

Mr Sean Applegate  
Secretariat  
Advisory Council on Intellectual Property  
PO Box 200  
WODEN ACT 2060

By email: sean.applegate@ipaustralia.gov.au

Dear Mr Applegate,

**RE: ACIP Options Paper for the Review of Patents and Experimental Use**

I note that the following comments are made by me on my own behalf, as a person with experience in research, the creation of new intellectual property, various forms of intellectual property registration, including patenting of inventions and their commercialisation in Australia and overseas. While experience and understanding of the issues has developed from my employment as well as my training and experience in a number of relevant professional associations, the views in this document are my own and are not to be taken as representing any of those organisations.

While the discussion that follows considers the four preferred options as set out in the ACIP Discussion Paper, I have included an alternate option based on similar issues that are under current active consideration in the United States. Noting ACIP's careful consideration of our national obligations under TRIPS, I have also considered the Free Trade Agreement between Australia and the United States and the beneficial effects of appropriate harmonisation of related legislation.

I would be happy to engage in further discussion of any of the issues in this submission, the relevant material presented by ACIP or that of other parties relevant to this matter.

Yours sincerely,

Kevin Croft

## Introduction

I have reviewed the Options Paper prepared by ACIP in its review of patents and experimental use.

In undertaking the review, ACIP was required:

*"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 exception provision (or some other provision) into the Australian patent legislation. In examining this question, ACIP should consider whether an experimental use exemption would help researchers more effectively use the patent system to commercialise their research and development."*

In response to the review, ACIP presents 4 preferred options and seeks comments on these and alternate arguments for any of the other proposals ACIP has drawn from prior submissions and discussions.

The four preferred options are:

- Option B**            No change.
- Option C1**        Modify the definition of exploitation to not include experimental use, without further defining the term.
- Option C7**        Exemption for fair experimentation with inclusive permitted uses.
- Option C8**        Exemption for experimenting on the subject matter of the invention, with inclusive permitted uses.

On these tasks, ACIP states: *"...the lack of significant objective/empirical evidence of a current and significant market failure cannot be ignored. The introduction of any form of experimental use provision necessarily would involve replacing current uncertainty with some new form of uncertainty."* (p.8).

Furthermore, the Options Paper and its recommendations do not demonstrate that an experimental use exemption would help researchers more effectively use the patent system to commercialise their research and development.

ACIP acknowledges that a number of participants in the review sought greater clarity as to which actions on a patent are permissible and non-infringing.

Given the preceding information, it is reasonable to conclude that the introduction of an experimental use exemption might benefit Australian researchers and businesses solely by providing greater clarity in relation to those acts which are infringing and those which are not. However, for any change that explicitly introduces an experimental use exemption, ACIP acknowledges that "it is unlikely to be possible to choose a format or wording that provides certainty in all circumstances. Some interpretation must ultimately be left to the courts." (p.9). As this is exactly the current circumstance, and in the absence either of evidence that "...some types of patents are inhibiting research and development in Australia..." or that change would help researchers more effectively commercialise their research and development, any change to the legislation in the manner proposed by ACIP will not resolve the issue.

While there are other alternatives examined below, in relation to the preferred options, I favour and strongly recommend **Option B** which makes no change to the existing legislation. It is this option which most clearly meets the requirements of the review.

## **Further comments**

The following further comments set out additional argument in response to the Options Paper and include consideration of some of the issues and proposals submitted by other organisations in response to the Discussion Paper. Recent events in the United States are also noted as they are relevant to this case.

In closing, I propose an alternate recommendation that meets the purposes of the review and the expressed needs of Australian researchers and business for increased certainty. This option is not one of those proposed by ACIP, although it draws on them. It is also intended as a means of providing for greater harmonisation of Australian law in this area with laws operating in European Community member countries and proposals that would change the relevant legislation in the United States.

### **Limitations of the review: Effect on the value of patents and patented research tools**

Perhaps because it lies outside the stated purposes of the review, the Options Paper fails to adequately address the effect that an explicit exemption for experimental use would have on the value of patents or the rights of patent owners.

ACIP also excludes patented research tools from its consideration and suggests that it be left to the courts "...to reach reasonable judgements on research tools..." (p.6). However, this approach cuts across all patents as each might be used for research.

The omission of full consideration of the effect of change on the value of Australian patents and the inappropriate exclusion of patented research tools, lead ACIP to preferring options that significantly undermine the rights of patent owners and the value of patents as they are or apply to research tools.

