Australian Government

IP Australia

Public Consultation Paper on the ACIP Report 'Patents and Experimental Use'

September 2006

Purpose

This consultation paper presents a brief overview of the Advisory Council on Intellectual Property (ACIP) Report, *Patents and Experimental Use*, published October 2005. It also provides the opportunity for parties to submit comments on the four questions contained on page 9. The submissions received will be used to assist in developing the Australian Government's response to the recommendations in the ACIP Report.

Background

In February 2003, 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, it was also noted that there was 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 made 5 recommendations for reform, including an amendment to the *Patents Act 1990* to include an experimental use exemption [see Recommendation 1].[1] It is noted that recommendation 1 of the ACIP Report differs slightly to the options presented in ACIP's *Patents and Experimental Use* Option Paper, published December 2004. The ACIP Report and Options Paper are available from the ACIP website at http://www.acip.gov.au/reviews.htm.

ACIP Recommendations[2]

Recommendation 1
"The Patents Act be amended to establish the following provision:

> 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.
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> 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."

[1] Australian Council on Intellectual Property Report (ACIP Report), *Patents and Experimental Use*, published October 2005, page 1.
[2] ACIP Report, *Patents and Experimental Use*, published October 2005, page 5.

Recommendation 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."

Recommendation 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."

Recommendation 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."

Recommendation 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."

Discussion of Recommendations 1- 4

Recommendation 1 of the ACIP Report recommends the introduction of an experimental use exemption into the Patents Act. The basic approach of ACIP was to use wording that was in harmony with the European provisions and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and to provide further guidance on their meaning through examples.

Page 3 of the ACIP Report provides some insight into how ACIP formulated its preferred option by stating: "After further consideration, ACIP concluded that the concept of ***fair*** experimentation provided the courts with too little guidance and ran the risk of Australian law breaching the TRIPS Agreement. Similarly, experimentation ***on*** an invention is thought to add little value in practice over the European concept of experimentation ***relating to*** an invention." [Bold emphasis added.]

The ACIP Report continues in the next paragraph "Therefore, and in the interests of harmonisation, ACIP considers that the European wording "acts done for experimental purposes relating to the subject matter of the invention" forms the most appropriate basis for an Australian exemption. Further practical guidance to both the courts and users of the system on the meaning of this phrase can be provided through the addition of an inclusive list of experimental acts. Compliance with TRIPS Article 30 can be ensured by including the proviso that the acts must not unreasonably conflict with the normal exploitation of the patent." In making their recommendation, ACIP acknowledged that the European wording has been interpreted differently in different jurisdictions.

ACIP also noted that it must be made clear to users of the system that the list of examples in recommendation 1 is not a list of *permitted* acts, as they are still subject to the test of whether they unreasonably conflict with the normal exploitation of the patent.

Recommendations 2-3 are directly related to recommendation 1 and will be considered in this context. Recommendation 4 is also related to recommendation 1, with a focus on the international environment.

Discussion of Recommendation 5

As noted on page 44 of the ACIP Report, many countries either currently provide or will provide in the near future some form of exception from infringement for activities relating to obtaining regulatory approval in order to enable generic pharmaceuticals to enter the market immediately after the patent term expires. This practice is often referred to as 'springboarding'. In many countries such exceptions are available throughout the entire period of patent protection. Some of these exception provisions also permit the development and manufacture of pharmaceuticals for export to jurisdictions where there is no patent protection. Additionally, some countries have, or are considering, extending the exception to non-pharmaceutical patents.

