

Received 23/4/04

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Director

ACIP Secretariat  
PO Box 200  
Woden ACT 2606

Attention: Dr Rod Crawford

April 22, 2004

Dear Rod,

Re: Patents and experimental use

Please find attached a response from the Walter and Eliza Hall Institute to the Issues Paper "Patents and Experimental Use" prepared by the Advisory Council on Intellectual Property. We strongly believe in the principles of experimental use exemption and enthusiastically support your efforts to clarify this aspect of Australian patent law. Our response is carefully considered since we have direct experience of the issues from the perspectives of our involvement in both basic medical research and also protecting and commercialising our own intellectual property. As a consequence we understand the issues with respect to balance and the need to foster a system that encourages innovation, translation of investment in science and appropriate commercial strategies and returns.

Our response to the Issues Paper has also been included in submissions from Bio21 and the NH&MRC. Please do not hesitate to contact me should you require further comment or clarification.

Yours sincerely,

Dr Julian Clark

Head Business Development

cc: Professor Suzanne Cory, Director

## Advisory Council on Intellectual Property

### Response to the "Patents and experimental use: issues paper"

Walter and Eliza Hall Institute

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The Walter and Eliza Hall Institute strongly believes in the principles of experimental use exemption. Experimental and research use is an essential part of an effective Patent System. Governments award patents 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. The incentive is a limited monopoly right to make use of the invention for commercial purposes (or more correctly a right to exclude others from making commercial use). The invention is defined by the claims that should demonstrate the actual commercial utility and hence the exact scope of the commercial monopoly when granted. Therefore, the invention can be used for further research (regardless of whether the research is commercial or not) so long as the user does not sell the invention (i.e. compete against the monopoly rights)<sup>1</sup>.

#### Question 1: Understanding of current law

Our understanding is based on the experimental use exemption being implicit in Australia. To the best of our knowledge this implicit exemption has not been formally challenged in Australia. Therefore, the basis of understanding is that the basic law derives from British law and that there is no precedent in Australia. This understanding makes it clear that exemption is required to test the validity of an invention and to make improvements to that invention. Provided that the inventor will not be financially disadvantaged experimental use exemption applies in any research organization whether public or private. Therefore a license is not required for research purposes.

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<sup>1</sup> In some cases this is quite straightforward. If someone invents a new mass spectrometer others cannot make and sell it but, after they buy it, they can use it to produce an improved mass spectrometer or to identify a new drug. In the former case they may need licensing if the new spectrometer contains a substantial embodiment of the old one but in the latter case no license would be required.

The problem arises when the invention itself is a research tool or reagent that is being sold. Use of the invention (without buying it) would then be a violation of the monopoly right even if it is not sold to others because the user(s) would be eliminating the potential market for the invention. One example is a database. If a subscription is bought and it is used to discover a new product there should be no license required unless this was an explicit condition of the sale. On the other hand the database (or any improvement that incorporates the original database) cannot be on-sold without a license. Another example is 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. A real problem is a research procedure that is patented but is not an entity that can itself be sold (eg animal breeding protocols, GTG patent etc). In this case it is difficult to see how such patent applications passed the industrial utility requirement since they do not represent something that can be sold (i.e. once it has been disclosed). The claims should have indicated the commercial utility which would then make it clear if a particular use of the invention impinges on the monopoly right or not.

We believe it should be an obligation of a patent examination to define the commercial uses and market that an invention covers so as to define exactly the monopoly right. Research on the invention should then be exempt if it does not impinge on the commercial monopoly right as described and granted.

**Question 2: Learnings from overseas experience**

We recommend following the UK/European model rather than the USA precedent. The US exemption is too restrictive and unworkable for academia. The US precedent of Madey is potentially dangerous and we recommend a review of court actions subsequent to this judgement to assess whether this has precipitated a major change in the US.

**Question 3: Constraints for experimental use exemption**

We are not aware of any specific restriction on exemption under any of the agreements. TRIPS is probably the most significant but does not directly address the issue. We believe that the issue of exemption will continue to be dominated by generic pharmaceutical entry and rights for spring-boarding. We can expect this issue to re-emerge in future development of the Free Trade Agreement.

