SUBMISSION

TO THE ADVISORY COUNCIL ON INTELLECTUAL PROPERTY

Patents and Experimental Use
ISSUES PAPER

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Question 1 (a) What is your understanding of current law on an experimental use exemption in Australia?
(b) What is the basis of this understanding and how certain are you of it?
(c) How has your understanding affected your research and development behaviour?

(a) Our understanding of the legal position in Australia regarding the experimental use exemption is similar to that expressed by ACIP in the Issues Paper. The current law is unclear because there is no explicit exemption and there is no relevant Australian case law. However, in our view if the judges of the Federal Court and High Court were given the opportunity to decide this issue they may well recognise a common law exemption or read an implied exemption into the *Patents Act* 1990 (Cth). There are various reasons for this. In particular, the Court is likely to look to relevant decisions in other jurisdictions with similar patent laws. The Court is likely to be influenced by *Frearson v Loe*, and also by the New Zealand decision in *Monsanto v Staufffer Chemical Company (NZ)*,[1] the Canadian decision in *Micor Chemicals Ltd v Smith Kline & French Inter-American Corporation*[2] and the US decision in *Whittemore v. Cutter*.[3] However, as with any matter based on judicial decision-making there can never be certainty as to the outcome. Hence, there is justification for creating greater certainty through the creation of an express exemption or express exemptions.

(b) We see the exemption as split into two separate components. The first relates to use of the patented invention for experimental purposes relating to the subject matter of the patented invention, including verifying the validity of the patent, inventing around the patented invention, improving the invention, etc. What we are referring to here is the classic notion of *research on the patented invention* as opposed to *research with the patented invention*. We believe that this exemption should apply irrespective of whether the research is non-commercial or commercial in nature. The crucial limitation is that the use must relate to the subject matter of the patented invention.

The second component of the exemption should cover non-commercial research, irrespective of whether this is *research on* or *research with* the patented invention. This separation of the exemption into two components can be read into some of the early case law. In the United States, for example, in the old case of *Whittemore v Cutter* a two-limb test was identified by Justice Story:

> It could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments [our second component] or for the purpose of ascertaining the sufficiency of the machine to produce its described effects [our first component].[4]

[1] [1984] FSR 559.
[2] (1971) 25 DLR (3d) 79.
[3] 1 Gall. 429, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813), as cited in *Roche Products, Inc v Bolar Pharmaceutical Co, Inc* 733 F.2d 858 (1984).
[4] Ibid at. 862.

In the United Kingdom, there are also two distinct exemptions, one relating to private, non-commercial use of the invention,[5] the other relating to experimental use of the invention for purposes relating to the subject matter of the invention.[6] Note that we do not agree with the proposition put forward on page 4 of the Issues Paper that paragraphs (a) and (b) in s60(5) of the UK *Patents Act* 1977 are conjoined. We discuss this point in more detail in our response to Question 2.

We believe that the two components to the exemption are justified for a number of reasons. The *research on* exemption is justified because this is a logical extension of the disclosure requirement (people should be allowed to test the validity of the patent and the adequacy of the disclosure) and the incentive goal of the patent system (people should be allowed to improve on the patented invention).

The non-commercial research exemption is justified on the basis that the patent grant only allows the holder to exclude others from *exploitation.* It should not be used in a way that stifles non-commercial research because this could negate the incentive goal of the patent system. We acknowledge that the payment of royalties for off-the-shelf patented products is unlikely to stifle non-commercial research and that there may be no good reason why non-commercial researchers should be exempted from payment of those royalties.[7] However, the situation becomes more problematic if licence negotiations have to be entered into and if refusal to licence is a possibility. This situation is most likely to impede non-commercial research when the patent claims a fundamental research tool. Most research use of a patented research tool is likely to be *research with* rather than *research on* the patented invention. Restrictive licensing of research tool patents could create impediments for both non-commercial and commercial research. We are not suggesting that all such uses of research tools should be exempt, because this would effectively reduce the value of research tool patents to zero. We are saying that there is justification for excluding non-commercial research from infringement. We discuss other measures that could be introduced to alleviate some of the detrimental effects of restrictive research tool patent licensing on research with commercial implications in our responses to Questions 15 to 20.

Issues associated with research tool patents are likely to be particularly problematic for biotechnology research, as discussed more fully in our response to Question 9 Indeed, we note that in the introduction to the Issues Paper ACIP specifically mentions the issues associated with the so-called 'junk-DNA' patents. These are classic examples of research tool patents, and most research that utilises them is likely to be *research with* rather than *research on* them.

We acknowledge that most commentators in the area have either focused their attention on the *research on* exemption, or have not made the distinction between the two

[5] See section 60(5)(a) of the *Patents Act* 1977 (UK).
[6] Section 60(5)(b) of the *Patents Act* 1977 (UK).
[7] This issue is explored more fully in Janice Mueller, 'No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools' (2001) 76 *Washington Law Review* 1at 33-35.

components of the exemption However there is some commentary that supports the distinction we are attempting to make. Most notably, Katherine Strandburg gives a detailed exposition on the two limbs of the exemption. [8] Rochelle Drefyss and others also discuss in some detail the form that a non-commercial research exemption might take.[9]

(c) We are not undertaking relevant research and development ourselves. However, we have recently completed an empirical study of the Australian medical biotechnology industry.[10] Our results indicate that, in that sector at least, most participants recognise a practice based non-commercial research exemption.[11] We found that many patent holders either assume that non-commercial use is exempt, think that it should be, or consider that it would be inappropriate or impractical to pursue researchers using their patented inventions for non-commercial research purposes. Similarly, those of our respondents who used patented technology for non-commercial research purposes generally expressed the belief that their use was exempt, or that it should be, or that they didn't need to worry about it because of the low risk that they would be pursued for infringement. In making these comments, none of our respondents raised the *research on* or *research with* distinction.

