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RESEARCH USE OF PATENTED KNOWLEDGE – A REVIEW

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ABSTRACT

This Working Paper reviews issues related to research access to patented inventions, with a particular focus on the role of research exemptions (or experimental use exemptions) in protecting such access. It outlines factors that may affect the ability of researchers to access patented inventions for legitimate research purposes, it reviews evidence of current and anticipated limitations on access, and explores different options for the formulation of research exemptions that balance research use and patent holder's rights.

1 Invaluable assistance and advice was provided by Professor Andrew Christie and Kim Weatherall.

2 The Intellectual Property Research Institute of Australia (IPRIA) is a national centre for multi-disciplinary research on the economics, law and management of intellectual property. It is based at the University of Melbourne, and is a joint venture of the Faculty of Economics and Commerce, the Faculty of Law and the Melbourne Business School. IPRIA undertakes research projects and holds public seminars about legal and regulatory developments in intellectual property and the economics and management of innovation. The Institute supports research visits from Australian and international academics, lawyers and policy makers.

RÉSUMÉ

Le présent document du travail passe en revue les questions concernant l'accès des chercheurs aux inventions brevetées, en examinant notamment le rôle que les exemptions de recherche (ou les exemptions pour utilisation expérimentale) jouent dans la protection de cet accès. Le document souligne les facteurs pouvant affecter la capacité des chercheurs s'accéder aux inventions brevetées à des fins de recherche légitimes, examine les indices concernant les limites actuelles ou prévues imposées à l'accès et étudie les différents options permettant de formuler des exemptions de recherche qui maintiennent un juste équilibre entre l'utilisation des inventions à des fins de recherche et les droits des titulaires des brevets.

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EXECUTIVE SUMMARY

This Working Paper reviews the literature on research exemptions in patent law in OECD countries. Concerns have been expressed, in a number of nations without a strong exemption, that patent law has the potential to limit scientific research. The limitation may occur where it is too difficult, or too expensive, for a researcher to obtain the permission, through a licence, for example, of a patent-holder to use a patented invention.

According to economic theory, innovation policies should be designed to balance the incentives to invest in innovative activity with the promotion of technology transfer. The first-best research exemption policy provides investors with an incentive to invest while not limiting those knowledge spill-overs which only have a small effect on this incentive to invest.

In addition to being in accordance with economic principles, any exemption that is to be proposed must comply with the requirements of current international legal obligations, in particular the TRIPs Agreement. As it now stands, the TRIPs Agreement is consistent with first-best research exemption policies.

Research shows that there is a wide variation amongst OECD countries in the exemptions that allow for the use of patented inventions either generally for research purposes, or specifically for the purposes of gaining regulatory approval. The survey also demonstrates that there is empirical evidence that suggests there may be valid reasons to be concerned about the impact of patents on scientific research. Much of the anecdotal evidence, however, indicates that researchers do not consider that patents have caused significant problems in the conduct of their research, although this may be partly because they are ignoring the law where it is unclear.

The specific options for a research exemption explored (including a statutory exemption, a "fair experimentation" model based on copyright law exemptions, the introduction of a licensing system, the adoption of an "open source" model that emphasises the public good associated with the scientific research, the use of patent pools and, finally, a re-interpretation of the nature of patent rights themselves) each have their advantages and disadvantages. This review considers that any proposed exemption should provide greater clarity for researchers, avoid unnecessary rigidity in its interpretation, not unreasonably impede either scientific development or investment in research, not reflect a substantial shift in the understanding and application of patent law, and contribute to the international harmonisation of patent law.

Three final points may be made. First, more research is needed to ascertain whether the absence of research exemptions is having a deleterious effect on scientific inquiry. Second, if an exemption is needed, research would need to be conducted into the optimal form of any research exemption. Third, the imperatives that give rise to the need for an exemption – sound economic policy and scientific innovation – require that care be taken in the formulation of any exception to the rights of patent holders.

I. INTRODUCTION

A. Background

This Working Paper reviews the recent and relevant literature, both economic and legal, on patent research exemptions among Organisation for Economic Co-operation and Development (OECD) countries. Briefly, a research exemption for patented inventions allows researchers to use an invention without infringing the rights of the patent holder of the invention. Such exemptions attenuate the deadweight losses associated with the public grant of a monopoly right over inventions. Without an exemption, it is possible that scientists and universities may be sued for patent infringement if they make use of a patented invention in the course of their research. As a result, there is growing interest in examining the role of research exemptions in protecting legitimate scientific research.

Patents, which are used as an antidote to the non-excludability and non-rivalry attributes of knowledge, enhance direct incentives to invest but may coincidentally limit the natural spill-over of knowledge.[3] Optimal public innovation policies are designed to achieve the optimal balance between the incentive to invest in inventive activity on the one hand, and the unfettered diffusion of knowledge on the other.[4] Patents also play an important role in technology transfer from universities to the private sector, since firms intending to invest in commercialising an invention require property rights in order to appropriate the returns generated.[5]

Concern over the effect of patents on scientific enquiry has escalated in recent years because of:

- Increased pressure on public research organisations to patent inventions arising from their research.[6]
- Increased use of the patent system.[7]

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3 A knowledge spill-over refers to the notion that investment by one party in knowledge creation can have benefits for other parties (in economic terms, this is a "positive externality"). Patents diminish knowledge spill-overs by preventing others from using the knowledge (although they are also seen as encouraging long-term spill-overs by forcing inventors to disclose their invention).

4 This tension is well-known in the economics literature, dating back to seminal work by Nelson (1959) and Arrow (1962).

5 The use of patents as a means of facilitating technology transfer is the source of much analysis in the literature. See Mowery et *al*. (2001) and Agrawal and Henderson (2002), for recent contributions.

6 In the United States, this originally occurred as a result of the *Bayh-Dole Act* 1980 which allowed universities to patent inventions in order to promote technology transfer. Licensing revenues are now seen as an important source of income for universities in most OECD countries.

7 OECD (2004).

- The effect of the *Madey v Duke*[8] decision in the United States which narrowed the scope of research exemptions.
- Increased propensity of patent owners to enforce their rights.[9]

These changes have altered the playing field for public sector research and for the diffusion of knowledge between the public and private sectors (which may occur either through disclosure or licensing). If research tools are increasingly patented, the scope for patent infringement also increases. In this environment, there are concerns that the threat of patent infringement could have adverse effects on research and development (R&D) in both the public and private sectors.

This Working Paper engages with the economic and legal literature in this area and is intended to provide background for future policy development. This Working Paper does not, however, provide policy recommendations. The purpose of this Working Paper is solely to critically review the work that already has been undertaken in this area.

B. Structure of the Working Paper

This Working Paper critically reviews existing work in this area, including summaries of:

- Current law regarding research exemptions in OECD member countries.
- Concerns that have been raised by researchers and academics in two countries where there is no clear research exemption – Australia and the United States.
- Proposals that have been put forward to introduce a research exemption.
- Advantages and disadvantages of each of the proposals.

Section Two provides the economic and legal framework that may be used to understand the current use of research exemptions and to underpin any reforms that are to be put in place in the future.

Section Three provides a description of the current exemptions in the laws of the OECD member countries. These comprise both statutory and non-statutory (case law) exemptions. There is also a specific discussion of the exemption in the patent law of the countries that allow for the testing of products for the purpose of regulatory approval.

Section Four addresses the concerns that have been raised with respect to the status of research exemptions. This Section reviews findings from empirical research that has been conducted in this area and summarises some concerns that have been raised by scientists during inquiries into the absence of a clear exemption in Australia and the narrowness of the non-statutory case law exemption in the United States.

Section Five appraises some ways exemptions may be institutionalised, including a statutory exemption, as in the European Union (EU) nations, a statutory licensing system, a "fair experimentation" exemption based on copyright law, and a scheme that has strong links with "open source" models. The Section will also include a discussion of the advantages and disadvantages of each proposal.

The Working Paper concludes with a number of suggestions for future research into the purpose and scope of a research exemption in patent law.

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8 307 F 3d 1351 (Fed. Cir. 2002).

9 Bessen and Meurer (2005) show that patent litigation has escalated in recent years.

II. THE ECONOMIC AND LEGAL FRAMEWORK FOR EXEMPTIONS

A. Introduction

This Section provides a brief overview of the two structures that underpin the research exemptions as they currently exist and any proposals that are put forward to promote the research use of patented inventions in research organisations. These two structures are economics and the law. The concerns of economists centre on the need to promote spill-overs while maintaining the optimal level of incentive to invest. The concerns, from the legal perspective, are more basic – any research exemption, current or proposed, needs to comply with international obligations, in particular the TRIPs Agreement.[10]

B. Economic framework

Patents are known to be imperfect solutions to the market failure associated with the creation of knowledge since they create deadweight losses associated with charging monopoly prices for goods whose marginal cost is close to zero. Nordhaus has shown that if stimulating investment in inventive activity was the prime concern, patents should be of infinite length.[11] However, if spill-overs are the primary concern, patents should not exist at all. The current system, where patents exist but are time-limited, is a compromise which reflects the inherent trade-offs.[12]

Given the existence of patents, the issue addressed in this Working Paper is whether there are any conditions under which exemptions to patent law are necessary. This issue has been raised due to concerns that the observed increased intensity of patenting may lead to a situation where the costs of patents outweigh the benefits.[13] In order to understand this issue, this section presents the economic arguments for and against exemptions from patent law.

1) Arguments against research exemptions

Academics opposed to the notion of a research exemption argue that patents do not prohibit research on the invention or idea: they merely add to the costs of doing research, since the researcher must pay commercial (*i.e.* monopoly) prices in order to use the product or process. In essence, they argue that an efficient allocation of resources – which provides the appropriate level of investment incentives for *all* research – requires researchers to pay the full costs of any inputs they use. If they use knowledge created by another researcher, they should pay for both the fixed costs of discovery as well as the on-going

10 The Agreement on Trade-Related Aspects of Intellectual Property Rights is binding in member states of the World Trade Organisation. Article 30 of the TRIPs Agreement requires that any exemption to patent rights satisfies certain requirements.

11 Nordhaus (1969).

12 Gallini and Scotchmer (2002), for example, have shown that other types of rewards for R&D (prizes, research grants) may be more efficient solutions to the under-investment problem.

13 Such a concern is not new: Machlup and Penrose (1950) show that concerns about the potential for patents to hinder scientific progress existed in the 19th century.

marginal costs. Thus, the existence of a research exemption would have an adverse effect on the rate of invention.[14]

Like anyone wishing to use a patent invention, university researchers have a choice about whether to pay a license fee, to search for other possible ways to invent around the patent, or work on another problem. Researchers who choose to license explicitly must pay the patent holder for these inputs. In order to do so, the researchers need to attract higher levels of funding (often from the government). This has the effect of supporting incentives for the upstream researcher as well as concentrating research funds on projects which are judged to have the best potential. Hence, licensing without exemptions provides an efficient way to balance investment incentives with appropriate spill-overs.

2) Arguments for research exemptions

Advocates of research exemptions highlight the adverse effects of patents, which fall into a number of categories: deadweight losses, transaction costs and fundamental uncertainty. They contend that the patent system is a necessary evil; not that it should be abandoned, just that its negative effects be attenuated. Exemptions assist in this regard by acting like a subsidy, in that they provide relief from the imposition of monopoly prices.

Proponents of research exemptions argue that since much research is cumulative in nature, there may be multiple licensing arrangements that need to be negotiated separately before any actual research can take place. These will probably involve significant transaction costs. These payments are deadweight losses from society's point of view and do not augment the incentive to invest for either party. Negotiating your way through a minefield of contracts (or cross-licensing arrangements) can also lead to well-known contractual problems such as hold-up. As a consequence, research will only be conducted up until the point where the transaction costs imposed are less than the total expected value of the research itself. This is of particular relevance with regard to an upstream, enabling invention which has little (or no) commercial value yet provides the potential for considerable commercial opportunities downstream. In this case, it is likely that important research projects will not be undertaken at all.

