



The Institute of  
Patent and Trade Mark  
Attorneys of Australia  
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Advisory Council on Intellectual Property  
Secretariat  
PO Box 200  
Woden ACT 2606

Attention: Dr Rod Crawford

Dear Sirs,

We make the following submissions on behalf of the Institute of Patent and Trade Mark Attorneys of Australia (IPTA) in response to the Issues Paper entitled "Patents and Experimental Use".

IPTA represents patent and trade mark attorneys registered in Australia, both in private and corporate practice. Although membership of IPTA is voluntary, over 90% of patent attorneys registered in Australia are members of IPTA, either as Fellows or as Ordinary Members of the Institute. Most of these members are also registered as trade marks attorneys in Australia. In addition, the membership of IPTA includes other registered trade marks attorneys who are not also registered as patent attorneys. Accordingly, it is considered that the views of IPTA are representative of the views of a large proportion of patent and trade mark attorneys registered in Australia.

Before addressing the specific questions raised in the Issues Paper we would like to make some general comments in relation to what we believe would be the essential requirements for a statutory experimental use exemption. We believe that the most important requirement for any statutory experimental use exemption is clarity. If it is not clear then there will be unnecessary expenditure by patentees and third parties on litigation and in seeking legal opinions. It is also important for the exemption to fall somewhere between the two extremes, i.e. between a situation where there is no exemption for any type of experiment, and a situation where every experiment is exempt. In the former case patents could unduly inhibit legitimate research, while in the latter case patents directed towards important tools used in research would be unenforceable. It is also important for exemption to be framed in a way which furthers Australia's goals in connection with international patent law harmonisation.

While in the interest of fairness we would prefer an experimental use exemption which draws a distinction between non-commercial use and commercial use, i.e. by defining a quantum of commercial flavour below which an experiment would be

exempt, we believe that any attempt to define an experimental use exemption in such terms would be doomed to fail. This is because in modern times most experiments performed have some commercial flavour, and defining in clear terms an allowable quantum of commercial flavour which would cover all potential circumstances would be an impossible task. It is for this reason that IPTA would prefer a statutory experimental use exemption which drew a distinction between experiments on a patented invention and experiments with or using a patented invention. Such an experimental use exemption would be limited to experiments conducted on a patented invention, and would be consistent with the law of the European Union. We believe such an experimental use exemption would provide a balance between the rights of patent holders to prevent others using their inventions and the rights of third parties to build upon and learn from inventions which are the subject of patents. More importantly, we believe such an experimental use exemption could be drafted in a way which draws a clear distinction between an experiment conducted on the subject matter of an invention (eg. for the purpose of finding out something unknown about the invention or testing an hypothesis relating to the invention) and an experiment conducted with or using an invention (eg. an experiment demonstrating the effectiveness of the invention to a third party or an experiment which uses the invention for its known purpose). The clarity of such an exemption can be tested by applying it to the following scenarios which represent common circumstances which arise in biomedical research:

Scenarios	Exempt
1. Use of a patented receptor implicated in a particular disease state in a screen for identifying ligands as potential leads for developing a therapy for the treatment of the disease state.	NO
2. Use of a patented compound as a standard in a screen/assay designed to identify other compounds having beneficial properties relative to patented compound.	NO
3. Use of a patented compound in setting up an assay or screen to test whether assay/screen works as it should.	NO
4. Use of a patented compound in a study to identify weaknesses or limitations of patented compound.	YES
5. Use of patented compound in the development of an analogue program (e.g. as synthetic starting point) to prepare compounds for testing as potential improvements over patented compound.	YES
6. Use of patented compound in a toxicity profile study to determine whether a particular toxic side effect is a class effect or an effect limited to the particular compound.	YES
7. Use of patented compound in a series of assays using different proteins to determine which, if any, of the proteins interact with the compound.	YES

