



ADVISORY COUNCIL ON INTELLECTUAL PROPERTY

Patents and Experimental Use

ISSUES PAPER

February 2004

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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 30 April 2004

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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 associated with 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 responsible for administering 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 on these programs that patents on non-coding regions ('junk') 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, including bio-medical research. There has also been increasing concern that there has been insufficient return on this investment through commercialisation of research and development in Australia and that inadequate use of the patent system may play a part in this.

In consideration of these issues, the Hon Warren Entsch MP, 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) is conducting an inquiry into Gene Patenting and Human Health. The ALRC report may cover the issue of experimental use however this will be only one of many questions covered by this enquiry which has a specific focus on human health.

As part of its inquiry process, ACIP is seeking input from interested parties through written responses to the Issues Paper and direct consultations. Once this input has been considered ACIP will prepare a report which they expect to submit to Parliamentary Secretary Entsch in October 2004.

In preparing this paper, ACIP notes a recent report¹ that states

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

¹ Gans & Stern *Assessing Australia's Innovative Capacity in the 21st Century* (IPRIA)

ACIP also notes a newly released OECD draft working paper² that concludes " on the whole, the patent system as applied to biotechnology inventions is doing what it is intended to do and that there is no widespread breakdown in the licensing of biotechnology patents(but) there is room to improve access and market penetration without undermining the patent system including:

- improved licensing practices
- a better defined experimental use exemption
- exploring alternative access arrangements such as open source/public domain mechanisms."

The main concern of this paper is the second of these mechanisms, an experimental use exemption, although the other two mechanism will also be explored briefly at the end of the paper as possible alternatives or complements.

Although Crown Use might be regarded as a form of licensing, this is the subject of another ACIP enquiry that has just commenced and so will not be considered in the present review.

The structure of this Issues Paper:

- explores the law on experimental use exemption as it currently exists in Australia;
- examines international practice on experimental use exemption and the effects of any of our treaty obligations;
- discusses the economic arguments and policy issues behind such an exemption; and
- considers possible alternatives such as improved licensing practices or access arrangements.

In each section, some of the current literature will be reviewed to try to tease out relevant issues after which some specific questions will be asked. Not all respondents may want to address all questions.

The purpose of the paper is to stimulate public debate on the issues it raises but ACIP would value additional information and comments on any other matters or issues that respondents feel are relevant to this enquiry. Any empirical information or data would be particularly valuable.

Written comments should be provided to the address below by 30 April 2004.

It is expected that consultations will be held during **May 2004**.

It would be appreciated if you could **advise your interest in taking part in consultations by contacting the ACIP Secretariat by 31 March 2004.**

Please address your advice, comments, written submissions and any queries to:

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² *Patents and Innovation: Trends and Policy Challenges* DSTI/STP92003)27 13-Oct-2003 p. 19

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 whose disclosure would be genuinely prejudicial to the party making the submission.

Current Australian law

Currently there is no explicit experimental use exemption to infringement in the *Patents Act 1990*. Indeed the only mention of 'experimental' (use) 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'. A patent cannot generally be granted where it has been secretly used before the priority date, the rationale being that it would give the applicant a de facto extension to the patent term. However, s.9 exempts 'reasonable trial and experiment' from the definition of secret use because it is a reasonable activity in the demarcation of an invention before a patent application that cannot be regarded as a de facto extension of term.

On the other hand, in s.13, 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.

However, there seems a widespread uncertainty amongst researchers as to whether there is an experimental use exemption in Australian law with some people asserting that the absence of an explicit mention of an experimental use exemption is an implicit argument of its existence.

Some believe that it is implicit in the patent system through

- the need to be able to test the validity of a granted patent
- the whole basis of the patent system with its incremental improvements and disclosure requirements.

Others³ argue that, although there appears to be no Australian court decision on experimental use exemption, it is imported into Australian law through the 19th century UK case *Freason v Loe* in which it was held that without

"the intention of selling and making use... but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made... is not an invasion of the exclusive rights granted by the patent."

One exception against infringement is provided by s.78 of the Patents Act when a person exploits a pharmaceutical substance that has been granted an extension under s.70 for regulatory approval of generic versions of the pharmaceutical substance.

Question 1 (a) What is your understanding of current law on an experimental use exemption in Australia?

(b) What is the basis of this understanding and how certain are you of it?

(c) How has your understanding affected your research and development behaviour?

³ Dr Andrew Blattman *Research Tolls: Is there a 'research exemption' to patent infringement in Australia* Spruson & Furguson Sept 2003

Overseas law/experience

Before analysing the policy issues involved in determining an experimental use exemption, it is useful to consider what is the experience and law in other countries. The recent OECD working paper states⁴:

In parallel to this analytical effort, policy makers might encourage the sharing of experience across countries: 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.

