



Australian Government

Advisory Council on Intellectual Property

Patents and Experimental Use

October 2005



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Advisory Council on Intellectual Property

The Hon Warren Entsch MP
Parliamentary Secretary to the Minister for
Industry, Tourism and Resources
Parliament House
CANBERRA ACT 2600

Dear Mr Entsch

I am pleased to present you with the Council's report on patents and experimental use. Patents encourage industrial innovation by awarding innovators with the exclusive right to exploit their inventions for a limited period. In return, innovators must reveal how their inventions work so that others may test them and pursue further research in the field. However, under current Australian law it is not clear that such experimentation is allowed, and this is creating a great deal of uncertainty in the research sector. As the business community is becoming more assertive in its use of patents, ACIP considers that the law should be appropriately clarified to avoid increasing inefficiencies and lost opportunities.

In preparing this report we widely circulated an issues paper and an options paper, and held consultations with interested parties. The majority of responses advocated that Australian patent law be amended to make it clear that the experimental use of patented inventions is allowed. However, there was a wide range of views on the best way of formulating such a provision and concern that the rights of patent owners could be unfairly derogated.

ACIP has formulated an exemption from infringement for acts of experimentation which it believes meets Australia's international obligations and enables patent owners to continue to exploit their patents as normal. ACIP recommends that such a provision be introduced, as it would optimise levels of both 'primary' and 'secondary' innovation in Australia.

I look forward to the Government's response to the report.

Yours sincerely

Professor Paul Greenfield
Chairman
13 October 2005

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1 Glossary of Terms

ACIP	Advisory Council on Intellectual Property
ACIPA	Australian Centre for Intellectual Property in Agriculture
ALRC	Australian Law Reform Commission
AUSFTA	Australia-United States Free Trade Agreement
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DHA	Department of Health and Ageing
EU	European Union
EUE	Experimental use exemption
FICPI	Australian Federation of Intellectual Property Attorneys
GTG	Genetic Technologies Limited
IPCRC	Intellectual Property and Competition Review Committee
IPRIA	Intellectual Property Research Institute of Australia
IPRs	Intellectual property rights
IPTA	Institute of Patent and Trade Mark Attorneys of Australia
NHMRC	National Health and Medical Research Council
OECD	Organisation for Economic Cooperation and Development
R&D	Research and development
TRIPS	World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization

2 Terms of Reference

Parliamentary Secretary the Hon Warren Entsch MP, having responsibility for patent, trade mark, design and plant breeders right matters within the portfolio of Industry, Tourism and Resources, asked the Advisory Council on Intellectual Property (ACIP) in February 2003 to:

examine whether some types of patents are inhibiting research and development in Australia and determine whether both Australian researchers and business would benefit from introducing an experimental use exception provision (or some other provision) into the Australian patent legislation. In examining this question, ACIP should consider whether an experimental use exemption would help researchers more effectively use the patent system to commercialise their research and development.

3 Executive Summary

Background

In recent years there has been a general movement towards greater use of patent rights both in Australia and around the world. This has been driven by factors such as an increasing realisation that successful innovation is a primary driver of economic growth, pressure on public research organisations to commercialise their research and development, and an increasing appreciation of the importance of intellectual property rights in successful commercialisation of technology.

There has been considerable concern expressed, both in Australia and overseas, that patent rights may in fact be inhibiting research and development, particularly in the biotechnology field. It has been claimed that patents may be inhibiting further research into disease prevention and cure because patents are restricting access to fundamental research products and tools. However, there has also been increasing concern that there is insufficient return on investment in Australian research and development due to unsuccessful commercialisation. This may mean that the current availability and breadth of patent rights are essential minimums.

Policy Issues

The objective of patent rights is to encourage and diffuse industrial innovation in a manner that benefits society as a whole. In general, the more innovation that occurs, the greater the potential gains to society. There is a wide divergence of views on what breadth of patent rights best encourages such activity. Providing patent holders with the rights to all acts relating to their inventions would provide simplicity, certainty and considerable incentive to innovate in new, unpatented fields. However, the obvious cost of granting broad rights for the initial (primary) innovation is a disincentive for others in society to experiment further in the field to generate secondary innovation. Most submissions to this review advocated that an exemption for experimental acts is part of the patent system's quid pro quo rationale, although the views of private companies were generally under-represented. ACIP considers that, by appropriately limiting patent rights, society should be able to obtain a net benefit by optimising the balance of primary and secondary innovation.

International Treaty Obligations

Australia is a signatory to the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Of particular relevance is Article 30, which enables members to provide limited exceptions to the exclusive rights conferred by a patent. The interpretation of the scope of this Article has been the subject of a Panel decision of the Dispute Settlement Body of the World Trade Organisation. ACIP's analysis of this decision leads it to consider that an appropriately formulated experimental use provision which allows for further experimentation to be conducted without unfairly devaluing patent rights would be compliant with the TRIPS Agreement.

Australian Law and Practice

Under current Australian law it is not clear whether experimental acts regarding a patented invention constitute infringement, due to an absence of both statute and case law on the subject. The greatest need expressed in submissions was for Australian law to be clarified so that both patent owners and non-owners alike would have certainty regarding their activities. Current practice in Australia appears to be that many researchers are largely unaware of patent laws or deliberately disregard them. Correspondingly, there appears to be a convention in Australian industry, at least until recently, of not pursuing possible infringements for experimental purposes.

Although there is some anecdotal evidence, there is no strong empirical evidence that the current situation is adversely affecting the balance between the incentives to innovate and the ability to use innovations for research and development. However, ACIP considers that this situation will change. There is evidence that more assertive IP practices are developing in Australia. Without clarification of the law, this would increase inefficiencies and lost opportunities. Also, new case law may determine the category of allowable uses of a patented invention to be very narrow. ACIP therefore considers that, if an experimental use provision can be drafted into patent legislation which prevents a damaging situation without introducing an even greater set of costs, then it should be introduced.

Overseas Law and Practice

As the harmonisation of international laws reduces costs for participants, there are strong arguments in favour of Australia adopting current world's best practice in this area of law, or at least the most common practice. However, the law on experimental use of patented inventions differs markedly around the world, and there is little movement to further rectify this. Under US case law experimental acts are only permitted if they are not in furtherance of the alleged infringer's legitimate business. This approach has been highly controversial and is considered by ACIP as one best avoided because it does not appear to follow the principles of the patent system. There is at least some degree of harmony within Europe, where most countries have a statutory exemption that is worded very like the following:

The rights conferred by a patent shall not extend to acts done for experimental purposes relating to the subject matter of the invention.

However, this wording has been interpreted in significantly different ways in different jurisdictions in the pharmaceutical field, particularly regarding clinical trials. This degree of uncertainty is unacceptable, and so other options must be considered.

Options Available

There is a wide variety of ways in which an experimental use provision can be formulated. ACIP considers that the distinction between basic and applied research has become too blurred to form the basis of an experimental use provision. Also, although the biological and medical sciences do involve special issues, ACIP believes that technological neutrality should be maintained wherever possible in substantive patent law. An appropriately formulated experimental use provision would provide scope for these issues to be properly considered by the courts on a case by case basis.

Of those options initially considered by ACIP to be the most viable, two were most favoured by those who made submissions to the review:

- an exemption for acts that constitute *fair* experimentation regarding the invention. This included a list of relevant factors to be considered by the court when deciding what constitutes “fair” similar in structure to the copyright “fair dealing” provisions.
- an exemption for acts that experiment *on* the invention. This option was similar to that recommended by the Australian Law Reform Commission in *Report 99: Genes and Ingenuity*.

Formulation of the Preferred Option

After further consideration, ACIP concluded that the concept of *fair* experimentation provided the courts with too little guidance and ran the risk of Australian law breaching the TRIPS Agreement. Similarly, experimentation *on* an invention is thought to add little value in practice over the European concept of experimentation *relating to* an invention.

The WTO Panel decision suggests that a European-type provision is more likely to be considered to be in accord with the TRIPS Agreement than other types. Therefore, and in the interests of harmonisation, ACIP considers that the European wording “acts done for experimental purposes relating to the subject matter of the invention” forms the most appropriate basis for an Australian exemption. Further practical guidance to both the courts and users of the system on the meaning of this phrase can be provided through the addition of an inclusive list of experimental acts. Compliance with TRIPS Article 30 can be ensured by including the proviso that the acts must not unreasonably conflict with the normal exploitation of the patent.

The resulting exemption is as follows:

The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.

Acts done for experimental purposes relating to the subject matter of the invention include:

- determining how the invention works;
- determining the scope of the invention;
- determining the validity of the claims;
- seeking an improvement to the invention.

ACIP notes that it must be made clear to users of the system that the list of examples is not a list of *permitted* acts, as they are still subject to the test of whether they unreasonably conflict with the normal exploitation of the patent.

Cost / Benefit Analysis

ACIP considers that the benefits of such a provision are:

- the limits to patent rights are clarified, thus reducing uncertainty and resulting inefficiencies and underperformance in the research industry;
- Australian law is ensured to meet international obligations. For example, the use of patented research tools would not be exempted in most cases;
- Australian law is substantially in harmony with European provisions;
- total levels of innovation are optimised through an appropriate balance of rights;
- courts have sufficient flexibility to reach appropriate rather than literal decisions.

The costs of such a provision are:

- some uncertainty over the boundaries of the exemption, which can only be established over time through case law.
- it is not in harmony with current US law, increasing complexity for those operating in both the Australian and US systems;
- patent holders and researchers must become familiar with the clarified law and keep abreast of its evolution;
- the risk of unforeseen, detrimental effects and loopholes.

ACIP considers that the benefits outweigh the costs, and so recommends that the above provision be introduced. ACIP accepts that not all ramifications can be foreseen and so over time modifications to the provision may be needed. Appropriate explanation of the new provision should be provided in the Explanatory Memorandum to the amendment, and a guide on the new provision should be provided and maintained by IP Australia as part of its suite of guides on particular topics. ACIP also recommends that Australia actively participate in international fora on the issue of harmonisation of experimental use provisions, such as the current review by the OECD Committee of Scientific and Technological Policy.

Regulatory Review Exception

Some parties made reference in their submissions to the absence under Australian law of an exception from infringement for activities undertaken prior to the end of the initial patent term relating to obtaining regulatory approval. ACIP's deliberations on an experimental use provision have been directed to the issue of experimentation generally. ACIP recognises that while some regulatory review activities may be done for experimental purposes relating to the subject matter of the invention, others may not. Therefore, whilst there is some overlap between the issue of an experimental use exception and the issue of a regulatory review exception, ACIP's report is concerned with the former not the latter. ACIP considers that the issue of regulatory review may warrant separate consideration.

4 List of Recommendations

Recommendation 1

The Patents Act be amended to establish the following provision:

The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.

Acts done for experimental purposes relating to the subject matter of the invention include:

- determining how the invention works;
- determining the scope of the invention;
- determining the validity of the claims;
- seeking an improvement to the invention.

Recommendation 2

Appropriate guidance be provided in the Explanatory Memorandum to the above amendment, explaining that the purpose of the exemption is to encourage the further development of patented fields of technology without unfairly devaluing patent rights or breaching the TRIPS Agreement, and that the exemption is not intended to derogate from any other exemption from infringement that exists under the Act.

Recommendation 3

IP Australia to provide general guidance on the new provision as part of its suite of guides on particular topics of patent law, and update this as the law develops.

Recommendation 4

IP Australia to consider actively participating in international fora on the issue of harmonisation of experimental use provisions, such as the current review by the OECD Committee for Scientific and Technological Policy.

Recommendation 5

The Government to consider reviewing the impact on Australian industry of the absence of an exception from infringement for activities undertaken prior to the end of the initial patent term relating to obtaining regulatory approval.

5 Introduction

5.1 *The Advisory Council on Intellectual Property*

The Advisory Council on Intellectual Property (ACIP) is an independent body established to provide advice to the Minister for Industry, Tourism and Resources and IP Australia on policy and administrative issues related to intellectual property. The Hon Warren Entsch MP, Parliamentary Secretary to the Minister for Industry, Tourism and Resources, has responsibility for intellectual property matters within the portfolio. IP Australia is the federal agency that administers the patent, trade mark, design and plant breeder's rights systems.

5.2 *Background to the Review*

In recent years there has been concern expressed, both in Australia and overseas, that patent rights may be inhibiting research and development rather than encouraging it, particularly in the biotechnology field. In mid-2003 the issue received widespread publicity in Australia on the Australian Broadcasting Corporation's Catalyst¹ and Four Corners² programs, where it was claimed that patents may be inhibiting further research into disease prevention and cure because patents are restricting access to fundamental research products and tools. In 2002 a decision of the US Court of Appeals for the Federal Circuit³ clarified that under US law experimenting on patented inventions was infringing activity, except in limited circumstances. This decision created much concern amongst research organisations and calls for reform. In 2004 a committee of the Organisation for Economic Co-operation and Development (OECD) noted that:

Although not widespread, cases of restricted access to patented inventions and delays in conducting or publishing research, indicate that governments must remain vigilant in ensuring that patenting does not unnecessarily hinder access to knowledge, reduce incentives to disseminate knowledge, or impede follow-on innovation. Ministers recognised the growing importance of patent licences and other market-based transactions in fostering knowledge diffusion and agreed that policy should encourage their development. 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.⁴

However, there has also been increasing concern that there is insufficient return on investment in Australian research and development due to unsuccessful commercialisation. Inadequate use of the patent system may play a part in this, but it may also mean that the current availability and extent of patent rights are essential minimums. For example, a recent report on Australia's innovative capacity⁵ states:

¹ <http://www.abc.net.au/catalyst/stories/s898887.hth>, broadcast 10 July 2003.

² http://www.abc.net.au/4corners/content/2003/20030811_patent/, broadcast 11 August 2003.

³ *Madey v Duke University* 307 F 3d 1351 (2002).

⁴ OECD Directorate for Science, Technology and Industry; Committee for Scientific and Technological Policy; *Research Use of Patented Knowledge*, 16 March 2005, DSTI/STP(2005)11.

⁵ *Gans & Stern Assessing Australia's Innovative Capacity in the 21st Century* Intellectual Property Research Institute of Australia 2003.

Australia is a poor performer in terms of global innovation, both in terms of ideas generated as well as the growth rate of ideas production.... It is well understood that the incentive to innovate disappears when firms cannot reap returns on their investments. As a consequence, policies that protect intellectual property are essential for creating a pro-innovation environment.

In light of such concerns, the Parliamentary Secretary the Hon Warren Entsch MP asked the Advisory Council on Intellectual Property (ACIP) to examine the issues.

The Australian Law Reform Commission (ALRC) recently conducted a concurrent inquiry into Gene Patenting and Human Health. Experimental use was one of many issues covered by the ALRC inquiry, which had a specific focus on human health. In its 2004 final report⁶, the ALRC recommended:

Recommendation 13-1. The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear 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; and
- (c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the *Patents Act*.

The government response to this recommendation has been deferred and will be provided in conjunction with its response to ACIP's report.

5.3 The ACIP Review Process

In November 2003 ACIP advertised in the national press to notify the public of the review and to invite participation. A questionnaire designed to gather data on current views and practices regarding the experimental use of patented inventions was mailed and emailed to several hundred recipients including tertiary research institutes and universities, IP professionals, business interests including business facilitators, biotechnology companies and Australian businesses that had applied for at least 5 patents in the previous three years. The Questionnaire was also placed on IP Australia's and ACIP's websites inviting response from any interested parties. Forty four responses to the questionnaire were received.

Using information gained from this exercise and ACIP's own research, ACIP published an Issues Paper in February 2004 to which it sought written responses on a number of questions. The Issues Paper was again circulated widely to companies, research institutes and peak bodies. Forty two submissions were received and ACIP held direct consultations with twenty six interested parties in Brisbane, Sydney, Melbourne and Canberra in June 2004.

⁶ ALRC Report 99 *Genes and Ingenuity: Gene Patenting and Human Health* (2004).

The main points arising from the questionnaire and submissions and consultations in response to the Issues Paper were:

- there is considerable uncertainty and difference of opinion about the current state of Australian law on an experimental use exemption.
- most participants strongly desired clarity as to whether an experimental use provision existed in the current law and which actions on a patent are permissible and non-infringing.
- many researchers believed there were a number of reasons why experimentation on patented inventions should be allowable;
- a minority of submissions argued that there were strong reasons why experimental use should be within the rights of the patentee;
- a significant proportion of researchers did not search for patents that might impact on a project before beginning it, and few had modified a project due to the possibility of infringement;
- there is only anecdotal evidence that the current level of uncertainty is detrimental to research, although this could change in the future.

After consideration of the responses, ACIP released an Options Paper to over a hundred and fifty organisations which discussed a number of possible options for action. Four of these options were identified as those most likely to satisfy the terms of reference of this inquiry and respondents were asked to comment on these. Thirty five submissions were received in response to the Options Paper. Although a wide range of views was expressed, most submissions favoured some form of explicit exemption for experimental acts. ACIP has incorporated these views into the final report, but notes that the views of private companies have generally been under-represented.

The Issues Paper, Options Paper, Final Report and submissions received are all available on the ACIP website at www.acip.gov.au.

6 Policy Issues

6.1 Background

General Principles and Experimental Use

Article 7 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out the objectives of intellectual property rights as follows:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Consistent with this, the report by the Intellectual Property and Competition Review Committee (IPCRC) noted that while strong clear IP rights were an important part of innovation, simply increasing the strength of IP rights would not necessarily lead to optimised economic welfare for society as a whole:

The creation of intellectual property involves intellectual effort and can entail substantial resource outlays. ...Without a system of intellectual property rights it is difficult to prevent 'free riding' by those who did not contribute to the original investment. Creators could therefore find it difficult to recoup the cost of their investment, let alone its economic value. Under these circumstances, economic incentives for intellectual property investment would likely be deficient, leading to under-investment in creative effort.

...(However) conferring intellectual property rights...can allow the owners of the results of this effort to unduly restrict the diffusion and use of these results. ...Additionally, while most intellectual property rights do not confer monopoly power, some do, and when this occurs, the owner of these rights could further restrict diffusion below the level that maximises society's gain from the stock of knowledge.

The IPCR Report concluded that:

Intellectual property laws must therefore involve some balance between the incentives to invest in creative effort and the incentives for disseminating material that is the subject of intellectual property protection. This balance turns on determining the appropriate scope of protection, in terms of the conditions under which protection is granted, the scope and effectiveness of the exclusive privileges provided by protection, and the duration of the protection given. Balancing between providing incentives to invest in innovation on one hand, and for efficient diffusion of innovation on the other, is a central, and perhaps the crucial, element in the design of intellectual property laws.⁷

A recent report by the UK Royal Society on the impact of IP on scientific research⁸ states that patent policy needs to balance:

- the need to provide recognition and incentives for discovery, invention and exploitation to achieve wealth creation and general benefit;
- the desirability of encouraging competition that stimulates further discovery, invention and exploitation; and

⁷ Intellectual Property & Competition Review, Final Report (2000) p.5-6, www.ipcr.gov.au.

⁸ The Royal Society *Keeping science open: the effects of IP policy on the conduct of science* (2003).

- the needs of current and future users of the creative work and resulting products to benefit from such innovation.