Another issue to contend with is that most research is, by its very nature, subject to fundamental uncertainty. Fundamental uncertainty occurs when information from past events cannot be used to form statistical probabilities over the outcomes of future events, since each event is so distinctive and novel.[15] This concept plays an important role in understanding scientific progress since many important scientific breakthroughs have occurred purely by chance. Since it cannot be known *ex ante* which scientific pathways will bear fruit, the greater the user and transactions costs associated with each pathway, the greater is the possibility that some important (but not as yet known as being important) research will not be undertaken. Interviews of researchers by Walsh, Arora and Cohen[16] find some evidence of patent owners "blocking" research pathways and there are other precedents for such behaviour in Merges and Nelson.[17]

The belief that uncertainty is pervasive within research has caused concern that the patent system is creating an anti-commons over knowledge. Nelson argues that capitalism's adeptness at driving technological progress can be partly attributed to the strength of the (publicly-funded) science base from

14 See Gans (2005) for more on this.

15 Knight (1921).

16 However, note that the Walsh et *al*. (2003) interviews were conducted before the *Madey v Duke* decision was handed down.

17 Merges and Nelson (1990).

which it draws many of its inputs.[18] As universities push for greater commercialisation of output,[19] there is greater pressure on university researchers to keep their research a secret (in order to fulfil the patenting criteria) and to turn research output into proprietary knowledge. This has increasingly resulted in the privatisation of the scientific commons and the creation of an anti-commons, where knowledge is under-used relative to the social optimum.[20] Such a strategy may temper the rate of technological progress. Moreover, it may change the direction of technological progress since if science is guided by the hand of commercial interests, it will focus primarily on puzzles that have commercial significance, rather than puzzles which are intrinsically interesting to scientists.

A canonical example of the type of problem that researchers face as a result of increased patenting in the public domain is the story of the OncoMouse.[21] In the early 1980s, researchers at the Harvard Medical School inserted a gene into a mouse embryo which made the mouse highly susceptible to cancer. The result was a research tool useful for all researchers looking to understand the onset of cancer. Realising the potential commercial value of their discovery, Harvard patented the OncoMouse and licensed it to DuPont who then aggressively marketed the research tool and enforced their property rights. Many scientists expressed their opposition to this development, since it goes against the fundamental tenets of "open science", where information is disseminated and diffused openly and freely.[22]

3) Potential policy implications

If it can be demonstrated that the concerns about the adverse effects of patents are valid,[23] then there is a strong case for government intervention to remedy the situation. Here, it is assumed that the concerns are valid, and some of the fundamental economic issues associated with designing a research exemption policy are considered.

A first-best patent policy provides investors with an incentive to invest while not limiting any knowledge spill-overs that will have only a small effect on this incentive to invest. These spill-overs can be seen as 'non-injurious spill-overs'. In other words, first-best policy should be designed to have the least damaging effect on the incentive to invest.[24] Ideally, non-injurious spill-overs are defined according to their ultimate use and the timing of that use. If the experimental use results in immediate, direct product market competition with the patentee, it will usually have a clear detrimental effect on the patentee's

18 Nelson (2004). Empirical evidence contained in Cohen et *al*. (2002) suggests that university research was an important source of new projects in the private sector for 31% of cases.

19 Which has happened increasingly in the United States since the passing of the *Bayh-Dole Act* in 1980.

20 See, for example, Heller and Eisenberg (1998).

21 As described in Murray and Stern (2005).

22 After considerable opposition to DuPont's strategy, the National Institutes of Health brokered a deal whereby non-profit research institutions were able to use the OncoMouse without the imposition of licenses. For-profit research organisations, however, were still required to enter into commercial arrangements with DuPont.

23 However, it is not easy to demonstrate that these concerns are legitimate. In Section Four, we review the available empirical literature on this issue.

24 It is implicitly assumed here that the existing level of investment in invention is not above the optimal level (in which case a policy that reduces incentives would be desirable).

incentive to invest. If however, the experimental use results in the launch of a product in a separate market many years later, there is probably little effect on incentives.[25]

It could also be argued that in certain instances all spill-overs of an invention should be freely disseminated, even if the impact on incentives is severe, because of the importance of the invention to overall social welfare. However, one of the problems with designing a policy based on the importance of spill-overs is that inventive activity is characterised by fundamental uncertainty: it cannot be known which R&D projects will lead to the creation of an invention (most will not), it cannot be known which of the inventions will lead to commercially useful products (most will not) and therefore the magnitude of spill-overs is unascertainable until after the fact. If spill-overs are expected to be large, it is probably the case that research grants are a better way to stimulate inventive activity than patents.

Research exemptions have a number of effects, including:

- To subsidise collection of information to enable prosecution of a patentee that may have acquired an invalid patent.
- To subsidise extension or improvement to the invention within the same technological trajectory.
- To subsidise application or adaptation of the invention within a different technological trajectory.
- To subsidise the process of inventing around the patent; and
- To subsidise expansion of knowledge of the user more generally.

Typically, the literature identifies the areas where exemptions should exist according to the type of organisations accessing the spill-over (for-profit or not-for-profit), the motive for use (test for validity, invent around), or the type of use (experiment on or experiment with). It can be understood that these are not convincing ways to identify the scope of research exemptions since they do not go to the heart of the matter, which is the effect of the exemption on the incentive to invest. Any policy designed to introduce a research exemption should take this into account. Any policy designed must also take into account the legal framework of patents – this is discussed in the next section.

C. Legal framework

Patentees are given a set of exclusive rights when a patent is granted. These rights centre on an exclusive right to use the patented invention. This exclusive right means that any use of the invention will represent an infringement of the patent unless authorised by the patentee.[26] The filing of an infringement action by a patentee allows the patentee to protect the investment that went into the production of the invention. Infringement actions, however, will not be available where the user of the patent has obtained a

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25 The time dimension is important since discounting future profits to a present value can reduce their value considerably. USD 1 received 10 years ago is worth 42 cents today if discounted at 10% per annum.

26 The laws of most OECD countries provide that patents provide patentees with the exclusive right to either use or exploit the invention. The Australian provision, for example, reads 'patent gives the patentee the exclusive rights, during the term of the patent, to exploit the invention': *Patents Act 1990* (Cth) s 13(1). In turn, "exploit" is defined to include: (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; or (b) where the invention is a method or process — use the method or process or do any act mentioned in paragraph (a) in respect of a product resulting from such use.

Patents Act 1990 (Cth) Schedule 1. Further detail of the laws of the OECD countries will be provided in Section Three.

licence from the patentee or where the law of the country provides that the particular use of a patented invention is exempted from the infringement provisions of the statute.

The particular use relevant to this Working Paper is where researchers use, or at least wish to use, a patented invention for research. Under most patent laws, subject to any exemptions, such research use would constitute infringing behaviour. That is, in most countries, researchers are liable to be sued for infringement, where there is no exemption for the research use of patents or licence acquired, when the work they are doing is for scientific progress generally.

If research like this is considered to be a public good then provision may need to be made for the exclusion of research use from the patent law's infringement provisions. There are a number of ways this could be achieved:

- Restricting the rights that attach to a patent to specific classes of action rather than the more general "use" or "exploit" where those classes do not include research uses.
- Amending the definition of infringement in order for research to fall outside the category of infringing behaviour.
- Introducing a compulsory research licence; and
- Including a statutory research use exemption.[27]

Adoption of each of these options would require an amendment of the patent law of those countries where the option does not exist.

The patent laws of individual nations, however, do not exist in a legislative vacuum. A number of international agreements underlie or limit the laws of each country. One of the most significant limitations on the scope of any research exemption in most countries is the TRIPs Agreement. Member States of the World Trade Organisation (WTO), which include all OECD countries, must comply with the Agreement. Article 30 of the Agreement states that:

> Members 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.

The Agreement does not, however, explicitly engage with the possibility of a research use exemption.

As the Agreement is silent on this point, standard legal practice is to refer to judicial decisions that have interpreted the provision in order to assess the broader effect of the Article. Only one dispute in this area has been heard by the WTO Dispute Settlement Body.[28] The decision related to Canada's regulatory approval exemption for patents; however, the Panel offered insight into the interpretation of Article 30 as it might apply to an experimental use exemption.

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27 Mechanisms for encouraging the research use of patented inventions will be discussed in more detail in Section Five.

28 *Canada – Patent Protection of Pharmaceutical Products*, also known as the "Stockpiling Case", discussed in Health Canada Report (2004), 39.

A number of conclusions may be drawn from the Panel's findings. First, the Article includes three 'separate and independent criteria that must be satisfied'.[29] These criteria are that, for an exception to comply with the Agreement, it:

- Must be limited.
- Must not unreasonably conflict with the normal exploitation of the patent.
- Must not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

All of these criteria must be met for the exception to be valid in terms of Article 30.[30]

Further, the Panel found that 'limited', with respect to the first criterion, should be judged against 'the extent to which the exclusive rights of the patent owner have been curtailed'.[31] The Panel explained further that the focus should be on 'which legal rights have been curtailed, rather than the size or extent of economic impact'.[32] In terms of the second criterion it was held that the "normal exploitation" mean the exclusion of 'all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'.[33]

In its discussion of the third criterion the Panel made specific reference to the experimental use exception:

> To make sense of the term "legitimate interests" in this context, that term must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms … We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws – the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement. It is often argued that this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a "legitimate interest" in using the patent disclosure to support the advance of science and technology. While the Panel draws no conclusion about the correctness of any such national exceptions in terms of Article 30 of the TRIPS Agreement, it does adopt the general meaning of the term "legitimate interests" contained in legal analysis of this type.'[34]

The conclusion that may be drawn from this decision is that a restriction on a patentee's rights and interests may be allowable under TRIPs if it is limited; does not "detract significantly" from the economic benefits that arise from the patent; and if it is for legitimate public policy purpose.

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29 Para 7.20.

30 Para 7.20.

31 Para 7.30.

32 Para 7.31.

33 Para 7.55.

34 Para 7.69.

D. Conclusion

The economic theory and legal context provided in this Section constitutes a framework against which current and proposed research exemptions may be assessed. The next Section will detail how the OECD member countries currently accommodate the research exemption issue. There is not the scope in this Working Paper, however, for a detailed analysis of the level of compliance of each nation's provision with the TRIPs Agreement or an analysis of the net economic effect of the exemption as it exists.

III. LAW REGARDING RESEARCH EXEMPTIONS IN OECD MEMBER COUNTRIES

A. Introduction

A number of OECD member countries have experimental use exemptions or defences in their patent law. There is a range of experimental use exemptions in place. Some countries have a statutory exemption while other countries, such as the United States, have a non-statutory case law exemption. In some countries, such as Australia, it is unclear whether an experimental use exemption even exists.

Further, the scope of the experimental use exemption varies considerably between the member countries that have an exemption.[35] For example, in the United States, whether or not the experimentation is commercially motivated appears to be an important factor in determining whether the experimental use exemption applies. However, in the EU, financial objectives appear to be less relevant as 'permissible experimentation may have some commercial objectives'.[36]

This Section provides a summary of the exemptions. A more complete list of the research use exemptions as they exist in the individual OECD countries is included in Appendix 1. The exemptions included in this Section will be discussed in three groups – statutory, case law and those that relate to the experimentation on products for the purposes of gaining regulatory approval for the invention.

B. Statutory exemptions

A number of countries have statutory exemptions. These include Iceland,[37] Japan,[38] Korea,[39] Mexico,[40] Norway[41] and Turkey.[42] Further, most EU countries have statutory exemptions that implement

35 The exceptions can also be seen to cover a range of issues such as experiments to verify the truth and sufficiency of a disclosure in a patent specification; experiments conducted in preparation for licensing; experiments aimed at acquiring data about a product to satisfy regulatory agencies; and experiments aimed at finding a new use for a patented invention (Martinez and Guellec, 2004).

36 ALRC (2004) Discussion Paper, 14.45.

37 *Patents Act 1993* s 3(3).

38 Section 69(1) of the *Patent Law*.

39 Section 96(1) of the *Patent Law*.

40 Article 22 of the *Industrial Property Law*.

41 *Patents Act* s 3.