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.". By 1861 it was well accepted that “an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee.”

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 recently decided not to review the CAFC *Madey* decision which therefore remains current US law.

Duke University supported by other universities, medical schools and various national organizations argues that the *Madey v Duke* decision “effectively eliminate[s] the experimental use exception for research institutions” since “[n]o research institution will be able to demonstrate that its experimental use of any patent fails to further the institution’s ‘legitimate business.’” In so doing, the decision disrupts the “balance between the need to promote innovation and the recognition that imitation and refinement through imitation are necessary to invention itself” which is embodied in the federal patent laws. “Without the experimental exemption, research institutions like Duke will be at the mercy of patent holders. This ‘proliferation of intellectual property rights’ now allows each individual patent holder ‘to set up another tollbooth’ delaying or even blocking further research innovation.”⁵

⁴ *Patents and Innovation: Trends and Policy Challenges* DSTI/STP92003)27 13-Oct-2003 p. 22

⁵ Jennifer Miller, Duke University *Sealing the Coffin on the Experimental Use Exception*
<http://www.law.duke.edu/journals/dltr/articles/PDF/2003DLTR0012.pdf>

Very recently Wegner⁶ 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 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 legislation specifically allowing for the case of experimental testing of a generic drug before the expiry of a patent on the original drug. The Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984 states that making, using or selling a patented invention 'solely for uses reasonably related' to gathering data in order to acquire FDA approval under federal laws that regulates drug manufacture, use or sale, is not an act of patent infringement. 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 be launched immediately after the extended term expires (though some details of the legislation means that this does not always occur in practice).⁷

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. However, 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. The Court's reasoning was that the essence of the patent system is that anyone can fully utilize the invention after the patent expires. If one assumed that the Biological Equivalence Test is not regarded as an "experiment" and therefore is prohibited during the patent term, then it would mean that generic drug makers would be forced to waste a substantial amount of time after the patent expired. This time period would allow the patent owner to enjoy market exclusivity beyond the patent term. The Court believed that such consequences would disregard the interest of society as a whole in the patent system.⁸

⁶ Harold C Wegner *The Post-Madey Research Exemption*
<http://www.foley.com/people/bio.aspx?employeeid=16338&&practiceID=&industryID=&genPageID=>

⁷ 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>

⁸ Katsuya Tamai *The Experimental use Exception: a Japanese Perspective*. www.law.washington.edu/casrip/Symposium/Number7/1-Tamai.pdf

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 essentially as follows: “*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. As in many other jurisdictions, the big question here has been, and still is, 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.

The German Supreme Court, in decisions during the mid-1990s known as *Clinical Trials I and II*, ruled that experiments or trials were permitted on a patented substance such as a pharmaceutical both to test its claimed properties and to test for indications different from those claimed, insofar as the experiments were directed to the substance itself. The German Constitutional Court in a decision in May 2000 affirmed the Supreme Court's decision, concluding that the owner of the patent had to accept such limitations on their rights in view of the development of the state of the art and the public interest.

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 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.⁹

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 matter of the invention.

According to Fysh¹⁰ (a Judge of the Patents County Court, London), there is an implicit 'and' that co-joins (a) with (b).

Fysh 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*

⁹ Heinz Goddar *The Experimental Use Exception: A European Perspective*
www.law.washington.edu/casrip/Symposium/ Number7/1-Goddar.pdf

¹⁰ Michael Fysh QC, *SC Legal Issues in Exploiting Drug Patents in Europe* LES-Italy Conference, Milan, 2002

time in question is mixed, being both private and commercial, the exception does not arise: *SK&F v Evans*¹¹ and *McDonald v Graham*¹². Likewise, keeping a product in-house for even possible commercial use in the future has been held to be both non-private and commercial. However, an exception was provided in *McDonald* where a party carries out an act that is designed purely to try to invalidate a patent even though this may have a commercial purpose.

The UK courts have also tried to decide what is meant by "experiment/experimental". In *Monsanto*¹³ 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*¹⁴ 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".

Fysh concludes "I believe that the exception may therefore have a very narrow effect under UK/Irish law. The qualification may cover such acts as verifications of various kinds (such as seeing whether a compound can be made as proposed or will work in a particular climate), assessment of validity, and in-house experiment for the purpose of improvement and modification etc. But the exception would not in my view exclude the use of a patented process in experiments specifically to test some other product or process with the view to the direct use of the results thereof for a commercial purpose."

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. But because of the limited case law there is still some uncertainty as to where this line actually falls.