Muharige⁹ suggests that the nature of this balance has changed over time, and should to continue to do so, as the nature of research and development changes. When the patent system was first being established in Europe and America, innovation was associated with independent inventors. Today research is dominated by large research establishments, both private and public:

Advantages (of the patent system) include incentives to finance an extensive research establishment in order to provide a pipeline of potentially patentable products, incentive to incur development costs for patented products, and encouragement of individual researchers to develop new and useful processes and products (provided there is a mechanism for the individual to reap the financial benefits). Disadvantages include a deterioration in the open exchange of information, extremely high transactional costs, and inhibition of the most efficient ways to actually conduct research. And, depending on one's viewpoint, the asserted advantage of encouraging development of new and useful subject matter may be considered a detriment by discouraging more basic research.

As enunciated in the IPCRC report, the scope of rights awarded to innovators is crucial in determining whether an intellectual property system achieves its purpose. One argument is that the right to experiment follows directly from the fundamental principles of patents:

It follows, from the principle that patents must serve the public good, that the extent of the right granted should be commensurate with the benefit which the inventor has provided to the public. In other words, the inventor is entitled to an extent of protection which prohibits the public from making use of the invention which he has made in all its practical aspects... However, it also follows that patents should not provide the patentee with a right to stop others engaging in scientific activities which owe nothing to the efforts and discoveries of the inventor.¹⁰

A list of permitted experimental uses was provided by Canada in its arguments before the World Trade Organisation (WTO) in a dispute with the European Union (EU) on the protection of pharmaceutical products¹¹:

- (a) testing an invention to determine its sufficiency or to compare it to prior art;
- (b) tests to determine how the patented invention worked;
- (c) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
- (d) experimentation for the purpose of "designing around" a patented invention;
- (e) testing to determine whether the invention met the tester's purposes in anticipation of requesting a licence; and
- (f) academic instructional experimentation with the invention.

⁹ Kate Murahige *Patents and Research - an uneasy alliance*, Academic Medicine Vol. 77 No. 12 (Dec 2002) p.1329.

¹⁰ Alan W. White, *Genes and Compound Per Se Claims: An Appropriate Reward?*, The CIPA Journal, February 2002, 89 & March 2002, 134.

¹¹ World Trade Organization Panel Report *Canada - Patent protection of Pharmaceutical Products* WT/DS114/R (2000) http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf p.75.

According to Eisenberg¹², distinguishing between using an invention for its intended purpose and experimenting on it, is consistent with the fundamental principles of the patent system in balancing the needs of the primary innovator with those of secondary innovators and end-users and is closely related to the disclosure requirements. The point is made “if the public had absolutely no right to use the disclosure without the patent holder's consent until after the patent expired, it would make little sense to require that the disclosure be made freely available to the public at the outset of the patent term.”

Eisenberg thinks this distinction might be applied equally to research tools. There is a fundamental distinction between research into the science and technology disclosed in patents, and the use in research of patented products or methods, the so-called 'research tools'. They are as subject to the patent right as is any other device or method, whether it is used to conduct research or for any other purpose. Use of an existing tool in one's research is quite different from study of the tool itself.

Basic Research

Because the patent system is essentially an economic/commercial instrument, it has been argued that basic research should not be bound by it. The historic norms of basic research have been said to include:

- the immediate publication of findings for use by all, and
- the pursuit of truth rather than self-interest.¹³

Such motivations do not appear to match those that underpin the patent system, and the 'social good' element has meant that basic research has traditionally been publicly funded. However, as Merges¹⁴ points out, the above norms are aspirational - and they are also subject to historic and cultural change. For example, the practice of asserting *informal* property rights over discoveries has always been practiced, although it appears to have become more prominent recently. In biotechnology the amount of free sharing appears to depend on the expense and difficulty in creating the material and whether the recipient is a direct competitor. There is now also the widespread practice of seeking *formal* property rights, particularly patents, over research results. Merges considers that few scientists see the intellectual property rights debate in polar terms - most think that the optimal policy entails a compromise between informal property rights in research results and formal patent rights. This complex compromise seems to have been effective during the elucidation of the human genome.

Merges advocates that patents have become more of a factor in pure science because in many fields the relationship between science and technology has grown a great deal closer. In the 1930s, science-based industries were centered in the electrical and chemical fields, where the conceptual distance between basic research and applied

¹² Rebecca S Eisenberg *Patents and the Progress of Science: Exclusive Rights and Experimental Use* The Chicago Law review Vol 56 (1989) p.1017.

¹³ Robert K. Merton *The Sociology of Science* (Chicago: University of Chicago Press, 1973).

¹⁴ Robert P. Merges *Property Rights Theory and the Commons: The Case Of Scientific Research* Scientific Innovation, Philosophy and Public Policy edited by Ellen Frankel Paul, Fred D. Miller, Jr., and Jeffrey Paul (1996) Cambridge University Press.

technology was often large. As a consequence, huge investments were required to translate the findings of the basic research laboratory into viable commercial products. However, this had changed by the 1970s and 1980s, particularly in important fields such as biotechnology and certain branches of physics. Another important factor suggested by Merton is that, by the 1970s, the advent of the venture-capital industry and related support institutions had provided start-up companies with a relatively ready supply of capital, provided the intellectual property was captured.

A concurrent trend has been a general decline of government funding for public research in recent years after the highs of the World War 2 and the early post-war years. This has led to both a relative and absolute increase in private funding of research, even in public research organisations. The trend has been further encouraged by initiatives such as the Bayh-Dole Act in the US¹⁵ and the requirement that the Commonwealth Scientific Industrial Research Organisation (CSIRO) obtain up to 25% of its funding from non-government resources¹⁶. The aim, and result, of these initiatives has been the greater commercial focus of public research organisations and the blurring of the traditional distinction between pure and applied research. There has also been increasing overlap in basic and applied research in private industry. In fields such as pharmaceuticals where scientific advances have conspicuous commercial potential, the pursuits of profit and knowledge often converge.

Nonetheless, publicly funded basic research remains of significant value to society. A 2000 study¹⁷ of the link between Australian patenting and basic science noted that previous research into the citation of documents in US patents has shown that publicly sponsored basic research plays a critical role “in the development of leading edge technologies such as pharmaceuticals, chemicals, advanced electronics and, especially, biotechnology”.

Biological and Medical Sciences

A number of commentators have suggested that there are fundamental differences between earlier sciences/technologies and biotechnology - and even some subdivisions within biotechnology - with regard to intellectual property. These differences are even recognised through specific provisions in international treaties. For example, Golod and Golod¹⁸ suggest that there a number of significant differences between synthetic compounds, such as polymers and pharmaceuticals, and genes, particularly human ones:

- the supply of genes is limited (probably to around 30,000 in the human genome) and no one person should monopolise such a limited resource.

¹⁵ In 1980 under the Bayh-Dole Act US universities became able to elect ownership of inventions made under federal government funding.

¹⁶ In 2003-2004, 36% of CSIRO revenue was external, from both the public and private sector, with 2.5% from intellectual property and royalties. CSIRO Annual Report 2003-2004, Table 11.

¹⁷ *Inventing our future. The link between Australian patenting and basic science*, Australian Research Council and Commonwealth Scientific and Industrial Research Organisation (2000), Foreword.

¹⁸ Jorge A. and Elina Golod *Human Gene Patents Academic Medicine* vol. 17 no. 12 Dec 2002 p. 1315.

- it is relatively easier to avoid or 'invent around' a patent claim to a small molecule (drug) than with a broadly claimed DNA.
- many genes are also discovery tools because they encode receptors important in transduction pathways.

Similarly, a recent discussion paper of the Nuffield Council on Bioethics¹⁹ says that DNA sequences are essentially just genetic information and this should distinguish them from other chemical compounds with regard to the patent system:

We distinguish four different uses to which DNA sequences can be put: in diagnostic tests based on genes, as research tools, in gene therapy and for the production of therapeutic proteins. We conclude that patents that assert rights over DNA sequences and their uses are, in some cases, supportable, but in others, should be treated with great caution.

It has been emphasised that one of the major differences between classical and biotechnological inventions is in the manner of describing each²⁰. Following on the structure of physical scientific thought most prevalent during the growth of the patent system during the 19th and 20th centuries, the language of inventive step, novelty and disclosure presume that technical inventions can be described by listing structural features or a given sequence of processing steps. This is a manner more suited to mechanical inventions, which develop from their element parts to their whole. Biotechnological inventions, on the other hand, are best described in functional terms rather than mechanistic ones. For example, an isolated gene's use is largely as an information source, and this should be emphasised when applying the utility criterion for grant of a patent.

On the other hand, many such as Bendekgey and Hamlet-Cox²¹ suggest that the current controversy with biotechnology and gene patenting is not unusual. As is often the case when a new area of science or technology emerges, some have argued that the application of the current patent system to a new category of invention, in this case gene-based inventions, will have a negative impact on innovation and the economy. Bendekgey and Hamlet-Cox state that there are three basic difficulties with these arguments:

- First, if the purpose of the patent system is to create incentives for innovation, then research tools, which by their use inherently promote further innovation, would seem particularly appropriate subjects for patent protection;
- Second, the types of companies that provide such products, typically small companies without publicly-traded securities and those whose securities are traded over the counter, are precisely those for whom patents are most important;
- Thirdly, there is no principled way to distinguish between a gene-based invention and any other research tool.

¹⁹ Nuffield Council on Bioethics *The Ethics of Patenting DNA* (2002) p.xi
<http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf>.

²⁰ N Siva *Legal Protection Of Human Biotechnology Inventions In Europe* BCL Dissertation Oxford University (2000).

²¹ Lee Bendekgey & Dianna Hamlet-Cox *Gene Patents and Innovation* *Academic Medicine* vol 77 no. 12 /December 2002 p.1373.

Bendeckey and Hamlet-Cox conclude that it has never been the role of the patent system to establish industrial policy with respect to any particular category of invention or sector of the economy and that any problems caused by the application of the patent system in particular sectors (eg higher health care costs) should be dealt with by non-patent policies in that sector (eg additional health care funding).

6.2 Submissions

General Principles and Experimental Use

Many thought that an experimental use exception was implicit in the patent system's *quid pro quo* of patent grant in return for early disclosure:

The underlying benefits of a patent system are always cited as being a granted limited monopoly in exchange for full disclosure of the information, ie the invention, to stimulate innovation. It is difficult to see how this exchange can take place without an explicit experimental research use exemption. Indeed, an experimental research exemption would maintain and further strengthen the patent system by providing for increased innovation and testing of published applications and granted patents.

Curtailing the experimental use exemption could stifle innovation and slow the advance of technology. The practical effect of barring research would be to allow a patent holder to stop not only commercial competition, as is a proper right under the patent system, but also all research that might lead to such competition, as well as barring improvement, challenge or avoidance of a patented invention. (Ludwig Institute, Issues24)²²

However, the Intellectual Property Research Institute of Australia (IPRIA) went further in arguing that experimental use was not an 'exemption' but inherent in the nature of the system. Anything that was not explicitly disclosed in a patent application should not be granted and so anything else would by definition be new and 'experimental':

It is important that the issue of experimental uses not be seen as simply a matter of creating a limited, 'tacked-on' defence based on some particular social policy justification... Patent law is informed by a *quid pro quo* rationale: the state awards monopoly rights in return for the disclosure of some specific and substantial utility. This same reasoning implies that the reward should be commensurate with the disclosure – meaning that *the rights conferred should extend as far as the specific and substantial utility disclosed – and no further*. This idea lies at the heart of this submission. If accepted, it follows that many experimental uses do not fall within the scope of the patent owner's rights. (IPRIA, Issues28)

On the other hand, one submission argued that there was no policy justification for an experimental use exception:

Epitan submits that introducing an experimental use exception would considerably reduce economic incentives for investment in the creation and commercialisation of intellectual property. A patent owner's compensation for the disclosure of its inventions is its right to (for the most part) control the use and exploitation of the patented invention for the patent period. This is the 'consideration' given in return for public disclosure of the invention. Introducing an experimental use exception into Australian patent legislation would, to a

²² Lists of submissions are in Part 12, Appendices. Full copies of non-confidential submissions are available at: www.acip.gov.au.

significant extent, strip patent owners of their right to control the use of their inventions. (Epitan, Issues20)

A similar view was put forward by Genetic Technologies Limited (GTG) in its consultation session with ACIP.

Many submissions pointed to the costs of not having a clear experimental use exception, including the specific costs to users of the patent system and the adverse impact on innovation and competition generally:

There are two issues that must be considered - knowledge of infringement and enforcement. (Firstly) it would be an enormous task for a researcher and associated IP officers to monitor granted patents and evaluate whether their daily work infringes any claims. Secondly, for the patent holder surveillance to support enforcement would be a major undertaking....there are literally thousands of laboratories and publications to monitor individually... In our view the removal of the (currently implicit) research exemption would adversely change the way in which science is done and reported, would reduce the public return on investment in research, would be extremely expensive to sustain, would make Australia less competitive and deliver minimal or no financial benefits to patent holders. (Walter & Eliza Hall Institute of Medical Research, Issues5)

and

We also submit two further and perhaps subsidiary reasons for supporting an experimental use exemption. First, it would be desirable to close off any legislative loopholes that may enable patentees to act in an anti-competitive fashion, particularly in view of the recent Ergas and Dawson Committee reports. Second, ...if further research demonstrates the invention to be robust, the results are likely to be published in high quality journals resulting in increased demand for the applauded invention, which is of benefit to the patent holder and public alike... If the invention does not work, then it is invalid and the patent register should be cleared of the unmeritworthy invention. Finally, if the research results in an improvement, a licence to the original technology will most likely be required, resulting in ultimate benefit to the patent holder and the public. (A. McBratney et al, Issues30)

Basic Research

Many submissions felt that there was now too much blurring between basic research and applied research for the nature of work to be useful distinction in patent law:

In this day I think it is more difficult to clearly separate basic or applied research. Certainly in the Biotechnology arena basic and applied research are very close sometimes overlapping. To try to allocate different rights to different types of research would add additional problems rather than alleviate one potential concern. (Soozy Smith University of Newcastle, Issues21)

Similarly:

One way of distinguishing between basic and applied or hybrid research is by using the non-commercial/commercial test. However, this test has considerable difficulties... For this reason, as well as the ever closer relationship between basic and applied research, we are of the view that it is not practical to distinguish between the two and that the European model offers the best compromise. (FICPI Australia, Issues3).

However, a few submissions thought that the distinction was important and should be incorporated in patent law:

Freedom to operate for researchers conducting basic research is fundamental to a university's teaching program and impinges on the quality of the teaching program and the students learning under it. There should be a full exemption for teaching and basic research

purposes otherwise it undermines the quality of our programs, our researchers and our students.

Until that commercial research appears in the form of products in the market place one must ask the question 'What is the purpose of the protection under the patent system and what is the loss to the patent holder?' (Georgia Sherry, Issues34)

and

Yes, basic, applied and hybrid research would certainly have different requirements from the patent system. In basic research in biology the availability of all manner of tools allows a range of problems to be examined in a number of ways... A researcher in such a situation is faced with a choice: potentially infringe someone's IPRs or pursue an alternative approach. This impacts negatively on discovery and innovation overall as many significant findings are serendipitous.

Applied or hybrid research by definition is concerned with achieving a defined outcome in relation to application of a technology. In many such cases the desire for the defined outcome will be sufficient incentive to negotiate access to protected material (particularly when commercial outcomes are concerned). Moreover the time and dollar implications will be part of the budget and project plan (whereas this would often not be the case in fundamental/basic research). (Ryan Wilson, Issues27)

One submission proposed solutions for dealing with the difference:

We have argued that basic or non-commercial research is different from commercial research and should have absolute protection from infringement in the form of an express exemption covering both *research on* and *research with* the patented invention. However, the bright line between basic and applied research is becoming decidedly fuzzy and the field of pure non-commercial, basic research is shrinking, for a host of reasons...

One solution that has been proposed in the literature is that researchers could have the option of self-defining as non-commercial users. Public statements have already been made to this effect by various research groups, including, for example, the Human Genome Project through its Bermuda Declaration and the Single Nucleotide Polymorphism (SNP) Project. Dreyfuss and others have suggested more formalized waiver mechanisms to enable reliance on a non-commercial research exemption... (Nicol/Nielsen, Issues17)

Biological and Medical Sciences

Many submissions argued that biotechnology and genetic technologies do raise special issues either because of

- their "informational" nature; or
- their strong upstream/downstream effects, including their potential for patent thickets; or
- their centrality to human health.

For example, the Department of Health and Ageing (DHA) stated:

The "patent thicket" problem may become a greater problem in human genetics than in other fields of technology because of the large number of potentially patentable inventions. Patentable inventions include at least 30,000 genes, 200,000 or more proteins, and the various forms and combinations of these basic elements... The number...and complex inter-relationship of genes, proteins, the regulatory mechanisms which govern the expression of genes and the production of proteins give rise to the potential for patent gridlock... The ability to invent around a patent is regarded as a strong inhibitor of monopoly in many fields of technology. (DHA, Issues40)

Similarly the Cancer Council of NSW submitted:

We would suggest that genetic technology poses a significant challenge to the patent system and the very nature of the subject matter requires a specific and targeted response at several different levels. These include changes to the criteria for application for gene patents introducing a utility requirement; vigorous, critical and informed examination of gene patent applications; a capacity to challenge inappropriate patents; provisions for effective licensing provisions, including compulsory licences; a better defined role for Government in the patent process where public interest needs to be safeguarded. In short special treatment with a clear experimental research exemption is warranted for genetic technology due to the impact of the subject matter on the wider community - a clear experimental use exemption should be seen as a minimum. (Cancer Council of NSW, Issues8)

However many stated that, even if biotechnology did present special problems, it was not possible to give special treatment to biotechnology because of the TRIPS Agreement:

There is little doubt that biotechnology and genetic technology do raise special issues.....(but) We sound a note of caution here in that Article 27 of the TRIPS agreement provides that there should be no discrimination between fields of technology. This provision makes it difficult to provide special treatment for these areas of technology under patent law. One thing that perhaps could be done is drawing up of guidelines to explain how the research exemptions and alternative patent use strategies might apply specifically in the areas of biotechnology and genetic technology. (Nicol/Nielsen, Issues17)

On the other hand, the DHA argued that the patent system had never been strictly technologically neutral:

Health notes the Issues Paper's discussion of technological neutrality and agrees that it is desirable to retain such neutrality as far as possible in the intellectual property system. However, it has never been the case that patenting has been universally applied to all fields of invention without exception and without guidelines addressing issues specific to individual technologies... There are examples such as plant breeder's rights where technology-specific arrangements apply... The Patents Act has special provisions for micro-organisms...individual circuits are protected by technology specific protection... The TRIPS agreement also recognises the right to take technology-specific action in respect to inventions, such as exemptions under article 27.3. Individual patent offices recognise the need for specific administrative guidelines for particular technologies and the need to update these guidelines in the light of experience, as has already occurred in some countries.

Health also notes there may be difficulty in making a clear distinction in some instances between research *on* the invention and research *with* the invention where the "invention" is a gene. (DHA, Issues40)

L. Palombi argued that the patent system had been created for a “bricks and mortar world” and was not suitable for information products like gene sequences. He suggested the creation of a special (*sui generis*) right for genetic sequences, as were created for circuit layout rights and plant breeder’s rights.

