medical researchers and a reduction of opportunities for research.

⁵ *Legally Speaking: Why Reform the U.S. Patent System?*, Pamela Samuelson, University of California, <http://www.Sims.berkeley.edu/~pam/papers/cacm%20patent%20reform.pdf>

⁶ *Science losing in patent race: Sulston*, Australian Biotechnology News, 8 July 2003

⁷ http://www.oecd.org/document/0,2340,en_2649_34487_25998799_1_1_1_1,00.html

Option C1: Definition of exploitation does not include experimental use

This option would potentially provide an acceptable environment for medical research and encourage competition in the development of predictive, diagnostic and therapeutic applications of new knowledge. However, it is likely to lead to uncertainty and require researchers to expend considerable resources in determining when an activity amounts to 'exploitation'. Although the research exemption in the patent law of Japan which is similar has been interpreted very broadly, the Australian courts' interpretation of what constitutes 'experimental use' may limit the scope of the exemption.

Option C2: General exemption with specific examples and/or guidelines

The impact would be similar to that of C1, but with the potential for an increased level of certainty on permissible areas of research. Technology-specific guidelines would be of particular benefit in complex fields such as biotechnology.

Option C3: Exemption for experimenting "on the subject matter of the invention"

This option provides an improved level of definition in relation to freedom to undertake research. There is a good degree of certainty in using this distinction because it is currently in use in many European countries. However, care would need to be taken to ensure that research, particularly on product patents, did not suffer from being considered as research 'with' rather than 'on' the invention. This could create difficulties in health research, particularly in biotechnology, because of the extensive and overlapping patents on genes and enabling technologies. Option C8 provides for further clarification of the exemption which should avoid an unacceptably narrow interpretation.

Option C4: Exemption for fair experimentation

As a principle, this option could provide an opportunity for balancing the interests of primary and secondary innovators and downstream users. However, as it is based on the *Copyright Act 1968* (Cth) (Copyright Act) and the property protection provided to in the Patents Act is completely different in its nature, there is no certainty as to how the courts would interpret such a provision. Therefore, this option is not supported.

Option C5: Exemption for exclusive permitted uses

This exemption generally covers the types of questions considered in the on/with distinction but does not describe the underlying rationale. This could lead to uncertainty and may also be more restrictive than the on/with distinction in C3 and C8. Therefore, this option could have an adverse impact on medical research.

Option C6: Exemption for inclusive permitted uses

The impact for medical research and healthcare of this exemption is likely to be similar to the impact of option C1.

Option C7: Exemption for fair experimentation with inclusive permitted uses.

While the fair experimentation exemption probably exemplifies the practice of many researchers there would be difficulties in transferring the provisions of the Copyright Act to the Patents Act. The principles underlying the Copyright Act are not the same as those underlying the Patents Act. The lack of certainty for researchers together with the tendency of the courts to interpret intellectual property questions narrowly may lead to an ineffective exemption. For example, 'fair experimentation' could be limited to non-commercial purposes in a similar manner to the United States decision in *Madey v Duke University*.

Option C8: Exemption for experimenting "on the subject matter of the invention", with inclusive permitted uses.

This is Health's preferred option. A more thorough discussion of this option is contained under 'Which options are preferred and for what reasons?'

Option D1 Modify pre-grant provisions to restrict patent rights to the utility disclosed

This option could provide a useful approach to promoting secondary research in the fields of human genetics and related technologies. However, it is not necessarily suitable for all fields of technology. It would be very costly for researchers to instruct solicitors and patent attorneys to consider which technologies are described by the patent claim. In addition to this, it would be necessary to consider whether this option would be compliant with Australia's international obligations. Overall, the impact on medical research and healthcare is uncertain and this option is not preferred.

Option D2 Introduce an exemption for acts that don't benefit from the utility disclosed.

This option would have similar implications for medical research and healthcare as Option D1. As with Option D1, its applications beyond research are difficult to assess.

The new German law on patenting of genes appears to draw on the concept of limiting the scope of patents to disclosed utility. This provision has been welcomed by the German biotechnology industry, suggesting that it strikes a balance between various interests and promotes innovation. However, as it appears to violate technological neutrality by focusing on human genes, it may be in contravention of the TRIPS Agreement it could not be considered as a serious option without further investigation. The recommendations contained in Chapter 6 of the Australian Law Reform Commission's report 'Genes and Ingenuity' may go some way to addressing these issues.

Option E Statutory licensing for experimental use

Health agrees with ACIP's analysis of this option and considers that its cost and complexity would make it unworkable. Compulsory licensing is available for application in extreme circumstances.

