Freehills

Senate Committee rejects proposal to ban Australian gene patents

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In brief

- A Bill to exclude genetic and biological materials from patent protection has been rejected by the Legal and Constitutional Affairs Legislation Committee of the Australian Senate.
- While the outcome is not certain, it appears more likely that the Australian legislation will not be amended to remove protection for inventions related to biological subject matter.

Background

As of about 2004, the matter of patent protection for genetic material has been under consideration by various Australian committees and commissions. These considerations culminated in the introduction of the Gene Patent Bill[1] into the Senate last year. The Senate referred the bill to a Senate Committee for consideration in 2011.

Also during this time, the Intellectual Property Laws Amendment Bill[2] for raising the threshold for obtaining a patent, and for exempting patent infringement arising from acts done for experimental purposes, or in connection with obtaining regulatory approval of a non pharmaceutical product, has been under consideration by the legislature.

Yesterday, the Committee rejected the Gene Patent Bill, and we report here the key issues reviewed and considered by the Committee.

Senate Committee review

Discovery and invention

The Committee was of the view that the relevant provisions of the Gene Patents Bill would make the distinction between discovery and invention more obscure than alleged.

Importantly, the expectation of the Committee is that the Intellectual Property Laws Amendment Bill 'would tighten the requirements for the grant of patents in all fields of technology through proposals to raise the standards for inventive step, usefulness, and disclosure of inventions'. The Committee also considered that a statutory codification of the case law regarding the definition of 'inherently patentable' subject matter might add clarity as to the issue of the difference between discovery and invention. These latter proposals were preferred over those in the Gene Patents Bill.

Scope of the Bill

The Committee was of the view that the broad scope of the Gene Patents Bill and its imprecise language would create a risk that worthy inventions, which meet all the other requirements of patentability, would be unable to obtain patent protection.

Access to healthcare

No evidence was received by the Committee that patents on human genes are systematically leading to adverse impacts on the provision of healthcare in Australia. Further, the Committee was of the view that the enactment of the Gene Patents Bill would not resolve the issue which had focussed public attention on the patenting of human genes, namely BRCA1 and BRCA2 genetic testing.

Freedom to research

The view of the Committee was that the Gene Patents Bill would not provide certainty to researchers regarding patent infringement and research freedom.

Importantly, the expectation of the Committee is that the Intellectual Property Laws amendment Billl is to 'clarify that

research and experimental activities relating to patented inventions are exempt from infringement'.

Investment in research and development

The Committtee was of the view that the evidence that it received indicated that patents over human genes have not hindered research in Australia, and in contrast, the Committee noted clear evidence that the relevant patents have encouraged and contributed to research and development activities.

Access to new products and knowledge

The Committee stated 'there is a clear risk that, without certainty in relation to patent protection for biological materials, companies will have less incentive to develop and commericalise new products for the Australian market', so that consumers would lose access to new products.

Ethical considerations

The stated view of the Committee is that a preferred approach to handling the ethical issues said to arise from human gene patents is to amend the legislation to provide an exclusion to patent protection for inventions from which ethical issues may arise. The exclusion is not to be technology specific, as proposed by the Gene Patents Bill.

International considerations

The Committee was of the view that the enactment of the Gene Patents Bill could breach international obligations under the TRIPS agreement to allow for patent of inventions in 'all fields of technology'.

Crown use and compulsory licensing

The Committee was not persuaded by the argument that the relevant licensing regimes are ineffective merely because evidence had showed that they have been rarely utilised.

What is perhaps of more importance is the concern of the Committee that the relevant provisions may be complex and on this point the Committee indicated that the subject of Crown Use (whereby an entity acting on behalf of the government may, in the relevant circumstances, exercise rights in the invention) may be an appropriate topic of future inquiry.

Implications

What becomes clear is that there are high expectations that the Intellectual Property Laws Amendment Bill, now before the legislature, should relevantly deal with the issues said to arise in relation to gene patents. It follows that prospective Australian patent applicants should develop an understanding of that Bill, and in particular should take note of the proposal in that Bill to include a new ground of validity, namely 'usefulness', ostensibly mirroring US Patent Law.

It will also be interesting to monitor for developments in Australia regarding Crown use, compulsory licensing and exclusion for inventions based on ethical considerations.

This article was written by Tom Gumley, Partner, Freehills Patent & Trade Mark Attorneys.

Endnotes

1. Human Genes and Biological Materials Bill 2010
2. Intellectual Property Law Amendment (Raising the Bar) Bill 2011

More information

For information regarding possible implications for your business, contact

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