genetic technologies

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

Patent Amendment (Human Genes and Biological Materials) Bill 2010 –
Submission by Genetic Technologies Limited

Executive Summary

Genetic Technologies (GTG) has not strayed far from the centre of the gene patenting debate since its inception. We hope that some of the arguments respectfully set forth in this submission will demonstrate to the Committee how potentially damaging the Patent Amendment (Human Genes and Biological Materials) Act 2010 (the Bill) could be to the Australian biotechnology industry as a whole. With specific respect to gene patents, the Bill as it currently stands does nothing to improve access to diagnostic tests (including BRCA), furthermore with the publication of the human genome and the refined national and international guidelines on patentability, we believe that the proposed legislation is simply out of date and unnecessary.

Genetic Technologies' respectfully submits that, rather than unilaterally deciding to adopt the Bill, a more vigorous and thorough debate is had to educe and better understand the issues at stake; and it is then hoped that further detailed consideration is given to the issue. It is GTG's respectful submission that:

- the Bill as it currently stands is very broad;
- the scope and reach of the Bill extends well beyond the patenting of human genetic material;
- the Bill potentially impacts a broad range of entities associated with biological innovation; and
- evidence does not support the view that:
    - the cost of new technologies captured by the Bill will be reduced;
    - access to these new technologies will be increased; or
    - investment in, or innovation of, these new technologies captured by the Bill will be improved.

Many of the general public appear to have strong almost innate views on the issue of patenting medical technology. This has certainly generated a great deal of political media interest. For some people with these strong views they appear to simply back-fill their argument with popularised rhetoric rather than empirical data, in support of a Bill which we believe goes far beyond their perceived initial mischief. To this end we feel that there are strong counterarguments, and although not as glamorous, they are worthy of attention.

Genetic Technologies Limited • **Website**: www.gtg.com.au • **Email**: info@gtg.com.au ABN 17 009 212 328
Registered Office • 60-66 Hanover Street Fitzroy VIC 3065 Australia • **Postal Address** P.O. Box 115 Fitzroy Victoria 3065 Australia
Phone 61 3 8412 7000 • **Fax** 61 3 8412 7040

It is our respectful opinion that if the Bill is seeking to right a perceived wrong with regard to the patenting of human genes, it goes far beyond this point.

Banning the patenting of genes would potentially affect GTG's future business operations:

If part of the thrust of this Bill is to curtail the operations of companies like GTG then it is worth noting that GTG's day-to-day operations as they currently stand will not be affected by the enacting of this Bill.[1] GTG's future business operations however, would likely be affected. In March 2010 GTG acquired BREVAGen™, a fully validated first in class breast cancer risk staging from a company in the United States. A component of the BREVAGen™ test is a panel of genetic biomarkers which have been shown to reflect a woman's five year and lifetime risk of developing breast cancer when assessed in conjunction with certain phenotypic factors. The U.S. company GTG purchased the BREVAGen™ asset from spent in excess USD 50M bringing this test to market. Like many other companies involved in technology commercialisation, GTG has serious concerns on the potential commercial impact such a broadly worded Bill would have with regard to a proposed Australian launch of BREVAGen™. This could have serious implications for the women of Australia. Despite the rhetoric behind the introduction of the Bill being to foster and promote research and development and improve access to novel and potentially beneficial technologies, it may be the case that if this Bill proceeds to enactment many new technologies simply will not come to Australia. As is further detailed below patents over medical innovation are, we believe, fundamental and critical to the biotechnology industry.

BRCA rights and testing in Australia is another example of the fact that if patent rights are not respected, companies such as Myriad, who spend hundreds of millions of dollars bringing medical innovation to market may simply go elsewhere. Recently Myriad chose to abandon one of the BRCA patents in the face of an action brought in the Federal Court of Australia. Australia simply does not have the market size in most cases to warrant a company entering the market on shaky commercial footing (as would be the case, we argue) if this Bill were to be enacted in its current form. Further examples have been provided below.

People's reflexive, emotional opinions appear to be dominating this debate at present. The proposition that patenting of medical innovation impedes research which in turn impedes medical advancement simply is not supported by empirical data. We invite those with this view to present empirical data (rather than opinion) to show otherwise:

One point must be made very clearly from the outset, despite the title referencing "*human* genes and biological materials", the proposed Bill in its current form appears at first blush to be very broad. In the substantive text of the Bill the supplied definition of "biological materials" is: DNA, RNA, proteins, cells and fluids. The list is non-inclusive, not limited to material of human origin and could be taken to include items such as: genes, nucleic acids, proteins, vaccines, antibodies, monoclonal antibodies, microbes, antibiotics, enzymes, hormones, immunoglobulins, stem cells, anti-toxins, anti-venoms, tissue and the list goes on. Basically a who's who of biotechnology research, development and commercialisation.

[1] GTG's foundational non-coding DNA intellectual property estate contains no claims to genetic sequences, DNA, biological materials or the like.

We respectfully submit that patents over medical innovation 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.[2] [3]

With specific respect to gene patents, we submit that the context for patenting DNA sequences has changed markedly since the 1990s. The publication of the human genome and the accumulation of filed patent applications have drastically reduced the scope for discovery of novel DNA sequences. At the same time national and international guidelines, along with developments in case law and prior art, have raised the bar on patentability. We believe that the proposed legislation is out of date and unnecessary.

If the Bill is seeking to right a perceived wrong with regard to the patenting of human genes, we believe it goes far beyond this point.