The best indication on how the courts approach experimental use has come from the Court of Appeal in the 1991 case *Smith Kline & French Laboratories Ltd v Attorney-General* where Hardie Boys J stated:

¹¹ *SK&F v Evans* [1989] FSR 513

¹² *McDonal v Graham* [1994] RPC 515 (CA)

¹³ *Monsanto v Stauffer* [1985] RPC 15 (CA)

¹⁴ *SF&F v Evans* [1989] FSR 513

"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..."

On this basis an academic institution, such as a university, would not have any more success raising a defence relying on the experimental use exemption than a more commercially orientated company.¹⁵

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.

While the primary purpose of the introduction of the exemption appears to have been to decrease the time it takes for generic drugs to enter the market following the expiration of a patent, its wording is broad enough to cover any situation where some form of regulatory approval may be needed prior to making, using, or marketing any patented product.

Question 2: What lessons, if any, do overseas experience and law hold for an experimental use exemption in Australia? In particular, are any of the overseas approaches to be preferred for Australia?

¹⁵ Jane Calvert and Greg Lynch (Baldwin Shelston Waters) 2001
<http://www.findlaw.com/12international/countries/nz/articles/682.html>

International Treaty Obligations

Australia is a signatory to a number of international treaties on patents and any developments on experimental use exemption (or alternatives) would have to be consistent with them. The major treaties are¹⁶:

- Paris Convention
- Patent Cooperation Treaty (PCT)
- Budapest Treaty
- Strasbourg Agreement
- Trade-Related Aspects Intellectual Property Rights (TRIPS)

Of these, compliance with TRIPS is likely to have the most significant effect on post grant provisions such as an experimental use exemption.

According to Article 30 of the TRIPS Agreement, World Trade Organisation (WTO) member states may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the 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 article 30 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 protection¹⁷, it was accepted that Article 30 should be read in conjunction with other articles of the treaty. Article 7 states "the protection and enforcement of intellectual property rights should contribute to 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."

As far as the Working Party has been able to determine there seems to have been no ruling on whether an experimental use exemption would fall within the scope of Article 30 and associated articles of TRIPS. Although both Canada and the EU in their WTO dispute over the use of generics before the expiry of patent term 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. 30.¹⁸

Question 3: What are the constraints for an experimental use exemption (or possible alternatives) under any of the international agreements to which Australia is a signatory?

¹⁶ Intellectual Property & Competition Review Final Report Appendix 3 p. 221 www.ipcr.gov.au

¹⁷ World Trade Organisation Panel Report *Canada - Patent protection of Pharmaceutical Products* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf

¹⁸ <http://www.gtz.de/biotech/dokumente/ipr/docs/P2trips.doc>

Policy issues

General considerations

As stated in the report on Intellectual Property and Competition Review (IPCR)¹⁹, 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."

Muharige²⁰ suggests that the nature of this balance has varied, and needs to continue to vary, over time as the nature of research and development has varied. When the patent system was first being established in Europe and America, inventions and discoveries were in the nature of bi-focals, lightning rods, and other clearly practical articles of the type we today may associate with the work of independent inventors. There were no large research establishments, either private or public, that dominate research today.

In the context of today's research community, which includes large universities, private foundations, government institutions, hospitals, and commercial institutions, what are the advantages and disadvantages that need to be balanced by the patent system? Muharige says

"Advantages include incentives to finance an extensive research establishment in order to provide a pipeline of potentially patentable products, incentive to incur development costs for patented products, and encouragement of individual researchers to develop new and useful processes and products (provided there is a mechanism for the individual to reap the financial benefits). Disadvantages include a deterioration in the open exchange of information, extremely high transactional costs, and inhibition of the most efficient ways to actually conduct

¹⁹ Intellectual Property & Competition Review Final Report "Executive Summary" www.ipcr.gov.au

²⁰ Kate Murahige *Patents and Research - an uneasy alliance*. Academic Medicine Vol. 77 No. 12 (Dec 2002) p.1329

research. And, depending on one's viewpoint, the asserted advantage of encouraging development of new and useful subject matter may be considered a detriment by discouraging more basic research."

The UK Royal Society in a recent report on the impact of IP on scientific research²¹ also states that patent policy needs to balance:

- the need to provide recognition and incentives for discovery, invention and exploitation to achieve wealth creation and general benefit;
- the desirability of encouraging competition that stimulates further discovery, invention and exploitation; and
- the needs of current and future users of the creative work and resulting products to benefit from such innovation.

