ADVISORY COUNCIL ON INTELLECTUAL PROPERTY

Patents and Experimental Use

OPTIONS PAPER

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(Please note: unless requested otherwise, written comments submitted to ACIP will be made publicly available.

Comments should be received no later than 28 February 2005

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Glossary of Terms

ACIP	Advisory Council on Intellectual Property
ACIPA	Australian Centre for Intellectual Property in Agriculture
AGS	Australian Government Solicitor
ALRC	Australian Law Reform Commission
AUSFTA	Australia-United States Free Trade Agreement
DH&A	Department of Health and Ageing
EU	European Union
EUE	experimental use exemption
FDA	United States Food and Drug Administration
FICPI	Australian Federation of Intellectual Property Attorneys
IPCRC	Intellectual Property and Competition Review Committee
IPRIA	Intellectual Property Research Institute of Australia
IPTA	Institute of Patent and Trade Mark Attorneys of Australia
JPO	Japanese Patent Office
OECD	Organisation for Economic Cooperation and Development
PCT	Patent Cooperation Treaty
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
WTO	World Trade Organization

Format of the Paper

Part I of the paper comprises a brief summary of the progress of the review to date.

Part II comprises those options that ACIP believes are available and an outline of the pros and cons of each.

ACIP asks that further submissions be specifically directed to these options, particularly Options B, C1, C7 and C8.

Part III comprises:

- a more in depth analysis of the main issues and the submissions received, and
- ACIP's considerations on each of these issues.

PART I OVERVIEW

Introduction

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 and design right systems.

In recent years, there has been concern expressed, both in Australia and overseas, that patent rights may be inhibiting research and development, particularly in biotechnology. In Australia, the concern has received widespread publicity on the ABC in programs such as Catalyst's "Genius of Junk" and Four Corners "Patently a problem". It was claimed there that patents may be inhibiting further research into disease prevention and cure.

However, it should also be noted that Australia spends, through public and private sources, considerable funds on research and development. There has also been increasing concern that there is insufficient return on this investment through the successful commercialisation of research and development in Australia and that inadequate use of the patent system may play a part in this.[1]

In consideration of these issues, the Parliamentary Secretary to the Minister for Industry, Tourism and Resources, has asked ACIP:

> *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.*

In undertaking this inquiry ACIP is mindful that the Australian Law Reform Commission (ALRC) has concurrently conducted an inquiry into Gene Patenting and Human Health. The ALRC inquiry covered the issue of experimental use; however this was only one of many questions covered by this enquiry, which had a specific focus on human health.

In its final report[2], 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

[1] AIC report to DEST, See http://www.dest.gov.au/highered/commercialisation/default.htm

2 ALRC Report 99 *Genes and Ingenuity: Gene Patenting and Human Health* http://www.austlii.edu.au/au/other/alrc/publications/reports/99/

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*.

Background to this paper

As part of its inquiry process, ACIP published an Issues Paper in February 2004 to which it sought written responses on a number of questions. It also held direct consultations with interested parties.

From submissions and consultations, ACIP noted that there was considerable uncertainty and difference of opinion about the current state of Australian law on an experimental use exemption. Whilst it was generally accepted that there is currently no **explicit** experimental use exemption to infringement in the *Patents Act 1990,* many researchers assumed that there is an **implicit** exemption in common law that allows them to freely experiment with patented subject matter – and that this was an intrinsic part of the patent contract. That is, an experimental use exception was implicit in the patent system's *quid pro quo* of patent grant in return for early disclosure.

Many researchers believed there were a number of reasons why experimentation on patented inventions should be allowable, including to:

- further knowledge not fully explained in the patent specification,
- determine the patent's sufficiency or to compare it to prior art,
- test the validity of a patent,
- determine how the patented invention works,
- test whether a proposed product or process falls within the scope of a patent,
- reduce transaction costs for researchers (patent searches, legal advice, licensing etc),
- promote the development of new ideas and improvements of the patent and correspondingly reduce the likelihood of excessive monopolization,
- improve on the invention, "design around" the invention or develop a further patentable invention;
- determine whether the invention met the tester's purposes in anticipation of requesting a licence; and
- facilitate academic instructional experimentation with the invention.

However, a few submissions argued that experimental use should be encompassed within a granted patent as an exclusive right of the patentee, as this was considered fair reward for being a pioneer in a given field, and that an experimental use exemption would provide a loophole that allowed competitors to effectively reduce the economic value of patented inventions. It would also make it more difficult to

determine infringements if the 'bright line' of no unauthorised use was diluted. Both these effects could reduce the incentives to innovate.

As there is no court decision in Australia which can be said to establish that there is an experimental use exception as part of patent law, there are reasonable arguments both ways as to whether such an exception would be considered to exist in Australia. Most submissions considered that this situation is unsatisfactory, whether considered from the position of patentees or third parties.

Responses to ACIP from interested parties indicated that some public researchers were uncertain and cautious about the situation; for example they ensured existing third party patents are not experimented on, thus eliminating potential IP infringements. Other researchers believed that the confusion was currently having little effect on research in Australia but that it could impact on research in Australia in the future. Still others, particularly those from the private sector, expressed more definite views on the state of the law and said it was already affecting their research activities.

Overall, it was strongly expressed by participants in the review that they wanted clarity as to whether an experimental use provision existed in the current law. They were also seeking greater certainty as to which actions on a patent are permissible and non-infringing.

ACIP has considered submissions received and discussions arising from consultations. It now believes that the most constructive way forward is to release an options paper for further comment. This Options Paper considers the responses received and discusses a number of possible options for action.

In putting forward possible options, ACIP has tried to capture both the perceived potential positive and negative effects of the options. Following consideration of these effects, ACIP has decided on four of these options as being those most likely to satisfy the terms of reference of this inquiry.

After consideration of the submissions and possible consultations regarding this paper ACIP expects to submit a final Report to the Government in mid 2005.

Submissions to this Paper

ACIP welcomes further submissions specifically directed to its favoured four options as outlined in Part II.

Written comments should be provided to the following address by 28 February 2005.

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Submissions may be made in electronic form or in hard copy. Unless marked confidential, all submissions will be made public and may be placed on the ACIP website at (**http://www.acip.gov.au**). The Committee's preference is for submissions to be made public; confidentiality should be reserved for material, the disclosure of which would be genuinely prejudicial to the party making the submission.

PART II OPTIONS

Introduction

Discussed in this section are all of the Options that ACIP has considered in the light of the Issues Paper that was circulated and the submissions that were provided as a result. Some of the general principles and issues affecting ACIP's considerations of these options are summarised below. These principles and issues are more fully discussed in Part III of this paper.

Guiding principles

The more important principles that ACIP has used in the consideration of the options include:

- the background concerns and terms of reference of this inquiry;
- the importance of optimising the patent system to promote innovation and economic growth;
- the understanding that optimising the patent system often requires balancing the needs of different participants, including initial (primary) and follow-on (secondary) innovators in a technological field;
- clarity and transparency are advantageous aims to reduce inefficiencies, including transaction costs, and to promote calculated risk-taking inherent in research;
- transaction costs are also reduced by keeping the IP system technologically and sector neutral;
- objective empirical evidence is preferable but anecdotal or subjective evidence of a problem can also be useful;
- the over-riding requirement that any changes are not in conflict with Australia's international treaty obligations;

Recent changes

In more detail, ACIP believes that some of the recent changes to the innovation system generally, and in the patent system in particular, are especially important to its terms of reference including:

- an increased realisation that successful innovation is a primary driver of economic growth;
- increased pressure on public research organisations to effectively commercialise their R&D;
- the increased importance of IP in successful technology commercialization;
- an ever increasing number of patents;
- the increased propensity of patent owners to assert their rights.

Experiment vs Research

The choice of terms used in legislation will effect how provisions are interpreted by the courts. The main choice appears to be between "experiment" and "research". The Macquarie Dictionary meanings of these terms are very similar. However, ACIP has chosen "experiment" as it pertains more to seeking to discover the unknown and testing principles.

Research Tools

The particular issue of patented research tools being used purely for their intended experimental purpose is not specifically addressed in the following options. ACIP considers that, under any of the options, the courts have the ability to reach reasonable judgments on research tools in a manner that does not unfairly single out and devalue patents for such inventions.

Generic Pros and Cons

In addition to the specific pros and cons 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, it was also been noted that a lack of guidance to the courts may have the potential to result in decisions that could be contrary to the purpose of the patent system and thus to Australia's interests.

Similarly, all options result in the Australian laws regarding experimental use having some potential to become different to 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.

Lastly, any legislative change to the status quo inevitably involves costs - in the process of enacting legislation, in the process of interpreting new legislation in the courts and in stakeholders having to alter their behaviour.

Options considered

Option A - Expressly preclude experimental use from allowable activity

The Patents Act be amended to establish that experimental use of a patented invention constitutes infringement of the patent.

This provision would be irrespective of the purpose of the use, the type of organisation the invention is being used by, and whether it involves experimenting on, or with, the invention. However, any grounds for exemption from infringement that may otherwise be available under the Act would not be overridden.

Pros:

- considerable clarity and certainty on the issue is provided, with a corresponding reduction in the costs of uncertainty;
- the value of Australian patents is increased/maintained and so primary innovation in new fields is further encouraged;
- improved licensing practices may be encouraged.

