

*Inventions, Patents and Research*

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presented to

‘Freedom to Tinker: Patent Law and Scientific Research Symposium’, ACIPA,  
Canberra, 19 March 2004

It is a pleasure to be here this morning to speak about the role of research in the patents system. As many of you know, the ALRC is currently running an inquiry into *Gene Patents and Human Health*. One prominent issue in the Inquiry has been the terms on which researchers should be able to use patented inventions in their research. I will say more about the scope of the Inquiry later, but let me move straight to the heart of the matter.

Many researchers assume that their use of a patented invention is immune from claims of patent infringement. They view their research as altruistic and in the public interest, so how could it be unlawful?

But the law does not necessarily conform to the assumptions of researchers. Nowhere does the *Patents Act 1990* (Cth) contain an express defence for research use. Some people say that a research use defence can be implied from the definition of ‘exploit’ in the Act. A patent gives the patent holder the exclusive right to ‘exploit’ the invention during the term of the patent, and ‘exploit’ is defined to include commercial activities like hiring, selling and importing. The argument runs that research use is not ‘exploitation’ in this commercial sense. However, this argument is strained because the definition of ‘exploit’ is not exhaustive, and it includes other terms like ‘use’ and ‘make’ which do not necessarily have a commercial connotation.

There is also the occasional judicial decision that supports the idea of a research use defence, but the case most frequently relied on in Australia, *Frearson v Loe*, is an English decision dating from the 19th Century. In short, the evidence that Australian law today recognises a research use defence is tenuous, or at least equivocal.

This uncertainty in the law has implications for all the relevant actors. Researchers ‘self-define’ the scope of their protected research activity. They often see the claimed defence as extending to the boundaries of their own research, at least until they have commercialisable outcomes. And they rarely seek out patent holders to obtain licences to use the invention.

On the other hand, patent holders often do not pursue researchers for infringement. There are many reasons for this: they may be unaware of what goes on in laboratories behind closed doors; research can increase the value of a patent, so patent holders do not always want to prevent it; it can be bad public relations to enforce patents against academic institutions; the cost of enforcement proceedings can make it uneconomic to pursue infringers; and recoverable damages recovered may be small.

The consequence is that the system seems to work, in a kind of a fashion, on a ‘speak no infringement, see no infringement’ basis. In fact, studies in Australia and overseas

show that there is little evidence that patents impede academic research, although there is still a lot of concern about the issue.

However, all the parties are forced to live with uncertainty and risk. And sometimes cases come along that undermine the assumptions on which the players have built programs and developed reputations, like the United States decision in *Madey v Duke University*.

If I were to ask the question, 'Should the patent system promote innovation?' everyone here today would answer, 'yes' without hesitation. Research generates ideas; some of those ideas have commercial applications; commercialisation hopefully makes profits; profits fund more research; and so the cycle continues. In this way, research and patents are part of the machinery that promotes economic growth, employment, and social well-being.

But if I were to ask, 'How should the patent system promote innovation?' the answer is not so obvious. There is often a conflict between the interests of researchers in conducting research *now* without impediment, and the interests of patent holders whose *past* research has yielded commercialisable outcomes.

The difficulty is that if past researchers knew that current researchers might deprive them of the fruits of their labours (for example by using their inventions for free), they may not have had the incentive to innovate in the first place.

What the patent system must do, therefore, is to balance competing interests to promote the public interest, and to do so in a way that is sustainable in the long term. Of course, there is no one correct answer to this problem. The balance may be drawn in different places by different societies, and it may vary over time according to their economic and social development. However, we should not underestimate the importance of the issues to individuals and the public of large. When we feel that current laws and practices may not promote the public interest adequately, it is time to reconsider them. That is the reason for the ALRC's current inquiry into *Gene Patents and Human Health*; and that is the reason for the current inquiry by the Advisory Council of Intellectual Property (ACIP) into the experimental use defence.

The need to put the research use of patented inventions on a sound footing has been under the spotlight recently in several countries, suggesting common concerns, particularly in the field of biotechnology.

In the United States, several Bills have been introduced into Congress to create an exemption for research for experimental purposes. Some proposals have been general; others have been limited to particular technologies such as genomics. The very narrow defence allowed by the US Federal Court in *Madey* has been said by some to guarantee reconsideration of the issue in the near future.

In Canada, in 2002 two government reports proposed an express exception for research or experimental use. Both the report of the Canadian Biotechnology Advisory Committee (CBAC) and the report of the Ontario Government were prompted by concerns in the biotechnology sector, but their proposals were general.

In the United Kingdom, in 2003 the Nuffield Council on Bioethics stated that policy makers in Europe should clarify the research exemption as a matter of urgency. It seems, then, that an international trend is emerging about the need for greater

certainty in this area, even if there is no agreement yet about the precise scope of such a defence.

In thinking about a possible research use defence, the ALRC has had to bear in mind a number of considerations. First, Australia has international obligations in relation to patent laws. Most of these stem from the 1994 *Agreement on Trade Related Aspects of Intellectual Property Rights* (the TRIPS Agreement). Article 30 of that Agreement allows States to make limited exceptions to patent rights, and this seems to extend to ‘research use’, but this may depend on the precise scope of the defence.

