

Dear Secretary

I am writing to you regarding the *Patent Amendment (Human Genes and Biological Materials) Bill 2010* (Private Member's Bill), which is being considered by the Senate Legal and Constitutional Affairs Committee. Given the current inquiry, Genzyme Australasia wishes to share some of the issues this Bill raises for development of treatments for rare diseases. Genzyme has raised these concerns with Members of Parliament and has been encouraged to communicate them with the Committee.

Treatments for ultra rare genetic diseases such as lysosomal storage disorders (LSDs) are challenging to develop, given the small numbers of patients affected and the complexity of biological therapies. Genzyme's treatments for LSDs are directed towards harnessing naturally-occurring biological and genetic material to replace or repair missing or defective molecules in patients with these conditions. This development requires significant investment to develop a therapy and prove that it is safe and effective, and is a highly risky investment.

For this reason, we are concerned about the possibility of amendments to Australian intellectual property law that would make development of therapies even more risky. We understand the community's concerns about ensuring appropriate access by patients, researchers and public organisations to biological and genetic material. For this reason, we support the work of IP Australia through the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*.

Genzyme's main concern is that a ban on patenting of biological molecules could mean that excellent basic research is never translated into therapies and tools that can benefit patients. For your information, I have enclosed a summary and a case study that looks at some of the issues faced by companies working in this space.

If you have any questions, please do not hesitate to contact me and I would welcome the opportunity to meet with you in the future to discuss this further.

Yours sincerely

David Pullar