

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 the longed-for 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 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.

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 (or to any other potentially-life changing test for that matter) 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 phenomena 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.

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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 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 had their work stopped by the existence of third-party patents, only about one per cent 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 5,500 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 Human Genes and Biological Materials Bill, AusBiotech has welcomed a legislative Bill that that was introduced into the Australian Parliament in June: The Intellectual Property Laws Amendment (Raising the Bar) Bill 2011.



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AusBiotech is generally 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 & Biological Materials) Bill 2010, 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 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 2010 does become law, Australians will be denied the improved access to health care that stimulated the debate in the first place.

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