

Australian Life Scientist

Attention all Biotechs: Deadline for submissions to second Senate Gene Patent Inquiry Feb' 25, 2011

AusBiotech and Medicines Australia (MA) warn of dire consequences if the recommendations of the private member's bill are upheld

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AusBiotech and Medicines Australia (MA) are urging all biotech and life sciences companies likely to be affected by proposed amendments to patenting legislation, as it relates to genes and other biological materials, to hurry up and make their submissions to the second senate Inquiry before the deadline of February 25, 2011.

The call comes just weeks after a number of federal MPs and senators introduced a private members bill recommending that "biological materials which are identical or substantially identical to such materials as they exist in nature, however made" should be denied patent protection.

The bill was immediately referred to the Senate Legal and Constitutional Affairs Legislation Committee for inquiry and reporting in June 2011.

"This [bill] would have far-reaching and possibly dire consequences for patient access, medical research and the biotechnology and medicines industry," AusBiotech and MA said in a joint statement.

"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."

Both organisations reaffirmed their position on the pointlessness of allowing gene sequences to be patented, stressing also that they would offer very little in the way of commercial or research benefits to those organisations seeking them.

“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 Senate Community Affairs Committee last week released the results of its long-standing inquiry into gene patents, which attracted 78 public submissions, including from AusBiotech and Medicines Australia, as well as eight public submissions.

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.

One of the key recommendations of the report was there to be an amendment which includes an exemption for research.

“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 organisations said.

“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.”

AusBiotech and MA also reiterated their shared opposition to claims that patenting can stifle research.

“There is little or no significant evidence to support the contention that gene patents stifle research.”

They pointed to a recent study of 381 scientists which found that none had had their research derailed by the presence of patents, with just one percent of scientists reporting that they had experienced delays or were forced to modify their work.

“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,” the organisations said.

"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 disappears, 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'?"

Finally, AusBiotech and MA noted that the amendments proposed in the private members' bill will not necessarily solve the key problems that have been articulated throughout the debate, citing the BRAC diagnostic test as an example. They said that, contrary to popular belief, a ban on gene patents would not result in more patients gaining access to the test. "Such technologies simply may not be developed and therefore no-one will benefit."