42 Section 75 of the *Patents Decree Law*.

Article 27(b) of the Community Patent Convention (CPC).[43] The Article states that: 'The rights conferred by a Community patent shall not extend to: … (b) acts done for experimental purposes relating to the subject-matter of the patented invention'.[44]

The courts of a number of EU countries have added their interpretation to the statutory provisions. This has produced significant variation in the scope of the exemption across the EU. The courts in Germany have, for example, taken a 'very liberal' approach to the experimental use exemption.[45] In particular, two decisions of the German Supreme Court in *Klinische Versuche I* and *Klinische Versuche II* (Clinical Trials I and II) illustrate this approach. As a result of these decisions the German position has been considered to be that 'experiments or trials were permitted on a patented substance … 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'.[46] The German Constitutional Court concluded, in 2000, that patent owners had to 'accept such limitations on their rights in view of the development of the state of the art and the public interest'.[47]

C. Non-statutory law exemptions

The status of any research exemption is less clear where there is no statutory exemption. A number of OECD member countries do not contain such a legislative provision. These include Australia, Canada, New Zealand and the United States. These countries will be discussed in turn.

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43 The nations that are members of both the EU and the OECD include Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Spain, Sweden and the United Kingdom. Austria does not have a research exemption, however, s 22(1) of Austria's Patent Law provides that a 'patent shall vest exclusive authority in the patentee to produce the subject of the invention industrially, to put it on the market, to offer it for sale or to work it'. As a result, in most instances, mere research use of a patented invention will fall outside these privileges and will, therefore, not be an infringement.

44 Although the CPC never came into force, it has had an influential role in the development of patent legislation in the EU member states. As a result, article 27(b) has been widely implemented into the national patent statutes of the EU member states, including those who are also OECD member countries: Smith (2003), 18.

45 It has been noted that the 'situation in Germany is very liberal in allowing such tests. In most EU countries … clinical tests are regarded as patent infringement': ACIP (2004) Options Paper, 40.

46 ACIP (2004) Issues Paper, 4.

47 Ibid.

i) Australia

There is no statutory exemption in Australia's *Patents Act 1990*. The existence of an experimental use exemption, therefore, would appear to rest on a 19th century case *Frearson v Loe*,[48] where Jessel MR stated that:

> …no doubt if a man makes things merely by way of bona 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 to improving upon the invention the subject of the patent, or with the view to seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent.[49]

However, during their inquiry into Patents and Experimental Use in Australia, ACIP sought advice from the Australian Government Solicitor (AGS) as to the existence of the exemption under Australian law. AGS considered that:

> 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.[50]

The existence of a non-statutory case law exemption in Australia is not, however, universally agreed upon. Some commentators argue that such a non-statutory exemption 'would unduly stretch the statutory language of the *Patents Act*'.[51] Smith, for example, argues that the 'framework of the *Patents Act 1990* makes it unlikely that an experimental use exemption exists under Australian law'.[52] Thus, the existence, let alone the scope, of any experimental use exemption that may exist at common law in Australia is unclear.

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48 *Frearson v Loe* (1876) 9 ChD 48. It may appear odd that a 130 year old decision of an English court can represent a legal defence in an Australian court in the 21st century. English case law, while not binding, is strongly persuasive in areas of law where there are no statutory provisions to the contrary. The Australian *Patents Act 1990* is silent on the point of research exemptions, and therefore, if an Australian court is asked to rule on the existence of an exemption, recourse may be made to English decisions – though such decisions would be less relevant if they, in turn, were based on a statutory exemption, such as that contained in s 60 of the UK *Patents Act 1977*.

49 *Frearson v Loe* (1876) 9 ChD 48, 66-67.

50 ACIP (2004) Options Paper, 33.

51 Health Canada Report (2004), 14.

52 Smith (2003), 22.

ii) Canada

In Canada, an experimental use defence is established by case law. This exemption is recognised in the statutory provision relating to "springboarding".[53] The defence is available when experimentation is 'not for profit'.[54] However, the Canadian Biotechnology Advisory Committee (CBAC) has concluded that the 'current Canadian experimental use exception is vague' and case law does 'little to amplify the meaning of the exception'.[55] For example, 'it is unclear whether a researcher conducting research using a patented invention could successfully be sued where that research has potential in the longer term to result in a commercial product' – a concern raised by the Ontario Ministry of Health and Long-Term Care.[56]

3) New Zealand

The situation in New Zealand is relatively clear as there is relatively recent case law recognising an experimental use exemption.[57] One such case is the decision of *Smith Kline & French Laboratories v Attorney General*,[58] where the court, referring to *Frearson v Loe*, accepted the existence of an experimental use defence. The court held:

> 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 … even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention … in a way that serves to advance him in the actual market place, then he infringes, for the marketplace is the sole preserve of the patentee.[59]

However, it has been noted that: 'Although the New Zealand courts have drawn distinctions between experimental and commercially directed research, the law is said to remain "uncertain as to where the line actually falls between pure research and research for gaining a commercial advantage"'.[60]

iv) United States

The experimental use exemption recognised in US case law is quite limited. This is due to the effect of a number of fairly high profile decisions, namely *Roche Products Inc v Bolar*,[61] and the more recent *Madey v Duke University*.[62] In *Roche Products Inc v Bolar*, the court made clear the narrowness of the

53 Section 55.2(6) of the *Patents Act 1985*. "Springboarding" relates to uses of patented information provided for the purposes of gaining regulatory approval for an invention.

54 *Micro Chemicals Ltd v Smith Kline & French Inter-American Corporation* (1971) 25 DLR (3d) 79, 89.

55 Canadian Biotechnology Advisory Committee (2002).

56 Quoted in ALRC (2004) Discussion Paper, 14.28.

57 TThe New Zealand Patents Act 1953 was recently reviewed, and the NZ Ministry of Economic Development (MED), in consultation with the Ministries of Health (MoH) and Research, Science and Technology (MoRST), is investigating whether a research exemption should be included in the new Patents Bill that is currently being drafted. More information is available on the MED Web site at http://www.med.govt.nz/templates/ContentTopicSummary____2168.aspx

58 *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560.

59 *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560, 566.

60 ALRC (2004) Discussion Paper 68, 14.16, citing G Lynch and J Scarlett, *Experimental Defence to Patent Infringement*.

61 *Roche Products Inc v Bolar Pharmaceutical Co* 733 F 2d 858 (Fed. Cir. 1984).

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

exemption, finding that the experimental use defence could not be interpreted 'to allow a violation of the patent laws in the guise of "scientific inquiry", when that inquiry has definite, cognisable and not insubstantial commercial purposes'. The court found that the exemption was limited to experiments 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry' and did not extend to use for business reasons.[63]

The Federal Circuit decision of *Madey v Duke* continued this theme, with the court confirming that earlier cases had made clear that the experimental use defence was narrow, and that 'use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defence'.[64] The court in *Madey v Duke* also held that 'the profit or non-profit status of the user is not determinative'. These findings have been criticised, as one possible understanding of the case renders 'the experimental use defence unavailable to research institutions simply because their legitimate business is research.[65] Critics also argue that 'the Court's decision will have a significant chilling effect on academic research and fails to recognise adequately that the purposes of the patent system include facilitating research into patented subject matter by persons other than the patent holder'.[66] Further, the National Research Council of the National Academies has said that a 'reasonable interpretation' of the case is that 'formal research enjoys no absolute protection from infringement liability regardless of the institutional venue, the purpose of the inquiry, the origin of the patented inventions, or the use that is made of them'.[67]

D. Legal exemptions for the purposes of regulatory approval

Further to the general research exemptions a number of countries have a specific exemption that relates to use of patented products (especially pharmaceutical patents) for the purposes of gaining regulatory approval for the product. The countries with a general statutory research exemption tend to have a specific, limited, regulatory exemption. For example, a number of EU member states also have exemptions in relation to parties wishing to seek regulatory approval to market pharmaceutical products.[68] In addition, although there is no express regulatory review exemption in Japanese law, case law provides that regulatory testing falls within the section 69(1) exemption.[69]

The countries that rely on their non-statutory law for a general research exemption may, nonetheless, have a legislative provision for regulatory approval purposes. In Australia, this regulatory exemption is limited to parties wishing to seek regulatory approval for pharmaceutical inventions protected by a patent which have had a patent term extension.[70] In New Zealand, the *Patents Act* provides for an exemption where the use of the invention is 'solely for uses reasonably related to the development and submission of information required under New Zealand law … that regulates the manufacture, construction, use, or sale of any product'.[71] Canada also has a limited statutory experimental use exemption which applies only to regulated inventions, for example, pharmaceuticals.[72] As the exemption is limited, its impact on broader

63 *Roche Products Inc v Bolar Pharmaceutical Co* 733 F 2d 858, 863 (Fed. Cir. 1984).

64 *Madey v Duke University* 307 F 3d 1351, 1362 (Fed. Cir. 2002).

65 ALRC (2004) Report, 13.15.

66 Ibid.

67 National Research Council (2004), 7.

68 See for example the discussion in Health Canada Report (2004), 22-38.

69 ACIP (2004) Options Paper, 40.

70 Section 78(2), *Patent Act 1990* (Cth).

71 *Patents Act 1953* s 68B.

72 Section 55.2(6) of the *Patent Act* (Canada).

research concerns is minimal. It has been argued that the statutory exemption 'preserves the common law exemption as identified in the Supreme Court of Canada decision, [but] it does nothing to clarify either its nature or extent'.[73] As a result of the *Bolar* decision, there is now a statutory experimental use exemption in US law. The relevant provision limits the exemption to where the use of the invention is 'solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products'.[74]

E. Conclusion

This Section has demonstrated that there is a wide variation in the exemptions that allow for the use of patented inventions either generally for research purposes or specifically for the purposes of gaining regulatory approval. Some of the exemptions are based in legislation and others rely on decisions of the courts. The next Section details some of the concerns that have been raised with respect to such exemptions and, in particular, the concerns raised in countries where there is either no clear exemption or an exemption that is seen by researchers as being too restrictive.

73 Canadian Biotechnology Advisory Committee, (2002).

74 *Patents Act* s 271(e). This provision has recently been the subject of the US Supreme Court decision, *Merck v Integra Lifesciences* (125 S. Ct. 2372 (2005)). It was held that the 'statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process', at 16.

IV. IMPACT OF PATENTING ON RESEARCH: CURRENT AND ANTICIPATED CONCERNS

A. Introduction

The common issue underlying both the effects of *Madey v Duke* and the more general effects of the anti-commons is that increased patenting may create incentives for patent owners to only disseminate knowledge via licence agreements or withhold information from "rivals" including other academics.[75] These issues can be summarized in the following question: has the increased use of patents[76] (coupled with the absence of a research exemption) adversely affected the quantity or quality of scientific output? Have researchers abandoned projects on cancer research, for instance, because of the licensing conditions placed on the use of the OncoMouse?

Given that the decision is fairly recent, there is very little empirical work examining whether *Madey v Duke* has had any material effect on the level or quality of research undertaken in universities in the United States. But there has been a lot of discussion about its potential effects (and the effects of stronger IP rights in general) on university research.[77] There is also concern amongst the private sector that the absence of a research exemption will affect their R&D practices. This Section provides a review of the anecdotal and statistical evidence on the effects of patents on the research activities of scientists in both the public and private sectors.

B. Anecdotal claims

Numerous formal inquiries into the need for an experimental use exemption in patent law have been recently undertaken. Submissions to these inquiries outline some of the concerns that scientists have about the effects of patents on their research activities.

1) Lack of evidence concerning current situation

The first point to be made is that some of those making the submissions in countries where the law was unclear, generally thought research was exempt. For example, in the Australian context, the submission by Nicol and Nielsen to the ACIP Options Paper stated that it was 'not aware of any empirical evidence that the current legislation adversely affects research and development'.[78] Another noted that 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'.[79] A further

75 Another concern is that increased patenting may change the trajectory of academic research away from basic research to more commercially-focused endeavours. However, this issue is tangential to the issues at hand in this Working Paper.

76 Between 1992 and 2002, the number of patent applications in Europe, Japan and the US increased by more than 40%: OECD (2004).

