



**Australian Government**

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**National Health and Medical Research Council**

**PATENTS AND  
EXPERIMENTAL USE**

**Response to Options Paper**

**2005**

The National Health and Medical Research Council (NHMRC) is pleased to have the opportunity to provide comments on the Options Paper on Patents and Experimental Use presented by the Advisory Council on Intellectual Property (ACIP).

## **Background**

The NHMRC was established in 1936. Its functions arise from the statutory obligations conferred by the *National Health and Medical Research Council Act 1992* (the NHMRC Act),<sup>1</sup> which require the NHMRC:

- to raise the standard of individual and public health throughout Australia;
- to foster the development of consistent health standards between the various States and Territories;
- to foster medical research and training and public health research and training throughout Australia; and
- to foster consideration of ethical issues relating to health.

The NHMRC also makes recommendations to the Commonwealth on expenditure:

- on public health research and training; and
- on medical research and training; including recommendations on the application of the Medical Research Endowment Account.

The NHMRC funds research on the basis of scientific excellence through competitive peer review mechanisms. NHMRC funding for research constitutes a significant component of Commonwealth research funding.

The mission statement of the National Health and Medical Research Council (NHMRC) is to ensure that excellence in research, research and health ethics, and health advice improves the health of all Australians.

## **Introduction**

The NHMRC recognises that the commercial exploitation of research findings benefits the economy through employment growth and national wealth generation, as well as being an essential step in the delivery of new diagnostics, treatments and preventive medicines to the community. It also presents new challenges for the research community to assist in the cultural change that is required to position Australia to capture the benefits from the generation and diffusion of knowledge and technology.

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<sup>1</sup> In 2002, the statutory obligations of the NHMRC were expanded with the introduction of the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002*.

## **The Need for a Research Exemption**

As outlined in its previous submission, the NHMRC believes that an exemption for experimental use is required in order to provide clarity to health and medical researchers as to whether their research infringes patent rights. To leave the situation as it currently is may leave the opportunity open for the private sector to enforce their patents on public sector researchers in the future, which in turn may result in researchers taking the “safe” option and avoid conducting experiments involving patented material or inventions – a situation which patent law intends to avoid. In fact, the aim of patent rights is to encourage innovation by granting a temporary monopoly on the rights to commercially exploit an invention in return for full disclosure of its details. However, there is no benefit from early disclosure if the information cannot then be used to further knowledge and create more inventions. The NHMRC considers that in order to eliminate uncertainty both in the scientific and legal realms, and to encourage research and innovation, an explicit research exemption should be adopted.

## **Comments on the Options presented in the ACIP Paper**

The purpose of the Options Paper presented by ACIP was to gauge stakeholder opinion on what form a research exemption should take, bearing in mind the arguments for and against each option, and its likely effect on particular sectors of the economy, business and research.

The options presented in the paper were the outcome of the previous Issues Paper and stakeholder submissions that were subsequently provided. The paper puts forward several options for consideration, but highlights four that ACIP are more inclined towards. Two of these are the NHMRC’s preferred option, and these are discussed in order of preference.

As discussed in its previous submission, the NHMRC wanted to be closely involved in the consultations concerning the general form and nature of a research exemption. This question is the major issue for the NHMRC and for medical researchers. It is also the question most relevant to the NHMRC’s expertise. As such, the NHMRC wishes to focus on the question “Which option(s) does the respondent prefer and for what reasons?”

## Option C7<sup>2</sup>

### **Exemption for fair experimentation, with inclusive permitted uses (C4 + C6)**

The Patents Act be amended to establish an exemption for acts that constitute fair experimentation on an invention. In determining whether an act is fair experimentation, the following must be considered:

- the purpose and character of the act;
- the subject matter of the invention;
- the availability of the invention in the marketplace; and
- the commercial effect of the act upon the patent holder.

Permitted acts of fair experimentation include, but are not limited to:

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

This is the NHMRC's preferred option for the following reasons:

- 1) The use of the words "fair experimentation" and their definition clearly describe the scope and intention of the exemption.

This is especially important for enabling scientists to judge whether their experiments contravene intellectual property laws or not. This, in turn, decreases the need for scientists to seek legal experts to determine the legality of their experimentation. The clarity of the language also enables legal experts to make reasonable judgements on a wide range of uses in order to determine whether they are permitted under the exemption or not.

