

19 March 2009

The Secretary  
Senate Community Affairs Committee  
PO Box 6100  
Parliament House  
CANBERRA ACT 2600

Dear Secretary

**Re: Senate Community Affairs Committee's inquiry into gene patents**

Thank you for this opportunity to contribute to the Senate's inquiry into gene patents.

A strong and predictable intellectual property system is fundamental to Australia's ability to attract global investment in pharmaceuticals research and development. This ensures that patients and consumers here and around the world will continue to have access to innovative and more effective treatments and diagnostic tests.

Medicines Australia believes that Australia's current intellectual property legislation should **not** be changed to provide special rules for the patenting of genetic materials and gene derivatives. That is:

- patenting of gene-based technologies, so long as these are novel and useful, should continue to be allowed without restriction and (in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights) without prejudice;
- patent term restoration provisions, as they apply to pharmaceutical products, should continue to be applicable to gene patents governing medical products for which regulatory approval is required;
- patenting of techniques to isolate particular genes should continue to not be patentable **unless** a technique is of itself innovative; and
- patenting of genetic sequences *per se* should continue to not be permitted as these are mere 'discoveries' not 'inventions'; that is, they should be excluded from patentability under 'prior art' considerations.

Medicines Australia believes that statements such as, "the fiction argued by proponents of gene patents is that once they remove a gene from its natural environment [...] they have a [patentable] invention[.]", highlight a troubling confusion among some policy makers about how, and on what types of subject matter patents are granted in Australia.

Such confusion is always unhelpful. However, when it becomes the basis for changes to existing law, confusion can be disastrous.

In order to be patentable, inventions must be demonstrably novel, involve an inventive step (which would not be obvious to a similarly skilled person using existing “art”) and, perhaps most importantly, useful. It is, therefore, categorically incorrect to suggest that genetic materials and gene derivatives may be patented simply because they have been removed from their “natural environment”.

Furthermore, in order to be patentable, inventions must fall within the scope of patentable subject matter. For example, inventions considered contrary to “public morality” are considered unpatentable, so are human beings and processes leading to their generation.<sup>1</sup>

These considerations ensure that patents are only granted in Australia (as elsewhere) when there is sufficient evidence that granting them will advance innovation and not undermine equitable public access to inventions.

Medicines Australia believes that the existing intellectual property system in Australia provides an adequate balance between the competing interests of providing rewards for investment in research and development and the public good. In relation to patent rights specifically, in Australia these provide [a globally accepted] balance between those who are willing to expend tremendous resources to bring new products to market; other skilled persons who utilise “prior art” to improve or transform existing inventions; competitors who wish to enter the market; and, society as a whole, which expects and deserves access to innovative products at fair and affordable prices.

New developments in health care are increasingly dependent on significant advances in gene-based technologies. Medicines Australia believes that uncertainty around the scope of intellectual property rights related to genetic materials and gene derivatives will harm both investment in research and development and, consequently, access to innovative, more effective treatments and diagnostic tests.

Thank you again for the opportunity to contribute to this inquiry. Medicines Australia looks forward to ongoing dialogue with Government on all aspects of intellectual property rights in Australia. If you have any questions about views expressed here, or if you would further information, please do not hesitate to contact me at [deborah.monk@medicinesaustralia.com.au](mailto:deborah.monk@medicinesaustralia.com.au) or at 02 6122 8500.

Yours sincerely



Deborah Monk  
**Director, Innovation and Industry Policy**

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<sup>1</sup> Medicines Australia strongly believes that such proscriptive exceptions to patentable subject matter should be limited as far as possible, as these are crude “on/off” switches that have the potential to stymie advances in whole fields of innovation.