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Commercial Law Update

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Raising the bar? The new patent law reforms and their impact on patentability of genetic material

On 22 June 2011, the Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 (Cth) (the Bill) was introduced to the Senate. If passed, it will represent the most significant reform of Australia's patent laws in recent history.

While the scope of the Bill is extensive, this article will specifically focus on the substantive patent reforms set out in Schs 1 and 2 of the Bill. The article then examines these proposed patent reforms in light of the broader public debate regarding the ethics and validity of gene patents.

BACKGROUND

An exposure draft of the Bill was first released in March 2011 and received much public comment and criticism. The release of the exposure draft followed a series of reports and inquiries, including the Australian Law Reform Commission (ALRC) report on gene patenting and health released in June 2004,¹ Australian Council on Intellectual Property (ACIP) reports released in November 2005 and February 2011,² a Senate Committee inquiry³ and IP Australia consultations. The Bill incorporates some, but not all, of the changes recommended by those reports and inquiries.

WHAT ARE THE KEY CHANGES FOR PATENT APPLICATIONS?

Schedule 1 of the Bill proposes a number of significant changes to the Patents Act 1990 (Cth) (the Act), including the following.

- » Increasing the patent examiner's powers: The Bill will remove the current restrictions on the type of information that patent examiners may consider when determining whether an application discloses an "inventive step" or an "innovative step". Also, examiners will be entitled to consider matters beyond "inventive step" and "novelty" during the reexamination stage.
- » Increasing the threshold for patentability: There is a more stringent test for the usefulness of a patent requiring a demonstration of "specific, substantial and credible use". Further, there is a new requirement that applications must disclose the usefulness of the patent in the specification, and the examiner must report on the usefulness of an application at the examination stage (rather than this only being raised by interested parties at the opposition stage).
- » More disclosure: The Bill increases the standard and amount of information which applicants are required to disclose to satisfy a provisional application. If the application has incomplete information, it could impact on the priority date.
- » Consistent standard of proof: The Bill replaces the existing inconsistent standards of proof with a new consistent "on the balance of probabilities" standard. This replaces the applicant friendly "benefit of the doubt" test for the granting of patents, and also changes the requirement that an examiner be "practically certain" that a granted patent would be invalid before rejecting the application.
- » Limiting amendments to patent applications: There is a new prohibition on amendments to applications which add new material to the disclosure contained in the specifications as filed. Any such amendment will be refused where it seeks to add material that a hypothetical skilled person could not directly derive by reading the information in the specification as filed.

Footnotes

¹ ALRC, Genes and Ingenuity: Gene Patenting and Human Health, Report 99, August 2004.

² ACIP, Patents and Experimental Use, October 2005; and ACIP, Patentable Subject Matter: Final Report, December 2010.

³ Senate Standing Committee on Community Affairs Inquiry into Gene Patents, 2009; Senate Community Affairs References Committee, Gene Patents, November 2010; Senate Legal and Constitutional Affairs Committee Inquiry into Patent Amendment (Human Genes and Biological Material) Bill 2010 (Cth).

⁴ Senate Standing Committee on Community Affairs Inquiry into Gene Patents, 2009; Senate Community Affairs References Committee, Gene Patents, November 2010; Senate Legal and Constitutional Affairs Committee Inquiry into Patent Amendment (Human Genes and Biological Material) Bill 2010 (Cth).

NEW EXEMPTIONS AGAINST PATENT INFRINGEMENT

Schedule 2 of the Bill expands and clarifies the types of activities that may be undertaken without infringing on the patent holder's rights.

Regulatory approval exemption

"Springboarding" refers to laws that allow generic companies to conduct activities that relate to obtaining regulatory permits and approval prior to the expiry date of a patent. Without springboarding laws, the monopoly enjoyed by a patent holder extends beyond the 20 years contemplated by the Act. Also, competitors from countries where springboarding is permitted are able to enter the market faster than an Australian generic company.

In 2006, the Act was amended to allow springboarding in relation to pharmaceutical products. The Bill proposes to expand this exemption to all products requiring regulatory approval. The activities must be undertaken solely for the purpose of obtaining regulatory approval, and would not apply to activities undertaken for a concurrent commercial purpose.