Possible ways of affecting the balance 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, description etc

2 *Post-grant*

- (a) exempt particular uses from infringement eg treatment of humans, regulatory approval
- (b) an experimental use exemption
- (c) compulsory 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 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.

²¹ *Keeping science open: the effects of IP policy on the conduct of science* Royal Society 2002

In addition, the IPCR Review 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.

Despite these improvements, it is inevitable for a variety of reasons that there will be disputation of the validity of some patents after acceptance by an examiner. The reviews therefore made recommendations for improvement for operation of the opposition hearings and the court system post-grant. The operation of the court system has also been the subject of a recent ACIP enquiry into whether the jurisdiction of the Federal Magistrates Service should be extended to include patents (as well as trade marks and designs). It is noted that, because of the costs involved to the litigants, post acceptance reviews of validity of patents will usually occur only for commercially valuable patents and will usually be driven by market forces. Commercially non-valuable patents, even if invalid, will not usually be challenged after acceptance even though they may add to the overall friction/inefficiencies of the system and may particularly affect public domain research.

In the light of these considerations ACIP thought it most fruitful for attention in the present review to focus its on *post grant* measures particularly affecting research and development, including an experimental use exemption.

Question 4: Is there any *empirical* evidence that the balance between the incentives for innovation and the ability to use innovations, particularly for research and development, is being significantly affected by the absence of an explicit experimental use exemption (or some other provision) in Australian patent law?

Question 5: Are there any overwhelming arguments for consideration of *pre-grant* conditions for patents as a complement or alternative to an experimental use exemption under Australian law?

Analogies from copyright

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. In *Sony v. Universal City Studios* (1984) the court examined the purpose and scope of the "fair use" defence and considered that the concept of fair use had been consistent with the purpose and policy of the copyright laws to motivate the creative activity of authors and inventors: "..... a prohibition of such use would inhibit subsequent writers from attempting to improve upon prior works and thus. . . frustrate the very ends sought to be obtained." Thus the "fair dealing" doctrine is a means of balancing the exclusive rights of the copyright holder with the public interest in the dissemination and use of information.²²

O'Rourke²³ 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.

Question 6: Does fair dealing (or fair use) in copyright law hold any lessons for "experimental use" in Australian patent law? For example, could any of the provisions for fair dealing/use be translated into an experimental use provision in patent law? Or do differences in the nature and application of copyright and patent rights limit the analogies between the two systems?

²² Steven J Grossman *Experimental Use or Fair use as a Defense to Patent Infringement* IDEA 1990

²³ Maureen O'Rourke *Toward a Doctrine in Patent Law* Columbia Law Review 100 (2000) p. 1177

Needs of basic research

Merton²⁴ describes the four historic norms of basic research as universalism, communism, disinterestedness, and organized skepticism. Briefly, "universalism" means that impersonal criteria, independent of the identity and characteristics of the individual scientist(s) who does the research, are employed to judge the soundness of scientific work. "Communism" means that scientific findings are made open to all, immediately, with no sense that they are or should be proprietary in any way. "Disinterestedness" means that scientists pursue truth rather than self-interest, that they are ideally indifferent to the success of an experiment or the reception of a research finding. "Organized skepticism" means that the scientific community should rigorously test research results before accepting them as true, and that all research is in some sense "born in doubt," false until dispositively proven true.

However, as Merges²⁵ points out, these norms are normative and aspirational - and they are also subject to historic and cultural change. Consequently, it is not surprising that sociologists of science have documented a set of practices that deviate in many respects from the norms Merton identified. 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. In biotechnology research, there appears to be greater reluctance to share widely biological materials useful to fellow researchers (such as genetically engineered mice, or particularly useful cell lines). The amount of free sharing seems to depend on how expensive and difficult it is to create the biological material as well as on whether the recipient is a direct competitor or just working in a related field.

There is now also the widespread practice of seeking *formal* property rights, particularly patents, over research results. This seems contrary to the historic aspirational norm of openness. However, like the internal tensions on informal intellectual property rights identified by sociologists of science in the pre-patent era, Merges 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.

Merges gives a number of reasons why patents have found their way into pure science. For the most part, the answer lies with changes in the relationship between science and technology since the 1930s. In the 1930s, the important science-based industries were centered around the electrical and chemical fields where the conceptual distance between basic research and applied technology was often large. As a consequence, huge investments were required to translate the findings of the basic research laboratory into viable commercial products. By the 1970s and 1980s, however, the relationship between science and technology had grown a good deal closer in many fields. In important fields such as

²⁴ Robert K. Merton *The Sociology of Science* (Chicago: University of Chicago Press, 1973).

