



Genetic Support Council WA (Inc)
Level 1, Oasis Lotteries House
37 Hampden Road
Nedlands WA 6009
Phone: (08) 9389 6722
Fax: (08) 9389 9377

e-mail: admin@geneticsupportcouncil.org.au
Web site: <http://geneticsupportcouncil.org.au>

Date: 12/05/2004

The Executive Director
Australian Law Reform Commission
GPO Box 3708
SYDNEY NSW 2001

Response to the ALRC Discussion Paper 68: Gene Patenting and Human Health

The Genetic Support Council Western Australia Inc. (GSCWA) is the peak body for genetic support groups in Western Australia. The Council represents some forty genetic support groups in Western Australia. The following reflects the GSCWA views in relation to Discussion Paper 68.

Consistent with the GSCWA'S submission on Issues Paper 27, the Councils response may best be summarised as follows:

- *That there is an overriding concern about patenting living material and the ethical issues of patenting human genes and parts.*
- *That gene patenting should be subject to the highest standards of accountability and that this does not in any way reduce an individual's equity of access to genetic testing and medical treatment.*
- *That gene patenting should not result in unreasonable increase in cost either to individuals or the public health system. As noted in Question 22-1, to date the GSCWA is not aware of any actual impact of gene patents on the provision of genetic testing services in Australia. There has however, been considerable press during 2003 relating to a USA company and Australian company planning to enforce their patent rights regarding a particular genetic test. The GSCWA was in fact contacted by the Australian company regarding its position opposing such an outcome*
- *That proper professional genetic counselling needs to be directly available to individuals seeking genetic testing and that the offering of genetic testing should be conditional on the availability of such counselling.*
- *That every attempt be made to harmonize any regulation or legislation and integrate this at State/Territory and Federal levels.*
- *Consumer/community consultation is paramount in the establishment of any bodies, ongoing operation of those bodies or further development of legislation/regulation.*
- *As noted in Proposal 7-1, it is a key concern to the GSCWA and its members that adequate protection exists to ensure that patenting genes and genetic technologies does not disadvantage individuals in obtaining access to these new discoveries. The risk of privatised monopolistic genetic health services that can determine cost and access to individuals seeking genetic testing, is considered to be very real. This has been the case in the USA and steps to limit this outcome have been taken in Canada, New Zealand and the United Kingdom to limit this, with varying success.*

The GSCWA supports the general position of the Department of Health Western Australia and The Cancer Council Australia in their responses to DP68.

List of Proposals and Questions

Chapter 6 Patentability of Genetic Materials and Technologies

Proposal 6-1 IP Australia should assess patent applications relating to genetic materials and technologies according to the same legislative criteria for patentability that apply to patent applications relating to any other type of technology.

Supported

Comment: The GSCWA is concerned however that patenting genes and genetic technologies have led to broad claims and exploitation of those claims into public health services. It is in these areas that some changes to the Patents Act are most desirable.

Chapter 7 Exclusions from Patentability

Proposal 7-1 The *Patents Act 1990* (Cth) (*Patents Act*) should not be amended specifically to exclude genetic materials or technologies from patentable subject matter.

Supported in principle

Comment: It is a key concern to the GSCWA and its members that adequate protection exists to ensure that patenting genes and genetic technologies does not disadvantage individuals in obtaining access to these new discoveries. The risk of privatised monopolistic genetic health services that can determine cost and access to individuals seeking genetic testing, is considered to be very real. This has been the case in the USA and steps to limit this outcome have been taken in Canada, New Zealand and the United Kingdom to limit this, with varying success.

Proposal 7-2 The *Patents Act* should not be amended specifically to exclude methods of diagnostic, therapeutic or surgical treatment from patentable subject matter.

Not Supported

Comment: It is of significant concern to the GSCWA and its members that adequate protection exists to ensure that patenting genes and genetic technologies does not disadvantage individuals in obtaining access to existing and new developments, tests and technologies. Excluding methods of diagnostic, therapeutic or surgical treatment from patentable subject matter would be beneficial and has been excluded in a number of countries overseas in some limited forms.

