

9 February 2005

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Dear Mr Applegate

## **Patents and Experimental Use – ACIP Options Paper**

### **Submission by The Cancer Council NSW**

I refer to the release of ACIP's Options Paper on the issue of patents and experimental use dated December 2004 and accordingly The Cancer Council NSW forwards the following comments in response to matters raised in the Paper. We welcome the opportunity to engage in further representations to ACIP and particularly to comment on possible options for research exemptions in the patenting system.

At the outset, it should be restated that the focus of The Cancer Council NSW has predominantly been on the issue of gene patents and the challenge this category of patent has caused to the wider intellectual property (IP) rights system. We consider that patents in general are a valid and appropriate mechanism for the protection of IP and an essential tool to encourage research, development, innovation and exploitation. Nevertheless the advent of gene patents inherently erodes and adds a potential contradiction for IP development by protecting rights yet seemingly also creating barriers to investigation. It is timely therefore to examine legislative options to encourage research work for the long term.

Science is a dynamic field and the associated laws governing it should also be responsive to challenges created by new discoveries and technology. We note ACIP has acknowledged that "...biological and medical sciences have undoubtedly thrown up new and important issues with which the patent system has to grapple..."<sup>1</sup> Gene patents constitute such a challenge to patent law and practice.

### **The Patenting System and genetic technology**

As noted by ACIP, the Australian Law Reform Commission (ALRC) has already undertaken a lengthy and detailed examination of gene patenting and most of the issues relating to gene patents and the patenting system in general have been

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<sup>1</sup> ACIP 'Patents and Experimental Use Options Paper, December 2004, p27

exhaustively covered in that inquiry. It is not our intention therefore to recycle the same comments but rather to focus on the need for a research exemption in the Patents Act as recommended by the ALRC and the options outlined by ACIP.

Of note, the final report of the Intellectual Property and Competition Review Committee (IPCRC), to which several references are made in the ACIP Options Paper commented:

*"Because patents can be used to appropriate the general application of ideas, and not just particular embodiments, they have the potential for conferring greater market power than other areas of intellectual property (IP) law. However, in practice alternatives and substitutes usually exist for patented products and processes"<sup>2</sup>.*

In the field of gene sequence discovery, alternatives and substitutes are not an option as they may be for disciplines of invention.

The IPCRC final report also commented specifically on patenting gene sequences:

*"In the controversial area of patenting gene sequences, the Committee considers that the tests for granting a patent should be non-technologically specific. The Committee strongly believes that mere discoveries should continue to be excluded from patentable subject matter. It recommends the Patent Office help ensure this outcome by requiring that granted patents disclose specific, substantial and credible uses."<sup>3</sup>*

The above cited observation remains at the apex of the gene patent debate and yet remains unresolved at this time. In light of this inherent shortcoming in patent evaluation, an explicit research exemption is one of several needed reforms for the patent system.

Patent claims currently recognised in various jurisdictions may assert rights over DNA variously including one or more of the following –

- the DNA sequence, whether comprising a complete or partial gene,
- promoters,
- enhancers,
- individual exons,
- expressed sequences as expressed sequence tags (ESTs) or cDNAs,
- whole transcribed genes as cDNAs,
- individual mutations known to cause disease,
- variation between people not associated with disease (polymorphisms),
- cloning vectors, formed from bacterial DNA, which are used to replicate DNA sequences,
- expression vectors, also formed from bacterial DNA, which are used to express proteins in replicated DNA sequences,

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<sup>2</sup> "Review of intellectual property legislation under the Competition Principles Agreement", final report by the Intellectual Property and Competition Review Committee, September 2000, p.9

<sup>3</sup> *ibid* p10

- isolated host cells transformed with expression vectors, which are cells that have been created to express particular proteins,
- amino acid sequences (proteins),
- the use of such proteins as medicines,
- antibodies, which are used as markers,
- nucleic acid probes, which are fragments of DNA that are used to locate particular parts of DNA sequences,
- methods for identifying the existence of a DNA sequence or a mutation or deletion in an individual,
- testing kits for detecting genetic mutations,
- whole genomes.

As demonstrated above, the breadth and comprehensiveness of the application of patenting encompasses all the elements of gene structure to the most basic level. Researchers funded by the Cancer Council NSW have stated that should gene patent rights be enforced, they could be potentially subject to over half a dozen different patents while undertaking research on a single project.

A research exemption therefore would be useful not only for encouraging basic research work but also for providing certainty and enabling a mechanism to avoid costly, convoluted and arguably unnecessary negotiations for research which has no direct or identified commercial application.

We note ACIP's view that the dividing line between basic, non-commercial research and applied commercial research has become blurred, however we would submit that basic research is still undertaken particularly in health sciences utilising genetic information<sup>4</sup>.