However, the NHMRC suggests some changes to the wording of the purpose of the act and the examples used. See Suggested Changes below.

- 2) The broad examples of permitted acts also increase clarity on the scope of the invention while retaining flexibility of interpretation.

The statement that "the commercial effect of the act upon the patent holder" is, however, especially important as there are a number of patented inventions which are research tools aimed at providing easier/more accurate/more efficient research methods. As the purpose of these inventions is to facilitate research, it would violate the monopoly rights of the patent holder if it does not have to be purchased for this purpose as this would eliminate the potential market for the invention. Therefore, permitted uses which include research for non-commercial purposes should bear in mind "the commercial effect of the act upon the patent holder" so as not to eliminate the potential market for the invention.

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<sup>2</sup> Advisory Council on Intellectual Property, *Patents and Experimental Use Options Paper*, December 2004, p13

Thus, the considerations and examples of permitted acts of fair experimentation are useful guides to illustrate which uses of the invention would be included in the experimental use exemption and which uses, such as the above, would not.

- 3) Another advantage of this option is that the examples are not too specific.

Therefore, while providing clarity on the exemption, the breadth of the examples means that there is no need to regularly update them.

### Suggested Changes

Although Option C7 is the NHMRC's preferred option due to the clarity it provides on the principles of the exemption, the NHMRC has some concerns.

Option C7 suggests that "The Patents Act be amended to establish an exemption for acts that constitute fair experimentation *on* an invention," and proceeds to use examples of permitted acts (determining how an invention works, its scope, validity, and improvements) which also refer to experimentation *on* an invention.

Although the permitted acts of fair experimentation are not limited to these examples, legal experts may interpret the definition and examples in a way that excludes experimentation *using* an invention, which in turn could result in action taken by private sector patent holders against public sector researchers who conduct *research with*, not *on*, the invention.

The language is crucial, as experimentation *using* the invention would encompass a variety of acts that research *on* the invention would not include. For example, the use of a patented invention for non-profit hospital based diagnosis. Also, the majority of patented research tools are likely to be used by researchers for their own purposes rather than as the subject of experimentation – that is, for research *with* or *using* the patented tool rather than research *on* the tool.

If experiments such as these are not included in the permitted uses, licence negotiation and the potential for licences to be refused could hinder research. Leaving uncertainty surrounding the permissibility of experimentation *with* an invention, or allowing legal experts to judge such experimentation as an infringement of patent rights, would also discourage non-commercial research rather than encourage it as the patent system aims to do, and would have a detrimental effect on public-sector research.

Aside from the negative consequences to research, the NHMRC believes that excluding non-commercial research from patent infringement is legally justified because a monopoly only grants a patent holder the sole right to *commercially exploit* their invention. As non-commercial experimentation utilising the invention would not involve making money from it, such purposes should be exempt from patent infringement.

The NHMRC therefore requests that research for non-commercial purposes be included in what constitutes fair experimentation. (Although, as in point 2, the commercial impact on the patent holder should be taken into account.) This can be done by altering Option C7 as follows:

- “The Patents Act be amended to establish an exemption for acts that constitute fair experimentation on *or with* an invention.”; and
- Adding the following to the examples of permitted acts of fair experimentation: “*using the invention for non-profit research*”.

## Option C1<sup>3</sup>

### **C1: Definition of exploitation does not include experimental use.**

The Patents Act definition of exploitation of a patented invention be amended to not include experimental use, such as through adding the phrase (other than experimental uses”. No further guidance on the meaning of this term is provided.

This option is the NHMRC’s second preference for the following reasons:

- 1) Modifying the definition of exploitation is the easiest way to amend the Patents Act to allow experimental use.
- 2) It provides the courts with a great degree of flexibility in interpretation. This would allow each case to be judged according to the particular situation.

However, as there are no further explanations or examples of what is meant by “experimental use”, there still remains some uncertainty as to the scope of the exemption. This is not only an important factor for legal experts, but for scientists who would want to make sure that their research does not infringe patent rights. As discussed in the previous section, this clarity is especially important in situations when research is conducted with, not on, a patented invention. Thus, Option C7 is preferred above Option C1 as the stated purpose of the act and examples provided in the former provide clarity while retaining some flexibility of interpretation.

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<sup>3</sup> Advisory Council on Intellectual Property, *Patents and Experimental Use Options Paper*, December 2004, p9