ACIP's deliberations on an experimental use provision were directed to the issue of experimentation generally. ACIP recognised that while some regulatory review activities may be done for experimental purposes, others may not. Therefore, whilst there is some overlap between an experimental use exemption and a regulatory review exception, the ACIP Report was concerned with the former and did not consider regulatory review issues in any depth. Nevertheless, as some submissions made specific reference to the issue of regulatory review, ACIP has suggested that it may warrant separate consideration.[3]

At present, Australia has a limited springboarding provision for pharmaceuticals. Australia is not bound by international treaties to restrict regulatory approval exceptions to specific industries. However, the Government would need to be convinced that a review to consider extending the current limited exception to non-pharmaceutical patents is justified. Of note, the Senate Economics Legislation Committee, in their recent inquiry into the provisions of the Intellectual Property Laws Amendment Bill 2006, has also recommended "the Government consider initiating an Interdepartmental Committee (IDC) to examine whether the springboarding provisions should be extended to other industries, in particular, the agricultural chemicals sector".[4]

ALRC 99 Report

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* (ALRC 99 Report), published June 2004. The ALRC 99 Report made 50 recommendations for reform, including Recommendation 13-1 - an amendment to the *Patents Act 1990* to incorporate an experimental use exemption provision.

[3] ACIP Report, *Patents and Experimental Use*, published October 2005, page 4.

[4] Senate Economics Legislation Committee Inquiry, *Provisions of Intellectual Property laws Amendment Bill 2006*, published 17 August 2006, paragraph 2.56

Recommendation 13-1

"The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to establish an exemption from patent infringement for acts done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that:

(a) the exemption is available only if study or experimentation is the sole or dominant purpose of the act;
(b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and
(c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the *Patents Act*."[5]

Discussion of Recommendation 13-1

The essential approach of the ALRC was to use specific words to restrict the exemption to appropriate acts and provide as much clarity to end users as possible.

The ALRC 99 Report recommended that the exemption should be established for acts done to study or experiment ***on*** the subject matter of a patented invention (for example, to investigate its properties or improve upon it such as when a patented genetic sequence is being used to investigate the function of a gene, or its association with disease), as opposed to research involving ***the use*** of the patent [emphasis added].[6]

The ALRC 99 Report stated that "An important aim of the ALRC's recommendation is to reduce the uncertainty faced by researchers and others using patented inventions for experimental or research purposes." (See paragraph 13.97 on page 342 of the ALRC 99 Report). The ALRC also believed that the new experimental use exemption must be applied to an unlimited range of possible situations and technologies.

From this, the ALRC recommended that the Patents Act be amended to incorporate an express experimental use provision that:

- is framed as an exemption (as opposed to a defence so that experimental use is considered a non-infringing act and therefore not part of the exclusive rights granted to a patent holder); and
- applies to all patented inventions (not just gene patents).

The ALRC also took into account a number of matters including Australia's obligations under the World Trade Organization's (WTO) TRIPS Agreement (see paragraphs 13.71-13.76 of the ALRC 99 Report).

It was also the ALRC's view that a commercial objective should not preclude the application of the exemption because the patent system is intended to facilitate research and promote innovation and commercialisation (see paragraphs 13.89-13.94 of the ALRC 99 Report). The ALRC did not find arguments for a 'private and non-commercial use' exemption compelling since such a limited exemption would have little practical

[5] Australian Law Reform Council (ALRC) Report 99, *Genes and Ingenuity: Gene Patenting and Human Health*, published June 2004, page 341.
[6] Letter from the ALRC on 'Experimental use exemption to patent infringement'.

application to the use of genetic materials and technologies – and this approach did not receive significant support in the submissions or consultations.[7]

Comparison between ALRC Recommendation 13-1 and ACIP Recommendation 1

Although the ACIP and ALRC 99 Reports take slightly different approaches, they have both reached the same broad conclusion – there is a need for an experimental use exemption to be introduced into the Patents Act to provide certainty for researchers and to foster research and innovation.

While there is a lot of commonality between the respective reports, the different approaches taken result in slight variations as to what could be considered an 'experimental use' and could also result in different interpretations by the courts.

It is noted that the timeframe for conducting the ACIP inquiry meant that the ALRC 99 Report was available for consideration prior to ACIP concluding its inquiry and establishing its recommendations.

Experimenting 'on' versus 'relating to' the subject matter of the invention

Whereas the ALRC recommendation relates to experimentation ***on*** an invention, ACIP's recommendation 1 adopts the wording of many European provisions and applies to experimentation ***relating to the subject matter*** of an invention.