Proposal 7-3 The *Patents Act* should not be amended to expand the circumstances in which social and ethical considerations may be taken into account in decisions about granting patents. Rather, social and ethical concerns should be addressed primarily through direct regulation of the use or exploitation of the patented invention.

Supported in principle

Comment: It is understood that the Patents Act already allows the courts and the Patents Office to take into account ethical considerations by excluding from patentability any invention that is not in the public interest or otherwise "generally inconvenient". It is believed however, that this provision has been generally under-utilised, but could be used in opposition or revocation proceedings and should be preserved. It is important to the GSCWA and its members that this does take place. Should the current provisions continue to be under-utilised, in particular if they are not easily applied, then direct regulation may be more appropriate.

Chapter 8 Patent Office Practices

Proposal 8-1 To ensure the on-going competence of Australian patent examiners in assessing patent applications, IP Australia should continue its efforts to provide examiners with continuing education in areas of technology relevant to their particular specialty. IP Australia should review and update its education programs regularly so that new developments can be incorporated as required.

Supported:

Comment: In principle, the GSCWA believes that any proposal that aims to make the patent examination process more rigorous and the adjudicating body better informed is worthy of support. It is acknowledged that the rate at which genetic technologies are progressing, there are difficulties for patent examiners to discover and manage the increasing volume of information. This increases the need to provide the necessary education programs to meet this demand.

Proposal 8–2 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to authorise IP Australia to establish panels of experts to advise patent examiners in assessing patent applications, as circumstances require.

Supported

Comment: In the establishment of panels of experts, it is seen as very important to include consumers in this process.

Proposal 8–3 IP Australia should ensure that appointments to the panel of experts reflect a balance of independent scientific and legal expertise, and that they be made only after consultation with relevant industry organisations and other stakeholders. IP Australia should also develop procedures for the operation of the panel, including procedures in relation to confidentiality, conflict of interest, and decision making by the panel.

Supported

Comment: As with 8.2

Proposal 8–4 IP Australia should develop examination guidelines, consistent with the *Patents Act*, the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving genetic materials and technologies.

Supported in principle

Comment: Guidelines need to include consumer input.

Proposal 8–5 The Commonwealth should amend the *Patents Act* to require patent examiners to be satisfied on the balance of probabilities when assessing all statutory requirements for patentability that are relevant at the stage of examination. (See also Proposal 6–3.)

Supported in principle

Comment: It would seem highly desirable to strengthen the validity of a patent at the examination stage. Comment at 8.2 would seem relevant in relation to the establishment of panels of experts with consumer input.

Chapter 9 Challenging and Enforcing Patent Rights

Proposal 9–1 IP Australia should develop and regularly update a searchable online database comprising patents and published patent applications. The database should be accessible to the public through IP Australia's website and should provide user-friendly access and search capabilities on a wide variety of bases. If a fee is charged for use of the database, it should be kept at a level that does not unreasonably limit access.

Supported

Chapter 16 Stem Cell Technologies

Proposal 16–1 IP Australia should develop examination guidelines, consistent with the *Patents Act 1990* (Cth), the *Patents Regulations 1991* (Cth) and existing case law, to explain how the criteria for patentability apply to inventions involving stem cell technologies. The examination guidelines should address, among other things, the patentability of inventions involving:

- (a) totipotent, pluripotent and multipotent cells; and
- (b) processes involving stem cell technologies.

Supported

Comment: This is a very contentious area with considerable community apprehension. This is particularly evident amongst GSCWA members. In developing examination guidelines, the widest possible consumer/community consultation is desirable.

Question 16–1 Should specific mechanisms be established to regulate the exploitation of patented stem cell technologies? If so, would any of the following initiatives be desirable:

- (a) establishing an Australian stem cell bank or collaborating with existing stem cell banks in other countries;
- (b) conferring responsibility on a new or existing body to consider the potential exercise of any patent rights that might arise from research conducted by Australian entities using human stem cell lines; or

- (c) developing guidelines and principles by the National Health and Medical Research Council and the Australian Research Council to ensure that the public interest in the commercial exploitation of inventions involving stem cell technologies is balanced with the public interest in dissemination of such technologies?

