Submission to the Senate Community Affairs Committee

Inquiry into Gene Patents.

Submitted by Genetic Technologies Ltd (GTG).

Genetic Technologies Ltd is a publicly listed Australian biotechnology company (ASX: GTG) specialising in the field of genetics and genomics. We have 61 employees in Australia and 5 overseas. Our 2008 financial year revenues were approximately $16.0 million. Some 75% of this revenue was derived from overseas, reflecting substantial overseas patent licensing activity as well as fee for service genetic testing activities by our Australian based laboratory, which receives a significant proportion of test samples from across the world.

The company was founded on privately funded research discoveries and inventions, which led to the insightful recognition of the importance of 'non-coding' Deoxyribo Nucleic Acid (DNA). These discoveries and inventions enabled us to patent strategies by which non-coding variation in DNA may be utilised to analyse genetic material and to map genes and traits of interest across all multi-cellular species. We wish to emphasize that these patents are not 'gene patents' per se. We did not patent the whole of non-coding DNA, nor even part of the non-coding DNA, but rather the recognition that non-coding DNA is not 'junk' and that variation in non coding sequence has utility. We further described the means by which such variation may be usefully applied. The resulting methods and processes through which non-coding DNA can be analysed and applied led to patent filings in 24 countries and these filings subsequently led to patents being awarded in all 24 countries. Today, these granted patents form the core of our substantial licensing activities. We also have significant ongoing research programs both in-house and in collaboration with a number of Australian Universities ($1.3 million Research and Development activity in 2008) and we have utilised our genetics expertise to build a DNA service testing laboratory – providing efficient, low cost, high throughput testing of material from humans, animals and plants.

Our company mission statement is:

"To develop a leading biotechnology company that - in an ethical and socially responsible manner – maximizes stakeholder wealth through development of a genetic testing business, the successful commercialisation of innovative, mid-stage research projects and an active global licensing program."

Senate Inquiry Terms of Reference

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

(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,
(ii) the provision of training and accreditation for healthcare professionals,
(iii) the progress in medical research, and
(iv) the health and wellbeing of the Australian people;

(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; and

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

GTG Response.

Gene patents and their derivatives have, from time to time, come under criticism in the local media, often receiving emotional and one-sided arguments, usually from people who do not understand genetics or the rules of the patent process.

The Senate Community Affairs Committee's (SCAC) terms of reference are worded in a manner alluding to a possible adverse effect from the granting of such patents by our current patent system – and then puts the question whether the Patents Act should be amended to disallow such patents.

GTG wishes to present its sincere belief that our patent system is "not broken - does not need fixing" and that gene patents, like all other patents, have provided a very positive system that has supported broad research efforts, encouraged innovation and provided resources to develop new products and services that have contributed to a betterment of the health and wellbeing of the Australian people. To this end, we do not believe that the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent monopolies over such materials ("gene patents").

We wish to provide further considered response from two perspectives (1) from general patent system principles and (2) from a focused GTG perspective.

(1) The Patent System and Gene Patents.

Gene patents and patentable subject matter have been the subject of numerous recent enquiries and policy reports both in Australia (1) and overseas (2-4). Major summary commentary from these reviews has been that there are broad positive outcomes from the current patent system with little adverse impact. There is also a current review by the Australian Government Advisory Council on Intellectual Property (ACIP) – addressing "Patentable Subject Matter" (5).

In 2004, the Australian Law Reform Commission (ALRC) completed a major inquiry into the controversial subject of gene patents, culminating in the release of its 700 page report *Genes and Ingenuity: Gene Patents and Human Health* (ALRC 99). In its media release, ALRC President Prof David Weisbrot said, "extra flexibility must be built into the patent system to accommodate genetic technology or there could be a 'chilling effect' on research and development—and the commercialisation of that research—with adverse implications for advances in healthcare"(6). He went on to say, "Australia needs to promote investment in research and development—biotechnology is hugely expensive and patent rights are the main way of rewarding innovation and investment".