Another interesting fact to consider is that many publicly-funded research entities require privately-funded companies to convert their basic discoveries into a viable improvement or output in diagnosis or treatment. One such publicly-funded research entity recently announced the commercialisation of a genetic test for Cancer of Unknown Primary developed in conjunction with several commercial entities.[4] This same publicly-funded research entity also offers BRCA testing commercially in Australia, un-licensed. It seems that some parties can approbate and reprobate as they see fit. Many of these Australian research institutes rely heavily on revenues from commercial activities.

We respectfully submit that private investment is usually contingent on access to patent rights protecting a sustainable competitive advantage. Good ideas will potentially sit on the shelf (even if they were generated by public institutions) without market exclusivity sufficient to drive commercialisation. This will be further impacted in the diagnostic arena if the proposed changes to the regulatory frameworks (both TGA and FDA) are enacted which require expensive preclinical testing to be compulsory for new diagnostic tests. Without patent protection such prerequisite studies would not be viable.

It is our view that in its purest form the patenting of medical innovation has not been shown to impede medical research, in fact the available data actually supports the point in the alternative. Again, this appears to be a case of people's emotions filling in the gaps where the empirical data clearly says otherwise. It has been asserted that Myriad's BRCA1 patents have impeded research, whereas the reality is there has been no reduction in the rate of peer-reviewed scientific publications containing BRCA1 sequence information since publication of the patent in 1998. Indeed there have been 184 such publications from Australia during this

---

[2] 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**

[3] 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.

[4] Circadian Technologies Limited ASX release 29 February 2009

time period.[5] Another good example of this can be seen with an Australian discovery and invention: Granulocyte macrophage colony stimulating factor (GM-CSF). This natural chemical was discovered in the 1970s, patented in most major territories in 1989 and progressed to market as *Leukine* by Immunex and as *Prokine* by Hoechst. Between 1976 and 2010 there were 4,500 peer-reviewed scientific publications with GM-CSF in the title. Australia, and a local Melbourne research hospital in particular, is one of the top publishers. Again there has been no reduction in the rate of peer-reviewed scientific publications containing GM-CSF information since publication of the patents in 1989. Of further note on this topic, is the fact that publication rates for GM-CSF or for BRCA were similar in the USA, Australia and those territories (such as Canada) where no patents exist.

Researchers already have unfettered access to patented technologies for research purposes, researchers already have access to published human genome sequence data, a patent for a diagnostic test itself (the method thereof) will still likely be patentable despite the Bill and perhaps most importantly the fundamental premise of the statute of monopolies enacted back in 1623 was full disclosure in return for market protection for a specified period of time. Stifling human advancement and secrecy was the exact thing that Act (the precursor to modern day Patent legislation) set out to avoid.

Argument has also been put forward that monopoly rights over medical innovation reduces patient access and drives up prices. The point is often made that making these technologies "open source" will bring down prices, benefiting all. Whilst GTG will make an argument to suggest that removing intellectual property protection will discourage investment in research and development at the outset (and hence the generation of new technological innovation *ab initio*), published research comparing Myriad's exclusive BRCA genetic test with two colon cancer genetic tests also offered by Myriad is an example directly on point where making certain technologies more accessible through multiple competitors (several not for profit) had no appreciable effect on price. The licensing of Myriad's breast cancer BRCA technology has remained exclusive, whilst Myriad's colon cancer testing technology has been non-exclusively licensed worldwide. Testing costs for the colon cancer test are not appreciably cheaper when performed by non-profit organisations.[6]

Reading through the submissions of various other parties with views contrary to GTG's, we have been amazed at the level of rhetoric which has been offered-up without a scrap of empirical data with which to support it. We politely invite those out there with the view that patenting medical innovation: impedes research, reduces investment in research and development, reduces access to new drugs/diagnostic tests etc. to present actual data (rather than their strongly worded opinion) to show otherwise.

---

[5] Clark, J. "Do patents and IP protection hinder research?" presentation by the Walter Eliza Hall Institute of Medical Research 11 February 2011, cited electronically at http://ausbiotech2010.com.au/speaker-presentations

[6] Cook-Deegan R, *et al.,* Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: Comparing breast and ovarian cancers with colon cancers. *Genetics in Medicine* (2010). 12(4): S15-S38.

No patents → No investment. No investment → No research. No research → No medical innovation.

In the area of biotechnology, products generally take seven to 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. Patents currently allow this. Patents encourage publication of research and invention as distinct from the alternative market tool 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. This in turn advances science. We respectfully submit that there would be significant negative consequences on innovation and research if the Bill were to impose limits on patentable subject matter. This would also be compounded through resultant administrative and legal complications and the confusion that would no doubt ensue. This has been exemplified in the European and UK experience.[7]

A number of parties have in the past expressed concern and criticism over GTG's 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 for screening of the BRCA1 and BRCA2 genes for predisposition to breast and ovarian cancer. 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 inventions. 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.

In summary, we respectfully submit that Genetic Technologies Limited does not support the proposed Bill; and that:

- the Bill as it currently stands is very broad as it extends well beyond the patenting of human genetic material. This has serious potential ramifications for the Australian biotechnology industry and other such industries associated with biological innovation;
- the Bill does not in fact achieve one of its main aims: promoting better access to medical tests, as diagnostic method patents are not covered by the Bill;
- unsupported opinion, rather than empirical data, appears to foster the view that research is impeded by patents over medical innovation. Researchers already have access to patented technologies for research purposes; and
- unsupported opinion, rather than empirical data, appears to foster the view that investment in future innovation captured by the Bill will not be severely impaired. It is GTG's view that under a regime such as the one proposed many new technologies will likely not make it to commercialisation.

This Bill effectively mandates worse not better health outcomes for all Australians.

Thank you for the opportunity to make this submission.

---

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