77 See David (2004), Cohen (2005) and National Research Council (2004), for example.

78 ACIP (2004) Options Paper, 36. This claim was based on their (2004) study.

79 ACIP (2004) Options Paper, 36.

submission noted that 'researchers are simply getting on with the job and developing working solutions to the problems that they encounter'. The same submission added: 'There is little data to show that the balance between incentives such as patenting and access for downstream research is being "significantly affected" by either the presence, absence or ineffectual nature of an explicit experimental use exemption'.[80]

Submissions to the ALRC Discussion Paper on Gene Patenting and Human Health also showed similar views. One stated that there 'is no real evidence that gene patents or licences are inhibiting research in biotechnology in Australia'.[81] Another that, 'in many cases, the existence of gene and other biotechnology patents has attracted crucial financial support from biotechnology and pharmaceutical industries … and has allowed the continuation of medical research'.[82]

It has also been noted that it is only in 'rare' instances that a research project may not progress because of concerns over patented technology:

> There also does not appear to be any evidence that patent holders will unreasonably refuse to license to universities, thereby further impeding research. To the contrary, access to intellectual property rights very rarely leads to the termination of a worthwhile project. Rather, other considerations such as lack of confidence in the technical success of the project, market demand, and limited internal resources account for the decision to discontinue a project.[83]

2) Concerns for the future

However, others have noted that 'the absence of evidence … is not evidence of absence' of a problem, and further 'it is risky to assume that the present lack of evidence is indicative of future trends'.[84] One reason for the current lack of evidence might include factors such as researchers being unaware of infringement issues or 'believe some kind of experimental use exemption does exist'.[85] They argue that 'it would only take 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" develop in the research community'.[86] This view is also supported by a comment made by the US Federal Trade Commission (FTC) in a recent report:

> The strength and contours of the defence have not been fully tested; as several panellists testified, corporations typically have not sued universities. Some, however, have questioned whether the truce will endure, and, if it does not, whether the existing experimental use doctrine will afford much protection.[87]

The one clear concern that has been raised is that the lack of a research exemption can produce uncertainty in the minds of researchers. In its recent report the FTC suggested that the *Madey v Duke* decision has the 'potential to upset the equilibrium regarding research uses of patented inventions and may

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80 McBratney *et al* (2004), 17.

81 ALRC (2004) Discussion Paper, 13.23.

82 ALRC (2004) Discussion Paper, 13.24.

83 Rowe (2005), 40.

84 McBratney, Nielsen and McMillan (2004), 1024.

85 Ibid.

86 Ibid.

87 Federal Trade Commission (2003), Ch 4, 35.

heighten any problems raised by uncertainty over the reach of the experimental use defence' thereby warranting 'continued attention as the implications of these recent developments in the law become better understood'.[88]

ACIP, however, found that while there is 'no strong empirical evidence' that the current uncertainty surrounding the existence and scope of an experimental use exemption in Australia is having a significant impact in innovation, it did note that '…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 limiting experimental use'.[89] A number of submissions to the ALRC also had this view. One stated that although gene patents do not appear to have an adverse impact on research currently 'this appears to be because patents are not being enforced rather than because they either encourage or inhibit biotechnology research'.[90] Another, supported by the Royal College of Pathologists of Australasia, noted that although there 'may be no evidence that research is being hindered by gene patents the field is very new and there has been little time to observe such impact'.[91]

3) Patented research tools

One further concern raised in relation to genetic research, in particular, is the need to use patented technology as a tool for research. Dreyfuss argues that the nature of much innovation has changed, and many inventions in the field of technology now:

> …have immediate, commercial applications as diagnostics or treatments and thus they qualify for patent protection. At the same time, they are of crucial importance to researchers, and as such, they have enormous power ... They cannot be invented around: for instance, any scientist who wants to study the genetics of breast cancer needs to utilize the BRCA 1 test.[92]

As alluded to by Dreyfuss, research tools are becoming particularly important in the field of biotechnology.[93] These pose a special problem in terms of formulating an experimental use exemption. As noted by the NRC:

- First, with the expansion of patenting of research tools the likelihood that research far removed from commercial applications will entail use of proprietary technology may be increasing.
- Second, at least in biotechnology, restrictions on access to rival-in-use foundational research tools can inhibit realization of their full potential because no single firm can conceive of all of the ways the discovery might be exploited.[94]

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88 Federal Trade Commission (2003), Ch 4, 37.

89 ACIP (2004) Options Paper, 38.

90 ALRC (2004) Discussion Paper, 13.27.

91 ALRC (2004) Discussion Paper, 13.28. Such a fear may be exacerbated by the perception noted in a submission to the ACIP Options Paper that, in relation to human genetics, the number of genes and complexity of interactions between them might give rise to a 'patent gridlock': ACIP (2004) Options Paper, 22. That is, the sheer number of expected patents in the area may produce a chilling effect on genetic research.

92 Dreyfuss (2004), 463.

93 The complexity of the tools involved in the biotechnology field may make this research sector a "special case". Most of the empirical work carried out into the impact of research use exemptions has focused on biotechnological research – this may suggest that there are particular concerns in this area or that this area has been the focus of study for other, unknown reasons.

4) Potential impact of litigation

Another effect that has been raised in the literature is the threat of litigation. This is seen as being particularly problematic for public research organisations that may not have substantial budgets. It has been argued by Barash that an:

> effect of extensive patent litigation against universities may chill many research activities, not just those in which an invention may be patented, by requiring researchers to investigate whether their proposed laboratory research infringes any known patent. While corporations have legal departments geared towards answering potential legal quagmires, universities do not have the infrastructure to render routine opinion work to researchers.[95]

Rowe disagrees with this analysis, arguing that the *Madey* decision is unlikely to have a negative impact on research in universities:

> The practical reality is that the decision will probably have little effect on the way in which researchers conduct their day-to-day business. This is mostly because the research marketplace will continue to guide and control the conduct of researchers and patent holders (especially considering that they may often reverse roles) thus providing an appropriate balance between enforcing patent rights and allowing innovation.[96]

Rowe also suggested that the type of research carried out in publicly-funded institutions may reduce the risk. That is, she argues universities are unlikely to become victims of patent infringement suits, noting that:

> It is highly unlikely that a patent holder will discover infringement or even sue an early stage researcher because, among other reasons, the damages would be too small to justify the cost of the litigation. Rather, serious negotiations between the researcher and the patentee occur toward the later stages of the product development process, because at that point they both have greater reason and incentives to strike a deal.[97]

It may, however, be acknowledged that, as a result of the push towards commercialising tertiary education, the nature of universities is changing: where once they were the domain of academic research, they are now significant patent owners in their own right.[98] There is, therefore, a chance that universities themselves will instigate patent litigation to protect their economic interests.

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94 National Research Council (2004), 110.

95 Barash (1997), 698. Rowe, however, questions whether it is necessary to give universities 'special treatment', arguing that 'to the extent university labs continue to look more like their commercial counterparts, it will become even more difficult to justify special treatment for universities': Rowe (2005), 58.

96 Rowe (2005), 35. Her evidence for this was, in part, based on the findings of the Walsh, Arora and Cohen research. This research is discussed in the next section.

97 Rowe (2005), 58.

98 For a discussion of some of the intellectual property issues relating to university research see Nottenburg, Pardey and Wright (2002).

C. Statistical and survey studies

The ideal conditions under which research exemptions should exist revolve around the impact of patenting on investment incentives. Unfortunately, there are no empirical studies which analyse this issue specifically. Rather, the empirical issue addressed is whether the increased rate of patenting has had an effect on the quantity or quality of scientific progress. The restriction of shared scientific knowledge has been known about in the academic profession for some time,[99] however there is suspicion that it has become more prevalent in recent years. It is also known that private sponsors of academic research often include clauses in the contracts forcing scientists to comply with delay-of-publication clauses.[100]

There are a number of important recent contributions to the debate on the effects of patenting on research activity which are discussed here.[101] These results need to be tempered with an understanding of the research environment in which the studies took place. To the extent, for example, that researchers were either ignorant of or unclear about the absence of research exemptions or the increased prevalence of patents, or thought they existed but chose to ignore them, then the studies will not be expected to find that increased intensity of patenting has any effect on research behaviour.

1) Effects on academic publications

The initial starting point for an empirical exploration of the effects of patenting of scientific progress is whether patenting changes an academic's subsequent publication behaviour. Using different approaches, a number of recent US studies have explored this question.[102] These studies generally find that there is a positive and statistically significant relationship between academics' patenting behaviour and their subsequent publication record. Azoulay, Ding and Stuart, for example, find that 'across many specifications ... both the flow and stock of scientists' patents are positively related to subsequent publication rates'.[103] This tends to suggest that patents are not crowding out the level of scientific publications. It also does not appear as though there has been any change in the quality of publications following patenting.[104]

However, Azoulay, Ding and Stuart do find some evidence indicating that the content of scientific endeavour changes with increased patenting activity. In other words, the trajectories of technical progress are affected by academics' patenting behaviour: primarily through their relationship with corporate partner investigators (and co-authors). This suggestion is based on the finding that 'patenting … changes the content of [the surveyed] publications by connecting them more tightly with the world of commerce'.[105]

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99 See, for example, Rosenberg (1996), Cohen (1995), King (1996), and Campbell *et al*. (2000).

100 See Thursby and Thursby (2002).

101 These are more detailed than the study that shows that the countries with two of the most divergent approaches to research use exemptions have the highest level of R&D intensity measured as a percentage of GDP (Germany has a rate of 2.6% and the US a rate of 2.7%): Health Canada Report (2004), 49.

102 Including those of Azoulay, Ding and Stuart (2005), Markiewicz and DiMinin (2004) and Murray and Stern (2005).

103 Azoulay, Ding and Stuart (2005), 2.

104 They are careful in their efforts to establish causality. Since there is an obvious self-selection problem here (patentors are more likely to be accomplished researchers than non-patentors), they avoid using standard fixed-effect models and apply an Inverse Probability of Treatment Weighted estimation technique to account for the dynamics of self-selection.

105 Azoulay, Ding and Stuart (2005), 29. This conclusion, however, raises the issue of "reverse causality". That is, it is very difficult, given the models they have adopted, to demonstrate with any degree of certainty that the "end product", patents, produce changes in the objects of study, or academic publications.

They are also candid about the fact that their study is not able to address whether patents are actually hindering scientific progress through greater use of secrecy or delaying publication.

Murray and Stern develop an interesting empirical approach to examine the implications of the anti-commons hypothesis. They take advantage of the fact that many new scientific discoveries are both patented *and* published in scientific journals and use this to construct a set of 169 patent-paper pairs from the United States *i.e.* scientific discoveries that resulted in both a patent and a paper (all of which were published in the leading journal *Nature Biotechnology* during the period 1997 to 1999). They then compare the pattern of forward citations to scientific articles of the patent-paper pairs with the pattern of forward citations from a control group made of *non* patent-paper pairs. By doing so, they are able to address whether knowledge that is patented differs in its cumulative impact on scientific pathways from knowledge that is not patented.[106]

The empirical approach adopted by Murray and Stern utilises the fact that patents are often granted with considerable delay, while the delay for scientific papers is much shorter. Thus, the knowledge contained in a patent-paper pair is diffused under two different institutional regimes: one where the knowledge has been published (but not patented yet), and one where the knowledge is both published and patented. If the anti-commons hypothesis is correct, and patenting hinders scientists' use of "private" knowledge, then forward citations for publications which are patented should be lower than for similar publications with no patent. And furthermore, the anti-commons hypothesis predicts that the citation rate for publications for which patents are granted should fall once the patent is granted.

The first observation from the study is that patent-paper pairs are an important phenomenon, at least in biotechnology. Of the 340 publications in the sample, 169 (almost 50%) were part of a patent-paper pair. The most important finding with regard to the issues at hand here is a small but statistically significant anti-commons effect: the citation rate for articles published and then patented falls by 9 to 17% after the patent has been granted. The authors are cautious, however, in proscribing policy implications since they correctly point out that the granting of the patent 'may enhance incentives for (unobserved) research (particularly by private sector organizations) or lead to more effective commercialization (which is far more costly than the basic research itself)'.[107]

Sampat adopted a similar empirical strategy to that developed by Murray and Stern, in that he constructed a set of patent-paper dyads (which is the equivalent of a "pair") and then looked at differential citation patterns.[108] His sample differs from the Murray-Stern paper in that he uses the population of genomic patents granted between 1990 and 2000 to construct a sample of 590 patents which were the result of research conducted at 15 major tertiary institutions in the United States. In addition, only patents which were the result of research that was funded by the National Institutes for Health were included. These 590 patents were then matched to academic publications, where possible – which resulted in 499 unique patent-paper dyads. His results show that genomic research publications which are patented at some later point in time do have fewer citations than similar non-patented research publications. The results are driven by patented genomic sequences: non-sequence genomic discoveries demonstrated no significant negative effect. Sampat also finds that patent grants do have a negative differential impact on citations across technology classes, over the life cycle of the research publication, and across different cohorts.

