

**Submission to the Advisory Council on Intellectual
Property in response to its Options Paper**

Patents and Experimental Use

**Intellectual Property Research Institute of Australia
(IPRIA)**

March 2005



**THE UNIVERSITY OF
MELBOURNE**

1. Preface

The Intellectual Property Research Institute of Australia (IPRIA) is a national centre for multi-disciplinary research on the law, economics and management of intellectual property. It is based at the University of Melbourne, and is a joint venture of the Faculty of Law, the Faculty of Economics and Commerce, and the Melbourne Business School.

IPRIA was established in 2002 as part of the Federal Government's Innovation Statement, *Backing Australia's Ability*. IPRIA's research focuses on ways to improve the protection, management and exploitation of intellectual property by business, research institutions and other users of the IP system, and on supporting high quality policy development by government in areas relating to intellectual property. It seeks to use the outcomes of its research to create and contribute to public debate on key issues relating to intellectual property. Part of IPRIA's missions is to provide objective contributions to law reform efforts.

This submission was prepared by the following people:

- **Sophie Waller**, Researcher, IPRIA
- **Kimberlee Weatherall**, Associate Director, IPRIA

Any questions in relation to the submission should be directed to:

Ms Kimberlee Weatherall, Associate Director, IPRIA

Phone: + 61 3 8344 1120

Email: k.weatherall@unimelb.edu.au

Intellectual Property Research Institute of Australia

The University of Melbourne

Law School Building

VIC 3010

Australia

Phone: + 61 3 8344 1127

Facsimile: + 61 3 9348 2358

Website: www.ipria.org

1. Introduction

IPRIA has already made a submission to ACIP in response to its earlier report *Patents and Experimental Use Issues Paper*. This is a supplementary submission that is directed at the '*Patents and Experimental Use Options Paper*' (Options Paper) in relation to the adoption of an experimental use exception (EUE) in Australian patent law.

This submission addresses the following issues, which can be divided into two categories:

a) *Issues that relate to the Options Paper generally:*

- Difficulties associated with leaving the courts to determine the scope of the experimental use exception;
- Differing expressions of the EUE stated in the Options Paper; and
- Comments regarding an exception for 'fair experimentation'.

b) *Issues in relation to three particular options:*

- Option B;
- Option C generally; and
- Option C3.

We hope that these comments are useful to ACIP in the development of their final report on this issue.

2. Difficulties with leaving the courts to determine the scope of the experimental use exception

A number of options put forward by ACIP noted the benefits of allowing the scope and content of the EUE to be determined by the courts (see for example options B, C1, C3 and C8). However, in relation to other options ACIP indicates that allowing the courts to determine the scope of the EUE is a potential difficulty (see for example options B and C1). Thus, ACIP appears to view the possibility of judicial determination of the scope of the EUE as both a positive and negative outcome.

The Options Paper does not contain any substantial discussion in regards to possible ways in which a court may interpret the EUE, and hence it is unclear how ACIP considers judicial consideration will affect the scope of the EUE. However, in all cases where there is judicial discretion to determine the law there are two possible difficulties that should be recognised.¹

First, in Australia only a small number of patent infringement cases are filed each year. IPRIA's research on IP enforcement indicates that between 1998 and 2003, only 18 patent infringement cases were filed on average per year, and, even then, only 7 patent *judgments* were issued on average each year in that period.² As a consequence it is likely to be some time before a decision is handed down that discusses the scope and content of the EUE, and even more time before a body of law arises regarding interpretation of the EUE. Thus, leaving the courts to determine the scope of the EUE may leave users of the patent system in state of uncertainty for an indefinite, but possible quite long, period of time.

Second, in relation to options B and C1 (where the scope of the EUE is left largely to the courts to decide) it is uncertain how the courts would define the EUE. It is possible that the courts could develop the EUE in a way that is undesirable. For example, it is possible that the case law could lead to development of an EUE that is as narrow as that in the US. As ACIP appears to regard the US approach as undesirable, this should be recognized consistently as a negative outcome, in relation to *each* option where judicial discretion is proposed.

