

Patent Infringement Exemption for Experimental Use

On 9 November, 2005 the Federal Government released a report by the Advisory Council on Intellectual Property (ACIP) entitled “Patents and Experimental Use”.

21 November 2005

The report was prepared in response to a request from the Government to examine whether some types of patents are inhibiting research and development in Australia and to determine whether both Australian researchers and businesses would benefit from introducing an experimental use exemption from patent infringement into the Australian patent legislation.

The ACIP review followed a recommendation in 2004 from the Australian Law Reform Commission (ALRC) that the Patents Act 1990 be amended to establish an exemption from patent infringement for acts done to study or experiment on the subject of a patented invention. This recommendation arose in response to submissions from numerous organisations regarding the uncertainty surrounding the state of the law in Australia relating to experimental use. Uncertainty exists because Australia has no statutory experimental use exemption and because the issue of experimental use has not been considered by an Australian court.

At the time of the ALRC recommendation there was focus on the issue of experimental use due to media coverage relating to the aggressive licensing practices of Genetic Technologies Limited in relation to their patented methods for genetic analysis and genomic mapping using non-coding DNA. There was also concern around the same time in relation

to the decision of the US Court of Appeals for the Federal Circuit in *Madey v Duke University* (307 F 3d 1351 (2002)). In that decision it was determined that an experimental use exemption exists in the US only in extremely limited, non-commercial circumstances.

Going further than the ALRC recommendation, the ACIP report recommends that the Patents Act 1990 be amended to establish that:

The rights of a patentee are not infringed by acts done for experimental purposes relating to the subject matter of the invention that do not unreasonably conflict with the normal exploitation of a patent.

Acts done for experimental purposes relating to the subject matter of the invention include:

- determining how the invention works;
- determining the scope of the invention;
- determining the validity of the claims;
- seeking an improvement to the invention.

It should be noted that it is not the intention of ACIP that all activities falling within the acts exemplified above necessarily avoid infringement. The report particularly points out that users of the patent system should be informed that the exemplified acts are not to be considered as permitted acts, as



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they will still be subject to the test of whether they “unreasonably conflict with the normal exploitation of the patent”. This language is derived from Article 30 of the World Trade Organisation agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) and was included to ensure that the exemption is TRIPS compliant.

In arriving at its main recommendation ACIP took into account a number of important considerations, including the need for a technology neutral approach and the need to honour Australia’s international treaty obligations, as well as the need to provide a balance between the rights of researchers to undertake their research and the rights of patentees to exploit and enforce their patent rights, particularly in relation to “research tool” patents. ACIP also considered the desirability of avoiding the possible development of problematic case law that could arise if no legislative basis for the exemption is provided, as well as the preference for harmonisation with approaches adopted in other jurisdictions. In the end, the approach recommended by ACIP is closely based on the European experience. Bearing in mind differing interpretations adopted in some European countries, ACIP has recommended that guidance as to the intended interpretation of the proposed legislation be provided by way of an Explanatory Memorandum.

As ACIP has conceded, uncertainty over the boundaries of the exemption may well arise and ultimately that uncertainty can only be clarified by case law. ACIP also conceded that modifications to the proposed provision might be needed over time.

Interestingly, the report includes the following further recommendation:

The Government is to consider reviewing the impact on Australian industry of the absence of an exception from infringement for activities undertaken prior to the end of the initial patent term relating to obtaining regulatory approval.

There is likely to be strong support for the main ACIP recommendation of amending the patent legislation to introduce a patent infringement exemption for experimental use. However, the recommendation to consider an exemption relating to regulatory approval is likely to be more controversial, particularly as the Patents Act 1990 already includes such an exemption for pharmaceutical patents that have had their terms extended due to regulatory delays.

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MORE INFORMATION

If you would like to learn more about patents, or any other area of intellectual property, Davies Collison Cave can customise a presentation to suit your intellectual property requirements.

For further information or advice on patent term extension for experimental use please contact:

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