Research exemption

Currently, there is no exemption under the Act for research and experimental use of a patented invention. In practice, research institutions tend to rely on an assumed implicit freedom to conduct research and experiments.⁴ However, recent attempts by Genetic Technologies Limited (GTG) to enforce its BRCA patents (as discussed below) highlight the uncertainty faced by researchers where patent rights are involved.

The Bill introduces a specific legislative exemption for acts done for experimental purposes and a nonexhaustive list of activities that would fall under the exemption. This list currently exempts the following activities relating to a patent:

- » determining the properties of an invention;
- » determining the scope of a claim relating to the invention;
- » improving or modifying the invention;
- » determining the validity of the patent or of a claim relating to the invention; or
- » determining whether the patent or the invention would be, or has been, infringed by the doing of an act.

What is considered as "experimental purposes" is otherwise undefined and the word "experimental" is intended to have its ordinary English meaning.⁵

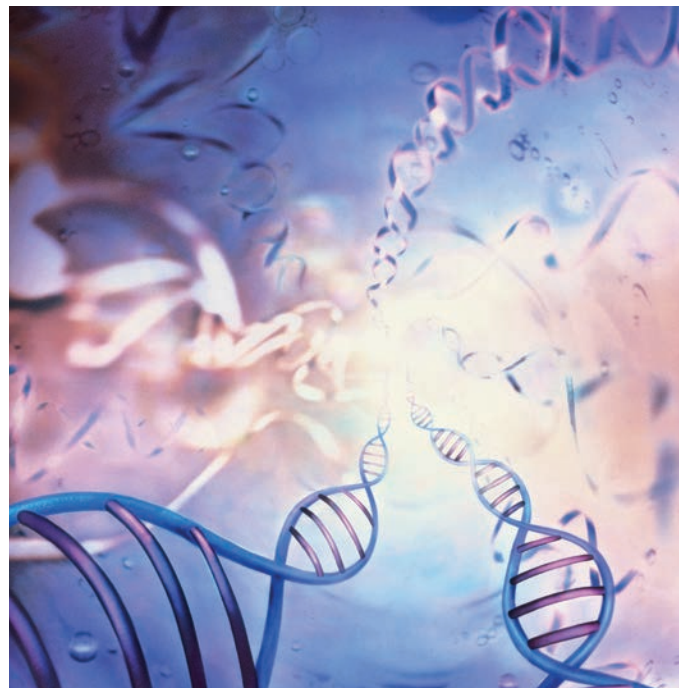
The Explanatory Memorandum to the Bill states that the exemption is sufficiently broad to encompass activities that may have future commercial applications, as long as they are conducted primarily for the purpose of research rather than having a predominantly commercial purpose.

The activities need to "relate to" the patented invention in the sense that it forms part of the subject matter of the experiment, whether as a central topic of research or subsidiary to it. Therefore, patented tools used for research but which do not form the topic of research will not be exempt.

WHEN WILL THESE CHANGES TAKE EFFECT?

If the Bill is passed, the Sch 1 changes will commence 12 months from the date of royal assent. This translates into a date in late 2012, assuming that the Bill is passed by Parliament relatively speedily. Importantly, the Sch 1 changes will not apply to patent applications where a request for examination has been filed before the date of commencement. Applicants who want the benefit of the current patents regime should therefore file their request for examination as soon as possible.

The Sch 2 changes will commence the day after the new legislation receives royal assent.



Footnotes

⁵ Explanatory Memorandum to the Bill.

GENE PATENTING IN AUSTRALIA

Patents over genetic material have received much attention. Although the current law specifically excludes the patenting of "human beings and the biological processes for their generation",⁶ gene patents are granted for isolated genetic material that satisfies the tests for patentability. The controversy lies in the fact that unrestrained monopolies on genetic material may have a profoundly adverse impact on researchers and the public.

