

**ADVISORY COMMISSION ON INTELLECTUAL PROPERTY: PATENTS AND  
EXPERIMENTAL USE**

**Mayne Pharma Pty Ltd's submission on issues raised in the Issues Paper of February 2004**

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**Question 1: Current law on experimental use exemption ("EUE")**

The current law in relation to experimental use, as described in your Issues Paper, is so unclear that we at Mayne Pharma cannot be sure whether it even exists, let alone the extent and usefulness of any such measure.

As to the current law, in our view, the definition of "exploit" under the Patents Act is most likely broad enough to encompass experimental use. Were an EUE to be introduced into Australian law, we feel it should be done through providing an exemption to infringement, rather than complicating the already complex meaning of "exploit". Further, the case law on what "exploit" means has incorporated some reference to whether or not there is a commercial purpose, which we think is a concept that should be avoided when defining an EUE.

For practical purposes, Mayne Pharma is understandably reluctant to rely on any of the current forms of explicit or implied EUE described in the Issues Paper in its development work, save for the limited "springboarding" exemption provided by section 78(2) of the Patents Act 1990. The nature and extent of the exceptions to infringement provided under 78(1) are too imprecise for us to rely on them in making decisions regarding patents currently in force in Australia. In particular, there is great uncertainty in the phrase "for a purpose other than therapeutic use". Given that this provision has never been tested in the courts, it provides little guidance as to what acts would not infringe a patent during the term of the extension of that patent.

We would certainly not rely on UK case law that had not been expressly imported into Australian law as the basis for proceeding with an act that may otherwise be an act of infringement.

**Question 2: Overseas experience**

The only comment we would make regarding the overseas equivalents of an EUE (or lack thereof) is that we do not consider an EUE that makes reference to a commercial intention, purpose or advantage as a useful test. One of the primary rationales for the patent system, as pointed out in the Issues Paper, is to promote innovation through requiring disclosure of inventions, so that other parties may learn from and improve upon that invention. Many, if not most, parties would seek to do so with commercial advantage in mind, but that should not make genuine experimentation an act of infringement.

### Question 3: International agreements

In the light of the Canada WTO decision, it is difficult to see how an EUE of the type described below would fall foul of any of the international agreements Australia is party to, particularly relating to TRIPS. Depending on the scope of the EUE, there should be a strong argument that it is an Article 30 limited exception.

### Question 10: Justification for EUE

In essence, the justification for an EUE is that a patent should not be permitted to extend beyond its own valid claims. The monopoly rights granted by a patent are serious barriers to competition and should only be permitted to remain where that monopoly is justified, and where those rights do not go beyond what is actually described and validly claimed in the patent.

The "deal" a patent owner makes with the public is for the exclusive right to the invention in exchange for public disclosure of that invention. What would be the point of that disclosure if the public could then not work that invention for the greater good? Part of the patent bargain must be that the public can use that invention, but not for the purpose disclosed in the patent itself.

We would therefore support the introduction of a provision that expressly exempted experimentation undertaken for the purpose of assessing validity or infringement of a patent, or for the purpose of obtaining legal advice, from being an act of infringement. It is obviously in the public interest for parties to be free to test both the validity of a patent, or if their product would infringe that patent.

This is not to say that we would not support a broader EUE, as discussed below; rather, that an exemption expressly directed to obtaining legal advice would also be useful.

### Question 11:

A test based on whether the experimentation is *on the invention itself* as opposed to *using* an invention *for its intended purpose* goes a long way to providing a useful test for an EUE. Such a test would make it plain that experimenting on an invention in order to understand, design around or improve on a patented invention is not an act of infringement. In this context, "understanding" may include experimentation for the purposes of determining whether the patent is valid or infringed. All of these activities should be strongly encouraged to maximise Australia's position as a nation that supports and allows innovation. Such an exception would play a key part in developing and maintaining a vibrant and internationally competitive pharmaceutical industry in Australia. As noted in the Paper, "Experimenting on a patented invention should be broadly permitted as a means of ensuring that the public receives the benefit of its patent bargain."

Further, such an exemption would have a minimal commercial impact on the patent owner as the exemption would not go so far as to permit any use of the patent for the purpose described in that patent. It would of course not permit the sale of the product described in the patent during the patent term.

Finally, such an exemption should be enshrined in legislation, rather than relying on the possibility of any future common law development of the principles in *Freason v Loe*.

We find the suggestions of the Australian Law Reform Commission in its Discussion Paper no. 68 at section 14 to be particularly useful, and agree that all of the activities described at paragraph 14.136 of their paper should be covered by any EUE. To the extent that their Proposal 14-1 covers those activities, we would support the introduction of such a defence.

**Question 12:**

In our view, a provision which made it plain that experimentation *on the invention itself* for the purpose of understanding, designing around or improving on a patented invention was not an act of infringement would be sufficient in and of itself, as long as "understanding" included work directed to determining the validity of the patent, and whether it would be infringed. Such a provision would not need to make reference to the purpose of the experimentation, ie. whether it was commercial or not, but simply whether or not the experimentation was on the invention itself.

**Date:** 4 May 2004