Comment: *It is most important to ensure that the use of stems cells is consistent with community expectations. Any new or existing body that may be given the responsibility of regulating the exercise of patent rights for stem cell technologies must be able to ensure that public interests are maintained.*

Chapter 20 Gene Patents and the Healthcare System

Proposal 20–1 The Australian Health Ministers' Advisory Council (AHMAC) should establish processes for:

- (a) an economic evaluation of medical genetic testing and other new genetic medical technologies; and
- (b) an examination of the financial impact of gene patents on the delivery of healthcare services in Australia.

Supported

Comment: *The proposed HGCA may well be the appropriate body to overview this process. Currently the AHMAC Advisory Group on Human Gene Patents and Genetic Testing would be best placed to fulfil this role. The GSCWA cannot emphasize enough the need to ensure that there is not an unreasonable cost for genetic testing to individuals or to the public health services. The outcome of higher costs to individuals is self evident however, higher costs to public health services will place additional demand on public health resources with ramifications for the provision of those services.*

Proposal 20–2 AHMAC should examine options for using government funding and purchasing power to control the cost of goods and services that are subject to gene patents and used in the provision of healthcare.

Supported

Comment: *Whilst government purchasing power can be beneficial, this may become ineffective in cases where there is a monopoly on these goods and services.*

Proposal 20–3 Where particular gene patent applications, granted patents or patent licensing practices are considered to have an adverse impact on medical research or the cost-effective provision of healthcare, Commonwealth, state and territory health departments should actively consider whether to: request re-examination of a patent; initiate proceedings to oppose a patent; apply for revocation of a patent; apply for the grant of a compulsory licence; or exploit or acquire a patent under the Crown use and acquisition provisions of the *Patents Act 1990* (Cth) (*Patents Act*).

Supported

The GSCWA would strongly recommend that this be implemented.

Proposal 20–4 Commonwealth, state and territory health departments should establish specialist offices to monitor and manage intellectual property issues relating to genetic materials and technologies. The offices should be staffed by qualified individuals who are capable of giving specialist legal and policy advice about intellectual property, biotechnology and human health. Health departments should also establish mechanisms to enable them to draw on expertise in other government departments and agencies to advise and assist them in dealing with intellectual property issues arising from gene patents.

Supported in principle

Comment: *This would be a desirable initiative. It is important however to seek an outcome that overcomes any further fragmentation within the field by creating yet another body. Until the HGCA becomes established, it may be worthwhile for one state or territory to be jointly funded by all states and territories to carry out this role.*

Proposal 20–5 The proposed Human Genetics Commission of Australia (HGCA) should monitor the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases. In conducting such monitoring, the HGCA should have the following functions:

- (a) providing information to IP Australia during the examination of a patent about the proper scope of the patent, in appropriate cases;
- (b) liaising with AHMAC, health departments, and other relevant stakeholders about the advisability of opposition, re-examination or revocation of a patent under the *Patents Act*, and about who might take such action and in what circumstances; and

- (c) liaising with AHMAC, health departments, and other relevant stakeholders about whether access to patented genetic inventions should be obtained under the Crown use, Crown acquisition or compulsory licensing provisions of the *Patents Act*.

Supported

Proposal 20–6 Pending the establishment of the HGCA, AHMAC should establish a mechanism for monitoring the application of intellectual property laws to genetic materials and technologies, where these may have implications for medical research or human health, both generally and in specific cases.

Supported

Chapter 22 Medical Treatment Defence

Question 22–1 In the absence of a general defence relating to medical treatment, should the *Patents Act 1990* (Cth) be amended to enact a new defence to claims of patent infringement based on the use of genetic materials and technologies in diagnostic or therapeutic treatment?

Not Supported

Comment: To date the GSCWA is not aware of any actual impact of gene patents on the provision of genetic testing services. There has however, been considerable press during 2003 relating to a USA company and Australian company planning to enforce their patent rights regarding a particular genetic test. The GSCWA was in fact contacted by the Australian company regarding its position opposing such an outcome. It would seem that a decision to exclude methods of diagnostic, therapeutic or surgical treatment from patentability, or to continue to allow patents to be granted and use other mechanisms such as Crown use provisions or statutory licensing schemes to address issues of costs and access, rather than a general defence to medical treatments would be a better outcome.

