



Response to the

Australian Government Advisory Council on Intellectual Property

PATENTABLE SUBJECT MATTER

Issues Paper

Mr. Mike Ralston
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The Australian Association of Pathology Practices appreciates the opportunity to respond to this important issues paper and our comments are below for your consideration.

OBJECTIVES OF THE SYSTEM

Summary

- *The objective of the patent system is currently an economic one;*
- *The patent system is the exception to the rule of free competition. Patents should only be made available where they benefit society as a whole;*
- *Benefits to society are achieved through patents only being granted for those innovations which satisfy certain criteria, with patentable subject matter being the first and most fundamental threshold;*
- *It is arguable whether the current economic rationale for the patent system is appropriate.*

Question 1 – Economic objectives of limiting patentable subject matter (Part 3)

1.a. *Can placing limits on inherently patentable subject matter be justified on economic grounds?*

1.b. *Should the subject matter of each individual invention be assessed to determine whether a patent is necessary to encourage innovation, or should such an assessment be done for entire fields of technology?*

We believe that regardless of whether placing limits is justifiable on economic grounds, granting of patents should not proceed on subject matter that does not satisfy the criteria of novelty, inventiveness and utility (capable of industrial application).

All inventions should be individually assessed firstly to ensure that they satisfy the criteria above. Patents on subject matter that do not satisfy the criteria should not be granted regardless of whether it may be considered necessary to encourage innovation.

It is important to ensure that granted patents satisfy the criteria because challenging a granted patent where no patent should exist at all, for example where it is a discovery rather than an invention such as a gene patent, transfers no rights to the challenger save open access to the discovery, and no way to recoup legal costs.

Question 2 – Economic effect of inherent patentability test.

What would be the consequences on innovation of imposing or removing limits on patentable subject matter? Are you aware of any empirical data on such consequences?

No further comments.

ETHICAL AND OTHER CONSTRAINTS ON THE PATENT SYSTEM

Summary

- *National security is a constraint on the patent system. According to this, patents should not be granted or published where this would compromise the security of the nation and the safety of the public.*
- *Ethics has been a long standing constraint on the patent system. According to this, patents should not conflict with wider social and legal standards;*
- *Ethical issues are currently assessed under the criterion of patentable subject matter, with specific provisions for the generation of human beings and inventions that are contrary to law.*
- *A key issue is the extent to which ethics should be a consideration of the patent system.*

Question 3 – Ethical reasons for limiting patentable subject matter (Part 4)

Can placing limits on inherently patentable subject matter be justified on ethical grounds? Is it appropriate for legislation to predetermine ethical limitations on patentable subject matter, or is it more appropriate for courts to determine such limitations on a case-by-case basis?

Is patent law an appropriate avenue for dealing with ethical issues? If not, what is an appropriate avenue?

We believe that ethical considerations are not only justifiable but are essential in the evaluation of patent applications specifically in the field of healthcare, where it is even more important that significant consideration should be given to the potential benefit to society as a whole of either granting or withholding a patent. We would consider the idea of human gene patents as contrary to the fundamental principles safeguarding the dignity and integrity of the person and, as such, fail one of the basic tenets of patentability, i.e. an affront to the public. In other words public health and policy concerns should require serious consideration when contemplating patentable subject matter and its limitation.

We would consider that patent law itself is not the appropriate avenue for dealing with such ethical issues, and nor are the courts. Justice Finkelstein in the case of *Bristol-Myers Squibb v F H Faulding & Co Ltd* stated that: 'Judges should not be called upon to resolve moral questions and, speaking generally, legal principles are not to be ascertained by reference to standards of ethics or morality.'¹

As most ethical issues in patenting are likely to arise in the biomedical area, the NHMRC may be a more appropriate body to have oversight of ethical aspects of biomedical patents. This oversight could be either direct or by the way of advice to the Patent Office on individual cases.

Question 4 – Ethical effect of inherent patentability test.

What would be the ethical consequences of imposing or removing limits on patentable subject matter? Are you aware of any examples of such consequences?