Cons

- experimentation by non-patent owners on patented inventions (secondary innovation) is discouraged by the cost of obtaining research licences (if made available at all) and the cost of maintaining knowledge of the IP landscape in all areas of research, regardless of their potential;
- as a country that is a net importer of innovation and where improvement (secondary) innovations is predominant, this may not be in Australia's best interests.
- alternatively, infringing behaviour may become and/or remain widespread to avoid the cost and effort of compliance (as has been found to occur in copyright), resulting in research becoming more secretive and a reduction in the dissemination of technology;
- may block educational activities to some degree.

ACIP Consideration:
Although this option appears to provide greatest clarity on the issue, ACIP considers that it does not address the main concerns of many researchers, particularly with regard to cumulative innovation, and that it would broaden patent rights to a point where total innovation levels may become sub-optimal.

Option B - No change

Maintain the current situation. There may be some uses of a patented invention which do not constitute infringement although it is uncertain whether experimental use is included in this. The courts would be left to decide on these points.

Pros:

- there is little non-anecdotal evidence of a current market failure, so the costs of current law being uncertain or perhaps inappropriate are outweighed by the dangers and costs in making significant changes to the law;
- lack of absolute certainty may in fact be desirable, as it enables the law to be interpreted according to actual cases rather than theory (inductive, not deductive);

Cons:

- if in future the courts may interpret narrowly and/or if patent holders enforce their rights more vigorously there may be inefficiencies due to excessive patent monitoring and licensing;
- leaving interpretation of the law to actual cases places potentially major costs on the parties, particularly the losing party;
- persisting with current uncertainty may result in some researchers adopting risk averse behaviour.

ACIP Consideration:

Although this option does not address the groundswell of concern over the current lack of clarity on the issue and runs the risk of not solving potential problems raised in submissions and consultations, the lack of significant objective/empirical evidence of a current and significant market failure cannot be ignored. The introduction of any form of experimental use provision necessarily would involve replacing current uncertainty with some new form of uncertainty. ACIP therefore considers that doing nothing until a significant problem becomes more empirically evident must remain an option that warrants further consideration.

Option C - Introduce an express provision allowing experimental use

There are a number of possible versions by which this option might be implemented. The general pros and cons common to each of these methods are:

Pros:

- provides some clarity, therefore reduces inefficiencies;
- encourages further secondary innovation by non-patent holders.

Cons:

- most versions may provide the impression that patent rights are otherwise absolute and that there are no other exemptions;
- appropriate drafting would be crucial, e.g., commercial/non commercial, on/with, degree of detail/flexibility and uncertainty;
- may reduce the value of patents, thus discouraging primary innovation;
- may fail to take into account the commercial impact on patent holders in cases where experimentation involves some exploitation of the invention;

- some of the acts allowed may be considered to be in breach of Australia's international treaties, especially TRIPS and the USFTA.

For the different versions by which this option may be enacted, it is unlikely to be possible to choose a format and wording that provides certainty in all circumstances. Some interpretation must ultimately be left to the courts. None of these options are intended to derogate from any experimentation that may otherwise be permitted under the Act.

In addition to these general pros and cons of this option, specific matters are listed with each method of implementation.

C1. Definition of exploitation 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". No further guidance on the meaning of this term is provided.

Pros:

- only need to modify an existing provision in the Act, not add a new one;
- makes clear that there is an inherent limit on the scope of patent rights;
- courts have a great deal of flexibility to interpret the definition as appropriate for each case.

Cons:

- increased scope for the courts to interpret the definition in a manner contrary to Australia's interests.

ACIP Consideration:
This option appears to be the simplest way of introducing a provision that expressly allows experimental use in some form. Although the lack of further clarification on the meaning of "experimental use" means a great deal of the current uncertainty is maintained, ACIP considers that the minimal changes required, clarifying that patent rights are inherently limited and allowing the law to evolve according to real world circumstances are major advantages.

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.[3]

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

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

Pros:

- provides courts with flexibility and a principles based approach;
- 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;
- examples and/or guidelines have the potential to be kept relevant.

Cons:

- uncertainty due to increased flexibility;
- formulating the examples/guidelines may in fact be a difficult task;
- regular updating of examples would require increased resources, depending on the detail of the examples;
- the interpretation of the operative provision ultimately takes priority over the examples.

ACIP Consideration:

The use of examples or guidelines in specific technologies has the potential to greatly aid the courts in complex technologies. However, ACIP considers that formulating and maintaining appropriate, widely agreed examples and/or guidelines containing the correct balance of detail will be a very difficult task, and may not provide a sufficient level of the intended guidance. The longevity of the value of these examples is also uncertain.

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.

Making explicit the existence of a commercial purpose does not preclude the application of the exemption but may need to add supplementary conditions to ensure the patent holder's legitimate rights are not unreasonably affected (e.g. in clinical trials).

Pros:

- the interpretation of exact wording (eg "experiment", "on the subject matter", "dominant purpose") is left to the courts, allowing flexibility;
- substantially in harmony with European laws, therefore reducing costs to exporters.

Cons:

- uncertainty over interpretation of wording/meaning, as has been noted to occur in the EU;
- experimentation 'on' and 'with' an invention are often intertwined and not easily separated.

ACIP Consideration:

On the surface this option has significant attractions, and it has strong support from major stakeholders. However, the more ACIP has analysed this option the more reservations it has discovered about the meaning of the "on the subject matter of the invention" in practice. As a result, ACIP now believes that such acts may sometimes be intertwined with experimental acts "with" the subject matter of the invention, and placing so much reliance on these words holds significant dangers. The divergent routes taken in different jurisdictions in Europe based on the similar, albeit broader, concept of "relating to the subject matter of the invention" are a clear concern in this regard, as it appears to show that the further clarification provided by this option has been, at least to some degree, illusionary.

C4. Exemption for fair experimentation - copyright fair dealing analogy

The Patents Act be amended to establish an exemption for acts that constitute fair experimentation on an invention (analogous to fair dealing in copyright). 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.

Pros:

- courts are provided with guidance on which issues are relevant to the decision, resulting in less reliance on interpretation of specific words.

Cons:

- uncertainty due to flexibility.

ACIP Consideration:

This option has the advantage of enabling the law to evolve on a case by case basis according to the key practical issues. However, ACIP considers that the fair dealing considerations in the above form may provide insufficient guidance to the courts regarding <u>how</u> these issues should be considered.

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

Pros:

- provides some clarity on the acts listed;

- formulated in language the research community may be more comfortable with.

Cons:

- limited to those acts, not easy to modify;
- a wide variety of controversial uses may be considered to fall within the first and fourth dot points, e.g., phase 3 clinical trials;
- the language provides false comfort, as it will ultimately be interpreted by legal experts, not technologists.

ACIP Consideration:

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

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

Pros:

- provides courts with flexibility due to a more principles based approach;
- is formulated in language the research community may be more comfortable with.

Cons:

- uncertainty due to increased flexibility;
- a wide variety of controversial uses may be considered to fall within the first and fourth dot points (above), e.g. phase 3 clinical trials;
- the language may provide false comfort, as it will ultimately be interpreted by legal experts, not technologists.

ACIP Consideration:

This option is similar to C4, in that, although it appears to provide further clarification of the nature of the exclusion, it does so without the underlying principles being evident. Therefore the advantage of this option over option C1 appears dubious.

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

Pros:

- provides some clarity on the examples listed, however also provides courts with flexibility due to a key issues based approach;
- is partly formulated in language the research community may be more comfortable with.

Cons:

- some uncertainty due to flexibility;
- the language may provide false comfort, as it will ultimately be interpreted by legal experts, not technologists.

ACIP Consideration:

ACIP considers that many of the problems of options C4 and C6 can be overcome by combining these two options. This combined option outlines the key practical issues that must be considered, but it now also provides a grounding for these issues by detailing acts that would normally be considered exempt.

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

Pros:

- the interpretation of exact wording (e.g., "experiment", "on the subject matter", "dominant purpose") is left to the courts, allowing flexibility;
- also provides clarity on the acts listed. ;
- partly in harmony with European laws, therefore reducing some costs to exporters;
- is formulated in language the research community may be more comfortable with.

Cons:

- experimentation 'on' and 'with' an invention can often be intertwined and may not easily separated;
- the language may provide false comfort, as it will ultimately be interpreted by legal experts, not technologists.

ACIP Consideration:

ACIP considers that combining option C3 with C6 may overcome many of the problems with the practical meaning of "on the subject matter of the invention", as this phrase would be interpreted in light of the listed acts.

Option D – Introduce a provision relating to invention utility that subsequently allows experimental use

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-Amgen[4])

Purely experimental use of the invention would therefore not be within the scope of the claims, however some infringement may still occur as an unavoidable part of a predominantly experimental activity.

Pros:

- solves the root of the problem through a principle-based approach, i.e., patent rights should only extend to the contribution made by the inventor.

4 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

Cons:

- possibly not compliant with TRIPS and AUSFTA, such as the requirement that patents are made available for products *per se*;
- significant transition period while granted patents age to expiry;
- the consequences extend beyond experimental uses to other uses;
- large short term costs in such a major change to the system;
- may be difficult to ensure that scope of rights is actually limited to the disclosed utility, and not just encompasses the utility (e.g., the words "a product for").

ACIP Consideration

Although ACIP is attracted to the principled approach of this option, the large scale of the change to patent law and the potential breaching of TRIPS and the AUSFTA present major problems.

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

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).

Pros:

- principles-based, directed to the root of the issue;
- a less radical change to the rights of patent holders than option D1, as it comprises an exemption to rights rather than an inherent limitation.

Cons:

- possibly not compliant with TRIPS and AUSFTA, as for option D1.
- the consequences extend beyond experimental uses to other non-disclosed uses;
- involves considerable uncertainty as it depends more heavily on the courts' interpretation of both the claims and the utility disclosed in the specification;
- may severely limit the range of allowable experimental acts, depending on interpretation of "to a sufficient degree".