As previously acknowledged, ACIP found no significant evidence that patent owners are using their existing rights in a manner that inhibits research and development in Australia. Therefore, any proposed change to the legislation risks penalising the patent owner by denying an existing right that has not been proven to be an inhibition to research and development in Australia. The loss of any right under the patent law necessarily diminishes the value of the patent and, contrary to one of the objectives of the review, this loss of value may hinder researchers who might otherwise use the patent system to commercialise their research.

The same effect is more pronounced with research tools, where the very purpose of patenting is commonly to provide the owner of the patent with the opportunity to license the invention to other researchers. While the Options Paper excludes research tools from its considerations, this exclusion is not granted within the stated purposes of the review, nor do any of the proposed changes to the existing legislation provide a fair treatment of these inventions.

### **The preferred Options C1, C7 and C8**

In the Discussion Paper, ACIP itself has provided succinct reasons for not accepting any of these changes. C1 merely obliges the patent owner to use the courts to determine the meaning of experimental use. The uncertainties of this approach and the cost of court proceedings would inhibit the vast majority of patent owners from seeking remedy through the courts. This would significantly devalue patents in Australia and may encourage "locking up" patentable subject matter as confidential information so as to ensure that it is not disclosed and cannot be infringed.

By introducing the notion of “fair experimentation on an invention”, C7 shares many of the same types of difficulties as C1. It is ultimately up to the patent owner to gamble on the court’s determination of the meaning of this term. However, both C7 and C8 introduce an inclusive list of non-infringing acts. This list is unsatisfactory specifically because it is incomplete. Other actions, which might today be clearly infringing, would become arguable under this change as a party being sued for infringement would propose that the action was “fair experimentation” but not on of those listed. The lack of limited permitted uses in Options C7 and C8 create a state of greater uncertainty than that which currently exists.

## **Flexibility and the courts**

At a number of points, ACIP proposes that certain of the cited Options provide for flexibility. However, the requirements of the review do not include this as a desired outcome. In fact, the “flexibility” that emerges from a number of the Options does not provide the greater clarity sought by respondents to the ACIP’s Discussion Paper. “Flexibility” is such that the situation after amendment of the legislation could both inhibit research and discourage researchers from commercialising their inventions using the patent system.

### **Example**

I offer the following example of the effect of a change to the Australian patent law if it were amended in the manner proposed in any of Options C1, C7 or C8:

Australian research might invent a new means of identifying new candidate molecules for treatment of a number of related disease conditions. This would be patented by its owner. A multinational company might read the patent when it becomes public and use the invention without licence in Australia to screen a large number of candidate molecules. The selected molecules might then be subject to further testing outside Australia in a manner that does not infringe the patent. From this, a new therapeutic might be developed for which the Australian patent owner might derive no benefit.

The patent owner would then be obliged to pursue the multinational company for infringing the patent. Even if the unauthorised use of the patent by the multinational could be proven by the patent owner, the further challenge would be to confirm that the actual use was not one of those permitted but not stated within the legislation.

If this situation occurred when the Australian patent owner was an SME or public sector research organisation, it is clear that neither of these is likely to have the resources to fight a long term legal action against a very large company, especially at a time when the infringing action has ceased.

### **Relevant matters outside Australia**

In the Options Paper, ACIP presents clear reasoning in relation to Australia’s obligations under TRIPS. Current events in the United States should also be considered in the development of ACIP’s final recommendations in this review.

Action now being pursued in the Supreme Court of the United States in the case of *Merck KGaA v. Integra Lifesciences I, Ltd, et al.* proposes amendment of United States Code 35 section 271(e)(1) in a manner that would exempt general pharmaceutical research including, among other things, efforts to identify lead compounds. While explicitly regulating the manufacture, use, or sale of drugs or veterinary biological products, the existing section 271(e)(1) provides a carefully defined very narrow exemption. Expansion of the exemption in this case in the manner proposed by Merck is vigorously opposed by several parties on the basis that it would nullify the commercial value of an entire class of patents and be contrary to the treaty obligations entered into by the United States. (The author is aware of a brief of Amicus Curiae prepared by Wisconsin Alumni Research Foundation in this matter. The same brief is being supported by other organisations with relevant

knowledge and experience in this area. It has been reported that similar briefs are anticipated from other interested parties.)

It is prudent that ACIP review the particulars of this case and carefully consider its relevance to the current situation in Australia as part of preparing a final recommendation from the review.