8. Use of patented compound in a study designed to understand and define biochemical pathways.	YES
9. Use of patented compound in a clinical trial designed to compare the therapeutic activity of your compound with the known therapeutic activity of the patented compound.	NO
10. Use of patented compound in a clinical trial designed to compare the therapeutic activity of your compound with the known activity of the patented compound where clinical trial is for a new therapeutic indication.	YES
11. Use of a patented compound in a clinical trial to demonstrate bioequivalency to the patent owner's approved product.	NO
12. Use of patented compound in an assay or screen to determine whether compounds have a new activity which would make them potentially useful in a way not envisaged in the patent (e.g. for a second medical indication).	YES
13. Use of non-exemplified (but patented) compounds in an assay or screen designed to determine whether they have beneficial properties relative to exemplified compounds (or commercial product) falling within the scope of the patent, but where no new use is contemplated.	YES
14. Use of patented platform research technology (eg. PCT, micro-arrays etc) for identification of disease markers to assist development of a diagnostic or therapeutic for that disease.	NO
15. Manufacture of patented compound to determine whether compound can be prepared consistently on a commercial scale using a processing plant set up for that purpose.	NO
16. Preparation of a patented compound as described in a patent specification to test the validity of the patent, eg. to determine whether disclosure is enabling or whether invention works.	YES

We believe that an "experimenting on" exemption could be readily applied to the scenarios above in circumstances where the patented receptor and patented compound were not obtained from the patentee or used under license from the patentee. On the other hand, if an exemption was to be based on a particular quantum of commercial flavour, it would be far more difficult to apply the exemption. For example, with respect to scenario 1, the answer may be different depending on whether the screen was conducted on a laboratory scale at a University under a project funded by a large pharmaceutical company, on a laboratory scale at a

University under a Commonwealth funded project, or on a high throughput basis by a large pharmaceutical company.

We now make the following comments in relation to the specific questions raised in the Issues Paper:

**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?

We are not aware of any Australian cases relating to experimental use as an exemption to patent infringement, although the point was touched upon in a recent Patent Office decision (*New York University v Nissin Molecular Biology Institute Inc.* (1994) AIPC 91-067).

In this case, which related to a request for release of a sample of a deposited microorganism based on a comparison experiment intended to be conducted by the requestor, the hearing officer was of the opinion that the New Zealand case, *Monsanto Company v Stauffer Chemical Company* [1984] FSR 559, and the United Kingdom case *Frearson v Loe* (1878) 9 ChD. 48, were relevant to the question of experimental use in Australia.

According to *Frearson v Loe* a patentee is not given an exclusive right to experimental use in relation to the invention. In that case it was decided that:

"... if a man makes things merely by way of bonafide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, with a view to improving upon the invention the subject of the patent, or with the view of seeking whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither use nor vending of the invention for profit, the mere making for the purpose of experiment, and nor for a fraudulent purpose, ought not to be considered within the meaning of the prohibition."

According to *Molins & Molins Machine Co Ltd v Industrial Machine Co Ltd* (1936) (54 RPC 94), in determining whether an activity amounts to infringement, the court is required to look at **all** the purposes of the tests and not only the predominant purpose. Even where the infringing activity forms only an underlying purpose, this will be sufficient for the party testing the invention to have infringed the patent. In

*Molins*, the invention consisted of a cigarette making machine which was being used primarily for the purpose of testing and improving it. However, the testing had to take place at a cigarette manufacturer. Although the primary purpose of the testing was improvement of the machine, there was an underlying hope that the owners of the factory might decide to buy the machine. Furthermore the cigarettes which were made, although limited in number, were ultimately sold to the public. Under these circumstances the party testing the cigarette machine was deemed to have infringed the patent.

When examining all the purposes of the "infringing" activity for the purpose of demonstrating infringement, it does not appear to be sufficient to merely show infringement of the patentee's monopoly in the absence of commercial gain. In *Monsanto Company v Stauffer Chemical Company* the court adopted the approach of Lord Wilberforce in *Pfizer Corporation v Ministry of Health* [1965] RPC 261. In this case it was stated that to prove infringement one merely had to show possession of the invention plus some additional ingredient which amounted to the infringer deriving some "advantage from the patent". Justice Eichelbaum, in *Monsanto*, interpreted this statement to mean that the "advantage" must take the form of a commercial advantage. However, the advantage need not necessarily come into existence immediately. If the experiment so much as provides a stepping stone towards an ultimate commercial goal then the deriving of a commercial advantage will have been satisfied.

The *Monsanto* case involved field trials of the chemical SC O224 (trimethyl sulphonium salt of glyphosate) for the purpose of obtaining data necessary to achieve permission for commercial use in New Zealand. The tests were structured in such a way that although there were only limited sales of the chemical, it was tested on the properties of some members of the community of ultimate users. It was held that this provided a stepping stone towards a full commercial launch since, irrespective of the limited sales, the ultimate users were made aware of the existence and efficacy of the product (despite the fact that it would not be available until some future date) and therefore the defendants had derived a commercial advantage.