6.3 ACIP Considerations

General Principles and Experimental Use

The objective of patent rights is to encourage and diffuse industrial innovation in a manner that benefits society as a whole. In general, the more innovation that occurs, the greater the potential gains to society. The state encourages innovative activity through awarding people the exclusive rights to new, useful products or processes they have created, in return for their full disclosure.

There is a wide divergence of views on what breadth of patent rights best encourages such activity. Providing patent holders with the rights to all acts relating to their inventions (other than being able to contest the validity of the patent itself) would provide simplicity, certainty and considerable incentive to innovate in new, unpatented fields. Patent holders would stand to gain a considerable market advantage, as they would become the gate keepers to all further innovation within the scope of the patent claims for the term of the patent.

However, the obvious cost of granting broad rights for the initial (primary) innovation is a disincentive for others in society to experiment further in the field to generate secondary innovation. Other innovators would have to obtain licences in order to legally experiment on the patented invention. Despite its simplicity and the strong incentive provided by broad rights, ACIP is concerned that such a regime would provide a net cost to society, and therefore not meet the objectives of the patent system.

ACIP is sympathetic to the argument that patent rights are inherently limited and that an exemption for experimental use is implicit in the patent system's *quid pro quo* rationale. The extent of the reward conferred by the state should be commensurate with the practical benefit which the inventor has provided to society, and this by definition would not include mere experimentation on the invention. The full details of an invention are published soon after a patent application is made so that others can both test the validity of the patent and learn from it. Most submissions to ACIP made arguments in this vein, however it should be noted that private industry was generally under-represented.

Limiting patent rights so that they do not extend to acts of experimentation would clearly encourage secondary innovation. All would be free to develop improvements to and new uses for patented inventions without having to obtain licences from patent owners. Patent rights must, of course, still provide sufficient protection to make primary innovation worthwhile, or else the system would fail. For example, if the normal use of a patented invention was determined to be a non-infringing act simply because it was part of a broader experimental purpose, then patents in such technologies would be significantly devalued and innovation discouraged. A balance of rights would have to be achieved, and this would in turn create cost and uncertainty, as each case would have to be considered on its own merits rather than according to a general rule. It is clearly difficult to specify what is the "normal use" and practical benefit of many patented inventions. Nonetheless, ACIP believes that, by appropriately limiting patent rights, society should be able to obtain a net benefit by optimising the balance of primary and secondary innovation.

Basic Research

ACIP concurs with the majority view that the distinction between basic and applied research is too blurred to form the basis of an experimental use provision. Providing an exemption for researchers who self-define as non-commercial users would only be a partial solution. ACIP considers that the question of infringement would be better decided according to individual circumstances rather than general categories. However, whether or not the balance of rights is optimal and a patent is being inappropriately devalued is a commercial question. ACIP considers that some form of commercial aspect may need to be taken into account in deciding whether an act should constitute infringement of a patent.

Biological and Medical Sciences

ACIP acknowledges that the biological and medical sciences do appear to involve special issues, and that international treaties allow such technologies to be excluded from patentability. However, ACIP believes that technological neutrality should be maintained wherever possible in substantive patent law. It would be better if an experimental use provision was formulated to provide scope in for these issues to be properly considered by the courts on a case by case basis. ACIP does not consider that the creation of a uniquely Australian sui generic system of protection for biotechnologies is warranted.

7 International Treaty Obligations

7.1 Background

TRIPS

Australia is a signatory to a number of international treaties on intellectual property rights, therefore any development of patent law must be consistent with them. The most important of these is the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement mandates that member states establish minimum standards of intellectual property protection.

Articles 28 and 30

The Articles that most directly relate to experimental use are Articles 28 and 30.

Article 28.1 mandates the extent of rights conferred by a patent:

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

Article 30 allows exceptions to this:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The interpretation of Article 30 was the subject of a decision by a Panel of the WTO Dispute Settlement Body – the Canadian Stockpiling Case²³. The European Communities made a complaint against Canada, claiming that certain provisions in the Canadian Patent Act were inconsistent with Article 28.1 of the TRIPS Agreement. Although both Canada and the EU presented arguments suggesting an experimental use exemption, to differing extents, was a consequence of the balance of the patent system, these arguments were not explicitly considered by the Panel in its ruling on this dispute.

²³ World Trade Organization Panel Report *Canada - Patent protection of Pharmaceutical Products* WT/DS114/R (2000) http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

Analysis of the Stockpiling Case

The Canadian provisions at issue were:

- a regulatory review provision that allowed the making of a patented product prior to expiry of the patent whose marketing is subject to government regulation in order to assure their safety or effectiveness, and
- a stockpiling provision that allowed generic manufacturers who had complied with the regulatory review process to stockpile the generic product for six months before the patent expired. The patented product could not be sold until after the expiry of the patent.

While Canada acknowledged that these provisions conflicted with Article 28.1, it argued that the provisions were authorised by Article 30. Article 30 comprises three criteria that are cumulative, 'each being a separate and independent criteria that must be satisfied'. Hence, if any one of these criteria are not met, then the exception will not fall within the scope of Article 30.²⁴ The Panel made the following findings in relation to these three criteria.

Criterion one - exception must be limited

The Panel found that 'limited' should be measured by 'the extent to which the exclusive rights of the patent owner have been curtailed'.²⁵ The Panel explained further that the focus should be on 'which legal rights have been curtailed, rather than the size or extent of economic impact'. The Panel took a narrow view of this criterion, on the grounds that the word 'exception' in itself 'connotes a limited derogation'. Hence, the Panel found that the phrase 'limited exception' must be read narrowly as only allowing exceptions that make 'only a small diminution of the rights in question'.²⁶ The Panel found further that in order to determine whether 'a particular exception constitutes a "limited exception", the extent to which the patent owner's rights have been curtailed must be measured'.²⁷

In relation to Canada's stockpiling provision, the Panel found that because there was no limitation on the amount of product that could be 'made' or 'used' during the six months prior to the patent expiring, the exception could be 'said to abrogate such rights entirely' during those six months.²⁸ Thus, the Panel found that the stockpiling provision was not a 'limited exception' that fell within the scope of Article 30,²⁹ and hence was not consistent with Canada's obligations under Article 28.1.³⁰

²⁴ Para 7.20.

²⁵ Para 7.30.

²⁶ Para 7.31.

²⁷ Para 7.32. Note that in discussing how this curtailment should be 'measured' the Panel rejected some of the arguments raised by the parties. For example, the EC argued that measurement should entail determining how many of the patent holder's rights enunciated in Article 28.1 are violated by the exception. The Panel rejected this argument, stating that a 'very small act could well violate all five rights provided by Article 28.1 and yet leave each of the patent owner's rights intact for all useful purposes'.

²⁸ Para 7.34.

²⁹ As the stockpiling provision did not meet the first criterion, the Panel did not consider any of the other criterion in respect of this provision.

³⁰ Para 7.38.

However, the Panel found that Canada's regulatory review provision was a 'limited exception' within the meaning of Article 30, because the exception was 'confined to conduct needed to comply with the requirements of the regulatory approval process'. As a result 'the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded'. The Panel also noted that although the review process could require large quantities of the patented product to be made, 'no commercial use is made of resulting final products'.³¹

From these examples, the Panel seems to be saying that an exception will be 'limited' for the purposes of Article 30 where the exception only allows for the patentee's rights to be curtailed in specific circumstances. Therefore, it could be argued that an experimental use exception meets this criterion because it only curtails the patent owner's rights in the specific circumstances of use for experimental purposes.

Criterion two – exception must not unreasonably conflict with the normal exploitation of the patent

The Panel found that the normal exploitation of a patent by patent owners 'is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'.³² The Panel applied the ordinary dictionary meaning of 'normal', and found that normal in the context of Article 30 meant an empirical conclusion about 'what is common within a relevant community' and 'a normative standard of entitlement'.³³

Although the Panel found that in some cases it might be normal to have a period of market exclusivity that is additional to the patent term, the Panel found this was not the case in respect of an additional period as a result of a regulatory review process. The Panel found that this period was not a 'normal' additional period of market exclusivity, because 'it is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity'.³⁴ Thus, the Panel found that the regulatory review provision did not 'unreasonably conflict with the normal exploitation of the patent'.

There are, however, inventions – such as, for example, research tools – the normal exploitation of which arguably does include acts done for experimental purposes. Therefore, an experimental use exception would need to exclude from its scope such inventions, or else it may breach this criterion.

Criterion three – exception must not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties

The Panel's comments in relation to this criterion relate fairly specifically to the facts of the case, and hence it is more difficult to draw general conclusions from their findings.

³¹ Para 7.45.

³² Para 7.55.

³³ Para 7.54.

³⁴ Para 7.57.

The EC argued that ‘legitimate interests’ equated to ‘legal interests’. The Panel rejected this argument, stating that as third parties would not have any legal interests, ‘legitimate interests’ must have a broader meaning in order for the criterion to make sense.³⁵

The Panel then focused on whether patent owners could claim a ‘legitimate interest’ in the economic benefits that could be derived from an additional period of market exclusivity that would exist if the regulatory review provision was not in place, and whether the regulatory review provision ‘unreasonably prejudiced’ this interest.³⁶ The Panel looked to see whether the additional period of market exclusivity could be considered a ‘widely recognised policy norm’.³⁷ The Panel found in the negative, noting the differing approaches taken by various countries, and stating that it was not appropriate to use the concept of ‘legitimate interests’ in Article 30 to adjudicate on an issue that was ‘still obviously a matter of unresolved political debate’.³⁸

Thus, the Panel found that no ‘legitimate interest’ was at stake in relation to the regulatory process provision, and hence the regulatory review provision was within the scope of Article 30, and as such was compliant with Article 28.1.

In discussing the issue of ‘legitimate interests’ in the context of Article 30, the Panel also made specific reference to the experimental use exception:

‘To make sense of the term “legitimate interests” in this context, that term must be defined in the way that it is often used in legal discourse - as a normative claim calling for protection of interests that are “justifiable” in the sense that they are supported by relevant public policies or other social norms... We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a **key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge** and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a “legitimate interest” in using the patent disclosure to support the advance of science and technology. While the Panel draws no conclusion about the correctness of any such national exceptions in terms of Article 30 of the TRIPS Agreement, it does adopt the general meaning of the term “legitimate interests” contained in legal analysis of this type.’³⁹ (emphasis added)

Here, the Panel is not making a positive finding that the experimental use exception is permitted by Article 30. Rather, the Panel uses the justifications given for the experimental use exception to illustrate the type of ‘legitimate interests’ that it considers are relevant in the context of Article 30. In respect of the experimental use

³⁵ Para 7.68.

³⁶ Para 7.61.

³⁷ Para 7.77.

³⁸ Para 7.82.

³⁹ Para 7.69.

exception, the Panel states that the exception is often justified on the grounds that it is an exception needed to protect the legitimate interests of third parties to undertake experiments. This confirms that the Panel considers ‘legitimate interests’ to include policy considerations.

Thus, the Panel appears to be saying that an experimental use exception protects the ‘legitimate interests of third parties’ that are within the scope of Article 30 by facilitating the public policy purpose of ‘the advance of science and technology’.⁴⁰ Therefore it is likely that an appropriately framed experimental use exception would meet this criterion.

Summary

Therefore, an experimental use exception would most likely satisfy Article 30 provided it:

- is limited to certain uses;
- ensures that it does not conflict with the normal exploitation of patents, and
- facilitates public policies such as the advancement of science and technology.

It is also worth noting that early on in its analysis the Panel made the following statement:

‘To the extent that some development activity might be permitted, consistently with Article 30 of the TRIPS Agreement, under other exceptions such as the traditional exception for experimental use of the patented product...’⁴¹

Here the Panel appears to be recognising that a generally accepted ‘traditional exception for experimental use’ exists, and that such an exception is within the scope of Article 30. Thus, if an Australian experimental use exception were drafted to fit within this ‘traditional’ experimental use exception, it would be compliant with Article 30. This factor supports using an exception such as that used in Europe, as such an existing exception may well fall within the ambit of a ‘traditional’ experimental use exception.

Article 27.1

As outlined in Part 6, Article 7 of the TRIPS Agreement states that IP rights should be to the advantage of producers and users, and conducive to social and economic welfare and to a balance of rights and obligations. One possible method of providing the correct balance may be to limit patent rights to the specific utility disclosed by the inventor. In theory this would provide sufficient protection to the patent owner while encouraging further innovation. However, Article 27.1 states that:

Subject to the provisions of paragraphs 2 and 3 (regarding exclusions from patentability), patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Given the limited definitive judgements by WTO dispute tribunals, it is not clear whether Article 27.1 requires that patents must be available for claims to products per

⁴⁰ Para 7.69.

⁴¹ Para 7.3.

se, i.e., without restriction to a specific utility. Some commentators state that the availability of such claims is required under TRIPS⁴², and an example may be recent changes to made India's patent laws in order to achieve TRIPS compliance⁴³. Others believe that TRIPS provides members with the freedom to determine the form and limitations of allowable claims, including "use-bound" claims, provided there is no discrimination based on the field of technology⁴⁴.

AUSFTA

The Australia-United States Free Trade Agreement (AUSFTA) largely reiterates the TRIPS Agreement provisions in this particular area of patent law. However, the AUSFTA does further restrict certain unauthorised uses of an invention under Article 17.9(7):

A Party shall not permit the use of the subject matter of a patent (other than those limited exceptions provided under paragraph 3 and Article 30 of TRIPS) without the authorisation of the right holder except in the following circumstances:

(a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices; or
(b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:

(i) the Party shall limit such use to use by the government or third persons authorised by the government;

(ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and

(iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.

7.2 Submissions

Partly because the AUSFTA was still being negotiated during the submission and consultation process to the Issues Paper of this inquiry, most submissions thought that Article 30 of the TRIPS Agreement was the main treaty obligation relating to experimental use:

In the light of the Canada WTO decision, it is difficult to see how an EUE...would fall foul of any of the international agreements Australia is party to...Depending on the scope of the EUE, there should be a strong argument that it is an Article 30 limited exception. (Mayne Pharma, Issues12)

⁴² For example, Phil Thorpe *Study on the Implementation of the TRIPS Agreement by Developing Countries*, p.17, Study Paper 7 for the UK Commission on Intellectual Property Rights report *Integrating Intellectual Property Rights and Development Policy* (2002).

⁴³ Under India's Patents Act 1970 act a range of subjects were not patentable, including product claims for pharmaceuticals. Under TRIPS, India had leave as a developing country to defer examining applications for pharmaceutical products until 1 January 2005. This has been implemented under the Patents (First Amendment) Act 1999 and Patents (Second Amendment) Act 2002..

⁴⁴ Carlos Correa *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre (2000), Part III.

One submission also invoked the parallel with copyright law:

As noted by Maureen O'Rourke, Article 30 closely parallels Article 13, which provides for limited exceptions to the rights of copyright holders. It is generally assumed that this provision allows the fair use/dealing provisions found in the copyright laws in most jurisdictions. Hence, O'Rourke concludes that: 'To the extent that Article 30 parallels Article 13, this suggests that some type of patent fair use is not only permissible but also expected under TRIPS.' We agree with this proposition. (Nicol/Nielson, Issues17).

Some suggested that because other countries had experimental use exemptions (in various guises) this implied a de facto acceptance of one under the TRIPS Agreement:

The European Union and the United States of America have long recognized the defence of research exemption as a legitimate limited exception to the exclusivity of rights granted to the patent holder. (ACIPA, Issues18)

However, some had doubts that an experimental use exception would be allowed under TRIPS:

...our client submits that an experimental use exception would unreasonably prejudice the legitimate interests of patent owners. Therefore, the introduction of such an exception may see Australia breaching its obligations under Article 30 of the TRIPS Agreement.

(Minter Ellison for Epitan, Issues20)

Many submissions pointed out that Article 27 of TRIPS requires technological neutrality and this would have to be reflected in any experimental use exemption.

7.3 ACIP Considerations

In light of the submissions to the review, analysis of the Stockpiling Case and the existence of experimental use provisions in the US and Europe, ACIP considers that an appropriately formulated experimental use provision, which allows for further experimentation to be conducted without unfairly devaluing patent rights, would be compliant with the TRIPS Agreement. Current interpretation of Articles 7 and 30 strongly suggests that an experimental use exception is a traditional and acceptable means of achieving the balance of rights and obligations needed to promote technological innovation and dissemination. However, it is not certain that an experimental use provision is mandatory in order for Australia to meet its TRIPS Agreement obligations.

Limiting the scope of patent claims to the specific utility disclosed by the inventor would ensure that experimental acts are non-infringing. Although it is not clear that the TRIPS Agreement requires that patents be available for products per se, ACIP recognises that it is long-held, standard international practice across all technologies to grant patent claims for all uses of a new product, and to not limit the scope of claims to those uses developed by the inventor and disclosed in the patent specification. The introduction of such limits would set Australia apart from most other countries and no doubt be controversial. For example, the interests of foreign companies seeking patent protection in Australia would be significantly affected, creating the potential for disputes under free trade agreements. This and the potential breaching of the TRIPS Article 27.1 pose significant barriers to such an option.

As far as ACIP can ascertain, AUSFTA Article 17.8(7) adds further restrictions to compulsory and statutory licencing, but not to other forms of an experimental use provision.

8 Australian Law and Practice

8.1 Background

Law

Currently there is no explicit provision in the *Patents Act 1990* regarding whether experimental use constitutes infringement. The Act gives the patentee very broad and explicit rights to exclusively 'exploit' the invention in the patent area (Australia and its continental shelf and water and air above). The dictionary of Schedule 1 says that:

'exploit', in relation to an invention, includes:

- (a) where the invention is a product - make, hire, sell or otherwise dispose of the product, offer to make, sell, hire or otherwise dispose of it, use or import it, or keep it for the purpose of doing any of those things
- (b) where the invention is a method or process - use the method or process or to do any act mentioned in paragraph (a) in respect to the product resulting from such use.

The only mention of 'experimental' (use) in the Act is in s.9 on secret use, where s.9(a) excludes from the definition of secret use any use for 'reasonable trial or experiment only'. However, experimental purposes are referred to in the Regulations. Patent applications involving micro-organisms that are not reasonably available must be accompanied by a deposit of the micro-organism in order to satisfy the requirement of a full description of the invention. Regulation 3.25 provides that the Commissioner must authorise release of a sample of a micro-organism if the requestor has undertaken to use it only for experimental purposes, or in relation to relevant legal proceedings. It has been argued that the intent of this regulation was to provide competitors with the same opportunity to access and experiment on micro-organisms as with any other invention, rather than micro-organisms being a special case where experimentation did not constitute infringement.

ACIP sought the advice of the Australian Government Solicitor on their understanding of the current Australian law on experimental exemption. Their advice was, in part:

We think it is likely that a court would find that, in some circumstances, use of a patented invention for experimental or research purposes would not constitute an infringement of a patent registered under the Act.

In the absence of any judicial consideration of the matter, it is difficult to predict how broadly or narrowly an Australian court would interpret the scope of an experimental or research 'exception'. However, it seems likely that the question of whether any given use can be regarded as having been undertaken for commercial advantage would be central to the formulation of any relevant test.

