Abbott Australasia Pty Ltd

Submission to the Senate Legal and Constitutional Affairs Committee on:

Patent Amendment (Human Genes and Biological Materials) Bill 2010

FEBRUARY 2011

Abbott Australasia Pty Ltd

1. Abbott Overview

Abbott Laboratories is a global broad-based health care company that operates in more than 130 Countries and employs more than 90, 000 people world wide. In Australia, Abbott has operated for more then 70 years and employs over 600 people across 9 divisions, these divisions are:

- Abbott International;
- Nutrition;
- Vascular;
- Diagnostics;
- Established Products Division;
- Diabetes Care;
- Molecular;
- Medical Optics; and
- Point of Care.

Within its pharmaceutical divisions (Abbott International and Established Products Division) Abbott manufactures and sells both innovative, patent protected products and generic products. Clinical areas covered by Abbott's products in Australia include immunology, anaesthesia, oncology, cardiovascular and HIV/Aids.

Globally Abbott employs more then 7000 scientists and researchers and spends approximately $2.5 billion per annum on research and development. Within Australia Abbott's research program led, in 2010, to the establishment and operation of 28 clinical studies across 128 sites involving more then 600 patients. This represents a local investment in research and development of more then $16 million, this investment is geared towards the development of new therapeutic products in oncology, diabetes and mental health.

2. Background

The issues canvassed in this Bill have for some time been subject to considerable community debate and concern not only in Australia but around the world. Locally this debate has been brought into focus by the case of patents over genes that have been identified as playing a role in causing breast and ovarian cancer and the actions of the company that holds the Australian rights to these patents.

Patent law is a complex policy area that involves not only domestic Australian law and policy but international trade agreements and international law. In response to these complex issues this Bill seeks to dramatically change patent law in Australia by singling out biological materials. This approach

will put Australia out of step with international approaches to this area of public policy and will have widespread implications for both the pharmaceutical and biotechnology industries. It should also be noted that this Bill will do nothing to address the particulars of the case that sparked this debate.

3. Current Approach to Patents

In order to gain a patent in Australia an application must be made to IP Australia. This application must meet the requirements as set out in the Patent Act 1990 which applies stringent criteria on what may be covered by a patent. This approach includes a threshold of patentability test that must be satisfied before a patent may be granted. Applications must meet all components of this threshold test before they can be successful. In the case of genes and biological material the test includes:

- That the gene, gene fragment or biological material is artificially-generated or isolated from its naturally-occurring environment;
- That its function is known and described in detail; and
- The requirements of novelty, inventive step and usefulness are demonstrated and clearly documented.

Given the vast increase in human knowledge around genes and biological material over the last 20 years the approach to patents for this material has changed, where once broad patents were provided for claims with little defined utility that is no longer the case. Patent offices in Australia and around the world have tightened their interpretation of the threshold for patentability so now the identification of a new gene or any biological material, without knowledge of its function and a defined practical use, will not be sufficient to gain a patent.

4. Issues with the Bill

The Bill seeks to include a specific section in the Patents Act 1990 that singles out biological material and prevents them from being considered patentable material. This section reads:

> (2) The following are not patentable inventions:
>
> (a) human beings, and the biological processes for their generation; and

(b) 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.

The Bill further seeks to define biological materials to include DNA, RNA, proteins, cells and fluids.

Those in favour of the Bill argue that it is a narrow Bill aimed at simply clarifying and applying existing law around the patentability of genes and its adoption will have little impact on industry. This argument ignores the breadth of what is being excluded from patentability. As it stands this Bill goes far beyond genes that exist in the human body and will exclude all biological materials from being patented, regardless of how they are developed and where they come from. This will have a detrimental effect on not only the health care and biotechnology sectors but in other fields including agriculture and animal production.

5. The Humira (adalimumab) Example

Abbott is the manufacturer of a product called Humira, this product treats the inflammatory reactions caused by autoimmune diseases. The diseases that can be treated with Humira, and other biological agents like it, cover a number of arthritis' including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis and other diseases including chronic severe Crohns Disease and Psoriasis.

Humira is made through a human like monoclonal antibody that is produced in Chinese Hamster Ovary cells which have been genetically engineered to secrete high quantities of a specific protein when grown in culture. From these cell-lines, production cell banks have been created which allows the mass production of the product.

Under current patent law in Australia Abbott has, through meeting the threshold of patentability, secured patents over Humira that protects the development of the specific cell banks required for its production. These patents along with others provide Abbott with sufficient protection for the intellectual property required to develop this product to allow the company to bring Humira to market in Australia. Humira was successfully launched to patients in Australia in 2004.

Should this Bill be successfully adopted and if Abbott had yet to bring Humira to market in Australia it would be impossible for Abbott to secure a patent over the product. The exclusion of biological material

however made, that is identical or substantially identical to such materials as they exist in nature, would preclude Humira from protection under the Patent Act.

In this hypothetical example, without the protection provided by a patent Abbott would face significant risks to its intellectual property should it seek to introduce Humira into Australia. The most likely outcome of this situation would be that Humira would simply not be made available in Australia.

6. Conclusion

The development of biological agents that aid in the treatment of chronic disease have greatly changed the management of those diseases. With more powerful and targeted medications, people with often debilitating illnesses can now lead a relatively normal life. Already in Australia more then 17 000 patients with autoimmune diseases, where Humira is one possible therapy, are provided with access to biologic medicines.

Autoimmune disease is not the only area that has benefited from the introduction of biological treatments. Areas including oncology and diabetes now have as standard of care biological therapies. New therapies in these clinical areas would also face the issues that would confront Humira should these amendments to the Patent Act be accepted. Many more patients with diseases not treated by Humira are also accessing biological treatments, this includes oncology patients and patients with diabetes.

Given the benefits of biological drugs considerable research effort has been expended in the development of new biological agents that will further enhance the treatment of chronic diseases. Any reform to the patent system that leads to a reduction in the protection provided to biological material will have the effect of denying Australian patients access to these new treatments.

While community concern around this issue is understandable, in seeking to find adequate responses legislators need to be careful that any changes to the law don't have wide spread, unintended consequences. The successful adoption of this Bill will lead to such consequences. The breadth of material excluded from patentability in this Bill goes well beyond the Human Gene and will have negative impacts on a number of industries including the pharmaceutical, agricultural and animal production industries.

It is clear from the example provided above that should this amendment to the Patent Act 1990 be successful it would dramatically impact new, improved medications being made available to patients in Australia. Given the advancements being made in genetics and the development of new and exciting biological agents such an amendment would place Australian patients at a severe disadvantage when compared to other jurisdictions around the globe that have not amended patent law to take such a prescriptive approach.

For these reasons Abbott does not support the Bill and would urge the Committee to recommend against the adoption of these amendments.