Australian Research Council

Submission To

The Advisory Council on Intellectual Property

Patents and Experimental Use: Options Paper

February 2005

Background

This document outlines the responses of the Australian Research Council (ARC) to options for modification of the Australian patent system to clarify the area of 'experimental use', as presented in the "Patents and Experimental Use – Options Paper" released in December 2004 by the Advisory Council on Intellectual Property (ACIP).

The ARC is an Australian Government statutory authority established under the *Australian Research Council Act 2001* (the ARC Act). The primary functions of the ARC, as specified in the ARC Act, are to make recommendations regarding the funding of research programs, administer funding to support research programs, and provide policy advice related to research and research training.

The ARC currently provides approximately $500 million per annum in funding for research programs and has established a range of competitive funding schemes for the support of research and research training under the National Competitive Grants Program (NCGP). A list of current NCGP funding schemes is available on the ARC web site at www.arc.gov.au. By the operation of a range of funding schemes under the NCGP, the ARC aims to:

- maintain and build on existing research and research training;
- build the scale and focus of research and research training;
- encourage inter-disciplinary approaches to research and research training;
- facilitate collaborative approaches to research and research training; and
- support research and research training in the National Research Priority areas.

ARC treatment of Intellectual Property

The ARC supports research programs in a wide range of universities and other organisations. It recognises the importance of maximising the benefits arising from research activity and emphasises the importance of effective management of intellectual property (IP) in its scheme funding rules and funding agreements.

As a funding body, rather than a body which conducts research, the ARC position on IP arising from ARC-supported research is that ownership and management of IP is the responsibility of the organisation which administers the ARC grant (in some cases in conjunction with other collaborating organisations). To promote the effective capture and management of IP arising from research, ARC funding agreements contain clauses which are worded along the following lines:

"The Institution must adhere to an Intellectual Property policy, approved by the Institution's governing body, which has as one of its aims the maximisation of benefits arising from research. The Commonwealth makes no claim on the ownership of Intellectual Property brought into being as a result of the projects for which Funding is provided."

In providing funding support, the ARC also requires compliance with the National Principles of Intellectual Property Management for Publicly Funded Research. Very

briefly, those principles require that organisations and researchers are aware of IP issues and have policies and practices in place to effectively manage and exploit IP.

Where the ARC funds research collaborations between researchers in the higher-education sector and other organisations in the public or private sectors (typically under the ARC Linkage Projects scheme), the ARC also requires up-front agreement between the parties involved regarding the treatment of IP:

"The Institution must not allow a Project to commence, nor Funding to be expended, until the Project's Collaborating Organisation and the Institution have entered into a written agreement that specifies that the Collaborating Organisation agrees to comply with this Agreement and which also includes conditions about:

- *the role of the Collaborating Organisation in the Project;*
- *the provision of the Collaborating Organisation Contribution to the Project; and*
- *Intellectual Property arrangements."*

Responses to ACIP options

It is the view of the ARC that a strong research and innovation system is an essential part of building and maintaining prosperity and international competitiveness. The ARC recognises the role of the patent system in supporting innovation, and broadly agrees with the guiding principles outlined at the start of Part II of the Options Paper.

It is vital that any modifications to existing arrangements be designed to enhance the effectiveness of Australia's innovation system, balancing the need to enable effective lines of research enquiry with the need to ensure that innovators reap appropriate rewards (including financial) from the inventions that they have created. Importantly, any modifications should have regard not only to the Australian domestic situation but also to the global standing, attractiveness and competitiveness of Australian research and innovation, as well as the business environment.

The ACIP paper presents a range of options for modification of the Patents Act, and identifies four as preferred. The ARC responses to each are as follows:

Option A

This option would exclude experimental use from allowable activity. The ARC is concerned that such an option would be likely, over time, to lead to significant restrictions on research in a broad range of areas. The ARC agrees with the ACIP considerations, and does not support this option.