### **Patent Criteria**

The granting of gene patents by patent offices using the established criteria has never been fully convincing and while the legal framework for intellectual property rights was not designed for what are really 'discoveries' regrettably the opportunity has long past to initiate needed substantial reforms. Rather, working to improve the existing system remains the practical and viable course of action to pursue. The provision of a research exemption fits comfortably within this wider framework of enhancements.

Patenting a DNA strip now involves using technology which is quite standardised – in some cases merely a computer program thus there is nothing novel (or arguably, patentable) in the process. In practice, this has been as straightforward as data mining software used by researchers who access publicly available databases and identify a gene(s) responsible for disease sourced from another organisation's data. Despite this being one of the methods utilised, the sequencing of individual genes is seen as being akin to discovery of non-naturally occurring compositions, and

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<sup>4</sup> ACIP 'Patents and Experimental Use Options Paper, December 2004, p27

therefore is generally accepted as meeting the criteria for patent issue (novel, innovative, useful).

We note nevertheless that the ALRC has examined patent application procedures and recommended an independent review on the appropriateness and adequacy of the manner of manufacture test (ALRC recommendation 6-2). The ALRC has also recommended that the Patents Act 1990 (Cth) be amended to include a 'usefulness' requirement for standard patent applications where patent applications must disclose 'a specific, substantial and credible use' (ALRC Recommendation 6-3(b)).

Given these clear and inherent weaknesses in the current patent system and their application to gene patents, an explicit research exemption appears to be a complimentary initiative to introduce as a reform - without breaching existing international obligations or the exploitation rights of patent holders.

### **International Agreements**

It is acknowledged that International conventions do present limitations to any changes to the patent system particularly with the provisions contained in the Agreement on Trade -Related Aspects of Intellectual Property (TRIPS) being the most likely restriction.

We note ACIP's quotation of Article 27.1 of TRIPS relating to the issue of technological neutrality for patents but we would also emphasise that it should not be read in isolation from Articles 27.2 and 27.3. Technological neutrality is tempered by exemptions from infringement for specific purposes in healthcare.

We would submit also that Article 30 of TRIPS would seem to provide for a research exemption:

#### *Article 30 – Exceptions to Rights conferred*

"Members may provide limited exceptions to the exclusive right conferred by a patent, provided that such exceptions do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"

We note with interest ACIP's consideration of TRIPS and the possibility of an implicit research exemption is likely to be encompassed within Article 30<sup>5</sup>. ACIP's view is commensurate with the ALRC's opinion on this matter and it would appear therefore not to pose a barrier to enabling a research exemption to be devised.

### **ACIP recommended options**

The ACIP Options paper canvasses a number of options with various sub-options each of which provide varying levels or exemptions or degrees of rights. It is worth

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<sup>5</sup> ACIP 'Patents and Experimental Use Options Paper, December 2004, p32

noting that the ALRC Inquiry recommended a research exemption with specific requirements and the ACIP approach should be considered within the context of the ALRC's suggested wording.

*ALRC Recommendation 13-1:*

"The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to establish an exemption from patent infringement for act done to study or experiment on the subject matter of a patented invention; for example, to investigate its properties or improve upon it. The amendment should also make it clear that :

- (a) the exemption is available only if study or experimentation is the sole purpose or dominant purpose of the act;
- (b) the existence of a commercial purpose or objective does not preclude the application of the exemption; and
- (c) the exemption does not derogate from any study or experimentation that may otherwise be permitted under the Patents Act. "

The European Union has proposed a research exemption in the Council Agreement relating to community patents which seems to pursue a similar objective to the ALRC proposal<sup>6</sup>:

*"Article 27*

*Limitation of the effects of the Community patent*

The rights conferred by a Community patent shall not extend to:

- (a) acts done privately and for non-commercial purposes;
- (b) acts done for experimental purposes relating to the subject-matter of the patented invention";

Bearing in mind the wording envisaged for a proposed research exemption, the four options in ACIP Options paper (B, C1, C7 and C8) are each considered below. It is worth noting that none of the four options is completely satisfactory in addressing the issue of a research exemption covering gene patents however this reflects more the difficulty in adapting laws designed for inventions to subject matter which is, in fact, a discovery and is still evolving.

We note that ACIP has drawn a distinction between experimentation "on" or "with an invention when distinguishing between acts which is a differentiation based on European practice. This poses a significant problem for genetic research for which borders of experimentation with or on a 'gene' are not as easily defined as for example, a molecule used in pharmacological research for new medicines.

We also note ACIP's preference not to adopt an overseas solution simply to achieve harmonisation of IP laws if it is not in the best interests of the Australian society<sup>7</sup>.