²⁵ 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

biotechnology and certain branches of physics, the jump from lab result to commercial product was much shorter than it had been in the past. Thus, for example, the basic Cohen-Boyer research on gene-splicing led to a commercial product (genetically engineered insulin) in only a few short years. Similarly, early work on lasers yielded commercial results after a relatively short time.

Merges suggests that another important factor - often overlooked - is the change in the ease of capital formation for science-intensive industries. In the 1930s, it was widely thought that only large, integrated companies could afford the "luxury" of long-term-oriented basic scientific research. By the 1970s, however, with the advent of the venture-capital industry and related support institutions, start-up companies based on new scientific findings often found a ready supply of capital from firms specializing in such speculative investments provided the intellectual property was captured.

A concurrent trend has been a general decline of government funding for public research in recent years after the highs of the World War 2 and the early post-war years as governments around the world have sought to decrease public spending. This has led to both a relative and absolute increase in private funding of research, even in public research organisations. The trend has been further encouraged by initiatives such as the Bayh-Dole Act in the US and the requirement that CSIRO should obtain up to 25% of their funding from non-government resources. The aim, and result, of these initiatives has been the greater commercial focus of public research organisations and the blurring of the traditional distinction between pure and applied research.

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. Stokes²⁶, 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 | <i>Pure basic research (Bohr)</i> | <i>Use-inspired basic research (Pasteur)</i> |
| | NO | | <i>Pure applied research (Edison)</i> |

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.

Thus 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

²⁶ Donald E. Stokes *Pasteur's Quadrant: Basic Science and Technological Innovation* (Washington, D.C.: Brookings, 1997).

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

Question 7: Do basic, applied or hybrid research have different needs with respect to the patent system? If so, how can the patent system accommodate these differences?

Shapiro²⁷ emphasises a related question - 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 observers are increasingly expressing concerns that our system is in fact creating a *patent thicket*, a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology.

Shapiro suggests that while the patent system may be a spur to innovation overall, there is a danger of imposing an unnecessary drag on innovation by enabling multiple rights owners to “tax” new products, processes and methods. Even the individual effects may be small, the cumulative effect of many small “taxes” can become quite large;. Even more important is timing. If one is faced suddenly with a patent desist demand and is unable or unwilling to meet the licensing conditions, it requires significant time to redesign a process or product or to invent around the patent. The timing problem is particularly important in industries such as telecommunications and electronic industries where speed to market is vital.

Heller and Eisenberg²⁸ discuss the “patent thicket” in the context of biotechnology patents, making a comparison to the classic “tragedy of the commons.” The tragedy of the commons refers to the fact that a resource can be overused if it is not protected by property rights; fishing grounds and clean water are standard examples. Heller and Eisenberg point out that quite a different problem arises when there are multiple blocking patents; they label this problem the “tragedy of the anti-commons.” The tragedy of the anti-commons arises when there are multiple gatekeepers, each of whom must grant permission before a resource can be used. With such “excessive” property rights, the resource is likely to be *under-used*. In the case of patents, innovation is stifled.

However, Bendekgey and Hamlet-Cox²⁹ assert that none of the proponents of patent thickets has produced evidence that research in any way has decelerated as a consequence of gene patenting. While Metz³⁰ has produced some evidence that individual researchers may have terminated individual research projects as a consequence of individual property disputes, Bendekgey and Hamlet-Cox suggest that the evidence falls far short of indicating

²⁷ Carl Shapiro *Navigating the Patent Thicket* <http://haas.berkeley.edu/~shapiro/thicket.pdf>

²⁸ Michael A. Heller and Rebecca S. Eisenberg *Can Patents Deter Innovation? The Anticommons in Biomedical Research* SCIENCE Vol. 280 1 MAY 1998 p. 698 www.sciencemag.org

²⁹ Lee Bendekgey and Diana Hamlet-Cox *Gene Patents and Innovation* Academic Medicine vol. 77 (Dec 2002) p.1373

³⁰ Jon Metz *Diagnostic Testing Fails the Test* Nature vol. 415 (2002) p. 577

that there has been any aggregate reduction in biological research as a consequence of gene patenting.

Nicol and Nielson³¹ in a recent Australian study state that it is actually quite difficult to obtain quantitative data on the numbers of projects that are abandoned and the reasons why project abandonment occurs. "It may be that this will occur because of patent thickets and perceived future negotiating difficulties (i.e. anticommons issues). However, we do acknowledge that projects will be abandoned or redirected for a whole host of reasons, and these may often be more to do with the intrinsic value and likelihood of success of the technology than the level of encumbrance."

Question 8: Is there any evidence for a "patent thicket" or "tragedy of the anti-commons" problem in research and development? If so, what are the issues/effects?

