

Australian Government Response to the Advisory Council on Intellectual Property Report Patents and Experimental Use

Background

In February 2003, the Advisory Council on Intellectual Property (ACIP) was asked by the former Parliamentary Secretary to the Minister for Industry, Tourism and Resources, the Hon Warren Entsch MP, to “examine whether some types of patents are inhibiting research and development in Australia and determine whether both Australian researchers and business would benefit from introducing an experimental use exemption provision (or some other provision) into Australian patent legislation”. This was in response, in part, to considerable concern being expressed, both in Australia and overseas, that patent rights may be inhibiting research and development. However, there was also concern that there was insufficient return on investment on Australian research and development due to unsuccessful commercialisation.

ACIP conducted extensive consultation throughout their inquiry. Essentially ACIP found that, while it was the general belief that an exemption for experimental acts was part of the patent system’s quid pro quo rationale, there was a need for greater certainty. The results of this inquiry were released in the ACIP Report, *Patents and Experimental Use* (the ACIP Report), published October 2005. The ACIP Report made five recommendations for reform. The first four recommendations were related to amending the *Patents Act 1990* to include an experimental use exemption. Recommendation 5 was quite distinct from the first four recommendations as it recommended that the Government 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. This practice is often referred to as ‘springboarding’. At present, Australia has a limited springboarding provision for pharmaceuticals.

ACIP’s inquiry was not the first inquiry to recommend an experimental use exemption. In December 2002, the Australian Government asked the Australian Law Reform Commission (ALRC) to undertake an inquiry into the intellectual property issues raised by genetic information. The ALRC released their findings in the ALRC Report 99, *Genes and Ingenuity: Gene Patenting and Human Health* (the ALRC 99 Report), published June 2004. The ALRC 99 Report made 50 recommendations for reform, including recommendation 13-1 for an amendment to the Act to incorporate an experimental use exemption provision.

Due to the overlap between the ACIP Report and recommendation 13-1 of the ALRC 99 Report, the Government also considered this recommendation when developing its response to the ACIP Report. The response to this recommendation of the ALRC 99 Report has been addressed in the Government Response below, which dealt with the issue in greater detail.

Provided below is the Australian Government Response to the ACIP Report.

Government Response

ACIP Recommendations	Government Response
<p>1. The Patents Act be amended to establish the following provision:</p> <p>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.</p> <p>Acts done for experimental purposes relating to the subject matter of the invention include:</p> <ul style="list-style-type: none"> - determining how the invention works; - determining the scope of the invention; - determining the validity of the claims; - seeking an improvement to the invention. 	<p>Accept in principle</p> <p>The Government will amend the <i>Patents Act 1990</i> to introduce an experimental use exception. Any exception introduced will reflect, to the extent possible, this recommendation and be consistent with our international obligations.</p>
<p>2. Appropriate guidance be provided in the Explanatory Memorandum to the above amendment, explaining that the purpose of the exemption is to encourage the further development of patented fields of technology without unfairly devaluing patent rights or breaching the TRIPS Agreement, and that the exemption is not intended to derogate from any other exemption from infringement that exists under the Act.</p>	<p>Accept</p> <p>IP Australia will provide appropriate guidance on the experimental use exception in the Explanatory Memorandum.</p> <p>The Explanatory Memorandum will also clarify that acts done for experimental purposes relating to the subject matter of the invention may also include ‘seeking new uses for, or determining new properties of, the invention’.</p>
<p>3. IP Australia to provide general guidance on the new provision as part of its suite of guides on particular topics of patent law, and update this as the law develops.</p>	<p>Accept</p> <p>IP Australia will provide general guidance on the experimental use exception, and update this guidance as the law develops.</p>

<p>4. IP Australia to consider actively participating in international fora on the issue of harmonisation of experimental use provisions, such as the current review by the OECD Committee for Scientific and Technological Policy.</p>	<p>Accept</p> <p>IP Australia actively participates in international fora on issues relating to intellectual property and will contribute to the current review by the OECD Committee for Scientific and Technological Policy.</p>
<p>5. The Government 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.</p>	<p>Accept</p> <p>Currently, there is no strong indication that there is an 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. However, some concerns have been raised by the agricultural chemical industry regarding the absence of such an exception.</p> <p>Further information on this issue is required before the Government could commit to a review.</p>

NOTE: For the purposes of consistency with Article 30 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, the term ‘exception’ will be used in place of ‘exemption’.