

19 September 2008

Mr Brendan Bourke  
Secretariat  
Advisory Committee on Intellectual Property (ACIP)  
PO Box 200  
WODEN ACT 2606

Dear Mr Bourke,

**Re: ACIP Review of Patentable Subject Matter**

Thank you for the invitation to make a submission regarding the ACIP review of patentable subject matter. The Royal College of Pathologists of Australasia (the College) is a professional organisation with an interest in the consequences of patenting on the delivery of genetic testing in healthcare.

**General comment**

In 2004 the Australian Law Reform Commission (ALRC) review of gene patenting [ALRC 99] noted that, "Although one cannot deny the legitimacy of patenting processes for isolating and purifying naturally occurring materials, or the legitimacy of patenting of new chemical substances that are the product of human ingenuity, there are attractive arguments for the view that such materials *should not have been treated as patentable subject matter*. However, the time for taking this approach...has long since passed" [ACIP Discussion Paper, page 60; our emphasis].

This conclusion recognised that the opportunity to subject many gene patent applications to appropriate scrutiny had been lost. Consideration of longstanding principles regarding patentability should have precluded many of the gene patents that have now been accepted.

The College welcomes the opportunity that the current review provides but it will be useful only if the principles that are clarified are translated into appropriate decision-making by patent examiners. Consequently, we recommend that conclusions of this review be partnered with recommendations designed to ensure that the principles are actually applied. Although the opportunity to prevent many gene patents may have been lost, the same issues will apply to future applications for the patenting of genetic sequences and proteins because research in these areas continues apace.

We now address each of the questions raised in the ACIP Discussion document.

**Economic objectives of limiting patentable subject matter.**

One issue that is tangential to this question but fundamental to the societal benefits of patenting is that there are economic disincentives to resolving disputes about the patentability of subject matter. Such disputes would not be about ownership of a patent, but about the right for anyone to have the patent. For example, challenging the patentability of the BRCA1 gene before an Australian court could cost millions of dollars and the successful litigant would have no capacity to recoup their costs because success would, by definition, render the patent null. This disincentive to challenge patents was recognised by the ALRC

99 report (page 478) when it suggested that challenges to gene patents might need to be made by a consortium of State, Territory, and Federal Health Departments.

One objective of the test for patentable subject matter should therefore be an assessment of the economic feasibility of subsequently challenging the patentability of that subject matter. This would mean that a patent application that might be challenged on the grounds of patentability would require a more stringent assessment than applications that could be challenged solely on the grounds of priority or precedence.

**Economic effects of inherent patentability test.**

No comment.

**Ethical reasons for limiting patentable subject matter.**

Ethical considerations must form part of the test for patentable subject matter. Ethical arguments reflect the primary goal of patenting to benefit society as a whole, to encourage innovation and optimise public access to new technologies.

Ethical considerations should not be left until after a patent has been granted for the courts to resolve, rather there should be a clear understanding of ethical limitations for patentable subject matter from the outset.

**Ethical effect of inherent patentability test.**

No comment.

**Other reasons for limiting patentable subject matter.**

No comment.

**Content and structure of current Australian law.**

The College considers that the content of current Australian law does not meet the objectives of the system. Naturally occurring sequences of DNA have been patented under these laws which represents patenting of discoveries of natural objects and, as such, these patents should not have been granted.

A chromosome consists of a length of DNA. Fragments of this DNA are copied, split, joined, and re-arranged in the human body. The presentation of such fragments in another context (e.g. a test tube) is not an invention. While the method may represent patentable subject matter, the isolated DNA sequences do not. Nor should a sequence made of a compilation of pre-existing DNA sequences be patentable as the joining together of naturally occurring sequences is also an established process in nature. The same applies to proteins derived from naturally occurring genetic sequences.

Whilst we recognise that this view has not always been shared by the courts and that a key precedent was set in 1912 when an American court held that purified adrenaline was patentable<sup>1</sup>, we are not persuaded that this decision represents an appropriate view of patentable subject matter.

**Issues with current Australian law.**

**A Combination of flexible and proscriptive tests**

The distinction between a discovery and an invention with utility lies at the heart of the test for patentable subject matter and should not be incorporated in the flexible concept of manner of manufacture. As noted by the US Supreme Court, "The laws of

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<sup>1</sup> Andrews LB (2002). Genes and patent policy: rethinking intellectual property rights. Nature Rev Genetics. 3:803-808.

nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of ... nature, free to all men and reserved exclusively to none’ .. Similarly, a newly identified genetic sequence should not be patentable on the basis of the manner in which it is presented.

