

25 February 2011

Ms. Julie Dennett  
Committee Secretary  
Senate Legal and Constitutional Committees  
PO Box 6100  
Parliament House  
Canberra ACT 2600  
Australia

Dear Ms. Dennett,

As Australia's leading supplier by volume of prescription medicines and of generic medicines, Alphapharm welcomes the opportunity to comment on the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

#### **Alphapharm, a key contributor to the Australian economy**

One in five of all Pharmaceutical Benefits Scheme (PBS) prescriptions are dispensed with an Alphapharm product. Most of these products are produced at our state-of-the-art manufacturing facility in Queensland by 400 of our more than 550 employees nationally. Last year, the plant produced more than 2.5 billion tablets and capsules, of which half were exported to some 50 countries. Pharmaceuticals are Australia's leading export of transformed goods. Generating more than \$4 billion a year, pharmaceutical exports are more significant to the economy than the exports of cars, wine or information technology. We are pleased to be a major contributor to Australia's balance of trade.

Alphapharm is part of Mylan Inc., which ranks among the world's leading generic and specialty pharmaceuticals companies and provides products to customers in more than 140 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios, supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies.

We fully concur with Mylan's submission to the Inquiry. The purpose of Alphapharm's submission is to provide a specifically local perspective of issues arising from the Bill.

#### **The impact of PBS reform**

Historically, patent holders in the pharmaceutical industry have been driven to maintain their returns on patent monopoly rights for as long as possible. Recent PBS reforms have given "Big Pharma" companies further incentive to achieve and maintain these rights. The creation of two formularies in 2007, F1 and F2, means that medicines producing similar health outcomes were delinked for the first time in PBS history. This is despite the PBS having been upheld internationally as arguably the best pharmaceuticals re-imburement scheme because of its basic tenet to pay equal cost for equal health outcome. The introduction of Expanded and Accelerated Price Disclosure (EAPD), via the 2010 PBS reforms, created an even greater incentive for Big Pharma companies to hold on to their monopolies, as F1 products are not subject to the very large price reductions it imposes.

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In an attempt to maintain its medicines in the F1 category, Big Pharma is practising evergreening and other aggressive ploys to delay the entry of generics, which threatens to severely affect the ongoing affordability and sustainability of the PBS.

**A two-tiered health system?**

In the near future, biological medicines – with their current very high costs – will be used increasingly to provide therapeutic care to Australians. It is imperative to ensure that the government can afford to provide these state-of-the-art treatments to all Australians and to ensure we do not create a two-tiered health system.

The patenting of genes – which are not inventions but mere discoveries – is anathema to any government policy focussed on providing the best subsidised pharmaceutical care to all Australians.

Alphapharm supports a robust, fair and equitable intellectual property framework. An appropriate period of monopoly rights should be awarded in exchange for clever inventions. It is society's dues for gaining access to such innovations.

The patenting of biological materials – as found in nature or if modified in ways that produce no material change in function – must not be allowed to continue. The practice threatens to severely inhibit medical and scientific research because the patent monopoly that these kinds of patents provide means that the biological materials are quarantined to the exclusive benefit of the patent holder. Such broad and unjustified patent monopolies reduce innovative competition in the development of new and inventive medicines. More importantly, they will interfere with the right of every Australian citizen to have future access to cost-effective, life-saving medicines.

In the strongest possible terms, we respectfully encourage the Committees to recommend the Bill be passed in its current form.

Yours sincerely,  
Alphapharm Pty Limited

Dr Martin Cross  
Managing Director