HUMAN GENETICS SOCIETY OF AUSTRALASIA

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The liability of members is limited

RACP, 145 Macquarie Street, Sydney NSW 2000, Australia
Telephone: 03 5772 2779 Fax: 03 5772 2778
Email: humangenetics@virtual.net.au
All correspondence to:
PO Box 362, Alexandra, VIC 3714
ABN No. 17 076 130 937

Committee Secretary
Senate Legal and Constitutional Committee
PO Box 6100
Parliament House
Canberra ACT 2600

February 8th 2011

Submission to Committee inquiry regarding the Patent Amendment (Human Genes and Biological Materials) Bill 2010

The Human Genetics Society of Australasia (HGSA) welcomes the opportunity to provide a submission to the inquiry on this Bill. HGSA supports the need for an environment that fosters investment in research and development. However, we have serious concerns relating to the current operation of the patent system in relation to patenting of genes and the balance of commercial benefits of patent protection versus social, community and health impacts. HGSA supports the amendments proposed in this Bill.

As previously noted in the HGSA response to the Advisory Council on Intellectual Property (ACIP), our concerns relate to the impact of gene patents on medical genetic testing and on the development of novel genetic therapies. These concerns relate to:
- Monopoly control and competition;
- Cost of medical genetic testing;
- Access to public sector testing and related services;
- Access to genetic counselling;
- Quality of testing due to the potential loss of quality assurance programs;
- Professional relationships between medical practitioners and laboratory scientists;
- Further development of medical genetic testing.

For consideration by the Senate Legal and Constitutional Committee, these issues are outlined below, under the terms of reference of the previous Senate Community Affairs Committee inquiry into gene patents:

(a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:

(i) the provision and costs of healthcare

- The HGSA is particularly concerned about the issue of exclusive licences for gene patents leading to monopolies that have a negative impact on health delivery for the reasons noted in the HGSA submission to ACIP (**Attachment 1**) and in our Position Statement on the Patenting of Human Gene Sequences (**Attachment 2**); Exclusive intellectual property rights and monopoly testing removes competition, which may result in excessive pricing and restricted access, particularly within the public health system which provides the majority of genetic testing. This would lead to even greater health care inequities between those who rely on public health service and those who can afford to pay for tests privately. The critical role of the Public sector in provision of genetic testing was emphasised in the Australian Genetic Testing Survey, providing an overview of the availability and prevalence of more than 400 types of genetic tests that were offered in 2006. It stated that "60% of the 57 laboratories were categorised as being in the public sector, with 20% being in the private sector and 20% being principally academic laboratories"(http://www.rcpa.edu.au//static/File/Asset%20library/public%20documents/Media%20Releases/AustralianGeneSurvey2006.pdf);
- Whilst the impact of monopolies has been minimal to date, it should be remembered that the potential impact is significant. The Human Genome Project has identified and sequenced over 20,000 genes, including almost 2,000 already implicated in different familial conditions. Increasingly, testing for medical management, prevention and health benefit is becoming possible for these conditions;
- Monopoly over testing may limit research and negatively impact on potential health improvements, for example, when Genetic Technologies (GTG) announced an intention to exercise their exclusive licensing rights to BRCA1and BRCA2 (familial breast / ovarian cancer genes). In response to this demand, HGSA along with Cancer Council Australia and the Royal College of Pathologists of Australasia wrote to the Commonwealth Health Minister seeking assurance that the Commonwealth would protect Australian genetic testing laboratories from patent infringement proceedings. Subsequently GTG have withdrawn this intention and are currently allowing public hospital laboratories to continue with testing;
- The currently patented genes and the potential for growth in patenting threatens to create logistical and costly impositions on all laboratories which must determine their legal rights, eg: in determining whether there are patents on genes that they may wish to test; in verifying the extent of patent claims; in identifying and clarifying any exclusive licence arrangements, particularly if they are claimed to be commercial-in-confidence. These issues arose for consideration concerning the GTG exclusive licence claims for BRCA1 and BRCA2. It appears that Myriad Genetics holds an exclusive patent for BRCA1 and a patent for BRCA2 which is not exclusive. Cancer Research UK also claims patent rights for BRCA2. In practice it is usual to test both BRCA1& BRCA2 for mutations at the same time.