ACIP Consideration

Although not as fundamental a change as option D1, this option is also attractive as an approach to address the root of the issue. However, the resulting major change to patent law and the potential breaching of TRIPS and the AUSFTA appear to rule it out of further consideration.

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 may operate in conjunction with options A or B.

Pros:

- total transaction costs may be lower than individual licensing agreements;
- enables further research to be conducted by public, non-commercial organisations without the costs of continually monitoring patent activity;
- rewards and encourages primary and secondary innovation;
- reduces non-payment by researchers where infringement currently occurs

Cons:

- experimental use is not defined;
- secondary innovators must pay to experiment even if only "on" the patented invention;
- 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). Other users may still need to obtain other forms of licences.
- difficulties in determining what constitutes public non-commercial research;
- particular rights holders may receive lower royalties than they would obtain by direct license negotiations (might be reduced by allowing patentees to opt out);
- may be difficult to police, and to determine fair royalties;
- initial problems and costs of setting up collecting societies for patents;
- 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);
- 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.

ACIP Consideration:

ACIP believes that the introduction of a system of statutory licensing does not warrant further consideration as, at best, it would be only a partial solution, be very complex to establish and also could carry too great a risk of failure.

ACIP's Preferred Options

From consideration of the pros and cons of each option, ACIP is presently more inclined towards the following four options:

Option B No change.

Option C1 Modify the definition of exploitation to not include experimental use, without further defining the term.

Option C7 Exemption for fair experimentation with inclusive permitted uses.

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

ACIP would particularly welcome comments on these four options. However, ACIP is also open to consider further any of the other options should a sufficiently strong argument be made in their favour.

ACIP asks that submissions especially set out to address the following points:

- Are there any new arguments for and against each of the options?
- What is the likely effect of each option on particular sectors of the economy?
- What is the likely effect of each option on respondents' own particular business and research activities? (Please note that any information marked commercial-in-confidence that is received on this point, will not be made public by ACIP.)
- Is there any other or new empirical evidence available for the Australian environment?
- Which option(s) does the respondent prefer and for what reasons?

PART III CONSIDERATION OF SUBMISSIONS

Policy issues

General IP Principles

Article 7 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states:

> 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)[5] 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.
>
> On the other hand, intellectual property can allow the owners of the results of this effort to unduly restrict the diffusion and use of innovation, both to consumers and to other innovators including researchers. Additionally, while most intellectual property rights do not confer monopoly power, some may effectively do so in particular markets at particular times, 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."

Needs of basic research

Because the patent system is essentially justified as an economic/commercial instrument it has sometimes been argued that (non-commercial) basic/fundamental research is of a different nature to commercial research and so should not be subject to the patent system.

[5] Intellectual Property & Competition Review Final Report "Executive Summary" www.ipcr.gov.au

Merton[6] describes the four historic norms of basic research as universalism, openness/sharing, disinterestedness, and organized skepticism. However, as Merges[7] points out, these norms are normative and aspirational - and they are also subject to historic and cultural change. For example, Merges suggests the practice of asserting *informal* property rights over discoveries has always been practised though it appears to have become more prominent recently. There is now also the widespread practice of seeking *formal* property rights, particularly patents, over research results.

Merges also considers that contemporary arguments on formal intellectual property rights are almost always a matter of degree with few scientists seeing the debate in polar terms - as a simple choice between the total absence of property rights (or their equivalent) and the wholesale adoption of strong, formal property rights (in the form of patents). He believes that most researchers 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.

Standard taxonomies usually place the pursuit of fundamental knowledge and the solution of practical problems at opposite ends of a one dimensional spectrum from 'basic' to 'applied' research. Stokes[8], by placing the two objectives at right-angles, recognises that many scientists (typified by Pasteur) combine both objectives simultaneously:

		Considerations of use including commercialisation?	
		NO	YES
Quest for fundamental understanding?	YES	***Pure basic research (Bohr)***	***Use-inspired, basic research (Pasteur)***
	NO / SOMETIMES		***Applied research (Edison)***

For scientists conducting research within ‘‘Pasteur’s Quadrant’’ the objective is to achieve the fundamental understanding necessary to solve practical problems. This hybrid motivation characterizes much research in the biomedical sciences as well as in material science, computer science, and theoretical work in engineering.

Likewise at the organisational level, there has also been increasing overlap. Private industry has been a growing source of funds for academic research in these areas, and universities have been increasingly inclined to patent their discoveries. The other side of the coin is that corporate research and development (R&D) often involves the pursuit of fundamental knowledge. In fields where scientific advances have conspicuous commercial potential (such as pharmaceutical research), the pursuit of

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

[7] 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

[8] Donald E. Stokes *Pasteur’s Quadrant: Basic Science and Technological Innovation* (Washington, D.C.: Brookings, 1997).

profit and the pursuit of knowledge often converge, creating substantial overlap in research pursued in academic and industrial settings.

Submissions

Many submissions[9] 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 U Newcastle sub21)

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 Aust sub3).

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 sub34)

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 sub27

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,

[9] A list of submissions is at Appendix 1. Non-confidential submissions are also available at: www.acip.gov.au

> 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 sub17)

Biotechnology and medical sciences

A number of commentators have suggested that there are fundamental differences between earlier sciences/technologies and biotechnology - and even some sub-divisions within biotechnology - with regard to intellectual property. For example, Golod[10] suggests that there a number of significant differences between synthetic compounds, such as polymers and pharmaceuticals, and genes, particularly human. Firstly, the supply of genes are limited (probably to around 30,000 in the human genome) and no one person should monopolise such a limited resource. Secondly, it is relatively easier to avoid or 'invent around' a patent claim to a small molecule (drug) than with a broadly claimed DNA. Finally, many genes are also discovery tools because they encode receptors important in transconduction pathways.

Siva[11] also emphasises that one of the major differences between classical and biotechnological inventions is in the manner of describing each. 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 patent grant.

On the other hand, Bendekgey and Hamlet-Cox[12] 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

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

[11] N Siva *Legal Protection Of Human Biotechnology Inventions In Europe* BCL Dissertation Oxford University 2000

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

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. Bendekgey 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).

Submissions

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 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. The uniqueness of genes in combination with award broad patents.... inhibits the ability to develop alternative(s)....

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 sub8)

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

> 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 sub17)

On the other hand, the Department of Health and Ageing 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. (DH&A)

Another submission suggested the creation of a special (sui generis) right for genetic sequences (as were created for circuit layout rights and plant breeders rights):

> ...recently, in response to the continuing debate in the United States about the patenting of DNA, Professor Rebecca Eisenberg from the University of Michigan argued that the patent system was created for *'a bricks and mortar world'* that has inherent and logical limitations to the seemingly unlimited expansion of patentable subject matter. She suggested that *"[a]t some point, we may need intellectual property rights that permit the creators of information products to capture the value of the information itself in order to motivate socially valuable investments. But if we have arrived at that point, then we need to look beyond the patent system for a suitable model."*.
>
> My suggestion is for the creation of a genetic sequence right or GSR. A GSR is a non-exclusive right to the gene or genome first identified by the discoverer to have a specific function or that is shown to be the cause human illness or disease. The GSR once registered is freely available subject to the registration of any proposed use by an individual or entity with the central registry and to the payment of a set and scaled royalty by the user to the GSR holder..... Of course, it follows that with the creation of a GSR, isolated genes and genomes would be specifically excluded as patentable subject matter. (L. Palombi sub16)

Experimental Use

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. White[13] argues 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.

[13] Alan W. White, *Genes and Compound Per Se Claims: An Appropriate Reward?*, The CIPA Journal, February 2002, 89 & March 2002, 134, http://pharmalicensing.com/features/disp/1020380197_3cd1c4257bd3

Smith[14] suggests specific justifications for experimental use not constituting infringement is not hard to find, and would include one or more of the following reasons:

1. May be needed to further knowledge not fully explained in the patent specification
2. Promotes the development of new ideas and improvements of the patent and correspondingly reduces the likelihood of excessive monopolisation
3. Needed to test the validity of a patent
4. Needed to test whether a proposed product or process falls within the scope of a patent
5. Reduces transaction costs for researchers (patent searches, legal advice, licensing etc)
6. There is minimal interference with the patentee's relevant economic interests.

A similar list was provided by Canada in its arguments before the WTO in its dispute with the EU on the protection of pharmaceutical products[15]:

(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.

According to Eisenberg[16], 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. Eisenberg states “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. However, the Nuffield report suggests that the use of gene sequences as research tools may represent a special case.

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[14] Craig Smith *Experimental Use Exception to Patent Infringement - where does Australia stand?* Intellectual Property Forum June 2003

[15] World Trade Organization Panel Report *Canada - Patent protection of Pharmaceutical Products* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf p.75

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

Submissions

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 simulate 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 Inst sub24)

However, 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 sub28)

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 significant extent, strip patent owners of their right to control the use of their inventions. (Epitan sub20)

A similar view was put forward by GTG Technologies 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 as well as the adverse impact on innovation and on 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 Institute sub5)

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. (McBratney et al sub30)

ACIP considerations

General Principles

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 innovative the activity that occurs, the greater the potential gains to society. The correct balance between providing incentives to innovate and the diffusion of the benefits must be developed according to this general principle. Part of the framework for this is the quid pro quo rationale for patents, where the state awards exclusive rights in return for the disclosure of a new, useful product or process.

