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25 February 2011

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

Dear Ms Dennett,

LEGAL & CONSTITUTIONAL AFFAIRS LEGISLATION COMMITTEE
INQUIRY INTO THE
PATENT AMENDMENT (HUMAN GENES AND BIOLOGICAL MATERIALS) BILL 2010

Eli Lilly Australia makes the following submission to the inquiry into the *Patent Amendment (Human Genes and Biological Materials) Bill 2010*.

Lilly opposes the Bill. The Bill has the potential to impede the development of a significant number of classes of treatments for diseases including: cancer, diabetes, Alzheimer's and autoimmune diseases. Rather than encouraging research and access for patients, the Bill risks the opposite. Lilly opposes the Bill because it is bad for Australians suffering from disease.

Lilly

Lilly is a leading, innovation-driven organisation committed to developing medicines that help people live longer, healthier and more active lives. We are committed to providing answers that matter for some of the world's most urgent medical needs, undertaking or supporting research and development globally. In 2010 Eli Lilly & Company invested more than $US4.88 billion in developing a portfolio of 70 potential new treatments for diseases including: diabetes, Alzheimer's disease, depression, schizophrenia, non-small cell lung cancer, breast cancer, melanoma, rheumatoid arthritis, lymphoma, prostatic hyperplasia and attention deficit hyperactivity disorder.

Lilly has a long history of investment in research and development, including clinical trial activity, in Australia. In 2010 Lilly set up a $250 million biotechnology investment fund in Queensland and partnered with a local Melbourne company Acrux Limited to commercialise, worldwide, a new medication.

The key issue

The Bill's proposed subsection 18(2)(b) would exclude patents on materials '*which are identical or substantially identical to materials as they exist in nature*'. This potentially has a very broad and unintended impact.

Biological medicines

Biological medicines are medicines whose active ingredients are derived from or made in biological systems, that is, in living cells or organisms. Among biological medicines, peptides, proteins, and antibodies are particularly promising for treating human diseases, for Lilly and generally.

Biological medicines are critical for the future of the treatment of many diseases and infections. Nearly half of the new treatments that Lilly is investigating are biological medicines.

How better medicines come about

An example of a biological medicine is insulin, which Lilly pioneered in the 1920's to treat diabetes. Since that time there have been significant advances in insulin-based treatments in an effort to make it more effective, more tolerable, safer and easier to use.

An important advance in insulin-based treatment was Lilly's HUMALOG product. Engineered through recombinant DNA technology, HUMALOG achieves the effect of human insulin, but faster. HUMALOG's faster time to action provides better control of blood glucose and improves patient convenience. A key hurdle in developing HUMALOG was subtly altering the action of insulin enough to improve its potency without changing its positive action or affecting its safety profile. This improvement required ground-breaking innovation and significant investment over a long period of time.

The only structural difference between HUMALOG and human insulin, as insulin exists in nature, is that two amino acids are reversed in their order: proline-lysine in insulin and lysine-proline in HUMALOG. Insulin and HUMALOG have identical amino compositions, identical molecular formulas ($C_{257}H_{383}N_{65}O_{77}S_6$), and identical molecular weights (~5,808) but they differ significantly in their pharmacological properties. HUMALOG might be considered 'substantially identical' to insulin as it exists in nature for the purposes of the Bill despite the significant innovation it contains and its patient benefits may never have been made available to the Australian public.

As an example of the promise of biological medicines for the future, therapeutic antibodies offer enormous potential. Therapeutic antibodies are being developed as treatments for many diseases, including various infectious diseases, cancers, autoimmune diseases (such as rheumatoid arthritis, multiple-sclerosis, psoriasis, Graves disease, Crohn's disease and systemic lupus erythematosus), Alzheimer's disease, Type I and Type II diabetes, cardiovascular disease, and various musculoskeletal diseases, among others.

Many of these antibodies are fully human in structure, meaning that they are derived from human antibody genes. Antibodies derived from human genes are generally considered to pose less risk to patients than antibodies derived by other means. Because they are derived from human genes, therapeutic human antibodies or the DNA that encodes them could be viewed as substantially identical to materials as they exist in nature.

The problem

The key challenge in creating safer, more effective biologic medicines is finding how to tweak the substance in just the right way to get a better result. Like HUMALOG and therapeutic antibody treatments many new or prospective biological medicines may be considered *'identical or substantially identical'* to their natural counterparts. Like HUMALOG and therapeutic antibody treatments, they have to be; they wouldn't work or wouldn't work as well otherwise.

If enacted the Bill would, at a stroke, deny patents to whole classes of new treatments despite the ingenuity, innovation and investment focused on their development. Denial of patent protection reduces or removes investment certainty for investors supporting the research and development required to bring new medicines to patients. Reduced certainty means reduced investment in medical research and development. The Bill is a threat to medical innovation not just in antibody treatments and protein hormones, like HUMALOG, but an enormous range of potential medicines.

A note on development

Understanding the development of medicines requires an understanding that invention is only the first step in the long road to producing safe, effective, better medicines. The process of taking a given invention, performing follow-up investigations and then ensuring that it works predictably, safely and is at least equal to or better than current treatments is extensive. It involves a range of screening processes followed by three distinct phases of clinical trials often involving hundreds, or thousands, of patients. It is very high risk. At the end of this process a lot of really interesting inventions go nowhere. The cost of this process is enormous involving hundreds of millions, sometimes billions, of dollars. Investors in the process seek patents to secure their investment. The scope of the proposed Bill would discourage investment in the development of innovative medicines and could mean that many inventions made in the lab never see the light of day as new medicines.

Australia's role

The biotechnology industry in Australia is rapidly developing, involving Australian know-how, universities, local companies, State governments and venture capitalists. Lilly is actively investing side by side with local scientists and inventors. We have recently taken a local Australian medicine global. Australia is set to play a significant role in bringing new and better medicines to the world.

A better way

If the objective of legislators is to allow access to discovery and innovation for research purposes or to allow patients to obtain second diagnostic opinions, a better way to proceed would be to frame an exemption to infringement under the *Patents Act 1990* to allow for exactly that.

If you have any queries concerning this submission, please do not hesitate to contact on or at at first instance.

Sincerely,

Chris Miskel
General Manager
Australia and New Zealand