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Dear Dr Crawford

Patents and Experimental Use Issues Paper

Introduction

Monash University believes that it is critical that the patent law in Australia contains provisions which allow *bona fide* experimental or research use of a patented invention as an exemption to infringement. As noted in the Issues Paper, currently there is no explicit experimental use exemption to infringement in the Australian *Patents Act 1990*, although it is widely believed that such an exemption would be recognised by Australian Courts. It is, however, becoming increasingly important that this exemption is given a statutory basis, and that any statutory experimental use exemption to infringement be as clear and definite as possible.

If no exemption from infringement of a patented invention existed in relation to *bona fide* experimental use, an impractical situation would arise in that all research and experimental activities would require "freedom to operate" searches, licensing negotiations and the like to be undertaken before any research or experimental activities took place. It is also in the public interest that such an exemption exists, so as to provide a situation allowing freedom of research, consistent with the philosophy of the patent system to encourage development of new and improved technologies.

Monash University considers that the current situation in relation to the nature and scope of the experimental use exemption requires clarification. Accordingly, Monash University considers that the most straightforward way to address the situation is to provide a statutory experimental use exemption from infringement of a patented invention which clearly sets out the extent of that exemption, so that both researchers and patentees can fully and readily understand its scope.

Basis of Experimental Use Exemption

A difficulty arises, however, in defining an appropriate basis for the exemption and for drawing the line between what might be exempt experimentation involving a patented invention and what is non-exempt.

Possible bases for drawing a distinction between exempt and non-exempt experimentation or research might include the nature of the organisation conducting the experimentation or research (i.e. whether the organisation is a commercial or non-commercial entity), or the purpose or intention of the experimentation or research (i.e. whether it is for commercial or non-commercial purposes). In the view of the University, however, both these methods of drawing a distinction have significant problems. Firstly, a distinction along the commercial/non-commercial lines would not be workable in that much current research and experimentation is performed with at least a small degree of commercial intent or motivation (even if commercial outcomes are never realised), even in academic research institutions such as universities, so that it would be almost impossible to make a distinction on a commercial/non-commercial basis. Furthermore, a recent court decision in the USA has made an extremely broad interpretation of "commercial", suggesting that the gain in reputation made from good research (even if absolutely non-commercial) contributes to the commercial goal of attracting more students to the university and hence is not exempt, an interpretation at odds with the need for a real exemption as outlined in this document. Secondly, it seems clear that defining the distinction on the basis of the type of institution would be impossible in that many types of institutions do both commercial and non-commercial research.

Accordingly, it is considered that a reasonable and practical basis for a statutory experimental use exemption should be based on the European model which draws "a distinction based upon whether the experimentation is *on the invention itself* – to determine how it operates, test it, or use it as a base to make different, improvement inventions – as opposed to *using* an invention *for its intended purpose*" – (see page 18 of the Issues Paper). As noted in the Issues Paper, a distinction on this basis is consistent with the fundamental principles of the patent system in balancing the needs of the "primary innovator" or patentee, with those of "secondary innovators and end users" such as researchers and experimenters, and is closely related to the disclosure requirements inherent in the patent system.

The University considers that any statutory experimental use exemption should make it clear to both researchers and patentees what is and what is not exempt. Accordingly, it is considered that the exemption should clearly include the following activities:

- (a) testing an invention to determine its sufficiency or to compare it to prior art;
- (b) tests to determine how the patented invention worked;
- (c) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;
- (d) experimentation for the purpose of "designing around" a patented invention;
- (e) testing to determine whether the invention met the tester's purposes in anticipation of requesting a licence; and
- (f) academic instructional experimentation with the invention

(refer to page 18 of the Issues Paper).

The distinction between experimentation "on" the invention itself and experimentation "using an invention for its intended purpose" is a practical and workable distinction. That distinction would result in the use of research tools for the purpose for which they were patented being categorised as non-exempt, and that is a fair and acceptable outcome.

As noted in the Issues Paper, there is a fundamental distinction between research into the science and technology disclosed in patents (which would be exempt under the above distinction), and the use in research of patented products or methods for the purpose for which they were patented (which would be non-exempt on the above basis). The use of a patented research tool in experimentation or research for the purpose for which it has been patented can be clearly

distinguished from research or experimentation on the tool itself. The latter is applicable in the case of investigating how the research tool works or investigating the mechanism by which it works. Accordingly, any research or experimentation which used a patented research tool for the patented purpose would not be exempt from infringement and would require an appropriate licence of the patented research tool, or other appropriate action, before the research or experimentation could be carried out using the research tool.

Clinical Trials

One particularly difficult area which has arisen in relation to the experimental use exemption from infringement relates to the conduct of clinical trials in the context of patents in the pharmaceutical and veterinary fields. In Germany and the UK, where the respective statutes do provide an exemption for acts which are "done for experimental purposes relating to the subject matter of the patented invention", the approaches and interpretations of the exemption differ. In Germany the conduct of pre-clinical and/or clinical tests is apparently allowed in view of the development of the technology and in the public interest. However, in the United Kingdom such pre-clinical and/or clinical trials apparently do not fall within the experimental use exemption on the basis that such tests are carried out "with the view to the direct use of the results thereof for a commercial purpose".

As noted above, it is not considered that a commercial/non-commercial distinction is practical or workable since most current research and experimentation has at least a small degree of commercial intent or motivation, and the same situation exists in respect of most clinical trials. Furthermore, it is not considered practical to attempt to distinguish between early-stage clinical trials on the one hand (where the motivation may be more experimental) and late-stage clinical trials on the other hand (where the motivation may be more commercial in producing data for product registration and marketing purposes).

Accordingly, in relation to clinical trials, the University considers that the most practical and acceptable basis may be to include clinical trials within the exemption as being experimentation "on" the invention itself, except where the clinical trial is directed specifically to use of the patented invention for its intended purpose (for example, trials of a generic equivalent of a patented product to establish its "bioequivalence" when used for the same purpose as the patented product).

Conclusion

In conclusion, Monash University strongly supports the need for a research exemption, clearly defined in law. The University submits that the most practical and straightforward distinction which can be made in relation to a statutory experimental use exemption from patent infringement is based on a distinction between experimentation "on" a patented invention and experimentation "using" a patented invention for the purpose for which it is patented. Such a distinction provides an appropriate balance between the rights of patentees to prevent others from using their inventions, and the rights of researchers and other third parties (consistently with the philosophy of the patent system) to build upon and learn from inventions that are the subject of patents.

Yours sincerely

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