

**Genomics Directorate Department of Health Western
Australia**

**Submission to the Advisory Council on Intellectual
Property**

**Patents and Experimental Use
Options Paper – December 2004**

February 28 2005

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Policy Issues, Genetics and the Patent System

The Genomics Directorate, Department of Health Western Australia welcomes the opportunity to respond to the ACIP Options Paper on an experimental use exemption option in the Australian patent system.

In response to concerns about the potentially restrictive impact of patents on research, particularly in the field of biotechnology, the Advisory Council on Intellectual Property Options Paper, *Patents and Experimental Use*, along with the recent Australian Law Reform Commission Inquiry, *Gene Patenting and Human Health*, have recommended amending the *Patents Act 1990* (Cth) to establish an exemption from patent infringement for experimental use.

Genomic technologies will incrementally fulfil their potential to decrease the burden of disease through preventive and early intervention strategies. These incremental developments will derive largely from research and development innovations within the publicly funded and not-for-profit biomedical and biotechnology sectors. The adoption of any systemic reform in the patent process that enhances these opportunities would clearly be of interest to health departments and of benefit to the community for whom health departments operate.¹

The consideration of an experimental use exemption for researchers in the patent system appears to have emerged as one such possible reform. The options regarding experimental use discussed in the ACIP paper have been considered by Genomics from a perspective that values high standards and equitable access to healthcare, which includes the development and implementation of advances arising from biomedical research. To achieve this aim, there is a need to provide a balance between the incentives and rewards to companies, institutions and researchers, to undertake the expensive commercialisation routes demanded of new products and devices for human use.

However, it is also acknowledged that the patent system operates uniformly across different technologies; the criteria for providing monopoly rights under the patent system being novelty, non-obviousness and usefulness. Consequently this response has been compiled with the aim to strike an appropriate balance between the public interest and the private commercial imperatives of innovation fostered by a broad-ranging patent system.

It is clear that a single, overarching patent system with minimal idiosyncrasies allows for some degree of interjurisdictional compatibility, facilitating entry into export markets. Aside from Australia's commitment to its international obligations in this area (most significant of these is the TRIPS Agreement), there are good arguments for maintaining a patent system that does not discriminate between technologies – not least to allow for simplicity of procedure within and between patent systems.

Nonetheless, convincing arguments have been made, particularly in relation to recent biotechnological inventions, for accommodating specific differences in technologies. Such arguments have acknowledged the uniqueness of genes and the likelihood that gene patents may cover a broader spectrum of unique research tools than originally intended, with implications for enabling important medical research. Indeed, patent rights in biotechnology appear capable of extending beyond their originally intended

¹ See I.R. Walpole, H.J.S. Dawkins, P.D. Sinden, P.C. O'Leary. "Human Gene Patents: the Possible Impacts on Genetic Services Healthcare". *Medical Journal of Australia*, 2003, 179, pp.203-205.

scope as scientists uncover the role played in health and disease by the complex interaction of various component parts of the genetic code. For example, one gene product may be involved in various yet unknown biochemical pathways, meaning that a patent holder with monopoly rights over a particular gene may potentially affect progress into other areas of research in the future. The Organisation for Economic Co-operation and Development has outlined the importance of future genetic research in a health care context noting that:

Future advances will provide a better understanding of the interaction between environmental factors and genetic heritage, will lead to the development of new products and services, including diagnostic tests, therapeutics and medications, and will contribute to more effective and efficient delivery of high quality health care more generally.²

It will be important to ensure that advances can continue to be derived from a better understanding of genetics and made available to those that will benefit from them. An experimental use exemption defined with some clarity as to its scope may improve opportunities for future medical advances.

Despite the aim of technological neutrality of the patent system, there are examples where technology specific arrangements have been or are capable of being applied, including in the areas of plant breeder's rights, micro-organisms and individual circuits, with possibility for further technology-specific provisions to be made under article 27.3 of TRIPS, as was noted by the Commonwealth Department of Health and Ageing submission to the ACIP Issues Paper. In light of this, the suggestion proposed by Nicol and Nielsen (Submission 17) that guidelines be drawn up "to explain how the research exemptions and alternative patent use strategies might apply specifically in the areas of biotechnology and genetic technology" seems a useful one in any bid to capture the benefits of the new genetics in the patent system.

On this point, in our submission to the ALRC Inquiry on human health and gene patents, Genomics recommended that Australia follow suit with the US model initiated by the National Institutes of Health:

The US National Institutes of Health has recently developed 'Principles and Guidelines for Recipients of NIH Research Grants' and 'Contracts on Obtaining and Disseminating Biomedical Research Resources'. These principles and guidelines were developed with the intention of helping recipients of public funding to balance the dual obligations of disseminating unique research resources while promoting utilisation, commercialisation and public availability of their inventions.

We suggest that consideration be given to developing principles and guidelines for the commercialisation of publicly funded research in the Australian context. As with the US guidelines, they would be targeted at publicly funded research, with the hope that 'these Principles and Guidelines will be adopted by the wider research community, so that all biomedical research and development can be synergistic and accelerated'.

