

Julie Dennett  
Committee Secretary  
Committee on Legal and Constitutional Affairs  
PO Box 6100  
Parliament House  
Canberra ACT 2600  
Australia

25 February 2011

Dear Ms Dennett

Thank you for the opportunity to comment on the Patent Amendment Bill 2010, which will have a significant impact on MSD and the pharmaceutical industry as a whole. MSD is the second largest pharmaceutical company in the world and has more than 850 Australian employees.

We believe that this bill, if passed, could have wide-ranging, unintended and harmful consequences for the pharmaceutical industry and for patients in Australia.

The broad definition of non-patentable inventions in the Patent Amendment Bill would exclude many life-saving medicines from the intellectual property protection necessary for introduction into the Australian market. The Bill states that "biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature" would not be patentable. Many vaccines and novel biologics will be denied the IP protection necessary for commercialisation if this provision is put in place. MSD alone has a number vaccines and biologics in its pipeline that could be threatened by this legislation and further analysis would need to be done to determine whether there is still a business case to market these products in Australia.

In addition, a significant proportion of MSD's current portfolio consists of biological medicines that may not have been viable in Australia had this legislation been in place when they were introduced. Australian patients suffering from Crohn's Disease, rheumatoid arthritis, infertility, and infectious disease would have been denied access to these world-class medicines.

Innovation in the pharmaceutical industry is currently undergoing a major shift as technological advances allow for the development of targeted, complex biological medicines that will provide significant health benefits for patients. Legislation such as the proposed Patent Amendment Bill will stifle this innovation resulting in poorer health outcomes for Australians.

This legislation would further diminish IP protection in Australia, reducing the country's competitive advantage relative to other knowledge-driven economies. Whereas the European Union has issued a directive to enable the patenting of gene sequences, this bill would not

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only ban this practice but would also ban the patenting of a wide range of other biological medicines.

Therefore, MSD recommends that the Senate Legal and Constitutional Affairs Committee declines to recommend this bill on the basis that it will have far-reaching and unintended consequences that will ultimately be to the detriment of all Australians.

Sincerely,

Uáne Orr

Managing Director  
MSD Australia