4. Is there any new or other empirical evidence available for the Australian environment?

Health is not aware of any new evidence about the relationship between patents and research in Australia. There is some additional evidence about the impact of patents on research in the United States.^{8 9} These articles suggest that the multiplicity of patents in the biotechnology sector and difficulties in obtaining licences are inhibiting innovation.

5. Which options are preferred and for what reasons?

Health's view is that competition in innovation is desirable. Most analysts of intellectual property policy appear to concur with the conclusion that 'multiple and competitive sources of invention are socially preferable to a structure where there is only one or a few sources'.¹⁰ This implies a liberal approach to freedom to undertake research. Reservation of research rights to the primary inventor, on the other hand, tends to inhibit research and secondary innovation. This can be a significant problem where broad patents are awarded on discoveries such as human genes, where there is significant potential for downstream innovation.

Health's response to the Inquiry's Issues Paper supported the principle of an exemption for experimenting on the subject matter of the invention, and also supported refining this approach by adding other qualifications. Option C8 appears to best reflect this approach. Health notes the reservations expressed by the Intellectual Property Research Institute of Australia and others on the effectiveness of such an approach^{11 12}. However, it continues to support this broad approach which it believes will provide greater certainty for researchers than the other options. Health recommends that further consideration be given to the drafting of the option, including provision for technology-specific guidelines where appropriate.

Health recommends that Option C8 be implemented by amending the Patents Act to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention. The section should specifically state that:

- (a) The exemption is available only if study or experimentation is the sole or dominant purpose of the act;
- (b) The existence of a commercial purpose or objective does not preclude the application of the exemption;
- (c) Study or experiment on the subject matter of a patented invention includes, but is not limited to:
 - (i) determining how an invention, including a product such as a gene or protein, works;
 - (ii) determining the scope of the claims;
 - (iii) determining the validity of the claims;

⁸ *A Question of Scale*, Genome Technology, Jan/Feb 2005, (www.genome-technology.com.home.asp)

⁹ *Solutions to Royalty Stacking Issues a Top Priority in Pharmaceutical and Biotechnology Sectors*, Press release, 31 January 2005, Frost and Sullivan (Business analysts and consultants)
<http://www.frost.com/prod/servlet/press-release.pag?docid=31572063>

¹⁰ *On the Complex Economics of Patent Scope*, Robert P. Merges and Richard R. Nelson, Columbia Law Review, May 1990 (<http://cyber.law.harvard.edu/IPCoop/90merg2.html>)

¹¹ *Patently a need to experiment*, Emma Caine and Andrew Christie, p. 42, Australian Financial Review, 27 September 2004

¹² *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry*, Dianne Nicol and Jane Nielsen, Centre for Law and Genetics, Occasional Paper No. 6, 2003, page 236.

(iv) developing an improvement, alternative or substitution to the claims.

Health further recommends that broad guidelines to be published by IP Australia every two or three years. Health suggests that the guidelines should be indicative and not have legal force; however, they would provide a guide for both researchers and patent holders. The guidelines would be prepared by a panel of experts and would state that they are subject to changes in technology.

Health considers that there are several reasons for adopting the on/with distinction:

1. The existence of a very similar exemption in Europe would provide some level of certainty to researchers in Australia. While the European countries' provisions tend to be drafted in a more general way, reflective of treaty drafting, cases interpreting their legislation provide an indication for Australian courts of the manner in which similar provisions have been interpreted.
2. The on/with distinction should provide an exemption that covers research into a range of health technology improvements and new inventions. The fields of product patents such as genetics and proteomics should be specifically mentioned. This will not only provide certainty about these technologies, but also provide an example of the types of technologies intended to be included as research 'on' the invention. It appears that this would not contradict the TRIPS Agreement or the US FTA as another example of identifying certain types of patent for exemption from the Patents Act exists in section 78 of the Patents Act. In fact, this option appears less likely to contravene our international obligations because it provides examples in an inclusive manner rather than exclusively identifying certain technologies.
3. Using the on/with exemption will reduce some costs to exporters.
4. As stated in its submission to the Australian Law Reform Commission Inquiry 'Gene Patenting and Human Health', Health considers that an experimental use exemption should be part of a broader reform of patent law and administration.

Of the four options preferred by ACIP, the other option that appears to be suitable from the perspective of promoting an effective and competitive research environment is Option C7. However, Health has reservations about the application of the 'fair experimentation' approach, as set out in its response to Question 6 of the Issues Paper and under 'What is the likely effect of each option on the activities of the Department of Health and Ageing?' in this paper.

OTHER ISSUES

Compliance with Treaty Obligations

As noted in the Options Paper, it is essential that any changes are not in conflict with Australia's international treaty obligations.