



# HUMAN GENETICS SOCIETY OF AUSTRALASIA

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## Position Statement

<b>Title</b>	<b>Patenting of Human Gene Sequences</b>
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<b>Replaces</b>	<b>HGSA Position Paper on the Patenting of Genes</b>
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### **Additional Statement to the Position Statement of the Patenting of Genes**

*In 2002 the Australian Government commissioned the Australian Law Reform Commission to review intellectual property rights over genes and genetic and related technologies with a particular focus on human health issues. In response the ALRC released its Report "Genes and Ingenuity – Gene Patenting and Human Health" in June 2004.*

<http://www.austlii.edu.au/au/other/alrc/publications/reports/99/index.html>

The report made a number of recommendations which are under consideration by the Australian Government. This position statement will be reviewed when the Australian Government releases its response.

## May 2001

At the present time, Australian and New Zealand law allows the patenting of genes and gene sequences when specific criteria are met, and IP Australia and the Intellectual Property Office of New Zealand have already awarded patents for complete genes of known function and usefulness. IP Australia accepts that patentable items can include: DNA, RNA, genes and viruses; mutation or genetic engineering; synthetic genes or gene sequences; mutant forms and fragments of gene sequences; DNA coding sequence for a gene; protein expressed by a gene; anti-sense DNA; general recombinant methods; and genes and gene sequences which have been separated from the human body and manufactured synthetically for re-introduction into the human body for therapeutic purposes. This very broad approach to the patenting of genes and gene sequences has arisen through the application of laws that could not have foreseen the developments in science that underpin biotechnology or the significance of biotechnology for human health care.

1. The HGSA views the patenting of genes and gene sequences with great concern and recommends that, as a matter of urgency, there should be broadly based consultation in Australia and New Zealand regarding potential consequences that may flow from the patenting of genes and gene sequences, in conjunction with a rapid review of existing patent laws.

The discussion should take into account the following matters:

### 1.1

The health care needs of Australians and New Zealanders (specifically health care that involves the use of genetic technology and the products of genetic technology) recognising the existing and differing health care systems in the two countries. The HGSA notes that Article 27.3(a) of the Trade-related Aspects of Intellectual Property Rights Agreement (TRIPS) provides that member states may exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals'.

### 1.2

The need for an environment that fosters investment in research and development. Consideration should be given to the commercial needs of those who invest in research and development, including government, companies, universities and research institutes. There should be a balance between private and public sector research funding. Claims that patents are essential for private sector investment must be examined rigorously.

### 1.3

A legal framework that achieves an appropriate balance between the legitimate requirement for intellectual property protection and the benefits that flow to the community as a result of invention, and that is consistent with Australia's and New Zealand's international treaty obligations with

regard to patenting. The HGSA asks the Australian and New Zealand Governments to begin discussion and negotiation at both national and international levels with a view to developing Australian and New Zealand positions on the patenting of genes and gene sequences, and internationally consistent patent laws.

The following require consideration as part of that discussion and negotiation :

- a. What can be patented. For example, there is a need for international agreement on the criteria that must be met for a gene or gene sequence to be patentable; at present, some jurisdictions require 'an inventive step' while others accept 'discovery' as sufficient. Further, for jurisdictions that require 'an inventive step', it is not clear what is 'the inventive step' in the process of revealing the DNA sequence of a gene. The HGSA opposes the patenting of DNA sequences of unknown function or utility, in agreement with the position of the Human Genome Organisation (HUGO Statement on Patenting of DNA Sequence, April 2000).
- b. Duration of patents. Shorter periods, for example 5-10 years rather than the current 20 years, may be more appropriate for the rapidly changing biotechnology industry. Also, it may be appropriate to have variable durations, depending on the nature of the invention eg. 5 years for a genetic test and 10 years for a gene based treatment.
- c. Price of products developed with patent protection and, with regard to products for use in health care, whether regulation should exist to limit excessive profits eg. the cost of developing a test kit for mutations in a gene is not great and this should be reflected in the price of the product.
- d. Licensing rules. The HGSA is concerned that exclusive licences within a health care system can have significant harmful effects (see section 2, below).
- e. Downstream effects eg. whether the primary patent can be applied to secondary uses of a gene defined by an inventor other than the primary patent holder.
- f. Limits on patents. For example, signatories to the TRIPS Agreement may exclude from patentability 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' (Article 27.3(a) of TRIPS) and products or processes for reasons of public policy or public morality (see Article 53(a) of the European Patent Convention).
- g. The benefits of rapid dissemination of new knowledge and its use in teaching and research for the further improvement of human health.
- h. The need for developing countries to participate in the benefits of biotechnology through technology transfer and appropriate pricing structures.
- i. The need for population/patient groups that provide DNA samples and medical information for research to have their contribution recognised in terms of ready access to the fruits of the research if it is successful.

