

NUMBER  
**96**

# ISSUES

SEPTEMBER 2011



**INTELLECTUAL PROPERTY**

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# Patent Amendment Bill Does Not Address Community Concerns

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The *Patent Amendment (Human Genes and Biological Materials) Bill* was introduced to the Senate late last year and immediately referred to a new Senate Inquiry. The Bill's contents have escalated concerns about this long-running and complex debate.

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**I**n my testimony to the Senate Inquiry's public hearing into the *Patent Amendment (Human Genes and Biological Materials) Bill* before Parliament in April this year, I gave evidence that the proposed Bill fails completely to address any of the valid concerns raised by the community about gene patents and should be rejected.

In this view, AusBiotech is aligned with an overwhelming two-thirds majority of the 114 written submissions made to the Senate Inquiry, including submissions from the Group of Eight, the Peter MacCallum Cancer Centre, the Royal College of Pathologists, the Walter and Eliza Hall Institute, Professor Ian Frazer, the Garvan Institute and the Consumers Health Forum.

The Bill does not serve the interests of patients, researchers or industry. In fact, the Bill threatens the very foundations of scientific research and development on biological materials, which are built on patents.

If the legislative amendment is progressed in its current form, researchers, industry and the legal fraternity have grave concerns that it would have far-reaching and unintended consequences for patient access to novel therapies, tests, vaccines, and even medical devices. Moving way beyond the banning of patents for genes, the Bill's impact will also be felt across diverse sectors of the Australian

community including those focused on agriculture and animal production and health, the development of high-yield crops, solutions to climate change and bioremediation.

Undeniably the hope of every Australian would be for a world-class health system that provided timely, safe and cost-effective access to essential treatments and life-enhancing medicines and technologies. Yet these hopes will be crushed by the Bill, as it will discourage innovation and investment in scientific and medical R&D in this country and thereby diminish or deny access to cures and treatments for illness and disease.

AusBiotech is working to demonstrate the consequences and effects of a ban on the patenting of genes and other biological materials to governments, parliamentarians, policy-makers and the general public. The Amendment would exclude from patentability "biological materials ... whether isolated or purified or not and however made, which are

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identical or substantially identical to such materials as they exist in nature”.

Sponsors and supporters of the Bill claim that its purpose is to “advance medical and scientific research and ... cure human illness and disease ... by enabling free and unfettered access to biological materials” but we challenge how that can be possible.

**Should the Bill proceed in its current form, it will cause many more problems than any issues that are currently real or perceived, because a lack of patents will lead to a lack of innovation and to a lack of novel, potentially life-altering products that are simply never developed.**

While no doubt well intentioned, we believe the Bill has missed the fundamental point. The exclusion of biological materials from patentable subject matter will not address the concerns being expressed by the Australian community. For example, patient access to the BRCA diagnostic test for breast cancer (or to any other potentially-life changing test) will not be improved by banning patents on biological materials because the patent for the test itself will still exist.

In Australia today, naturally occurring materials such as genes are already considered discoveries, not inventions, and therefore are not patentable subject matter. Yet we are perplexed by the suggested amendments to the *Patents Act 1990*, which is already crystal clear on the point that the mere identification of a new gene is not sufficient to secure a patent.

As the Group of Eight submission notes, the distinction between discovery and invention “is clear from the current wording of the *Patents Act 1990* and [we] believe that the *Patent Amendment (Human Genes and Biological Materials) Bill* is unnecessary”.

The existing law requires patent applicants to provide substantive evidence about their technology in support of its novelty, utility and inventiveness. Without reservation, we are in favour of the rigorous and consistent application

of the existing law, in relation to all technologies, to ensure the continued distinction between discovery and invention.

AusBiotech believes that the proposed Bill to prohibit the patenting of genes and biological materials will not address any of the expressed concerns. Should the Bill proceed in its current form, it will cause many more problems than any issues that are currently real or perceived, because a lack of patents will lead to a lack of innovation and to a lack of novel, potentially life-altering products that are simply never developed.