¹ Finkelstein J in *Bristol-Myers Squibb v FH Faulding & Co Ltd* (2000) 97 FCR 524

The ethical consequences of removing limits on patentable subject matter have been quite dramatic in the field of DNA and gene sequencing. It has led to a dramatic escalation of patenting applications from ESTs, whole gene sequences, and most bizarrely of all, to a patent claim on all intron sequences within the whole genome. One of the most worrying outcomes is that patents may lead to there being only one testing provider for the patented gene. The consequences of this may be a disruption of universal health care and inequity of access for testing, and separation of testing from both the clinical provision of genetic medicine and appropriate pre and post test counselling. This has occurred in the US particularly in the area of breast cancer genetics and the BRCA genes. Currently in the US there is only one provider nationwide, the owner of the patent (Myriad Genetics Inc). They have successfully prevented all other genetics testing providers from performing testing. As of autumn 2006 Myriad have performed in excess of 100,000 BRCA tests at between \$2,000 and \$3,000 a test, a not insignificant return on investment.

Subsection 18(2) of the Australian Patents Act 1990 excludes human beings from patentable subject matter:

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

However it would appear that elements isolated from the human body or produced by means of a technical process, including the sequence or partial sequence of a gene are indeed considered to potentially constitute a patentable invention, as has now been demonstrated many times.

We would argue that these two provisions are conflicting, and agree with the statement made by the Danish Council of Ethics in 2001 which stated that ... 'You cannot simultaneously forbid patents on the human body or elements thereof and then permit a sequence or partial sequence of a human gene, albeit isolated from the human body to be patented.'²

Question 5 – Other reasons for limiting patentable subject matter.

Other than economics, ethics and national security, can placing limits on inherently patentable subject matter be justified on any other grounds?

Because of both the expense and the uncertainty around both pre and post grant challenges to patents there are relatively few that strike out invalid patents or that provide guidance as to examination of other patents. Therefore, as pointed out in 2003 by D.Nicol and J.Nielsen of the UTAS Centre for Law and Genetics³, there is little to stimulate improvement in patent application examination practices in Australia. They have proposed that the following legal options warrant further consideration:

- The addition of an industrial applicability/utility requirement at the examination stage and crafting of more biotechnology-specific guidelines for assessing description criteria;
- The possible exclusion of methods of diagnostic testing, which would require further analysis;
- The creation of an express research exemption. Basic and applied research would, however, have to be clearly distinguished.

² Danish Council of Ethics in *Kingdom of the Netherlands v European Parliament and Council of the European Union* (2001)

³ Nicol D, Nielsen J, Centre for Law and Genetics, UTAS, Occasional Paper No.6 *Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry*. (2003)

We conclude that it is highly probable that improper patent laws and inappropriate patents in the area of gene patenting will have an adverse affect on both downstream innovation and health care of the Australian population. Certainly the paucity of case law around diagnostic testing patents in Australia suggests that nothing will ever change unless options like those above are implemented.

PATENTABLE SUBJECT MATTER 1959 – TODAY

Summary

- *In the NRDC decision, the test for manner of manufacture was recast as a succinct set of traditional principles adaptable to new fields of innovation, leading to an expansion in what is considered patentable subject matter. An important issue is whether these principles meet the desired objectives of the patent system and are being applied correctly;*
- *There are still limits to patentable subject matter. The recent decision Grant v Commissioner of Patents interpreted the approach in NRDC to mean that a subject must involve a physical phenomenon or transformation in order to be patentable. It is arguable whether this is appropriate;*
- *It is not clear whether there is a separate threshold requirement of newness that an invention must exhibit before it needs to be tested against manner of manufacture, novelty and inventiveness. This may need to be resolved;*
- *The Patents Act 1990 continued the trend of introducing new legislative provisions for specific aspects of s.6 of the Statute of Monopolies, including inventive step. To be patentable, a subject must be:
an invention (which may involve a threshold of newness),
a manner of manufacture
novel,
inventive, and
useful, in that it meets its promise.*

Specific exclusions exist for:

- human beings;*
- subject matters that are contrary to law;*
- certain foods and medicines and*
- certain uses of a person's name.*

Prohibition Orders which prevent a patent being granted may be imposed on inventions where publication would compromise national security.

