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## Media release

### Careful consideration needed before action in gene patent debate

**Responding to last week's introduction of legislation on the patenting of genes to the federal parliament and tabling of the Senate inquiry's report, AusBiotech and Medicines Australia are urging a pause for informed thought and further debate to avoid unintended consequences.**

The legislative amendment, which would exclude from patentability "biological materials which are identical or substantially identical to such materials as they exist in nature, however made" would have far-reaching and possibly dire consequences for patient access, research and industry.

The long-standing senate inquiry into gene patents by the Senate Community Affairs Committee has released its report, with 16 recommendations, primarily to make amendments to the existing provisions of the Patents Act and to ensure any proposed changes do not result in unintended consequences.

The Report aligns with the call for a considered approach that takes into account the complexities surrounding the debate, and also recommends an amendment to include a research exemption. The committee received 78 public submissions, including submissions from AusBiotech and Medicines Australia, and conducted eight public hearings.

AusBiotech and Medicines Australia share the view that all Australians should have access to world-class medical science. The proposed amendments for bans on gene patents that extend beyond human genes to include all biological materials, may result in the issue not being one of public access to diagnostics, but rather that such potentially life-altering products are simply never 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.

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 and thresholds for patentability ensure applicants must demonstrate "novelty, inventive step and usefulness" to secure a patent.

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 patents system already has built-in safeguard provisions, such as Crown Use and Compulsory Licensing, which allow the Government or third parties to exploit a patent in certain circumstances.

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 study before making a decision 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 gene patents 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 belief 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.

Both bodies support the ongoing review and amendment of legislation in this area 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 note that the ramifications of a ban on the patenting of biological material would extend far beyond the medicine, with serious negative impacts likely on innovations to deliver in the health and productivity of plants and animals, such as the development of high-yield crops.

Following through with the proposed amendment 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 new diagnostic test will not be improved by placing a ban on gene patents. The unintended consequences should be avoided at all costs as one of these may result in poor access for patients to new and much-needed medicines and diagnostics. They 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** is

For further information, please contact:

Lorraine Chiroiu, Communications Manager, AusBiotech

**M:** 0429 801 118 **E:** [lochiroiu@ausbiotech.org](mailto:lochiroiu@ausbiotech.org)

or

Jamie Nicholson

Manager, Media Communications, Medicines Australia

**M:** +61 0419 220 293 **E:** [jamie.nicholson@medicinesaustralia.com.au](mailto:jamie.nicholson@medicinesaustralia.com.au)