

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

SUBMISSION TO THE ACIP INQUIRY INTO PATENTS AND EXPERIMENTAL USE

Background

The National Health and Medical Research Council (NHMRC) funds research on the basis of scientific excellence through competitive peer review mechanisms. NHMRC funding for research constitutes a very significant component of all Commonwealth research funding and is at a similar level to that of the Australian Research Council (ARC).

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. Consequently, the NHMRC has introduced a number of important measures to foster commercial realisation of the outcomes from the research it funds, such as IP guidelines, Development Grants and Industry Fellowships. Patent activity has also been introduced into the assessment criteria of a number of mainstream schemes such as program and project grants.

The NHMRC welcomes the opportunity to respond to the *Discussion Paper*. In making its comments the NHMRC acknowledges that this is a very complex issue that requires detailed consideration and consultation with all sectors of the research community before any changes are introduced.

General Comments

The NHMRC has made a submission to the Australian Law Reform Commission *Inquiry into Gene Patenting and Human Health* and the general approach outlined in this section is drawn from that submission.

The NHMRC strongly supports the establishment of a broadly based experimental and research use defence to a claim of a patent infringement.

The NHMRC considers that any experimental or research defence:

- should be aimed at reducing undue impediments to research while at the same time ensuring that the value to the patent system is not eroded;
- must be clearly defined and the bounds of the defence must be clear to patent holders and researchers. In order for the limits of the defence to be clear, the limits of the original patent will also need to be clear. For example, if the commercial utility of the patented invention is properly defined (so that it is clear how the invention will be commercialised and the extent of the commercial monopoly granted through patenting) then it should be easier for researchers to determine what is covered by the patent and what is permitted through application of the experimental/research use defence;
- should be supported by guidelines issued by IP Australia explaining the defence and the limits of the defence (including practical examples of how it is intended to reply);

- should be clearly communicated to researchers who in turn need to be educated about the defence;
- should be developed in close consultation with stakeholders.

Comments by the NHMRC's Research Committee

Research Committee is one of four principal committee of the NHMRC. Its role is to provide advice and make recommendations to Council on the application of the funding for health and medical research and to provide advice on matters relating to medical research including intellectual property matters.

The Need for a Research Exemption

Research Committee strongly supports the introduction of a research exemption. The fact that a research exemption is not explicitly stated in Australian law has left health and medical researchers confused as to whether they are infringing patent rights in the course of their research. The decision by the US Court of Appeals for the Federal Circuit in *Madey v Duke* (2002) in which research was interpreted to be a commercial activity has added to this confusion.

Research Committee notes that patents are awarded to inventors as an incentive to replace commercial secrecy with public disclosure of the invention so that it can contribute to further economic developments in the future. A patent provides a limited monopoly right to the inventor to exclude others from making commercial use of the invention.

It is logical, therefore, that the intention in developing the patent system must have been for the invention to be used for research, regardless of whether it is commercial or not, so long as the user does not sell the invention (ie compete against the monopoly rights awarded by the patent).

In some cases this is straightforward. For example, if someone invents a new mass spectrometer, others cannot make or sell it, but they can use it to produce an improved mass spectrometer or identify a new drug. In the former case they may need to obtain a licence if the new spectrometer contains a substantial embodiment of the old one, however, in the latter case, no licence would be required.

The situation is not so clear-cut where the invention itself is a research tool or reagent that is being sold. In these cases, using the invention without buying it would violate the monopoly right granted by the patent even it is not sold to others, because the users would be eliminating the potential market for the invention. For example, a licence would not be required, unless this was a specific condition of sale, if a researcher subscribes to a database and uses it to discover a new product. On the other hand, the database (or any improvement that incorporates the original database) cannot be sold without a license. Another example is polymerase chain reaction (PCR). If PCR is used to identify a new gene, there should be no license fee, however a diagnostic kit that incorporates a PCR reaction would require a license before it is sold.

More problematic is the situation where a research procedure, such as an animal breeding protocol, is patented but is not in itself an entity that can be sold. It is hard to see how such patent applications pass the industrial utility requirement since they do not represent something that can be sold once it has been disclosed. These problems could be overcome if

the claims indicate the commercial utility, thereby making it clear whether a particular use of the invention impinges on the monopoly right or not.

Research Committee therefore recommends that patent law be amended so that the commercial use and market that the invention covers are defined in the patent examination process. Research on or using the invention should then be exempt if it does not impinge on the commercial monopoly right as described and granted. This would greatly assist researchers in clarifying whether they are, indeed, infringing patent law in the course of their activities.

Possible form of a research exemption in Australia

Research Committee recognise that there may be practical problems in developing and applying a research exemption for patents in Australia. The discussion paper reviews a number of models that are used internationally. It is clear that some countries such as Japan have already adopted a research exemption. Research Committee recommends that, in making a decision, ACIP explore these models and examine how the lessons learnt from them can be applied to the Australian situation.

The issues of which body should have oversight of research exemptions and the availability of patent examiners with a suitable background to administer any research exemptions also need to be addressed. The ALRC Discussion Paper recommends that a Human Genetics Commission of Australia be established to provide high-level, technical and strategic advice to Australian governments about current and emerging issues in human genetics. While this may be a suitable centralised body to provide advice on research exemptions and gene patenting, this is only one component of the research sector.

Finally, Research Committee supports the comments made by Shapiro on page 14 of the discussion document regarding the danger of imposing an unnecessary drag on innovation by enabling multiple rights owners to tax new products, processes and methods. Research Committee agrees that although the individual effects may be small, the cumulative effect of many small 'taxes' can become large. How an Australian research exemption deals with this situation will have to be thought through carefully.

Possible Further Steps

Research Committee strongly supports the introduction of research exemption. Full and fair consultation with all stakeholders should be undertaken in all stages of its introduction, from developing a model through sorting out the practicalities of which model would be most suitable for Australia.

Research Committee is interested in being involved in development of a research exemption, as well as the forthcoming public consultation process.