3. Differing expressions of the EUE stated in the Options Paper

In the Options Paper, three different ways of expressing the EUE are stated, although not all of these are incorporated into different options. The reason for expressing the EUE in

¹ The ALRC also noted in their report *Genes and Ingenuity* that the 'full benefit of reform will not be achieved unless the scope of any new experimental use exception is carefully defined': page 331.

² This figure is for the time period 1997-2003. See Kimberlee G Weatherall and Paul H Jensen *An Empirical Analysis into Patent Enforcement in Australia, 1997-2003* (2005), 30.

different terms is not made clear, although the effect of the various different wordings used is potentially quite significant. We submit that the resulting uncertainty should be resolved before a final report is released.

The various differing expressions of the EUE being referred to are those that allow experimentation:

- *On the invention* (see option C7);
- *On the subject matter* of the invention (see for example C8); and
- *Relating to the subject matter* of the invention (not incorporated into a specific option).

A number of observations can be made in relation to the different ways in which the EUE is expressed in the Options Paper.

First, the relationship between ‘*on the subject matter* of the invention’ and ‘*relating to the subject matter* of the invention’ is unclear. For example, as a matter of interpreting the ordinary meaning of the words in it is unclear whether experimentation ‘*on the subject matter* of the invention’ is broader or narrower than experimentation ‘*relating to the subject matter* of the invention’. The Options Paper appears to suggest that the European ‘relating to’ exception is broader, however the reasoning behind this suggestion is not provided.³

Second, in terms of achieving harmonisation with Europe⁴, it is unclear what is the effect of drafting an exception to experimentation that is ‘on the subject matter of the invention’. ACIP says that drafting an exception in terms of allowing experimentation ‘on the subject matter of the invention’ would be ‘substantially in harmony with

³ Options Paper, page 11.

⁴ Where the exception is worded in terms of ‘*relating to the subject matter* of the invention.

European laws'.⁵ Comments made in the ALRC report '*Genes and Ingenuity*' (ALRC Report) indicate that harmonisation would be beneficial and could be achieved by the adoption of an exception worded in terms of experimentation 'on the subject matter of the invention'.⁶ However, the reasoning behind these statements is not made clear in either the Options Paper or the ALRC Report, and hence is uncertain what will be the effect of the Australian exception being worded differently to that in Europe.

Third, neither ACIP nor the ALRC discuss why an EUE using the word 'on' is preferred to one incorporating the phrase 'relating to'.

Another issue is in respect of option C7. In option C7, ACIP states that the EUE would be for fair experimentation 'on an invention'. At first glance, 'on an invention' appears to be broader than an exception allowing experimentation 'on the subject matter of the invention', but again the Options Paper does not make clear what the relationship between the two is intended to be.

In sum, for the benefit of the public reading any legislation that is introduced as a result of the current debate, it is submitted that ACIP needs to clarify the issues discussed above and in particular:

- Discuss what ACIP thinks is the relationship between the differing expressions of the EUE;
- Discuss why ACIP prefers one expression of the EUE over another; and
- In relation to each particular expression of the EUE outline:
 - the perceived benefits of using that expression; and

⁵ Options Paper, page 12.

⁶ See for example comments at page 333 of the ALRC Report.

- the perceived effects on the scope of the EUE of that expression.

5. Comments regarding an exception for ‘fair experimentation’

In options C4 and C7, ACIP puts forward the idea of allowing an exception for acts that constitute ‘fair experimentation’ on patented inventions.

As ACIP acknowledges in the Options Paper, the idea of ‘fair experimentation’ has been borrowed from the ‘fair dealing exception’ found in copyright law. Hence, it is important to assess whether applying the same underlying conceptual framework to patent law is appropriate. Although the Options Paper cites various submissions that touch on this point, ACIP does not provide a substantive discussion of the issue.