One way this balance is affected is the state granting broad patent rights that extend beyond the actual invention disclosed by the inventor. An example is granting rights to all uses of a new product, not just to those uses developed by the inventor and disclosed in the patent specification. Such broad rights may further increase the incentive to innovate in new, unpatented fields, because patent holders may stand to gain a market advantage much greater than the contribution they have directly made to society. To some extent, they could then become the gate keepers to further innovation within the scope of the 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. In this scenario, other innovators would have to obtain licences to experiment on the subject of the patent claims, and to use it in any new way they successfully invent.

Thus the result of such broad rights may be more primary innovation in entirely new areas free from patents, but less secondary innovation in those areas already subject to patents. On balance, ACIP considers broad rights that extend beyond the invention itself may provide a net cost to society, and so may not meet the objectives of the system. This is particularly true in Australia which is a net importer of IP and where much innovation is incremental.

An option that would permit experimentation and encourage secondary innovation is to ensure patent rights only extend to the contribution made to society by the inventor. An example is granting rights only to the use of a new product that is disclosed in the

specification, not to all uses of the product. Such rights would still provide the incentive to innovate in any field, because innovators would then be adequately protected for the advances they make. However all would be free to develop new uses and obtain the corresponding patents for these new uses, without having to obtain a licence from a patent owner. Under such a system it may be more difficult and costly to ensure that existing rights are not infringed because the crystal clarity that all uses of the product infringe would be lost, or that they are adequately compensated where infringement is unavoidable during the course of experimentation. Nonetheless, ACIP believes that, in principle, society should be able to obtain a net benefit through an increased level of secondary innovation. The option could be achieved by requiring the patent claims which define the scope of the exclusive rights to be limited by the utility disclosed in the specification. However, as discussed in the next section, it is uncertain whether such an option would be contrary to Australia's treaty obligations.

Basic Research

Although it has some sympathy with the view that basic, non-commercial research has some different requirements from applied commercial research, ACIP believes that the dividing line between the two has become blurred. It is therefore of the view that it would be difficult to build into patent law an experimental use exception based on this distinction.

Biological and Medical Sciences

Biological and medical sciences have undoubtedly thrown up new and important issues with which the patent system has to grapple. However, ACIP believes that such challenges have not been unknown in the past, most recently with computer software and business schemes, and that the patent system has managed to adapt to such challenges. While it accepts that the patent system has never been absolutely technologically neutral it believes that this has been largely confined to administrative matters and not to substantive patent law. Technological neutrality in patent law avoids problems of dividing lines between technologies that would be difficult to distinguish and maintain in a world where inventions are increasingly multi-disciplinary. ACIP is therefore of the view that technological neutrality should be maintained wherever possible in substantive patent law, such as in an experimental use exception. Technological neutrality is also required by Article 27.1 of TRIPS, as considered in the next section.

Experimental Use

According to the general principles outlined above, patent rights clearly should not extend to some experimental uses of an invention, where such cases are beyond the contribution made to society by the inventor. Patent holders should be adequately protected for the advance they have made and no more, while all innovators should be free to further develop the general field of a patented invention and so increase the benefits to society. The early disclosure required for the grant of a patent as part of the quid pro quo of the contract between society and patentees is to encourage further innovation. It also allows others to test the validity of a patent and its boundaries. Nevertheless, infringements occurring during the course of experimentation that do affect the legitimate interests of the patent holder must be adequately compensated.

The question is how these principles can be followed in practice – and what is the best option for doing so.

International Treaty Obligations

Background

Australia is a signatory to a number of international treaties on patents, and any developments on experimental use constituting infringement therefore have to be consistent with them. The one most likely to have a significant effect is the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

According to Article 27.1 of the TRIPS Agreement:

> 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 (i.e., are useful).

It is not clear whether this requires that patents must be available for claims to products *per* se, i.e., without restriction to a specific utility. For example, the report of the 2002 workshop of the OECD Working Party on Biotechnology states:

> Confining the scope of…patent product claims to their use for a particular purpose…, many experts consider, would probably conflict with the WTO TRIPS Agreement…Article 27(1). However, the interpretation of TRIPS Article 27(1) is not settled. ..... [a] patent office may choose or be asked to apply stricter guidelines when interpreting whether an invention is novel, useful or represents an inventive step. The revised USPTO guidelines, for example, specify that utility in the case of genetic inventions has to be "specific and credible"[17].

Article 28 provides that:

> 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 provides that:

> 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.

As with many of the Articles in TRIPS, the precise scope of these articles is being developed through the dispute resolution procedures under the WTO. In the dispute between Canada and the EU over stock-piling of pharmaceutical products by generic manufacturers prior to the expiry of patent protection[18], Canada conceded that its

[17] *Genetic Inventions, Intellectual Property Rights and Licensing Practices – Evidence and Policies*, OECD Working Party on Biotechnology, January 2002.

[18] World Trade Organization Panel Report *Canada - Patent protection of Pharmaceutical Products* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf

stock-piling provision would be a violation of Article 28.1. However, it was accepted that Article 30 should be read in conjunction with other articles of the treaty, such as Article 7 that states IP rights should "contribute to the mutual advantage of producers and users of technology in a manner conductive to social and economic welfare, and to a balance of rights and obligations".

Although both Canada and the EU in their WTO dispute presented arguments suggesting an experimental use exemption, to differing extents, was a consequence of the balance of the patent system, including the disclosure requirement, these arguments were not explicitly considered by the panel in its ruling on this dispute. However, according to one commentator, it seems clear from the drafting history of TRIPS that an act performed for experimental purposes was intended to be one of the exceptions allowable under Art. 30[19].

The USFTA largely reiterates the TRIPS provisions in this particular area of patent law. However, the USFTA 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.

Submissions

At least partly because the USFTA was still being negotiated during the submission and consultation process to the Issues Paper of this inquiry, most submissions thought that TRIPS and particularly Art. 30 was the main treaty obligation relating to experimental use:

> In the light of the Canada WTO decision.....depending on the scope of the EUE, there should be a strong argument that it is as Article 30 limited exception. (MaynePharma sub12)

[19] http://www.gtz.de/biotech/dokumente/ipr/docs/P2trips.doc

One submission also invoked the parallel with copyright law:

> The international agreement that is most likely to cause problems is the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). As noted in the Issues Paper, Article 30 is the most important provision in TRIPS in relation to the experimental use exemption, because it allows for limited exceptions to the patent holder's exclusive rights ..... 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 sub17).

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

> 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 sub18)

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

> It is difficult to imagine a situation where the experimental use of an invention that has the effect or end result of a) destroying the validity of first patent, b) avoiding infringement of the first patent or c) improving upon the first patent, would not i) *'unreasonably conflict with a normal exploitation of the invention'* or ii) *''unreasonably prejudice the legitimate interests of the patent owner.'* (L. Palombi sub16)

and

> ....., 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.
>
> (Epitan sub20)

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

ACIP considerations

In considering whether experimental use is an inherent result of the *quid pro quo* of the patent contract, whereby the patent grant should be limited to the contribution that has been directly made to society, ACIP is mindful of a long-held, standard international practice across all technologies to grant patent claims for all uses of a new product, and not to limit the scope of product claims to those uses developed by the inventor and disclosed in the patent specification. It is not entirely certain whether such a practice is fully embodied in TRIPS, given the limited definitive judgments by WTO dispute tribunals. However it is accepted that any approach to experimental use based on limiting the scope of patent claims to uses explicitly described in the specification (so that all other uses would be new and 'experimental') may carry risks of violating TRIPS, particularly Article 27.1

On the other hand, ACIP considers that TRIPS does not preclude experimental use being made to not constitute infringement in some other way. Because two of the

main negotiators of TRIPS, the United States and the European Union, each had experimental use exceptions, albeit in different forms, ACIP agrees that an experimental use exception would most likely have been one of the exceptions implicitly allowed under Article 30. It also agrees with the arguments of both Canada and the EU in their WTO dispute that an experimental use exception is a consequence of the balance of the patent system as enshrined in Article 7 of TRIPS.

As far as ACIP can ascertain, the USFTA adds no further restrictions on an allowable experimental use exemption. Its Article 17.9(7) appears to be related to compulsory/ statutory licensing and not experimental use per se.

Australian law

Background

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 also sought the advice of the Australian Government Solicitor (AGS) 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.[20]

[20] 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* has not been applied by an Australian court.[21] 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.[22]

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.[23]

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.[24]

Submissions

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 sub25)

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, the Walter and Eliza Institute stated:

> 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.

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21 However, we note that, in a decision under reg 3.25(1) of the *Patents Regulations 1991*, a delegate of the Commissioner for Patents assumed that the principle in *Frearson v Loe* applies in Australia (see *New York University v Nissin Molecular Biology Institute, Inc* (1994) AIPC 91-069). In that case, 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' (at 33,330).

22 At page 5.

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

24 House of Representatives, 10 October 1990 at 2565.

Some public researchers were more cautious, 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 sub6)

Others stated that the law in Australia was uncertain:

> Some speculate that such a defence can be inferred from old English case law..... Others argue that an implies experimental use defence may exist in Australian law, as it does in other common law jurisdictions .....Despite a (widespread) assumption that the experimental use exception applies in Australia, the evidence that Australian law recognizes research use as a defence is equivocal. This uncertainty in the law has implications for all relevant actors, including researchers. (ACIPA sub18)

However, some researchers, particularly private sector ones, expressed more definite views on the state of the law and said it was already affecting their behaviour. For example, one company said in a confidential submission that it was their understanding that preclinical and clinical trials were not exempt from patent infringement and was forcing them to consider taking certain of these activities off-shore.