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(1) Australian Law Reform Commission (ALRC): Genes and Ingenuity: Gene Patents and Human Health (ALRC 99), 2004.

(2) Human Genetic Materials, Intellectual Property and the Health Sector. CBAC Report, 2006.
http://strategis.ic.gc.ca/epic/site/cbaccccb.nsf/vwapj/CBAC_Report_e.pdf/$FILE/CBAC_Report e.pdf

(3) Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation: Reaping the benefits of genomic and proteomic research: intellectual property rights, innovation, and public health. National Research Council Report, 2005.
http://www.nap.edu/catalog/11487.html

(4) Genetics, genomics, and the patenting of DNA. WHO Report, 2005.
http://www.who.int/genomics/patentingDNA/en/

(5) Advisory Council on Intellectual Property (ACIP) – Issue Paper: Patentable Subject Matter. July 2008 (Review Current).

(6) Australia Law Reform Commission – Media release of 31st August 2004.
http://www.alrc.gov.au/media/2004/mr3108.html

Despite often emotive and stock negative arguments presented by some of our professional bodies and media reports against commercialisation of gene patents, objective research on this topic has identified a more balanced perspective and rationalisation over the utility of gene patents (7-10).

Gene patents, more specifically patent claims to nucleotide sequences, such as genes, plasmids, and probes, are fundamental and critical to the biotechnology industry. They are the foundation of the industry. In the human health area, such claims protect therapeutic proteins, like human insulin; monoclonal antibodies like HerceptinÂ® used in the treatment of breast cancer; and diagnostic probes for genetic diseases, which are the foundation for personalized medicine. Banning such patents risks shutting down a large part of the industry and creating a major roadblock to progress in patient care (7,8).

The patent process does not limit research activity significantly, and indeed commercial activity is widespread even among academic researchers in the biological and medical sciences (9,10).

In the area of Biotechnology, products generally take about ten years of research and development to bring to market. Inventors and investors need an appropriate system under which they have faith that the product that they plan to market will justify the cost of the research and development they are required to commit to in advance. The existing patent process currently allows this. Patents encourage publication (the patent) of research and invention as distinct from the alternative approach of keeping an invention secret. Patent publication permits follow up research in both the free literature and in modified improved patent innovations building on the original patent product findings. Such general principles are equally applicable to ‘gene patents’.

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(7) Karny, GM, In Defense of Gene Patenting: The Principles of Our Patent System Are Sound and Bring Immense Benefits. *GEN* Vol. 27(7), 2007. http://www.genengnews.com/articles/chitem.aspx?aid=2052&chid=0

(8) Caulfield T, Cook-Deegan R, Kieff S, Walsh J: Evidence and anecdotes: an analysis of human gene patenting controversies. Nat Biotech 2006, 24:1091-1094.

(9) Walsh J, Cho C, Cohen W: Patents, Material Transfers and Access to Research Inputs in Biomedical Research: Final Report to the National Academy of Science’s Committee Intellectual Property Rights in Genomic and Protein-related Inventions. NAS 2005. http://www2.druid.dk/conferences/viewpaper.php?id=776&cf=8

(10) International Intellectual Property Experiences: a Report of Four Countries: Project on Science and Intellectual Property in the Public Interest. American Association for the Advancement of Science Report, 2007. http://sippi.aaas.org/Pubs/SIPPI_Four_Country_Report.pdf

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A good Australian example of the positive impact of the incentives permitted by the patent process in this area is the collaboration of the Adelaide based biotechnology company Bionomics and Professors S Berkovic and I Schafer from Melbourne in their ground breaking discovery of the *SCN1A* gene in childhood epilepsy. This work spanned a decade, provided cross funding and training for healthcare professionals and significantly advanced medical research in this health area. Because of this patented work, Australia was one of the first countries worldwide for which genetic diagnostics became available for this disease.