Although we did not explore fully the question of whether or not *research on* the patented invention was generally considered to be exempt by industry participants, some respondents did acknowledge that all such research is exempt irrespective of whether it is done in the public sector or the private sector.[12]

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

Experience from the common law approach in the US suggests that this is not the best option. As noted in the Issues Paper, in the recent decision in *Madey v Duke University*[13] the court gave a very narrow reading to the notion of philosophical inquiry, excluding any conduct that is 'in keeping with the alleged infringer's legitimate business, regardless of commercial implications'.[14] Consequently, Duke University could not rely on the

[8] Katherine Strandburg, 'What Does the Public Get? Experimental Use and the Patent Bargain' (working draft:16 July 2003). Available at: http://www.law.berkeley.edu/institutes/bclt/ipsc/papers/attendees/IPSC_2003_Strandburg.pdf (last accessed 16 April 2004).

[9] Rochelle Cooper Dreyfuss, 'Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course' (April 8, 2003). NYU Law School, Public Law Research Paper No. 59. http://ssrn.com/abstract=394000 (last accessed 16 April 2004). See also an unpublished article by Richard Nelson cited in Strandburg, above n8, at her n199 and her discussion at 79-82.

[10] Dianne Nicol and Jane Nielsen, *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry* Centre for Law and Genetics Occasional Paper No. 6 (2003). Available at http://www.ipria.org/publications/reports.html (last accessed 16 April 2004).

[11] Ibid. See generally the discussion of our results at 219-222.

[12] Ibid at 220.

[13] 307 F 3d 1351 (Fed Cir, 2002) at 1362.

[14] Ibid, at 1362.

defence because use of a patented invention in a research project clearly furthers the University's legitimate business objectives. This was the case even though the patented laboratory equipment that was the subject matter of the case was designed specifically for basic research in a non-profit research laboratory.[15] As a result it is difficult to see how the common law defence in that jurisdiction will have any ongoing usefulness. Indeed, calls have been made for further legislation to fill the void.

In our view the UK legislative approach provides some assistance. We are of the view that there are two distinct limbs to the statutory exemption in the UK legislation, one for private, non-commercial use of the invention,[16] the other for experimental purposes relating to the subject matter of the invention,[17] and that these limbs are not conjoined. We note that there are in fact eight distinct exemptions in s60(5). Although there is no 'and' or 'or' between the penultimate and final exemptions to provide definitive guidance as to how they should be interpreted, it would lead to illogical consequences if they were all joined with an 'and' and it is difficult to see how the exemptions in paras (a) and (b) are conjoined, but not the other six in paras (c) to (h).

This interpretation is affirmed in the case law. In all cases in which s60(5)(b) has been raised, it has been considered in isolation from the exemption in para (a) of that section. In *Smith Kline & French Laboratories Ltd v Evans Medical Ltd*, for example, Aldous J clearly treated the two defences separately, concluding that the exemption in para (a) was open on the facts, but not the exemption in para (b).[18]

We see merit in adopting a clear exposition as to the nature of a research/experimental use exemption in Australia, along somewhat similar lines to the UK approach. Experimental use for purposes related to the subject matter of the patented invention (*research on the invention*) should be exempt because there must be legally available avenues for testing and improving on the invention. We agree with the judgment of Dillon LJ in the Monsanto case that for this limb of the exemption there should be no distinction drawn between non-commercial experimentation and experimentation that may have a commercial end in view.[19] The crucial question in respect of this exemption is whether or not the experimentation relates to the subject matter of the patented invention. In accordance with the views of Dillon LJ, this would include such uses as: 'limited experimentation to establish whether the experimenter could manufacture a quality product commercially in accordance with the specification of a patent'.[20] His Honour went on to explain the distinction further:

> Trials carried out in order to discover something unknown or to test a hypotheses or even in order to find out whether something which is known to work in specific conditions … can fairly, in my judgment, be regarded as experiments. But trials

[15] Strandburg, above n8 at 6.
[16] See section 60(5)(a) of the *Patents Act* 1977 (UK).
[17] Section 60(5)(b) of the *Patents Act* 1977 (UK).
[18] [1989] 1 FSR 513.
[19] *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515 at 538.
[20] Ibid, citing *Micro-Chemicals Ltd v Smith Kline & French Inter-American Ltd* (1971) 25 DLR 79 at 89 with approval.

> carried out in order to demonstrate to a third party that a product works or, in order to amass information to satisfy a third party, whether a customer or [a regulatory] body … that the product works as its maker claims are not, in my judgment, to be regarded as acts done "for experimental purposes".[21]

We believe that a distinction of this nature may be apt for the Australian situation, provided that other alternatives are explored for other uses, particularly when they relate to research tool patents.

With regard to the non-commercial use component, we believe that the UK approach may be too narrow. The provision in s60(5)(a) of the UK legislation refers to *private* non-commercial use. This provision has not received much judicial attention, as noted by Aldous J in *Smith Kline & French v Evans*.[22] In that case His Honour interpreted 'private' not to mean secret or confidential but 'in the sense of denoting that the act was done for the person's own use'.[23] We submit that the justification for the non-commercial use component of the proposed exemption is its *public* nature both from the perspective of the purpose of the use (for the benefit of the public) and from the perspective of disclosure (disclosing to the public rather than keeping secret or confidential). The justification for the exemption is that it would encourage publicly funded non-commercial research, the results of which should be freely released into the public domain, in accordance with Mertonian norms.