It is recommended that Australia establish guidelines, similar to those of the US National Institutes of Health, to ensure that research findings are not being withheld from the public domain. Additionally, NHMRC should oversee the promulgation of information to the public.³

² OECD, *Draft Guidelines for the Licensing of Genetic Inventions*, February 2005.

³ Department of Health, Western Australia submission to ALRC Issue Paper 27, *Gene Patenting and Human Health*, October 2003.

Guidelines, while not legally enforceable, are capable of setting the tone for the research setting and offering up to the community a benchmark for the sanctioning of research behaviours. It is well known that consumer and industry trust sway market forces making for powerful tools in market regulation.

In discussions about the role of the patent system, commentators insist on the idea that a balance must be struck between individual reward and the public interest. Nevertheless, the idea of a “balance” should be seen as something context specific that varies according to the cultural or economic climate in which the patent system operates. Increasingly, it appears that the idea of “pure research” and an academic system as operating separate from commerce is diminishing. This goes some way towards explaining current concern about the need for clarification regarding the existence and scope of an experimental use exemption in the patent system as increased commercialisation is fostering an increased concern with the enforcement of patent rights. We are in agreement with ACIP’s view that it would be difficult to build into patent law an experimental use exemption based on a distinction between basic, non-commercial research and applied commercial research (p.27).

After taking into consideration the anecdotal evidence obtained from ACIP’s inquiry, the ALRC inquiry and our own previous consultations with researchers and scientists, it is our belief that clarification of an experimental use exemption is required. Emphasis on the commercialisation of research is more than likely going to compound the confusion and unwillingness of researchers to undertake research in the future as patent holders become more savvy and aggressive in exercising their patent rights to recoup costs and ensure their own competitiveness in the expanding markets.

We have adopted for consideration here ACIP’s preferred options pertaining to an experimental use exemption – B, C1, C7 and C8 – and noted our comments below.

Of the options, we would support the introduction of C7 or C8, believing they provide the greatest clarity on the scope of the experimental use exemption.

Options Considered

In the Options paper, ACIP lists a total of 13 options for consideration in relation to the scope of an experimental use exemption for patented inventions. Of these, it notes four preferred options: **Options B, C1, C7 and C8**. Options and comments are outlined below.

Option B No change.

Comment

The option to make no change to the current patent system will not clarify researchers' rights where research with regard to a patented invention is concerned. This runs counter to one of ACIP's more important guiding principles that states that "clarity and transparency are advantageous aims to reduce inefficiencies, including transaction costs, and to promote calculated risk-taking inherent in research" (p.5). No change to the current system with respect to an experimental use exemption will not ensure clarity on whether an experimental use provision exists in current law nor will it offer "greater certainty as to which actions on a patent are permissible and non-infringing". Clarification on both these points was reported by ACIP as strongly sought by participants in the inquiry (p.3).

Increasing commercialisation of research and development in the university environment means that the belief by researchers that an experimental use exemption exists where initially there is no clear aim to commercialise findings may unwittingly result in costly litigation for the academy further down the track if commercialisation is subsequently undertaken. Equally, it may increase risk aversion on the part of researchers and adversely impact on innovation in important research areas.

ACIP notes a lack of objective/empirical evidence of a current and significant market failure in light of uncertainty surrounding the experimental use exemption in Australian patent laws. This is cited as a reason for maintaining the *status quo* as suggested in **Option B** (p.8, *ACIP Consideration*). In response to this – firstly, it would be a mistake to perpetuate the current uncertainties and carry these over to future innovation and market cultures. Secondly, as Australia seeks to ensure sufficient return on investment in research and development through improved use of the patent system then it holds that appropriate reforms should be undertaken to foster that objective.⁴

Option C1 Modify [in the Patents Act] the definition of exploitation [of a patented invention] to not include experimental use, without further defining the term.

Comment

Ambiguous and unclear in intent, therefore open to misinterpretation that could only be clarified through legal challenges. Again, this option does not offer "greater certainty as to which actions on a patent are permissible and non-infringing".

⁴ The ACIP Options Paper outlines a concern expressed in the Australian Institute for Commercialisation Ltd report to the Department for Education Science and Training suggesting inadequate use of the patent system is being made to ensure sufficient return on research and development investment (p.1).

Option C7 Exemption for fair experimentation with inclusive permitted uses

Comment

This option seems to offer the greatest flexibility to researchers while retaining the essential parameters for rewarding innovation for inventors and apparently falling within the scope of international treaty obligations. However, it does afford a great deal of flexibility to the courts in determining outcomes for specific cases due to the uncertainty of what constitutes “fair experimentation”. This is a weakness in the sense that court rulings are not always determined according to criteria premised on objective and fair criteria determined to meet an appropriate balance where intellectual property rights are concerned and are often bound by the specific nature of the case in question. A good example of this occurring was in *Madey v Duke University*, a frequently cited judgement in the U.S. that was seen to have considerably narrowed the extent of the experimental use exemption. Professor Rebecca Eisenberg commented in reference to this case: “The experimental use defence was taken out in an inside job, a casualty of an intra-academy squabble over control of resources.”⁵