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<sup>6</sup> <http://www.eurunion.org/legislat/iiprop/patents.htm>

We support that view although if a research exemption is to succeed in its aim and be legally robust, it would be preferable to have a definition which is within the parameters of process and practice accepted in other jurisdictions.

- **Option B: No change. Courts to decide the basis of infringement of patents.**

ACIP argues the merit of this option on the basis that there is "...no objective/empirical evidence of a current and significant market failure..."<sup>8</sup> We would submit that the lack of enforcement by patent holders of their patent rights does not mean that enforcement will not occur at some stage. The actions of Myriad Genetics and Genetic Technologies in respect of genetic testing of the BRCA1 and BRCA 2 genes have demonstrated that patent holders can be both willing and vigilant in respect of their commercial rights.

A 'no action' option appears inconsistent with the other preferred options suggested by ACIP and an inappropriate direction to follow in light of the need for the patent system to be responsive to subject material for which it was not designed. Relying purely on litigation and the development of caselaw to resolve definitional issues is an expensive solution. Option B therefore is not supported.

- **Option C1: Patents Act be amended to define exploitation as not including experimental use, without further defining the term.**

This option operates by specifically excluding an activity without defining the nature of what is being excluded and appears to resemble the current German research exemption. Exclusion from within a definition however does not provide the same degree of certainty as that of a specific exemption with a direct reference to an activity. We would submit that an explicit inclusion of an exempt activity also conveys a better degree of intent within legislation particularly when being interpreted by the courts. Option C1 therefore is not supported.

- **Option C7: Exemption for fair experimentation with inclusive permitted uses.**

This option establishes exemption for acts that constitute fair experimentation "...on an invention..." and sets out considerations for determining whether an act is fair or not. While we would support the concept of fair experimentation on an invention, the definition however may be too restrictive for medical and health sciences dealing with genetics which have a high level of discovery involved. A combination of C7 and C8 definitions may be preferable.

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<sup>7</sup> ACIP 'Patents and Experimental Use Options Paper, December 2004, p44

<sup>8</sup> 'Patents and Experimental Use Options Paper', ACIP, December 2004, p8

- **Option C8: exemption for experimenting on the subject matter of the invention, with inclusive permitted uses.**

We note the variation in wording in Option C8 from Option C7 which permits an exemption 'on the subject matter of an invention' rather than on the invention itself.

From a health research perspective, the definition used 'on the subject matter of an invention' may be more beneficial given the continuing discovery process of the role of individual genes and the inter-relationship with other genetic material in disease development and progression. It is a similar wording to the research exemption proposal of the European Union (previously cited). The definition nevertheless may still be too restrictive for medical and health science research dealing with genetics.

In both C7 and C8, examples of permitted acts of experimentation may include, but are not limited to, determining how the invention works, the scope of claims, the validity of those claims and developing an improvement to the invention. These examples of experimentation are satisfactory given genetics is an evolving science .

We note ACIP's view that definitional problems will be overcome by listing examples of acts which would normally be considered exempt.<sup>9</sup> As this will always be subject to the legal interpretation, that view may well be correct, however further refinement of the definition may still be preferable rather than relying predominantly on examples for guidance.

### **Conclusion - The Cancer Council NSW Position**

In addressing the question of patents and an experimental provision, The Cancer Council NSW emphasises the importance of balancing the protection of intellectual property with the unusual potential reach and impact of gene patents. The importance of supporting Australia's research efforts particularly in the biotechnology industry is not at issue however it is argued that a research exemption which does not infringe on the commercial exploitation rights of patent holders, equally is intended to support this effort.

The Cancer Council NSW therefore supports the inclusion of a specific reference to a research exemption in the Patents Act rather than an implied exclusion. In our view, options C7 and C8 have a closer association with a research exemption from patent infringement while giving some guidance and intent of meaning which is essential for legal interpretation.

We would submit however that with genetics, the process of discovery is ongoing hence the separation between "experimentation on an invention" and "on the subject matter of the invention" may be simply an artificial and unnecessary distinction. Rather we would support a definition which covered "experimentation on an invention and/or on the subject matter of an invention". This is more

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<sup>9</sup> 'Patents and Experimental Use Options Paper', ACIP, December 2004, pp13,14.

appropriate with an evolving science with a high level of discovery and indeterminate parameters.

We acknowledge the basis of patent law as being technologically neutral, however the nature of genetic science does not permit patent law to be biologically neutral. Equally changes to law often lag well behind advances in practice hence the opportunity exists to make adjustments to patent law before problems arise rather than being purely reactionary after legal disputes commence.

Should queries or clarification be required on this document please contact me (telephone 02 9334 1934) or our Senior Policy Officer, Mr Charles Latimer (02 9334 1749).

Yours sincerely



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**Chief Executive Officer**