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106 In doing so, they are relying on the assumption that forward citations are a good way to measure this. This assumption is criticised in the literature that uses forward citations as a measure of patent quality since it is known that many citations are included by the patent examiner for reasons not related to the value of the underlying knowledge.

107 Murray and Stern (2005), 31.

108 Sampat (2004).

2) Other effects on scientific research

A recent survey conducted by the American Association for the Advancement of Science (AAAS) asked 4 017 scientists in the public and private sectors a range of questions about the effects of patenting on their research activities.[109] A total of 1.111 (or 28%) of the scientists responded to the survey, of which 843 were actively conducting research or specialising in intellectual property. The survey asked scientists whether their research had been affected by difficulties in acquiring the right to use patented technology. Of the 179 respondents to this question, 40% stated that their research was affected, either through delays in their research, changes to the research project, or abandonment of the research project.[110] Bioscience was the field where the effects were largest, with industry-based researchers twice as likely as university-based researchers to report problems.

Another survey of researchers undertaken in the United States by Walsh, Arora and Cohen reported researchers' perceptions on the effects of patenting on research conduct. Their results are quite different to those of the AAAS. The major finding was that '[t]he vast majority of respondents say that there are no cases in which valuable research projects were stopped because of IP problems relating to research inputs'.[111] The researchers found that they 'did not observe as much breakdown or even restricted access to research tools as one might expect because firms and universities have been able to develop "working solutions" that allow their research to proceed'. These 'working solutions' include a combination of 'licences, inventing around patents, infringement (often informally invoking a research exemption), developing and using public tools, and challenging patents in court'.[112]

These findings are in keeping with the results of an earlier, smaller, German study.[113] The work of Straus suggests that 'patents on research tools have not had a discernible effect on the cost of pace of research in Germany'.[114] The reasons proposed for this include that 'it is difficult to detect infringement of research tools which are used behind laboratory doors' and 'public research bodies claim that their staff are often unaware of the legal implications of using patented research tools'.[115] The conclusion reached was that 'many groups act as if an "informal research exemption" exists for the use of patented research tools'.[116]

However, this does not mean the law is satisfactorily reflecting desired economic policy. Placing researchers in a position where they feel the best route is to ignore, infringe, or challenge a patent suggests that researchers may be sitting on a litigation time bomb which is exposing the research community to increasing risk of litigation. Placing firms in a position where they move off-shore specifically to undertake licence-free research suggests an inefficient research environment.

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109 Hansen, Brewster and Asher (2005).

110 The most common causes of changes to (or abandonment of) the research projects were: complex licensing arrangements, high royalties, no licensing possible, and breakdowns in licensing negotiations.

111 Walsh, Arora and Cohen (2003), 286.

112 Ibid.

113 The results of the survey were discussed in OECD (2002).

114 OECD (2002), 47.

115 OECD (2002), 47-48.

116 OECD (2002), 48.

D. Conclusion

This Section has raised a number of concerns with respect to the impact of patents on future scientific research. The empirical work relating to the publication of scientific papers seems to suggest that increased patenting may have a negative impact on the quantity and quality of subsequent research, although the results are not conclusive. However, this research really addresses the broader picture of patenting activity on scientific research. As yet, there has been no statistical analysis of the effects of the *Madey v Duke* decision. Future research on this issue will help answer the question about whether the absence of a research exemption is adversely affecting scientific research.

There is also mixed evidence on whether patenting adversely affects researchers' ability to undertake specific research projects. Much of the anecdotal evidence suggests that researchers do not consider that patents have caused significant problems in the conduct of their research, although this may be partly because they are ignoring the law where it is unclear. However, the recent survey by the AAAS reported that researchers in both public and private sectors have encountered problems in using patented technologies.

Overall, this review of the literature suggests that there is a legitimate concern that the effects of increased patenting activity may increase over time. Given the importance of patented technology as research tools, particularly in the biotechnology field, this raises the policy question of whether an exemption should be put in place now to guard against future restrictions on research or whether there needs to be concrete evidence of an effect before an exemption is introduced or increased. The next Section details the various forms of exemptions that have been put forward as options and the advantages and disadvantages of each form.

V. MECHANISMS FOR ENCOURAGING RESEARCH USES OF PATENTED INVENTIONS

A. Introduction

A wide variety of options are available to address some of the problems and issues outlined above that are associated with experimenting with patented inventions. These range from a statutory exemption (as exists in the EU and some OECD members) to non-legal solutions such as the creation of publicly accessible databases. The NRC considered that, in light of the *Madey v Duke* decision, there should be limited protection to 'shield some research uses of patented inventions from liability for infringement'.[117] The NRC concluded:

> We believe [the] circumstances may justify providing some sort of safety valve, but designing a targeted solution is an altogether more difficult matter than deciding whether one is needed. For one thing, not all activities that could be considered research deserve protection. Curiosity-driven inquiry that advances fundamental knowledge perhaps should not be subject to infringement liability, but R&D that is directed at commercializing the patented product should not be free to ignore intellectual property. Where to draw the line is far from obvious.[118]

It may be that the best solution is actually a mix of a number of the options discussed below. Unfortunately, there is no empirical research that suggests which of them is the most effective in promoting effective scientific research.

One issue needs to be raised prior to the discussion of specific options for a research exemption – the scope of the analysis of each of the options. Section Two included a description of the economic and legal frameworks against which any exemption should be judged. The detail required for an analysis of:

- The balance between injurious spill-overs and the incentive to invest; and
- Compliance with the TRIPs requirements

means that an assessment, in these terms, of each of the options below is not possible given the scope of this Working Paper. There is, therefore, no conclusion as to which of these possibilities is the "best", either economically or legally. Significant future research may be necessary in this area.

B. Statutory exemption for experimental use

1) Possible forms of statutory exemption

A statutory experimental use exemption is one mechanism commonly used to encourage research and innovation with respect to patented inventions. As discussed above, a statutory exemption for experimental use currently exists in a number of OECD member countries, such as the EU member states and Japan. As

117 National Research Council (2004), 7.

118 National Research Council (2004), 110.

noted by one commentator, EU member states 'have included the experimental use exemptions in legislation without apparent negative effects'.[119] A statutory approach has also been recommended by a number of inquiries in the context of reforming the law in Australia.[120] While a statutory experimental use exemption has the advantage of creating some legal certainty, there may still be considerable scope for courts to interpret the provision.

A statutory exemption has, in addition, had significant academic support. In a survey of the literature, Hagelin discusses a number of authors who have made various experimental use exemption proposals. One of the earliest commentators, according to Hagelin, was Richard Bee. Bee, in 1957, proposed an extremely narrow experimental use exemption, not unlike that outlined in *Madey v Duke*. Another commentator, Walters, proposed an experimental use exemption 'for universities and individuals only if they derive no monetary benefit from the research exemption'. Karp considered a similarly narrow exemption, except that 'Karp would extend the experimental use exemption to corporations and allow the commercial use of exempted research if the patentee is paid a reasonable royalty for the exempted research'.[121]

It is worth noting that there are a number of issues that arise in formulating a statutory experimental use exemption. These include:

- Whether the experimentation is on a patented invention and/or is research involving the use of a patented invention.
- The purpose or intention of experimentation or research, in terms of its technical, scientific or commercial motivations.
- The technical, scientific or commercial outcomes of experimentation or research; and
- The nature of the organisation conducting the experimentation or research, for example whether the organisation is a commercial or not-for-profit entity.[122]

In the EU, the experimental use exemption allows experimentation 'relating to the subject matter of the invention'. This differentiates between experiments that are on the invention, as opposed to experiments that actually use the invention. To illustrate the difference, the ARLC notes the example that 'work to provide an improved polymerase chain reaction (PCR) methodology would probably qualify as experimental use, but not work which simply used PCR as a standard methodological step'.[123] However, the ALRC also goes on to highlight the difficulties associated with allowing experimentation 'relating to the subject matter of the invention': 'Inevitably, there will be doubts about where permitted experimental use merges into broader research use that is not covered by the defence'.[124] To address this issue, CBAC

119 ALRC (2004) Discussion Paper, 14.142.

120 The ALRC has recommended that the *Patent Act 1990* (Cth) be amended to include an experimental use defence (see (2004) Discussion Paper, Proposal 14-1), and a number of the preferred options by ACIP expressed in its Options Paper also include statutory amendments to include an experimental use exception. CBAC has also recommended reform in Canadian legislation, for a 'research and experimental use exception' which provided that: 'It is not an infringement of a patent to use a patented process or product either: (a) privately and for non-commercial purposes; or (b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process': CBAC (2002), 15.

121 Hagelin (2005), 37-40. See also Mueller (2004).

122 ALRC (2004) Discussion Paper, 14.134.

123 ALRC (2004) Discussion Paper, 14.102.

124 Ibid.

suggests an experimental use exemption that is more explicit in its scope, being: '...to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process'.[125]

A number of the options for reform put forward by ACIP in its Options Paper included an EU-style exemption, which distinguished between experimenting on the subject matter of the invention, and experimenting with the invention. One such option was an exemption for experimenting 'on the subject matter of the invention' with certain inclusive permitted uses also specified. The exemption would be available where the experiment was to 'investigate' the subject matter's 'properties or improve upon it [and] the exemption is only available if experimentation is the sole or dominant purpose of the act'.[126] ACIP also put forward another set of other statutory options such as exemption for certain permitted uses, and changing the definition of 'exploit' to exclude experimental use.[127]

One experimental use law reform legislation that has been proposed in the United States was the Research, Experimentation and Competitiveness Act of 1990 (RECA). That proposal was very broad, and 'did not distinguish between for-profit and non-profit research organizations, nor between commercial and non-commercial research purposes'.[128] However, it did exclude from the exemption any patented invention with the 'primary purpose of research and experimentation', such as research tools.[129] Some commentators, such as Barash, have supported 'a limited adoption of the RECA exemption only for universities and non-profit research centres'.[130] Barash is concerned, however, that a broader exemption would have a negative impact on universities and non-profit research institutes.[131]

2) Analysis of a statutory exemption

A number of the advantages and disadvantages of a statutory experimental use option were discussed in the ACIP Options Paper. The advantages of such a mechanism include:

- Provides some clarity, therefore reduces inefficiencies.
- Encourages further secondary innovation by non-patent holders.[132]

However, ACIP also outlined a number of disadvantages of a statutory experimental use exemption:

- Most versions may provide the impression that patent rights are otherwise absolute and that there are no other exemptions.

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125 CBAC (2002).

126 The permitted acts would include, but would not be 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'.

127 ACIP (2004) Options Paper, 9-12.

128 Hagelin (2005), 47.

129 H.R. 5598 101st Cong., 1st Sess ss 401-403 (1990). This piece of legislation was withdrawn before it was considered by the full house of representatives: Hagelin (2005), 47.

130 Hagelin (2005), 48.

131 His concern is based on an assessment of academic research culture as being one that does not pay heed to patents when conducting research. Such a culture would increase the likelihood of litigation and therefore may 'chill' research activities: Barash (1997), 698. If this research culture changed then, arguably, a broad research exemption would not have the feared impact on university research.

