

24 February 2011

The Secretary  
Senate Legal and Constitutional Affairs Committee  
PO BOX 6100  
Parliament House  
CANBERRA ACT 2600

Dear Secretary

**RE: Senate Committee Inquiry into Patent Amendment (Human Genes and Biological Materials) Bill 2010**

Sanofi-aventis welcomes this opportunity to submit to the Senate Legal and Constitutional Affairs Committee's Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

Sanofi-aventis is an integrated healthcare provider with products ranging from prescription medicines for diseases such as cancer and diabetes, to vaccines, generic medicines and complementary medicines. Our company invests over \$30 million in research and development activities in Australia each year and employs around 50 people in clinical trial work.

Our company has a significant and increasing presence in the biologics sector, with a number of new vaccines and cancer treatments in development, and the recent announcement of our acquisition of one of the world's leading biotechnology companies, Genzyme.

The research and development of new medicines, particularly biologic medicines, is a complex, expensive and protracted endeavour, taking over a decade and costing over \$1 billion for each successful new medicine. The existence of a stable intellectual property regime providing patent protection and financial return for medical inventions such as biologics is critical for ongoing investment in new medicines, as well as patients' access to these treatments.

The proposal in this Bill to effectively ban patenting of *"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"*, is deeply concerning.

Such a ban would remove the intellectual property protection under which companies like sanofi-aventis conduct clinical trials of new biological medicines, register and make those new treatments available for patients in Australia. Without appropriate patent protection in place, there is a significant risk that new biological medicines under development for treatment of diseases such as cancer, would not be made available for patients in this country.

Sanofi-aventis understands that the proposed amendment is a response to concerns regarding access to patented technologies for research purposes by clinicians and researchers. However, as it stands, the proposed amendment goes far beyond research access. Banning patents on biological material would remove the incentive for investment in financially uncertain product development, which would effectively stop biological innovation and research in medicine in Australia.

If there is concern over the ability of scientists to access patented inventions for research purposes, the appropriate solution is through the “research-use exemption” approach as recommended by Medicines Australia and AusBiotech. Clarification of research-use exemption in Australia would allow scientists to conduct research using patented inventions, so long as the invention is not exploited for commercial benefit.

Ongoing investment and research into new developments in gene-based technologies is critical for maintaining innovation in healthcare and must not be put at risk by the undermining of intellectual property rights. Sanofi-aventis strongly urges the Senate Legal and Constitutional Affairs Committee to reject the proposed amendment to the *Patents Act 1990*.

If you have any questions or require further information about this submission, please contact me at sanofi-aventis on

Yours sincerely

**Dr Alex Condoleon**  
**Medical Director**