A USA National Institutes of Health task force has recently released a draft report on its findings about the effects of gene patenting on medicine, research and business (11). The report did not show "widespread overpricing" of genetic diagnostic tests that were patented and exclusively licensed relative to those that are unpatented or non-exclusively licensed. Their findings also indicated that patents covering genetic tests and related licensing practices do not appear to be impeding patient or clinical access to the tests.

We believe that there would be significant negative consequences on innovation and research if there were any attempt to impose limits on patentable subject matter. This would also be compounded through resultant administrative and legal complications and confusion that would no doubt ensure. This has been exemplified in the European and UK experience (12).

Moreover, to expressly prohibit the grant of the gene patent class would discriminate against the Biotechnology sector. Such discrimination would be contrary to the principles of international harmonization and the AUSFTA and would violate Australia's international obligations under the TRIPS agreement.

(2) Focused GTG Perspective.

In both the ALRC discussion paper Gene Patenting and Human Health (2004) and the current ACIP issue paper on Patentable Subject Matter (2008), a number of submissions have expressed concern and criticism over GTG's proper pursuit of its patent and license rights. Arguments have been mounted over restricting access and increasing health care costs. The example often put forward being GTG's exclusive rights (obtained from Myriad Genetics, USA) for screening of the *BRCA1* and *BRCA2* genes for predisposition to breast and ovarian cancer.

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(11) GenomeWeb Staff Reporter: HHS Committee Opens Public Comment on Gene Patents (March 2009).
http://www.genomeweb.com/node/913102?emc=el&m=332604&l=1&v=c0782f0861

(12) Brennan,D.J. The Trouble with Legislating Exclusions from the Concept of Invention (2008) 19 *Australian Intellectual Property Journal* 6.

It is GTG's contention, that we have never sought to refuse to license others in areas covered by our patent portfolio. Indeed we have a corporate mission of actively seeking to engage with others in order to facilitate broad licensing of our rights.

In the field of *BRCA* testing, it is our firm contention that we have acted to improve accuracy and efficiencies of this test process since we first started to market such services in 2003. At that time, it was not uncommon to have patients waiting anywhere up to two years to receive their test results from the state funded laboratories. Testing was performed by all manner of different test protocols among the state laboratories and many of these were slow and sub-optimal in their specificity and accuracy. GTG in 2003, for the first time in the Australian market, introduced full DNA sequencing – the acknowledged gold-standard - for its *BRCA* testing process. Turn around time was reduced to months and today we can fast track such testing to within the same week. We contend that we have materially improved this aspect of healthcare and that we have provided a benchmark against which many of the state laboratory services can be measured. In this way and by our own service activity, we believe that we have been a positive contributor to improving the health and well being of the Australian people.

In the context of GTG offering commercial testing for *BRCA* and the impact this may have on the costs of healthcare, we contend that our service has met a previously unfulfilled demand in the Australian health care sector. We do not force any customer to use our service and we charge a publicly published price. GTG contends that it operates the most cost effective *BRCA* testing laboratory in the country and would welcome any subjective review of efficiencies and costs-charges incurred for such testing across all laboratories. It is a salient point that in all the time GTG has been offering these services, we have not been asked to tender in an open and transparent manner by any state or federal Health body – we would welcome such a process.

As presented in the body of this submission, GTG is an Australian company built on so-called "gene patents". We are a significant contributor to the Australian economy and have produced a positive contribution (~ $60 million) to Australia's balance of payments. We are proud of our innovative, intellectual and inventive foundations and of our role in helping make Australia a world leader in the Biotechnology sector. We have been praised as a role model in encouraging other inventors, both in the private sector and the Universities, to have faith in their creative thoughts, innovation and hard work and to believe in a patent system that will ultimately reward their sacrifice.

GTG would be open to any request to give evidence to the public hearings flagged in the invitation for submissions to this inquiry.

End of GTG submission to the Senate Community Affairs Committee Inquiry into
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