At the centre of the global debate are patents held over the BRCA1 and BRCA2 genes, which are associated with the development of breast and ovarian cancer.⁷ A US District Court in 2010 held that the BRCA genes were not "markedly different" from natural DNA, and the claims for analysing and comparing the genes were "mental processes" and therefore not patentable under US patent laws.⁸

GTG is the exclusive licence holder of the BRCA gene patents in Australia. In 2002-2003 and 2008, GTG sparked headlines when it issued "cease and desist" letters to hospitals and laboratories across Australia to prevent them from carrying out testing in relation to the BRCA genes.⁹ Although GTG ultimately withdrew its threats on both occasions, its actions have provoked general public outcry, the overhauling of GTG's own board of directors¹⁰ (twice), two Senate Standing Committee inquiries,¹¹ the introduction of a private member's Bill in the Australian Parliament,¹² and a pending case in the Federal Court of Australia.¹³

Legislative interventions

The Patent Amendment (Human Genes and Biological Materials) Bill 2010 (No 2) (Cth) (Heffernan Bill), introduced by Senators Heffernan, Coonan, Siewert and Xenophon, was a direct

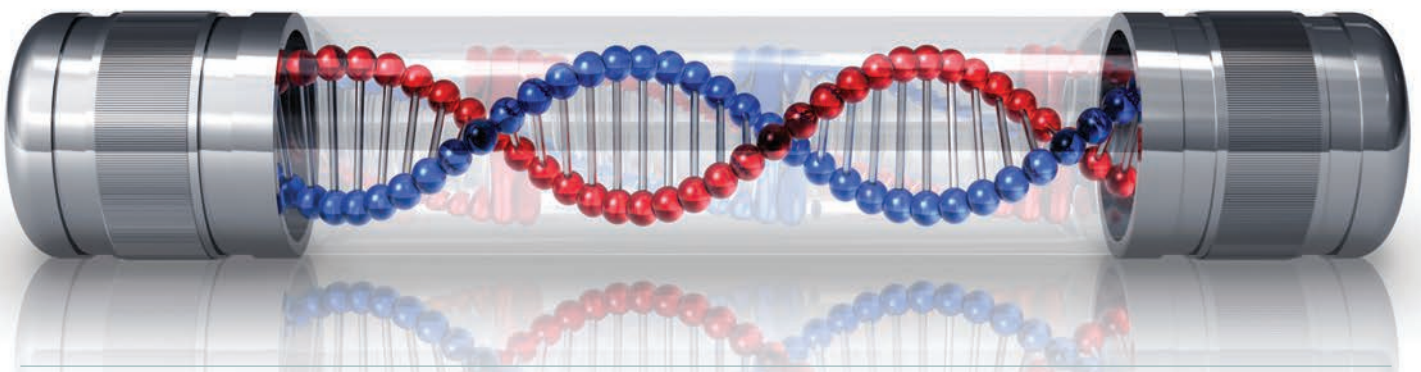
response to GTG's actions. It sought to expand the current ban on patenting biological material to include:

*... 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.*¹⁴

Many observers, including the ACIP, are critical of such a blanket prohibition. Their concern is that the broad language used in the Heffernan Bill will cause uncertainty for the entire biotechnology industry, with no clear benefit for the general community. A further Senate Committee inquiry was convened to examine its potential impact. That Committee's report is scheduled to be released on 21 September 2011.

The current Bill before the Senate addresses the issue of gene patents in a manner that steers away from the subject matter prohibition in the Heffernan Bill. By raising the threshold of the tests for patentability, it prevents patents over genes that are not sufficiently inventive, novel or useful. This is arguably a better means of improving the quality of gene patents without eroding commercial incentives for the biotechnology industry.

In addition, the Bill's exemption for experimental use gives greater certainty to researchers on their right to conduct research and also to patent holders on when they can enforce their rights, but fails to deal with public health access issues. For example, in the case of the BRCA gene patents, the exemption leaves hospitals and cancer screening services in a grey area as their role is arguably more commercial than experimental. Interestingly, the Bill does not adopt the ACIP recommendation to introduce an exclusion that prevents the patenting of an activity that is "wholly offensive to the ordinary reasonable and fully informed member of the Australian public".¹⁵



Footnotes

⁶ Patent Act 1990 (Cth), s 18(2).

⁷ See Nicol D, "Recent decisions from the United States and Europe on patenting of biotechnology inventions and their potential impact on Australia" (2011) 24(2) IPLB.

⁸ Association for Molecular Pathology v United States Patent and Trademark Office No 9 Civ 4515 (SDNY).

⁹ Senate Standing Committee on Community Affairs, Gene Patents, 2010, ch 2.

¹⁰ GTG, "New position re BRCA testing", 2 December 2008, available at www.gtlabs.com/announcements/new-position-re-brca-testing.

¹¹ Senate Standing Committee on Community Affairs Inquiry into Gene Patents, 2009; Senate Legal and Constitutional Affairs Committee Inquiry into Patent Amendment (Human Genes and Biological Material) Bill 2010 (Cth).