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

The international agreement that is most likely to cause problems is the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). As noted in the Issues Paper, Article 30 is the most important provision in TRIPS in relation to the experimental use exemption, because it allows for limited exceptions to the patent holder's exclusive rights. We submit that both components of the exemption that we propose would be allowed under Article 30. As noted by Maureen O'Rourke, Article 30 closely parallels Article 13, which provides for limited exceptions to the rights of copyright holders.[24] It is generally assumed that this provision allows the fair use/dealing provisions found in the copyright laws in most jurisdictions. Hence, O'Rourke concludes that: 'To the extent that Article 30 parallels Article 13, this suggests that some type of patent fair use is not only permissible but also expected under TRIPS.'[25] We agree with this proposition.

Question 4: Is there any empirical evidence that the balance between the incentives for

[21] Ibid at 542.
[22] Above n18 at 517.
[23] Ibid
[24] Maureen O'Rourke, 'Towards a Doctrine of Fair Use in Patent Law' (2000) 100 *Columbia Law Review* 1177.
[25] Ibid at 1202.

innovation and the ability to use innovations, particularly for research and development, is being significantly affected by the absence of an explicit experimental use exemption (or some other provision) in Australian patent law?

As noted above in response to Question 1, we believe that at present a practice based research exemption operates in Australia, which may well be broader than any statutorily enacted exemption. Thus, at present, infringement action against non-commercial users of patented inventions is rarely, if ever, pursued. There is little or no evidence to suggest that the lack of an express exemption is discouraging innovation or significantly affecting the ability of non-commercial users to use patented inventions.

We do not have much concrete evidence as to the impact of the lack of an express *research on* exemption on the incentive/use balance. However, we surmise that again in practice such use would generally be considered to be exempt by participants in the industry, irrespective of whether they are patent holders or users.

Nevertheless, the lack of express exemptions may encourage some patent holders to change their enforcement practices in the future. We are already seeing moves to enforce research tool patents against public sector research institutions involved in research that has commercial links.[26] It is not too fanciful to predict that others may attempt to enforce patents against public sector researchers in accordance with the Madey formulation.[27] If the Australian courts were to create a common law exemption for non-commercial research, but to restrict it by using the narrow Madey version of *philosophical inquiry,* then public sector researchers could be faced with patent infringement actions, irrespective of whether their research is non-commercial or commercial in nature. This could have a stultifying effect on non-commercial research in Australia for various reasons, including:

- the cost and time associated with involvement in patent infringement litigation;
- shifting of research projects away from areas where researchers fear that they may be pursued for infringement; and
- delays and increased costs caused by patent searching and licence negotiation.

The lack of an express *research on* exemption could create similar problems in future.

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

We believe that good patents, clear exemptions, good licensing practices and alternative patent use-strategies are all intimately linked. In our view, none of these options in

[26] See, for example, Australian Broadcasting Corporation Four Corners, 'Patently a Problem' broadcast on 11 August 2003, transcript available at http://www.abc.net.au/4corners/content/2003/transcripts/3922059.htm (accessed 12 August 2003).
[27] Above n11.

isolation provides a complete solution to the problems associated with the disincentives to research and innovate created by some patenting and patent licensing strategies. A combination of solutions is required. With regard to pre-grant conditions, there are significant benefits for holders and users of patents where:

- examination practices are of a sufficiently high standard to ensure that only valid patents are issued, or appropriate administrative structures are in place to enable challenges to questionable patents;
- patents are of an appropriate breadth. If patents are too broad then a single patent holder may have too great a control over a whole area of research, but if they are too narrow a patent thicket is more likely to arise, requiring multiple licences to be entered into to ensure freedom to operate;[28]
- the novelty, inventive step and industrial applicability criteria are set at a suitably high standard to ensure on the one hand that true inventors are appropriately rewarded for their inventive ingenuity and on the other hand that others are not given too great an award for trivial or routine improvements over the prior art.

There may well be some inadequacies with the current pre-grant arrangements in Australia. However, the recent amendments to the novelty and inventive step requirements need to be tested before further changes are made. Although there is no explicit requirements for *specific, substantial and credible utility* to satisfy the industrial applicability requirement, it is likely that the Australian Law Reform Commission will recommend this in its Gene Patent and Human Health inquiry.[29] It may also recommend improvements to the description requirements to better deal with patent breadth issues.[30] Hence, we are of the view that although the pre grant conditions for patents should be monitored on an ongoing basis, there is little further that should be done on this issue for the purpose of this inquiry.

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

The existence of fair dealing provisions in copyright law provides further justification for the introduction of equivalent provisions in patent law.[31] 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

[28] This issue is also explored in Dreyfuss, above n9 at 5.
[29] See, for example, its Proposals 6-3 and 6-4: Australian Law Reform Commission, *Discussion Paper 68: Gene Patenting and Human Health* (Sydney: ALRC; 2004).
[30] Question 6-1, ALRC Discussion Paper, Ibid.
[31] As discussed in detail from the perspective of US patent and copyright law in O'Rourke, above n22.

copyright system and the patent system. One way of looking at the distinction between copyright and patent is to compare how copyright material and patented inventions are used. When copyright material is used for research and study it is used to *assist in* the research or study. On the other hand, patented inventions are more likely to be *part of* the research or study. There are other differences included in the nature of the rights, for example copyright protects the owner from unauthorized copying, whereas patents give monopoly rights. It is relatively easy to define what might be a fair dealing in copyright law (e.g. 10% of the pages or a single chapter) but impossible to define the same concept in patent law (10% of the claims perhaps?). We argue that it is unnecessary to take the analogy between copyright and patent law too far because there are sufficient precedents in patent law itself.

