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## Media release

### The time to speak out on gene patents is now

**Responding to the introduction of legislation on the patenting of human genes and biological materials to the federal parliament and its referral to a second Senate Inquiry, AusBiotech and Medicines Australia are urging those affected to contribute their views.**

The legislative amendment proposed in the private member's bill, if progressed in its current form, would exclude "biological materials which are identical or substantially identical to such materials as they exist in nature, however made" from patent protection. This would have far-reaching and possibly dire consequences for patient access, medical research and the biotechnology and medicines industry

The bill was immediately referred to the Senate Legal and Constitutional Affairs Legislation Committee for inquiry and reporting in June 2011. Those with an interest and relevant contribution to make, have until 25 February 2011 to make submissions.

AusBiotech and Medicines Australia strongly support the view that all Australians should have access to world-class medical science. However, the amendments proposed in the private members' bill for a ban on patents for all biological materials may result in potentially life-altering products simply never being developed.

Governments are not in the business of bringing therapeutics and diagnostics to market and so we rely on a 'social contract' with industry and investors to provide the money and take the risks to develop novel medicines and diagnostic technologies.

The biotechnology and medicines industry does not dispute that the DNA sequences of humans exist without any intervention of man and thus are not considered inventions. The mere identification of a new gene is not sufficient to secure a patent - the threshold for patentability requires applicants to demonstrate "novelty, inventive step and usefulness".

The inclusion of human gene sequences in a patent has never and would never give the patent owner any rights or ownership in relation to the gene(s) that exist in the human body.

The long-standing inquiry into gene patents by the Senate Community Affairs Committee released its report last week. The Committee received 78 public submissions, including submissions from AusBiotech and Medicines Australia, and conducted eight public hearings. The Report calls for a considered approach that takes into account the complexities surrounding the debate, and recommends an amendment to include a research exemption.

With R&D programs coming at a cost of hundreds of millions of dollars, patents are an important element in the value proposition that both public and private investors consider before deciding to invest. Logically, any reduction in investment will correlate with a decrease in the number of new medicines and tests being developed. In the event that the current incentives for corporate and venture capital investment in the form of patentability disappear, the question is: Who will partner with

public research institutes and biotechnology companies to provide the money and development capability to translate Australian inventions from 'bench to bedside'?

There is little or no significant evidence to support the contention that gene patents stifle research. A recent study concluded that of 381 scientists surveyed, none had had their work stopped by the existence of third-party patents and only about 1% had a delay or were required to modify their work, and said the fee was in the range of US\$1-100. In the specific case of the Myriad gene patents, 49 Australian research organisations have published their BRCA-related results over the past 12 years.

Research activities and patents in Australia enjoy a continuing and beneficial coexistence. Nevertheless, to avoid any possibility of misinterpretation, IP Australia is currently advancing the amendment of the Patents Act to introduce a research use exemption, which was supported by the Senate inquiry's recommendations.

Both AusBiotech and Medicines Australia support the ongoing review and amendment of legislation to ensure that Australian industry and researchers have a set of clear rules to guide them as they strive to bring life-changing healthcare innovation to patients. The safeguard provisions should be reviewed to confirm they are straightforward, intelligible, not cost-prohibitive and, thereby, readily accessible to all Australians.

It is important to consider the ramifications of a ban on the patenting of biological material which would extend far beyond medicine, with serious negative impacts likely on innovations to deliver benefits in the health and productivity of plants and animals, such as the development of high-yield crops.

The amendment proposed in the private members' bill will not necessarily deliver solutions for the issues that some stakeholders are articulating. For example, as is the case with the BRCA diagnostic test, patient access to the diagnostic test will not be improved by placing a ban on gene patents. Such technologies simply may not be developed and therefore no-one will benefit.

**AusBiotech** is Australia's voice on biotechnology, and represents more than 3,000 members, encompassing medicines, medical diagnostics and devices, agriculture, alternative fuels and climate change.

**Medicines Australia** represents the research-based biopharmaceuticals industry in Australia. Our members research, develop, manufacture, market and export new medicines which help Australians live longer, healthier and more productive lives.

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