



**The Institute of  
Patent and Trade Mark  
Attorneys of Australia**

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*Via Email*

Sean Applegate  
Secretariat  
The Advisory Council on Intellectual Property  
PO Box 200  
Woden ACT 2606

RE: Options Paper on Patent Experimental Use

Dear Sirs

The following comments are made on behalf of The Institute of Patent Attorneys of Australia (IPTA) in response to the options paper or released in December 2004.

We have considered the four preferred options put forward by ACIP. Our preferred option is option C8 which is substantially in line with our previous submissions. Before making further comments on this option we make the following brief observations to the other preferred options set out by ACIP.

**Option B (No change)**

As explained in our original submission we believe that it is, on balance, preferable to introduce a specific exemption in relation to experimental use in order to clarify the availability and scope of exemption. The uncertainty in relation to the law and its scope are manifestly clear from the submissions made to ACIP in response to the issues paper.

**Option C1 (Modify the definition of exploitation to not include experimental use, without further defining the term)**

This option is philosophically attractive in that it avoids providing an exemption. It is also attractive from the viewpoint of simplicity. However, this option is unlikely to resolve the uncertainty problem for a considerable period. In this regard the approach would rely on the evolution of the law through the courts which is likely to take some considerable time and will, in the interim, either discourage legitimate experimental use or potentially result in an overly broad interpretation by users. A particular difficulty is that it may take several court decisions before the limits of enforceable patent rights are workably defined. Whilst it is accepted that there are difficulties in defining an exemption it is submitted that option C8 provides scope for the law to develop whilst providing at least some measure of certainty in the interim.

**Option C7** (Exemption for fair experimentation with inclusive permitted uses)

This option also lacks the ability to provide a sufficient degree of certainty to persons wishing to avail themselves of the exemption. The consideration of listed matters in order to determine whether an act is fair experimentation is very subjective and involves matters which would require information not be readily available to persons seeking to take advantage of the exemption or their advisers. Any attempt to assemble the requisite information in order to provide a level of comfort in relation to the application of the exemption would involve considerable effort and expense.

**Option C8** (Exemption for experimenting on the subject matter of the invention, with inclusive permitted uses)

As mentioned above this is the option preferred by IPTA. There are however some issues that we would like to highlight to ensure that the option is appropriately implemented.

There is a potential for difficulty if the "sole or dominant purpose" test is misapplied, particularly in the case of research tools. It is our view that the test needs to be applied to the "act" that would otherwise constitute infringement. This is best explained by way of an example. If an experimental research program is developed to determine whether snake venoms have beneficial pharmacological activities it may involve the performance of a number of acts that potentially infringe a patent notwithstanding that the overall purpose of the program is experimentation.

There might, for example, be a patent in existence which has independent claims directed to the following aspects:

1. A screening assay to identify compounds within a venom which have a beneficial pharmacological property; and
2. The compounds found.

It should not be possible to use the patented screening assay for the purposes of screening other venoms to locate additional compounds with the same activity under the guise of experimental use by arguing that the purpose is improvement of the compound. In this scenario the dominant purpose is to identify new compounds. The correct result is achieved by the currently proposed test provided each "act" is independently assessed.

It is of course appropriate to assess each act against each independent claim in a patent since those claims could equally exist in their own right in separate patents. This is an important point because it should not be open to a person seeking to rely on the exemption to show that the "act" they are performing is experimental having regard to one independent claim in a patent and then seek to apply the exemption in relation to other independent claims.

It is also suggested that the exemplified permitted acts of experimentation should be expanded to include another specific example "determining new properties or uses of the invention". It is in our submission required to ensure the correct application of the exception in scenarios such as the following. A patent has independent claims directed to:

1. A new compound

2. A method of making the compound
3. The use of the compound in a therapeutic treatment

It would be appropriate for the exemption to allow others to experiment on the invention so as to, for example, find a second medical use for that compound. The current list of permitted uses does not clearly allow the use of the compound per se to identify new uses. This is because it is not clear that an "improvement" would include an alternate use. There is also some tension in our view in the wording used in referring to permitted acts because the examples are more in the nature of activities that are made up by a series of acts. This is particularly important to clarify because otherwise the dominant purpose test proposed could be applied to a broad activity rather than the individual infringing acts. It is our view that the "acts" should be clearly limited to those specific acts that would otherwise constitute infringement of the claims of the patent.

### Summary

IPTA supports the adoption of Option C8 with the qualification that the specific wording ultimately adopted must clearly identify that the dominant purpose test applies to the acts that would otherwise constitute infringement of the patent. In order to ensure that this does not preclude the exception applying to finding new properties or uses of patented inventions, a further specific example of "determining new properties or uses of the invention" should be added to the list.

We thank you for this opportunity to comment on the options and would be pleased to elaborate if required.

Yours sincerely



Leon Allen  
Convenor  
Patent Legislation Committee