In addition, we note that the literature that exists on this point has a predominant US focus and as such has limited value in the Australian situation. There are significant differences between US fair use provisions and Australian fair dealing provisions. There are also differences between the US common law experimental use exemption from patent infringement and the statutory-based exemptions in other jurisdictions. We have already submitted that the latter are more likely to provide assistance in Australia.

On the other hand, we suggest that copyright law may provide other lessons for patent law, particularly with respect of the automatic/statutory licensing provisions available to a number of users of copyright material. We explore this issue further in our response to Question 20.

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

We have already argued the *research on* exemption should apply across the full spectrum of research types, from basic through hybrid to applied provided that it is strictly limited to purposes related to the subject matter of the patented invention.

We have also argued that basic or non-commercial research is different from commercial research and should have absolute protection from infringement in the form of an express exemption covering both *research on* and *research with* the patented invention. However, the bright line between basic and applied research is becoming decidedly fuzzy and the field of pure non-commercial, basic research is shrinking, for a host of reasons including reduced public sector funding and increased pressure from public funding agencies for researchers to commercialise their research. Hence, public sector research will often fall into the hybrid rather than the basic category. We suggest the failure of many research organisations to profit from commercialisation opportunities may ultimately lead to a strategic reversal back to the traditional Mertonian values of basic research.[32]

[32] The lack of return for investment in technology transfer is being documented by an increasing number of commentators. See, for example, Anne Monotti and Sam Ricketson, *Universities and Intellectual Property* (Oxford University Press: Oxford; 2003) at paras 9.51-6.53.

Hybrid research poses different problems from pure basic research that may require a more complex solution. As noted above, increasingly, public sector research is becoming hybrid in nature, with both non-commercial and commercial components. It could be argued that provided that the research has some non-commercial component it should be exempt. On the other hand, if this research has a commercial end in view then it seems logical for commercial rules to apply, irrespective of the nature of the institution carrying out the research. Otherwise, patent holders are deprived of legitimate rights, research institutions obtain a significant advantage over their private sector counterparts and the shield of research institution immunity could be used as a front for research activity with clear commercial goals.

One solution that has been proposed in the literature is that researchers could have the option of self-defining as non-commercial users.[33] Public statements have already been made to this effect by various research groups, including, for example, the Human Genome Project through its Bermuda Declaration and the Single Nucleotide Polymorphism (SNP) Project. Dreyfuss and others have suggested more formalized waiver mechanisms to enable reliance on a non-commercial research exemption, which would apply in the following circumstances:

- unwillingness or inability on the part of the patent holder to supply the patented materials on reasonable terms;
- agreement by the researcher to publish the work;
- agreement by the researcher to refrain from patenting the results of the research, or to patent and non-exclusively license on reasonable terms.[34]

We agree that if a non-commercial research exemption is created it will be necessary to provide some formalized structure to identify which research is non-commercial and which has commercial aims. A self-defining option is attractive. It may be appropriate for a waiver provision of this nature to be required for all basic research in addition to the types of hybrid research where the researcher has made a commitment not to commercialise. However, the problem with requiring basic researchers to sign a formal waiver in the circumstances set out above is that it would require them to conduct patent searches and approach relevant patent holders. Given that the patent landscape is becoming increasingly complex, these obligations may be quite onerous in some areas of research. In our view basic researchers should be freed entirely from obligations of this nature. We suggest that it would be sufficient for researchers to make undertakings in accordance with the second and third dot points above, that is, to publish their work and to refrain from patenting the results of their research.

Dreyfuss points out that given the nature of this type of research, it may be necessary to provide for a buyout from the waiver to enable patenting and commercial development.[35]

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[33] See Dreyfuss, above n9 at 9.

[34] Strandburg has isolated these requirements from the work of Rochelle Dreyfuss, above n9 and from Richard Nelson, in an unpublished article. See Strandburg above n8 at 79. See also Mueller, above n7 at 54-66.

[35] Dreyfuss, above n9 at 11.

We believe that there is merit in this proposition, given the serendipitous nature of basic research.

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

In any industry, a number of factors may give rise to an anti-commons effect. In our empirical study, we undertook to examine this issue with particular reference to the medical biotechnology industry. We are therefore qualified to present evidence on this point only in relation to this industry, although we are of the view that the structure of this industry makes it particularly susceptible to an anti-commons occurring. It is an industry in which we could expect to see evidence of an anti-commons and the absence of an anti-commons would tend to suggest that the research community is finding ways to deal with any issues that arise.

The preconditions for an anti-commons within a particular industry are essentially a proliferation of intellectual property rights over essential research inputs and high transaction costs that make exchanging these rights difficult. In the medical biotechnology field, there a number of factors that suggest that this industry may be prone to an anti-commons. The number of granted patents has increased exponentially and there is some diversity in the types of patent holders. A considerable number of broad patents have been granted and these patents often represent fundamental research tools for use in further research. Finally, defensive patenting strategies and aggressive enforcement of patents makes a number of research areas inaccessible. Clearly these factors are not confined to the medical biotechnology industry, and are present in a number of other industries.

An anti-commons may not result in the complete breakdown of research within a particular field. We identified in our study the different manifestations of an anti-commons as:

- project abandonment due to bargaining breakdown;
- overlapping royalty commitments leading to excessive royalty stacking; or
- redirection of research efforts from heavily encumbered research areas.