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, Golod³² 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. Thirdly, synthetic drugs are designed on paper or computer screen and then synthesised - this is sometimes seen as being more inventive than the act of finding and purifying a gene, particularly now the procedure has become automated. Finally, many genes are also discovery tools because they encode receptors important in transconduction pathways.

Similarly, the Nuffield Bioethics Report³³ says that DNA sequences are essentially just genetic information and this should distinguish them from other chemical compounds with regard to the patent system.

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

Siva³⁴ 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

³¹ Dianne Nicol and Jane Nielsen *Patents and Medical Biotechnology: an Empirical Analysis of Issues Facing Australian Industry* Centre for Law and Genetics Occasional Paper No 6 p.190. (available at www.ipria.org/publications/reports.html)

³² Jorge A. and Elina Golod *Human Gene Patents* Academic Medicine vol. 17 no. 12 Dec 2002 p. 1315

³³ Nuffield Council on Bioethics Report July 2000 *The Ethics of Patenting DNA* <http://www.nuffieldbioethics.org/filelibrary/pdf/theethicsofpatentingdna.pdf>

³⁴ N Siva *Legal Protection Of Human Biotechnology Inventions In Europe* BCL Dissertation Oxford University 2000

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, that 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, in order to characterise an isolated gene, mechanistic description only requires that the component chemical substances be described. This is not very useful in order to convey biological information. The gene is better described as coding for so and so protein. Its use is largely as an information source, and this should be emphasised when applying the utility criterion for patent grant.

Of particular concern in biotechnology are patents on upstream research that may affect research downstream. Eisenberg³⁵ suggests from a strategic perspective, the issue for upstream firms is how to use intellectual property rights in advances that facilitate future research to capture a share of the commercial value of the future discoveries that they facilitate, while the issue for downstream drug developers is how to resist these strategies. From a public policy perspective, how one weighs competing concerns depends upon how one views the relative need for incentives at different points in the course of cumulative innovation.

Suzanne Scotchmer³⁶ has argued cogently that upstream research is both riskier and less likely to have a high stand-alone value than downstream research, which by definition is closer to market. She therefore argues for giving broad rights to early innovators that allow them to force subsequent improvers to license from them. However, Eisenberg retorts that one gets a very different picture of the relative contributions of early and subsequent innovators from observing biotechnology and genomics research. The “upstream” work of sequencing the genome looks relatively routine, riskless and uncreative compared to the “downstream” work of figuring out what it all means and how to use the information to develop new diagnostic and therapeutic products. More generally, in the biomedical field, upstream research is relatively cheap and heavily subsidized with public funding. Downstream research is relatively costly and risky and relies primarily on private funding. This configuration of risk and cost argues for focusing on motivating and rewarding downstream research more than upstream research.

Bendeckey and Hamlet-Cox³⁷ 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. 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

³⁵ Rebecca S. Eisenberg *Reaching Through the Genome* Federal Reserve Bank of Dallas April, 2002

³⁶ Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law* 5 J. Econ. Perspectives 29 (1991)

³⁷ Lee Bendeckey & Dianna Hamlet-Cox *Gene Patents and Innovation* Academic Medicine vol 77 no. 12 /December 2002 p.1373

whose securities are traded over the counter, are precisely those for whom patents most important. Thirdly, there is no principled way to distinguish between a gene-based invention and any other research tool.

Bendekey 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). It should be noted that the IPCR Report came to a similar conclusion about the need for the patent system to be technologically neutral and not determinative of industrial policy, for example in its recommendations on strengthening the utility criteria and on compulsory licensing.

Question 9: Does biotechnology, and genetic technology in particular, have special issues that warrant special treatment under patent law with respect to experimental use?

Formulating an "experimental use" exemption

A significant issue in legislating for an experimental use exemption would be deciding what would and would not constitute "experimental use". According to Smith³⁸, it would need to consider:

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
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 (eg importation of a product for experimentation) fall within the exception.

In defining an experimental use exemption, the policy reasons for such an exemption are paramount. Smith suggests justification of an experimental use exemption 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.

³⁸ Craig Smith *Experimental Use Exception to Patent Infringement - where does Australia stand?* Intellectual Property Forum June 2003

A similar list was provided by Canada in its arguments before the WTO in its dispute with the EU on the protection of pharmaceutical products³⁹:

- (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.

Many of these reasons are consistent with early case law on an experimental use exemption - for example, the original US exemption by Judge Story in the nineteenth century for 'philosophical inquiry' when 'philosophical' is interpreted with the contemporary meaning of as 'scientific' ie to understand how an invention operates or to study the invention to make further improvements. Likewise, in the nineteenth century UK *Frearson* case, the court acknowledged that the defendant "said he did this merely by way of experiment, and no doubt if a man makes things merely by way of *bonâ fide* experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent."

