

Received 23/4/04

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A comment on patents and experimental use

Dear Rod Crawford

An experimental use exemption is needed and should be implemented into the Australian patent system. The current debate and increasingly tense legal situation requires the law to be clarified quickly, rather than waiting for judicial interpretation. This will only occur if the federal government takes the initiative to make amendments to the Patents Act. In doing so, the government should recognise that the success of any experimental use exemption will depend largely on clear wording of the statute, such that researchers have a clearer basis to pursue research and so that courts will effectively impose the statutory intention.

Below I have included some general discussion on some of the problem areas that an experimental use exemption would have to address. In addition, I have included a statutory experimental use exemption model, which I hope could be used to help formulate a clear experimental use exemption in Australia.

A genetic sequence exemption?

There has been some support for enacting a statutory provision specifically dealing with genetic sequences. Such a provision would at least solve the problem for genetic sequences. Unfortunately, such a provision would probably fall outside of our obligations under the TRIPS agreement, as it would discriminate against this particular technology. In addition, this could lead to a somewhat messy patent system and would generate much commercial uncertainty if the government were to enact new provisions each time "troublesome" technologies arose. Thus, a single, comprehensive exemption remains the preferred approach.

The commercial / non-commercial distinction?

Whether research is done for commercial purposes has been a common device used for identifying patent infringement. However, as noted by Hardie Boys J in *Smith Kline & French Laboratories v Attorney General (New Zealand)* (1991) IPR 143 using such a distinction can be problematic as most research will have a commercial objective to some extent. Therefore, identifying a clear benchmark can be difficult. However, in my opinion, Hardie Boys J has actually achieved a clear benchmark in *Smith Kline* by stating "But if he goes beyond that, and uses the invention or makes available to others, in a way that serves to advance in the actual market place, then he infringes."

Rather than trying to ascertain whether a researcher is conducting experiments for commercial purposes, it would seem more prudent to consider whether the "infringing act" affects the commercial interests of the patentee, as for the patentee, this is the heart of the issue. Support for this can be found in German case law. In *Klinische Versuche II* [1998] RPC 423, it was noted that "if experiments.... were aimed at hindering the patentee's distribution of its product then they might fall outside the exception."

Such an approach has several benefits. Firstly, it would certainly satisfy those who argue for a broader research exemption as it would allow *any party* to develop or improve products so long as they did not affect the commercial interest of the patentee. This would also circumvent one of the loopholes identified in the commercial purpose test, namely corporate sponsors "piggybacking" off the immunity of universities. In addition, it would also provide a clearer basis for research to be legally commenced and thus stimulate greater innovation. There would be less need to contact a patent attorney before pursuing particular research avenues. Rather, it would delay the need for legal advice until the commercialisation stage, at which point researchers would then need to consider issues of licensing or infringement.

Overall, the benchmark identified by *Hardie Boys J* would seem more beneficial than maintaining the traditional commercial purpose distinction. The only down side to this, is that it would greatly infringe upon the rights of research tool patent holders. Thus, it should only be used with some kind of additional qualification.

The on / with distinction?

The *on / with* distinction, utilised in some European jurisdictions, also carries some benefits. Experimentation *on* an invention occurs where the invention is used in a manner that is different to the purpose for which it was originally designed. This is considered to relate to the subject-matter of the patent. However, experimentation *with* the invention involves using the invention for the purpose for which it was designed and thus falls outside the exemption. The "experimentation *on*" distinction appears to deal with the problem of research tools relatively well as it protects against the use of research tools for their designed use. Thus, it would be of benefit to include the *on* distinction in the Australian approach. However, the distinction does not adequately solve the problems surrounding broad product patents. Ideally, it would be preferential to also implement a narrow "*with*" exception that could allow limited experimental use of genetic sequences, drugs and the like, while leaving other research tools unaffected.

Proposed wording for a statutory research exception

In light of the above discussion, I propose the following wording that could be used as a basis for formulating a clear statutory research exemption to patent infringement in Australia;

For the purposes of this Act, an act shall not constitute an infringement of a patent for an invention if:

- (a) it is done *on* an invention for *teaching* purposes relating to the subject-matter of the invention, and having regard to the scope or purpose of the patent, it does not use the invention or make the invention available to others, in a way that advances on the commercial interests of the patent holder, taking account of the legitimate interests of third parties; or
- (b) it is done *on* an invention for *experimental* purposes relating to the subject-matter of the invention, and having regard to the scope or purpose of the patent, it does not use the invention or make the invention available to others, in a way that advances on the commercial interests of the patent holder, taking account of the legitimate interests of third parties; or
- (c) it is done *with* a *product* invention for experimental purposes, where;
 - (i) it does not infringe any other patent claim relating to the *use* of the product; and
 - (ii) having regard to the scope or purpose of the patent, it does not use the invention or make the invention available to others, in a way that advances on the commercial interests of the patent holder, taking account of the legitimate interests of third parties.

Essentially, the above section comprises a number of important concepts. Firstly, it uses the U.K. legislation as the basis for the model and so incorporates the words "relating to the subject-matter of the invention". Secondly, it expressly incorporates the *on / with* distinction. Thirdly, it adopts the words of Hardie Boys J and states that infringement does not occur until the research advances on the commercial interests of the patent holder. In addition, it invites a court to consider the scope and purpose of a patent as well as the "legitimate interests of third parties", thus is consistent with TRIPS.