It is important to recognise that the European EUE, and a ‘fair experimentation’ EUE are different in nature. The European EUE is based on the idea that some acts fall outside the monopoly rights of the patentee. On this approach, once an experiment is found to be ‘on the subject matter of the invention’, it is permitted without further inquiry. Conversely, fair dealing in copyright is based on the idea that in certain cases, the public benefits to be gained by allowing an infringement on balance outweigh the rights of the copyright owner. Under a fair experimentation defence, the alleged infringers would need to prove not *only* a permissible purpose, but *also* that the experimentation was *fair*.

As ACIP appears to recognise implicitly,⁷ the concept of ‘fair’ acts must be adjusted when transplanted from copyright law into patent law. Ordinarily, in determining whether a dealing is ‘fair’ in copyright law, the court will consider five factors (see *Copyright Act* 1968 (Cth) s 40(2)):

- the nature and purpose of the dealing;
- the nature of the work copied;

⁷ By the chosen list of factors to be taken into account in determining whether experimentation is ‘fair’.

- the availability of the work within a reasonable time at an ordinary commercial price;
- the effect of the dealing on the potential market for or value of the work; and
- the proportion of the work copied.

Not all these factors are appropriate in the patent context, a fact which the ACIP Options Paper appears implicitly to recognise. It is instructive to compare this list of factors to the list proposed by the ACIP Options Paper. A comparison indicates that the Options Paper appears to:

- replace the concept of the ‘nature of the work’ with ‘the subject matter of the invention’ (this makes sense, as it appears to get at the same concept of considering the ‘merit’ or degree of originality/inventiveness of the protected matter); and
- delete the concept of ‘the amount taken’.

It is easy to see why the concept of the ‘amount taken’ has been removed. This kind of exception can be logically applied to copyright works because it is possible to use only part of a work. For example, consider the exception under fair dealing, which allows reproduction of a ‘reasonable portion’ of a work for the purposes of research or study.⁸ In relation to certain published works, a ‘reasonable portion’ of the work is defined as 10% of the work.⁹ However, the same cannot be said for an invention. An invention is either used or it is not used.¹⁰

However, removing the ‘amount taken’ factor, without identifying some analogous concept for patent law, may significantly change the kind of defence provided. This point is best illustrated by an example. Suppose the patentee allows experimental use of their invention, as long as two conditions are met:

⁸ *Copyright Act 1968* (Cth), section 40(3).

⁹ *Copyright Act 1968* (Cth), section 10(2).

¹⁰ Infringement of a patent requires that all the integers claimed by the patent are used: *Olin Corp v Super Cartridge Co Pty Ltd* (1977) 180 CLR 236 at 246, cited in Jill McKeough, Andrew Stewart and Philip Griffith, *Intellectual Property in Australia* (3rd ed, 2004) [14.18].

- a) payment of a nominal licensing fee; and
- b) that the researcher provides the patentee with an annual report on their use of the invention.

Given that there is only a nominal fee payable and the conditions appear to be ‘reasonable’, if the researcher fails to comply with either of these conditions, then arguably the experimentation will not be ‘fair’. This is so despite the fact that under a European-style EUE the act *would* fall within the exception. Thus in this example, the result of adopting a ‘fair experimentation’ defence rather than a European-style EUE may be:

- Increased compliance costs for researchers as they must comply with any ‘reasonable’ conditions that the patentee makes in return for use of the invention; and
- Patentees can effectively monitor who is using their invention for experimental purposes.

We therefore submit that ACIP needs to identify what factors are analogous to the ‘amount taken’ factor used in copyright law, that can be effectively applied to a ‘fair experimentation’ exception in patent law. It is beyond the scope of this submission to explore all the possible analogous concepts. Some possible candidates, however, are worth discussing, if only to indicate the difficulty of the issue.