Wegner⁴⁰ states that, in contrast to the recent views of the American courts (as expressed in *Madey*) which is influenced by whether there is a 'commercial taint', the majority view around the world ignores whether the invention was tested by a commercial operation or for non-commercial purposes and, instead, focuses upon the qualitative question of whether the use of the invention was to explore the nature of the invention itself versus using the invention for its intended purpose. Thus the modern trend particularly in Europe is to draw a distinction based upon whether the experimentation is *on the invention itself* – to determine how it operates, test it, and use it as a base to make different, improvement inventions – as opposed to *using* an invention *for its intended purpose*.

The distinction seems 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. As 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."⁴¹

³⁹ World Trade Organisation Panel Report *Canada - Patent protection of Pharmaceutical Products* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf p.75

⁴⁰ Harold C Wegner *The Post-Madey Research Exemption* www.foley.com/FILES/tbl_s31Publications%5CFileUpload137%5C1588%5Cpost-madley%20whitepaper.pdf

⁴¹ Rebecca S Eisenberg *Patents and the Progress of Science: Exclusive Rights and Experimental Use* The Chicago Law review Vol 56 (1989) p.1017

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 points out that the use of gene sequences, especially ESTs and SNPs, as research tools may represent a special case. In Nuffield's view, such sequences may not satisfy the criterion of utility for patentability and so should be rarely be granted and so an experimental use exemption would then not apply.

Strandberg⁴² in discussing the *Madey* decision suggests a similar distinction between *experimenting on* and *experimenting with* a patented invention. The goal of any experimental use exemption should be to balance a patentee's reasonable efforts to recoup their investment and attempts to exert undue control follow innovation. This balance is already enshrined in many aspects of patent law, including the disclosure requirement. It implies that experimental use aimed at understanding, designing around, or improving a patented invention is merely an extension of the disclosure requirement. This has little to do with the free rider problem that the patent system is trying to solve. 'Experimenting on' a patented invention should be broadly permitted as a means of ensuring that the public receives the benefit of its patent bargain. Indeed, investigations testing and/or building on a patent's disclosure often form part of the applied research conducted by many companies both in Australia and overseas. For example, such testing may be conducted to examine the validity of a disclosed example or claim, to examine the sensitivity of a disclosed example or claim, or to examine the application of disclosed example or claim in a new context.

However, Strandburg states that 'experimenting with' patented inventions, particularly research tools, poses more difficult questions because the patentee's ability to recoup investments is entangled with their ability to exert control over subsequent research. Strandberg suggests a two tiered licensing scheme to provide a more effective scheme for speeding the pace of commercially significant research while preserving incentives to invest. In the proposed scheme a research tool patentee would be entitled to a limited period of complete exclusivity to perform research or to license the tool voluntarily. After the expiration of this period, compulsory licenses would be available through the remainder of the patent term, primarily serve as an encouragement for voluntary licences.

Question 10. What is the justification for an experimental use exemption?

Question 11: Is a criterion based upon whether the experimentation is *on the invention itself* as opposed to experimenting *with* an invention for *its intended purpose (use)* a useful criterion for determining "experimental use" in Australian patent law?

Question 12 : If so, is it sufficient by itself?

Question 13. Should an experimental use exemption cover only the situation where experimentation is the *sole* purpose of the use of the invention?

Question 14: If not, what are alternatives or supplementary criteria for an experimental use exemption?

⁴² Katherine J. Strandburg *What does the public get? Experimental Use and the Patent bargain* www.law.berkeley.edu/institutes/bclt/ipsc/papers/attendees/IPSC_2003_Strandburg.pdf (Feb 2004)

Alternatives or supplements to an experimental use exemption

Some have suggested that an experimental use exemption is not justified either because its potential benefits are outweighed by its potential disadvantages/costs to the patent system or because it is too difficult to define it effectively. Others suggest that any problems could be better solved by better use of licensing techniques. This section briefly looks at possible alternatives or supplements to an experimental use exemption.

Improved licensing practices

Idris⁴³ 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.

Results from a recent OECD public research organisation (PRO) survey on patenting and licensing show that the USA has a huge lead over other OECD countries in academic patenting, receiving over 8000 patents in 2000. But even in the US only a small number of patents are licensed, the average number per university being 24 per year. And licensing income, even in the best performing universities, rarely represents more than 10% of research budgets⁴⁴.