Chapter 24 Patents and Competition Law

Proposal 24–1 The Australian Competition and Consumer Commission (ACCC) should develop guidelines regarding the relationship between Part IV of the *Trade Practices Act 1974* (Cth) and intellectual property, with particular regard to patented genetic materials and technologies. The guidelines should extend to patent pools and cross-licensing involving patented genetic materials and technologies.

Supported

Proposal 24–2 The ACCC should review the conduct of firms dealing with patented genetic materials and technologies, as the need arises, to determine whether their conduct is anti-competitive within the meaning of Part IV of the *Trade Practices Act*. The ACCC should liaise, on an ongoing basis, with Commonwealth, state and territory health departments and other stakeholders to identify and assess any emerging competition concerns in this field.

Supported

Chapter 25 Prices Surveillance

Proposal 25–1 The Australian Competition and Consumer Commission should conduct informal price monitoring of patented medical genetic tests and other genetic inventions involved in the provision of healthcare services if evidence emerges that such prices are having an adverse impact healthcare services.

Supported

Chapter 26 Crown Use and Acquisition

Proposal 26–1 The Australian Health Ministers' Advisory Council should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth or a State to exploit a patented invention under the Crown use provisions of the *Patents Act 1990* (Cth) (*Patents Act*) for the purposes of promoting human health. Similarly, the Commonwealth Department of Health and Ageing should develop a policy regarding the circumstances in which it is appropriate for the Commonwealth to acquire a patent for the purposes of promoting human health.

Supported

Proposal 26–2 The Commonwealth should amend the *Patents Act* to clarify that, for the purposes of the Crown use provisions, an invention is exploited ‘for the services of the Commonwealth or the State’ if the exploitation of the invention is for the provision of healthcare services or products to members of the public.

Supported

Proposal 26–3 The Commonwealth should amend the *Patents Act* to provide that when a patent is exploited or acquired under the Crown use or Crown acquisition provisions of the *Patents Act*, the Crown must pay such remuneration or compensation as is:

- (a) agreed between the parties; or
- (b) determined by a prescribed court to be just and reasonable having regard to the economic value of the patent.

Supported

Question 26–1 Should the Commonwealth amend the *Patents Act* to require a patent holder to transfer ‘know-how’ relating to the patented product or process to the Crown when the Crown uses or acquires a patent under the Act.

Comment: Only in the case where the “know how” is necessary for the crown to achieve the objective for which the acquisition was made.

Chapter 27 Compulsory Licensing

Question 27–1 Should the Commonwealth amend the *Patents Act 1990* (Cth) to clarify the test for the grant of a compulsory licence? If so, should the Commonwealth

- (a) clarify the circumstances in which the ‘reasonable requirements of the public’ will not have been satisfied; or
- (b) specify that s 135 is not an exhaustive list of the circumstances in which a patented invention would fail to satisfy the ‘reasonable requirements of the public’?

Comment: The advantage of the compulsory license would enable some pressure to be brought in the case of a monopolistic patent.

Proposal 27–1 The Commonwealth should amend the *Patents Act 1990* (Cth) (*Patents Act*) to insert the competition-based test that was recommended by the Intellectual Property and Competition Review Committee as an additional ground for the grant of a compulsory licence. The amendment should also provide for an independent review of the operation of the compulsory licensing provisions in addressing competition concerns arising in relation to patented inventions. This review should be conducted five years after the new test commences operation.

Supported

Chapter 28 A Statutory Licensing Scheme

Question 28–1 Should the Commonwealth amend the *Patents Act 1990* (Cth) to include a statutory licensing scheme for patented inventions? If so:

- (a) should the scheme be available only to a limited class of patents or a limited class of users;
- (b) should the scheme be voluntary or compulsory in nature; and
- (c) how should a reasonable royalty for the scheme be determined and who should administer the scheme?

Comment: Experience overseas suggests that statutory licensing schemes have resulted in prohibitive costs to public health services and may well result in a reduction in access and equity which the GSCWA would not support

For your consideration

Terry Keating
Executive Director