HUMAN GENETICS SOCIETY OF AUSTRALASIA

ARBN. 076 130 937 (Incorporated Under The Associations Incorporation Act)
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

Australian Senate Community Affairs Committee
PO Box 6100
PARLIAMENT HOUSE
CANBERRA ACT 2600
community.affairs.sen@aph.gov.au

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Submission to the Senate Community Affairs Committee Inquiry into Gene Patents

The Human Genetics Society of Australasia (HGSA) welcomes the opportunity to provide a submission to this inquiry. 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.

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 Community Affairs Committee, these issues are outlined as per the following terms of reference as provided:

(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 licenses 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 last week when the first ever Australian Genetic Testing Survey was released, 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, last year 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 (public sector) 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 in the recent event concerning 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 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;
- 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 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. It 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, 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 recent indications from GTG (that they might choose 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,

Associate Professor David Thorburn
President, Human Genetics Society of Australasia
http://www.hgsa.com.au/

On behalf of the HGSA Ethics and Social Issues Committee

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.