The *Patents Act 1952* had previously defined the exclusive rights of the patentee in terms 'make, use, exercise and vend', and these words have been widely interpreted by the courts. As the author in Lahore, *Patents, Trade Marks and Related Rights* observes, it appears that the definition of 'exploit' in the current Act attempts to encapsulate the decisions in which the words 'make, use, exercise and vend' had been interpreted under the previous legislation.⁴⁵

⁴⁵ At para 24,000. See also *Bedford Industries Rehabilitation Association Inc v Pinefair Pty Ltd* (1998) 40 IPR 438 at 449 per von Doussa J.

As far as we are aware, the so-called ‘experimental use’ principle expounded in *Frearson v Loe*⁴⁶ has not been applied by an Australian court. However, the Explanatory Memorandum for the Patents Bill 1990 states that:

... it is not intended that clause 13 ... modify the present law relating to certain acts which have been held not to constitute infringement - for example, use of an invention for certain experimental or trial purposes.⁴⁷

It is likely that some weight would be given to this statement in interpreting the scope of the term ‘exploit’, given that there is some ambiguity as to whether the definition extends to non-commercial uses of a patented invention.⁴⁸

In our view, recognition that use for experimental or research purposes may not constitute an infringement is consistent with the scope and purpose of the Act as a whole. It seems clear that the statutory scheme was designed to protect the commercial interests of inventors. This purpose is reflected in the following comment from the second reading speech for the Patents Bill 1990:

The essence of the patent system is to encourage entrepreneurs to develop and commercialise new technology. Since a patent confers a limited monopoly over the use of the patented technology, the patent owner has the opportunity to make a profit from it, gaining a return on investment in innovation. The international character of the patent system makes patents a useful tool in penetrating export markets.

It is against this background that the Patents Bill was formulated.⁴⁹

In a decision under reg 3.25(1), a delegate of the Commissioner for Patents assumed that the principle in *Frearson v Loe* applies in Australia⁵⁰. The delegate considered that the term ‘experimental purposes’ in reg 3.25(1) ‘should be construed analogously to those experimental uses of an invention that do not give rise to infringement of a patent’.

Regulatory Review Exception

Since 1999 the *Patents Act* has allowed for extensions of patent terms of up to five years for pharmaceutical substances in order to compensate for the delays involved in gaining marketing approval from the federal government⁵¹. However, the rights awarded during this period are limited, as it is not an infringement to exploit a pharmaceutical invention:

- for a purpose other than therapeutic use, or
- solely for purposes in connection with obtaining regulatory approval⁵².

Such exceptions are known as regulatory review, springboarding, safe harbour or Bolar-type⁵³ provisions, and enable generic manufacturers to be in a position to

⁴⁶ *Frearson v Loe* (1876) 9 ChD 48.

⁴⁷ At page 5.

⁴⁸ See s.15AB of the *Acts Interpretation Act 1901*.

⁴⁹ House of Representatives, 10 October 1990 at 2565.

⁵⁰ *New York University v Nissin Molecular Biology Institute, Inc* (1994) AIPC 91-069.

⁵¹ s.70.

⁵² s.78

⁵³ After the US CAFC decision *Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc* (1984).

market the invention immediately after the extended term expires. These provisions have recently been subject to review.⁵⁴

Other IP Rights Systems

Research exceptions do exist under other IP right systems. An experimental use exemption exists under the *Plant Breeder's Rights Act 1994*. Plant Breeder's Rights (PBRs) provide sui generis protection for new plant varieties for up to 20 or 25 years depending on the variety. The owner of a PBR has the exclusive right to direct the production, sale and distribution of the variety, receive royalties from the sale of plants, or to sell or licence their rights. However, a PBR does not extend to acts done:

- privately and for non-commercial purposes; or
- for experimental purposes; or
- for the purpose of breeding other plant varieties.⁵⁵

Similarly, the *Copyright Act 1968* provides that copying may be allowed for the purpose of research or study⁵⁶. This provision is discussed in more detail in Part 10.3.3.

Practice

General trends

There has been a general movement towards greater use of patent rights both in Australia and around the world. This is evidenced by a substantial growth in applications for patents in recent years⁵⁷, and has been driven by a combination of factors.

There has been an increasing realisation that successful innovation is a primary driver of economic growth. It has been said that innovation accounts for around 50% of long term economic growth in industrialised countries⁵⁸. In the foreword to the 2004 funding plan for the Australian government's \$8.3 billion, 10 year science and innovation initiative *Backing Australia's Ability*, the Prime Minister said:

Ideas, knowledge and skills are becoming the essential raw materials of economic and social progress. They enable us to make the most of our rich natural resources, develop new industries and to find solutions to contemporary and emerging problems in areas such as environment, health and national security. ...The Australian Government's goal is for Australia to build a world-class innovation system.⁵⁹

⁵⁴ *Evaluation of the Pharmaceutical Industry Investment Program*, Productivity Commission, (2003), Part 8.3, *Pharmaceuticals Industry Action Agenda Discussion Paper* (2001) Chapter 4.5 and *Second Year Implementation Report*, Department of Industry Tourism and Resources (2004) Pg 19.

⁵⁵ *Plant Breeder's Rights Act 1994*, s.16.

⁵⁶ ss.40 and 103C.

⁵⁷ See <http://www.ipaustralia.gov.au/about/statistics.shtml> and WIPO *PCT Statistical Indicators Report*, http://www.wipo.int/ipstats/en/statistics/patents/pdf/yearly_report_2004.pdf

⁵⁸ David Mortimer *Going for Growth – business programs for investment, innovation and export* (1997) produced for the Department of Industry, Science and Tourism.

⁵⁹ http://backingaus.innovation.gov.au/pm_message.htm

Similarly, according to an Australian Research Council - CSIRO report on Australian patenting:

It is becoming increasingly clear that participation in the 'new economy' driven by science and technological advances will be the way to achieve global prosperity in the 21st century.⁶⁰

There is increasing pressure on public research organisations to commercialise their research and development, as noted in a recent Department of Education, Science and Training (DEST) report on the Australian science and innovation system:

...Across universities and government research organisations there has been increased attention over the past decade to managing IP issues to identify, protect and commercialise research results and to promote best practice. There are signs of an improvement in the rate of commercialisation since it became the focus of government policy but the scope to increase revenue flows remains considerable.⁶¹

There is also increasing appreciation of the importance of intellectual property rights in successful commercialisation of technology. For example, *Backing Australia's Ability 2001* states that:

A strong intellectual property protection regime...is central to building a strong national innovation system in Australia. It promotes research and development through helping to better capture returns from commercialising Australian ideas and products.⁶²

However, the DEST report noted that the costs and uncertainties in obtaining and enforcing patents were major reasons Australian businesses did not utilise patents more. A key finding of the report was that patenting reform was likely to be an ongoing issue, with the objective of maximising the amount of innovation without stifling research and competition. DEST analysis of Australian-invented patents issued in the US showed that, despite a 5% average annual growth, Australia's relative position has declined steadily from 8th to 10th over the last 20 years due to much higher growth by countries such as Korea, Singapore and Taiwan.

Patent thickets

Some observers⁶³ have expressed concerns that the current patent system and the increasing number of patents may have the potential of creating a "patent thicket", i.e. a dense web of overlapping intellectual property rights that a company must hack its way through in order to commercialise new technology. This situation has also been described as the "tragedy of the anti-commons", where an excess of property rights means that resources are under used because permission must be granted by multiple gatekeepers, thus stifling innovation.

⁶⁰ *Inventing our future. The link between Australian patenting and basic science*, Australian Research Council and Commonwealth Scientific and Industrial Research Organisation (2000), Summary and Conclusions.

⁶¹ *Mapping Australian science and innovation*, Department of Education, Science and Training (2003), executive summary, pg. 6.

⁶² <http://backingaus.innovation.gov.au/2001/commercial/ip2001.htm>

⁶³ For example, Carl Shapiro *Navigating the Patent Thicket*
<http://haas.berkeley.edu/~shapiro/thicket.pdf>

Although concerns have been expressed of this occurring in Australia, little empirical evidence is available. Some overseas evidence has been provided⁶⁴, however others have asserted that this falls far short of indicating that there has been any aggregate reduction in research⁶⁵. In a recent major review of the balance between competition and patent law and policy, the US Federal Trade Commission found there to be some evidence of thickets developing:

In some industries, such as computer hardware and software, firms can require access to dozens, hundreds, or even thousands of patents to produce just one commercial product. One industry representative from a computer hardware firm reported that more than “90,000 patents generally related to microprocessors are held by more than 10,000 parties.” Many of these patents overlap, with each patent blocking several others.... (A)s more and more patents issue on incremental inventions, firms seek more and more patents to have enough bargaining chips to obtain access to others’ overlapping patents. One panellist asserted that the time and money his software company spends on creating and filing these so-called defensive patents, which “have no...innovative value in and of themselves,” could have been better spent on developing new technologies.⁶⁶

Experimental use exemption

It appears that in Australia the industry convention has been to consider experimental use of patented inventions to be non-infringing activity. This may be changing however, with IP practices becoming more aggressive and increasing uncertainty over the boundaries of legitimate activity. The survey of Australian companies and research institutes conducted by ACIP in November 2003 revealed that:

- although most respondents believed that some experimental uses of patented inventions would be infringing acts, there was considerable diversity of opinion on which acts these were. Some thought that infringement only occurred when the patented invention was being used commercially;
- most researchers considered it important to be able to experimentally use others’ patented inventions. If no experimental uses were allowed, it was believed this would cause enormous disruption;
- prior to committing to a research plan, a significant proportion of researchers never conducted a search for patents that might impact on the research;
- most researchers had never stopped or modified a research project due to the possibility of infringement of a patent.

In their 2003 study of the Australian biotechnology industry⁶⁷, Nicole and Nielsen found that:

...(t)he data...indicates that research institutions are putting in place good strategies for managing their own patents. Furthermore, they are actively involved in transferring their technology to industry, both through collaborations and, to a lesser extent, through licensing. At the same time, however, licensing-in activity within the research sector is

⁶⁴ Jon Metz *Diagnostic Testing Fails the Test* Nature vol. 415 (2002) p. 577

⁶⁵ Lee Bendekgey and Diana Hamlet-Cox *Gene Patents and Innovation* Academic Medicine vol. 77 (Dec 2002) p.1373

⁶⁶ Federal trade Commission, *To promote innovation: the proper balance of competition and patent law and policy*, executive summary, pg. 6 (2003).

⁶⁷ *Patents and Medical Biotechnology: An empirical analysis of issues facing the Australian industry*, Centre for Law and Genetics, Occasional Paper No. 6 (2003), pg. 218-222.

relatively low. To a large extent, this was justified by research institution respondents on the basis that their research is exempt from patent infringement. Indeed, some respondents put forward the argument that that all research as such is exempt, whether it is conducted in research institutions or private sector.

However, the report notes that such arguments appear fallacious, as it would mean that research tool patents could never be enforced. Nicol and Nielsen concluded:

...at the present time there appears to be a general practice based research exemption operating in Australia, even though the law is not clear. Quite how long this situation will continue remains to be seen. ...There can be little doubt that patent holders have the right to enforce their patent rights against research institutions in some situations. Although there is little evidence of this occurring in practice, it appears that some patent holders are now prepared to take this step. In part this is justified by the increasing commercial focus and patent activity within research institutions.

Due to this increasingly commercial focus, some respondents considered that there are no such things as not-for-profit institutes and that universities should be treated little differently to other organisations. The report further found:

Because of these difficulties and uncertainties involved in drawing the line between basic and commercial research, a number of technology transfer personnel stated that ideally freedom to operate should be confirmed from the outset. There does seem to be a great deal of sense in this proposition. However, it has to be balanced against the high costs involved in undertaking patent searches and, where necessary, negotiating licences.

One case that has caused significant public controversy, and appears to be part of a broader shift towards more assertive use of patent rights in Australia, is that of Australian company Genetic Technologies Limited (GTG). GTG has been active in requiring that public and private research institutions both in Australia and around the world enter into licensing agreements to use its 'research tool' patents for methods of genetic analysis and genomic mapping using non-coding DNA.

The controversy has arisen over the validity of GTG's patents, the effect of such patents on further innovation and the company's negotiating methods. GTG offers non-commercial organisations a "nominal, one-off fee" for all non-commercial applications for the life of the patents. As of August 2005, six non-commercial licenses have been issued⁶⁸, one example being to the University of Sydney for AU\$1500. GTG has issued around 18 commercial licenses, a few of these to Australian companies, ranging in value from AU\$125,000 to AU\$7.5 million⁶⁹. In the US, large biotech company Applera Corporation is contesting the GTG patents in court. In New Zealand the Auckland District Health Board brought legal action against GTG, alleging groundless threats of infringement. Following mediation both parties agreed not to pursue further legal action and certain New Zealand research institutes paid a total of NZ\$ 450 000 for licences to use GTG's patents⁷⁰. No similar actions have been taken in Australia.

⁶⁸ www.gtg.com.au, August 2005.

⁶⁹ Rimmer, M "The freedom to tinker: patent law and experimental use", *Expert Opinion on Therapeutic Patents*, February 2005, Vol. 15(2), p 187.

⁷⁰ Genetic Technologies Limited *Quarterly Activities Report and Appendix 4C of the ASX Listing Rules for the quarter ended 30 June 2005*.

8.2 Submissions

Law

There was considerable uncertainty and difference of opinion about the current state of Australian law on an experimental use exemption. Some thought there was strong evidence based on previous case law, mainly from overseas:

Based on the above authorities, it is considered that in Australia *bonafide* experimental use of an invention should, in general, not constitute infringement. Some possible examples of what may be considered *bonafide* experiment use are the use of an invention to determine whether it works or whether it can be improved, the use of an invention to determine whether a proposed product or process would infringe the patent, and the use of an invention to further elucidate its properties. (IPTA, Issues25)

Many researchers assume that, while there is no explicit general experimental use exemption in Australian law, there is an implicit exemption that allows them to freely experiment with patented subject matter. For example:

Our understanding is based on the experimental use exemption being implicit in patent law ...the basis of the understanding is that the basic law derives from British law and that there is no precedent in Australia. This understanding makes it clear that exemption is required to test the validity of an invention and to make improvements to that invention. (Walter and Eliza Hall Institute of Medical Research, Issues5)

However, the majority of submissions thought the law to be uncertain and that this needed to be resolved. For example:

(We have) little understanding at this point...Edith Cowan University takes a cautious approach by ensuring existing third party patents are not experimented on thus eliminating potential IP infringements. (Edith Cowan University, Issues6)

And:

Despite a (widespread) assumption that the experimental use exception applies in Australia, the evidence that Australian law recognises research use as a defence is equivocal. (ACIPA, Issues18)

The IP Research Institute of Australia drew attention to the consequences of allowing the law to develop naturally:

...in Australia only a small number of patent infringement cases are filed each year. IPRIA's research on IP enforcement indicates that between 1998 and 2003, only 18 patent infringement cases were filed on average per year, and, even then, only 7 patent *judgements* were issued on average each year in that period. As a consequence it is likely to be some time before a decision is handed down that discusses the scope and content of the EUE (experimental use exemption), and even more time before a body of law arises regarding interpretation of the EUE. Thus, leaving the courts to determine the scope of the EUE may leave users of the patent system in a state of uncertainty for an indefinite, but possibly quite long, period of time. (IPRIA, Options18)

On the issue of preclinical and clinical trials, private sector researchers were certain that these were not exempt from patent infringement.

Practice

Most submissions provided declaratory, anecdotal or personal evidence on the practical effect of current Australian law. Most submissions stated that there was not currently a major issue in Australia, although the situation may change:

Despite working in one of the largest research organisations in Australia and having some familiarity with the work of some of the other major research universities, I am not aware of any empirical evidence that the current legislation adversely affects research and development. I acknowledge, however, that other may have a different view about what might be an adverse effect. (Kevin Croft University of Sydney, Issues29)

and

...widespread uncertainty exists about the existence at common law of such an exemption - and its scope if it does exist. While this uncertainty does not appear to be hampering Australia's research effort, if the Australian courts were to adopt the approach that has been applied in the United States, the impact on our public sector research institutions is likely to be significant. (Group of Eight Universities, Issues7)

However, one confidential submission stated that it was a significant issue for them. It would force them and others in the pharmaceutical industry to take certain manufacturing developments and clinical trial activity out of Australia and into other countries such as the US, where there are provisions allowing the experimental testing of generic drugs before the expiry of the patent.⁷¹

Based on their empirical study of the biotechnology industry, Nicol and Nielsen concluded:

...we believe that at present a practice-based research exemption operates in Australia, which may well be broader than any statutorily enacted exemption. Thus, at present, infringement action against non-commercial users of patented inventions is rarely, if ever, pursued. There is little or no evidence to suggest that the lack of an express exemption is discouraging innovation or significantly affecting the ability of non-commercial users to use patented inventions.

Nevertheless, the lack of express exemptions may encourage some patent holders to change their enforcement practices in the future. We are already seeing moves to enforce research tool patents against public sector research institutions involved in research that has commercial links. (Nicol/Nielsen, Issues17)

On the specific issues of a patent thicket or anti-commons, a number of university research and IP administrators stated that they were not aware of any evidence of any problem in their institutions to date. This was more generally confirmed by Nicol and Nielsen:

The preconditions for an anti-commons within a particular industry are essentially a proliferation of intellectual property rights over essential research inputs and high transaction costs that make exchanging these rights difficult... Despite these preconditions being present in the medical biotechnology industry, we could find little evidence at this stage of an anti-commons. (Nicol/Nielsen, Issues17)

This was backed up by the Department of Health & Ageing, who stated:

The evidence for the "patent thicket" or "anti-commons"...exists mainly in the US where the majority of biotechnology research and patenting is undertaken... (T)he relative lack of empirical evidence in Australia may have resulted from the misplaced assumption by many

⁷¹ See Part 9.1.1.

Australian scientists that the research is legally protected from patent infringement actions or that infringement action would not be taken (by patentees). (DHA, Issues40)

McBratney et al. referred to evidence indicating an absence of thickets overseas, but signs they may be emerging in Australia:

On this issue it is also useful to look at the outcome of a February 2004 meeting to discuss research into the “anti-commons” and restrictions on access to research tools and innovations, funded by the National Academy of Science in the United States. The Academy research appears to have been found that while some of the preconditions for a breakdown of downstream research were present (growing number of patents, many biotechnology firms and increase in university patenting, defensive patenting), the “vast majority of respondents (over 90%) say [that a breakdown] ‘never happens’.” The research did not indicate an anti-commons “tragedy” and the situation was “manageable”.

A 2002 OECD expert workshop that covered similar ground also concluded: “The responses elicited in the American survey were generally in line with those in the German study. There is in fact little evidence so far of breakdowns in negotiations over IP rights or evidence that biomedical research has slowed. Indeed...firms and research organisations in the United States reported ‘working solutions’ which allow them to continue to innovate relatively unimpeded. ...*It would appear that access to patented technology has rarely been blocked.*”

However, we also acknowledge that absence of evidence is not evidence of absence... Further, one cannot assume that the present lack of evidence is indicative of future trends. Our contributors, particularly those from IMBcom, believe it would take only a small number of significant infringement suits against researchers, which would be facilitated by the current ambiguity in the law, to see a significant degree of “shyness” in develop in the research community. In fact, these contributors note that they have observed “preliminary evidence for the germination of patent thickets.” They have also observed an increasing tendency by licensors, using tough bargaining tactics, to create high barriers for access to their technology... (A. McBratney et al, Issues30)

8.3 ACIP Considerations

ACIP considers that patent rights should not extend to acts of experimentation that aim to increase society’s body of knowledge and which do not unreasonably devalue patents. This is not clearly the case under current Australian law. ACIP believes that some uses of a patented invention would probably be allowed by the courts, but this would depend heavily on the circumstances in each case. If a mechanism were introduced to ensure that experimental use did not constitute infringement, it appears that this would be in sympathy with the objectives of the Patents Act.