Furthermore, there is a current proposal initiated by the American Intellectual Property Law Association ("AIPLA") to amend section 273 of United States Code 35 to provide broad exemption from the infringement provisions of the Title 35 by the addition of a new subsection (c), as follows:

(c) (EXPERIMENTAL USE)- The rights granted to the patent owner under section 154 and acts of infringement described in section 271 shall not include making or using the patented subject matter for purposes related to scientific or philosophical inquiry, including to discern or discover (1) the validity of the patent and the scope of protection afforded under the patent; (2) features, properties, inherent characteristics or advantages of the patented subject matter; (3) novel methods of making or using the patented subject matter; and (4) novel alternatives to the patented subject matter, improvements thereto or non-infringing substitutes therefore. In addition the exemption under this subsection from the rights granted under section 154 and described in section 271 (a) shall extend to making or using the patented subject matter in activities that are incidental to preparations for commercialization of a non- infringing alternative to the patented subject matter. Otherwise, subject to section 271(e)(1), making or using patented in connection with preparations for its use in commerce is encompassed by under section 154 and the acts of infringement described in section 271.

This proposal is the subject of a number of meetings in the United States to consider the implications of the proposed change. While the stated intent of this proposal is to clarify the circumstances under which patented intellectual property could be used in the conduct of research, the proposal creates unacceptable ambiguity by broadening the scope of the exemption. The effect would be to include all research tools as exempt from patent infringement.

It is anticipated that this proposal will be the subject of vigorous debate in the United States. While undermining patent value, especially for research tools, it is likely that this type of exemption is also in breach of obligations under TRIPS.

The proposed language needs to be clear that the proposed "experimental use" exemption is intend only for the limited purposes delineated and not a free right to use patented research tools in their originally intended purposes in the conduct of research. The use of terms such as "related to" and "including" could properly lead one to believe the intent is much broader than the language implies. We therefore suggest that the wording be changed as follows:

(c) (EXPERIMENTAL USE)- The rights granted to the patent owner under section 154 and acts of infringement described in section 271 shall not include making or using the patented subject matter for purposes of scientific or philosophical inquiry to discern or discover: (1) the validity of the patent and the scope of protection afforded under the patent; (2) features, properties, inherent characteristics or advantages of the patented subject matter; (3) novel methods of making or using the patented subject matter; and (4) novel alternatives to the patented subject matter, improvements thereto or non-infringing substitutes therefore. In addition the exemption under this subsection from the rights granted under section 154 and described in section 271 (a) shall extend to making or using the patented subject matter in activities that are incidental to preparations for commercialization of a non- infringing alternative to the patented subject matter. Otherwise, subject to section 271(e)(1), making or using patented in connection with preparations for its use in commerce is encompassed by under section 154 and the acts of infringement described in section 271.

Adopting this revised proposal with the clearly delineated exemptions from patent infringement would bring U.S. practices into closer parity with countries of the European Community and others with similar legislation in other parts of the world.

### **An alternate option**

Given the preceding, I remain convinced that ACIP, in its final report, should recommend no change to the current Australian legislation. However, if a change that meets the desire by Australian researchers and businesses is to be implemented, I suggest that the change be prepared in a manner that reflects the developing situation in the United States. This would give an explicit research exemption together with an exclusive list of acts which are identified as not infringing the rights of patent owners. From the Discussion Paper, the proposed outcome could be achieved through a combination of Option C3 and Option C5, which I shall refer to as Option C9, as set out in the following text box.

#### **C9. Exemption for experimenting “on the subject matter of the invention” for exclusive permitted uses**

The Patents Act be amended to establish an exemption from acts that experiment ‘on’ the subject matter of a patented invention, for example, to investigate its properties or improve upon it. The exemption is only available if experimentation is the sole or dominant purpose of the act.

Making explicit the existence of a commercial purpose does not preclude the application of the exemption but may need to add supplementary conditions to ensure the patent holder’s legitimate rights are not unreasonably affected (e.g. in clinical trials).

The Patents Act be amended to establish an exemption for experimental use, where experimental use is limited to the following acts:

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

This amendment would provide the certainty sought by Australian researchers and business. It would ensure that there is an exemption from infringement for some experimentation conducted in Australia on any granted Australian patent. It would not, however, provide Australian researchers with a right to use the patented inventions of others in their research activities.

It may be suggested that this amendment retains the possibility research and development in Australia might be inhibited as a consequence of the exercise by patent owners of their rights. However, given the current legislation and the lack of evidence that patent owners are typically acting in this manner, there is no reason to think that legislative change of the type proposed here would cause a change in the behaviour of patent owners.

### **Conclusion**

I conclude with the observation that the newly proposed Option C9 would provide comfort to some people. However, it seems clear that this comfort would not address the desire of many researchers to practise their profession without any obligation to any patent holder. At the same time, I reiterate that the Discussion Paper demonstrates that ACIP was unable to find evidence that the current legislation inhibited research and development in Australia or that change would encourage commercialisation of research and development.

Succinctly, "If it ain't broke, don't fix it."

Kevin Croft  
1 March 2005