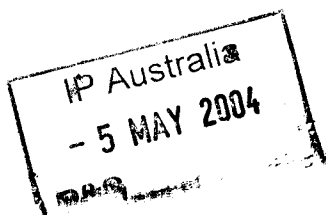


30 April 2004



Dr Rod Crawford  
ACIP Secretariat  
PO Box 200  
WODEN ACT 2606



*Building a  
Cancer Smart  
Community*

Dear Dr Crawford

**Advisory Council on Intellectual Property  
"Patents and Experimental Use" Issues Paper**

I refer to the release of the Issues Paper by ACIP and an invitation to provide comments on the matters raised in the paper and accordingly please find attached a submission from The Cancer Council NSW which sets out our views.

The Cancer Council NSW has taken an active interest in the area of patents particularly gene patents and we believe this area of commercial law requires amendment and reform.

The aspect we would like to emphasise is that patents are not merely legal instruments for commercial use but may have significant influence on a range of other endeavours throughout society. It is the potential impact on human health therefore which is most of interest to us.

The inquiries of both the Advisory Council on Intellectual Property and Australian Law Reform Commission addressing patenting questions are therefore very timely and perhaps, almost overdue.

If you have any questions please do not hesitate to contact through my Assistant, Mr Ron Gale on 02 9334 1934 or our Senior Policy Officer, Charles Latimer on 02 9334 1749.

Yours sincerely

A large, stylized handwritten signature in black ink, appearing to be 'A Penman', written over the 'Yours sincerely' text.

**Dr Andrew Penman**  
Chief Executive Officer

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## **Submission to the Advisory Council on Intellectual Property (ACIP) Patents And Experimental Use Issues Paper, February 2004**

### **Introduction**

The Cancer Council NSW welcomes further consideration of the impact of patents on research and development particularly in the area of bio-medical research by the Advisory Council on Intellectual Property (ACIP).

The ACIP Issues Paper poses a number of questions with some commonality with the ALRC Inquiry into gene patents and human health. We note that the Issues Paper approaches this patent inquiry with two major levels of inquiry – first, by raising the question as to whether patent rights may be inhibiting research and development, particularly in biotechnology; and second conversely, citing increasing concern that there has been insufficient return on bio-medical research through commercialisation of research and development in Australia and that inadequate use of the patent system may play a part in this<sup>1</sup>.

Of particular interest to our organisation in the ACIP Issues Paper are questions 1 (a)(b)(c), 2 and 3 addressing an experimental use defence; Question 9 which addresses whether genetic technology has special issues which require different treatment under patent law; and questions 19 and 20 which examine the matter of compulsory licensing provisions. We have addressed these questions in this paper.

By way of explanation, The Cancer Council NSW currently funds cancer research projects which, for example, examine how people's genetic background affects their response to H. Pylori infection (associated with stomach ulcers) and their likelihood of developing stomach cancer; or determine whether UVA-induced gene mutations play a role in the development of skin cancer; or examine aspects of familial breast cancer. These studies and projects involve genetic material and fall within the jurisdiction of gene patents so patent law is a matter of interest to us.

### **The Australian Law Reform Commission Gene Patenting Inquiry and the ACIP Issues Paper**

As noted on page (i) of the ACIP Issues Paper, the ALRC has also been conducting an inquiry into gene patenting and has raised a number of similar questions to those posed in the ACIP Issues paper with the obvious difference being the wider application of the ACIP Inquiry.

We take this opportunity therefore to state our views on those matters of direct interest to us to ensure continuity of perspective between both the ACIP and ALRC Inquiries.

- **Current Patenting Criteria**

The ALRC has recommended a specific issue be referred to ACIP under Proposal 6.2 of Discussion Paper 68 which states: *"The responsible Minister should request the*

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<sup>1</sup> ACIP Patent and Experimental Use Issues Paper, February 2004, page i

*Advisory Council on Intellectual Property to review the appropriateness and adequacy of the 'manner of manufacture' test as the threshold requirement for patentable subject matter under Australian Law"*<sup>2</sup>.

The current patenting criteria listed in section 18 of the Patents Act 1990 (Cth) has raised considerable discussion particularly on the meaning and relevance of some of the requirements.

In particular, the requirements regarding 'manner of manufacture' and 'involving an inventive (or innovative) step' appear to be unsuitable for application to gene patents.

The meaning of 'manner of manufacture' is obscure, as acknowledged in the ALRC Issues Paper, and other commentators have noted that it is ill-suited for genetic patents. The manner of manufacture criteria sets the test as belonging to the useful arts rather than fine arts, providing a material advantage and being in a field of economic endeavour. This is so broad that any number of gene patent claims would be permissible under the Act. A strong concern exists that gene patents are actually being granted where there is no obvious utility in the application.

**In determining the eligibility for the granting of a gene patent we support the need for an emphasis on the importance of the principle of utility (ie a clear and obvious purpose) to be applied.**

- **Experimental Research defence**

In relation to Questions 1,2 and 3, we note the law reform options proposed by the ALRC include a proposal for a research use defence to be available under Proposal 14-1 contained in ALRC Discussion Paper 68. We strongly support the direction undertaken by the ALRC in regards to a research defence and commend it to ACIP.