(ii) the provision of training and accreditation for healthcare professionals

- Enforcement of patents may take testing off-shore or to a sole licenser resulting in the loss or lack of development of local expertise and opportunities for training. This loss is experienced not only by laboratory workers, but also by clinical geneticists and genetic counsellors, who lose the connection with local laboratories, and the concomitant skills in interpreting results.
- Monopoly rights may create disenfranchisement of other laboratories, usually public hospital/research laboratories, through loss of expertise and trained staff, which may further negatively impact on skill and scientific developments transferable across the range of laboratory tests.

(iii) the progress in medical research

- Monopoly testing may create a restricted knowledge base and remove the opportunity of shared knowledge and improved result interpretation, as currently occurs in the wider scientific community;
- It may also limit further investigation that currently occurs in public hospital laboratories as new variants are identified. In this developing area the line between service and research is not always clear;
- This may result in a lack of experience with the distribution of variants based on local population, hence limiting our ability to interpret results in the clinical context.

(iv) the health and wellbeing of the Australian people

- Alongside the proposed amendments to the patent system HGSA recommends that there ought to be a separate regulatory regime to assess the clinical utility of the genetic tests and to ensure broad access through national funding;
- Under the current model in the public sector, access to testing is through specialist genetics/cancer genetics and associated medical services and is limited to individuals assessed to be at high risk. Testing occurs in conjunction with appropriate genetic counselling. This process limits unnecessary testing and ensures consent is well informed and valid;
- Exclusive intellectual property rights may encourage commercialisation and direct marketing to the wider, generally low risk, community, and thus may exploit anxiety, not only to the individual, but also to the wider family, have questionable clinical utility and be costly to individuals.
- Genetic tests with health implications should not be available in direct to consumer form but through request by a qualified health care professional in an appropriate clinical setting, in order to provide the person with the relevant information and counselling so that consent to testing is well informed and valid. This is especially the case with patented tests, where lay individuals may have unrealistic expectations of the potential of such tests. Patenting does not guarantee efficacy or clinical utility in all cases.

(b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the *Patents Act 1990* should be amended, in light of the any matters identified by the inquiry

- Through Council of Australian Governments (COAG) arrangements, State public hospitals receive a significant amount of funding for genetic tests from the Commonwealth, therefore it is appropriate that this matter is considered at that level;
- As noted in the attached HGSA position statement (**Attachment 2**), attention must be paid to regulating the way in which commercial benefit from a patent can be achieved, in particular this submission again recommends that the patent holder should not be able to enter into exclusive arrangements with clinics conducting that specific patented genetic test, but instead make the test available to all who are prepared to pay an agreed standard fair price;
- Current law has been based on a precedent which it is argued is not appropriate to apply to human genes;
- The criteria for granting of patents, eg inventiveness, usefulness, novelty are supported but it is argued that identifying naturally occurring genetic material and its function is not an invention but a discovery. This submission reiterates the concern that gene sequences are not of themselves a new 'manner of manufacture' and that they have more of a collaborative genesis than other inventions;

- This extends to isolation and copying DNA sequences and similar processes. It is noted that the methodologies used in the testing process for a particular gene mutation are generic to testing processes for other conditions;
- The Australian Law Reform Commission (ALRC) review, *Genes and Ingenuity: Gene Patenting and Human Health*, which was published in 2004 (hereafter denoted as the ALRC report), indicated that a new approach to patentability of genetic materials was not warranted at that stage. In light of more recent instances of patent holders choosing to demand strict adherence to exclusive licence rules we would suggest that it is now appropriate to review the *Patents Act 1990* with respect to specific aspects of human gene patenting;
- HGSA supports the experimental use exemption as proposed in the ALRC report (Rec 13-1) (see appended notes);
- HGSA supports the wide dissemination of research tools developed from public-funded research as proposed in the ALRC report (Rec 11-1 and 12-1);
- HGSA supports the enactment of legislative amendment to clarify the relationship between anti-competition laws and intellectual property rights as proposed in the ALRC report (Rec 24-1);
- HGSA supports the expansion of the role of the Australian Consumer and Competition Commission (ACCC) in reviewing the conduct of companies which hold gene patents as proposed in the ALRC report (Rec 24-3).

