



Dr Rod Crawford

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Advisory Council on Intellectual Property
PO BOX 200
WODEN ACT 2606

RE Issue Paper

Dear Dr Crawford,

We refer to the paper from the Advisory Council on Intellectual Property calling for submissions in relation to "Patent and Experimental Use".

In summary it is MLA's **recommendation** to the ACIP that greater clarity needs to be included in the statutory provisions to remove the current uncertainty & to provide an express experimental use defence against an allegation of patent infringement. This recommendation has been formed based on comments received from both within MLA and its advisers from the wider IP professional community. The following is a detailed review and comment on the paper.

Overview of Issues Relating to Third Party Experimental Use of a Patented Invention in Australia

Background

The present review by the Advisory Council on Intellectual Property (ACIP) stems from concerns that basic research may be hindered by third party patent rights and more generally, that broad patents covering fundamental research technology may be discouraging basic research in Australia. An inquiry by the Australian Law Reform Commission (ALRC) into the patenting of gene technology with a focus on human health issues but encompassing experimental and research use of patented gene related technology is also currently being conducted. This aspect of the inquiry has broader implications and the issues raised apply to other technologies, not just gene technology. Both the Issues Paper released by the ACIP in February of this year and the Discussion Paper issued by the ALRC (ALRC Discussion Paper 68) together provide a comprehensive overview of the current position in Australia regarding experimental use of a patented invention and that of Australia's major foreign trading partners, as well as related issues such as Australia's obligations under the TRIP's Agreement. The ACIP review and the ALRC inquiry have raised the issue of whether research and business entities would benefit from the inclusion of provisions into Australian patent legislation which specifically provide an experimental use exception to the monopoly rights conferred by a granted patent.

Executive summary

The scope of any general exemption for experimental use from infringement of third party patent rights in Australia is unclear. Many of Australia's major trading partners

have statutory exemptions for experimental use or have local case law acknowledging the existence of the exemption. However, the extent of the exemption appears to vary widely between different jurisdictions. The ALRC has recommended that statutory provisions be enacted in Australia to provide an express experimental use defence against an allegation of patent infringement. The discussion below draws from the overviews provided by the ACIP Issues Paper and the ALRC Discussion Paper.

Recommendation

Status in Australia

At the present time, neither the Patents Act 1990 (*Cth*) nor the associated Patent Regulations 1991 contain a specific exemption to infringement for experimental use, other than the so-called "springboard" provisions (s.78(1) & (2)). The exemptions provided by these provisions are limited and only relate to patents in respect of pharmaceutical substances, which have been granted an extension of patent term under the Act. Specifically, the exemptions allow for third party exploitation of the patented pharmaceutical substance(s) solely for the purpose of having goods included in the Australian Register of Therapeutic Goods or for obtaining regulatory approval overseas. The provisions also allow for third party exploitation of the pharmaceutical substance(s) other than for therapeutic use, and exclude the exploitation of all additional forms of the invention other than specifically the pharmaceutical substance(s) from infringement of the patent.

However, it is understood that a general exemption for experimental use may exist in Australia under the common law, albeit a narrow one. Importantly, although the experimental use exemption does not appear to have ever been confirmed by an Australian court, it has nevertheless been considered to exist in the common law in this country by virtue of the United Kingdom case *Frearson v Loe* (1878) 9 ChD 48, as noted in the ACIP Issues paper. Other leading foreign cases also provide guidance on how far an experimental use exemption may extend in Australia, but it remains a grey area as to where experimental use ends and infringement of patent rights begins. Given some major jurisdictions around the world have enacted statutory provisions providing for experimental use exemptions to patent infringement and the case law of countries such as New Zealand, Canada and the United States has acknowledged the existence of exemption for experimental use under third party patent rights, it is unlikely that an Australian Court in the future would reject the notion of an experimental use exemption, particularly in light of the past persuasive value that court decisions in the United Kingdom and New Zealand have traditionally had in Australia.

Scope of experimental use exemption

While some jurisdictions such as the United Kingdom, and many European jurisdictions such as Germany have enacted statutory law dealing with the issue of experimental use, the perceived scope and implementation of those provisions appears to vary from jurisdiction to jurisdiction. Nonetheless, from the overseas experience, there appears to be a general view that experiments *on* a patented invention rather than *with* the patented invention, would not constitute infringement of a patent granted in respect of the invention. This excludes experimental use of an invention in a broader research context.