Current practice in Australia appears to be that many researchers are largely unaware of patent laws or deliberately disregard them. Correspondingly, there appears to be a convention in Australian industry of not pursuing possible infringements for experimental purposes, although there are some examples of this changing.

Although there is some anecdotal evidence, there is no strong empirical evidence that the current situation is adversely affecting the balance between the incentives to innovate and the ability to use innovations for research and development. Patent “thickets” do not appear to be forming and affecting cumulative innovation. Laws should only be introduced when necessary, so without a clear market failure in the Australian research sector an obvious option is to allow case law to evolve naturally in this area according to practice rather than theory.

However, given the very small number of infringement actions in Australia, it would most likely take many years for a body of law to develop in this area. This would perpetuate current uncertainty and potentially increase inefficiency and lost opportunities due to the costs of what may be unnecessary compliance checking. The greatest need expressed in submissions was for Australian law to be clarified so that both patent owners and non-owners would have certainty regarding their activities. ACIP considers that there is a good chance of more assertive IP practices developing in Australia, exacerbating such inefficiencies. Also, case law focuses more on the case in hand than on the broader picture, and so carries the risk of developing law that does not take all the appropriate factors into account and is not in Australia's best interests. As experimental use and the extent of rights awarded is an important aspect of patent law, this would potentially be very damaging. For example, the law may develop in line with United States law and clarify that the category of non-infringing uses of a patented invention is narrow or virtually non-existent.

ACIP therefore considers that, if a provision can be drafted which prevents a damaging situation without introducing an even greater set of costs, then it should be introduced. Some have argued that experimental use should be part of a broader reform of patent law. This is beyond ACIP's brief, however it is noted that a review of the manner of manufacture requirement, a fundamental and closely related issue, is being considered by the government.

9 Overseas Law and Practice

9.1 Background

Rather than ‘re-invent the wheel’, it is sensible to learn from other jurisdictions and consider whether Australia should adopt current best practice, or at least harmonise its laws with others. Harmonisation of substantive patent laws reduces costs and uncertainty for patent owners and non-patent owners alike, and ensures that Australian companies are not at a disadvantage relative to their overseas competitors. However, despite having the TRIPS Agreement as a common base, the law on experimental use of patented inventions differs markedly around the world. As a recent OECD working paper emphasised in relation to experimental use:

...there are significant cross country differences in patent regimes, and many countries have experimented with various policy mechanisms, but there have been few attempts to systematise this experience and disseminate “best practices” across countries.⁷²

WIPO’s draft Substantive Patent Law Treaty does not cover exceptions to infringement, other than prior use⁷³. The OECD Committee for Scientific and Technological Policy is currently reviewing the situation across OECD countries, assessing the strengths and weaknesses of different approaches to facilitating research use of patented knowledge. The Committee’s final report will include policy recommendations and is to be produced by the end of 2006⁷⁴.

9.1.1 United States

In the US there is no statutory basis for allowing experimental use, however a limited defence does exist under case law. The origin of this defence is an opinion by Supreme Court Justice Story in *Whittemore v. Cutter (1813)* where he stated: “[I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”

However, the exception was said to be “truly narrow” by the Court of Appeals for the Federal Circuit (CAFC) in *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc (1984)* when it was held that the experimental use rule could not be construed so “as to allow a violation of the patent laws in the guise of ‘scientific inquiry,’ when that inquiry has definite, cognizable, and not insubstantial commercial purposes. The defence is also limited to ‘tests, demonstrations, and experiments’ not ‘in keeping with the legitimate business’ of the alleged infringer.”

This interpretation was confirmed in *Madey v Duke University (2002)* where the CAFC stated “[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged

⁷² *Patents and Innovation: Trends and Policy Challenges* DSTI/STP92003)27 13-Oct-2003 p. 22

⁷³ <http://www.wipo.int/patent/law/en/harmonization.htm>

⁷⁴ OECD Directorate for Science, Technology and Industry; Committee for Scientific and Technological Policy; *Research Use of Patented Knowledge*, 16 March 2005, DSTI/STP(2005)11.

infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative." One commentator has suggested that the cardinal mistake of recent US court decisions, including *Roche* and *Madey*, has been to interpret "philosophical" as its current meaning. It is argued that when the term was used in the nineteenth century by Justice Story it meant "scientific" and so included any experimentation on (but not with) the invention⁷⁵. In 2003 the US Supreme Court declined to review the CAFC *Madey* decision.

The *Madey* decision appears to have major implications for publicly funded organisations in the US, as many had previously believed themselves exempt from patent infringement. According to one commentator, "university researchers accustomed to standing on the shoulders of giants by studying patented technologies freely may now be forced to rent space on those shoulders instead."⁷⁶ However, some have argued that the *Madey* decision may be able to be distinguished on factual grounds⁷⁷.

There has been much controversy in the US over the decision, with issues such as those outlined in this report being extensively debated⁷⁸. Various proposals to reform US law regarding experimental use have been made over the years, however none have gained traction.⁷⁹ In recent years it has been a hallmark of US policy that strong, broad patent rights are believed to provide the optimum climate for innovation and economic growth. However, it appears that a correction of sorts may be occurring.⁸⁰ The Federal Trade Commission's 2003 report on competition and patent law recommended:

- the introduction of a post-grant review and opposition process;
- the standard of proof required to invalidate a patent be lowered;
- obviousness standards be tightened and examination quality improved;
- more caution in extending the scope of patentable subject matter;
- more policy-oriented interpretation of patent law;
- increased communication between patent institutions and antitrust agencies, and more questioning of patents that raise competition concerns.⁸¹

⁷⁵ Harold C Wegner *The Post-Madey Research Exemption* (2003)
http://www.foley.com/files/tbl_s31Publications/FileUpload137/1588/post-madley%20whitepaper.pdf.

⁷⁶ Tom Saunders *Renting Space on the Shoulders of Giants: Madey and the Future of the Experimental Use Doctrine* 113 *Yale Law Journal* (2003).

⁷⁷ Mark Janis *Experimental use and the shape of patent rights for innovation, economics of innovation and science policy*, Department of Economics, Iowa State University (2003).

⁷⁸ See for example, Congressional Research Service Report for Congress, *Scientific Research and the Experimental Use Privilege in Patent Law*, 28 October 2004, p 9-10.

⁷⁹ A recent example is the Genetic Research and Diagnostic Accessibility Bill 2002 (HR 3967), which would have exempted the use of patented genetic sequence information for non-commercial research purposes.

⁸⁰ See for example, Adam B. Jaffe and Josh Lerner, *Innovation and its discontents – how our broken patent system is endangering innovation and progress, and what to do about it*, Princeton University Press (2004).

⁸¹ Federal Trade Commission, *To promote innovation: the proper balance of competition and patent law and policy*, (2003), Executive Summary.

Similarly, in relation to experimental use, the Commission said:

The Federal Circuit's ruling in *Madey v Duke University* has a potential to upset the equilibrium regarding research uses of patented inventions and may heighten any problems raised by uncertainty over the reach of the experimental use defense. This warrants continued attention as the implications of these recent developments in the law become better understood.⁸²

9.1.2 Europe

In the early 1970s there began moves to introduce a unitary patent for all European Union countries called the Community Patent. The Community Patent Convention 1975 (CPC) contained the following provision for experimental use:

The rights conferred by a Community Patent shall not extend to acts done for experimental purposes relating to the subject matter of the invention.

The Community Patent continues to be debated today and is unlikely to be implemented in the near future. However, the wording of the experimental use exemption is unchanged in the current draft⁸³, and most European countries have introduced a statutory exemption using identical or very similar wording. Interestingly, this wording has been interpreted in significantly different ways in different jurisdictions, and even by courts within the same jurisdiction. Other fields of technology don't appear to cause such problems, as long as experiments are directed towards better understanding the content of a patent, or towards further research with regards to the invention⁸⁴.

There is also significant variation between European countries regarding regulatory review exceptions. In the interests of harmonisation, the EU has issued a new directive which would enable generic manufacturers to begin the approval process eight years after the first marketing authorisation⁸⁵.

United Kingdom

Section 60(5) of the *Patents Act 1977* provides that:

An act which apart from this sub-section, would constitute an infringement of a patent for an invention shall not do so if -

- (a) it is done privately and for purposes which are not commercial
- (b) it is done for experimental purposes relating to the subject matter of the invention.

⁸² Federal Trade Commission, *To promote innovation: the proper balance of competition and patent law and policy* (2003), Chapter 4 pg.37.

⁸³ Article 27(b).

⁸⁴ Heinz Goddar *The Experimental Use Exception: A European Perspective*, Centre for Advanced Study and Research on Intellectual Property, Symposium Publication Series Number 7, July 2002. www.law.washington.edu/casrip/Symposium/Number7/1-Goddar.pdf

⁸⁵ Directive 2004/27/EC, 31 March 2005.

Fysh⁸⁶ (a Judge of the UK Patents County Court) states that there have been few decided cases in which subsections (a) and (b) have been directly at issue but these tend to interpret them quite narrowly. If the purpose *at the time in question* is mixed, being both private and commercial, the exception does not arise: *SK&F v Evans*⁸⁷ and *McDonald v Graham*⁸⁸.

The UK courts have provided some guidance on what is meant by "experiment/experimental". In *Monsanto*⁸⁹ the Court of Appeal imposed a limitation according to size, scale, recipient and methodology of the experiment but also according to whether it seeks to generate genuinely new information or if it merely seeks to verify existing knowledge. Dillon LJ stated:

"Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something is known to work in specific conditions, e.g. of soil or weather, will work in different conditions can fairly, in my judgement, be regarded as experiments. But trials carried out in order to demonstrate to a third party, whether to a customer or to a body such as the PSPS (Pesticides Safety Precautionary Scheme) or ACAS (Agricultural Chemical Advisory Scheme), that the product works as its maker claims are not, in my judgement, to be regarded as acts done 'for experimental purposes'."

The same court in *SK&F v Evans*⁹⁰ also interpreted the phrase "relating to the subject matter of the invention" narrowly to mean "in the sense of having a real and direct connection with that subject matter".

A recent study of the UK biotechnology industry and public research sector for the Department of Trade and Industry⁹¹ states "there is evident uncertainty...about the extent of the patent research exemption, which is widely seen as problematic". The study concludes that more investigation of the problem is needed in the UK.

Germany

Section 11.2 of the *German Patent Act 1981* closely follows the CPC provision:

The effect of the patent shall not extend to acts done for experimental purposes which are related to the subject matter of the patented invention.

The experimental use exception was considered in two cases that related to testing a patented product for new uses and properties. The result is that Germany has a liberal approach to clinical trials when compared with other jurisdictions.

In Clinical Trials I the patent was for interferon-gamma as a polypeptide of defined amino acid sequence obtained by genetic engineering. The alleged infringements consisted of clinical trials on the active substance of interferon-gamma for the purpose

⁸⁶ Michael Fysh QC, *SC Legal Issues in Exploiting Drug Patents in Europe* LES-Italy Conference, Milan, 2002.

⁸⁷ *SK&F v Evans* [1989] FSR 513.

⁸⁸ *McDonald v Graham* [1994] RPC 515 (CA).

⁸⁹ *Monsanto v Stauffer* [1985] RPC 15 (CA).

⁹⁰ *SK&F v Evans* [1989] FSR 513.

⁹¹ Intellectual Property Institute *Patents for genetic sequences: the competitiveness of current UK law* (2004) p.6.

of finding further indications. The Court of Appeals held that the defendants were infringing the patent because they had not carried out experiments on the substance itself, such as to determine whether it actually has the properties of the active substance interferon-gamma. Because the intention of the clinical trials was to establish the administration form and dosage with which interferon-gamma was able to alleviate certain diseases, they did not relate to the nature of the active substance protected in the claims. Instead they related to the *uses* of subject-matter of the invention, and the patent owner has the rights to all possible uses of the product, “irrespective of whether the inventor has already recognized the individual possibilities”.

However, the Federal Supreme Court found that such clinical trials were within the scope of the exception. “The subject-matter of the patented invention” was interpreted to mean the claimed technical teaching, which also includes the *use* of the inventive substance:

Viewed from this starting point, the wording of the Act when examined naturally rather indicates that s.11.2...in principle exempts all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use. There are then included, for example, utilization acts for experimental purposes undertaken with the subject-matter of the invention in order to discover the effects of a substance or possible new uses hitherto unknown. Since the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.⁹²

In *Clinical Trials II* the Supreme Court reaffirmed that the exemption should be granted regardless of any additional motivations or commercial purposes. The court supported this approach using the Community Patent Convention:

According to the memorandum of the agreement Article 31 allows the invention protected by the Community patent to be used for experimental purposes “for example, to test its usability and possibility of further development”. These examples contain commercial-oriented goals. They make it clear that the purpose that the experiment is intended to service does not at all have to be of a purely scientific nature. According to this, the commercial orientation does not from the outset turn the experimental activity into an impermissible patent infringement.⁹³

This approach appears to be firmly set and potentially influential, as outlined by Rimmer:

In May 2000, the German Constitutional Court affirmed that the decision in *Klinische Versuche I*...was in full conformity with the right of property under Article 14, Section 1 of the German Constitution. As a result...manufacturers of generic drugs can now enter the market significantly earlier, as they can start clinical trials already during patent life of a patented drug...

(These decisions) provide a strong theoretical framework in which to understand the defense of experimental use. The judges emphasise that the research exemption is consistent with the larger objectives of patent law...

⁹² *Klinische Versuche (Clinical Trials) I* (1997) RPC 623, Federal Supreme Court of Germany.

⁹³ *Klinische Versuche (Clinical Trials) II* (1998) RPC 423, Federal Supreme Court of Germany.

William Cornish observes: ‘Given the forcefulness of the judgements from the German Supreme Court in *Klinische Versuche I and II*, there must be a strong likelihood that their outcome will be followed in courts elsewhere in the EC’.⁹⁴

9.1.3 Japan

Under Japanese Patent law, Section 69.1 provides that:

Patent rights shall not extend to exploitation of a patented invention for the purpose of experiment or study.

This provision was first introduced in 1909 while Japan was still a developing country and reverse engineering was needed in all fields of technology. The experimental use exception was recognized explicitly so that people could develop new technology.

A 1987 change to the Japanese Patent Act to allow for pharmaceutical extensions did not also explicitly allow for exemption of testing of generic drugs for regulatory approval, even under their Biological Equivalence Test. After conflicting positions by the lower courts, the Japanese Supreme Court ruled in 1999 that such testing fell with the experimental use exemption of s.69.1.

9.1.4 Canada

Although there is no statutory basis for an experimental use exemption in Canada, one does exist under common law. The origin of this is a 1971 Supreme Court decision regarding research aimed at obtaining a compulsory licence:

The use Micro was making of the patented substance here was not for profit but to establish the fact that it could manufacture a quality product in accordance with the specifications... (the) experiments were not carried out for the purpose of improving the process but to enable Micro to produce it commercially as soon as the licence it had applied for could be obtained. I cannot see that this sort of experimentation and preparation is an infringement. It appears to me the logical result of the right to apply for a compulsory licence.⁹⁵

However, in 2002 the Canadian Biotechnology Advisory Committee (CBAC) found the experimental use exemption to be “vague” and said that “Later cases do little to amplify the meaning of the exception”⁹⁶. Since the Supreme Court decision, Canada has eliminated its compulsory licensing provisions, thus putting into question the scope and nature of the research exception in Canada. CBAC recently provided an Advisory Memorandum to the government on biotechnology and patent law⁹⁷. One of the recommendations was that the law should be clarified:

We recommend that the *Patent Act* be amended to include a research and experimental use exception that includes the following statement:

⁹⁴ Rimmer, M “The freedom to tinker: patent law and experimental use”, *Expert Opinion on Therapeutic Patents*, February 2005, Vol. 15(2), p 184.

⁹⁵ *Micro Chemicals Ltd v Smith Kline & French Inter-American Corporation* (1971) 25 DLR (3d) 79.

⁹⁶ Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (2002).

⁹⁷ Canadian Biotechnology Advisory Committee, *Rationalizing Patent Law in the Age of Biotechnology*, Advisory Memorandum (September 2004).

It is not an infringement of a patent to use a patented process or product either:

- (a) privately and for non-commercial purposes, or
- (b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.

A further report on a research exception is expected to be publicly released in late 2005.

9.1.5 New Zealand

The New Zealand Patents Act 1953 does not specifically exclude experimental use from patent infringement. However, the New Zealand courts have adopted such an exemption and have affirmed that there is a distinction between research of an experimental nature and research with a commercial advantage in mind. In the Court of Appeal in the 1991 case *Smith Kline & French Laboratories Ltd v Attorney-General* where Hardie Boys J stated:

Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself, and does no more than further his own knowledge or skill, even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention or makes it available to others, in a way that serves to advance in the actual market place, then he infringes...

At the end of 2002, the New Zealand Government introduced an amendment to the Patents Act 1953 introducing an exemption from patent infringement where third parties “make, use, exercise, or vend” a patented invention for purposes reasonably related to the development and submission of information required to be submitted to government agencies in order to gain regulatory approval to manufacture, construct, use or sell a product.

9.1.6 Regulatory Review Exceptions

Many countries either currently provide or will provide in the near future some form of exception from infringement for activities relating to obtaining regulatory approval in order to enable generic pharmaceuticals to enter the market immediately after the patent term expires. In some countries the exception also permits development and manufacture for export to jurisdictions where there is no patent protection. Whereas the Australian regulatory review exception is only available during the extended patent term, in many other countries such exceptions are available throughout the entire period of patent protection (ie. during the initial 20 year patent term as well as any extension period).

In the US, the Hatch-Waxman Act⁹⁸ provides an exception from infringement throughout the patent term for the making, using and selling of “a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulated the manufacture, use or sale of drugs or veterinary biological products”⁹⁹ To date, whether an activity is “reasonably related” to seeking government approval has been narrowly interpreted. However, the

⁹⁸ *Drug Price Competition and Patent Term Restoration Act 1984.*

⁹⁹ 35 USC s.271(e)(1).

Supreme Court recently found that the use of patented compounds in preclinical studies is protected at least as long as there is a reasonable basis to believe that the compound tested *could be* the subject of an Food and Drug Administration submission and the experiments will produce the types of information relevant to such a submission¹⁰⁰. This case has been returned to the lower court for the evidence to be reviewed according to the appropriate standard, and so the exact scope of the exception remains uncertain.