As an example, there has already been considerable controversy over patents covering genes and in Europe, a situation exists where there are patents held by both Cancer Research UK and Myriad Genetics on the same gene. This type of circumstance needs to be borne in mind when considering a proposed Australian research exemption and its likely impact and effect. The view from overseas literature is that both overseas patents cover BRCA2 sequencing and diagnostics therefore an Australian research exemption should be framed to overcome circumstances such as these where there are multiple parties involved.<sup>3</sup>

Equally this new example is instructive in demonstrating the level of complexity which the gene patenting issue may cause and the need for further amendment of the current patenting legislative provisions and regulatory practice.

We have foreshadowed to the ALRC that we believe that developments in gene patenting will outstrip the rate of change possible through the law reform proposals of their Inquiry. The same comment is pertinent for the ACIP inquiry as biotechnology is a very dynamic field and developments in this science move swiftly.

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<sup>2</sup> The Australian Law Reform Commission, "Gene Patenting and Human Health Discussion Paper 68" February 2004, p.138

<sup>3</sup> Journal of the National Cancer Institute, Vol . 96, No 7, April 7, 2004 p.506

We have sought perspectives from researchers currently engaged in cancer research whose work may fall under a gene patent of some form.

Our discussions with researchers confirmed various findings of the ALRC with particular reference to the lack of knowledge about patents, their application and other rights. Certainly there has been a presumption of non-applicability of patents by some researchers to their work.

There is a significant gap in knowledge as to what is, or what is not, covered by a gene patent and sometimes other patents. It is not uncommon for a health research project to not only utilise a specific gene sequence but also various research tools, all of which are covered under different patents. Little specific understanding of the potential legal ramifications and requirements of patents has been found to be common knowledge among many academic researchers. For example, in many respects it has not really occurred to many researchers that their work could be subject to a gene patent.

**An experimental research use defence is therefore vital in this respect.**

Equally improving the level of understanding of researchers in regard to patent rights is a step which we would endorse.

- **Genetic technology and patenting**

The ACIP Issues Paper refers in Question 9 to the matter of whether biotechnology and genetic technology in particular has special issues that warrant special treatment under patent law with respect to experimental use.

We would suggest that genetic technology poses a significant challenge to the patent system and the very nature of the subject matter requires a specific and targeted response on several different levels. These include changes to the criteria for application for gene patents introducing a utility requirement; vigorous, critical and informed examination of gene patent applications; a capacity to challenge inappropriate patents; provision for effective licensing provisions, including compulsory licences; a better defined role for Government in the patent process where the public interest needs to be safeguarded.

In short, special treatment with a clear experimental research exemption is warranted for genetic technology due to the impact of the subject matter on the wider community – a clear experimental use exemption should be seen as a minimum.

These are views which we have placed before the ALRC and are applicable in this context as well.

- **Licensing**

The ACIP Issues Paper refers in Questions 19 and 20 to the matter of compulsory licensing and whether it is a partial or whole alternative to an experimental use provision. We would argue that compulsory licensing is not an alternative, whole or partial to an experimental use exemption. This question presupposes that the only application of licensing is for research purposes rather than ensuring the value of research is available to the wider community.

The fact that use of the compulsory licensing provisions is rare, as noted on page 22 of the ACIP Issues Paper, does not provide a basis for reliance on this sole mechanism.

Some researchers who are involved not only in genetic research but also with the provision of genetic testing in the health system, have expressed concerns with the cost to health care. To them the risk of the development of monopoly services is foreseeable and avoidable and the granting of patents and licenses can have a significant impact with a positive influence.

There has been confusion about the legality of genetic testing in the public health system in NSW following statements in the media by companies holding BRCA1 and BRCA2 gene patents or associated licences. Initially this resulted in an instruction to halt testing which subsequently lapsed when no legal threat eventuated. This was not due to any direct request from patent holders in Australia but rather occurred due to a perceived legal risk and from observations of overseas experience particularly in New Zealand where attempts have been made to enforce patents.

This is a matter of considerable concern to us and demonstrates the need to have effective provisions to not only safeguard the public health system in this country but also to give confidence to health practitioners that they can deliver services without the threat of litigation. The ALRC has set out a number of proposals which outline roles for Commonwealth, state and territory health departments as well as the Australian Health Ministers Advisory Council (AHMAC) which include further scrutiny and support for intervention where patents may be inappropriately granted. This direction, we would suggest is prudent and would in no manner, undermine or weaken the patenting system, rather it is only to safeguard and balance public and private sector interests.

**Compulsory licensing provisions should be retained as a separate and distinct option rather than as a substitute for an experimental research exemption.**

## **Conclusion**

In summary therefore, The Cancer Council NSW supports amendments to the patenting system which will ensure that:

- The criteria applied to patents should be further defined through reviewing 'the method of manufacture test' as recommended by the ALRC;
- An experimental research exemption is available to researchers;
- An effective licensing system with provision for the use of compulsory licenses where required, separate and distinct from an experimental research defence.

We would welcome further discussions with ACIP on matters raised in the Issues Paper.

April 2004