**Question 4: Impact of current uncertainty**

We have no empirical evidence that the ability to use inventions for research has been affected to date. However, certain patents describing methods or procedures such as the GTG patent (non-coding DNA) and the Dove application (mutagenesis and mouse breeding) are causing concern since in the absence of a clear research exemption they attempt to extract advantage from standard procedures with inadequate demonstration of scope and utility in the claims. The current debate implies that research may be affected but the vast majority of researchers are not at all aware of the issues or continue to work on the established understanding of the implicit exemption.

**Question 5: Argument for pre-grant conditions**

We see no argument for pre-grant conditions to complement or be an alternative to experimental use exemption.

**Question 6: Learnings from copyright law**

The copyright system provides lessons that can be learnt and a more extensive framework for the determination of an exemption, than by simply calling it research.

**Question 7: Needs of different types of research**

To the extent that differences between basic, applied and hybrid research exist we doubt that any specific needs with respect to the patent system could be easily defined. There is variation within organizations, i.e. sponsored research at WEHI, CRCs, publicly funded research grants in industry. Importantly, contemporary

science is converging with fast iterations between basic and applied experiments. Most successful scientists aspire to the Pasteur model "*use-inspired basic research*".

#### **Question 8; Evidence for a "patent thicket"**

There is no clear evidence yet of a "patent thicket" problem in research. Such a problem does not occur with experimental use exemption. The difficulties occur further downstream when commercialisation may lead to problems of excessive royalty demands and the need for capping.

#### **Question 9: Special issues for genetic technology**

An amendment has been made for the pharmaceutical industry to gain an extension of time, traded against the experimental use exemption to allow for research and development before patent expiry. The Biotech industry may have a faster route to other markets and has a high requirement for a research exemption. eg the use of patented proteins and growth factors in cell culture of an academic nature. It is important that the specific issues related to experimental use of genetic sequences and molecular structures are clarified.

#### **Question 10: Justification of experimental use exemption**

Justification for an experimental use exemption would be to clarify a grey area of the law. The Patent Act is silent on the issue and is therefore open to interpretation. To leave it to the courts to decide would exclude the input of all the concerned parties, and mean that many issues would be abandoned to avoid incurring high court costs

The removal of research exemption would have a major and severely damaging impact on both research and its commercialisation. There are two issues that must be considered – knowledge of infringement and enforcement. It would be an enormous task for a researcher and associated IP officers to monitor granted patents and evaluate whether the daily work infringes any claims. Secondly, for the patent holder surveillance to support enforcement would be a major undertaking and there would be few benefits of any action. Firstly, there are literally thousands of laboratories and publications to monitor individually and secondly the proof of commercial loss or disadvantage would be challenging. A statute of limitations having a six-year retrospective claim period further exacerbates the situation. In our view the removal of research exemption would adversely change the way in which science is done and reported, would reduce public return on investment in research, would be extremely expensive to sustain, would make Australia less competitive and would deliver minimal or no financial benefits to the patent holders.

**Question 11: Experimenting with the invention for its purpose**

Criteria should be developed from the EU experience.

**Question 15: Licensing practices**

Licensing practices are not a direct issue when there is an experimental use exemption. The discussion in the Issues Paper addresses issues of improving licensing in Australia is not directly relevant to experimental use exemption. Furthermore, the implication in the paper that the benefits of experimental use exemption are outweighed by its potential disadvantages/costs to the patent system is in our belief erroneous. Experimental exemption is already practised and there is no apparent burden to the system.

**Question 17: Patent pools as solutions**

Patent pools are unlikely to keep up with increasing rates of change particularly in biotechnology related areas. The asymmetry of power and influence between the various players would make it difficult to function effectively and equitably

**Question 19: Compulsory licensing**

Compulsory licensing is likely to introduce other undesirable habits such as stalling and less disclosure. This has rarely been invoked by other countries and is not a solution to the general lack of clarity. In the biotech area open source principles would be counterproductive, flying in the face of the very monopolistic protection required for recouping R & D costs. E.g. it would be dangerous to equate inventive biological research with the open source development of Linux

**Question 20: Open source**

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**Implementation:**

When experimental use becomes law it will be essential that there are supporting explanations of what activities are covered by the defence and that common law defence also applies. A broad education and training program of researchers, IP managers and commercial interests will be required.

**Contact:**

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