(c) whether the *Patents Act 1990* should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

The HGSA recognizes the important role of the patent system as it has functioned thus far, however, we must emphasise that the current benefit / risk balance associated with human gene patents ought to be improved, in particular we recommend that exclusive patents on gene sequences themselves should not be granted. HGSA does not support patenting of diagnostic, therapeutic and surgical methods as per the TRIPS agreement and point 1.1 in the HGSA Position Statement.

Yours sincerely,

A/Professor Julie McGaughran
President, Human Genetics Society of Australasia
http://www.hgsa.com.au/

See attachments:
HGSA Submission to the ACIP review of patentable subject matter (2008)
HGSA Position Statement on the Patenting of Human Gene Sequences (2001)

Appendix:

Relevant excerpts from the Australian Law Reform Commission (ALRC) report: *Genes and Ingenuity: Gene Patenting and Human Health:*

13. An Experimental Use Exemption

13–1 The Commonwealth should amend the Patents Act 1990 (Cth) (Patents Act) to establish an exemption from patent infringement for acts 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 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.

11. Publicly Funded Research and Intellectual Property

11–1 The Australian Research Council and the National Health and Medical Research Council should review the National Principles of Intellectual Property Management for Publicly Funded Research (National Principles) to ensure that publicly funded research, where commercialised, results in appropriate public benefit. (See also Recommendations 12–1 and 17–2).

12. Patents and Human Genetic Research

12–1 The Australian Research Council and the National Health and Medical Research Council, in implementing Recommendations 11–1 to 11–3, should recognise the public benefit in ensuring the wide dissemination of research tools.

24. Competition Law and Intellectual Property

24–1 The Commonwealth should amend section 51(3) of the Trade Practices Act 1974 (Cth) (Trade Practices Act) to clarify the relationship between Part IV of the Act and intellectual property rights.

24–3 As the need arises, the ACCC should review the conduct of firms dealing with genetic materials and technologies protected by intellectual property rights, to determine whether their conduct is anti-competitive within the meaning of Part IV of the Trade Practices Act.

ATTACHMENT 1

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PO Box 362, Alexandra, VIC 3714
ABN No. 17 076 130 937

Brendan Bourke
Secretariat, Advisory Council on Intellectual Property
47 Bowes Street, Woden ACT 2606
Brendan.Bourke@ipaustralia.gov.au

September 19, 2008

Dear Brendan,

The Human Genetics Society of Australasia (HGSA) welcomes the opportunity to comment on the ACIP review of patentable subject matter. HGSA has a number of concerns about the current operation of the patent system in Australia. Many of these are discussed in detail in our Position Statement on "Patenting of Human Gene Sequences", which I have attached. This statement was endorsed by HGSA in 2001, and we have been awaiting a Government response to the 2004 ALRC Report before updating it. In the absence of this response the Position Statement remains current and relevant.

Most of our concerns with the current patent system in relation to patenting of gene sequences have been discussed in the ALRC report. HGSA accepts the need for an environment that fosters investment in research and development. Our concerns relate to the balance of commercial benefits of patent protection versus social, community and health impacts. As noted in the ALRC report, issues of particular concern to HGSA include:
Impact of gene patents on medical genetic testing and on development of novel genetic therapies, such as
- Monopoly control and competition;
- Cost of medical genetic testing;
- Access to public sector testing and related services;
- Access to genetic counseling;
- Quality of testing due to the potential loss of quality assurance programs;
- Professional relationships between medical practitioners and laboratory scientists;
- Further development of medical genetic testing.

