HUMAN GENETICS SOCIETY OF AUSTRALASIA

ARBN. 076 130 937 (Incorporated Under The Associations Incorporation Act)
The liability of members is limited

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Brendan Bourke
Secretariat, Advisory Council on Intellectual Property
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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.

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,

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President, Human Genetics Society of Australasia