

Dr Rod Crawford

Secretariat

Advisory Council on Intellectual Property

Dear Dr Crawford,

I wish to submit the following comments in response to the Issues Paper on Patents and Experimental Use distributed by the Advisory Council on Intellectual Property in February 2004. In the following responses I have attempted to address the questions raised in the Issues Paper. I regret that this response has been delayed and hope it might be considered with the other submissions that you have received.

While the following comments are made by myself and on my own behalf, they draw on my experience in the area. This includes my work in the private and public sectors since 1986 that has led to my current appointment as Deputy Director of the Business Liaison Office of the University of Sydney where I am also Manager of the Intellectual Property and Licensing Unit.

I also have a number of relevant professional associations. In particular, I am currently Secretary of the Licensing Executives' Association, Australia and New Zealand, an active member of Knowledge Commercialisation Australasia and Vice President for International Relations in the Association of University Technology Managers.

It is my understanding that the current Australian law provides exemption for experimental use of patented subject matter in the manner expressed in *Freason v Loe*. In this, I understand that any party has the right to undertake experimentation for the purpose of testing whether an improvement can be made to a patented invention and for the purpose of making such an improvement. However, it is my understanding that such exemption is limited to acts that are directed in such a manner that the improvement, if made, would fall outside the scope of the patent in relation to which the work is undertaken. I am also aware of the provisions of s.78 of the Patents Act in relation to certain pharmaceutical substances.

I have an enduring view that a party's use of an invention in experimentation is not infringing if that experimentation is for the purpose of testing the validity of the patent, including, for example, but without limitation, testing whether the invention can be reduced to practice. However, I have not identified an explicit provision to this effect in the Patents Act as it exists at this time.

In response to review of international law in this area, I understand that most comparable legal jurisdictions provide for extremely limited experimental use exemption but that most also share with the current Australian legislation some lack of clarity on this limitation.

In reviewing Article 30 of the TRIPS Agreement, it is not clear to me that the limited exceptions do not provide for more or less than the three types of exemption I have identified above.

Despite working in one of the largest research organisations in Australia and having some familiarity with the work of some of the other major research universities, I am not aware of any empirical evidence that the current legislation adversely affects research and development. I acknowledge, however, that other may have a different view about what might be an adverse effect.

In the absence of significant change to the operation of the entire patent law, which I understand is not intended, I am aware of no substantive arguments in favour of any new pre-grant conditions for patents as a complement or an alternative to an alternative use exemption.

It is my opinion that the three areas of exemption that I have described above provide the equivalent of "fair use" in copyright law.

I am not able to identify any substantial distinction between basic, applied or hybrid research as identified in the Issues Paper such that any of these would require differential treatment under the patent law.

I have no awareness of a "patent thicket" problem in research and development, nor any special issues in any area of biotechnology that warrant special treatment under patent law with respect to experimental use.

Without proceeding through an exhaustive review of the other issues raised, I note that there is no evidence that changes can be made to the Australian patent law that would easily address proposals for improved licensing practices, creation of patent pools or provide for compulsory without appearing likely to put the legislation in conflict with our major trading partners and perhaps our treaty obligations.

I note that "open source principles" have apparently been adopted by some software creators for purposes other than those that typify the motivations of patent owners. However, many patent owners appear to have applied an "open source"-type principle in neither claiming nor taking action against parties whose research activities would fall outside the exemptions that I have identified above.

In summary, there appears to be opportunity for legislative change that clarifies the rights of parties other than the owner of a patent or patent application to test the validity of that patent or patent application, or for the purpose of making an inventive improvement to it or seeking to test that such an inventive improvement can be made. However, there appears to be neither need, nor benefit to be achieved, in implementing changes to the patent law that would provide for a significantly more liberal right for non-owners to undertake experiments using patented technologies.

I would like to close with two examples. First, in 2003, the University of Sydney was identified by some media as being the first Australian university to sign and licence with Genetic Technologies that allowed University staff and students to undertake research using the so-called "junk DNA" patents owned by that company. The licence did not provide the University with any material, only the right to exercise the inventions described in the patents for research. While much was made of this in the press and I received a number of comments from researchers at the time, the licence terms, including the fee, were judged not to be onerous or constraining and the existence of the licence provided certainty for a number of researchers. Concerns were expressed that this might encourage other patent owners to approach the University and require the execution of licences allowing University staff and students to undertake or continue their research. However, no other party has the University for such a licence, nor has the University been notified of any infringement of any patent within its research.

Finally, Stanford University received licence income in the order of \$US250 million from commercialisation of the "Cohen-Boyer" patent. However, the patent was for a research tool that was commercialised by others under licence from Stanford. The expression "One man's patent is another man's research tool." has been coined with reference to this type of successful commercialisation of a research tool. Changes to the patent law might provide a disincentive to inventors to invent new research tools and this might be more damaging to the process of research than all of the risks identified in the Issues Paper.

I welcome the opportunity to provide further information in relation to the matters raised in the preceding paragraphs. To this end, I welcome your call or email to the number or address set out herein.

Yours sincerely,

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