A submission to the ALRC from HGSA expressed concern that patents may provide a monopoly over all uses of the gene, thus potentially affecting both healthcare services and research. The nature of the monopoly created is of particular concern as it relates to totally new products entering the healthcare market. This is not simply an improvement to a device already in the medical health market. Rather, this relates to genetic tests that have not existed before and have great utility for healthcare. The potential of patents to create 20 year monopolies over all uses of a gene sequence is of great concern in that setting.

A submission to the ALRC from the Royal College of Pathologists of Australasia (RCPA) emphasised that the RCPA, the HGSA and the American College of Medical Genetics all recommend that 'diagnostic genetic tests' be 'broadly and non-exclusively' licensed. The RCPA submitted that monopolistic genetic testing is 'fundamentally wrong' because of its effects on equitable access to healthcare and innovation in testing.

ATTACHMENT 1

The ALRC recognised that, while adverse effects of gene patents may not yet be manifest, this position may change, particularly if patent holders become more active in enforcing patent rights. The nature of this change, and whether existing legal mechanisms such as those in patent law and competition law may be used effectively to address problems for healthcare, is not entirely clear. This concern has come to the fore recently. In the Australian context, the most publicised concerns have been in relation to patents held by Australian biotechnology company Genetic Technologies Limited (GTG). The ALRC report noted that GTG had stated more than once that it did not intend to enforce the BRCA patents (associated with testing for pre-disposition to breast and ovarian cancer) and that it would allow the existing public hospital cancer genetics laboratories in both Australia and New Zealand to continue to perform tests on the BRCA genes unhindered. However the GTG position has evidently changed. In 2008, GTG requested all Australian laboratories performing these tests to cease and desist. Actions such as this renew concerns about monopoly control and competition, costs, access, quality and effects on restricting the broadest possible training of genetics professionals and further development of medical genetic testing.

We note that the ALRC found that a new approach to the patentability of genetic materials was not warranted at this stage in the development of the patent system. However, it considered that the manner of manufacture test was obscure and difficult to understand. The ALRC also found that it was unclear whether the test had the ability to consider social and ethical issues according to the traditional principle that an invention not be "generally inconvenient".

HGSA supports the ACIP summary points of Section 3, namely that:
• 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.

We note the ACIP summary that ethics has been a long standing constraint on the patent system. According to this, patents should not conflict with wider social and legal standards.

We note the ACIP statement that a monopoly would be of benefit provided it was:
only for a limited term;
for a 'manufacture' that is 'new';
provided to the true first inventor, and
not contrary to law, mischievous to the State nor generally inconvenient.
In regard to patents of gene sequences, there are strong arguments that gene sequences are of themselves not a new manufacture, that their identification is rarely due to a single group of first inventors but are derived from incremental advances by many researchers, and that monopoly control of genetic testing has many potentially negative impacts on society and can thus be interpreted as mischievous to the State and generally inconvenient.

Specific comments on questions raised in the ACIP review are as follows.

Questions 3 to 5 on ethical issues, HGSA makes the following comments.
HGSA believes the patent system should consider health care needs and impact of patents on teaching and research for the further improvement of human health. HGSA is concerned about the potential impact of patenting human gene sequences on restricting the ability for independent testing and confirmation of the effects of genomic changes on health. This could lead to genetic testing being offered commercially before the results of testing can be properly interpreted and used, and the health, family and social ramifications evaluated by independent investigators. It could potentially result in direct marketing of tests to the public without regard for accepted clinical guidelines and without adequate pre- and post-test counselling. It could potentially lead to 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. It could potentially lead to 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.

Question 10 – Preferred patentable subject matter.
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).

HGSA would be very interested in participating in the round-table or one-on-one discussions flagged in the request for responses to this ACIP review.

Yours sincerely,

Associate Professor David Thorburn
President, Human Genetics Society of Australasia

ATTACHMENT 2

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Position Statement

Title	**Patenting of Human Gene Sequences**
Document Number	2000 PS01
Publication Date	May 01
Replaces	**HGSA Position Paper on the Patenting of Genes**
Review Date	2012

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

ATTACHMENT 2

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