From paragraphs 13.10-13.24 of the ALRC 99 Report, it is clear that the ALRC considered the various European provisions in depth when developing recommendation 13-1. It is also clear from paragraph 13.92 of the ALRC 99 Report that the ALRC concluded that the exemption should more closely resemble the law of the United Kingdom and other member States of the European Union than the more restrictive position reflected in United States case law.

However, the ALRC did not adopt the exact wording of the European provisions because of the uncertainty in Europe about the effect of commercial intention on the availability of the exemption (see paragraph 13.83 of ALRC 99). Experimentation "on" an invention, as distinct from "with", was considered to provide more certainty than "relating to the subject matter of an invention".

On the other hand, it is apparent from pages 60-61 of the ACIP Report that ACIP's main concern with the 'experimentation ***on*** an invention' approach is that there is a wide range of acts that could fall within its scope. ACIP argues that applying the 'experimentation on'/'experimentation with' distinction would be difficult in areas such as biotechnology where claims to products are common. If the uses of an invention are not defined by the claims, it would be difficult to determine whether an act is experimenting 'on' or 'with' it.

ACIP further argues that its approach is preferable because:

- it is more likely to comply with the TRIPS Agreement;
- it is in harmony with European provisions, and so reduces complexity for users;

[7] ALRC Report 99, *Genes and Ingenuity: Gene Patenting and Human Health*, published June 2004, pages 339-341.

- it provides scope for decisions to be made that reflect the overall intent of the legislation rather than the meaning of an exact word; and
- certainty is better achieved by providing the courts with a list of inclusive acts.

Dominant purpose

The ALRC recommendation states that the exemption is available only if study or experimentation is the sole or dominant purpose [see, for example, paragraph 13.88 of the ALRC 99 Report]. The exemption should not apply where the use of the invention is directed to other purposes – such as to enable processes for the manufacture of an invention to be developed or improved.

ACIP expressed concern that proving what the 'dominant purpose' of the act was could be difficult as it would involve determining the intent of the alleged infringer. Documentary evidence of a dominant experimental purpose could be manufactured, thus creating a loophole for infringement. The credibility of such documentation would have to be assessed, increasing complexity and cost [see page 61 of the ACIP Report]. ACIP believed that it was better to assess whether the act "does not unreasonably conflict with the normal exploitation of the patent", as required by TRIPS. ACIP also provided a list of inclusive acts to assist the courts in determining what constitutes "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" (see below).

Study

In paragraph 13.86 of the ALRC 99 Report, the term 'study' is discussed in the context of what kinds of experimental uses of genetic materials or technologies should be regarded as involving experimentation on a patented invention, and therefore be protected by an experimental use exemption. The ALRC believes that a good starting point is that study or experimentation for the purpose of improving, further developing, or testing should be covered.

ACIP on the other hand, considers that the use of the term 'study' adds insufficient benefit to change from the European word "experimental", which pertains more to seeking to discover the unknown and the testing of principles [see the last paragraph on page 69 of the ACIP Report].

Commercial purpose

The ALRC recommendation states that the existence of a 'commercial purpose or objective' does not preclude the application of the exemption [see paragraph 13.91]. The ALRC contemplates that some commercially-orientated research could fall outside the scope of the exemption. This situation could occur, for example, when trials are conducted to simply prove the known characteristics of a patented invention to the satisfaction of another party. Hence, the ALRC preferred this approach as it provides greater certainty and clarity for researchers.

ACIP evaluated the ALRC recommendation and adopted a different approach. ACIP considered that the term 'commercial purpose' had the potential for a wide range of interpretations. Again, ACIP sought to clarify the scope of the exemption by providing that it only applies to acts that do not unreasonably conflict with the normal exploitation of

the patent and by providing an inclusive list of experimental acts. ACIP believed that this approach provides the courts with a genre of acts to work from, but also provides the flexibility to go outside that genre when necessary [see page 70 of the ACIP Report].

Inclusive list of experimental acts

The ALRC did not include an exclusive list, stating in paragraph 13.86 "It is not a simple matter to describe what kinds of experimental uses of genetic materials or technologies should be regarded as involving experimentation *on* a patented invention, and therefore protected by an experimental use exemption."