Canada and New Zealand have broad exceptions that are not restricted to drugs and that are available throughout the patent term¹⁰¹. Neither country provides an extension of term for pharmaceuticals. In Europe, by 30 October 2005 members of the European Union are obliged to introduce an exception from infringement for trials necessary for obtaining approval for generic medicinal products.¹⁰²

9.2 Submissions

Many submissions thought that the US situation post-*Madey* was too narrow and that the "commercial" purpose test was a major problem:

The trouble with 'commercial' purpose or outcome being used as the boundary of experimental use is that it is excepted (sic) that it is usually possible to find a 'commercial' element in any testing of any third party. For this reason, the (LCA) committee is inclined not to promote the 'commercial intent' as the boundary. (LCA, Issues1)

However, some submissions supported a commercial test as used in the NZ *Smith Kline* case:

...in my opinion Hardie Boys J has actually achieved a clear benchmark in *Smith Kline* by stating "But if he goes beyond that, and uses the invention or makes it available to others in a way that serves to advance in the actual marketplace, then he infringes." Rather than trying to ascertain whether a researcher is conducting experiments for commercial purposes, it would seem more prudent to consider whether the "infringing act" affects the commercial interests of the patentee, as for the patentee, this is the heart of the issue. (David Whiley, Issues39).

The European Union statute approach was supported by a number of submissions. For example:

The approach taken in the EU is reasonable in that it provides for an express legislative provision covering experimental use. Furthermore, it recognizes that development of the state of the art and the public interest is a paramount consideration in exempting research from infringement. In particular, the distinction based upon whether the research is on the invention itself (how it operates, if it works and to build upon it) as opposed to using the invention for the purpose for which it was made is a good one and avoids having to determine the issue of whether it is basic research or commercial research. (University of Adelaide, Issues34)

Many saw this as also benefiting the patent holder:

If a company owns patent rights, anyone working on the patent device experimentally can potentially broaden the market. When and if the new items become commercialised the

¹⁰⁰ *Merck KGaA v. Integra Lifesciences I, Ltd.* (03-1237) 331 F.3d 860, 13 June 2005.

¹⁰¹ S.55.2(1) and s.68B respectively.

¹⁰² European Union Directive No.2004/27/EC, Article 10.6.

patent owner still gets benefit and, no doubt, a share of new invention that must utilise the original work patented. (C. Cole, Issues22)

On the other hand, some saw problems with the European, particularly German, approach:

[T]he German Court had (problems) in reaching its conclusion....that a use testing a patented compound for new uses was an experimental use of the patented invention.... It resolved the difficulty in concluding that where the invention was a new compound research into "the invention" could include any use of it since all such uses fell within the claim. (John Richards Ladas & Parry, Issues14)

McBratney et al. were also concerned with the interpretation of the European concept "subject matter of the invention" by the German Federal Supreme Court in the Clinical Trials I case:

There are some real difficulties with the Supreme Court's analysis. The most glaring is that the court elides the nature of the invention with the nature of the patent rights in the invention... The Supreme Court says it would be wrong to treat a product and its use as *two separate subject-matters*, but in fact there is only ever one subject matter (the product) and its accompanying right (use). The Court says that the subject matter (product) *includes* use (right). With respect, this incorrectly conflates the issue of subject matter of the invention with the exclusive rights attaching to the invention. Using this expanded definition of "subject matter", the court is then able to conclude that experiments to find a new use were in fact experiments on the subject matter of the product invention...

We submit that the analysis applied by the Appeal Court is correct, and that it is clearer, simpler and more sound than that of the Supreme Court. (A. McBratney et al, Options3)

One submission, while favouring the UK approach, believed it also had some limitations:

In our view the UK legislative approach provides some assistance. We are of the view that there are two distinct limbs to the statutory exemption in the UK legislation, one for private, non-commercial use of the invention, the other for experimental purposes relating to the subject matter of the invention, and that these limbs are not conjoined...

With regard to the non-commercial use component, we believe that the UK approach may be too narrow. The provision in s60(5)(a) of the UK legislation refers to *private* non-commercial use... We submit that the justification for the non-commercial use component of the proposed exemption is its *public* nature both from the perspective of the purpose of the use (for the benefit of the public) and from the perspective of disclosure (disclosing to the public rather than keeping secret or confidential). The justification for the exemption is that it would encourage publicly funded non-commercial research, the results of which should be freely released into the public domain, in accordance with Mertonian norms. (Nicol/Nielsen, Issues17)

One submission to the review argued that Australia should follow some other countries in exempting clinical trials of patented inventions:

Generally speaking, large pharmaceutical companies can take advantage of the differing "experimental use" laws in each jurisdiction around the world by setting up laboratories and clinical trials in jurisdictions that allow them an "experimental use" exemption. Needless to say, smaller pharmaceutical companies, like Acrux and many other(s)...do not have the capability to utilise such opportunities and would thus be prejudiced in a global market if patent laws pertaining to experimental use were construed too narrowly. (Acrux Limited, Options1)

A similar point of view was made regarding regulatory review exceptions. For example:

For its part, Nufarm undertakes a significant amount of its research and development activities in Australia. However, due to restrictions on the importation and use of materials subject to patent in Australia, Nufarm is forced to undertake many research projects in India and New Zealand – countries that permit the use of patented materials for the purposes of generating information for regulatory approval. (Nufarm Limited, Issues10)

9.3 ACIP Considerations

There are persuasive reasons for adopting a solution identical or similar to one that already exists in other jurisdictions, however ACIP's first priority is for a solution that is in Australia's best interests.

ACIP considers that the current US approach is best avoided, as this reduces allowable experimental activity to a narrow set of circumstances that does not appear to be in accord with the fundamental principles of the patent system. The European approach has more potential, although the fact that it has been interpreted differently in different jurisdictions must be acknowledged.

In their current form, none of the overseas solutions are clearly the best option for Australia and so other options must be considered.

In regards to regulatory review exceptions, ACIP's deliberations on an experimental use provision have been directed to the issue of experimentation generally. ACIP recognises that while some regulatory review activities may be done for experimental purposes, others may not. Therefore, whilst there is some overlap between the issue of an experimental use exception and the issue of a regulatory review exception, ACIP's report is concerned with the former not the latter. It appears that the domestic and international competitiveness of some Australian enterprises is being compromised under current law, however others may be benefiting through licensing their patents. ACIP considers that the issue of regulatory review may warrant separate consideration.

10 Mechanisms Available

There are many possible combinations of mechanisms, concepts and wording that could be used to formulate a provision allowing experimentation. This section discusses those options outlined in the ACIP Options Paper, with some minor variations.

Generic pros and cons

In addition to the specific pros and cons briefly considered under each option, there also exist some generic positive and negative matters that are common to all options:

- 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, 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 not meet international treaty obligations.
- all options result in the Australian laws regarding experimental use differing from foreign laws to some extent. While this allows for a solution to be tailored to best suit Australia's own industrial landscape and interests, on the other hand it could also introduce costs for users in dealing with differing systems, and, in spirit, may run counter to the general movement towards international harmonisation of intellectual property laws.
- any legislative change to the status quo inevitably involves costs - in the processes of enacting and interpreting legislation and in stakeholders having to learn about the change and alter their behaviour if necessary.

10.1 Pre-grant mechanisms

Pre-grant criteria are those that must be satisfied in order for a patent to be granted, and include patentable subject matter, novelty, inventiveness, utility and fair basis. Pre-grant conditions were considered at length recently by the ACIP working party on Patent Enforcement and by the Intellectual Property & Competition Review. On the basis of these reviews, the government strengthened the pre-grant criteria and standards of proof required to bring them into line with international best practice.

In addition, the IPCR Review Committee recommended that the existing flexible definition of patentable subject matter ('manner of manufacture' and associated case law) and that technological neutrality be retained in the patent system. The ALRC has since recommended that the manner of manufacture criterion be reviewed and that the usefulness criteria be made explicit.

ACIP considered the following pre-grant option:

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

The Patents Act be amended so that, in order for a patent to be granted, patent claims must not merely be read in light of the specification, but must be restricted in scope to the utility of the invention disclosed in the specification (e.g. through a stricter interpretation of fair basis or the definition of “invention”). The scope of the claim would be determined using a purposive construction by a person skilled in the art (Catnic; Kirin-Amgen¹⁰³).

This option is based on the reasoning that the extent of patent rights awarded should be commensurate with the practical benefit provided to society. Purely experimental use is by definition not a practical use, and would therefore not be within the scope of patent claims. Although it provides a very principled approach, this option may not be compliant with the TRIPS Agreement on the issue of making patents available for products per se, and the consequences extend beyond experimental uses to other uses.

Submissions

Many submissions felt the pre-grant conditions for patents were sufficiently strong after the recent changes, for example:

It is our view that the current provisions of the Patent Act 1990 as recently amended are appropriate. This is subject to the laws being rigorously applied during examination by IP Australia. (IPTA, Issues25)

Most submissions to ACIP considered Option D1 to be too far-reaching and complex to be viable, or unfairly prejudicial to patent owners. For example:

In our view the ACIP review into experimental use is not the place for a consideration of the issues underpinning this Option, and a far more extensive enquiry would be required before introducing statutory amendment to alter the scope of patent claims. We do not consider that the concept of ‘restricting the scope of a patent claim to the utility disclosed in the specification’ is as simple as the articulation of that concept in this Option (Freehills, Option13).

Others believed that there was still a need for criteria such as utility, sufficiency and fair basis to be reformed. Some emphasised the particular problems relating to genetic technologies, and supported the ALRC recommendations regarding manner of manufacture and usefulness:

Health sees the revision of pre-grant conditions...as a primary concern. Provision of an experimental use provision would be an important supplement...but not a substitute or alternative... The uniqueness of genetic materials may enable existing patent holders to limit the capacity and incentive of researchers to "invent around" patented inventions related to genetic materials. (DHA, Issues40)

Some believed Option D1 could help address this:

103 House of Lords *Kirin-Amgen and others v. Hoechst Marion Roussel Limited and others* (21 October 2004)

<http://www.parliament.the-stationery-office.co.uk/pa/ld200304/ldjudgmt/jd041021/kirin-2.htm>

DEST see potential for a modified form of (Option D1) being used to address this issue of demonstrable utility, whilst simultaneously providing the courts with the means to determine fair experimental use (DEST, Options10).

Others argued that its far-reaching consequences would be justified:

The scale of the change to the law required to implement Option D1 may not be as significant as ACIP implies. In particular, the proposed amendment arguably represents a more coherent and principled interpretation of the EXISTING doctrine of fair basis and/or the concept of an invention... Option D1 would clearly affect the interests of product patentees to a significant extent, however...the changes arguably do not affect the LEGITIMATE interests of product patentees (S. Elkman, Options31).

ACIP Considerations

Although ACIP is attracted to the principled approach of this option, the large scale of the change to patent law, the resulting difference between Australian law and that of most other countries and the potential breaching of Article 27.1 of the TRIPS Agreement present major obstacles.

10.2 Definition of exploit

C1. Modify the definition of exploitation so that it does not include experimental use.

The Patents Act definition of exploitation of a patented invention be amended to not include experimental use, such as through adding the phrase “other than experimental uses” or “other than for experimental purposes”. No further guidance on the meaning of this term is provided.

A patent provides the owner with the exclusive rights to ‘exploit’ the invention, therefore one of the simplest ways of limiting these rights would be to modify the definition of exploit. This would only involve modifying an existing provision in the Act and make it clear that there is an inherent limit on the scope of patent rights.

Submissions

Some submissions believed that this was an area that should not be tampered with:

...in our view, the definition of "exploit" under the Patents Act is most likely broad enough to encompass experimental use. (However) we feel it should be done by providing an exemption to infringement, rather than complicating the already complex meaning of "exploit". (Mayne Pharma, Issues12)

Most submissions believed that this option would provide insufficient clarity for those in the industry and was not a significant improvement on the current situation. For example:

...the question would still remain as to what constituted “experimental use”, particularly when considering any commercial orientation... thus providing little clarity on the matter in at least the short to medium term (Acrux Limited, Options1).

Also:

...without further guidance on the scope of this inherent limitation, we submit that the impact of such a legislative amendment would have an unknown and unquantifiable

effect on calculated risk-taking, promotion of innovation, an economic growth... Leaving disputants to the adversarial and often costly court system...provides little relief to patentees or researchers where transaction costs are almost certain to increase (A. McBratney et al,Options3).

However, some did favour this option:

This seems the simplest and best way forward. It does not try to be over-precise, inventive or prescriptive, but critically reinforces the notion that there are limits to a patentee's exclusive rights (M. Cuthbertson, Options22).

ACIP Considerations

The major advantages of this option are that it requires minimal changes to the law, it clarifies that patent rights are inherently limited and the law is allowed to evolve according to real world circumstances. However, ACIP considers that such evolution would be slow and users of the system would have too little guidance and courts too much flexibility, which may result in law which breaches the TRIPS Agreement and does not optimise overall levels of innovation.

10.3 Exemptions

Rather than place an inherent limit on the extent of patent rights, another option is to provide an explicit exemption from infringement for particular acts, as used in Europe and as proposed in Canada.

10.3.1 General exemption with specific examples/guidelines

C2. General exemption with specific examples and/or guidelines

The Patents Act be amended to establish a general exemption for experimental use, with specific non-binding examples and/or guidelines of exempted acts provided in the Patents Regulations as guidance to users and the courts.¹⁰⁴

The examples or guidelines would be technology specific, developed in cooperation with experts in key technologies, and would be updated regularly to ensure currency.

This would avoid the problems with defining those experimental uses that should be exempt and provides the courts with significant flexibility, yet provides guidance in difficult technology areas. If the examples appear to be inconsistent with the first interpretation of the provision, then the interpretation may be reconsidered in case relevant material has been overlooked. However, one possible disadvantage is that the formulation and maintenance of the examples/guidelines may be a difficult task.

¹⁰⁴ A good model may be Reg 40-5.09 of *A New Tax System (Goods and Services Tax) Regulations 1999*.

Submissions

Although this option received some support from the Department of Health and Ageing due to its ability to provide an increased level of certainty in difficult fields such as biotechnology, the majority of submissions were not in favour of it.

ACIP Considerations

The use of examples or guidelines in specific technologies has the potential to greatly aid the courts. However, ACIP considers that formulating and maintaining appropriate, widely agreed guidelines containing the correct balance of detail would be a very difficult task. Those technologies for which guidelines are not available would remain areas of great uncertainty, and there remains the potential for breaches of international obligations.

10.3.2 Experimenting “on” the subject matter of the invention

C3. Exemption for experimenting “on the subject matter of the invention”

The Patents Act be amended to establish an exemption from acts that experiment ‘on’ the subject matter of a patented invention, for example, to investigate its properties or improve upon it. The exemption is only available if experimentation is the sole or dominant purpose of the act.

This option is very similar to that recommended by the ALRC and uses the distinction between experimenting *on* the invention itself as opposed to experimenting *with* the invention for its intended purpose. This leads courts away from exempting the normal use of research tools and is partially in harmony with European laws. However, the major disadvantage is that experimentation ‘on’ and ‘with’ an invention are often intertwined and not easily separated, particularly for claims to products per se.

Submissions

Several submissions preferred such an approach over words such as “related to”:

...we believe such an experimental use exemption could be drafted in a way which draws a clear distinction between an experiment conducted on the subject matter of an invention (e.g. for the purpose of finding out something unknown about the invention or testing an hypothesis relating to the invention) and an experiment conducted with or using an invention (e.g.. an experiment demonstrating the effectiveness of the invention to a third party or an experiment which uses the invention for its known purpose (IPTA, Issues25).

The Department of Health and Ageing stated:

There are both in-principle and practical reasons for adopting this approach. However, it should also be noted that there are also practical problems in some fields of technology in making this distinction...including biotechnology, with its tendency towards broad patents...Research using knowledge of the structure of a gene, directed towards identifying treatment for disease associated with abnormal forms of the gene, may be regarded as research *with* the gene. Research intended to identify variation within the gene may be regarded as research *on* the invention. However, clinical diagnostic testing, which can be regarded as technology subject to commercial application, could in principle be thought of as research *on* the invention. This is in the sense that it is research directed towards identifying the exact structure or properties of the "invention" in the specific individual

being tested. The distinction between research genetic testing and clinical diagnosis is also clouded by the fact that, although the objectives may differ, the processes generally remain identical. This problem seems inherent in the patenting of "inventions" which are also a form of discovery. (DHA, Issues30)

Those who favoured such an approach preferred Option C8 over Option C3 due to the further assistance it provides to courts on the meaning of the on/with distinction.

ACIP Considerations

Although sound in theory, applying the on/with distinction would be difficult in areas such as biotechnology, where claims to products per se are common. If the uses of an invention are not defined by the claims, it would be difficult to determine whether an act is experimenting "on" or "with" it. Therefore, ACIP considers that the on/with distinction at least requires further explanation to be viable, such as in Option C8.

10.3.3 "Fair" experimentation - copyright analogy

The fundamental goal of most types of intellectual property is much the same - to encourage creativity and innovation by allowing creators to capture the fruits of their efforts without other's free-riding. The Australian *Copyright Act 1968* provides that certain copying does not infringe the rights of copyright owners, thus accommodating the public interest in the dissemination and use of information. The Act allows four "fair dealing" purposes:

- research or study¹⁰⁵;
- criticism or review¹⁰⁶;
- reporting of news¹⁰⁷, and
- professional advice given by a legal practitioner or patent attorney¹⁰⁸.

The most commonly used aspect of fair dealing is that for research and study. Fair dealing for research and study is determined by a set of non-exclusive factors, which are to be taken into account in determining whether a dealing is fair. For example, the following will be considered to determine whether a dealing is fair for the purposes of research and study:

- the purpose and character of the dealing;
- the nature of the work or adaptation;
- the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;
- the effect of the dealing upon the potential market for, or value of, the work or adaptation; and
- in a case where only part of the work or adaptation is copied—the amount and substantiality the part copied taken in relation to the whole work or adaptation¹⁰⁹.

¹⁰⁵ Ss.40 and 103C.

¹⁰⁶ Ss.41 and 103A.

¹⁰⁷ Ss.42 and 103B.

¹⁰⁸ S.43(2).

Similar provisions exist in the US under the concept of "fair use". O'Rourke¹¹⁰ has argued that the traditional assumption that patentees will efficiently license their inventions is breaking down. She states that for patent law to achieve its constitutional goal of encouraging invention it should, like copyright law, use a fair use defence to address problems of market failure.

ACIP considered the following option:

C4. Exemption for fair experimentation - copyright fair dealing analogy

The Patents Act be amended to establish an exemption for acts that constitute fair experimentation relating to an invention. In determining whether an act is fair experimentation, the following must be considered:

- the purpose and character of the experimentation;
- the subject matter of the invention;
- the availability of the invention in the marketplace;
- the commercial effect of the experimentation upon the patent holder.

In this option courts are provided with significant flexibility but are guided on which issues are relevant to the decision, resulting in less reliance on interpretation of specific words.

Submissions

Many submissions, particularly from researchers, thought that there were lessons both in principle and in practice to be learnt for an experimental use exemption from fair dealing/use in copyright law. For example:

I believe that the USA decision in the Sony v Universal City Studios (1984) with respect to "fair dealing" captured the essence of what needs to be considered in patent law that is "The fair dealing doctrine is a means of balancing the exclusive rights of the copyright (patent) holder with public interest and the dissemination and use of information". This should be considered in the patent process and on deciding "experimental use". (Soozy Smith University of Newcastle, Issues21)

Also:

It seems very difficult to draw a clear line between what is "fair" to the patentee and what is in the best interests of society... It seems therefore that the only viable approach is likely to be to give the trier of the facts...guidelines that should be followed to make such a determination... Three of the criteria used for judging fair use in copyright cases in the United States may provide a useful starting point for setting out such guidelines (John Richards of Ladas & Parry, Issues14).

