

29 April 2011

AusBiotech Opening Statement

to the Senate Legal and Constitutional Affairs Committee regarding the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

Thank you for the opportunity to appear before the Committee today on behalf of Australia's biotechnology industry, to discuss an issue that is of vital importance to the public's access to new treatments, diagnostics and technologies, to Australia's biotechnology industry and to the continued growth of investment in innovation in Australia.

AusBiotech is Australia's biotechnology industry organisation, which represents over 3,000 members, encompassing medicines, medical devices and diagnostics, agricultural, environmental and industrial sectors in biotechnology.

AusBiotech shares the genuine concerns raised by the community and others:
that clinicians and scientific researchers should be free to conduct research on, or use, biological materials that may be the subject of patents;
that public access to innovative and beneficial tests and therapeutics should be improved; and
that the thresholds for patentability should be properly set and rigorously applied.

AusBiotech believes that the proposed Bill fails completely to address any of these valid concerns and should be rejected. 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 this Bill becomes law, it is likely to have far-reaching and serious consequences. In this view, AusBiotech is aligned with an overwhelming two-thirds majority of submissions made to the Senate Inquiry.

While we believe the architects of the Bill are well intentioned, AusBiotech and many others feel that the Bill has been drafted with little regard to the consequences and that the Bill actually places at risk:

- the timely access of Australians to life-changing medicines and diagnostics;
- the ability of clinicians and researchers to conduct medical and agricultural research in this country; and
- the future of the Australian biotechnology and medicines industry.

The absence of patents for biological materials will extinguish the promise of future returns, and therefore halt investment in innovation based on biological materials. Since investment will no longer be available, it will be impossible to translate novel biological discoveries through the critical R&D processes to regulatory approval. –Consequently Australians will have access to fewer new medicines, tests and technologies, and not more as is claimed by the Bill's proponents.

Further, AusBiotech believes that the interests of all sectors of the Australian community will be better served by Parliament focussing its energy on amendments to the Australian Patents Act that do not discriminate between technologies, including those involving genes and other biological materials and, importantly, those future technologies yet to be developed.

AusBiotech strongly supports:

- patentability thresholds that are properly set and rigorously applied;
- a research use exemption enshrined in the law;
- safeguards that are readily-accessible and adequate in their reach to ensure all Australians have access to beneficial technologies and are protected against a patent owner who, in the course of exercising their patent rights, may act unethically or unreasonably in granting a license to a medicine, test or technology; and

- the establishment of an additional safeguard in the form of a tribunal-like model and/or the appointment of a 'Patents Ombudsman' to whom the public, clinicians, researchers and industry could turn in the first instance with a grievance.

AusBiotech is in favour of the Government's "Raising the Bar" Bill 2011 which, when taken together with the erudite recommendations from the Australian Law Reform Commission 99 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.



Dr Anna Lavelle
Chief Executive Officer
AusBiotech Ltd