

Australian Patents Act - proposed amendments to prevent gene patenting

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A private member's Bill, the Patent Amendment (Human Genes and Biological Materials) Bill 2010 was recently introduced in Australia's Parliament. The Bill, originating in the Senate, is sponsored by Liberal senator Bill Heffernan, Labor MP Melissa Parke and independent senator Nick Xenophon.

The Explanatory Memorandum for the Bill states that the amendments proposed in the Bill will "advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials...that are identical to such materials as they exist in nature."

The purpose of the Bill as stated by Senator Heffernan during its introduction is "to amend the Patents Act 1990 to prevent the patenting of human genes and biological materials existing in nature." In particular, the Bill will amend section 18 of the Act to add a further definition of what is not a patentable invention:

“biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.”

A definition of biological materials as including DNA, RNA, proteins, cells and fluids will also be added.

This Bill appears to have been put forward in reaction to the gene patents debate that is underway in Australia and other countries. In his introductory speech, Senator Heffernan said:

I [question] the legality of a practice which had allowed [a patentee] and its exclusive Australian licensee...to monopolise human genes BRCA 1 and BRCA 2, genes linked to breast and ovarian cancers. No one invented these genes. Yet, relying on four patents granted by IP Australia, on 8 July 2008 [the licensee] attempted to close down all public laboratory genetic breast and ovarian cancer gene testing when it sent a letter threatening to sue each of them for patent infringement. I said then and I say now that this is a disgrace.

AusBiotech, Australia’s biotechnology organisation, has called for an informed debate on the issue. In its press release of 18 November 2010, AusBiotech stated that it supports access for patients to life-changing medical tests, therapies and devices. It also supports a research exemption to patent infringement, and the certainty derived from the patent system in driving and facilitating medical innovation, which gives us social and economic benefits, including the development of new diagnostic tests based

on genes.

These pursuits will be impacted in an unintended manner if the fundamental changes to the Patents Act that are being called for are allowed to proceed.

The outright banning of gene patents, which campaigners are seeking, will undoubtedly reduce, and in some cases eliminate, investment in related research, and ultimately is more likely to profoundly diminish public access to future gene-based developments in healthcare.

The Bill has been referred to the Senate Legal and Constitutional Affairs Committee, which is due to report back to Parliament on 16 June 2011. The Committee is seeking written submissions from interested individuals and organisations. Submissions close 25 February 2011.