Option C4 received some support, however most of those who favoured such an approach preferred Option C7 due to the further guidance it provides to courts. IPTA criticised the concept of fair experimentation because it would lead to lack of clarity and certainty:

¹⁰⁹ S.40(2).

¹¹⁰ Maureen O'Rourke *Toward a Doctrine in Patent Law* Columbia Law Review 100 (2000) p. 1177

Whilst in theory this approach does have some attraction it is submitted for the reasons given above that in practice an approach of this type would lead to uncertainty because of the complex analysis required to determine what constitutes experimental use. (IPTA, Issues25).

Others thought that the analogy could not be pushed very far:

Conceptually, there is linkage between the two forms of exemption. Both are necessary to properly maintain the balance between owners and users of intellectual property. However, this is probably where the analogy ends. It is difficult to see how the fair dealing/use provisions could be directly translated into patent law because there are fundamental differences between the copyright system and the patent system. One way of looking at the distinction between copyright and patent is to compare how copyright material and patented inventions are used. When copyright material is used for research and study it is used to *assist in* the research or study. On the other hand, patented inventions are more likely to be *part of* the research or study. (Nicol/Nielson, Issues17)

Similarly:

In contrast to copyright, the nature of patent protection is far stronger... Commensurate with the strength of patent protection, it is also far more difficult to obtain... also commensurate with the strength of the right, patent protection is significantly shorter than copyright protection... A further difficulty with infringement in relation to patent rights is the potential impact that any enforcement action may have on the patent itself... According to anecdotal evidence, in Australia around 60-80% of patents are struck down when challenged.

It would therefore be quite misconceived to say that the copyright fair dealing exceptions to infringement could, or should, be transmogrified generally into patent law. Such exceptions would only upset the delicate balance between rights and other tempering factors in patent law that have thus far served society relatively well. (A. McBratney et al, Issues30)

ACIP Considerations

This option has the advantage of enabling the law to evolve on a case by case basis according to the concept of fairness, rather than analysis of words such as “on” or “relating to”. However, ACIP considers that the listed issues to be considered by the court by themselves provide insufficient guidance.

10.3.4 Exclusive permitted uses

C5. Exemption for exclusive permitted uses

The Patents Act be amended to establish an exemption for experimental use, where experimental use is limited to the following acts:

- determining how the invention works;
- determining the scope of the claims;
- determining the validity of the claims;
- developing an improvement to the invention.

The greatest need expressed by most of those who participated in the review was for the law to provide them with certainty regarding their daily activities. One of the best ways of providing this would be an exemption for specific acts only. This provides some clarity on the acts listed, can be ensured to meet international treaties and is formulated in language the research community may be more comfortable with. However, the exemption is strictly limited to those acts and is not easy to modify as technology evolves.

Submissions

Some support for this approach was expressed. For example:

We believe that a company like ours essentially needs clarity as to what we can do and what we can't do. Limiting an "experimental use" exemption to specific acts would minimise any ambiguity... (Acrux Limited, Options1).

Similarly, the Intellectual Property Committee of the Law Council of Australia stated that, if an experimental provision is to be introduced, it must reduce uncertainty rather than increase it:

...the Committee agrees that the specified permitted uses in C5 provide some clarity and are formulated in language with which the research community may be comfortable. The Committee also agrees with ACIP that the exception would be limited to acts within the particular categories. However, in contrast to ACIP, it sees that as a virtue not a contra, because defining the scope of exceptions by such categories is about the best that can be done to satisfy the need for certainty (LCA, Options20).

However, most submissions were not in favour of it. For example:

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 (DHA, Options11).

ACIP Considerations

Although this option appears to provide considerable certainty for the specified acts, ACIP considers it to be far too inflexible for the courts to apply reasonably and difficult to modify as circumstances and technologies evolve.

10.3.5 Inclusive permitted uses

C6. Exemption for inclusive permitted uses

The Patents Act be amended to establish an exemption for experimental use, in which permitted acts include, but are not limited to:

- determining how the invention works;
- determining the scope of the claims;
- determining the validity of the claims;
- developing an improvement to the invention.

Rather than limit allowable acts to those specified, another more flexible option is make the list inclusive so that other acts that fall within the genre suggested by the list may also be exempted.

Submissions

This option received no support though submissions, as most believed it to be as open-ended and uncertain as Option C1.

ACIP Considerations

Although this option appears to provide clarification on the nature of the exemption through the use of specific examples, the flexibility it provides to the courts is too great and too likely to result in Australian law being in breach of international treaties.

10.3.6 “Fair” experimentation, with inclusive permitted uses

C7. Exemption for fair experimentation, with inclusive permitted uses (C4 + C6)

The Patents Act be amended to establish an exemption for acts that constitute fair experimentation relating to an invention. In determining whether an act is fair experimentation, the following must be considered:

- the purpose and character of the act;
- the subject matter of the invention;
- the availability of the invention in the marketplace; and
- the commercial effect of the act upon the patent holder.

Permitted acts of fair experimentation include, but are not limited to:

- determining how the invention works;
- determining the scope of the claims;
- determining the validity of the claims; or
- developing an improvement to the invention.

In order to provide further assistance to and limitations on the decisions of the courts, an inclusive list of permitted uses could be added to the “fair experimentation” option.

Submissions

This option received support from several submissions. For example:

This option addresses both underlying principles and guidance regarding experimental use... In addition, by drawing on the copyright ‘fair dealing’ analogy it has the advantage of providing the courts with a further point of reference in interpreting ‘fair experimentation’ (DEST, Options10).

And from the National Health and Medical Research Council (NHMRC):

This is the NHMRC’s preferred option for the following reasons:

- 1) The use of the words “fair experimentation” and their definition clearly describe the scope and intention of the exemption. This is especially important for enabling scientists to judge whether their experiments contravene intellectual property laws or not. ...(and) decreases the need for scientists to seek legal experts to determine the legality of their experimentation...
- 2) The broad examples of permitted acts also increase clarity on the scope of the invention while retaining flexibility of interpretation.
- 3) ...the examples are not too specific. Therefore, while providing clarity on the exemption, the breadth of the examples means that there is no need to regularly update them (NHMRC, Options26).

However, there were also several who argued against such an approach, as for Option C4:

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* (DHA, Options11).

Also:

The real and practical danger here is that fresh legislation which has all the hallmarks of another area of law with a rich case history, and where some broad analogies can be drawn, may well be interpreted in light of that other area of law despite its inappropriateness. Decision-makers faced with some guidance or none at all will tend to opt for the former... (A. McBratney et al, Options3).

McBratney et al. discussed in detail several perceived problems with the listed factors to be considered by the court.

ACIP Considerations

This approach has much to recommend it. However, ACIP considers that, despite the list of inclusive acts, there is a significant chance that the concept of “fair experimentation” will be interpreted by the courts in a manner which is not in Australia’s best interests and/or fails to meet Australia’s international obligations. Although ACIP considers there is little chance of inappropriate copyright concepts being imported into this provision, the concepts in this option appear to stray too far from those specified under Article 30 of the TRIPS Agreement – namely, unreasonable conflict with a normal exploitation of the patent. ACIP does not believe that the concept of “fair experimentation” and the list of factors to be considered by the court adequately capture these requirements.

10.3.7 Experimenting “on” the subject matter of the invention, with inclusive permitted uses

C8. Exemption for experimenting “on the subject matter of the invention”, with inclusive permitted uses (C3 + C6)

The Patents Act be amended to establish an exemption from acts that experiment ‘on’ the subject matter of a patented invention, for example, to investigate its properties or improve upon it. The exemption is only available if experimentation is the sole or dominant purpose of the act.

Permitted acts of experimentation include, but are not limited to:

- determining how the invention works;
- determining the scope of the claims;
- determining the validity of the claims; or
- developing an improvement to the invention.

So as to provide further assistance to the courts, the inclusive list of permitted acts could be added to Option C3.

Submissions

Several submissions supported this option and believed that its problems could be overcome. For example:

Due to the potential difficulties of the research “on” and research “with” distinction, further guidance will be needed. ...Overall, we believe that if decision-makers are provided with the inclusive list of permitted acts...and a clear explanation of the intent behind the provision in the explanatory memorandum, they should be in a position to make the decision in a guided and appropriate manner on the facts before them. (A. McBratney et al, Options3).

And:

Health notes the reservations expressed by...others on the effectiveness of such an approach. 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 (DHA Options11).

The University of Western Sydney stated:

In supporting Option C8, we are of the view that...it is critical to exclude experimentation “with” the patent subject matter as this would likely impede innovation across a wide range of technologies and in particular, in the area of research tools, diagnostics and methodologies. UWS has successfully negotiated commercial licenses and assignments of intellectual property for a range of methodology and process patents which leverage their value on the basis of exclusivity of use, including experimental use “on” an “with” the patent. (UWS, Options35)

Some saw its similarity with European law as a big advantage:

We agree that this alternative is most likely to provide the greatest degree of clarity in the law and has the advantage of being partially in harmony with the position in Europe...

Being able to refer to UK decisions on (the on/with point) could be of considerable assistance to courts in Australia and would assist in establishing basic principles for interpreting the law. (University of Adelaide, Options13)

However, many concerns were not alleviated. For example:

...the issue of what comprises experimentation ‘on’ the subject matter of the invention, rather than ‘with’ the subject matter of the invention, is likely to remain contentious. In some areas (such as genetics), it appears that the distinction is very fine, if it exists at all. Unanticipated advances in a range of fields may well result in even more problematic areas. The longevity and effectiveness of this option is thus brought into question and the ARC does not support it. (Australian Research Council, Options5).

Some thought this option too adventurous:

Generally (C7, C8 and several other options) go too far down the path of making unique law for Australia... It is totally inappropriate for Australia to go about inventing new concepts in the IP arena... This can only generate unnecessary confusion, wasted time, and more fees for patent attorneys (M. Cuthbertson, Options22)

There were also some concerns over the condition of “sole or dominant purpose”:

...it raises questions as to whether or not it is the purpose of the person doing the act that is to be considered; or is the purposes to be determined on some objective basis.... Most current research and experimentation (including academic research institutes such as the University) has at least some degree of commercial intent or motivation. Such research would seem to be excluded under the “sole purpose” concept, and under the “dominant purpose” concept it would in many cases be difficult for the researcher and the University to assess whether the non-commercial or commercial aspects of the research was the “dominant purpose”, again leading to uncertainty (Monash University, Options25).

ACIP Considerations

This option is attractive because it appears to lead the courts away from exempting the normal use of patented research tools, which would be in breach of the TRIPS Agreement by conflicting with the normal exploitation of such patents, and it provides practical guidance in the form of the inclusive examples. However, ACIP’s main concern with the on/with approach is that, while those who advocate the use of “on” know what they intend by it, there is a wide range of acts that could fall within its scope. These include:

- determining the scope of the claims;
- determining the validity of the claims;
- determining how an invention works;
- determining whether an invention meets a potential licensee’s needs;
- seeking an improvement to the invention;
- seeking new uses for the invention;
- seeking an alternative to the invention (a new invention);
- using the invention for academic instruction.

While some of the above acts would no doubt be included in any reasonable interpretation of the word “on”, others are far more arguable. This is particularly the case for product per se inventions in the biological and medical fields, as raised in some submissions. Inventions are defined by the patent claims, and in these technologies in particular a significant proportion of granted claims are for products

per se, in which a utility is neither implicitly nor explicitly defined. It can become very debatable whether an act is experimenting “on” or “with” a product when what the product is used for is not specified. Interpretation of such claims could range from infinite uses to none at all. As discussed earlier, ACIP considers that solving this through a pre-grant mechanism is not a realistic option.

Some of those who supported Option C8 advocated that even further guidance would have to be provided. Some submissions to the review provided detailed examples of acts regarding product per se claims and whether each should be considered as either “on” or “with” the invention. ACIP considers that the courts would not necessarily reach the same decisions for these examples, and would use the entire patent specification, including the utility disclosed in the description, to determine the appropriate boundary of “on” and “with” on a case by case basis.

Another problem is the need for the “dominant purpose” criterion, as it is probably common for experimentation “on” and “with” an invention to be inextricably linked. One concern is that proving what was the dominant purpose of an act could be very difficult, as it would involve determining the intent of the alleged infringer. Documentary evidence of a dominant experimental purpose could be manufactured, thus creating a loophole for infringement. The credibility of such documentation would have to be assessed, increasing complexity and cost.

In light of these issues, ACIP considers that the word “on” provides little benefit over “relating to” when applied to realistic situations. Both options require further clarification and guidance to the courts, and significant grey areas would still remain. There may even be a small number of situations where experimentation “with” an invention is in fact justifiable, in Australia’s overall best interests and compliant with TRIPS Article 30.

10.3.8 Acts that don’t benefit from the utility disclosed

D2. Introduce an exemption for acts that don’t benefit from the utility disclosed
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The Patents Act be amended to establish an exemption for any act which obtains a benefit or utility of the invention not described to a sufficient degree in the patent specification (as interpreted by a person skilled in the art).
--

This approach is principles-based in a similar manner to Option D1, yet not as radical a change to patent law because it comprises an exemption to rights rather than an inherent limitation.

Submissions

This option received little support in submissions. Most considered it too far-reaching and vague a proposition.

ACIP Considerations

Although not as fundamental a change as Option D1, the complexity of its implementation and the potential breaching of international treaties rule it out of further consideration.

10.4 Statutory licenses

The Copyright Act includes a statutory licensing regime that allows educational and other institutions to copy certain copyright works without the permission of the copyright owner as long as they undertake equitable remuneration, usually through a collecting society. It is similar to compulsory licensing under the Patents Act, but the scope of the statutory copyright licenses is limited and they do not apply to most commercial uses¹¹¹. The license fee is usually negotiated between the collecting society and a peak institutional body such as the Vice Chancellors Committee. Where agreement cannot be reached it is set by the Copyright Tribunal which is administered by the Federal Court. Together with the fair dealings available to individuals, the statutory licenses available to institutions form an important part of the balance between the incentives to create and the diffusion of results in the copyright area.

ACIP considered the following option:

E. Statutory licensing for experimental use.

The Patents Act be amended to establish a system of statutory licensing, similar to that for copyright, whereby patented inventions may be used for public, non-commercial experimental purposes, upon payment of royalties to the patent holder through a collecting society. Such royalties are negotiated between institutions or their peak bodies representing researchers and collecting societies representing patentees. If a negotiation breaks down an independent Tribunal (e.g. of the Federal Court) would arbitrate a royalty. Collection and distribution of royalties is determined by sampling.

This option could work in conjunction with others options, particularly in the area of research tools. Statutory licensing could ensure that inventions essential for the further development of particular technologies can be accessed with fair compensation to the patent owner. The total transaction costs of a statutory licensing scheme may be lower than individual licensing agreements for such inventions. It would enable further research to be conducted without the costs of continually monitoring patent activity, and would capture payments by infringers that are currently being lost.

¹¹¹ Intellectual Property & Competition Review p. 117 www.ipcr.gov.au

The disadvantages are:

- as such a system would probably be considered in conflict with normal exploitation of the patent, statutory licences would only be made available for public, non-commercial users in accordance with AUSFTA Article 17.9(7). Public, non-commercial research would have to be defined;
- secondary innovators would have to pay to experiment “on” patented inventions,
- particular rights holders may receive lower royalties than they would obtain by direct license negotiations;
- if patent holders are allowed to opt out of the scheme, then holders of very valuable patents will do so, resulting in a scheme only for less-used patents;
- may be difficult to police, and to determine fair royalties;
- general transaction costs of major change;
- a practice of patenting purely in order to obtain experimental use royalties may emerge (i.e., patent thickets may be encouraged).

Submissions

Most submissions did not support such an approach. For example:

It seems to us that such an option is more likely to be relevant to the use of ‘research tools’, for example in the genetic research area. We imagine, but do not know, that the ‘value’ to a user could not be readily estimated as it can in the copyright area (which is, for example, able to roughly correlate audience size with value for music broadcaster) (Freehills, Options13).

However, there was some support expressed:

...my preference would be a registration or statutory licensing scheme that allowed uninhibited use of patented and patent applied for inventions with a clear proviso that if any commercial product or process resulted then the original patent owner could recover some sort of down stream royalties (I. Turnbull, Options 16).

ACIP Considerations

The introduction of a system of statutory licensing does not warrant further consideration because it would only be a partial solution at best, be very complex to establish and carry too great a risk of failure.

10.5 Improved licensing practices

Improving the licensing practices of both public and private organisations may be a method of ensuring access to fundamental research technologies. It is generally considered that the potential of public research institutions is not being realised, often due to sub-optimal patenting and licensing practices.¹¹² The recent Nicol and Nielsen study¹¹³ found that, although there is significant licensing activity within the

¹¹² For example, Kamil Idris *Intellectual Property - a power tool for economic growth* WIPO Publication 2002, and OECD *Patents and Innovation: Trends and Policy Challenges* DSTI/STP92003, October 2003.

¹¹³ Dianne Nicol and Jane Nielsen *Patents and Medical Biotechnology: an Empirical Analysis of Issues Facing Australian Industry* Centre for Law and Genetics Occasional Paper No 6 p.190 (available at www.ipria.org/publications/reports.html)

Australian biotechnology industry, it may be that at present licensing is less than in other countries. A number of their respondents stated that getting a license is not an easy process, and the study stated that this “may be a product of inequality of bargaining power and levels of experience between our respondents, and parties in jurisdictions where industry is more established.”

Submissions

One university technology transfer administrator said that in his experience there were no problems with licensing:

....in 2003, the University of Sydney was identified by some media as being the first Australian university to sign and licence with Genetic Technologies that allowed University staff and students to undertake research using the so-called “junk DNA” patents owned by that company... While much was made of this in the press and I received a number of comments from researchers at the time, the licence terms, including the fee, were judged not to be onerous or constraining and the existence of the licence provided certainty for a number of researchers. Concerns were expressed that this might encourage other patent owners to approach the University... However, no other party has (approached) the University for such a licence, nor has the University been notified of any infringement of any patent within its research. (Kevin Croft University of Sydney, Issues29)

Many submissions thought that licensing practices could be improved, although this was not a realistic alternative to an experimental research exemption. For example:

While alternatives to an experimental use defence such as improved licensing practices warrant consideration, they are in practice unlikely to adequately address problems in the absence of an effective research exemption... Even where holders of patents on upstream research tools are willing to engage in licence negotiations, case by case negotiations for permission to use research tools may create significant administrative burdens which are costly and could delay research (DHA, Issues40).

On the other hand, one submission thought that improved licensing practices were an alternative rather than a supplement to an experimental use exemption:

Epitan believes that improved licensing practices can address any perceived inadequacies more effectively than the introduction of an exception to, and consequent contraction of, the patent owner's exclusive rights... Promotion of improved licensing practices would better balance the interests of patent owners against the interests of the wider community, as more interested parties would have access to the benefits of patented inventions, and patent owners would be given an opportunity to be involved in on-going research and development of their technology... By promoting licensing over and above a legislative infringement exception, patent owners will not feel marginalised and hence will be unlikely to see an incentive to move their research and development programs to other jurisdictions in which such exceptions do not exist. (Epitan, Issues20).