132 ACIP (2004) Options Paper, 8.

- Appropriate drafting would be crucial.[133]
- 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.[134]

Rowe also argues that a 'narrow experimental use exception … strengthens incentives to invent and innovate, while a broad experimental use exception would provide disincentives to invest in patenting and innovation'.[135]

Some of the difficulties associated with a statutory exemption allowing experimentation 'on the subject matter' of the invention were also highlighted by ACIP. These included:

- Experimentation 'on' and 'with' an invention can often be intertwined and may not easily be separated.
- The language may provide false comfort to researchers, as it will ultimately be interpreted by legal experts, not technologists.[136]

These difficulties may be somewhat mitigated by including a list of permitted uses. Listing some examples of which uses are permitted may help cast light on what is meant by allowing experimentation 'on the subject matter of the invention'.[137] ACIP also noted that one benefit of this type of statutory exemption is that the interpretation of the meaning of the provision would include scope for the courts to apply the exemption flexibly.[138]

This type of exemption received support from many of the submissions that ACIP received as part of its inquiry. For example, one submission noted that:

> 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).[139]

However, other submissions thought that the on/with distinction was not particularly helpful, particularly in areas such as biotechnology where inventions that are patented are 'also a form of discovery'.[140] Another submission commented that the on/with distinction was difficult for courts to define,

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133 That is, as has been reinforced in this Working Paper, there are many areas of complexity that relate to research exemptions. Therefore, any statutory exemption would have to be very clear as to, *inter alia*, whether it applies to research on or with a patented invention and whether it is available for commercially-oriented research or only for purely non-commercial research.

134 ACIP (2004) Options Paper, 8.

135 Rowe (2005), 9.

136 ACIP (2004) Options Paper, 14.

137 ACIP (2004) Options Paper, 14. See, for example, ACIP recommendation below at Section V.B.3.

138 ACIP (2004) Options Paper, 8.

139 ACIP (2004) Options Paper, 53.

140 ACIP (2004) Options Paper, 54.

and has led to differences in interpretation across jurisdictions such as the United Kingdom and Germany.[141]

3) ACIP recommendation

ACIP recently published its Report on an Australian patent research exemption.[142] The Council recommended that the *Patents Act 1990* be amended through the inclusion of the following provision:

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

- Determining how the invention works.
- Determining the scope of the invention.
- Determining the validity of the claims.
- Seeking an improvement to the invention.[143]

ACIP based this provision on the wording of the European provision because 'it is in harmony with European provisions, thus reducing complexity for users' and it 'provides scope for decisions to be made that reflect the overall intent of the legislation'.[144]

Broader benefits of this option were considered to be:

- A clarification of patent rights and the reduction of uncertainty.
- Further ensuring the compliance of Australian law with international obligations.
- The optimisation of 'total levels of innovation … through an appropriate balance of rights'; and
- The provision of 'sufficient flexibility' to the courts so that they may 'reach appropriate rather than literal decisions'.[145]

ACIP considered the 'costs' of the recommended provision to be:

- 'Some uncertainty over the boundaries of the exemption which can only be established over time through case law'.
- 'It is not in harmony with current US law, increasing complexity for those operating in both the Australian and US systems'.
- 'Patent holders and researchers must become familiar with the clarified law'; and
- 'The risk of unforeseen, detrimental effects and loopholes'.[146]

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141 ACIP (2004) Options Paper, 54.

142 ACIP (2005) Report.

143 ACIP (2005) Report, Recommendation 1.

144 ACIP (2005) Report, 69.

145 ACIP (2005) Report, 72.

146 Ibid.

C. Copyright analogies – Fair use and fair dealing

1) Scope of a fair use/fair dealing exemption

A number of commentators have put forward a mechanism to allow an exemption for 'fair experimentation',[147] which is based on the concept of fair dealing and fair use found in copyright law in the jurisdictions of a number of OECD member countries.[148] Such an option was also put forward by ACIP in the following terms:

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.
- 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.
- Developing an improvement to the invention.[149]

O'Rourke also postulates an exemption based on an analogy with copyright law, which would involve consideration of five factors:

> … (i) the nature of the advance represented by the infringement; (ii) the purpose of the infringing use; (iii) the nature and strength of the market failure that prevents a license from being concluded; (iv) the impact of the use on the patentee's incentives and overall social welfare; and (v) the nature of the patented work.[150]

O'Rourke notes that while 'this test resembles that of copyright fair use, it diverges to reflect the different incentive scheme of patent'.[151]

2) Analysis of fair use/fair dealing exemption

There are a number of issues worth discussing in relation to allowing an exemption for 'fair experimentation'. ACIP notes a number of benefits of such an exemption:

147 See, for example, O'Rourke (2000) and de Larena, (2005).

148 For example, Australia, the United Kingdom and the United States.

149 ACIP (2004) Options Paper, 13.

150 O'Rourke (2000), 1205.

151 Ibid.

- 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.[152]

The NRC also discusses some of the advantages of a 'fair experimentation' exemption:

> They are finely tuned to the needs of basic research, while preserving the incentives to innovate in technologies useful in research and elsewhere. They do not discriminate between sectors, for example, between for-profit and non-profit or university and corporate research performers. And they are broadly consistent with other industrialized countries' policies.[153]

However, ACIP also notes a number of difficulties with the concept. The flexibility of such an exemption could in itself lead to further uncertainty. Further, and perhaps more problematically, the 'language may provide false comfort, as it will ultimately be interpreted by legal experts, not technologists'.[154]

A number of submissions to ACIP regarding the fair experimentation exemption thought that the analogy between patent and copyright law 'could not be pushed very far'.[155] One such submission stated that:

> 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 ... 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.[156]

Rowe also doubts whether the fair use analogy is appropriate:

> The fair use doctrine has been quite troublesome in copyright law, and has engendered extensive litigation (about ten times more cases than the experimental use exception). Part of the reason for this problem is the ad hoc nature of the doctrine, lacking precise definition in order to remain flexible to adapt to new technologies on a case by case basis. It relies on the application of four factors that are broad and vague to determine whether use is fair. However, the application of these factors have led to inconsistent and unpredictable results ... It is to be expected that an experimental use exception that resembles the fair use doctrine will cause a tremendous increase in litigation as parties and courts struggle to decide which activities are covered by the exemption in any given case.[157]

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152 ACIP (2004) Options Paper, 13.

153 National Research Council (2004), 114.

154 ACIP (2004) Options Paper, 13.

155 ACIP (2004) Options Paper, 55.

156 Ibid.

157 Rowe (2005), 59.

D. Licence-based exemption

1) Scope of a licence-based exemption

A number of commentators, particularly in the United States and at least one expert review body, have put forward proposals of various licensing schemes. One of the options put forward by ACIP involved statutory licensing for experimental use. Under this option, the Patent Act would:

> 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.[158]

Hagelin also summarises various proposals for qualified exemptions, such as that of Eisenberg who proposes that where the 'researcher is using the patented subject matter to make further advances in the technology in competition with the patent owner', the researcher 'would be entitled to a compulsory licence to use the patented technology for research purposes upon payment of reasonable royalty damages to the patent owner'.[159]

Mueller makes a proposal in relation to research tools 'to permit non-consensual use of research tools not readily available for licensing on reasonable terms or via anonymous marketplace purchase'. Mueller also proposes 'the adoption of a reach-through royalty structure that would link the royalty payment with the ultimate commercial value of the products developed from use of the patented research tool'.[160]

Strandburg supports Mueller's proposal, but modifies it with a compulsory licensing system. Strandburg's proposal is that 'patent rights for research tools might consist of two periods: a few years – perhaps three to five – of complete exclusivity followed by a period to complete the patent term during which compulsory licenses would be available'.[161]

2) Analysis of a licence-based exemption

ACIP notes a number of advantages associated with a statutory licensing scheme for experimental use. These include:

- 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.

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158 ACIP (2004) Options Paper, 16.

159 Hagelin (2005), 43-44.

160 Mueller (2001), 58.

161 Strandburg (2004), 143. Thomas also supports a licensing scheme to facilitate use of research tools. For him, such a regime would ensure 'a royalty award of sufficient amount to maintain incentives for the development and patenting of new research tools, yet [alleviate] the access restrictions and up-front costs currently associated with acquisition and use of many proprietary research tools': Thomas (2004).

- Reduces non-payment by researchers where infringement currently occurs.[162]

Strandburg also argues that her proposal may provide a solution in relation to research tools:

> Experimentation "with" patented inventions – the case of research tools – poses more difficult questions because the patentee's ability to recoup tool development investments is entangled with her ability to exert undue control over tool-based research. After considering proposals for research tool exemptions based on the non-profit status of the researcher, I conclude that a more effective scheme for speeding the pace of commercially significant research while preserving incentives to invest in tool development is a two-tiered compulsory licensing scheme … This two-tiered scheme would implicitly sort out situations in which the research tool is a mere "tail wagging a dog" of complicated research.[163]

However, it appeared to ACIP that the disadvantages far outweighed the benefits:

- 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 [international obligations[164]]. 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 licence negotiations (might be reduced by allowing patentees to opt out).
- If patent holders are allowed to opt out of the scheme, then holders of very valuable patents will do so, resulting in a scheme only for less-used patents.
- May be difficult to police, and to determine fair royalties.
- Initial problems and costs of setting up collecting societies for patent [royalties].
- General transaction costs of major change.
- A practice of patenting purely in order to obtain experimental use royalties may emerge (*i.e.*, patent thickets may be encouraged).[165]

In summary, ACIP considers 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’.[166]

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162 ACIP (2004) Options Paper, 16.

163 Strandburg (2004), 146.

164 This would include the TRIPs agreement.

165 ACIP (2004) Options Paper, 16.

166 Ibid.

E. "Open Source" model

1) Scope of an "open source" model exemption

One other significant mechanism to encourage legitimate research has been proposed by Dreyfuss.[167] Her proposal relates specifically to her concerns regarding university research, as noted above:

> …a university or other non-profit research institution that wants to use patented material and cannot obtain a license from the patentee on reasonable terms could use the technology without permission if it is willing to sign a waiver. The waiver would require the institution to promptly publish the results of work conducted with the patented technology and to refrain from patenting discoveries made in the course of that work.[168]

Nelson supports such a proposal,[169] but 'would allow the researchers to patent their work, but require them to agree to license on a nonexclusive basis for reasonable royalties'.[170] Under this proposal, universities would be immune from being prosecuted for patent infringement if the following conditions hold:

i) The patented material was not available to researchers on "reasonable" terms.

ii) The investigators agreed to publish the results.

iii)The university agreed not to patent any output of the resulting research.[171]

Nelson acknowledges the problems associated with defining "reasonable" and identifying direct outputs of a particular research project. However, it has two major things in its favour: it opens up the possibility that university researchers will have open access to important research tools and it prevents universities from engaging in undesirable subsequent patenting. Somewhat surprisingly, given their traditional role as the promoters of open science, Nelson sees the universities themselves as the major obstacle to this implementation of such a policy since they are behaving more and more like revenue-maximising entities and patent royalties are seen as an important vehicle for obtaining money for something they previously provided for free. For Nelson, the purpose is 'not to eliminate university patenting, but to establish a presumption that university research results, patented or not, should … be made available to all that want to use them at very low transaction costs and reasonable financial costs'.[172]

One issue that would need to be addressed under an open source system is the commercialisation problem. While open source licensing does not prevent commercialisation (in fact, the open source definition requires that there be no discrimination against persons, groups or fields of endeavour), there is a question over whether firms that are unable to secure exclusive property rights to a university invention

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167 See Dinwoodie and Dreyfuss (2004) for a summary of this and other policies and their compatibility with TRIPs.

168 Dreyfuss (2004), 471.

169 Nelson (2004).

170 Dreyfuss (2004), 471.

171 An similar alternative mechanism is suggested by a submission in the ACIP Options Paper: ACIP (2004) Options Paper, 21.

172 Nelson (2004), 469. To enact this, Nelson suggests amending the *Bayh Dole Act* in a way which reflects the importance of all university research output by explicitly encouraging the widest possible licensing arrangements.

would be prepared to invest money into its commercialisation.[173] The manner in which this problem could be resolved has yet to be answered in the literature and requires further research and analysis.[174]

2) Creative Commons

The Creative Commons is a system of alternative licensing for intellectual property rights.[175] The system provides intellectual property owners with a standardised set of licence agreements to facilitate the sharing of their intellectual property with others.[176] As with most licence agreements, Creative Commons licences allow the intellectual property owner to retain her or his intellectual property rights while permitting the users of the intellectual property to utilise it in a manner consistent with the terms of the licence.[177]

Creative Commons licences may contain the following terms, or some combination thereof:

- Attribution – allows users to use, reproduce and communicate the subject matter of the intellectual property right as long as they give the creator credit.
- Non-commercial – allows users to use and reproduce the subject matter of the intellectual property right as long as it is not for commercial purposes.
- No derivative – allows users to use the subject matter of the intellectual property right as long as they do not use it to produce subject matter that would attract intellectual property protection in its own right (derivative works); and
- Share-alike – allows users to produce derivative works as long as they allow these works to be shared under the same licensing conditions.