A comment received from Professor Eric Haan and Jean Murray of South Australia considered that the ACIP Options Paper weighed heavily on the courts in determining outcomes of patent cases. They stated: “The paper evaluates the various options from the perspective of lawyers and courts and what is easiest for them, rather than from the perspective of geneticists and researchers and states trying to encourage useful and affordable research and development”.⁶ This is an important consideration in weighing up the options and one that is acknowledged by ACIP:

All options necessarily leave the exact interpretation of legislation to the courts, some more than others. This provides flexibility and enables decisions to be made appropriate to individual circumstances. However, it has also been noted that a lack of guidance to the courts may have the potential to result in decisions that could be contrary to the purpose of the patent system and thus to Australia’s interests. (p.6, *Generic Pros and Cons*)

As ACIP indicates, it is inevitable that courts will have the final say in determining the outcome of patent cases, however, there may be case for further refinement of the conditions under which the experimental use exemption operates, particularly with respect to biotechnology and genetic technology (for reasons discussed above). To this end, the use of specific guidelines as discussed at page 3 of this document, might be beneficial to Australian innovation and may better enable courts to make judgements according to industry priorities. It would also be of benefit to ensure that Recommendations 10-1 and 10-2 of ALRC Report 99 are implemented, so that judgements rely on interpretations by technologists as well as by legal experts:

Rec 10–1 Courts exercising jurisdiction under the *Patents Act 1990* (Cth) (*Patents Act*) should continue to develop their practices and procedures for dealing with patent matters in order to promote the just, efficient and cost effective resolution of patent disputes.

Rec 10–2 Courts exercising jurisdiction under the *Patents Act* should continue to develop procedures and arrangements to allow judges to benefit from the advice of assessors or scientific advisors in litigation involving patents over genetic materials and technologies.⁷

⁵ Rebecca Eisenberg, “Patent Swords and Shields”, *Science*, 2003, 299: 1018-1019

⁶ Comments received from Eric Haan and Jean Murray, January 2005.

⁷ ALRC Report 99, *Gene Patenting and Human Health*, August 2004.

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

Comment

This option is more in line with the European model of the experimental use exemption arising from the case law in that it permits further research on a patented invention or research directed toward better understanding of the content of a patent. This is useful for the fact that it would increase harmonisation of laws with the European bloc, an important region of trade for Australia.

However, it does not overcome the considerable ambiguity of the “with/on” distinction when determining the scope of permissible infringement activity and a patented invention.

Other Considerations

While legal reform to improve clarity of the experimental use exemption appears to have emerged as an important option to safeguard and promote innovation in research and development, there may be other ways in which to supplement such efforts. One approach we propose would be an informal optional mechanism to meet the research exemption objectives and also serve to build productive relationships between industry and research. The proposal is for research leaders, when they become aware of a patent over a particular tool or technology that may be important to their research, to notify the owners/licencees of the patented invention of their research and research objectives. This could be effected by letters of request to use a patented invention for the purposes of further research. Such a notification system would offer excellent opportunities for contact and collaboration between innovators. If, as anticipated, this increased the collaborative approach to R & D, it may also prove an effective means by which to attract investment and financial support for innovations by individuals or institutions who are not themselves in a position – either through lack of funding or lack of experience – to further develop or commercialize research. The benefits that could emerge from such a notification system would contribute to the rapid production and accessibility of new inventions by the public and to the effective marketing of innovation, all of which are seen as contributing to a strong economy, as outlined by the Department of Education, Science and Training:

One of the key ways that publicly funded research can have a productive impact is through it being translated into marketable products, processes and services. This is an important aspect of the Australian research and innovation system. Bringing research results and outputs to the market in a timely and effective manner helps demonstrate the relevance and value of that research, ensuring that it contributes to the economy and to the broader community. It is therefore important for researchers and research institutions to build strong, ongoing connections with industry and investors who can help bring ideas, inventions and innovations to market.⁸

It would probably not be possible to enforce mandatory response by patent owners to these letters of request to exploit their patent in order for them to exercise their rights, but it may prove a useful way of encouraging a collaborative approach in the intellectual property arena in Australia.

⁸ Department of Education, Science and Training website
<http://www.dest.gov.au/highered/commercialisation/default.htm> accessed 7/2/05

Conclusion

Genomics supports the option of an experimental use exemption, believing that greater certainty is required for researchers who do, and should be encouraged to, play a vital part in the process of developing and contributing to the commercialisation of and public accessibility to new research findings. As the OECD has suggested, in order to achieve these aims “a clear enabling environment and regulatory structure will be essential”.⁹

First and foremost, we would support the introduction of Option C7 as outlined by the ACIP Options Paper, believing it provides the greatest clarity on the scope of the experimental use exemption. Second to that, we would support Option C8, which would give Australia a compatible exemption to that of the EU, aligning the patent systems of two important trading partners.

⁹ OECD, *Draft Guidelines for the Licensing of Genetic Inventions*, February 2005, page 3.