

## **Response to ACIP's Issues Paper on Patents and Experimental Use**

### **Q1. (a) What is your understanding of current law on an experimental use exemption in Australia?**

This is a particularly hot item throughout the world. There was a large discussion on the "experimental use" issue at the recent AUTM conference in San Antonio, USA and then again at the recent KCA conference in Perth, Australia (March 2004). However, prior to these discussions I believed that you could use patented technology in your academic research without infringing a granted patent.

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

Again prior to the above I was fairly confident that I was permitted to do this and probably gained this understanding from patent attorneys or at least my interpretation of what patent attorneys were saying.

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

I personally do not carry out R & D now. However, when I was a research scientist I did not consider whether the work I was doing would be seen as an infringement. From my current role I feel fairly confident to say that in general most academics believe that they are free to do their research and more than 80% of them would not carry out IP searches to check infringement.

### **Q2 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?**

I read with interest the background on overseas cases cited in the Issues Paper and call also on the feedback received at the AUTM conference. I appreciate that each of the overseas cases come under different laws but I firmly believe that patents and patent rights should try to be uniform throughout the world. This being said I think that Australia needs to consider the overseas aspect and ensure that Australian rights match or equal them. I have concerns over the interpretation in the *Duke v Madey* decision. If as Miller (your ref 5) says "the decision effectively eliminates the experimental use exception for research institutions" since "no research institution will be able to demonstrate that its experimental use of any patent fails to further the institutions legitimate business" then the same would be said for Australian research institutes. In this day of decreased government funding and the need for Universities to "commercialise their research outputs" we too would be hard put to say we are not furthering our business. One of the outcomes at AUTM was to decide whether the

academic is working WITH the patented technology or ON the patented technology the ON being acceptable. I particularly liked the philosophy behind the Japanese Supreme Courts ruling that is “that the essence of the patent system is that anyone can fully utilise the invention after the patent expires”. I think quite clearly that one should not hide behind the “experimental use” right to reverse engineer patents but I support the use of patented products in academic research even if the ultimate end product can itself be commercialised.

**Q3 What are the constraints for an experimental use exemption (or possible alternatives) under any of the international agreements to which Australia is a signatory?**

As indicated in the Issues Paper the most likely treaty to be considered would be TRIPS. This being so any decision regarding experimental use needs to be in line with this treaty. Article 30 employs reasonably comprehensive language to allow members to provide limitations to exclusive rights of patent owners. Australia and indeed the other members need to decide whether experimental use can come under Article 30 and if yes what is the definition of experimental use. I note that the paper recommends that Article 30 needs to be read in conjunction with other articles of the treaty and in my mind I believe Article 7 fully encompasses what “Innovation” is all about.

**Q4** I do not feel I have the information to make a comment.

**Q5** I do not feel able to comment.

**Q6 Does fair dealing (or fair use) in copyright law hold any lessons for “experimental use” in Australian patent law?**

I believe that the USA decision in the Sony v Universal City Studios (1984) with respect to “fair dealing” captured the essence of what needs to be considered in patent law that is “The fair dealing doctrine is a means of balancing the exclusive rights of the copyright (patent) holder with public interest and the dissemination and use of information”. This should be consider in the patent process and on deciding “experimental use”.

**Q7 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?**

In this day I think it is more difficult to clearly separate basic or applied research. Certainly in the Biotechnology arena basic and applied research are very close sometimes overlapping. To try to allocate different rights to different types of research would add additional problems rather than alleviate one potential concern. I would not advocate different rights for different research.

**Q8 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?**

As I indicated earlier I do not believe that academics actually consider whether their research is infringing a patent. I thus cannot see any indication that a “patent thicket” is a concern to academic researchers. Of course in the case of Companies carrying out research where they do consider whether their R & D is infringing they may very likely opt to terminate a project if its commercial path did not look clear and the costs to ensure it had a clear IP path were too large.

**Q9 Does Biotechnology and genetic technology, in particular, have special issues that warrant special treatment under patent law with respect to experimental use?**

Patenting in the Biotechnology arena only really began to boom in the mid 90’s. Whilst working with Gene Shears in the early 90’s I recall that the amount of Biotech patents lodged in the USA were in the 10s of thousands with a huge increase to the 100s of thousands by the mid 90s which of course has escalated on a log scale since. The author correctly says that many of the requirements laid down by patent law are more suited to mechanical inventions. Nevertheless these requirements need to be applied to Biotech and with the advent of automated gene sequencing I think more stringent adherence to utility is required. It would be more useful to know that a certain sequence codes for a certain protein and this could be patentable but to just identify a sequence and propose it will code for a protein is not acceptable in my view.

Since there has been a flurry of patents filed and granted on “genes sequences” I believe this could down the track be a serious impediment to research and ultimately innovation. Academics are not flush with funds and they would not be able to afford a “licence” yet their research may be infringing these so called “gene” patents. I think that Biotechnology is one arena where experimental use is a necessity due to the plethora of existing encompassing patents.

**Q10 What is the justification for an experimental use exception?**

The experimental use exception would allow academic researchers to have the freedom to continue their research to understand and develop more potential treatments for disease without being thwarted by existing broad encompassing patents.

**Q11 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?**

This is definitely a route to consider and a view that is being aired by Universities and research institutes in the USA.

**Q12 If so is it sufficient by itself?**

I believe that what ever criterion is selected it needs to be short succinct and easy to interpret.

**Q13 Should an experimental use exemption cover only the situation where experimentation is the sole purpose of the use of the invention?**

I believe that experimental use should also cover the situation where the patented technology may be a step in a process. If this process then proves to be “commercially” successful then the contribution that the technology makes to the final outcome needs to be assessed and the owner fairly compensated. I do not support having to pay a licence fee before the new process has been shown to be successful both experimentally and commercially.

**Q14 If not what are alternatives or supplementary criteria for an experimental use exemption?**

As above I believe until the new process has been shown to be a commercial success and it would not be so without access to the “patented” technology then the early development work should come under experimental use.

**Q15 Are improved licensing practices by research organisations a whole or partial alternative to an experimental use exemption in Australia?**

Universities do not have the funding to continually licence technologies. For example The University of Newcastle has 5 Faculties. If only 10 academics from each of these faculties were working with technologies that were patented then we would need 50 licences which even if they only cost \$1000 would be a further drain to the constantly reducing research pie. Further careful consideration of what the licences were actually providing would be required and what we had to give them in return. I am not convinced this is the way forward.

**Q16 If so, how could licensing practices be improved to provide better outcomes for researchers?**

I am not aware that there are many licences currently in place in Australia for research use. I am conscious that the University of Sydney has signed a licence with an American company but cannot comment on its content or effect.

I thank you for the opportunity to respond and look forward to being advised of the consultation dates and venues.

Yours sincerely,



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