There is little evidence to support claims that gene patents stifle research or that there is currently anything other than free and unfettered access to biological materials among the Australian research community. A recent study concluded that of 381 scientists surveyed, none had their work stopped by the existence of third-party patents, only about 1% had a delay or were required to modify their work, and those that had been required to pay a fee to access patented technologies reported a modest charge in the range of US\$1–100.

In the specific case of the Myriad gene patents (and the exercise of said patent rights to which much of the controversy around this issue can be traced back), there have been over 5500 *BRCA1* primary sequence publications in the 12 or so years since the patent was granted in Australia. With no fewer than 49 Australian research organisations having contributed to this total, it is disingenuous for claims to be made that the existence of the patents has stifled national or international research in this field of endeavour.

AusBiotech is supportive of ongoing review and legislative amendment to ensure that Australian industry and researchers have a set of clear rules to guide them as they strive to innovate.

Instead of the *Patent Amendment (Human Genes and Biological Materials) Bill*, AusBiotech has welcomed a legislative Bill that was introduced into the Australian Parliament in June: the *Intellectual Property Laws Amendment (“Raising the Bar”) Bill 2011*.

AusBiotech is in general supportive of this package of intellectual property reforms developed by IP Australia and contained in the “Raising the Bar” Bill. Specifically, AusBiotech is in favour of a broad research use exemption

from patent infringement becoming enshrined in Australia's patent law so this country's researchers and industry may be confident as they strive to innovate.

In its submission to the Senate Inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill*, AusBiotech stated its belief that the thresholds for patentability should be properly set and rigorously applied across all forms of invention (i.e. in a technology-neutral manner).

Therefore, AusBiotech is in favour of the government's "Raising the Bar" Bill which, when taken together with the erudite recommendations from the Australian Law Reform Commission (1999) report, the Senate Inquiry into Gene Patents (2010) and the Advisory Council on Intellectual Property 2010 review, will deliver the solutions to address the issues identified by clinicians, researchers, industry and the community.

Patents are important parts of the package that Australian innovators use to attract critical funding to progress early research through to the proof-of-concept stage. Similarly, granted patents in key markets will inform a commercial decision to invest significant amounts of money in a technology development

plan. Since the Australian government is not in the business of spending the hundreds of millions of dollars needed to translate inventions from "bench to bedside" we rely here on corporations and venture capitalists to invest

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and take the risks to develop and commercialise novel medicines and diagnostic technologies. We envisage that the Bill will lead to a reduction in research commercialisation with the direct consequence of fewer innovative products reaching the Australian community.

If the *Patent Amendment (Human Genes and Biological Materials) Bill* does become law, Australians will be denied the improved access to health care that stimulated the debate in the first place.

## "Raising the Bar" Reforms Will Safeguard Aussie Ideas

Exporters, researchers and brand owners will be the big winners from a range of reforms proposed to Australia's intellectual property (IP) system.

Innovation Minister Senator Kim Carr said that a modern economy needs a strong IP system to protect its great ideas. The ability of Australian businesses to successfully compete in the global economy will depend on the protection of their great ideas.

"Australian ideas are our most valuable commodities that will sustain us beyond the resource booms that come and go. They should have the necessary support and protection to make them a commercial success. And these reforms will ensure that the IP system benefits all Australians," Senator Carr said.

The *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* brings significant improvements to the patent, trade mark, copyright, design and plant breeder's rights systems. The key reforms include:

- raising patent standards to ensure that Australian innovators are well placed to take their inventions to the world;

- increasing penalties for trade mark counterfeiters;
- improvements to border security measures for goods that infringe copyright and trade marks;
- providing free access to patented inventions for researchers;
- cutting red tape and delays when seeking an IP right.

"The improvements strike a balance between the level of complexity required to support a robust IP system and a need for accessibility," Senator Carr said.

"Raising patent standards will align Australia with key trading partners and mean that foreign companies can bring the best and newest technologies to Australia confident that their IP can be protected.

"The improvements raise the quality standard of our IP rights and bolster protection for innovators by raising the penalties for trade mark infringers.

"The reforms will provide a researchers' exemption from patent infringement and allow them to experiment and pursue new lines of research."

Source: Department of Innovation, Industry, Science and Research