Despite these preconditions being present in the medical biotechnology industry, we could find little evidence at this stage of an anti-commons.[36] Our results can be

[36] This result essentially reinforced findings in other studies conducted in respect of the US medical biotechnology industry and the German industry. See John Walsh, Ashish Arora and Wes Cohen 'Effects of Research Tool Patenting and Licensing on Biomedical Innovation' in W.M. Cohen and S.A. Merrill (eds.), *Patents in the Knowledge-Based Economy* (Washington: National Academies Press, 2003) available at: http://books.nap.edu/books/0309086361/html/285.html#pagetop (accessed 3 October 2003) and J. Straus, H. Holzapfel and M. Lindenmeir, *Empirical Survey on Genetic Invention and Patent Law*, (Munich: 2002) (copy on file with authors) respectively.

summarised as follows:

- although patent searching obligations have become more onerous, costly and time-consuming, industry participants informed us that generally speaking only a small number of patents (generally no more than 1-4) required closer examination;
- participants often needed to license in patents, but again, the number of patents in respect of which licences were required was generally low (around 1-3);
- in instances where licences were not sought or successfully negotiated, other options such as inventing around and redirection of research efforts generally ensured there were few research hold-ups. In some cases particular research areas were abandoned; and
- participants were often acutely aware of the potential for royalty stacking and acted to minimise problems associated with royalty stacking when imposing royalty obligations. Royalty stacking rarely became problematic.

We present these results[37] as evidence that an industry that is particularly susceptible to an anti-commons or patent thicket has thus far managed to avoid this form of bargaining breakdown. This is not to say that the potential for an anti-commons does not exist for this and other industries, or that measures should not be put in place to assist in ensuring that patent thickets do not unduly hinder research. We do urge caution, however, in implementing regulated change to a market environment that has adopted mechanisms to deal with a patent landscape that has increased in complexity.

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

There is little doubt that biotechnology and genetic technology do raise special issues. We have discussed some of our own research findings on these issues throughout this submission, and particularly in our response to Question 8.

Much of the academic commentary on the need for an experimental use exception focuses on biotechnology in general and biomedical research tools in particular. However, we note that this commentary is primarily focused on the situation in the US. One example is the following comment by Janice Mueller:

> The problem of access to patented research tools is currently more acute and better documented in biotechnology than in any other scientific field. Biotechnology is research intensive. A high percentage of basic research tools and laboratory techniques of biotechnology are subject to proprietary restraints such as patents or material transfer agreements…[38]

Despite this and related comments in the literature, there is other empirical evidence in the US that shows that the medical biotechnology industry is in fact finding working

[37] For a full discussion of the results see Nicol and Nielsen, above n10 at 174-195.
[38] Mueller above n7 at 11. Footnotes omitted.

solutions to these issues.[39] Nevertheless, fundamental biomedical research tool patents remain controversial.

The difficulties associated with use of patented research tools in biomedical research are well illustrated in the US-based patent dispute between Integra Lifesciences and Merck.[40] In that case, Merck attempted to rely on the statutory exemption in US patent law designed to exempt use of patented drugs for the purpose of obtaining regulatory approval of generic drugs during the patent period. Merck argued that this exemption extended more broadly to use of patented research tools in the drug discovery process. The court rejected this argument on the basis that Merck's use was general biomedical research rather than activities *solely* related to obtaining regulatory approval, reversing previous broader interpretations of this exemption.[41]

Whilst the Integra case is about commercial use of patented biomedical research tools, it illustrates the difficulties involved in finding an appropriate balance between holders and users of these types of patents. The decision led Groombridge and Calabro to raise the option of implementing a collective-rights licensing regime for research tool patents as a way of minimising transaction costs.[42] We had already been considering this option for some time, and discuss it more fully in our response to Question 16.

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

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

We discuss the justifications for the two components of the experimental use exemption proposed by us in our response to Question 1.

[39] Walsh, Arora and Cohen, above n36; see also J.P. Walsh, A. Arora and W.M. Cohen, 'Working Through the Patent Problem', (2003) 299 *Science* 1021.
[40] *Integra Lifesciences I, Ltd v Merck KgaA* 331 F.3d 860 (Fed. Cir. 2003). See also Nicholas Groombridge and Sheryl Calabro, 'Integra Lifesciences v. Merck – Good for Research or Just Good for Research Tool Patent Holders' (2003) 22 *Biotechnology Law Report* 462 and Harold C. Wegner, 'The Post-Madey Research Exemption' (Foley & Lardner; 2003). Accessed from: http://www.foley.com/people/bio.aspx?employeeid=16338&&practiceID=&industryID=&genPageID= (accessed on 19 April 2004)
[41] Discussed more fully in Groombridge and Calabro, ibid at 465-466.
[42] Ibid at 470.

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

We have already suggested that this is an appropriate criterion for one limb of the exemption. As Strandberg has pointed out:

> Unlike proposals that echo copyright's "fair use" analysis and require courts or juries to make complicated multi-factor analyses, the proposal for a categorical "experimenting on" exception reduced the question to an objective analysis of the nature of the research in question. While difficult line-drawing issues may still arise in particular cases, the difference between "experimenting on" a patented invention to improve it and using it as a tool for other research is a factual question that can be evaluated by judges and juries without the need for policy-driven balancing.[43]

We see merit in these arguments as they relate to the *research on* component of the proposed exemption.

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

For reasons previously discussed, we do not believe that this component of the exemption is sufficient of itself. We argue that a second component is required to protect non-commercial research, particularly when this relates to use of patented research tools.

Question 13. Should an experimental use exemption cover only the situation where experimentation is the sole purpose of the use of the invention?
Question 14: If not, what are alternatives or supplementary criteria for an experimental use exemption?