Subsection (a) relates purely to use of the patented invention for teaching purposes. Effectively, it is intended to only encompass activity that simply involves the demonstration of the invention so as to educate students and is not intended to cover any research that would result in further study or improvement of the invention. Arguably, this does not encompass any activity that would not be covered by subsection (b). However, it has been incorporated for two purposes. The first is simply to highlight the key principle that teaching activity should not be liable to patent infringement. The second

is to indicate that the activity covered by subsection (b) does extend beyond mere teaching of the invention. In addition, the subsection also incorporates the words of Hardie Boys J. In this subsection, it is arguable that these words also have little relevance as it would be hard to envisage that teaching activity could involve any form of commercialisation. However, the words have still been incorporated so as to encompass inventions that may be used almost exclusively in the classroom.

Subsection (b) is very similar to the U.K. statutory research exception. However, it differs in two ways. To begin, it expressly incorporates the word "on". This does not change the subsections effect when compared to the U.K. exemption, however, the word is still important as it distinguishes subsection (b) from subsection (c), which incorporates the "with" distinction. More importantly, subsection (b) again uses the words of Hardie Boys J. Here the words are of greater importance as they expressly prevent research from infringing upon a patent until it advances on the commercial interests of the patentee. Thus, should give greater certainty to researchers as to when infringement occurs.

Subsection (c) is probably the most controversial as it incorporates a narrow exception to research *with* a patented invention. The most crucial factor relating to the success of this subsection is that it relates only to *product* inventions. Just as importantly, it is then qualified by the subsection (c)(ii), which limits the research if it infringes any other patent claim relating to the *use* of the patented product. Essentially, this recognises that most *product* claims for inventions are also followed by *process* claims relating to use. Overall, this would allow any research to be conducted *with* a patented invention so long as the invention was not used for its *patented use*. This could aid in the resolving the problem relating to drugs or genetic sequences. As a final qualification, the subsection also includes the words of Hardie Boys J. Therefore, the results from such research could not be commercialised unless licences could be obtained for use of the invention.

Examples – PCR process patent and a "mutant gene" patent

So as to illustrate how the proposed section might apply, two brief examples are provided; PCR (a means for amplifying DNA) and a "mutant gene" (as a means for detecting a predisposition to cancer).

Subsection (a)

Under subsection (a), both the PCR process and the "mutant gene" could be used for teaching purposes without infringing either patent. Essentially, this would enable any experiments, falling within the scope of these patents, to be performed so as to enable the inventions to be understood by students. However, any attempt to further research or improve these inventions would fall outside the ambit of this subsection.

Subsection (b)

Under subsection (b), research could be performed on both the PCR process and the "mutant gene" so long as it related to the subject matter of the patent and did not advance on the commercial interests of the patent holder. Effectively this could encompass the teaching purposes from subsection (a) but would also allow research into improving these inventions so long as the results were not then commercialised.

Subsection (c)

It should first be noted that subsection (c) would not apply to PCR. This is because PCR is a process and therefore is not a *product* patent. It is worth noting that it is for this reason that subsection (c) would not apply to the *use* of most research tools and so would not affect the need for researchers to acquire licences.

In contrast, the subsection may apply to the "mutant gene" as a *product* patent. However, the gene could *not* be used in research for its patented use, being the detection of a predisposition to cancer, without infringing the patent. Nevertheless, this would still enable the gene to be used in many other ways, such as to see if it could be involved in other diseases. Subsequently, this subsection would free up the use of many sequences for which patented uses are either not described or are very limited.

So would the proposed section be consistent with TRIPS?

It should be noted that before any research exemption could be added to the *Patents Act 1990* (Cth), one would have to ascertain whether the exemption would be consistent with our obligations under the TRIPS agreement. For the purposes of the above proposed section, there are two articles from the TRIPS agreement that should be considered;

To begin with, article 27 states "...*patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*" The proposed section does discriminate between *product* patents and *process* patents in subsection (c). The question then is whether this discrimination against *product* patents amounts to discrimination between technologies. On the whole, it would more likely not amount to discrimination as it applies to product patents generally, irrespective of the field of technology.

Given the proposed section is broader than those in other jurisdictions, one would also have to consider whether the section is in conflict with article 30. Article 30 states "*members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*" Essentially, the proposed section achieves compliance with this article in three ways. Firstly, it prevents any research that would advance "on the commercial interests of the patent holder", which is effectively analogous to the wording of article 30. Secondly, it

expressly includes the words "taking account of the legitimate interests of third parties" from the article. Finally, it enables a court to have regard to the "scope or purpose of the patent" when considering if there has been an infringement. This would allow the court to take into account any practical matters relating to the alleged infringement.

Conclusion

Although there is currently no specific research exemption to patent infringement in Australia, it is evident that there is an increasing need for one to be implemented. The major factor impacting on this has been the recent shift towards basic researchers and universities as being targets for patent infringement. In addition, there are now broader concerns that our patent system may ultimately curb innovation rather than promote it. The issues for the implementation of such a research exemption are complex. These include the growing commercial activity of universities and the problems associated with research tools and genetic sequences. Nevertheless, the growing debate and uncertainty needs to be resolved. The question is no longer *if* a statutory research exemption should be implemented, but *when* one should be implemented. The Australian Government should, as a matter of priority, seek to amend the *Patents Act 1990* (Cth) and incorporate a research exemption to patent infringement.

Regards

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