



**Pfizer Australia Pty Ltd**

38 - 42 Wharf Road  
West Ryde NSW 2114  
Australia

Tel +61 2 9850 3333  
ABN 50 008 422 348

**John Latham**  
Chairman and Managing Director

25 February 2011

Committee Secretary  
Senate Legal and Constitutional Committees  
PO Box 6100  
Parliament House  
CANBERRA ACT 2600

Dear Committee Secretary

**Patent Amendment (Human Genes and Biological Materials) Bill 2010**

Thank you for providing Pfizer Australia with the opportunity to comment on the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

Pfizer is the nation's leading pharmaceutical company, employing nearly 2,000 Australians. In addition to our innovative and generic medicines, we have animal health, hospital, consumer and nutrition businesses, with high quality export manufacturing facilities in New South Wales, Victoria and Western Australia. Pfizer is one of the world's largest investors in medical research and development.

Pfizer agrees with the Bill's sponsors and supporters that access to innovative medicines is critical to the future health of our nation.

It is necessary we recognise the access we currently enjoy in Australia is a result of many factors, one of which is the commercial viability of research and development. This commercial viability is only possible as a result of Australia's internationally aligned intellectual property provisions.

These provisions will be drastically altered should the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* be passed. Any amendment to the Patent Act to prohibit the granting of patent protection over genetic and biological materials would be in conflict with Australia's harmonisation of its patent laws with major jurisdictions, particularly the US and Europe. It is important the far-reaching implications of the proposed amendments are recognised; these changes will impact not only access to innovative biopharmaceuticals but also access to animal health and agricultural products in the future.

The intent and eventual implication of the *Bill* (should it be passed) are drastically misaligned. This Bill would have very damaging unintended consequences.

We wish to re-submit our 2009 Senate Inquiry submission as the issue and our position on the matter remains unchanged. **We strongly urge the Committee to recommend that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 is rejected**, for reasons stated in our original submission. However, we wish to be clear that we would welcome amendments to provide clarity and certainty to the research community and the Australian public as to the importance of the ongoing freedom to conduct essential research.

The matter of Gene patenting in Australia has been extensively examined over the last decade.

The current inquiry follows the recent Senate Community Affairs Inquiry into 'Gene Patents' (November 2010); the Australian Government's Advisory Council on Intellectual Property (IP) report '*Review of Patentable Subject Matter*' (February 2011); and the Australian Law Reform Commission (ALRC) 2004 report '*Genes and Ingenuity: Gene Patenting and Human Health*'.

After extensive examination of the issues and broad community and international consultation on the matter, none of the previous inquiries and reports recommended the changes now proposed in this Bill.

On the contrary, the most recent of these reports, the Australian Government's Advisory Council on Intellectual Property (IP) '*Review of Patentable Subject Matter*' released on 16 February 2011, makes the following comments in relation to the patenting of human genes and genetic material:

*"We have found that no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products. Accordingly, we do not recommend the introduction of such a specific exclusion."*

Australian Government's Advisory Council on Intellectual Property (IP): Review of Patentable Subject Matter, pg 60

Further on the matter of biological processes the Council found:

*"No case has been made for the abolition of the current specific exclusion preventing the patenting of human beings and biological processes for their generation. It should be retained."*

Australian Government's Advisory Council on Intellectual Property (IP): Review of Patentable Subject Matter, pg 60

The Advisory Council's views coincide with Pfizer Australia's views on the matter. In our submission to the Senate Community Affairs Committee Inquiry into Gene Patents (26 March 2009) we stated:

*"We do not believe that there are fundamental problems with Australia's patents system covering gene technology. Although there have been a small number of high-profile cases concerning gene patents, these need to be balanced against the large number of cases where patents are working as they are intended to – creating incentives to harness knowledge of genetic science and improve human health. Our advice to the Senate Committee is that Australia's patent laws – and IP Australia – work well for the Australian community, the research community, and for investors."*

*"As knowledge of genetics has grown – particularly with the publication of the Human Genome in 2001 – the number of patents on individual genes has dropped sharply. This is because the threshold for 'novelty' and 'inventiveness' at the heart of the patent system is now very much higher than it was when the first gene patents were issued. Also, as patent offices worldwide have gained experience with genetic technologies, the patents now granted are much more specific than the early gene patents, and they are increasingly granted to biotechnologies rather than on isolated genes themselves."*

Pfizer Australia, Submission to the Senate Community Affairs Committee Inquiry into Gene Patents, pg 2

Banning patents on biological materials will have a devastating impact on Australian patients' access to innovative medicines. It would effectively be a ban on patenting all biotherapeutic products, as well as many commercial, research and manufacturing processes.

In our submission to the previous Senate Inquiry, we drew particular attention to the impact such amendments would have had on the development and availability of medicines including, insulin, monoclonal antibodies and other types of biotherapeutics that depend on gene technology including vaccines, human growth factors and some hormones:

*“A ban on patents for “microbial genes, ... proteins and their derivatives” suggested in the Senate Committee’s terms of references could have a particularly damaging effect on Australia’s biotechnology industry, as microbial genes are at the heart of all genetic technologies. Banning patents on derivatives could see the withdrawal of some medicines from Australia. All insulin used in Australia, for example, is based on recombinant gene technology.”*

Pfizer Australia, Submission to the Senate Community Affairs Committee Inquiry into Gene Patents, pg 3

Pfizer Australia agrees with IP Australia’s assessment that the Australian patent system is functioning effectively, and that specific problems that arise with gene patents can be dealt with within the existing patent system.

We are very much sympathetic to the concerns held by many about the impact of patents on the ability of scientists to conduct research on biological materials without having to determine whether doing so would infringe a patent. As such, we would welcome the implementation of measures such as an explicit research-use exemption. This would clarify that scientists are free to conduct research on, or use patented inventions, so long as it is not their intention to infringe a valid patent by selling the invention without the inventor’s permission. The *Patent Amendment (Human Genes and Biological Materials) Bill 2010* will not provide Australian scientists with such provisions. Pfizer would support alternative legislation that provides this clarity without the unintended consequences of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

We fear a ban on the patenting of all genetic material and derivatives in Australia would halt commercial development and supply and access to a wide range of innovative medicines and health technologies in Australia. Similarly, access to animal health and agricultural products will be impeded. The Bill will reduce research and development in Australia; it will reduce the chances of further medical discoveries particularly in the promising fields of biologics and vaccines; it will reduce Australians’ access to new medicines available elsewhere in the world.

For these reasons and those outlined in our previous submission **we strongly urge the Committee to recommend that the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* is rejected.**

Pfizer Australia thanks the Committee for the opportunity to express its view and is available at any time to provide further information or briefings if this would assist Members.

Yours faithfully

**John Latham**