2. The HGSA is concerned that, in response to commercial considerations,

gene patenting may result in:

2.1

Genetic testing being offered commercially before the results of testing can be properly interpreted and used, and the health, family and social ramifications evaluated.

2.2

Direct marketing of tests to the public without regard for accepted clinical guidelines and without adequate pre- and post-test counselling.

2.3

Attempts to narrow the definition of "normal" and broaden the definition of "disease" in order to create a market for a genetic test, prevention or treatment.

2.4

Patent holders not developing new treatments or prevention strategies, or developing them more slowly than they could, or developing them for only some of the potential applications. That is, being in a position to determine the direction and pace of developments.

3. With regard to tests and treatments based on past or future gene patents, the HGSA considers that for both Australia and New Zealand:

3.1

There should be national guidelines for access to such tests and treatments.

3.2

The cost to individuals should be minimised through a national funding program that is limited to tests and treatments of proven clinical utility and cost effectiveness.

3.3

The price of genetic tests and gene-based treatments purchased by the national funding program should be negotiated with the patent/licence holder(s) by Government or one of its agencies.

3.4

Payment of a fee for a genetic test under the national funding arrangement should be contingent on the provision of genetic counselling.

3.5

Fees under the national funding program for genetic tests and gene-based treatments should be payable only for services provided by accredited laboratories and clinical services, respectively.

3.6

Patent holders should not issue exclusive licences for genetic tests.

The HGSA is concerned that a genetic testing monopoly:

- a. Is likely to reduce access to genetic testing because of higher cost -

government will be less able to fund testing and, if this occurs, access to clinically indicated genetic tests will be determined, for many people, by capacity to pay;

- b. Provides no incentive for the technological improvement and price reduction that comes with competition;
- c. Will disrupt the professional relationships that exist within regional genetic services between laboratory scientists, medical consumers of testing services and clinicians whose expertise covers both areas and, by doing so, reduce the quality of medical services;
- d. Militates against independent assessment of quality assurance;
- e. Limits the experience of those training in laboratory sciences in the public sector;
- f. Would result in Australia and/or New Zealand being left without an expert testing service in the event that the sole licensee ceases business; and
- g. Could result in irreplaceable loss from the public sector of a large part of its genetic testing workload and, as a consequence, of its genetic testing skills and molecular genetics expertise.

### 3.7

Patent holders should not issue exclusive licences for the delivery of gene-based treatments.

The HGSA is concerned that a monopoly with respect to a gene-based treatment:

- h. Is likely to reduce access to gene-based treatments because of higher cost - government will be less able to fund these treatments and, if this occurs, access to clinically indicated treatments will be determined, for many people, by capacity to pay;
- i. Provides no incentive for the technological improvement and price reduction that comes with competition;
- j. May slow the introduction of treatments into clinical practice because companies with an exclusive licence will not have the incentive, resulting from competition, to rapidly develop new technology.

### **Documents referred to in the preparation of this position statement**

1. The Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997).
2. Patenting of Human Gene Sequences and the EU Draft Directive (British Society of Human Genetics, 1997).
3. Patenting and Clinical Genetics (British Society of Human Genetics, 1998)
4. Position Statement on Gene Patents and Accessibility of Gene Testing (American College of Medical Genetics, 1999)

**Ratified by HGSA 17 May 2001**