The Law Council of Australia summed up the current situation thus:

> There is no court decision in Australia which establishes that there is an experimental use exception as part of patent law. Absent of such a decision there are reasonable arguments both ways as to whether such an exception is part of the common law applicable in Australia. That position is unsatisfactory whether considered from the position of patentees or third parties.

ACIP considerations

In weighing up these opinions and submissions, ACIP considers that it is currently uncertain which experimental uses of a patented invention might constitute infringement of the patent under existing Australian law. ACIP believes that some uses probably don't constitute infringement of a patent under current law, but this may depend heavily on the interpretation of the law by the courts in each case.

Although absolute clarity in law is an unrealistic goal, ACIP is sympathetic to the view that the current level of uncertainty on experimental use is unsatisfactory for all sides in the patent system and so may well be detrimental to innovation in Australia.

If a mechanism were introduced to ensure experimental use did not constitute infringement, it appears that this would be in sympathy with the objectives of the current Act.

Empirical Evidence

Background

ACIP is especially interested in receiving further *empirical* evidence that the general balance between the incentives for innovation and the ability to use innovations, particularly for research and development, is being significantly affected by the lack of clarity in Australian patent law on whether experimental use constitutes infringement.

Of particular interest is the issue of cumulative innovation. Whether pure, applied or hybrid, or whatever the field of technology, the essence of science is cumulative. The notion of "cumulative innovation," each discovery building on many previous findings, is central to the scientific method. Some academic observers are increasingly expressing concerns that the current patent system may, in fact, 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 actually commercialise new technology.

Submissions

Most evidence was declaratory, anecdotal or personal. Most submissions stated that there was not currently a major issue in Australia, though 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 USyd sub29)

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. (Go8 sub7)

However, one confidential submission stated that it was a significant issue for them and 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 who have enacted Bolar provisions (from *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc* - see US law below).

In the only systematic empirical study in Australia, by Nicols and Nielsen on the biotechnology industry, the authors 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 sub17)

On the specific issues of patent 'thicket' or 'anti-commons' a number of university research or IP administrators stated that they were not aware of any evidence of any problem in their institutions:

> I do not believe that academics actually consider whether their research is infringing a patent. I thus cannot see any indication that a "patent thicket" is a concern to academic researchers. (Soozy Smith U Newcastle sub21)

and

> Not in our experience. Universities have for a long time been involved in trying to unravel rights to IP ownership and issues of freedom to operate and these are generally solvable issues at the research level because there is goodwill and the desire to achieve a solution. However, this is not to say that there is not concern by researchers regarding the possibility that their research might be curtailed and is reason why clarification on this matter is required. (Georgia Sherry U Adelaide sub34)

This was also confirmed by Nicol and Nielsen's study of the biotechnology industry:

> 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 sub17)

One submission referred to overseas empirical evidence:

> 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 (US). 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 blocke*d."
>
> 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..... (McBratney et al sub30)

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 Australian scientists that the research is legally protected from patent infringement actions or that infringement action would not be taken (by patentees). (DH&A sub40)

ACIP considerations

Although there may be inefficiencies due to a lack of clarity in Australian law on whether experimental use constitutes infringement, there is no strong empirical evidence that this is currently affecting the general balance between the incentives for innovation and the ability to use innovations, particularly for research and development. This may be partly due the finding that many researchers seem to be relatively unaware of or are ignoring patent rights as well as to some form of current Australian industry convention of not pursuing possible infringement for experimental purposes.

There also appears to be no strong empirical evidence in Australia of any form of patent 'thicket' affecting cumulative innovation.

Nevertheless, the potential exists for this situation to change appreciably over time, either due to the introduction of more aggressive IP practices, or to new case law narrowing or eliminating any experimental use, e.g., following United States experience.

ACIP is inclined to the view that, given the cumulative nature of innovation, such changes could have an impact, and significantly discourage overall innovation and investment in Australia. Therefore, it believes that methods of allowing some form of experimental use should be considered. However, ACIP is also mindful of the legitimate rights of the patent holder, including the right to own patent portfolios.

Overseas Experience

Background

Rather than ‘re-invent the wheel' it seems most sensible to first see what can be learnt from other countries. As a recent OECD working paper emphasises in relation to experimental use:[25]:

> ..... 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.

In addition adoption of best, or at least harmonized, practice would mean that Australian companies would not be at a disadvantage relative to their overseas competitors in our major trading partners.

USA

The "experimental use exception" does not have direct statutory basis in the US. The origin of the experimental use defence there is linked to 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 was confirmed in *Madey v Duke (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 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." Despite some early evidence that it might do so, including asking for an *Amicus curiae* from the U.S. Solicitor General, the US Supreme Court decided not to review the CAFC *Madey* decision which therefore remains current US law.

Recently Wegner[26] has suggested that the cardinal mistake of recent US court decisions, including *Roche* and *Madey*, denying a broad interpretation of the experimental use exception has been to interpret "philosophical" as its current meaning – and not as the term was used in the nineteenth century as used by Justice

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

[26] Harold C Wegner *The Post-Madey Research Exemption* http://www.foley.com/people/bio.aspx?employeeid=16338&&practiceID=&industryID=&genPageID=

Story when it meant "scientific" and so included any experimentation on (but not with) the invention.

The *Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc* decision did, however, lead to the US Congress to enact the Hatch-Waxman Act specifically allowing for the case of experimental testing of a generic drug before the expiry of a patent on the original drug. In addition, it allowed for the extension of the patent term to compensate for the time testing of the original drug for FDA approval. The provisions of the Act were therefore designed to balance each other - the original patent holder is given an extension of term to compensate for FDA approval while the generic manufacturer can test and gain FDA for their generic drug so that it can launched immediately after the extended term expires (though some details of the legislation means that this does not always occur in practice).[27]

Japan

Under Japanese Patent law, Section 69.1 provides that patent rights shall not extend into experiment or research. 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.

EU

Most European national patent laws contain clauses similar to Art. 11.2 of the present German Patent Act (in force since 1981), which in translation reads:

> *"The rights conferred by the Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention."*

A similar provision can be found in Art. 9 of the Draft Council Regulation on the Community Patent 1 of August 1, 2000, which will be the basis of the forthcoming Community Patent.

Most of the case law on "experimental purposes" in European countries, and particularly in Germany, has been developed on the basis of pharmaceuticals particularly whether during the duration (period of protection) of a pharmaceutical patent, pre-clinical and/or clinical tests may be conducted. The situation in Germany is very liberal in allowing such tests. In most EU countries, including the United Kingdom (see below), clinical trials are regarded as patent infringement.

In all other technical fields, Goddar states that the experimental use exception has not caused any problems in case law in Europe. As long as tests/experiments are directed

[27] Sara E Eurek *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?* http://www.law.duke.edu/journals/dltr/articles/2003dltr0018.html

toward better understanding the content of a patent, or toward doing further research with regard to the invention, no essential problems have ever been observed.[28]

UK

Although UK law is now aligned with EU law, it is worth considering UK law in more detail because of the precedence-setting that UK courts have had for Australian courts in the past.

The relevant statutory source in the United Kingdom is the Patents Act 1977 (as amended) where section 60 states:

> 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 mater of the invention.

Fysh[29] (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*[30] and *McDonald v Graham*[31].

The UK courts have also tried to decide what is meant by "experiment/experimental". In *Monsanto*[32] 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 *SF&F v Evans*[33] 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".

It is noted that a study of UK biotechnology industry and public research sector recently released by the Department of Trade and Industry[34] states “there is evident uncertainty ... about the extent of the patent research exemption, which is widely seen

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[28] Heinz Goddar *The Experimental Use Exception: A European Perspective* www.law.washington.edu/casrip/Symposium/ Number7/1-Goddar.pdf

[29] Michael Fysh QC, SC *Legal Issues in Exploiting Drug Patents in Europe* LES-Italy Conference, Milan, 2002

[30] SK&F v Evans [1989] FSR 513

[31] McDonald v Graham [1994] RPC 515 (CA)

[32] Monsanto v Stauffer [1985] RPC 15 (CA)

[33] SF&F v Evans [1989] FSR 513

[34] Patents for genetic sequences: the competitiveness of current UK law (May 2004) http://www.dti.gov.uk

as problematic". The study concludes that more investigation of the problem is needed in the UK.

New Zealand

New Zealand's 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.

Submissions

Many submissions thought that the US situation post-*Madey* was too narrow. For example:

ACIPA invoked the recent US Federal Trade Commission report[35] on the patent system and competition to argue:

> The Federal Trade Commission was critical of the decision of the Federal Court in *Madey* v *Duke University* in its recent report.....In its workshops, the Federal Trade Commission considered three scenarios in relation to the scope of the research exemption. One involved research on a patented invention to see how or if it works. Panellists generally supported a research exemption for this purpose. A second scenario involved research to improve a patented invention, either creating a blocking situation (in which both the initial and the follow-on innovator need licenses to use the other's invention) or designing around the initial patent. Panellists expressed a range of views – from support through uncertainty and doubt – whether this research should be exempted. Third, there is the possibility of using a patented item as a research tool to create an unrelated product. Panellists generally voiced objections to exempting patented items produced for use by researchers. (ACIPA sub18)

Most thought that the "commercial" purpose test used in *Madey* was a major problem:

> The trouble with 'commercial' purpose or outcome being used as the boundary of experimental use is that it is excepted 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 sub1)

[35] Federal Trade Commission *To promote innovation: the proper balance of competition and patent law and policy* October 2003 http://www.ftc.gov/os/2003/10/innovationrpt.pdf

However, some submissions supported a commercial test as used in the NZ *Smith Kleine* 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 sub39).