Creative Commons licences, however, are currently only available for copyright material.[178]

(3) Analysis of "open source" model exemption

Dreyfuss outlines a number of benefits of her open source model proposal:

> It eliminates the need for courts to characterize research as aimed as satisfying intellectual curiosity or for commercial purposes….By providing this special right to university and non-profit researchers, the proposal also recognizes the differences in resources between universities and

173 Hope (2004) discusses the possibility of using an open source licensing system in the biotechnology area particularly for research tools and other "upstream" developments.

174 It may be noted that, in the software field, various methods for dealing with patents are developing. The Open Innovation Network, for example, was recently announced. OIN is a company that has, and will acquire, patents and will offer them royalty-free to individuals and organisations under certain conditions to encourage innovation in open source software development.

175 The Creative Commons itself is a non-profit organisation based at Stanford University.

176 See, generally, Lessig (2004) and Merges (2004).

177 The licence itself comes in three forms: computer-readable, lawyer-readable and human-readable. The computer-readable form enables the licence to be built into electronic uses; for example, search engines can perform searches for material licensed in a particular form.

178 Science Commons encourages open access to science research publications and there is an intention to develop the project to include licences for materials such as cell lines and research tools. An organisation has been established that seeks to apply aspects of the Creative Commons model to software patents – see, generally, www.patentcommons.org.

> genuine commercial actors. At the same time, it eliminates the problem of creating a comparative advantage for universities over commercial enterprises when the university is, in fact, engaged in commercial work. Most important, the waiver serves to enrich the public domain because all resulting work is published and not patented (or licensed nonexclusively).[179]

However Dreyfuss also acknowledges a number of difficulties with a waiver mechanism:

> Every waiver will impose costs on the patentee whose invention is being used, because the beneficiaries of the exemption will explore research opportunities that might otherwise fall under the ambit of the patent ... Another question is whether anyone would ever file a waiver. Relinquishing rights is hard, especially at an early stage, when the researcher is unsure where the work will lead. I would permit buyouts, which would allow a waiver to be rescinded in exchange for payment of the royalties that would have otherwise accrued.[180]

F. Patent pools

One solution to the problem of patented research tools is the use of patent pools.[181] A patent pool is 'an agreement among patent owners to licence a set of their patents to one another or to third parties'.[182] Such pools are formed as a commercial response that deals with one of the significant concerns associated with the use of patents for research tools – that patents may affect the rate of research activity by creating a complex web of negotiations that must be resolved before the patented research tool can be used. This may occur in a world where innovation is cumulative in nature and multiple owners hold complementary patents (the semiconductor industry, for example). In this environment, each must obtain a license to the other's patent in order to produce a final good. As pointed out by Lerner and Tirole, this is not a new solution: versions of this idea have been around since the 1856 sewing machine pool.

Building on the work of Cournot,[183] Shapiro shows that both the producers and consumers are better off if the two patent owners can find a way to agree to use the other's patent, either through royalty-free cross-licensing, patent pools or package licensing arrangements. Lerner and Tirole extend the analysis to examine whether patents must be essential (*i.e.* have no external substitutes) as well as being complementary in order to be included in the patent pool. Although the "co-operation" involved in patent pools is often viewed sceptically in the eyes of competition law, the benefits of such co-operation are potentially large: for one, it avoids the problem of "multiple patent burdens" where licensing fees can stack up. In simple terms, it provides potential licensees with an opportunity for one-stop shopping.

G. Utility option

The last option to be discussed may be described as a 'utility option'. This would involve introducing a provision 'relating to patent utility that subsequently allows experimental use'.[184] The chief proponent of this approach argues that patents are best viewed as rights that attach to the use of an invention in a

179 Dreyfuss (2004), 471-472.

180 Dreyfuss (2004), 472.

181 See Lerner and Tirole (2004) and Shapiro (2001).

182 Lerner and Tirole (2004), 691.

183 Cournot (1838).

184 ACIP (2004) Options Paper, 14.

'manner which utilises the inventive step'.[185] That is, a patent 'should not confer the exclusive right to appropriate the value of uses which do not utilise the inventive step'.[186]

The example provided by Elkman is helpful:

> If an invention is embodied in the form of an electron microscope, an exact replica of the electron microscope could be constructed and subsequently used in ways which do not utilise the inventive step, *i.e.* in a manner which is unrelated to electron microscopy. For example, the physical object could be used as a sculpture or it could be used as a paper weight or (if sufficiently large) it could be used as the anchor to a ship. If the physical object is used for purposes unrelated to electron microscopy, the inventive idea is not being used and thus the value of the invention has not been appropriated.[187]

This understanding may be applied to a research use exemption. The research use of a patented invention as an 'object of scientific invention is neither novel nor inventive'.[188] That is, it 'does not involve an appropriation of any inventive step'.[189] As a result, it cannot be seen as an infringement of the patent rights. This approach, then, does not involve the introduction of an exemption but a rethinking of what is protected by the granting of a patent.

One of the benefits on this utility option is that it 'solves the root of the problem through a principle based approach'.[190] However, there are a number of disadvantages also acknowledged by ACIP, including the 'large short term costs in such a major change to the system'.[191] The impact of any reform, therefore, must be assessed in terms of the cost of its institution as well as the perceived benefits of its introduction.

H. Conclusion

This Section has focussed on the major options that have been proposed for a patent law research exemption. These have included a statutory exemption, as currently in place in the EU, a "fair experimentation" model based on copyright law exemptions, the introduction of a licensing system, the adoption of an "open source" model that emphasises the public good associated with the scientific research, the use of patent pools and, finally, a re-interpretation of the nature of patent rights themselves. Each of these options have their advantages and disadvantages.

The survey of the options included in this Section suggests a number of concerns that arise with respect to any proposed research use exemption. These are that the exemption should:

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185 Elkman (2004), 18.

186 Elkman (2004), 7.

187 Ibid.

188 Elkman (2004), 19.

189 Ibid

190 ACIP (2004) Options Paper, 14.

191 ACIP (2004) Options Paper, 15. This is the main argument against any proposal for the amendment of national patent laws to follow the Austrian provision. That is, to limit the privileges that attach to patents to specific purposes that do not cover research uses would be a major change and may pose significant problems to the patent system (as noted above, Austria's Patent Law provides that a 'patent shall vest exclusive authority in the patentee to produce the subject of the invention industrially, to put it on the market, to offer it for sale or to work it').

- Provide greater clarity for researchers (for example, through the inclusion of specific instances where the exemption would operate) – researchers should be able to understand the provisions in order to effectively comply with the law.
- Avoid unnecessary rigidity in its interpretation (allowing for the exemption to be adapted to new research methods and areas of technology).
- Not unreasonably impede either scientific development or investment in research (the two tensions that prompt the call for an exemption).
- Not reflect a substantial shift in the understanding and application of patent law (in order to minimise legal battles over the scope and effect of any changes).
- Contribute to the international harmonisation of patent law (in addition to complying with the current legal obligations such as the TRIPs Agreement).

Each of the options detailed in this Section accommodates a number of these concerns. It is not clear that any of the options respond to all of the concerns substantially better than the other options. Further, there is little empirical data that can be used to support the adoption of any one of the particular forms of exemption detailed here.

VI. CONCLUSION

A. Summary

The summary provided in this Working Paper suggests that there is reasonably strong evidence suggesting that patents may have some deleterious effects on scientific research. A research exemption may be an effective safety mechanism to minimise the chance that patents will adversely affect future research. There is, however, insufficient empirical data at this stage to demonstrate that any particular form of the exemption will be more effective than others in guarding against future restrictions on scientific work. The strongest argument may, therefore, be to introduce statutory exemptions in those nations that do not have them in order to further harmonise patent laws.

If existing research exemptions are harmonised, and if a research exemption is introduced in countries where currently there is none, it is important that the exemption complies with the economic rationale that can be seen to justify the exemption. That is, as the exemption may be seen as a subsidy to researchers, it is necessary to ensure that the knowledge produced under the exemption does not operate as an injurious spill-over for the holder of the patent. A research exemption, therefore, must be established in such a way as to encourage investment in non-commercial research but should not adversely impact on the returns on investment of the patent holder.

B. Future research

A further conclusion that may be drawn from the material in this Working Paper is that there is insufficient empirical evidence that points toward the most effective form that research exemptions should take. This, in turn, suggests that more empirical research needs to be carried out in this area.

Possible directions for research range from the purely legal to the empirical. A purely legal option could entail the detailed examination of all current exemptions and proposed reforms with respect to their compliance with international obligations, including, in particular, the constraints on patent exemptions contained in the TRIPs Agreement.

The more empirical options could take a number of forms. In order to evaluate whether research exemptions affect academic behaviour, various studies could be designed to compare whether academic behaviour is different in countries with statutory exemptions (*e.g.* Europe) from those where exemptions are narrow (*e.g.* the US) or non-existent. Specific options include:

- A comprehensive survey of university researchers (across OECD countries) to see whether the different legislative environments (weak/strong research exemptions) have differing effects.[192]

[192] One of the concerns with qualitative research in countries without a clear exemption is that it would be difficult to ascertain whether the behaviour of the researchers is an effect of the law itself or of an ignorance of the law.

- A "before and after" experiment to examine the effect of the *Madey v Duke* decision on university research (in the same way as Stern and Murray, but using data from before and after 2002); and
- An examination of incentives to invest in invention by private sector firms (over time and across countries) to see whether research exemptions affect their investment behaviour.

Each of these would go some way to assessing the need for, and impact of, research exemptions in patent law.

C. Conclusion

This Working Paper is built on an acceptance of the importance of both patent protection for inventors and the benefits that are gained from non-commercial scientific research. A research exemption appears to provide a suitable balance between these two imperatives. The value of these public goods is such, however, that the boundaries of the exemption need to be carefully drawn.

APPENDIX 1

SUMMARY OF EXPERIMENTAL USE EXEMPTIONS IN LAW OF OECD COUNTRIES

Country	Statutory Provision & Relevant Statute	Comments
Australia	Currently there is no statutory experimental use exemption in the *Patent Act 1990* (Cth).	No statutory research exemption, however it is generally accepted that there is an exemption to some degree at common law.
Canada	Currently there is no statutory experimental use exemption in the *Patent Act 1985*.	An experimental use exemption is established by case law and is available when experimentation is 'not for profit'.
European Union	Most EU Member States have a provision in their national statute which is similar to that of article 27 of the Community Patent Convention: 'The rights conferred by a Community patent shall not extend to: …(b) acts done for experimental purposes relating to the subject-matter of the patented invention…'	Austria is the only EU member country that does not have a research use exemption.
Iceland	Section 3(3) of the *Patents Act 1993* states: 'The following are excepted from the [patentee's] exclusive right…use of the invention for experiments which relate to the invention itself…'	
Japan	Section 69.-(1) of the *Patent Law* states: 'The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research.'	
Korea	Section 96.-(1) of the *Patent Law* states: 'The effects of the patent right shall not extend to the following: (i) working of the patented invention for the purpose of research or experiment…'	
Mexico	Article 22 of the *Industrial Property Law* states: **'**The right conferred by a patent shall not have any effect against: I. a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented…'	

New Zealand	Currently there is no statutory experimental use exemption in the *Patent Act 1953*.	An experimental use exemption is established by case law.
Norway	Section 3 of the Patents Act states: '…The exclusive right shall not include: …(3) Exploitation by experiment relating to the subject matter of the invention…'	
Switzerland	Currently there is no statutory experimental use exemption in the Patents Law.	The Swiss Law is currently undergoing revision.
Turkey	Section 75 of the *Patents Decree-Law* 'The following acts shall remain outside the scope of the rights conferred by the patent: …(b) acts involving the use of the patented invention for experimental purposes…'	
United States	Currently there is no statutory experimental use exemption under US statutory law.	Case law indicates that the exemption at common law is very narrow.

