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Dr Rod Crawford
Secretariat
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PO Box 200
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Dear Dr Crawford

Find enclosed Edith Cowan University's (ECU's) response to the ACIP - Patents and Experimental Use Issues Paper dated February 2004.

ECU has limited experience in the area of experimental use with relation to patents, however we are an institution that pro-actively encourages innovation and relating research outcomes to realistic and applied challenges. As a result the response attached demonstrates limited knowledge in certain areas of IP protection yet illustrates an avid awareness of the importance of such issues.

I trust you will find the ECU response useful and wish you luck in this necessary, yet challenging, endeavour.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Bill Louden', is written over a horizontal line.

Professor Bill Louden
Pro Vice-Chancellor (Research)

Advisory Council on Intellectual Property

Patent and Experimental Use

ISSUES PAPER

February 2004

Response from Edith Cowan University

- 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?

Response 1:

- (a) Little understanding at this point. Awareness that this is a potentially contentious issue requiring clarification.
(b) Basis of understanding is via interaction with Patent Attorneys who provide services and a high level of confidence to ECU.
(c) ECU takes a cautious approach by ensuring existing third party patents are not experimented upon thus eliminating potential IP infringements. With regard to our own IP, all experiments are kept confidential and confidentiality is secured wherever possible. The issue of publishing versus confidentiality is an ongoing one in an academic environment.

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?

Response 2:

Lessons can be learnt from the experiences in other countries. More specifically ECU believes that the following examples should be preferred for Australia:-

USA - compensates the patent holder to gain Federal approval via an extension of the patent term. In recompense this system also permits experimental use to allow alternative products to be launched immediately following expiry of the patent term.

Japan - permits experimental evaluation to prevent patent holder to enjoy market exclusivity beyond the patent term as this would, "*disregard the interest of society...*".

Europe - experimental evaluation should be permitted, "*in view of the development of state of the art and the public interest*".

New Zealand - recognises that experimentation may have an ultimate commercial objective. The issue is where that ends and infringement begins is often a matter of degree. This is a pragmatic approach to take yet requires more definitive guidelines.

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?

Response 3:

ECU is not in a position to make informed comments on international agreements at this stage.

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

Response 4:

ECU is not in a position to make informed comments on international agreements at this stage.

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?

Response 5:

If we are to adopt a clarified system of permitting experimental use exemption then there is no need to consider further pre-grant conditions.

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?

Response 6:

From a non-legal viewpoint, the "fair dealing" purposes outlined in the paper seem to be a pragmatic approach to a complex issue. Purposes such as research/study, criticism/review/ and the reporting of news all serve to stimulate and encourage further creativity and innovation. The purpose of professional advice given by a legal practitioner or patent attorney is not too dissimilar to current patent processes and should be upheld.

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?

Response 7:

There is an argument for a differential patent system to accommodate basic, applied and hybrid research.

For basic research, the recognition of commercial potential is generally a secondary matter. As a result, the lead-time for seeking formal protection is generally longer than that for applied research with a commercial focus.

By its very nature applied research is generally directed towards the solution to existing problems. Inherently providing commercial potential from the planning stage. In these circumstances the lead-time for formal protection is much shorter.

The problem arises when defining basic research (Pasteur's Quadrant) as opposed to pure applied research (Edison's Quadrant). It is likely that an area of overlap would see a blurring of the definitions.

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?

Response 8:

ECU has no evidence or experience of "patent thickets" and hence is not in a position to comment.

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

Response 9:

No. In order to prevent a plethora of potentially conflicting policies, the patent system should remain technologically neutral.

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

Response 10:

A major justification for an experimental exemption is to permit experimentation on a patented invention to permit validation and confidence in the patent claims.

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?

Response 11:

Yes, the criterion should be on the invention itself.

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

Response 12:

No. Limitations on the spectrum of validation processes are required to protect the interests of the originator.

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

Response 13:

Yes. Existing patent law provides for disclosure thereby permitting experimental use, further design, understanding and improvements to a patent. Additional liberties would serve to undermine the originator's control of the innovation.

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

Response 14:

N/A

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

Response 15:

Theoretically, more creative employment of licensing options has the ability to provide an alternative to experimental use exemption. In practice, however, the general lack of experience in licensing options introduces inherent limitations to this alternative.

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

Response 16:

One solution would be to simplify current licensing processes, which tend to be problematic, and providing educative support.

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

Response 17:

The fields of pharmacology, chemical engineering, genomics, mechanical engineering, aeronautical engineering, (micro)electronic engineering, ICT and biotechnology readily lend themselves to patent pooling.

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

Response 18:

If the disadvantages were managed effectively then the benefits would be valuable. Addressing potential "price-fixing" is a challenging yet necessary activity if patent pooling is to be more readily introduced.

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

Response 19:

The impediments to compulsory licensing render this option undesirable in Australia. However, the supporting paper references experiences in the USA and Canada whereby these impediments are largely overcome without affecting long term incentives to innovate. Clearly these alternatives warrant further investigation.

Question20: For this to happen, do Australia's compulsory licensing provisions need to be changed? If so, how?

Response 20:

It appears that experiences/practices in the USA and Canada can provide indications of how the Australian provisions could be modified.