There should be an explicit, proscriptive test for patentable subject matter that precludes discoveries from consideration, irrespective of the utility of those discoveries.

**B Value of existing body of case law.**

The existing body of case law has not provided sufficient guidance regarding the test for patentable subject matter. As noted in the Discussion Paper, in 2000 the Intellectual Property and Competition Review Committee (IPCRC) concluded that, “mere discoveries – that is, the identification and specification of the nature, structure and properties of existing matter and its interaction – should *continue* to be excluded from the class of patentable subject matter...” [page 52; our emphasis]. This statement confirms that the principle of the non-patentability of discoveries was clearly recognised prior to 2000 yet despite this patents for the discovery of many naturally-occurring gene sequences were granted.

**C General inconvenience, mischievous to the state and hurt of trade.**

No comment.

**D Archaic language.**

We support the use of contemporary language in all laws and regulations.

**E Threshold of inventiveness.**

Inventiveness should be an explicit element of the test of patentable subject matter. As suggested in the Discussion Paper, this may require “replacing the concept of manner of manufacture in the Act with a new concept that purely relates to inherently patentable subject matter”.

**F Threshold of utility.**

We endorse the ALRC view regarding the need for a more stringent definition and assessment of utility. This matter has already been addressed by the United States Patent and Trademark Office (USPTO) in relation to gene patents.

**G Scope of rights awarded.**

We strongly oppose the view that patents for naturally occurring genetic materials be granted, particularly without restriction on their utility being identified by the discoverer.

The utility of a discovery is not limited by context or the inventiveness of the applicant. A discovery may have unlimited potential and in such a case one must question whether the contribution of the applicant matches the benefits provided by owning the patent and the associated costs to society. When Samuel Morse sought a patent on all uses of electromagnetic waves, the US Supreme Court ruled that he could not patent every conceivable use of electromagnetic waves - he could only patent his invention, the telegraph<sup>1</sup>. Genetic sequences represent a discovery and the same logic should apply.

We emphasise the nexus of inventiveness and scope of utility. When there is unequivocal evidence of the subject matter being an invention, it may be appropriate not to restrict utility. But when there is hesitation about the subject matter being an invention versus a discovery, if the decision is made to grant a patent the proposed utility should be precisely described and delimited.

#### **H Requirement for grant.**

No comment.

#### **International integration.**

Whilst aiming for "best practice" could separate Australia from markets in which "adequate practice" yields significant commercial returns, Australia should not compromise on core principles such as discoveries not being patentable subject matter. There is no suggestion that compliance with the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) would require such a compromise.

Article 27 of the TRIPS agreement mandates that patents should be available for inventions that are new, inventive, and capable of industrial application. The synthesis or method of analysis of genetic material may fulfil these criteria, and thus be patentable subject matter, but genetic material identified in nature cannot be regarded as being either new or inventive. We do not dispute the necessity for Australian patent law to comply with TRIPS. We simply reject the notion that gene sequences identified in nature are anything but discoveries, and argue that a fundamental principle of patenting has not been applied in the granting of many gene patents in recent years, both in Australia and overseas.

Our concerns are not unique to the Australian setting. There has been widespread international concern about the practice of patenting human genetic sequences. Hence Australia would not be pursuing an unusual path if human genetic sequences were deemed to be non-patentable discoveries. The same principle would apply to other biological discoveries being revealed by studies of proteomics in human health and disease.

#### **International compliance of current Australian law.**

No comment.

#### **Preferred patentable subject matter.**

As noted above, we do not consider it necessary or appropriate to have a special test for patentable subject matter for genetic material. The core principles of inventiveness, novelty etc should apply. But greater stringency is required if an application involves something that might be a discovery, or for which unlimited scope of utility is claimed. It may also be appropriate to have a more stringent assessment in new fields of human endeavour. For example, the introduction of computer software and genetic tests led to patent decisions by the USPTO which were subsequently questioned, with the USPTO introducing more stringent requirements for, and assessments of, utility.

We have also noted above that ethical considerations should be part of the test for patentable subject matter. Hence we do not support the position that, "all subject matters are patentable". We would support the third option noted in the discussion paper i.e. "all subject matters, except for a narrow or definable range, are patentable".

**Legislative structure.**

No comment.

Thank you for considering our submission and should you wish to seek clarification of any part of it please do not hesitate to contact us.

Yours sincerely,

Dr Tamsin Waterhouse  
**Deputy Chief Executive Officer**