Second, we have to consider how any Australian reform would compare with existing laws and practices of other countries. Australia is a small player in a global market. For economic reasons, as well as legal ones, our patent laws can not be too far out of alignment with those of major trading partners.

Third, should any research defence be confined to patents over human genetic materials and technologies, or should it be broader? Our Terms of Reference force us to think in these terms, but there are powerful reasons to take the wider view. The TRIPS Agreement generally requires that patent rights be enjoyed ‘without discrimination as to field of technology’ (Article 27); and we have also heard strong views in submissions to the Inquiry that any such defence should be available on a universal basis.

Finally, we need to be aware of how a research use defence relates to other legislative provisions, such as those dealing with research for the purpose of obtaining regulatory approval, or ‘spring-boarding’.

The ALRC has come to the preliminary view that uncertainty about the existence of a research use defence should be removed. An essential attribute of the rule of law is that the law should be clear and accessible so that people can know the legal consequences of their actions, and plan their conduct accordingly. The ALRC believes that the *Patents Act* should be amended to give the research use defence a clear statutory basis.

Some of the benefits that may flow from a statutory defence will depend on the scope of the defence, but other benefits arise simply from the fact of clarification, whatever its scope. An express statutory defence would:

- avoid potential under-investment in research, which can arise from decision-making in conditions of uncertainty;
- create cleaner intellectual property (and therefore more valuable intellectual property) for researchers who use a patented invention in developing other commercialisable products;
- give more accurate commercial valuation of a patent holder’s intellectual property portfolio; and
- avoid costly litigation to resolve uncertainty, in all but the most difficult cases.

The scope of any defence is obviously critical. We do not believe that a person should be free from the operation of patent law simply because he or she is ‘doing research’. That claim is too easy to make and carves out too big a hole in the exclusive rights of the patent holder.

Our preliminary view is that a defence should be available if two conditions are met. First, the activity of the researcher must be ‘studying’ or ‘experimenting’. This draws

a contrast with commercial activities like ‘hiring, selling or importing’ the invention. Second, the subject matter of that study or experimentation must be the patented invention itself, for example, to investigate its properties or improve upon it.

A researcher should be able to investigate the properties of a patented egg timer with impunity, so that she can make a better egg timer. But that does not mean that she should be able to use the egg timer to make and sell the perfect boiled egg, without regard to the patent holder’s rights.

We see this as fundamental to the ‘basic deal’ underlying patent law. The inventor gets an exclusive right to exploit the patent for the term of the patent. But in return she must disclose the invention. The purpose of disclosure is to avoid the duplication of research effort, and to allow the invention to be prodded, poked and improved upon. On the other hand, so long as that is all the researcher is doing, her motives should not be relevant, even if they are commercial.

As you will have gathered from what I have said so far, the research use defence that we have proposed is quite narrow and might fail to meet the expectations of some researchers if this reform were considered on its own.

However, a significant part of our Inquiry has been directed to improving the way in which patented inventions are worked. If patented research tools could be licensed easily and cheaply, I suspect that much of the pressure for a broad research defence would evaporate.

Empirical evidence about licensing practices in Australia is limited. A study of the Australian biotechnology sector by Di Nicol and Jane Nielsen in 2003 has suggested that there is liberal licensing of foundational biotechnological inventions, and Australian researchers currently have little difficulty in accessing core research tools. How can we ensure that this continues?

We believe that industry can take a greater role in developing and promoting model licence agreements, which can be used by the parties as the basis for their negotiations, and which may reduce transactions costs. Industry can also facilitate the cross licensing of patents, in appropriate cases, through patent pools and patent clearinghouses. There are precedents for this in the fields of aeronautics and electronics. Governments already have programs to educate researchers about licensing and commercialisation of research, and these should be enhanced. And greater use can be made of existing Crown use and compulsory licensing provisions of the *Patents Act* to meet the public interest in the face of restrictive licensing practices by patent holders.

Let me finish with a few comments about the scope of our Inquiry. We obtained our Terms of Reference from the Attorney-General in January 2003 and must report by June 2004. We have been asked to examine the impact of gene patents in three areas: (a) the cost-effective provision of healthcare; (b) the conduct of research and its subsequent commercialisation; and (c) the biotechnology industry.

Our Terms of Reference are thus both broader and narrower than the topic of this symposium: broader because we are looking at an array of patent issues, not just the research use defence; and narrower because our focus is on one field of technology.

In the 1950s an American economist, Fritz Machlup, undertook an extensive economic evaluation of the United States patent system. At the conclusion of the study he said:

‘If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.’

Whatever might be said of the patent system as a whole, it is still possible to improve the way it operates if particular features can be identified as good or bad. I would like to invite you to participate in that process. The reforms that I have identified today are still under review and we welcome any input into the Inquiry. You can obtain a copy of our Discussion Paper free of charge in a variety of formats, and you can make a submission to the Inquiry, so long as we receive it by 16 April 2004.