The United Kingdom *Frearson* case provides guidance on how this may be interpreted in Australia. In particular, in *Frearson* the court stated:

"... no doubt if a man makes things merely by way of *bona fide* 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, but with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent."

As also acknowledged in the ALRC Discussion Paper, further guidance is provided by the United Kingdom case of *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515 as to the extent of the experimental use exemption under common law. More particularly, as noted by the ALRC, the High Court in that case stated that an experiment is:

- something done on a small scale having regard to the nature of the subject matter of the invention; and
- done for the purpose of finding out something about the invention (for example, whether it works or can be improved upon).

In the subsequent appeal to the United Kingdom Court of Appeal, additional clarification as to the extent of an experimental use exemption was provided where it was stated that the nature of such experiments must be "to discover something unknown or to test a hypothesis".

Together, while not binding on Australian courts, such case law implies that acts such as the following are unlikely to constitute an infringement of a patent in Australia:

- experiments to determine if a patented invention works;
- experiments to find out something new about the patented invention;
- experiments for the purpose of improving on a patented invention; and
- experiments to test a hypothesis about how a patented invention works.

Acts that most likely would be outside of an experimental use exemption include the use of a patented invention in research for purposes unrelated to the patented invention. This also applies to so called "research tool" inventions in the biotechnology field which are commonly used in research for research purposes unrelated to the research tool itself. As with other reagents and items that may be required to conduct research, the mere fact that an item or process may be used in research does not exempt the researcher from the need to purchase a patented reagent or item, or the need to obtain consent or a licence from the patent holder in the case of a patented process. For instance, the making of a patented substance by a researcher for use in research in general, without the consent of the patent holder, would likely constitute patent infringement.

Areas of uncertainty

However, in view of the absence of statutory provisions for an experimental use exemption and case law in Australia in this area, only an educated opinion with regard to overseas case law may be made in relation to whether acts, while arguably not involving experimental use *with* a patented invention are nevertheless related to experimental use *on* the invention, would or would not constitute an infringement of the patent. For example, in the situation noted in the preceding paragraph, the question arises as to whether there would be infringement in the instance the researcher made or generated the patented substance without the consent of the patent

holder, for use in an experiment to find out more about the patented substance. Another situation that can be readily envisaged, is where a third party supplies a patented substance for use by a researcher in an experiment *on* a substance. Both the ALRC Discussion Paper and the ACIP Issues Paper also mention acts which would appear to fall into the current "grey area" between an experimental use exemption and patent infringement in Australia, including:

- testing to determine whether an invention meets the tester's purpose in anticipation of requesting a licence from the patent holder;
- academic instructional experimentation with a patented invention; and
- importation of a patented substance for experimenting *on* the substance.

The commercial nature of the experimental use

The ALRC Discussion paper and the ACIP Issues paper also consider the impact of the "commerciality" of the experimental use on the question of patent infringement. While the United Kingdom Patents Act 1977 (as amended) provides an exemption for experimental use from patent infringement in S.60 of that Act, there appears to be debate as to whether the commercial nature of the use is relevant to the application of the exemption. In the New Zealand Court of Appeal case of *Smith Kline & French Laboratories Ltd v Attorney-General (NZ)* [1991] 2 NZLR 560, it was acknowledged that experimentation may well have a commercial focus but may nevertheless be exempt, although "where it [the experimentation] ends and infringement begins must often be a matter of degree." In that case, the view was further expressed that "*utilising the invention or making it available* to others, in a way that served to advance in the actual market place," amounts to infringement.

In the United States' case of *Mady v Duke University* 307 F 3 D 1351 (2002) the Court of Appeals for the Federal Circuit (CAFC) adopted a harsh view in stating that use:

"...in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defence."