This decision was applied in the more recent New Zealand decision, *SmithKline & French Laboratories v The Attorney General* (NZ) 22 IPR 143 where it was held that the importation of samples of a patented pharmaceutical and submission to the Department of Health for approval constituted a use of the patented invention. In that case it was also considered that the mere importation of the samples did not constitute infringement (*Pfizer Corp v Ministry of Health* (1965) RPC 261) and that the mere submission of test results to the Department of Health did not constitute infringement (*Upjohn Co v T Kerfoot* (1988) FSR 1).

Based on the above authorities, it is considered that in Australia bonafide experimental use of an invention should, in general, not constitute infringement. Some possible examples of what may be considered bonafide experiment use are the use of an invention to determine whether it works or whether it can be improved, the use of an invention to determine whether a proposed product or process would infringe the patent, and the use of an invention to further elucidate its properties.

While the line between bonafide experimental use and use which provides some commercial advantage is unclear, the *Monsanto* case is persuasive authority for the proposition that an experiment must stop short of trials forming a direct springboard for commercial gain to be considered bonafide experimental use.

**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?

This issue is examined in some detail in the Issues Paper. Clearly for the reasons explained in the discussion the position in the United States results in an exception that is too narrow. As discussed above it is IPTA's view that the European model should be adopted in the interests of certainty and at least some uniformity.

**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?

As identified in the discussion paper there are significant obligations regarding exemptions under International arrangements. It is evident that in order to comply with these obligations any exemption will have to be narrow. Additionally, any exemption that extended to patents relating to research tools that only have application in conducting experiments would appear to breach these obligations.

**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?

In relation to question 4 we are not aware of any empirical evidence. Anecdotally it is believed that there are difficulties caused by the current certainty of the law in this area in Australia.

**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?

It is our view that the current provisions of the Patent Act 1990, as recently amended are appropriate. This is subject to the laws being rigorously applied during examination by IP Australia.

**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?

Whilst in theory this approach does have some attraction it is submitted for the reasons given above that in practice an approach of this type would lead to uncertainty because of the complex analysis required to determine what constitutes experimental use.

**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?

It is our view that the current patent system adequately provides for each of basic applied and hybrid research in relation to patentable subject matter. Any experimental use defence however needs to distinguish between basic research on one hand and on the other hand applied or hybrid research.

**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?

We are not aware of any evidence.

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

IPTA is strongly of the view that biotechnology and genetic technology do not warrant special treatment under the patent law. Submissions to this effect have been made to the ALRC in relation to the inquiry into gene patenting and human health. The discussion paper produced by the ALRC recognises that a distinction should not be made.

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

The justification for an experimental use exemption is to encourage innovation and not stifle experimentation and discovery.

**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?

Yes.

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

Yes, other restrictions would unnecessarily complicate the application of the exemption.

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

Yes.

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

Not applicable.

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

Licensing practices certainly do not provide a complete solution to the requirement for an experimental use exemption. We are not aware of any evidence of licensing adequately addressing this issue and it is submitted that a licence should not be required to allow bonafide experimental use.

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

Not applicable.

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

We do not believe that patent pools are a realistic or desirable way of addressing the problem.

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

No.

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

We do not believe that the use of compulsory licensing provisions is an appropriate way of addressing an experimental use exemption. It is submitted that the right to make bonafide experimental use of an invention should be automatic to the limited extent set out above. We are of the view that the compulsory licensing provisions do not appear to work well in as much as they are not used and believe that some consideration should be given to reform in this area.

**Question 20:** For this to happen, do Australia's compulsory licensing provisions need to be changed? If so, how?

It is suggested that this issue requires a broad examination and consultation so that appropriate suggestions for reform can be made.

**Question 21 (19):** Are open source principles a realistic whole or partial alternative to an experimental use exemption in Australia?

We are of the view that open source principles do not provide a realistic or desirable alternative to an experimental use exemption.

**Question 22 (20):** Are the potential benefits of open source likely to outweigh their potential disadvantages?

It is believed that the disadvantages that would result from an open source including uncertainty prevent this being an appropriate way to address the issue.

IPTA will be pleased to answer any queries which may arise from the above submissions, and to participate in any further discussions in connection with any proposed experimental use exemption to patent infringement.

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