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PUBLIC AFFAIRS & POLICY

Thursday, 30 April 2009

Senator Claire Moore
Chair
Senate Standing Committee
On Community Affairs
Parliament House
Canberra ACT 2600

Dear Senator Moore

RE: Senate Inquiry into Gene Patents

With the Senate Community Affairs Committee inquiry into Gene Patents underway, we felt it appropriate to write to you to express some concerns Pfizer Australia has with some of the views expressed in many of the submissions provided to the Committee.

At the time we write this letter to you, the Senate Community Affairs Inquiry into Gene Patents has received over fifty submissions, the bulk of which argue for a ban on the patenting of genetic material.

Most of these submissions focus on the patenting of human genetic material. However, the Committee's terms of reference are much broader: *"human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form"*.

We feel that, in arguing for a total ban, many of those making submissions would not have been aware of the consequences of a ban on treating disease. In particular, we want you to be aware that banning patents on "microbial genes ... proteins and their derivatives" could seriously impact both the manufacture and supply of many innovative medicines in Australia.

Such a ban would effectively be a ban on patenting all biotherapeutic products, as well as many commercial research and manufacturing processes. The Pharmaceutical Research and Manufacturers of America (PhRMA) reported that, in 2008, 633 biologic medicines were in

development for over 100 medical conditions[1]—including cancer, infectious diseases, autoimmune diseases (such as rheumatoid arthritis), HIV/AIDS, asthma, and cardiovascular disease. Without patent protection for both the products and the manufacturing processes, these products would not be developed or supplied in Australia.

We would like to give you three concrete examples of types of medicines that may cease to be available in Australia if a ban on patenting genetic material is introduced in Australia.

In our submission to the Inquiry, which I have attached for your reference, we drew particular attention to insulin.

When insulin was first developed to treat diabetes, it was extracted from a variety of animal sources, mostly pigs and horses. However, because this insulin was from a non-human source, after about a year, people's bodies began to reject this life-saving medicine. Around twenty years ago, gene technology allowed the gene for human insulin to be inserted into a bacterial plasmid, so creating an artificial insulin which the human body would not reject. Today, all insulin used in people is recombinant insulin produced by micro-organisms. Although we understand that recombinant insulin is now off-patent, this product would not have been commercially viable to develop if there had been a ban on patenting of *"microbial genes ... proteins, and their derivatives."* Other so-called 'protein drugs' developed similar recombinant gene technology include:

- human growth hormone;
- clotting factor for haemophilia patients; and
- erythropoietin to stimulate the production of red blood cells in kidney dialysis and cancer patients.

Another group of medicines manufactured using recombinant DNA technology are interferons. Interferons are proteins naturally produced by the immune system when the body is attacked by foreign substances, such as viruses, bacteria and tumours. Interferons work by preventing the replication of foreign bodies (such as viruses and tumours), triggering 'killer cells' in the immune system, and increasing resistance of human cells to foreign infection. Although interferons were first identified in the 1950s, they could not be made into an effective medical treatment because there was no practical way of manufacturing them in large volumes. This changed with gene technology, which allowed interferon DNA to be inserted into bacteria, which could then be manufactured en masse. Interferons are now used to treat:

- some cancers, including some varieties of leukaemia;
- many viral infections, including hepatitis and genital warts; and
- some autoimmune diseases, such as rheumatoid arthritis.

A third important group of medicines developed using gene technology are monoclonal antibodies. They are amongst the most promising new treatments for cancer; some are substantially more effective than conventional chemotherapy. These medicines are very similar to the antibodies found in the immune system, but they have been modified to target specific

[1] PhRMA (2008) *Medicines in Development: Biopharmaceutical.* Available from http://www.phrma.org/files/Biotech%202008.pdf

chemicals or cells in the body. Unlike insulin and interferons, which occur naturally in the body, monoclonal antibodies are the product of DNA technology, and combine elements of human and mouse genes. Developing monoclonal antibodies involves:

1) using the immune systems of mice to create an antibody to human cancer cells;
2) fusing these mouse antibodies with myeloma cancer cells, so that the antibody cells continue to grow indefinitely; and
3) 'humanising' these fused cells by introducing human genetic material, so that the body's immune system will not attack foreign material that originated in mouse cells.

The processes for fusing the antibodies with myeloma cells, as well as 'humanising' the fused cells depends entirely on gene technology.

Other types of biotherapeutics that depend on gene technology include vaccines, human growth factors and some hormones.

Apart from medicines that incorporate genetic material, the development of biotherapeutics also depend on gene technologies to isolate and manufacture these materials. For example, extracting specific genes for research and incorporation into new medicines relies on what are called 'restriction enzymes'. These are used to cut long strands of DNA at specific points, so that specific genes can be isolated for research and commercial development. They are derived from microbial genes, and are normally patented. Many other reagents and laboratory techniques used to advance biological products also depend upon such microbial DNA.

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 fear a ban on the patenting of all genetic material and derivatives in Australia would halt commercial development and supply of all of these types of medicines in Australia, as well as substantially curtail DNA testing and research and commercial development of biological medicines.

For this reason, we urge you **to oppose a ban on the patenting of genetic material**.

Pfizer Australia thanks you for the opportunity to express our view and would welcome an opportunity, should you require, to provide further briefings to you on this important issue.

Yours sincerely,

David Miles
Manager, Government Affairs