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Baxter

25 February 2011

Ms Julie Dennett
Secretary
Senate Standing Committee on Legal and Constitutional Affairs
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Ms Dennett

Submission to Senate Standing Committee on Legal and Constitutional Affairs - Inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (the Bill)

Baxter Healthcare (Baxter) provides this submission to the Senate Standing Committee on Legal and Constitutional Affairs (the Committee) in its inquiry on this Bill.

We ask the Committee to consider our submission in the context of the effects the Bill (if passed in its current form) would have on our company's business and on the Australian biotechnology and pharmaceutical industries more generally.

The Bill proposes to exclude the patenting of the following under Australian law:

> "*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*."

In our view, the effects of this ban on the patenting of biological materials would be extremely broad, and may have serious consequences for Baxter's continued research and development and other operations in Australia, as outlined in more detail below.

Baxter Healthcare – background and technology

Baxter is a global company developing, manufacturing and marketing products which save and sustain the lives of people with haemophilia, immune disorders, infectious diseases, kidney disease, cancer, trauma, and other chronic and acute medical conditions. Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products which advance patient care worldwide.

Baxter has been in Australia for over fifty years and currently employs over 1,050 nation-wide. We have significant Australian based manufacturing facilities in Old Toongabbie NSW; a sales and marketing facility with a technical service centre at Baulkham Hills NSW; distribution and warehousing depots in NSW, QLD, VIC, SA, WA and TAS; and six TGA-licensed aseptic compounding pharmacy facilities in NSW, QLD, VIC, SA and WA. Across the Asia Pacific region, Baxter is a partner within multilateral trade and economic forums involving ASEAN and APEC nations to reduce disparities of care and maintain an open trading environment.

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Baxter's BioScience business is a leading manufacturer of recombinant and plasma-based proteins to treat haemophilia and other bleeding disorders; plasma-based therapies to treat immune deficiencies, alpha 1-antitrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions; products for regenerative medicine, such as biosurgery products and technologies used in adult stem-cell therapies; and vaccines. Baxter provides vaccines for meningitis C, tick-borne encephalitis, seasonal flu and (as mentioned above) pandemic flu. Baxter's Vero cell technology, used in flu vaccine production, provides benefits over more traditional egg-based vaccine production methods.

Baxter's Bioscience business current patent position

Our company currently owns or licenses over 55 granted and allowed Australian patents and over 45 Australian patent applications containing claims which could potentially fall within the broad wording of the proposed ban on patentability outlined in the Bill. These numbers reflect over two thirds of the total Baxter Bioscience patent portfolio.

Our company's patent portfolio covers a range of biological materials critical to the development and commercialization of products for hemophilia, immunoglobulin, critical care, pulmonology, regenerative medicine and vaccine therapy. More specifically, our patents and patent applications include claims in relation to pandemic and seasonal influenza vaccine compositions, purified antigenic polysaccharides vaccine compositions, purified Ross River antigen vaccine and vaccine carrier protein conjugates; various recombinant and plasma fractionated and purified blood coagulation factors including, but not limited to, Factor VII, Factor VIII, Factor IX, prothrombin and Von-Willebrand Factor; purified alpha-1 proteinase inhibitor; plasma fractionated and purified immunoglobulin and albumin; recombinant hyaluronidase; compositions comprising fibrin, fibrinogen, collagen and fibronectin and numerous other purified or recombinant peptides, proteins, including antibodies, genetic vectors and cellular systems for the efficient production of biological materials. Baxter is at various stages of development of these products throughout numerous countries of the world including Australia. Baxter therefore continues to depend on effective patent protection in Australia (and other countries of the world) in order to protect its investment in providing these life-saving therapies to people of need.

Potential effect of Bill on Baxter Healthcare

If passed in its current form, the Bill may have serious consequences for the operation of Baxter's business.

Patents are key assets for Baxter. If Baxter is not able to seek and obtain protection for its research by way of a patent, this could potentially have the following consequences:

- inability to attract and retain investors;
- inability to continue research in the area due to lack of funding and inability to protect the results of research;
- loss of key revenue from licensing of patented technology;
- inability to recoup significant investment in the development of a biologic drug;

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- disincentive to invest significant funding in the development of a biologic drug without the opportunity to obtain a reasonable profit.

Submission

For the reasons outlined above, we strongly urge the Committee to reject the proposed amendment to the *Patents Act 1990*.

As an alternative, we urge the Committee to review and consider the recommendations of the Australian Law Reform Commission's report on gene patenting and human health from 2004.