It is arguable whether the above structure is the clearest and most appropriate way of implementing the test for patentable subject matter.

- *The latest judicial guidance on the principle of general inconvenience is that it is for Parliament, not the courts, to decide issues of ethics and social policy. An important issue is whether this approach is suitable and the degree to which ethics should form part of the test for patentable subject matter;*
- *Patent examiners assess patentable subject matter as part of the normal process of assessing a patent application. Only a small percentage of applications are objected to the grounds of patentable subject matter and these usually checked by a Supervising Examiner or Assistant General Manager.*

Question 6 – Content and structure of current Australian law

*Does the content of current Australian law meet the objectives of the system? Are decision makers focusing on the appropriate principles?
Is the legislative structure of current law appropriate for the content?
Is the current law clear to decision makers and users of the system? Does the content or structure of the current test cause you any significant problems?*

We submit that the practice of current Australian law does not meet the objectives of the system. Naturally occurring sequences of DNA have been patented under these laws. This represents the patenting of discoveries of natural objects and, as such, these patents should not have been granted.

The presentation of such a DNA molecule in a test tube, rather than in vivo, does not represent an invention. 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) represents a triumph of the method but not a triumph of invention. While the method may represent patentable subject matter, the isolated DNA sequences do not. Furthermore, a sequence made of a compilation of pre-existing DNA sequences should not be patentable. The joining together of naturally occurring sequences does not represent an invention as fragmentation and joining of DNA fragments is an established process in nature. The proteins derived from naturally occurring genetic sequences should also be not patentable.

We recognise that this view has not been shared by courts for almost 100 years, and that a key precedent was set in 1912 when an American court held that purified adrenaline was patentable.⁴ We are not persuaded that this decision represents a correct or appropriate view of patentable subject matter.

Question 7– Issues with current Australian law

Do you have any comments on issues A to H identified in Part 11.3.1?

- A. combination of flexible and proscriptive tests*
- B. value of existing body of case law*
- C. general inconvenience, mischievous to the state and hurt of trade*
- D. archaic language*
- E. threshold of inventiveness*
- F. threshold of utility*
- G. scope of rights awarded*
- H. requirement for grant*

A. Combination of flexible and proscriptive tests

The characterisation and isolation of genes is now so routine that little ingenuity is required to describe a newly discovered gene, so the requirement for invention in gene patents has come to rely on whether the gene sequence was obvious not whether the method used to obtain it was obvious. The association between a gene and a disease is a process of observation and discovery rather than invention. With the finalisation of the Human Genome

⁴ Andrews LB (2002). *Genes and patent policy: rethinking intellectual property rights*. Nature Rev Genetics. 3:803-808.

Project no more genes or partial gene sequences should be patentable. Gene discoveries have always been the result of collaborative efforts amongst many workers with the final gene sequencing often the final step in the process, a point clearly put by the Institut Curie in its opposition notice filed with the EPO against the Myriad Genetics patent on the BRCA1 gene.⁵

'Myriad Genetics may have won the very last stretch in the race to breast and ovarian cancer predisposition genes in 1994, but between 1990 and 1994 the international public consortium had singly achieved detailed localization of the BRCA1 gene, and provided significant information as to its features, and its possible use in the detection of breast and ovarian cancer susceptibility. What remained to be done was the final gene sequencing, a technological procedure the outcomes of which warrant, at the most, protection by limited monopoly rights.'

The various technologies invented to determine these final gene sequences are certainly worthy of patenting, but the isolation of the natural genetic sequence itself should not be patentable. It is quite unclear how there can be any flexibility in this process.

B. Value of existing body of case law

There is little or no case law around gene sequence patents in Australia, however changes recommended by the ICPRC and ACIP requiring all prior art to be disclosed to the examiner will make the assessment of inventiveness more thorough. Further replacing the presumption of patentability with the onus of proof on the patent applicant may help discourage frivolous claims of novelty.

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

See answers to Q3 and Q4. No further comments.