As noted above, ACIP took a different approach in its recommendation by providing an inclusive list of experimental acts. As noted above, the intention was to give the courts guidance on the meaning of the European-style provision by providing a genre of experimental acts to work from.

Further information on the differences and similarities between the ACIP and the ALRC 99 Reports can be sourced directly from the respective reports. Both reports also include extensive discussions and summaries of the various submissions that were considered relevant to their deliberations.

New Zealand's Experimental Use Exception

In February 2006, the New Zealand Ministry of Economic Development (MED) released an options paper entitled *An Experimental Use Exception for New Zealand's Patent Legislation*. This options paper queried whether New Zealand patent legislation should explicitly provide for an exemption from patent infringement for the purposes of experimentation. This options paper also canvassed the merits or otherwise of recommendation 13-1 from the ALRC 99 Report and the recommendations from the ACIP Report.

The majority of submissions supported the inclusion of an experimental use provision, expressing a preference for an exception based on the ACIP recommendation. Many of these submissions also suggested slight modifications to the ACIP proposal. These modifications were mainly directed to clarifying, restricting or expanding the list of 'included acts' to further clarify the concept of 'experimental purposes relating to the subject matter of the invention'.[8]

The New Zealand Government believed the suggested modifications added little to the ACIP recommendation, with one exception. This modification suggested that the fourth 'included act' (i.e. seeking an improvement to the invention) should be amended to include 'seeking new uses for, or determining new properties of, the invention'. It was considered that this clarification would ensure that, for example, activities such as determining a use or property of a patented gene that were not investigated by the patentee could fall within the scope of the exception.[9]

[8] New Zealand Ministry of Economic Development (MED), *An Experimental Use Exception for the Patents Act: Analysis of Submissions*, published June 2006, pages 10-12.
[9] MED, *An Experimental Use Exception for the Patents Act: Analysis of Submissions*, published June 2006, page 12.

After considering the submissions and advice from officials, the New Zealand Cabinet has agreed that an experimental use exception be incorporated into New Zealand's patent legislation, and that the wording of the exception be based on the wording proposed by ACIP in their final report. The agreed New Zealand Cabinet wording is as follows:

> "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."

In drafting this exception, the New Zealand Cabinet further agreed that it be made clear that the words 'seeking an improvement to the invention' include 'determining new properties of, or new uses of, an invention'.[10]

It is proposed that the experimental use exemption provision will be introduced in late 2006 when the New Zealand Government introduces its new patent legislation.

More information on the New Zealand decision, including copies of the options paper, the submissions, analysis of the submissions, and the cabinet documents can be found at: <http://www.med.govt.nz/templates/ContentTopicSummary____20388.aspx>.

Questions

To assist in developing the government response to the ACIP Report, IP Australia is seeking specific comments on the inclusion of an experimental use exemption into the Patents Act. In particular, we welcome comments on the following questions:

1. How effective and appropriate do you think recommendation 1 of the ACIP Report would be if introduced?

2. How effective and appropriate do you think recommendation 13-1 of the ALRC-99 Report would be if introduced?

3. If ACIP recommendation 1 was accepted, what, if any, changes should be made to the list of acts done for experimental purposes relating to the subject matter of the invention?

4. Has your industry has been impacted by the absence of an exception from infringement for activities undertaken prior to the end of the initial patent term relating to obtaining regulatory approval? If so, please provide details.

[10] New Zealand Office of the Associate Minister of Commerce, Cabinet Paper, *An Experimental Use Exception for New Zealand's Patent Legislation*, published 22 June 2006, page 7.

The Process

IP Australia invites written comments on the above questions and any other matters relating to the inclusion of an experimental use provision in the Patents Act by **29 September 2006**.

Please e-mail comments to Anthony.Murfett@ipaustralia.gov.au in the first instance.

Comments may also be sent by mail or fax to:

Anthony Murfett
Domestic Policy Section
IP Australia
PO Box 200
WODEN ACT 2606

Facsimile: (02) 6281 7247

Confidentiality

All comments will be treated as public unless the author clearly indicates to the contrary.

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