The European Union statute approach was supported by a number of submissions, such as:

> 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)

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 patent owner still gets benefit and, no doubt, a share of new invention that must utilise the original work patented. (Colin Cole CQU sub22)

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 of Lardas & Parry sub14)

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 sub17)

Finally, some said overseas experience showed that any statutory exemption would be ineffectual:

> Members consulted suggested that of the jurisdictions that have adopted an experimental use exemption, it has largely been ineffectual. Due to difficulties experienced by the exemption in other jurisdictions, consulted Members suggested that government should only proceed .....if a provision could be crafted that would clear up the current ambiguities about what researchers can and cannot do ..... and if that provision did not introduce further ambiguity and uncertainty .... the use of an exemption should be carefully examined at the international level, because of the complexity of the issue and the desirability of having greater international harmonisation (AusBiotech sub41).

On the other hand, one submission suggested an experimental use exception may still be worthwhile despite these difficulties:

> A research use exemption applies in the United Kingdom (UK) and a number of other jurisdictions, and a research use defence applies in the United States (US). Both have been interpreted very narrowly by courts for the same reasons as suggested above, that is, courts are generally reluctant to derogate from a patentee's rights.
>
> Where a statutory exemption exists, this judicial caution not only limits the effectiveness of the exemption for the researcher in the case at hand, but the body of precedent that is thereby built up has an impact on how the terms of the legislation are interpreted in future. The statutory exemption itself then becomes riddled with common law exceptions and qualifications and it is effectively plagued with the very problems of ambiguity or ineffectiveness that it was designed to overcome..... In the UK, such doubts are amply demonstrated by the conflicting views of Mr Michael Fysh QC (as discussed in the ACIP Issues Paper) and the Chartered Institute of Patent Attorneys (CIPA), and by conflicting case law……
>
> In light of the number and nature of problems associated with introducing a statutory experimental use exemption, we previously submitted to the ALRC that it would be better to focus on the issue of reforming the compulsory licensing system. However, on discussing the matter further, we believe that if an appropriate exemption could be crafted, it would remove a significant ambiguity in Australian patent law (McMcBratney et al sub30)

ACIP considerations

Although, in the interests of simplicity and harmonisation of IP laws, there is a strong case for adopting a solution similar to one that already exists overseas, ACIP has come to believe that this should not be an over-riding consideration if this solution, in some aspects, may not be in the overall best interest of Australian society.

ACIP considers that the current US approach should be avoided, as this reduces allowable experimental use to an extremely narrow set of circumstances with little usefulness in the real world.

While the European solution based on the "on/with" distinction has considerable (in principle) merit, ACIP believes that it is not without problems in practice, as shown by the German Supreme Court's 'Clinical Trials' decision.

Part of the problem is that the decision of whether an experiment is "on" or "with" the invention in particular technologies such as genetics appears to be an especially difficult matter. Another problem appears to be in trying to determine how far experimenting on an invention may be carried out before it causes undue harm to the patent holder's legitimate interests. For example, in the case of pharmaceuticals, how

far can a patent holder's competitor go in conducting clinical trials on a pharmaceutical product to determine its properties, limitations, etc., before the patent holder's market interests are unreasonably harmed? It suggests that, if adopted, the European 'on/with' approach may have to be supplemented by other test(s).

Mechanisms Available

In regard to patents, possible ways of affecting the balance between providing an incentive to innovate and in diffusing the results of the invention can be divided into two categories - (1) those *pre-grant* conditions that impact on the number and nature of patents granted and (2) those *post-grant* conditions that affect the rights of the patentee once the patent has been obtained. Each of these categories has a number of possibilities for affecting the balance:

1. Pre-grant

(a) patentable subject matter e.g. excluding treatment of human beings, laws of nature etc

(b) criteria affecting the breadth of the right (claims) - non-obviousness, utility, fair basis etc

2. Post-grant

(a) exempt particular uses from infringement, e.g., treatment of humans or modify definition of exploit

(b) an experimental use exemption or preclusion

(c) compulsory or statutory licensing

(d) other licensing practices such as patent pooling, crown use etc

(e) alternative access arrangements such as open source/public domain mechanisms.

Pre-grant Mechanisms

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 has strengthened the pre-grant criteria to bring them into line with international best practice. This included:

- increasing stringency for the inventive step test by both extending the prior art base to include all relevant information anywhere in the world and the ability to combine documents, as would be considered reasonable by a person skilled in the art.
- ensuring that examination of a patent application covers all aspects of use being specific, substantial and credible.

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 two reviews recognised that the effective quality of granted patents and the costs and benefits of the patent system depends on how the grant criteria (threshold tests) are actually applied during examination. They made a number of recommendations for improvement of quality of examination before acceptance including replacing the case law requirement that the applicant be given the benefit of the doubt during examination by a statutory requirement that a balance of probabilities test be applied by examiners to the novelty and inventive step criteria for patent grant.

Post-grant Mechanisms

Modify definition of exploit

The current Patents Act 1990 defines the rights of the patent owner in s13 as "to exploit the invention or to authorise another person to exploit the invention" where 'exploit' is defined very broadly in schedule 1 as:

> '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.

One possible way of modifying this might be limit the definition to only exploitative activities which have a direct commercial outcome. Then activities by others such as those experimentations which do not directly infringe the commercial interests of the patent holder might be excluded from the definition.

As stated by the AGS opinion quoted earlier, there is some evidence from overseas case law such as *Frearson v Loe* and from Australian case law on the 1952 Patent Act as well as from Explanatory memoranda and Second Reading speeches on the 1990 Patent Act that the term 'exploit' would be probably interpreted by the courts to have largely commercial connotations and so might allow some experimental uses. However, the AGS opinion also notes:

> Given the uncertainty as to the potential ambit of the exception, and the potential difficulty in determining when a particular activity will fall within that exception, it may be preferable to amend the Act to make specific provision in relation to this issue

Exemption or Preclusion

If an explicit experimental use exemption (or even a preclusion) is to be adopted in Australian legislation then a significant issue for clarifying the law would be deciding what would and would not constitute "experimental use".

One possible criterion is the European approach based on the distinction between experimenting *on the invention itself* as opposed to experimenting *with* the invention *for its intended purpose*.

An alternative criterion coming out of the TRIPS treaty might be based on whether the economic interests of the patent owner were adversely affected.

According to Smith[36], the criteria might also need to consider in detail:

1. Whether the experiments have a commercial purpose and what is meant by this (is privately funded pure research commercial)
2. What relationship must exist between the experiments and the patented invention
3. Whether commercial availability of the patented invention is relevant

[36] Craig Smith *Experimental Use Exception to Patent Infringement - where does Australia stand?* Intellectual Property Forum June 2003

4. Whether research must be the single or dominant purpose, or merely a purpose
5. Whether experimentation by a contracted third party comes within the exception
6. Whether associated activities (e.g., importation of a product for experimentation) fall within the exception.

Copyright Analogies – fair use and fair dealing

As made explicit by the IPCR report, the fundamental goal of most types of intellectual property, including patents and copyright, 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 is allowed as a limitation on the rights of copyright owners. In the current Act there are four "fair dealing" purposes:

- research or study (ss. 40 and 103C);
- criticism or review (ss. 41 and 103A);
- reporting of news (ss. 42 and 103B); and
- professional advice given by a legal practitioner or patent attorney (s. 43(2)).

The most commonly used aspect of fair dealing relates to the provisions regarding 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, s. 40(2) states that 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 adaptation.

Similar provisions exist in the USA under the concept of "fair use" which was first introduced into their statutes in 1976, codifying previous case law. Grossman[37] states that the "fair use" doctrine is a means of balancing the exclusive rights of the copyright holder with the public interest in the dissemination and use of information. O'Rourke[38] has raised similar issues again recently, arguing 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.

[37] Steven J Grossman *Experimental Use or Fair use as a Defense to Patent Infringement* IDEA 1990

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

Improved licensing practices

Idris[39] states that "the primary business of universities is teaching and research, but to the extent that the rich intellectual activity of universities and research centers is also applied to the solution of practical problems, this supports and feeds the cycle of creation and economic development". However, despite some notable success stories, Idris concludes that this potential is generally not being realised, often due to sub-optimal patenting and licensing practices by research organisations.

Nicol and Nielsen[40] recently found that, although there is significant licensing activity within the 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. "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."

Compulsory licensing

The Australian *Patents Act 1990* already 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". However, there has been only one reported application to the Federal Court for a compulsory license and that was rejected.

Compulsory licensing was examined by the IPCR committee[41] which recommended replacement of the current public policy test by a competition test. However, the Government's response was to add the competition test onto the public policy test in an attempt to gain the best of both worlds. This has yet to be enacted.

A survey of international intellectual property law by Julian-Arnold[42] revealed that the three most prevalent compulsory licensing provisions are where a dependent patent is being blocked, where a patent is not being worked, or where an invention relates to food or medicine. Additionally, compulsory licensing may be implemented as a remedy in antitrust or misuse situations, where the invention is important to national defence or where the entity acquiring the compulsory license is the sovereign (crown use).

From the patent owner's point of view, compulsory licenses appear inconsistent with the grant of a patent which is the grant of a right to (temporarily) exclude. However, the IPCR found that experience in other jurisdictions, most notably the United States and Canada, can lead to more efficient outcomes without harming the long-term incentives to innovate.