ACIP Considerations

Improving licensing practices would be a useful supplement, as anything that reduces the transaction costs between licensee and licensor is desirable. However, this does not address the fundamental question of whether a patent right is absolute or whether some limited uses should be allowed. It is beyond the scope of this review to suggest ways of achieving improved licensing practices.

10.6 Improved Compulsory licensing

The Australian *Patents Act 1990* contains compulsory licensing provisions that might be invoked if the invention has not been reasonably exploited by the patentee in Australia or if the patentee attaches unreasonable conditions to licenses without satisfactory reasons so that the "reasonable requirements of the public with respect to the patented invention have not been satisfied"¹¹⁴. However, there has been only one reported application to the Federal Court for a compulsory license and that was rejected.

The IPCR Committee found that the experience in other jurisdictions, most notably the United States and Canada, was that compulsory licensing can lead to more efficient outcomes without harming the long-term incentives to innovate¹¹⁵. The Committee recommended replacement of the current public policy test by a competition test. The Government's response was to add the competition test onto the current public policy test, and this has yet to be enacted.

Submissions

Many submissions thought that compulsory licensing was in principle a useful supplement to an experimental use exception. However, at least in its current form, it was not an alternative to an experimental use exemption. For example:

Health's view is that both compulsory licensing and experimental use exemption can in principle address problems raised by gene patents. It sees them as having separate rather than interchangeable functions and considers that both should be available as in most European countries... (DHA, Issues40)

A number of submissions also suggested ways in which compulsory licensing could be improved in Australia:

The current compulsory licensing mechanism is too expensive and too slow to be of much benefit to those who need it most, even assuming that the amendments the government has approved following the Ergas Report four years ago will be implemented... The compulsory licensing process must be made cheaper, easier and quicker if it is to be used more often. One possible entity to handle compulsory licensing matters would be the (Australian Competition and Consumer Commission)... (McBratney et al, Issues30)

On the other hand, some submissions thought that compulsory licences were not relevant to an experimental use exception:

Given the lack of usage of the compulsory license provisions under the various Patent Acts in Australia, FICPI believes that they are not an appropriate way of dealing with the experimental use exemption issues. We do not believe that the issue of "Patents and Experimental Use" is an appropriate forum to consider the very specific topic of reform of the compulsory license provisions of the Patent Act 1990. (FICPI, Issues3)

¹¹⁴ S.133(2)(a).

¹¹⁵ Intellectual Property & Competition Review p. 163-4 www.ipcr.gov.au.

ACIP Considerations

As for improved licensing practices, ACIP considers that while increased use of compulsory licensing provisions would be a useful supplement to an experimental use provision, it is not an in-principle alternative. Compulsory licensing should be reviewed in a broader context than this enquiry, although ACIP notes that the potential for change appears to have been reduced by Article 17.9(7) of the AUSFTA.

10.7 Communal licensing - patent pools and collecting societies

Communities of intellectual property owners who deal with each other on a recurring basis have sometimes developed institutions to reduce the transaction costs of bundling multiple licenses. Copyright collecting societies have evolved in the music industry to facilitate licensing transactions so that commercial users may readily obtain permission to use numerous copyrighted works held by different owners. Such 'natural' monopolies are usually accepted by governments because the efficiency benefits of lower transaction costs are generally thought to outweigh the costs of reduction in free competition of individual contract negotiations.¹¹⁶

Similarly, patent pools have emerged in manufacturing industries at various times in the past in the US, sometimes with the help of government. Such pools have developed when licenses under multiple patent rights have been necessary to develop important new products. Competition authorities have put stringent conditions on such patent pools in more recent years. The potential benefits of patent pools include:

- the elimination of problems caused by 'blocking' patents or 'stacking' licenses;
- significantly reducing licensing transaction costs;
- distributing risks and costs of R&D among the pool's partners;
- institutionalised exchange of technical information not covered by the patents.

Potential disadvantages include:

- inflated costs by encouraging collusion and price fixing;
- the shielding of invalid patents.

Submissions

All submissions that commented on patent pools thought that they were useful in some technologies but they were not an alternative to an experimental use exemption, for example:

Patent pooling is not a suitable alternative to a research exemption because the use of the patent is limited to members of the pool. By contrast, the defence of experimental use is available to conceivably the whole public - whether or not they are a member of a pool. (ACIPA, Issues18)

ACIP Considerations

As for compulsory licensing, ACIP believes that patent pools are not a mechanism worthy of further consideration.

¹¹⁶ Intellectual Property & Competition Review p. 118-9 www.ipcr.gov.au

10.8 Open source/public domain mechanisms

Some have suggested that knowledge obtained through public sector research should go straight into the public domain, as it is the public who funded it. It has also been consistently found that the money generated by patent licensing represents only a very small fraction of the total budgets of public sector research organisations, even in the most patent intensive US universities.

One model for public domain access is open source software. The Royal Society¹¹⁷ states that the success of the open source software movement indicates that a high rate of innovation can occur in the computer industry without recourse to patenting:

Open source software promotes the scientific endeavour and has been particularly valuable in areas such as biomedical research. Significantly, it is also making considerable inroads into the commercial arena. Although certain vendors are opposed to it, many are building a lucrative business around it: some provide documentation and support, while others are adopting open source software for core products.

However, open source software such as Linux has not been without difficulties. There have been some problems with divergence of standards in the absence of control of patents, while others have freely taken the original open source innovations and patented their own improvements. Some commentators have suggested patenting with royalty-free licensing as a solution to these problems.

Open source has also become more prevalent in bioinformatics, both for commercial and non-commercial laboratories. For example, Laird¹¹⁸ suggests that

Until recently, open source has often appeared to bioscientists as some sort of novelty, or, worse, a threat to IP protection. In the last few years, though, solid achievements in clustering, genomic data management, Web publication, and scores of specific "vertical" applications have established open source as a serious technical alternative. Big Pharma and other biosciences are just starting to realize how open source can systematically cut costs, improve security, allow their own workers to shift attention back to their "core competences" from proprietary IT expertise, and even promote better science.

Submissions

Some submissions thought that open source might be of use in some areas, particularly information-based inventions such as computing and genetics which had similarities to copyright:

The Commonwealth and its relevant funding agencies should provide support for open source projects to help promote access to genetic databases and scientific information. Although not a substitute for a research exemption, such projects will help the dissemination of genetic information and biological inventions.

The free software foundation and the open source movement have been a source of inspiration to public researchers involved in the human genome project. Many researchers have been keen to ensure that scientific information and biological software remains in the public domain through the use of creative contracts. They have sought to live up to the impression that the scientific community is completely open and a place where ideas are shared freely. (ACIPA, Issues18)

¹¹⁷ The Royal Society *Keeping Science Open: the effects of IP policy on the conduct of science* (2003) p.8

¹¹⁸ Cameron Laird *Freely available software plays special role for Big Pharma and others*, IBM Open Source Projects (2002) <http://www-106.ibm.com/developerworks/linux/library/l-osbio.html>

Similarly:

We believe that open source principles warrant consideration, particularly in relation to information-based patents. However, we do have some reservations as to the extent to which open source principles could provide broadly applicable alternative patent use strategies... One of the major problems in the area of patent law is that significant expenditure is involved in obtaining and maintaining patents. Unless there is some mechanism for recovering these costs, people will be unwilling to embark on the patenting process. (Nicol/Nielsen, Issues17)

Some submissions saw this inability to recoup financial investment in research as a major limitation in the general use of open source mechanisms:

In the biotech area open source principles would be counterproductive, flying in the face of the very monopolistic protection required for recouping R&D costs. It would be dangerous to equate inventive biological research with open source development of Linux. (Walter & Eliza Hall Research Institute, Issues5)

ACIP Considerations

Again, although mechanisms such as open source system may be useful supplements in certain technologies, ACIP does not believe they have to potential to be broad solutions to the issue of experimental use.

11 Formulation of the preferred option

11.1 ACIP Considerations

Some of those who made submissions to the review are in favour of a broadly stated exemption due to its flexibility. However, most of those who participated in the review desire a provision that provides them with the highest degree of certainty possible in their daily activities, meaning a much more prescriptive provision. ACIP believes that any provision that is flexible enough to exempt the range of experimental acts that most commentators believe to be beneficial to society, both now and in the future, will not be able to provide the degree of certainty desired by the majority. Expressly *precluding* all experimental acts would be the only method of achieving such certainty, but this would be contrary to the principles of the patent system.

Also, as a provision becomes more detailed, there will be increasing focus on the meaning of individual words. As the wording may not always reflect actual circumstances as well as they might, there will be a corresponding trade off in the ability of courts to follow the intent of the law. Therefore there is considerable benefit in allowing courts some free reign to make decisions based on the concept of fairness rather than on literal interpretation of statutory language. This provides support for a broadly stated provision. However, such freedom also increases the risk of courts making decisions that are damaging, or not compliant with international obligations by not taking into account all appropriate issues. A balance must be achieved.

As discussed in Part 10, ACIP concludes that none of those options discussed in the Options Paper are sufficient, so a new option must be formulated. ACIP considers that a specific exemption using the European wording “acts done for experimental purposes relating to the subject matter of the invention” forms the most appropriate basis because:

- it is in harmony with European provisions, thus reducing complexity for users and increasing the likelihood that the provision would satisfy TRIPS Article 30;
- it provides scope for decisions to be made that reflect the overall intent of the legislation, rather than the meaning of specific wording in particular circumstance. For example, there may be unusual cases where experimentation “with” should be exempted, and
- better further guidance can be provided to the courts than concepts such as “on” and “fair”.

Some submissions suggested using the words “study” or “research” as well as experiment. “Study” may include use of the invention for the purpose of academic instruction. However, ACIP considers these add insufficient benefit to change from the European word “experimental”, which pertains more to seeking to discover the unknown and the testing of principles.

A few submissions had major concerns with the concept “subject matter of the invention”. In regards to product inventions, A. McBratney et al were concerned the concept had the potential to be interpreted in the manner of the German Clinical Trials I case. There the subject matter of a product was determined to be both the product and its uses, thus rendering experimental uses of the product to be exempt from infringement. The concept of inventive contribution as also involved, which was seen to be an inappropriate conflation of separate criteria. A. McBratney et al. argued that these issues could be avoided by simply using “the invention” instead.

Some suggested the exemption include the statement “the existence of a commercial purpose does not preclude the application of the exemption”, similar to the recommendation of the ALRC. ACIP considers that this point can be made at a higher level, as discussed below.

As outlined in Part 9, the main concern with the European wording is its potential for a wide range of interpretations. ACIP considers that further practical guidance to both the courts and users of the system on the meaning of the phrase “acts done for experimental purposes relating to the subject matter of the invention” can be provided through the addition of an inclusive list of experimental acts. This provides the courts with a genre of acts to work from, but also with the flexibility to go outside that genre when necessary. It also goes some way to addressing the concerns expressed in some submissions.

The list of permitted acts proposed in the options was:

- determining how the invention works;
- determining the scope of the claims;
- determining the validity of the claims; or
- developing an improvement to the invention.

Many submissions made suggestions on how to improve these:

- DHA suggested that the first listed act be “determining how an invention, including a product such as a gene or protein, works”. This would clarify that the exemption also applies to product claims in controversial areas such as the biological and medical sciences. ACIP considers that the provision should not be technology specific, even if only inclusively.
- FICPI Australia suggested that the first act be “determining how the invention works or what its properties are”. Similarly, IPTA suggested adding the act “determining new properties or uses of the invention”. ACIP considers that these concepts are adequately encompassed by the above first and last points. Those properties not covered by “how the invention works” would not be properties of the invention, but potentially properties of another invention.
- A. McBratney et al. were concerned about including the concept of “improvements to the invention”, as those non-incremental improvements that don’t result in a cross-licence or other compensation to the original patent holder should not be exempt. Closely related to this is the question of when an improvement becomes a new invention, and so the experimental act is no longer exempt, and the difficulties in untangling the changing purposes of a

research project. This last act was seen to be the critical one where most argument would centre and become a point of endless dispute. ACIP considers that the last listed permitted act is necessary because the main justification for introducing an exemption for experimental acts is to encourage further (secondary) innovation, as long as the normal exploitation of the patent is not inhibited. The first listed permitted act, determining how an invention works, does not adequately encompass the concept of secondary innovation.

- FICPI Australia suggested that “developing an improvement to the invention” be changed to “researching” to avoid the strong commercial connotations of the former. ACIP has chosen “seeking”. FICPI also suggested that the list of permitted acts be placed in the Regulations rather than the Act to allow them to be much more easily improved. In ACIP’s view, the list of permitted acts should be in the Act itself, because they are core to the provision.
- NHMRC suggested adding the example “using the invention for non-profit research”, which would mean that basic research is always exempt from patent infringement. Similarly, Monash University suggested adding “academic instructional experimentation”. As outlined earlier, ACIP considers that a purely commercial/non-commercial test is not a useful one, but the addition of further guidance as discussed below should provide the courts with the scope to exempt such acts if individual circumstances warrant it.

The above results in the following provision:

The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention. Acts done for experimental purposes relating to the subject matter of the invention include:

- determining how the invention works;
- determining the scope of the invention;
- determining the validity of the claims;
- seeking an improvement to the invention.

This provision must be tested for compliance with the TRIPS Agreement. As outlined in Part 7, the three criteria of Article 30 are:

1. Exceptions must be *limited*, meaning they must ‘only make a small diminution of the rights in question’. ACIP considers that this is satisfied because the exception is *limited* to experimental purposes only.
2. *Exceptions must not unreasonably conflict with the normal exploitation of the patent.* It is not clear that this criterion is met. There remains scope for the courts to interpret the provision as exempting the normal use of patented research tools, which would be inappropriate in most cases.
3. *Exceptions must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.* ACIP considers that this is satisfied because the WTO Panel found that ‘legitimate interests’ includes policy interests of the type protected by an experimental use exception.

ACIP considers that criterion two is best covered by including it as an explicit proviso, rather than through use of related concepts such as “experimentation on”, “fair experimentation” or “commercial”. The resulting exemption is as follows:

The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.

Acts done for experimental purposes relating to the subject matter of the invention include:

- determining how the invention works;
- determining the scope of the invention;
- determining the validity of the claims;
- seeking an improvement to the invention.

ACIP notes that it must be made clear to users of the system that the list of examples is not a list of *permitted* acts, as they are still subject to the test of whether they unreasonably conflict with the normal exploitation of the patent.

11.2 Cost / benefit analysis

ACIP considers that the benefits of such a provision are:

- the limits to patent rights are clarified, thus reducing uncertainty and resulting inefficiencies and underperformance in the research industry;
- Australian law is ensured to meet international obligations. For example, the use of patented research tools would not be exempted in most cases;
- Australian law is substantially in harmony with European provisions;
- total levels of innovation are optimised through an appropriate balance of rights;
- courts have sufficient flexibility to reach appropriate rather than literal decisions.

The costs of such a provision are:

- some uncertainty over the boundaries of the exemption, which can only be established over time through case law. ACIP expects there to be considerable concern expressed on this by those in industry. ACIP recognises that any provision which is flexible enough to encompass the appropriate range of acts, both now and in the future, is not able to provide the high degree of specificity and certainty that most participants desire;
- it is not in harmony with current US law, increasing complexity for those operating in both the Australian and US systems;
- patent holders and researchers must become familiar with the clarified law and keep abreast of its evolution;
- the risk of unforeseen, detrimental effects and loopholes.

ACIP considers that the benefits outweigh the costs, and so recommends that the above provision be introduced. ACIP accepts that not all ramifications can be foreseen and so over time modifications to the provision may be needed. Appropriate explanation of the new provision should be provided in the Explanatory Memorandum to the amendment, and a guide on the new provision should be provided and maintained by IP Australia as part of its suite of guides on particular topics. ACIP also recommends that Australia actively participate in international fora on the issue of harmonisation of experimental use provisions, such as the current review by the OECD Committee of Scientific and Technological Policy.

12 Appendices: Participants in the Review

12.1 Submissions to the Issues Paper

1. Law Council of Australia
2. Monash University
3. FICPI Australia
4. Daya Shanker, Deakin University
5. Walter & Eliza Hall Institute of Medical Research
6. Edith Cowan University
7. Group of Eight
8. The Cancer Council NSW
9. Peter Evans
10. Nufarm Ltd
11. CHAP AirTech Pty Ltd
12. Mayne Pharma Pty Ltd
13. Medicines Australia
14. Ladas & Parry LLP
15. Craig Humphris & Greg Moss-Smith, GroPep Limited
16. Luigi Polombi, PhD candidate, University of New South Wales
17. Dianne Nicol & Jane Nielsen, Centre for Law and Genetics Law Faculty,
University of Tasmania
18. ACIPA
19. Mark Horsburgh, Fisher Adams Kelly
20. Epitan Limited
21. The University of Newcastle Research Associates (TUNRA) Limited
22. Colin Cole
23. Flinders Technologies Pty Ltd
24. Ludwig Institute for Cancer Research
25. IPTA
26. Chris Sotiropoulos
27. Ryan Wilson
28. IPRIA
29. Kevin Croft, Manager IP & Licensing Unit, University of Sydney
30. McBratney et al
31. Cullen & Co
32. NHMRC
33. Meat & Livestock Australia
34. The University of Adelaide
35. DSTO
36. Ian Turnbull
37. Note Printing Australia
38. Access Genetics
39. Royal Children's Hospital
40. Department of Health & Ageing
41. AusBiotech
42. Fox Design Pty Ltd

12.2 Submissions to the Options Paper

1. Acrux DDS
2. Adam Johnston
3. Amanda McBratney et al.
4. Australian Centre for IP in Agriculture (ACIPA)
5. Australian Research Council (ARC)
6. Australian Society for Medical Research (ASMR)
7. Australian Vice-Chancellors' Committee (AVCC)
8. Bio21
9. The Cancer Council
10. Department of Education, Science & Training
11. Department of Health & Ageing
12. FICPI Australia
13. Freehills
14. Genomics Directorate, Department of Health WA
15. Human Genetics Society of Australasia (HGSA)
16. Ian Turnbull, barrister
17. The Institute of Patent and Trade Mark Attorneys (IPTA)
18. Intellectual Property Research Institute of Australia (IPRIA)
19. Kevin Croft, University of Sydney
20. Law Council of Australia (LCA), IP Committee
21. Luigi Palombi, University of NSW
22. Matthew Cuthbertson, CRC for Sensor Signal & Information Processing
23. Mayne Pharma
24. Medicines Australia
25. Monash University
26. National Health & Medical Research Council (NHMRC)
27. Nufarm Limited
28. Patent Value
29. Peter Evans
30. ResMed Limited
31. Saba Elkman
32. Science Industry Action Agenda (SIAA)
33. University of Adelaide
34. University of Melbourne
35. University of Western Sydney

12.3 Consultations

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Malcolm Royal & Leon Allen (IPTA)

Michael Caine & John Slattery (patent attorneys)

Terry Healy (CSIRO)

Duncan Bucknell (Mayne Pharma)

Saba Elkman (IPRIA)

Peter Huntsman & Karen Sinclair (FICPI)

Mervyn Jacobson & Ian Christensen (GTG Technologies)

Bernard Lee, Matt Gallagher & Greg Healy (NuFarm)

Ian Pascal (LCA)

Donald Jack

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Alastair Wilson & Jason Rasheed (NHMRC)

Matthew Rimmer (ACIPA)

Ryan Wilson (Plant Health Australia)

Group of 8 Universities