APPENDIX 2

SUMMARY OF CASES CITED

Case name	Jurisdiction of relevance	Area of relevance	Summary of findings
Canada – Patent Protection of Pharmaceutical Products - WTO Doc WT/DS114/R (2000)	WTO Member States	Canada's regulatory approval exemption in the context of the TRIPs Agreement	Provides guidance for the interpretation of Article 30 of the TRIPs Agreement.
Frearson v Loe - (1876) 9 ChD 48	Australia (arguably)	Research use exemption under English common law[193]	Experimentation is not an infringement of a patent if aimed at improving the invention or not for profit.
Micro Chemicals Ltd v Smith Kline & French - (1971) 25 DLR (3d) 79	Canada	Research use exemption in the 'context of research aimed at sustaining a compulsory licence'.[194]	Research use of patented inventions allowed where research is not for profit.
Klinische Versuche I - [1997] RPC 623; *Klinische Versuche II* - [1998] RPC 423	Germany	Research use exemption in the context of research into new indications of a patented substance	Experiments are allowed on patented substances in order to test the properties of the invention and to 'test for indications different from those claimed, insofar as the experiments were directed to the substance itself'.[195]
Smith Kline & French v Attorney-General - [1991] 2 NZLR 560	New Zealand	Research use exemption in the context of regulatory approval	If the researcher keeps the research to her or himself it is not an infringement
Roche Products v Bolar - 733 F 2d 858 (Fed. Cir. 1984)	United States	Research use exemption in the context of regulatory approval	Research exemption available where research was for 'amusement, to satisfy idle curiosity, or for strictly philosophical inquiry'.[196]
Madey v Duke University - 307 F 3d 1351 (Fed. Cir. 2002)	United States	Research use exemption in the context of university research	Research in keeping with the business of the researcher will infringe whether or not the research is for profit.
Merck v Integra Lifesciences - 125 S. Ct. 2372 (2005)	United States	Regulatory approval exemption	Research into pharmaceuticals permitted if for the provision of information for the regulatory approval of the drug.

193 In England this common law exemption has been complemented by a statutory exemption.

194 CBAC (2002), 14.

195 ACIP (2004) Issues Paper, 4.

196 733 F 2d 858, 863 (Fed. Cir. 1984).

BIBLIOGRAPHY

Advisory Council on Intellectual Property (ACIP) (2004), *Patents and Experimental Use: Issues Paper*, Australian Government: Canberra.

Advisory Council on Intellectual Property (ACIP) (2004), *Patents and Experimental Use: Options Paper*, February, Australian Government: Canberra.

Advisory Council on Intellectual Property (ACIP) (2005), *Patents and Experimental Use*, Report, Australian Government: Canberra.

Agrawal, A. and Henderson, R. (2002), 'Putting patents in context: exploring knowledge transfer from MIT', *Management Science* 48(1), 44.

Arrow, K. J. (1962), 'Economic welfare and the allocation of resources for invention', in *The Rate and Direction of Inventive Activity: Economic and Social Factors*, NBER Report, Princeton University Press: Princeton.

Australian Law Reform Commission (2004), *Gene Patenting and Human Health*, Discussion Paper 68.

Australian Law Reform Commission (2004), *Genes and Ingenuity: Gene Patenting and Human Health*, Report 99.

Azoulay, P., Ding, W. and Stuart, T. (2005), 'The impact of academic patenting on the rate, quality and direction of (public) research output', Columbia University, available from: http://econ.arizona.edu/downloads/Seminars/05F_Azoulay.pdf.

Barash, E. H. (1997), 'Experimental uses, patents and scientific progress' 91 *Northwestern University Law Review* 667.

Bessen, J. and Meurer, M. (2005), 'The patent litigation explosion', Boston University School of Law Working Paper No. 05-18.

Campbell, E. G., Weissman, J. S., Causino, N. and Blumenthal, D. (2000), 'Data withholding in academic medicine: characteristics of faculty denied access to research results and biomaterials', 29 *Research Policy* 303.

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

Cohen, J. (1995), 'Share and share alike isn't always the rule in science', 286 *Science* 1715.

Cohen, W. M. (2005), 'Patents and appropriation: concerns and evidence', 30 *Journal of Technology Transfer* 57.

Cohen, W. M., Nelson, R. R. and Walsh, J. P. (2002), 'Links and impacts: the influence of public research on industrial R&D', 48 *Management Science* 1.

Cournot, A. (1838), *Researches into the Mathematical Principles of the Theory of Wealth*, New York: Macmillan.

David, P. A. (2004), 'Can "open science" be protected from the evolving regime of IPR protections?', 160 *Journal of Theoretical and Institutional Economics* 1.

de Larena, L. (2005), 'What copyright teaches patent law about "fair use"' 84 *Oregon Law Review* (forthcoming).

Dinwoodie, G. B. and Dreyfuss, R. C. (2004), 'International intellectual property law and the public domain of science', 7 *Journal of International Economic Law* 431.

Dreyfuss, R. (2004), 'Protecting the public domain of science: Has the time for an experimental use defense arrived?' 46 *Arizona Law Review* 457.

Elkman, S. (2004), 'The research exemption to patent infringement: A doctrine in search of a principle' (2004) Intellectual Property Research Institute of Australia, Working Paper 10/04.

Federal Trade Commission (2003), *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, Washington.

Gallini, N. and Scotchmer, S. (2002), 'Intellectual property: when is it the best incentive system', in Jaffe, A., Lerner, J. and S. Stern (eds.) *Innovation Policy and the Economy* Vol. 2, MIT Press: Cambridge.

Gans, J. (2005), 'The dynamic effects of intellectual property practices' *Intellectual Property Research Institute of Australia*, Working Paper, forthcoming.

Hagelin, T. (2005), 'The Experimental Use Exemption to Patent Infringement: Information on Ice, Competition on Hold' (August 5, 2005). http://ssrn.com/abstract=776865

Hansen, S., Brewster, A. and Asher, J. (2005), 'Intellectual Property in the AAAS Scientific Community', American Association for the Advancement of Science, New York.

Health Canada, *Report: The Research or Experimental Use Exception. A Comparative Analysis*, Paper prepared for Health Canada by the Centre for Intellectual Property Policy and the Health Law Institute, August 2004.

Heller, M. and Eisenberg, R. (1998), 'Can patents deter innovation? The anti-commons in biomedical research', 280 *Science* 698.

Hope, J. E. (2004), *Open Source Biotechnology*, unpublished PhD thesis, Australian National University.

King, R. T. (1996), 'Bitter pill: how a drug firm paid for a university study and then tried to undermine it', *Wall Street Journal*, April 25, Section A1.

Knight, F. (1921), *Risk, Uncertainty and Profit*, Houghton Mifflin Co.: Boston, MA.

Lerner, J. and Tirole, J. (2004), 'Efficient patent pools', 94 *American Economic Review* 691.

Lessig, L. (2004), *Free Culture: How Big Media Uses Technology and the Law to Lock Down Culture and Control Creativity*, Penguin Press, New York.

Machlup, F. and Penrose, E. (1950), 'The patent controversy in the nineteenth century', 10 *Journal of Economic History* 1.

Martinez, C. and D. Guellec (2004), 'Overview of Recent Changes and Comparison of Patent Regimes in the United States, Japan and Europe', Section 7, in *Patents, Innovation and Economic Performance* - Proceedings of an OECD Conference, OECD, Paris.

Markiewicz, K. R. and DiMinin, A. (2004), 'Commercializing the laboratory: the relationship between faculty patenting and publishing', UC Berkeley, available from http://faculty.haas.berkeley.edu/elf/ECON222/MarkiewiDiMinin3_04.pdf.

McBratney *et al* (2004), Submission to ACIP Issues Paper, available from: http://www.acip.gov.au/expusesubs/Amanda%20McBratney%20et%20al,%20Uni%20of%20Qld.pdf

McBratney, A. M., Nielsen, K. and McMillan, F. (2004), 'Australia Experiments with "Experimental Use" Exemption' 22 *Nature Biotechnology* 1023.

Merges, R. P. (2004), 'A New Dynamism in the Public Domain' 71 *University of Chicago Law Review* 183.

Merges, R. P. and Nelson, R. R. (1990), 'On the Complex Economics of Patent Scope', 90 *Columbia Law Review* 839.

Mowery, D. C., Nelson, R. R., Sampat, B. N. and Ziedonis, A. (2001), 'The growth of patenting and licensing by U.S. universities: An assessment of the effects of the Bayh-Dole Act of 1980', 30 *Research Policy* 99.

Mueller, J. M. (2001), 'No "Dilettante affair": rethinking the experimental use exception to patent infringement for biomedical research tools' 76 *Washington Law Review* 1.

Mueller, J. M. (2004), 'The evanescent experimental use exemption from United States patent infringement liability: Implications for university and non-profit research and development' 56 *Baylor Law Review* 917.

Murray, F. and Stern, S. (2005), 'Do formal intellectual property rights hinder the free flow of scientific knowledge? An empirical test of the anti-commons hypothesis', NBER Working Paper No. 11465, Cambridge, MA.

National Research Council of the National Academies (2004), *A Patent System for the 21st Century*, National Academies Press, Washington, DC.

Nelson, R. R. (1959), 'The simple economics of basic scientific research', 67 *Journal of Political Economy* 297.

Nelson, R. R. (2004), 'The market economy, and the scientific commons', 33 *Research Policy* 455.

Nicol D. and Nielsen, J. (2004), 'Patents and medical biotechnology: An empirical analysis of issues facing the Australian industry', Intellectual Property Research Institute of Australia, Report 01/04.

Nordhaus, W. (1969), *Invention, Growth and Welfare: A Theoretical Treatment of Technological Change*, MIT Press: Cambridge.

Nottenburg, C., Pardey, P. and Wright, B. (2002), 'Accessing Other People's Technology for Non-Profit Research', 46 *Australian Journal of Agricultural and Resource Economics* 389.

OECD (2002), *Genetic Inventions, Intellectual Property Rights and Licensing Practices*, OECD, Paris.

OECD (2004), *Patents and Innovation: Trends and Policy Challenges*, OECD, Paris.

O'Rourke, M. A. (2000), 'Toward a doctrine of fair use in patent law', 100 *Columbia Law Review* 1177.

Rosenberg, S. A. (1996), 'Secrecy in medical research', 334 *New England Journal of Medicine* 392.

Rowe, E. A. (2005), 'The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?' (2006) 57 *Hastings Law Journal* (forthcoming).

Sampat, B. N. (2004), 'Genomic patenting by academic researchers: bad for science?', Georgia Institute of Technology, Atlanta, available from: http://mgt.gatech.edu/news_room/news/2004/reer/files/sampat.pdf.

Scherer, F. M. (2002), 'The economics of human gene patents', 77 *Academic Medicine* 1348.

Shapiro, C. (2001), 'Navigating the patent thicket: cross license, patent pools and standard-setting', in Jaffe, A., Lerner, J. and Stern, S. (eds.) *Innovation Policy and the Economy*, Volume I, MIT Press, Cambridge, MA.

Smith, C. (2003), 'Experimental Use Exception to Patent Infringement – Where Does Australia Stand?' 50 *Intellectual Property Forum* 14.

Strandburg K. J. (2004), 'What does the public get? Experimental use and the patent bargain' [2004] *Wisconsin Law Review* 81.

Thomas, J. R. (2004), CRS Report for Congress, *Scientific Research and the Experimental Use Privilege in Patent Law*, October 28, 2004.

Thursby, J. G. and Thursby, M. C. (2002), 'Who is selling the ivory tower? Sources of growth in university licensing' 48 *Management Science* 90.

Walsh, J. P., Arora, A. and Cohen, W. M. (2003), 'Effects of research tool patents and licensing on biomedical innovation', in Cohen, W. M. and Merrill, S. A. (eds) *Patents in the Knowledge-Based Economy*, National Academies Press: Washington DC.