¹² Patent Amendment (Human Genes and Biological Materials) Bill 2010 (No 2) (Cth).

¹³ Cancer Voices Australia (ABN 93 322 703 427) v Myriad Genetics Inc, Federal Court of Australia File NSD643/2010.

¹⁴ Above note 12.

¹⁵ Above note 2.

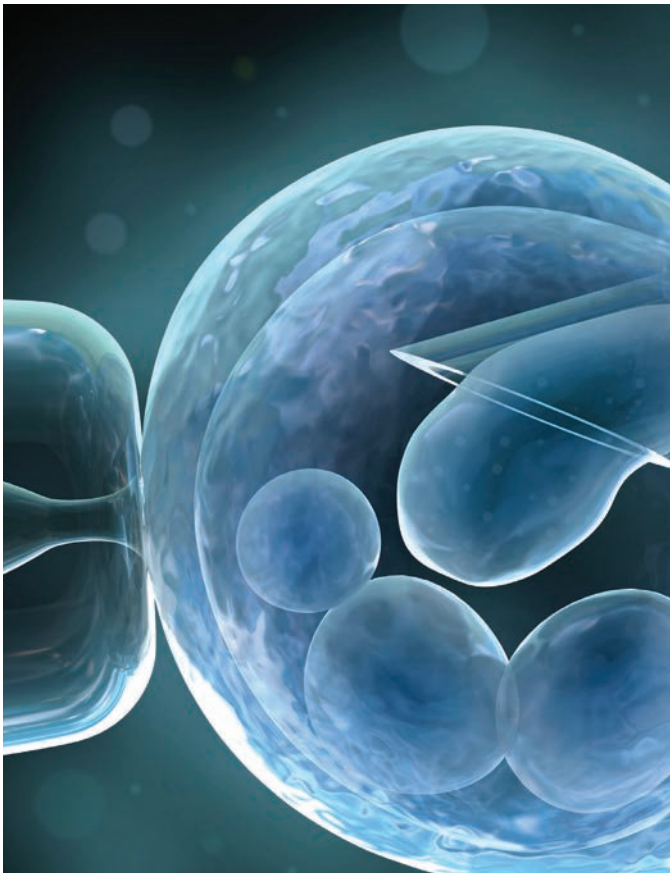
FEDERAL COURT PROCEEDINGS

In June 2010, Cancer Voices Australia and a breast cancer patient filed an application challenging the BRCA patents. This case is the first time an Australian court will examine the validity of gene patents. The final hearing is scheduled to be held in late February 2012. Ethical arguments will undoubtedly be raised by the applicants, though it remains to be seen whether the Federal Court will take a more expansive approach than that contemplated by the Bill.

CONCLUSION

If passed, the new legislation will have a significant impact on all stakeholders in the patent process -- including prospective patent applicants, generic competitors, researchers and the general community seeking to use a patented invention.

While the problems with gene patenting will be addressed to an extent by the Bill, it is likely to fall short of community expectations. In the meantime, all eyes will be on the results of the Federal Court case in relation to the BRCA genes.



Tip 1: File your request for examination as soon as practicable if you want the benefit of the current regime.

Schedule 1 of the Bill will not apply to current patent applications where a request for examination has been filed before the date of commencement of those changes (expected to be late 2012).

Tip 2: Take advantage of the new research and experimental use exemption and the regulatory approval ("springboard") exemption.

You should consider what steps can be taken now to take advantage of the new exemptions once they come into effect, which could occur by late 2011.

Tip 3: The research exemption will not extend to "research tools".

"Research tools", being something that is used to facilitate an experiment rather than being something that is the subject of the experiment, are not covered by the new research exemption.

Tip 4: There is a new requirement to disclose the usefulness of the patent in the specification and a new statutory definition of "useful".

You should consider and, if necessary, obtain advice on the impact of the new requirement to disclose the usefulness of the patent in the specification -- particularly given the new requirement to demonstrate a "specific, substantial and credible use".

Tip 5: Take extra care to ensure that no later amendments will be required.

If the Bill is passed, there will be a new prohibition on certain amendments being made after the date of filing. An attempt to add new material to the disclosure contained in the specification as filed could be refused outright or require you to lodge a new application.