The OECD report also considered the impact of licensing on diffusion of public research.⁴⁵ Licensees often require exclusive licenses because they offer more protection for the cost of bringing the innovation to market; however, exclusive licenses by definition limit the diffusion of technologies. The survey found the mix of exclusive and non-exclusive licences granted by PROs to be fairly balanced, with research institutions often including clauses in the licensing agreement to protect public interest and access to the IP for future research.

Nicol and Nielsen⁴⁶ very 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."

Question 15: Are improved licensing practices by research organisations a whole or partial alternative to an experimental use exemption in Australia?

Question 16: If so, how could licensing practices be improved to provide better outcomes for researchers?

⁴³ Kamil Idris *Intellectual Property - a power tool for economic growth* WIPO Publication 2002

⁴⁴ *Patents and Innovation: Trends and Policy Challenges* DSTI/STP92003)27 13-Oct-2003 p16

⁴⁵ *ibid* p.17

⁴⁶ Dianne Nicol and Jane Nielsen *Patents and Medical Biotechnology: an Empirical Analysis of Issues Facing Australian Industry* Centre for Law and Genetics Occasional Paper No 6 p.190 (available at www.ipria.org/publications/reports.html)

Patent pools

Heller & Eisenberg⁴⁷ 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 collectives have evolved to facilitate licensing transactions so that broadcasters and other producers may readily obtain permission to use numerous copyrighted works held by different owners. Similarly, in the automobile, aircraft manufacturing, and synthetic rubber 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. Recent patent pools sanctioned in the US have included semi-conductor, DVD and MPEG technologies.

Potential benefits of patent pools include:

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

Potential 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.

Scherer⁴⁸ has suggested that in biotechnology, the asymmetry of relevant actors' positions - ranging from university scientists through genome-researching firms, vector providers, and instrument makers to specific biopharmaceutical developers - is likely to make it more difficult to find sufficient community interest to organise comprehensive low-royalty cross-licensing such as patent pools.

Question 17: In what fields are patent pools a realistic whole or partial alternative to an experimental use exemption in Australia?

Question 18: Are the potential benefits of patent pools likely to outweigh their potential disadvantages?

⁴⁷ Michael A. Heller and Rebecca S. Eisenberg *Can Patents Deter Innovation? The Anticommons in Biomedical Research* Science Vol. 280 1 May 1998 p. 698

⁴⁸ Frederik M Scherer *The Economics of Human Gene Patents* Academic Medicine Vol 77 no. 12 p 1348

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 Ergas committee⁴⁹ 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. There has been comment that the Government's response, being an "and" rather than an "or", makes compulsory licenses even harder to obtain.⁵⁰

A survey of international intellectual property law by Julian-Arnold⁵¹ 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).

Julian-Arnold found that compulsory licenses were rarely applied for where a dependent patent was being blocked. The reasons were largely practical for the applicant: prior to application for a compulsory license, an improvement invention must be created, a patent application granted, the improvement patent applicant may have had to survive a lengthy opposition proceeding, and an attempt at voluntary negotiations must have been made. Thus the time and money involved discourage application for a compulsory licence.

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 Ergas report 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.

Question 19: Is compulsory licensing a realistic whole or partial alternative to an experimental use exemption in Australia?

Question 20: For this to happen, do Australia's compulsory licensing provisions need to be changed? If so, how?

⁴⁹ Intellectual Property & Competition Review p. 163-4 www.ipcr.gov.au.

⁵⁰ Tanya Shanti-Spishbah *A little more reformation, a little more action* Honours Thesis ANU

⁵¹ Gianna Julian-Arnold *International Compulsory Licensing: the rationales and the reality* IDEA 1993

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 Society⁵² 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 been particularly prevalent in bioinformatics both for commercial and non-commercial laboratories. For example, Laird⁵³ suggests that

"Bioscience is special. Its scales of money, people, and time involved in research are without equal. Its culture of regulation and IP protection is closer to legal work than to other scientific fields. 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. "

Even though open source has been especially useful in bioinformatics, Laird refers to other areas of science where it has been equally useful. Many of the projects have the active participation of IBM⁵⁴, however, open source principles may not be limited to computer related applications

Question 19: Are open source principles a realistic whole or partial alternative to an experimental use exemption in Australia?

Question 20: Are the potential benefits of open source likely to outweigh their potential disadvantages?

⁵² Royal Society *Keeping Science Open* p.8 www.royalsoc.ac.uk/files/statfiles/document-221.pdf

⁵³ Laird *Open source projects* <http://www-106.ibm.com/developerworks/linux/library/l-osbio.html>

⁵⁴ John Wolpert *Breaking Out of the Innovation Box* Harvard Business Review August 2002