Option B

This option maintains current arrangements. The ARC has neither sought nor received direct evidence that current arrangements are having significant impacts on research activity but it acknowledges that the current situation in many fields is not static and that IP issues are increasingly central to research in many fields. Hence the ARC is of the view that this option is likely to be unsustainable in the long term.

Options C1 to C8

These options introduce, in various forms, express provisions allowing experimental use. They differ primarily in how they attempt to define, or guide the interpretation of, the term ‘experimental use’.

Option C1 adds no further guidance, allowing the law to evolve by interpretation in the courts. While the ARC acknowledges the simplicity and flexibility of this approach, it is not clear that such an approach adds sufficient clarity compared to current arrangements, at least until a body of case law is established. The ARC therefore does not support this option.

Option C2 provides guidance by reference to specific, non-binding examples or guidelines. The ARC agrees with the ACIP considerations in this case. While it is likely that specific examples will prove greatly helpful in certain areas of technological complexity, the effort involved in creating and maintaining a sufficiently rich set of examples, in the face of rapid technological change and convergence, should not be underestimated. In the long run, it is likely that unanticipated technological advances will overtake such a system. The ARC does not support this option.

Option C3 provides for experimenting “on the subject matter of the invention”. The ARC agrees with the ACIP considerations and does not support this option.

Option C4 provides for fair experimentation in a way similar to the fair dealing allowed under copyright law. The ARC agrees with the ACIP considerations and does not support this option.

Option C5 provides exemptions for exclusive permitted uses. The ARC sees this option as unduly rigid and does not support it.

Option C6 provides exemptions for inclusive permitted uses. The ARC agrees with the ACIP considerations and does not support this option.

Option C7 combines options C4 and C6. It thus provides both underlying principles and issues regarding experimental use and guidelines about what acts might constitute fair experimental use. As such, the ARC feels that this option is most likely to enhance clarity for the various parties involved, while still allowing significant flexibility in interpretation by the courts in specific cases. The ARC supports this option.

Option C8 combines options C3 and C6 (apparently incorrectly identified as C2 + C6 in the options paper). Although this option does provide a comprehensive and somewhat attractive framework in a manner similar to option C7, it appears to the ARC that the objections to option C3 still stand. That is, the issue of what comprises experimentation ‘on’ the subject matter of the invention, rather than ‘with’ the subject matter of the invention, is likely to remain contentious. In some areas (such as genetics), it appears that the distinction between working ‘on’ a certain technology, and working ‘with’ the technology is very fine, if it exists at all. Unanticipated advances in a range of fields may well result in even more problematic areas. The longevity and effectiveness of this option is thus brought into question and the ARC does not support it.

Options D1 and D2

These options address the issue by adding provisions prior to the award of a patent, such that patent rights are restricted to the utility of the invention. The ARC agrees with the ACIP considerations and recognises the possible restrictions under international treaties. It does not support these options.

Option E

This option would establish a statutory licensing system for experimental use. The ARC agrees with the ACIP considerations and does not support this option.

Conclusion

Although there appears to be mainly scattered and anecdotal evidence for problems related to experimental use of patented inventions in the Australian system, the ARC recognises that these issues are of growing concern in the research and innovation sectors and that technological advances in many fields are such that these issues are likely to gain significance into the future. Accordingly, the ARC welcomes an attempt to enhance clarity and reduce uncertainty about experimental use. Any modifications to current arrangements must carefully balance the needs of both researchers and the holders of patent rights. It is vital that Australia remains attractive and competitive in both research and innovation, including that of the business sector, and, to the fullest extent possible, any change should enhance such activity rather than detract, particularly by comparison with overseas practice. The ARC sees the ACIP option C7 as a reasonable balance between careful definition and flexible interpretation and supports this option.

The ARC notes that the Australian Law Reform Commission released its report *Genes and Ingenuity: Gene Patenting and Human Health* in June 2004 and that the OECD has distributed for comment *Draft Guidelines for the Licensing of Genetic Inventions* (February 2005). The ARC would welcome ACIP taking these into account in its consideration of patents and experimental use.