We believe that the component of the exemption protecting *research on* the subject matter of the patented invention should only cover the situation where such experimentation is the *sole* purpose of the use of the invention (or, at the very least, is the dominant purpose). The reason for this is that any lowering of this standard would create uncertainty and would have the potential to create a disincentive for innovation and disclosure. Furthermore, we submit that it is unnecessary to expand the exemption beyond this sole purpose standard provided that the second non-commercial research exemption is also created, and that alternative patent use strategies are put in place, particularly as they relate to biotechnology research tool patenting. We discuss possible criteria for the non-commercial research exemption in our response to Question 7.

[43] Strandburg, above n8 at 48. Footnotes omitted.

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

There is no doubt that research organisations are improving their technology transfer practices, in terms of licensing-out their intellectual property to the commercial sector. We found extensive evidence that this was the case in our empirical study. However, the process of commercialisation is still complex and time consuming. We also encountered expressions of concern associated with over patenting and overvaluing by researchers and technology transfer officers.[44] Similar concerns have also been reported in other studies.[45]

We did not collect detailed information on licensing-in by research organisations in Australia, in part because of reliance on the practice based research exemption. However, the evidence we collected suggested that licensing-in was similarly complex.

The risk of having an express research exemption is that it will more clearly demarcate the boundaries between protected and unprotected research, with the result that more patent holders may decide to assert their patent rights against researchers conducting hybrid research. This will mean that more licensing-in will need to be undertaken by research organisations where research is of a hybrid nature, which is likely to slow the progress of research projects and increase their cost.

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

It is desirable to streamline the process of licensing-in and licensing-out, particularly with regard to patent searching and negotiating licences. Where broadly applicable research tools are involved, there may be the capacity to have fairly standard form, non-exclusive licensing. We suggest that it may be useful to explore the option of using clearinghouse mechanisms to reduce the transaction costs in licensing research tools, particularly between research organisations. A clearinghouse could perform one or more of the following functions: facilitating the search for technology that is available for licensing or free use; smoothing the progress of negotiations; and monitoring or enforcing negotiated agreements.[46] Clearinghouses are already being established. In the US, for example, the Public Intellectual Property Resource for Agriculture (PIPRA) facilitates sharing of access to agricultural technologies by US-based public-sector agricultural research

[44] Nicol and Nielsen, above n10 at 242-244.

[45] See, for example, Rebecca Eisenberg, 'Bargaining over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?' in Rochelle Dreyfuss et al, (eds) *Expanding the Boundaries of Intellectual Property* (2001) 223; See also Dreyfuss, above n9 at 3.

[46] G. Graff and D. Zilberman 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology (2001) 3 *Intellectual Property Strategy Today* 1; G. Graff, A. Bennett, B. Wright, and D. Zilberman 'Intellectual Property Clearinghouse Mechanisms for Agriculture: Summary of an Industry, Academia, and International Development Round Table' (2001) 3 *Intellectual Property Strategy Today* 15 both available at:
http://www.biodevelopments.org/ip/ (accessed 20 September 2003).

institutions.[47]

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

Patent pools have been used successfully in a number of industries to overcome issues relating to access to core patents. In some cases, government imposed patent pooling arrangements have been successfully implemented. In others, industry pools have been developed in response to patent hold-ups in a particular area of research. In a vast majority of these cases, entering into a patent pool was necessary and beneficial for all parties concerned in that they each held particular blocking positions. Where this is not the case, a patent pool is unlikely to be a desirable option.

In our study, we conducted research as to the desirability of establishing patent pooling arrangements in the medical biotechnology industry.[48] The ALRC is also considering this issue in relation to this industry.[49] There may be a number of reaons why players in the biotechnology industry will be reluctant to enter into patent pooling arrangements and many commentators have been pessimistic about the likelihood of patent pools being successfully implemented in the biotechnology industry.[50] Patent pools are generally likely to emerge in industries with the following characteristics:[51]

- the parties involved have a long relationship[52] and are in a horizontal arrangement;
- they form a fairly homogenous group;[53]
- they are engaged in repeat-play transactions;[54] and
- they hold similar portfolios of mutually blocking patents.

Industries without these characteristics are unlikely, however to see the emergence of, or benefit from, patent pooling arrangements. In biotechnology, for example, the industry comprises diverse, heterogeneous players, and parties are often involved in one-off

[47] R. Atkinson *et al,* 'Public Sector Collaboration for Agricultural IP Management' (2003) 301 *Science* 174-5.
[48] See also United States Patent and Trademark Office, *Patent Pools, A Solution to the Problem of Access in Biotechnology Patents?* (2000).
[49] See ALRC Discussion Paper, above n29, Proposal 23-3.
[50] See, for example, M. Heller and R. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698; Arti K Rai, 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' (1999) 94 *Northwestern University Law Review* 77 at 132-5; Frederic M Scherer 'The Economics of Human Gene Patents' (2002) 77 *Academic Medicine*, 1348 at 1363.
[51] See generally Robert P Merges, 'Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organisations' (1996) 84 *California Law Review* 1293. Merges examines a number of industries in which collective rights organisations have successfully emerged to allow the smooth exchange of intellectual property rights.
[52] Arti K Rai, 'Intellectual Property Rights in Biotechnology: Addressing New Technology' (1999) 34 *Wake Forest Law Review* 827 at 840.
[53] Ibid at 841.
[54] Merges, above n51 at 1297, 1299.

transactions. The cumulative structure of research within this industry means that many transactions for the exchange of intellectual property rights take place between parties in vertical relationships. The results of our study offer support to these arguments in that the levels of cross licensing within the industry were shown to be relatively low. Caution should therefore be exercised in imposing pooling arrangements within particular industries that are unlikely to benefit from these arrangements, and in assuming that bargaining difficulties are likely to give rise to patent pooling arrangements. In many cases, patent pooling arrangements have arisen after protracted negotiation or in response to litigation. This is not to say that the feasibility of patent pooling arrangements should not be considered in respect of particular industries.

