

Law Council of Australia (LCA)

Intellectual Property Committee of the LCA (*the Committee*)

Submission to the Advisory Council on Intellectual Property (ACIP) in relation to its Options Paper (*the Options Paper*) on Patents and Experimental Use dated December 2004

1. Summary of the Committee's position

- 1.1 We do not think adoption of any of ACIP's preferred Options is justified by the evidence ACIP has obtained.
- 1.2 The evidence ACIP has obtained calls for changes that will give certainty to what is within an experimental use exception. The targeting of particular subjects as proposed by the Committee, will maximise the prospect of obtaining certainty.

2. The effect of absence of proof of the need for an experimental use exception on which of the Options is appropriate.

- 2.1 The Committee has accepted the need for an experimental use exception. The need is to obtain certainty that particular subjects are excepted from infringement (see Sections 3 and 4 of the Committee's submission to ACIP of 18 May 2004).
- 2.2 The Committee reiterates that it is not desirable to change the law unless there is a demonstrable need for change. We reserved our position on what should be covered by the exception of 'experimental use' in view of the possibility that information obtained by ACIP in relation to ACIP's Issues Paper, would put us in a better position to define the exception.
- 2.3 The Options Paper shows again (the Issues Paper of February 2004 also showed this) that there is no proof that the advancement of technology in Australia is in some way being held up by lack of an experimental use exception.
- 2.4 ACIP itself states at page 38 of the Options Paper one of its considerations of the submissions it has received, in the following terms.

Although there may be inefficiencies due to a lack of clarity in Australian law on whether experimental use constitutes infringement, there is no strong empirical evidence that this is currently affecting the general balance between the incentives for innovation and the ability to use innovations, particularly for research and development.

Accordingly, no need has been established for an experimental use exception involving broad discretion for courts to decide what is allowable. What is needed is to make particular uses certain as not infringing.

- 2.5 The Committee considers that the lack of evidence of impediment of research due to uncertainty whether particular potentially 'experimental' uses infringe, should have these consequences.
 - (i) As the need for amendment is related to the need for 'certainty', no amendment is justifiable if it increases uncertainty.

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- (ii) Any amendment is likely to bring with it some degree of uncertainty. To do all that can be done to achieve certainty and limit introducing new causes of uncertainty, the exception should relate to specific subjects.
 - (iii) There is no justification for introducing a general discretion for courts to determine what is and what is not 'experimental use' beyond what occurs in determining whether particular impugned conduct falls within any of the specified exceptions.

2.6 We consider the two ACIP Papers show that there is a proper balance between incentives for innovation and the ability to use innovations for research and development. Therefore there is no social or economic need and thus any justification for reduction of patentees' rights except to add certainty as to what is excluded. Put simply, the proper balance currently applies; there is no justification for risking losing that balance by making changes that might adversely affect it.

3. ACIP's reminder of Australia's relevant obligations under TRIPS

3.1 On page 29 of the Paper, ACIP provides a timely reminder that Article 30 of TRIPS provides as follows.

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate rights of the patent owner, taking account of the legitimate interests of third parties.

Continuing the theme of driving for 'certainty', the Committee observes that it will risk breach of Article 30 unless the exceptions are applied in a way that does not unreasonably conflict with normal exploitation of the patent.

3.2 This imports a further reason why Australia is not in a position to make exceptions for experimental use except where any discretion is rather limited.

4. ACIP's preferred options

4.1 ACIP's preferred options are four, as follows.

- 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.

ACIP seeks comments on these four options but says that it is also open to consider further any of the other options should a sufficiently strong argument be made in their favour.

4.2 Option B (no change) is excluded by the Committee for the reasons previously explained by the Committee – essentially, there is a need for bringing certainty to an experimental use exception which this Option does not fulfil.

4.3 The fundamental difficulty with each of Options C1, C7 and C8 is that they introduce uncertainty where the identified need is to do the opposite. There is no proven need for wide judicial discretion which each of these Options would involve. The process which

ACIP has itself adopted shows that there is no need for these Options to be adopted and indeed, the need is for them not to be adopted. What Option should be adopted?

5. The Committee's submission as to what Option should be recommended

5.1 Option C5 provides exemption for 'exclusive permitted uses'. The Committee submits that the five subjects for permitted use should be the ones specified by the Committee in paragraph 4.2 of its submission to ACIP of 18 May 2004. Those subjects were expressed as follows. The 'subject' referred to within each of the following, is the claimed subject of the patent.

- Uses to better understand whether and if so, how the subject works.
- Uses to determine properties of the subject not disclosed by the patent.
- Uses to better determine the limits of the subject.
- Uses to determine whether another subject will or will not infringe the subject, or to determine the validity of the subject, or both.
- Uses to determine whether an improvement of the subject or other such advance in technology, can be made.

The Committee suggests that these five subjects should be supported by including any acts reasonably incidental to the subjects.

5.2 The Committee observes that courts will inevitably have some discretion in applying the facts of any case to these nominated subjects. The Committee considered in view of Australia's overriding obligation to observe TRIPS whether the subjects of exception should be expressly limited by wording tracking that of Article 30 of TRIPS as follows.

No particular use shall be excepted which unreasonably conflicts with normal exploitation of the patent or which unreasonably prejudices the legitimate interests of the patent owner.

The Committee rejected that option because it would introduce uncertainty. It was felt that the categories proposed for C5 in 5.1 above comply with Article 30 of TRIPS.

5.3 Turning to the ACIP comments on Option C5, we agree that the specified permitted uses in C5 provide some clarity and are formulated in language with which the research community may be comfortable. We also agree with ACIP that the exception would be limited to acts within the particular categories. However, in contrast to ACIP, we see that as a virtue not a contra, because defining the scope of exceptions by such categories is about the best that can be done to satisfy the need for certainty.

5.4 We do not agree that a wide variety of controversial uses may be considered to fall within the first and fourth dot points of Option C5 but to the extent that they might, the position against that vice will be strengthened by importing the Committee's proposal (in 5.2) based on Article 30 of TRIPS.

5.5 We do not see how on any basis phase 3 clinical trials could be justified as falling within a permitted use. Such trials are for the purpose of proving the properties of a pharmaceutical in use. That is not related to determining how an invention works. It is related to proving that it does in fact work in a particular setting (ie it relates to commercial not patent utility) nor would it have anything to do with an improvement to the invention if it were simply a phase 3 clinical trial using the invention itself.

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- 5.6 Finally, as to its Option C5, ACIP makes the point - 'the language provides false comfort, as it will ultimately be interpreted by legal experts, not technologists'. Whatever may be the truth about 'false comfort', the law will always be interpreted by legal experts and that applies to every one of the Options proposed by ACIP which involves changing the Patents Act.