

An Open Letter to the Australian Parliament

March 2011

Patent Amendment Bill 2010 – misses the points of patient access and research exemption

We write with regard to the private members' bill, the '*Patent Amendment (Human Genes and Biological Materials) Bill 2010*' (the Bill) that was introduced in the Senate in November 2010.

Should the Bill become law we hold grave concerns about the unintended consequences on the access of Australians to life-changing medicines and diagnostics, on the ability of scientists to conduct medical research in this country and on the future of the Australian biotechnology and medicines industry.

Instead of addressing community concerns about access to innovative medicines and diagnostic tests, the Bill puts at risk such potentially life-altering products being available in a timely manner to anyone in Australia.

Australians can today be assured that the identification of a naturally-occurring biological material such as a gene is a discovery not an invention. The existing law protects this difference by requiring 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 patent system in this country, in relation to all technologies, to ensure the granting of high quality patents and the continued distinction between discovery and invention.

The Bill seeks to exclude from patentability all biological materials and so its impact will be felt across diverse sectors of the Australian economy and community including those focused on agriculture, animal production, diagnostics, vaccines and biopharmaceuticals to treat major diseases such as arthritis, cancer and multiple sclerosis.

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." While no doubt well intentioned, we challenge how this can be possible and believe that the architects of the Bill have missed several fundamental points.

There is no evidence to support the notion that patents stifle research or that there is currently anything other than free and unfettered access to biological materials among the Australian research community. Nevertheless, the common practices undertaken by our researchers would definitely benefit from an explicit research use exemption being enshrined in the law. Yet free and unfettered access of clinicians and researchers to biological materials alone will never equate to more new medicines for Australians. Indeed the opposite is more likely with fewer innovative products and technologies reaching the community since the absence of patents for biological materials will be a serious disincentive for foreign and domestic private investors and others interested in commercialising innovation in Australia.

As the Government and our hospitals are not in the business of spending the millions of dollars necessary to translate technologies from 'bench to bedside', Australia must rely on companies and financiers to take the risks and invest in the commercialisation of novel medicines and diagnostic technologies. This Bill is a tragedy in the making for a 'smart country' like Australia; Australian innovations will be lost as they follow the funding to the US, Europe and Asia. Global pharmaceutical companies may not include Australia in their market launch plans and ultimately Australians will have delayed access to new medicines and tests.

Far from advancing medical research, the ambiguous language of the Bill will seriously delay research progress by tying up parties in the Courts for what could amount to years of legal debate and cost to determine what can and what cannot be patented. Such uncertainty will surely be further disincentive to investors as it will drive up the costs of research. It's also possible that such uncertainty coupled with the lack of investor confidence arising from the absence of patents for biological materials in Australia could spill-over into other parts of our economy and trigger real or perceived views of the country's sovereign risk.

The Bill will not address the specific concern being expressed by the Australian public about access to diagnostic tests (eg: to the BRCA diagnostic test or to other potentially life-changing tests) because the patent for the test itself will still be allowable under the Bill. However, the interests and needs of the public can be protected via existing provisions that already exist in law. We believe that a review of these safeguards is needed followed by an effective legislative response to ensure the safeguards are readily-accessible and not cost-prohibitive if required.

We fully support the ongoing work of IP Australia to make improvements to the patent law and its application to support research and innovation, particularly the inclusion of an explicit research use exemption. In this way, research, IP protection, innovation and commercialisation activities in Australia will continue to enjoy a beneficial coexistence. It is critical that Australian research institutes and universities be allowed to retain the source and the benefit of significant revenue derived from royalties payable on their licensed, patented technologies.

The Bill is also inconsistent with recent events in the United States. In March 2010, the Southern District of New York Court drew a distinction between DNA molecules and other biological material and ruled that the isolated DNA and cDNA sequences claimed in the Myriad patents-in-suit were unpatentable products of nature. Responding to this ruling, the US Department of Justice (DoJ) clearly distinguished between the patentability of isolated human genomic DNA and the patentability of a range of DNA materials when they are combined with human ingenuity such as in cDNAs, gene mutants and vectors. The DoJ has called for the US Federal Court of Appeals to uphold this critical distinction by reversing the District Court's invalidation of the claims limited to DNA molecules such as cDNAs and similar man-made nucleic acid products. Regrettably, the DoJ's stand on this issue has been overstated and even misrepresented by some stakeholders participating in the debate in Australia.

Undeniably the hope of every Australian would be for a world-class health system that provides timely, safe and cost-effective access to essential treatments and life-enhancing medicines and technologies. Yet these hopes will be dashed if the Bill becomes law. It will discourage innovation and investment in scientific and medical R&D in this country and thereby diminish or delay access to the longed-for cures and treatments for illnesses and diseases.

This Bill must be rejected lest Australians be denied the improved access to health care that originally stimulated the debate.

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