In the *Mady* case, the court specifically distinguished between experimental use for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" (which would fall within the scope of the experimental use defence in the United States the existence of which had been acknowledged by previous case law in that country), and furthering the "legitimate business interest" of an alleged infringer. Understandably, significant concern has been generated in the United States regarding the practical workability of the experimental use exemption in view of the CAFC's further comments that while research projects may have no commercial application whatsoever, they nevertheless further the legitimate business objectives of institutions such as Duke University. The legitimate business interests of research entities in the eyes of the CAFC including "educating and enlightening students and faculty" participating in the research. The relevance of basic research to the business interests of a research institution in the view of the CAFC, is further reflected in the courts comments that research institutes benefit from such research projects as they act "to increase the status of the institution and lure lucrative research grants, students and faculty" to the institution.

The current status of the exemption for experimental use in the United States is therefore arguably far more restrictive than in other jurisdictions. The position in the United States is also at odds with the view expounded in the *Frearson case*, that *bona*

fide experiment with a view of improving upon invention or seeing whether an improvement can be made or not, does not constitute an infringement.

The ALRC recommendations

Even when jurisdictions have enacted specific provisions in their patent of legislation to provide a experimental use exemption to infringement of a patent such as the United Kingdom, interpreting the provisions is the domain of the courts and the clarification of the boundaries of the exemption is still inherently ongoing on a case by case basis. Nevertheless, the ALRC has expressed its view in the ALRC Discussion Paper that an express experimental use defence should be incorporated into the Patents Act 1990 (*Cth*) to remove the existing uncertainty in this area in Australia. In support of this, the ALRC further noted that such:

"..... a reform received broad support in submissions. The existing uncertainty is unhelpful to the research community and commercial organisations. It has the potential to lead to under-investment in basic research and hinder innovation because researchers are concerned that their activities may lead to legal action by patent holders."

The ALRC also highlighted the need for any such provision to be carefully crafted to minimise the risk of overcoming some areas of uncertainty but introducing others. In particular, the ALRC stated that:

"However, the full benefit of reform will not be achieved unless the scope of any new experimental use of defence is carefully defined. In those jurisdictions in which common law defences are more firmly established than in Australia, significant doubts exist about the ambit of the defence. Doubts may persist even where statutory defences exist, as in the United Kingdom and other members states of the European Union, unless the scope of the defence is articulated."

The ALRC further notes that in its preliminary view, the key element of a statutory experimental use exemption is the "required relationship between the experimentation or research and the patented invention". The ALRC further suggests that "at a minimum, experimentation that seeks further knowledge about the patented invention and its uses should be covered. The defence should also extend to experimentation or research on the patented invention aimed at improving the invention". On the question of the issue of commerciality of the experimental use, the ALRC states that it would:

".... be unrealistic to insist that the purpose of experimentation be solely to gain more technical or scientific knowledge and that it have no commercial motivation."

Importantly, the ALRC also acknowledges the difficulties that research in the genetic field pose in drafting a statutory experimental use exemption.

In this regard, once a gene or nucleic acid has been sequenced, the composition and make-up of the material is then known. However, the expression of a gene in the body is tightly controlled and involves interaction of the gene with other molecules. An understanding of the regulation of the expression of a gene is important to gaining an understanding of the function of the gene and its role in a physiological context. An understanding of gene expression is also required for developing possible therapies for the treatment of diseases or conditions with a genetic basis, or for obtaining a desired physiological outcome. While aspects of this would clearly constitute experimentation *with* the genetic material rather than *on* the genetic material, careful consideration would need to be given as to what aspects should be covered by an experimental use exemption and which would not, in order to safeguard

the legitimate interests of the patentee while at the same time allowing basic research within the constraints of experimental use. The ALRC has suggested that experimentation on patented genetic materials aimed:

"...at discovering another function of a genetic sequence or its inter-relation with another genetic sequence should generally be covered by such a defence. On the other hand, the use of some genetic materials, such as gene promoters and repressors, ... should not be covered by the defence because the material is not itself being investigated, but is being used as a research tool to investigate a gene and its expression.

In view of the importance of genetic technology to public health, agriculture and related areas such as inventions in the pharmaceutical field, particular consideration will need to be given to the impact of any statutory exemption to infringement for experimental use in these areas, both on the rights of the patentee and in regard to clarifying experimental use in relation to patent rights in this country. In the broader context of experimental use, the boundaries of where the infringement of patent rights commence must be clearly delineated in any statutory provision.

Yours Faithfully

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Managing Director