It should also be remembered that patent pools are promoted as a solution to patent thickets, or anti-commons issues, so they do not assist where single blocking patents are used in an exclusionary manner. For this reason, they are not an alternative to an experimental use exemption, but should be viewed as a supplementary means of ensuring the free flow of contractual rights between industry participants.

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

The benefits of patent pools are numerous.[55] First they reduce or eliminate transaction costs, which can be barriers to successful bargaining. Second, they streamline the process of exchanging rights, so that bargaining bottlenecks are unlikely to inhibit the research process. Often, rights are traded at predetermined rates, so that transactions are not subject to the same uncertainties and delays they otherwise would be. They will also assist in reducing or avoiding infringement litigation. Finally, they allow the integration of complementary technologies and clear blocking positions. These benefits are significant and should result in the promotion of patent pools where appropriate.

The main disadvantage of patent pools is the possibility that anti-competitive conduct will be entered into by members of a pool.[56] Anti-competitive conduct is most likely to be a threat where the members of the pool comprise a large proportion of the potential research and development in a particular innovation market.[57] In most cases, this should be sufficient to alert the relevant competition authorities to the fact that an anti-competitive arrangement exists. The problem in some industries such as biotechnology is that many patented genetic materials and technologies are non-substitutable. Smaller cross-licensing arrangements are more difficult to monitor, and perhaps more likely to give rise to potentially anti-competitive conduct that will go unchecked. As in many cases where parties possess market power, there is a possibility of anti-competitive conduct. This should not, however, lead to the assumption that it will occur.

[55] See generally US Department of Justice and the Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) (the Antitrust Guidelines) at §5.5.
[56] The anti-competitive risks of patent pools are canvassed in detail in the Antitrust Guidelines, ibid at §5.5.
[57] Ibid.

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

Australia has provisions in the *Patents Act 1990* (Cth) that allow a person to apply to court for a compulsory licence where 'the reasonable requirements of the public have not been met' (see ss 133 and 135). This provision has rarely, if ever, been used. There are a number of difficulties: attempts must first have been made to obtain a licence; an application has to be made to the Federal Court; there is no judicial guidance on what constitutes the reasonable requirements of the public; and reasonable remuneration has to be paid. Again, there is no judicial guidance on what amounts to reasonable remuneration.

The compulsory licensing provisions are fairly unworkable at present. The unwieldy procedure for obtaining a compulsory licence makes it unlikely that the provisions would be frequently utilised. Without streamlining the process for application for a compulsory licence, the provisions are unlikely to be effective. Few applicants will have the resources or the time to pursue an application. Further, the threat of utilising compulsory licensing provisions may act as a spur to negotiations for voluntary licences in some instances. This threat is likely, however, to be largely non-existent in Australia given the under-utilisation of the Australian scheme. The inequality in bargaining power between many companies, particularly where those companies are start-ups, reinforces this problem.

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

Modifying existing compulsory licensing provisions

In order the make the compulsory licensing provisions more workable, there are at least two steps that, in our view need to be undertaken. First, the 'reasonable requirements of the public requirement' requires clarification. This could be done be clarifying the circumstances in which the 'reasonable requirements of the public' have not been satisfied, or by stating that s135 is not an exhaustive list of the circumstances in which a patent would fail to satisfy the 'reasonable requirements of the public'.[58] Any attempt to more clearly circumscribe the circumstances in which the reasonable requirements of the public test have not been satisfied is prone to the same difficulties that currently exist. It would be difficult to delineate with any precision the circumstances in which this test has not been met.

Specifying that s135 is not an exhaustive list of the circumstances in which a patented invention would not satisfy the test has its own difficulties. It assumes of course, that there are additional grounds on which the test could apply, and it does not clarify the existing components of the test. There are a multitude of bases contained in national

[58] ALRC, above n29, Question 27-1.

legislation that may ground applications for compulsory licences.[59] Stating that s135 is not an exhaustive list is sure to give rise to interpretational difficulties, as the bounds of the test will become increasingly unclear.

Settling on a solution to the problems raised by the section is therefore challenging. It is hard to see how the section itself could be amended to provide any level of certainty on the scope of the reasonable requirements of the public provision. Despite these difficulties, we conclude that it would be preferable to attempt to set out more clearly the circumstances in which the reasonable requirements of the public test have been satisfied, paying close attention to the grounds in national legislations of other countries for the issue of compulsory licences.

Second, s133 fails to provide relief to holders of dependant patents in the form of a ground for application for a compulsory licence.[60] We are of the view that the position in relation to dependent patents requires clarification and legislative amendment. Given the cumulative nature of biotechnology research, cases of dependent patents are very likely to arise in the context of gene patents. This is therefore a ground that should be provided for in s133. In many cases, owners of dependent patents will be able to obtain a voluntary licence. But if negotiations prove to be unsuccessful, a dependant patent holder should not be precluded from seeking a compulsory licence. At present, s133(3B) gives rise to considerable illogicality.

A dependant patent may constitute a new application, or a minor improvement over an original invention. Original patents may facilitate follow-on invention in that they may make follow-on research possible. In other cases, follow-on research would simply be slowed or only possible at greater cost if the follow-on researcher did not have the prior research to build on.[61] There are therefore differing degrees of follow-on invention and dependency. We are not suggesting that an application for a compulsory licence should be available to every holder of a dependent patent.

