

# Submission to the Senate Legal and Constitutional Affairs Committee

## Patent Amendment (Human Genes and Biological Materials) Bill 2010 - Inquiry

### Private Submission of Geoffrey Burton

---

#### Importance of the Bill

I write to support the passage of the Patent Amendment (Human Genes and Biological Materials) Bill 2010. The Bill, if passed, removes an impediment to Australian research and development. It will encourage investment in innovation; increase the value the Australia's genetic resources, support Australian medical research and increase legal certainty for biotechnological research. By doing so, it provides an incentive for the owners and managers of Australia's biological resources to conserve and make available biological resources for commercial scientific investigation.

The Bill corrects an anomaly in the Australian patent system and aligns the system with its public purpose. Moreover, it makes it consistent with intellectual property policy of the government of the world's largest intellectual property market – the United States. A copy of the legal and policy opinion of the United States Government on the non-patentability of genes (genomic DNA) is at [Attachment A](#).

#### Relevant Qualifications

This submission is made in my private capacity. I would ask the Committee however to note that I current hold the position of Adjunct Senior Fellow, United Nations University Institute of Advanced Studies and was formerly Australia's nominee to the Convention of Biological Diversity as its Competent National Authority for Genetic Resources.

#### Importance of Genes to Australia

Australia is a megadiverse country. It holds 9.6 % of the world's species - much of it unique, ancient and rare<sup>1</sup>. Accordingly Australia has an abundance of genetic resources. The successful utilisation of the genetic make-up of this huge resource depends on the creation of legal certainty for users and for the creation of a race-to-market for new products and processes developed from these species.

The economic value and public health importance of genetic resources found in nature is demonstrated by US National Institutes of Health research that shows 75% of all anticancer drugs are derived from molecules found in nature and that 50% of drugs sold globally are similarly derived (see [Attachment B](#)). Despite Australia's burgeoning biotechnology industry and medical research sector there is a lack of research investment into Australia's genetic resources. An impediment to investment is the existence of the capacity to patent genes found in nature. It prevents other

---

<sup>1</sup> [Arthur D Chapman Number of Living Species in Australia and the World 2005 \(Australian Government\)](#)

researchers from developing new and useful products once a specific gene is patented. This inhibits public and private research investment and produces research self-censorship through fear of litigation.

Australia provides world-class legal certainty for users of genetic resources from Commonwealth areas through regulations under the Environment Protection Biodiversity Conservation Act 1999.<sup>2</sup> In addition, all nine Australian Governments (through COAG) have agreed on a common approach to the utilisation of genetic resources in their respective jurisdictions.<sup>3</sup> The continued existence of the ability to patent individual genes found in nature damages the ability of all Australian governments to create conditions for the maximisation of research and development on genetic resources found in their jurisdictions. It denies them opportunity to create a competitive race by users of Australian genetic resources to develop and market new products. It consequently devalues the commercial worth of the genetic makeup of Australia's biodiversity and denies Australian governments, institutions and private landowners the opportunity to obtain a fair and equitable share in the benefits flowing from the utilisation of their genetic resources.

#### Bad law

It is the agreed presumption that within Australia and in other jurisdictions that patent protection is granted where an invention satisfies three conditions: it is novel, useful and is inventive. In the ordinary course of events things found in nature do not meet these criteria. Trees, rocks and waters may be useful and may be new (to man) but they are not inventions. Accordingly they do not qualify as patentable. It is an anomaly that they do so in the case of genomic DNA.

Mere discoveries do not constitute inventions. Blurring this principle brings the Patent system into disrepute and hinders innovation and economic efficiency. The Patent Amendment (Human Genes and Biological Materials) Bill 2010 seeks to redress this anomaly and correct the balance between invention and discovery.

The proponents for this Bill are not alone in this view. The government of the United States takes the view that genomic DNA is not a product of nature. At Attachment A page 18 it says in relation to the BRCA gene (breast cancer gene):

#### **Unmodified Genomic DNA Is A Product Of Nature.**

No one doubts that the native BRCA genes *in situ* are products of nature. The unique nucleotide sequence that induces human cells to express the BRCA1 protein was not invented by appellants or, for that matter, by scientists at NIH. Nor was the fact that certain mutations in those sequences and not others (see, e.g., claim 7 of the '282 patent) are associated with an increased risk of breast and ovarian cancer. The BRCA genes, their deleterious alleles, and their relationship to breast cancer are the products of evolution, not human invention. Like the mutually non-inhibitive qualities of the bacterial strains in Funk Brothers, the cancer-inhibitive qualities of the BRCA gene products are

---

<sup>2</sup> See link:

< <http://www.environment.gov.au/biodiversity/publications/access/regs/pubs/regs.pdf>. Accessed 25 February 2011

<sup>3</sup> Seen Link <http://www.environment.gov.au/biodiversity/publications/access/nca/index.html> accessed 25 February 2011

“manifestations of laws of nature, free to all men and reserved exclusively to none.” 333 U.S. at 130.

Indeed, the relationship between a naturally occurring nucleotide sequence and the molecule it induces a human cell to express — that is, the relationship between genotype and phenotype — is simply a law of nature. The fact that a particular segment of the human genome codes for the BRCA1 protein in a human cell, for example, rather than for adrenaline or insulin or nothing at all, is not within the power of science to alter. Such basic natural relationships may not be the subject of a patent.

The United States government in its amicus curiae brief goes on to rebut the four major arguments used to justify the granting of patents over genes: namely that;

- “Isolation” transforms a product of nature into a man-made invention.
- Isolated genomic DNA is patent-eligible merely because it is a literal composition of matter
- Isolated genomic DNA is rendered patentable on the theory that it is “pure”
- Isolated genomic DNA is patent-eligible because it is useful or requires investment to identify.

Each of these arguments has been used in the Australian context and each is flawed. The view that extraction of DNA, even if the result of complex and expensive application of technology, justifies the grant of a patent fails to meet the criteria for a patent for want of an inventive step or novelty. Nor does the assertion that extracted DNA warrants the grant of a patent because it is pure and that DNA is itself a complex chemical composition have validity. Gold is not found in pure form in nature. It requires the hand of man to remove impurities to create pure gold. Yet pure gold is not an invention nor is it novel. It may be uncommon, but does not qualify its refiner to claim patent protection over pure gold. Similarly, many minerals and all biological matter found in nature are complex chemicals but again, this does not, of itself, justify the grant of patent protection. To do so would allow the patenting of the nature.

Moreover, the claim that the act of isolation of a gene turns it into an invention fails the crucial tests for the grant of a patent. Isolation is not inventive; it is an application of an existing process. The result may be a discovery but it is not an invention. Indeed, the argument contains a fatal flaw: if the isolated DNA is an invention, then it has to be different from the DNA found in nature. But if it is different from DNA found in nature, the patent holder cannot claim monopoly protection against users of the same DNA found in nature. The claim defeats itself.

For these reasons, and for the reasons set out above, the Committee should support the Bill as presented. Patent protection is granted for inventions that are novel, useful and contain an inventive step. As demonstrated, the patenting of genes found in nature does not meet this test and patent law should be amended to reflect this fact. Failure to do so involves significant costs to Australian innovation and economic efficiency.