D. Archaic language

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

E. Threshold of inventiveness

The feeling is that Australia has followed the US in the past with a low threshold of inventiveness in relation to gene patents. This has led to much criticism both here and in the US. Until such time as gene patents are no longer allowed or until such time as the law really does demand an appropriate level of inventiveness, as an interim measure stricter administrative guidelines should be provided to patent examiners requiring much closer examination of prior arts.

F. Threshold of utility

There currently appears to be no specific requirements relating to a requirement upon the applicant for a patent to demonstrate either specific or substantial utility. Such requirements would prevent frivolous or speculative applications where no specific benefits to the public can be defined. The ALRC has already endorsed more stringent requirements in relation to gene patents.

G. Scope of rights awarded

Broad patent rights assigned to gene sequences appear to be inconsistent with one of the main tenets of patent law, that they should result in benefit to society. Excessively broad claims may grant right to the applicant far beyond that suggested by their original inventiveness, and may have unintended consequences such as those arising from the GTG patent on intron sequences.

H. Requirement for grant

No further comments.

⁵ Institut Curie, Paris, October 10, 2001. Press Release: *The Institut Curie, the Assistance Publique-Hôpitaux de Paris and the Institut Gustave-Roussy file a joint opposition notice to the Myriad Genetics patent with the European Patent Office.*

INTERNATIONAL TREATIES

Summary

- *International treaties require that Australia's current and future patent laws:*
 - *help promote technological innovation and the transfer of technology, to the advantage of society;*
 - *provide patents for inventions in all fields of technology (including plants and animals), provided they are new, inventive and capable of industrial application, and*
 - *are developed with the aim of to reducing differences between Australia and other countries, particularly the US.*
- *It is arguable that such requirements provide Australia with the flexibility to provide the most appropriate laws for the local economic and ethical environment.*
- *Inventions which would be contrary to ordre public or morality and methods of treating humans and animals may be excluded from patents.*
- *There is little judicial guidance on what "in all fields of technology", ordre public and morality encompass. This may make it more difficult to ensure the international compliance of any changes to the law.*

Question 8 – International integration

Is it more important to achieve best practice or to harmonise with a major jurisdiction? Are any jurisdictions preferable over others?

We believe that Australia should seek to achieve best practice whilst complying with its obligations under the TRIPS agreement. We further believe that there is sufficient disagreement in regard to the patentability of human gene sequences in Australia, the UK and Europe that WIPO should re-open debate on this important topic.

Question 9 – International compliance of current Australian law

Is current Australian law compliant with our international obligations?

No further comments.

Question 10 – Preferred patentable subject matter

*According to what you believe are the appropriate objectives and constraints of the patent system, what sorts of subject matters do you think should be inherently patentable and what should not?
Would your preferred content be compliant with Australia's international obligations?*

Whilst we are of the firm opinion that genes sequences are discoveries rather than inventions and, as such, should not be patentable, we are also mindful of the fact that many patents

have already been granted in this area, and that change may now be very unlikely. The ALRC has previously pointed out that:⁶

Whatever the merits of that argument, the Inquiry was faced with the fact that since the 1980s—in Australia and internationally—large numbers of patents have been granted on genetic sequences, provided they have been isolated from their natural state and otherwise satisfy the statutory requirements for patentability. The Inquiry ultimately concluded that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed. Rather, it was preferable to focus on reforms that would make the system work better.

However we strongly believe that future patents on gene sequences should ensure that the novelty, inventive step and utility requirements are set at a high standard sufficiently above that of prior art. Such patents should be neither too broad, giving too great a control, nor too narrow which may result in multiple patents over a single gene.

We further believe that consideration should be given to excluding methods of diagnostic testing using gene sequences from patentability

Question 11 – Legislative structure

What sort of legislative structure would be appropriate to achieve your preferred content identified in Question 10? Are any foreign structures preferred?

In principle, when should statutory provisions excluding specific subject matters be used? Should such provisions be expanded, such as by including the exceptions from patentability allowed under TRIPS?

No further comments

Question 12

Do you have any other comments?

No further comments

⁶ ALRC, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No. 99, 2004