

ARCS

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**Patent Amendment Bill does not address community concerns**

A Bill, known as the 'Patent Amendment (Human Genes and Biological Materials) Bill 2010' was introduced to the Senate late last year and immediately referred to a new Senate Inquiry. The Bill's content has escalated concerns about this long-running and complex debate, and so far has prompted 110 written submissions.

The Senate Inquiry is due to report in June 2011 and will conduct hearings in the interim, which will supplement the information provided in the written submissions. AusBiotech is amongst an estimated 65% of these submissions that either strongly opposes the Bill, or opposes the Bill but believes Parliament should investigate other options to achieve the Bill's intended goals, such as IP Australia's "Raising the Bar" Bill.

If the legislative amendment is progressed in its current or similar 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.

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. 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.

We are also 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. We fully support the ongoing work of IP Australia to introduce amendments to the Patents Act 1990 to enshrine an explicit research use exemption thereby allowing research, IP protection, innovation and commercialisation activities in Australia to continue a beneficial coexistence.

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 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 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 endeavor.

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 VCs 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 this Bill does become law, Australians will be denied the improved access to health care that stimulated the debate in the first place.