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[39] Kamil Idris *Intellectual Property - a power tool for economic growth* WIPO Publication 2002

[40] Dianne Nicol and Jane Nielsen *Patents and Medical Biotechnology: an Emperical 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)

[41] Intellectual Property & Competition Review p. 163-4 www.ipcr.gov.au.

[42] Gianna Julian-Arnold *International Compulsory Licensing: the rationales and the reality* IDEA 1993

Statutory licenses

Unlike the Patents Act, the Copyright Act has no compulsory licensing provisions. However, there is 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. In this sense, they are like compulsory licensing under the Patents Act but the scope of the statutory copyright licenses is limited and importantly they do no apply to most commercial uses[43]. 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 use/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.

Communal licensing - patent pools and collecting societies

Heller & Eisenberg[44] suggest in theory people can always avoid blockages to research and development by the efficient trading of their rights. In practice, however, avoiding blockages requires overcoming transaction costs, strategic behaviors, and cognitive biases of participants. According to Heller and Eisenberg, recent empirical literature suggests that communities of intellectual property owners who deal with each other on a recurring basis have sometimes developed institutions to reduce transaction costs of bundling multiple licenses.

For example, in the music industry, copyright collecting societies have evolved 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.[45]

Similarly, in manufacturing industries, patent pools have emerged at various times in the past in the US, sometimes with the help of government, when licenses under multiple patent rights have been necessary to develop important new products, recently in semi-conductor, DVD and MPEG technologies. Nowadays competition authorities put stringent conditions on such patent pools.

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

[43] Intellectual Property & Competition Review p. 117 www.ipcr.gov.au

[44] Michael A. Heller and Rebecca S. Eisenberg *Can Patents Deter Innovation? The Anticommons in Biomedical Research* Science Vol. 280 1 May 1998 p. 698

[45] Intellectual Property & Competition Review p. 118-9 www.ipcr.gov.au

Potential criticisms include:

- patent pools inflating the costs over competitively priced goods by encouraging collusion and price fixing that may attract anti-competition considerations.
- pools shielding invalid patents.

Open source/public domain mechanisms

Some have suggested that, given that public sector research is already paid for in the public good so there is no need for patent incentives and the knowledge should go straight to the public domain. In addition, as mentioned earlier, it has been consistently found that the money generated by patent licensing represents only a very small fraction of public sector research organisation's total budgets, even in the most patent intensive US universities.

One model for public domain access is open source software. The Royal Society[46] 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 (e.g. 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 authors have suggested patenting with royalty-free licensing as a solution to these problems, though who should bear the costs of patenting is not clear.

Open source has also become more prevalent in bioinformatics both for commercial and non-commercial laboratories. For example, Laird[47] 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. "

[46] Royal Society *Keeping Science Open* p.8 www.royalsoc.ac.uk/files/statfiles/document-221.pdf

[47] Laird *Open source projects* http://www-106.ibm.com/developerworks/linux/library/l-osbio.html

Submissions

Pre-grant Mechanisms

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 sub25)

and

> In our client's submission these amendments to the patent system represented the appropriate measures aimed at ensuring that access to patented technology is not improperly withheld from the public, and that further measures, particularly those which restrict the rights conferred by patents, are unnecessary and would be unfairly prejudicial to patent owners. (Epitan sub20)

Others believed that there was still need for changes to pre-grant conditions:

> We consider that the threshold test for acceptance, novelty, and inventive step criteria have been sufficiently reformed and will act to prevent unmeritorious inventions from registration. However, the criteria of utility, sufficiency and fair basis require varying levels of reform before they will contribute in the same manner. (McBratney et al sub30)

Another suggested that even novelty and inventive step were still problematic:

> There are arguments for the consideration of pre-grant considerations for patents as a complement to an experimental use exemption under Australian law. There remain problems with the application of patent criteria of novelty, inventive step and utility as highlighted by the *Alphapharm* case..... In his dissenting judgement.....Justice Kirby maintains....."From time to time, specialist lawyers need to be brought back to such basic principles. Otherwise, they may take possession of provisions enacted by the Parliament and read them with spectacles focussed only on the glosses of decisional history..... (ACIPA sub18)

Other submissions emphasised the particular problems relating to genetic technologies:

> Health (DH&A) 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.....
>
> The ALRC included a proposal, supported by Health, that ACIP inquire into ... the 'manner of manufacture' test as the threshold requirement of patentable subject matter. Health also proposed the strengthening of the inventive step criterion and that the current assessment of usefulness be clarified and strengthened. (DH&A sub40)

Post-grant Mechanisms

Definition of exploit

One submission felt that the current definition of ‘exploit’ in the Patents Act 1990 would allow experimental use which does not affect the commercial interests of the patent holder and so no change to the law was required:

> Experimental use is not an infringement in Australia because such a use does not fall within the definition of 'exploit'.....which has a clear commercial flavour. Any commercial

> exploitation of the result of research ...does fall within the definition and is therefore actionable. A change in this situation would give university commercialisation an unfair advantage akin to the springboard doctrine situation. Australian law is a combination of statute and precedent. Codification has rarely led to improved clarity compared to precedent. (Mark Horsburgh Fisher Adams Kelly sub19)

Another submission agreed that the definition probably did allow for experimental use but believed that an explicit experimental use exemption was still desirable:

> .....in our view, the definition of "exploit" under the Patents Act is most likely broad enough to encompass 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". Further, the case law on what "exploit" means has incorporated some reference to whether or not there is a commercial purpose, which we think is a concept that should be avoided when defining an EUE (experimental use exemption). (MaynePharma sub12)

However, another submission felt that most research would be infringing and so an explicit experimental exemption was definitely required:

> 'Use', on any dictionary meaning, by a salaried research scientist whilst at work for an institution in the business of making money must surely be within the concept of exploit even if the aim were peer review and professional advancement. No one is likely to want to test this implied exception. The proposed express defences would provide the certainty necessary for scientists (if not lawyers) who want to get on with doing science. (Ian Turnbull sub36)

Experimental Use Exclusion

Many submissions thought that the European criterion based on the 'on/with' distinction was a good starting point for clearly delineating an experimental use exemption:

> It is important for the exemption to fall somewhere between the two extremes, i.e. between a situation where there is no exemption for any type of experiment, and a situation where every experiment is exempt. In the former case patents could unduly inhibit legitimate research, while in the latter case patents directed towards important tools used in research would be unenforceable. It is also important for exemption to be framed in a way which furthers Australia's goals in connection with international patent law harmonisation.
>
> ..... 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 sub25)

However, some submissions doubted that the distinction would be adequate in itself, particularly in the biotechnology and pharmaceutical fields:

> The criterion based upon whether the experimentation is *on* the invention itself as opposed to experimenting *with* an invention .....may be useful in determining experimental use but it is unlikely to be sufficient of itself.....The main issue for AusBiotech members is the drafting terminology in regards to clinical trials, such as, the differences between the experimental and clinical trial stages.....A standard Operating Procedure (SOP) may be a parameter to assist in defining the difference between an experiment and non-experimental or commercial usage. That is, if the technique is used 1-3 times, it could be classified as experimental. If the procedure is carried out many times through something like a clinical

> trial, then that would be considered as use of the technology for a process rather than an experimental use.....(AusBiotech sub41)

Similarly 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 o*n* 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. (DH&A sub30)

In a supplementary submission the DH&A suggested possible solutions to the problem:

> We envisage that the mechanism for dealing with this would ideally be a section which made the 'on/with' distinction and referred to regulations which included some circumstances in which research using a new technology could be regarded as being research 'on' the invention. The regulations would need to have a reasonable level of detail but not so much that it would require updating too often.....Other possibilities include the Commissioner making a determination about what qualifies as research 'on' or simple guidelines with no legislative force. The problem with the determination is that there could be appeals ..... and with respect to the guidelines they are not binding. ..... (however) The potential uncertainties associated with defining a research exemption would be less of a problem than the existing uncertainty for researchers ..... (and) These uncertainties may be resolved over time by judicial decisions. (DH&A supplementary sub)

Some submissions, however, suggested that these problems with the on/with distinction were sufficient to invalidate its use as an experimental use criterion:

> Although both Clinical Trials I in Germany and the SKF case in England tried to use the "research into the invention" rather than "research using the invention" test to (draw a distinction between a situation that will effectively destroy the value of the invention to the original inventor and where experiments do not have this effect, for example ..... to improve on it or designing around it) the problems that the German Supreme Court experienced may indicate that the "into the invention" rather than "of the invention" distinction may not be the best way to achieve the objective. (John Richards of Ladas & Parry USA sub14)

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 U Newcastle sub21)

One attorney from the USA suggested that some details of their criteria for fair use in copyright law might be useful tests for patent law:

> 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. They are:
>
> (a) the purpose and character of the use, including whether such a use is of commercial nature or is for nonprofit educational purposes;
>
> (b) the nature of the copyright work; and
>
> (c) the effect of the use upon the potential market for or upon the value of the copyright work.
>
> Substitution of the words "patented invention" for "copyright work" in this test would cover most of the issues that would need to be considered when making an assessment of what should be permitted and, if it is felt desirable to provide for compensation to the owner of the patents for the experiments carried out the basis on which such compensation should be awarded. (John Richards Lardas & Parry USA sub14)

However, IPTA criticised this approach because it would lead to lack of clarity and certainty:

> 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 sub25

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 sub17)

Similarly:

> We accept that there are some similarities between copyright and patent law..... As noted in the ACIP Issues Paper, one must acknowledge that both copyright and patent laws aim to encourage creativity and innovation by allowing creators to capture the fruits of their efforts without others' free-riding .....However, ... they achieve their aim of acting as an incentive to further creation or innovation in very different ways.....
>
> 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. This is obviously a very large deterrent to patentees aggressively litigating to enforce their patent rights. ..... Thus the strength of patent protection is tempered not only by the criteria for patentability, but also the formal processes required to obtain protection, the costs of maintaining registration, the shorter patent duration, its vulnerable nature, and the tests for and dangers of enforcement.....
>
> 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. (McBratney et al sub30)

Most submissions agreed that, post *Madey* in the US, the commercial intent or not of the experimentation was not a good criterion for an exemption:

> Attempting to draw a distinction on whether or not there are commercial overtones to use is (also) fraught with difficulty because, as Madey v. Duke made clear, almost everything can have a commercial overtone. (John Richards of Ladas & Parry USA sub14)

However, one submission thought a general exemption for experimenting <u>on</u> the invention, irrespective of commercial intent or not, should be supplemented by an exemption for both experimenting <u>on and with</u> the invention if the purpose was non-commercial (basic) research:

> We believe that the two components to the exemption are justified for a number of reasons. The research on exemption is justified because this is a logical extension of the disclosure requirement (people should be allowed to test the validity of the patent and the adequacy of the disclosure) and the incentive goal of the patent system (people should be allowed to improve on the patented invention). The non-commercial research exemption is justified on the basis that the patent grant only allows the holder to exclude others from exploitation. (Nicol/Nielson sub17)

On the other hand, one submission stated that public sector (non-commercial) research should not get special treatment:

> Markets for intellectual property should be regulated to allow competition and promote commercial activity. From my understanding of the present situation this is reasonably achieved by the current legislation. I do not support any change which provides legislative exemption from existing intellectual property rights for universities or CRCs who claim that they are acting in a manner differing from any other commercial activity. Universities and CRCs are operating in direct competition with commercial operations such as Fox Design. (Fox Design Pty Ltd sub42)

Others suggested that an experimental use exemption should be composed of a specific list of activities that are exempt from the definition of exploit:

> We find the suggestions of the ALRC in its discussion paper no. 68 at section 14 particularly useful, and agree that all of the activities described in paragraph 14.136 of their paper should be covered by any EUE:
>
> 119A Infringement exemptions - experimental use:
>
> (1) The rights of patentees are not infringed by any act of exploitation of a patented invention required for carrying out:
>
> (a) a determination of how the patented invention works; or
>
> (b) a determination of the scope of one or more of the claims of the patent; or
>
> (c) a determination of the validity of one or more claims of the patent: or
>
> (d) a determination of whether a product or process falls within the scope of one or more claims of the patent; or
>
> (e) development towards a non-infringing product or process; or
>
> (f) development towards an improvement to the patented invention
>
> (2) Subsection (1) applies whether or not the exploitation is for a commercial purpose. (Mayne Pharma sub12)

There was some disagreement about whether an exemption should only apply when experimenting was the <u>sole</u> use of the invention:

> We believe that the component of the exemption protecting *research on* the subject matter of the patented invention should only cover the situation where such experimentation is the

> *sole* purpose of the use of the invention (or, at the very least, is the dominant purpose). The reason for this is that any lowering of this standard would create uncertainty and would have the potential to create a disincentive for innovation and disclosure. Furthermore, we submit that it is unnecessary to expand the exemption beyond this sole purpose standard provided that the second non-commercial research exemption is also created, and that alternative patent use strategies are put in place, particularly as they relate to biotechnology research tool patenting. (Nicol/Nielsen sub17)
>
> On the other hand:
>
> I believe that experimental use should also cover the situation where the patented technology may be a step in a process. If this process then proves to be "commercially" successful then the contribution that the technology makes to the final outcome needs to be assessed and the owner fairly compensated. I do not support having to pay a licence fee before the new process has been shown to be successful both experimentally and commercially. (Soozy Smith U Newcastle sub21)

Improved Licensing Practices

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 the University for such a licence, nor has the University been notified of any infringement of any patent within its research. (Kevin Croft U Sydney sub29)

However, many submissions thought that improved licensing practices were a good idea though 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
>
> Statutory licensing schemes in the fields of copyright law allows copyright material to be utilised without the copyright owner's consent, subject to equitable remuneration. Such an arrangement, if adapted to certain categories of patented inventions such as research tools and diagnostic tests, would facilitate research by reducing the time and cost of biotechnology patent searches, increase certainty and decrease licence fees. (DH&A sub40)

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

> Our client submits that the adoption of an experimental use exception goes beyond what is required to address perceived inadequacies in the current patent system. 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..... . For many inventors, it is not only any financial benefits associated with their inventions that are of primary importance, but a continuing involvement in the evolution of the invention..... 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 sub20)

Compulsory Licensing

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..... Health notes that compulsory licensing has been rarely used in Australia and considers that it unlikely to be used in the future to the extent that it would have a meaningful impact on access to patented inventions for research purposes. (DH&A sub40)

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 (a substantial lessening of competition test is to be added to the present grounds for applying for a compulsory licence). 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 ACCC..... It would fit well with the intent behind the compulsory licensing system. The ACCC is already perceived as the "corporate watchdog" and it would be more likely than the Patent Office to have the relevant resources and personnel trained for the task. (McBratney et al sub30)

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 sub)

Patent Pools

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 sub18)

Similarly

> Patent pools are generally likely to emerge in industries with the following characteristics
>
> - the parties involved have a long relationship and are in a horizontal arrangement;
> - they form a fairly homogenous group
> - they are engaged in repeat-play transactions, and
> - they hold similar portfolios of mutually blocking patents.
>
> Industries without these characteristics are unlikely, however to see the emergence of, or benefit from, patent pooling arrangements. In biotechnology, for example, the industry comprises diverse, heterogeneous players, and parties are often involved in one-off transactions.....
>
> It should also be remembered that patent pools are promoted as a solution to patent thickets, or anti-commons issues, so they do not assist where single blocking patents are used in an exclusionary manner. For this reason, they are not an alternative to an experimental use exemption, but should be viewed as a supplementary means of ensuring the free flow of contractual rights between industry participants. (Nicol/Nielsen sub17)

Open Source

Finally, on whether open source mechanisms were a realistic alternative or supplement to an experimental use exception, 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 sub18)

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 sub17)

Many 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 sub5)

ACIP considerations

Regarding pre-grant mechanisms, ACIP believes that the novelty and inventive step criteria, as recently amended following ACIP and IPCR inquiries, are appropriate, provided that they are sufficiently rigorously applied during examination and upheld by the courts.

The IPCR report also recommended adoption of the recent US utility criteria as part of the major tests for granting a patent, but only that this be part of patent office guidelines – this was accepted by Government. However, because it is part of the *quid pro quo* that has long been at the heart of granting patents, ACIP believes it should be written into patent law to ensure that only those patents are granted and upheld that which have specific, credible and substantial benefits for society. Nevertheless, it is not clear that this, by itself, will prevent broad claims that go beyond the scope of what is disclosed in the specification as the invention. In particular, it may not stop the practice of granting product claims *per se.* ACIP is also unclear whether product claims *per se* are required under TRIPS. It therefore means that a viable option may not be an experimental use exemption based on the principle that any new (experimental) use of a product not already disclosed would not infringe.

ACIP also notes that changes to pre-grant conditions cannot be applied retrospectively and that any patents that might be currently causing problems for the experimental use, or secondary innovation generally, may have considerable time before expiry. Such problems can only be resolved by post-grant mechanisms.

On post-grant mechanisms, ACIP is inclined at this stage to the view that mechanisms such as patent pools and open source systems, by themselves, are not sufficient solutions to the problem of experimental use across the whole range of technologies, although they may be useful supplements in particular technology areas.

Improved licensing practices are a useful supplement to any experimental use exemption in cases where use is not, in fact, exempt from infringement. ACIP believes that anything which reduces the transaction costs between licensee and licensor should be desirable. However, improved licensing practice does not tackle the fundamental question that a patent right is not absolute and some limited uses of an invention are not, and should not be, infringement of that right.

Similarly ACIP is of the view that compulsory licensing could be a useful supplement to an experimental use exemption but that it is not an in-principle alternative. It also appears to ACIP not to be a practical alternative given the lack of use of compulsory licensing provisions in Australia to date. Therefore ACIP agrees that compulsory licensing should reviewed in a broader context than the present experimental use inquiry but also notes that the room for change seems restricted by Article 17.9(7) of the recent USFTA.

The remaining post-grant mechanisms are developed as options in Part II of this document where ACIP's understanding of their pros and cons are considered in some detail.

Appendices

Appendix 1. List of submissions:

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

Appendix 2 Consultations

Brisbane

Annita Nugent (patent attorney)
Amanda McBratney et al (University of Queensland)
Peter Kambouris
Anne Fitzgerald, Neale Hooper, Helen Munro & David Ferris

Sydney

Andrew Penman & Charles Latimer (NSW Cancer Council)
Luigi Polambi
Kevin Croft (Sydney University)
Philip Kerr & Simon Williams (patent attorneys)
Adam Johnston

Melbourne

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 & Deon Venter (GTG Technologies)
Bernard Lee, Matt Gallagher & Greg Healy (NuFarm)
Ian Pascarl (LCA)
Donald Jack
Neil Ireland & Raymond Evans (patent attorneys)
Dean Ellison (Monash University)

Canberra

Anne Deegan, Peter McInnes& Donn Corcoran (Dept of Health & Ageing)
Alastair Wilson & Jason Rasheed (NHMRC)
Matthew Rimmer (ACIPA)
Ryan Wilson (Plant Health Australia)
Group of 8 Universities