We propose therefore, that the existing test contained in s133(3A) be utilised in formulating a ground in s133 for the issue of a compulsory licence in circumstances of dependency. An application should therefore be available to a holder of a dependent patent where the dependent patent involves an 'important technical advance of considerable economic significance' over the invention for which the compulsory licence is sought.[62] Such an amendment would ensure that a compulsory licence is not available for every instance of dependency. Indeed, only holders of patents for new and important applications would be likely to fall within the ambit of such a test. It is likely that only patent holders whose patented inventions fell into such a category would go to the trouble of applying for a compulsory licence in any event.

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[59] See Jane Nielsen and Dianne Nicol, 'Pharmaceutical Patents and Developing Countries: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Journal* 21 at 32-33.

[60] It may be that the reasonable requirements of the public test could be relied on by the owner of a dependent patent.

[61] See Frederic M Scherer, above n50 at 1361-2; Suzanne Scotchmer 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law' 5 *The Journal of Economic Perspectives* (1991) 29 at 31.

[62] Dee also Nicol and Nielsen, above n10 at 239.

It should also be noted that the Intellectual Property and Competition Review Committee (IRCRC) recommended the inclusion of a competition-based test as a ground for issue of a compulsory licence as a result of their review of intellectual property and competition law.[63] The IPCRC in fact recommended repeal of s135 of the Patents Act and the amendment of s133(2) to include a competition test.[64] This amendment would effectively remove a ground (that is, the 'reasonable requirements of the public' ground) for issue of a compulsory licence. Instead, we would support the adoption of the Government's response to the IPCRC Report, that a competition based test be an additional ground for the grant of a compulsory licence. Despite the fact that the provisions are, at present, cumbersome, there is desirability in retaining (a clarified version of) the reasonable requirements of the public test. There is certainly a risk of anti-competitive conduct with respect to the use of a number of upstream patents, particularly, for example, in the biotechnology industry. Many compulsory licences have been issued in the United States to remedy anti-competitive conduct.[65]

New compulsory licensing provisions: the statutory licensing option

There has been extensive commentary on the compulsory licensing option as an alternative to an experimental use exemption. Strandburg, for example, proposes a two-tier scheme in which research tool patent holders have a period of complete exclusivity followed by a period during which compulsory licences become available.[66] However, in our view the type of compulsory licensing generally referred to in the literature is not the sort of licensing provided for in the *Patents Act,* where one-off applications are made to the court or the patent office and decided on case-by-case basis, following full hearing on the merits.

We refer to the type of licensing referred to in the literature as statutory licensing, to distinguish it from existing compulsory licensing provisions. We propose that statutory licensing in patent law could operate similarly to the educational and other automatic licensing provisions under the *Copyright Act.* Educational institutions have to pay remuneration for the use of copyright material, but they do not have to negotiate individual licences. Nor do they have to apply for compulsory licences. They merely fill out the appropriate remuneration form and pay the appropriate remuneration to approved collection agencies. There are generally standard rates for fees, and if there are disputes these are resolved by the Copyright Tribunal.

In our view, there may be some attraction in creating a statutory licensing scheme for some types of patents, particularly research tool patents in hybrid or applied research. Strandburg's two-tier scheme may well be an appropriate additional mechanism for

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[63] Intellectual Property and Competition Review Committee *Review of Intellectual Property Legislation under the Competition Principles Agreement Final Report* (Canberra: AGPS, 2000) (hereafter IPCRC Report) at 162-3.

[64] Ibid.

[65] Frederic M Scherer, 'Comment' in Robert Anderson and Nancy Gallini (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* (1998: University of Calgary Press, Calgary) 104 at 108.

[66] See, for example, Strandburg, above n8 at 67-77;

ensuring that research tool patent holders secure appropriate benefits from their patents. We have previously noted that the regime might require:

- registration of patents by the owners, putting the onus on owners to notify users that they have a patent and will pursue infringers;
- payment of standard licence fees;
- collection of fees by approved collecting agencies;
- the creation of a Patent Tribunal to resolve disputes and determine fee structures.[67]

We note that the Australian Law Reform Commission (ALRC) has taken up this suggestion for exploring the option of establishing a statutory licensing regime and has called for submissions on this point.[68] One of the questions that the ALRC asked was whether statutory licensing should be voluntary or mandatory. At present we still are leaning towards the view that a voluntary scheme would be most appropriate, at least in the first instance. As noted in ALRC's Discussion Paper at 750-752, a voluntary scheme would be least likely to offend against the provisions of the TRIPS Agreement. In effect, a voluntary scheme would give statutory force to the type of clearinghouse mechanisms discussed by us in response to Question 16, in much the same way as the voluntary licensing schemes apply under the *Copyright Act* 1968.

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

We acknowledge that open source principles are being applied with some significant success in relation to copyright in particularly in software applications. There is a growing body of commentary exploring whether these open source principles could be applied in other areas. One of our colleagues, Janet Hope, is exploring the applicability of open source principles in the biotechnology industry for her PhD thesis at the ANU. We believe that open source principles warrant consideration, particularly in relation to information-based patents. However, we do have some reservations as to the extent to which open source principles could provide broadly applicable alternative patent use strategies, as discussed below,

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

One of the major problems in the area of patent law is that significant expenditure is involved in obtaining and maintaining patents. Unless there is some mechanism for recovering these costs, people will be unwilling to embark on the patenting process. Other alternatives to patenting are public disclosure and contracting. The difficulty with

[67] Nicol and Nielsen, above n10 at 239-241.
[68] ALRC, above n29, Chapter 28.

public disclosure is that once research results have been disclosed the researcher has no control over downstream uses. Whilst conditions can be imposed on downstream use by contracting, the difficulty here is that such contracts are only of value whilst the research results remain secret, which is the antithesis of open source principles.