One candidate for consideration might be the extent to which the *experimental* purpose is an important (or main) purpose of the experiment, and the degree of any commercial purposes.¹¹ This, however, may privilege 'basic research' over the kind of practical-end-oriented research currently being encouraged by the Federal Government. Considering the purpose of the experiment, and whether the purpose is commercial, may provide some disincentives for CRC-style or industrially applied research. Thus, for researchers, this increases the already significant compliance costs involved in industry-linked

¹¹ Although, arguably, these issues would be covered by the direction to consider the ‘purpose and character of the act’: the first factor listed by ACIP.

research at just a time when the Federal Government is seeking to encourage such research.

Another possible candidate would be the extent to which the researcher takes, and retains, the 'benefit' of the experiment. For example, if the patented invention produces gold, is the researcher proposing to keep the gold?¹² This, however, would be difficult for the researcher to evaluate. They would need to consider, in particular, what the 'benefit' of the invention is – something which could require legal advice. They would also need to consider whether they are retaining that benefit, and whether there is anyway to *avoid* retaining that benefit consistent with their experimental purpose. Again, significant compliance costs may ensue, and this increase in costs may not be in Australia's interest.

In summary, if the 'fair experimentation' option is considered to be a serious option, it is submitted that ACIP will need to identify and discuss in greater detail than at present what factors it would anticipate the court looking at to make determinations. In particular, it will need to consider whether a concept analogous to the concept of the 'amount taken' could possibly exist in patent law.

6. Comments in relation to particular options

In this section we discuss comments in relation to specific options put forward by ACIP in the Options Paper.

Options B – no change

Option B is one of the options preferred by ACIP. ACIP appears to prefer this option due to the concern that there is no evidence of a 'market failure' attributable to the present lack of an EUE in Australian law. ACIP notes¹³ that one reason that there is no empirical evidence for a market failure is because 'many researchers seem to be relatively unaware of or are ignoring patent rights'.

¹² On the concept of the 'utility contribution' of the invention, see IPRIA's earlier submission in response to the ACIP Discussion Paper.

¹³ At page 38 of the Options Paper.

However, it is necessary to consider the status quo in relation to how researchers go about their research. First, researchers undertake their research without interference from the patentee. Second, researchers know this is the case, so they do not waste a lot of time doing compliance checks to make sure they are not infringing a patent.

It is possible that the present debate about the EUE may have already changed this status quo, and many researchers may now have a greater awareness of the patent system and how it may apply to their research.¹⁴ Evidence of a possible ‘market failure’ may in fact be the increasing awareness of researchers in respect of patent law and the potential impact of patent law on their research.

Thus, even though there may be no evidence of an increase in patentees filing suits against researchers, there may be evidence that researchers are becoming concerned about using patented material in their experiments. This change in the status quo from the perspective of researchers may have associated costs, such as researchers undertaking compliance checks before beginning a research project, and research projects stalling due to the current uncertainty. These costs could be addressed by the introduction of an EUE.

Option C – Introduce an express provision allowing experimental use

The pros listed in relation to Option C¹⁵ option are very brief, and do not specifically address the benefits that could arise as a result of an EUE being introduced in Australia. While ACIP acknowledges that an EUE may ‘reduce inefficiencies’ generally, it does not acknowledge the impact that an EUE could have on researchers. For example, an EUE could allow researchers to begin projects without having to undertake extensive compliance checks.

¹⁴ This comment was also made in the Bio21 submission to the ALRC report ‘*Genes and Ingenuity*’, page 324.

¹⁵ Page 8.

Option C3 – Exemption for experimenting ‘on the subject matter of the invention’

ACIP states that Option C3 would be introduced in conjunction with ‘supplementary conditions’, including conditions in relation to clinical trials. As these ‘supplementary conditions’ could potentially have a large impact on the operation of any EUE that is introduced, it is important that the type of supplementary conditions contemplated by ACIP are fleshed out, as well as the effect that these supplementary conditions would have on the operation of the EUE.