AMGEN

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21st February, 2011

Committee Secretary
Senate Legal and Constitutional Affairs Committee
PO Box 6100
Parliament House
Canberra ACT 2600
Email: legcon.sen@aph.gov.au

Dear Sir/Madam,

Please find enclosed a submission from Amgen Australia Pty Ltd in relation to the Senate Committee inquiry into the Patent Amendment (Human Genes and Biological Materials) Bill 2010.

Thank you for the opportunity to provide comment on this proposed legislation, we would welcome the opportunity to address the committee if public hearings are scheduled..

Amgen has grave concerns about the potential impact of the proposed legislation for its operations in Australia.

It is Amgen's view that the proposed Patent Amendment (Human Genes and Biological Materials) Bill 2010 will have the effect of preventing many innovative new medicines reaching Australian patients; and sending negative signals about the Australian operating environment with disastrous impacts on inward R&D investment and clinical trial activity.

Amgen therefore requests that the Senate Committee recommend the Bill be rejected.

It would be appreciated if you could add us to any mailing list around the progress of this Inquiry.

Should you require any further information, please do not hesitate to contact either myself or our Head, Government Relations and Policy,

Yours sincerely,

Ian Noble
Director, Corporate Affairs
Amgen Australia Pty Ltd

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Patent Amendment (Human Genes and Biological Materials) Bill 2010

Submission to the Senate Legal and Constitutional Affairs Legislation Committee

February 2011

Amgen Australia Pty Limited

Level 7, 123 Epping Road
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Executive Summary

A biotechnology pioneer since 1980, Amgen was one of the first companies to realise the new science's promise by bringing safe and effective biological medicines from lab, to manufacturing plant, to patient, and is now a leading human therapeutics company in the biotechnology industry.

Amgen's protein-based therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, osteoporosis and other serious illnesses.

Human therapeutics based on biological materials represents Amgen's core business. Hence, the proposed legislation to exclude biological materials from being patentable inventions will have devastating consequences for Amgen's Australian operations.

Amgen Australia requests the Senate Committee to recommend that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 be rejected because:

1. It will prevent many innovative new medicines reaching Australian patients
2. It will send negative signals about the Australian operating environment with disastrous impacts on inward R&D investment and clinical trial activity.

Introduction

1. Medicines based on biological materials will provide the cures of tomorrow

Before the availability of modern biologically-based medicines, there were many diseases that we could either not treat or only relieve symptoms without actually treating the underlying condition.

Now that we can replicate complex, natural proteins through biotechnology, we have new ways of treating and preventing illness—and a way to ensure medically necessary amounts of important therapeutic proteins.

Biotech medicines include injectable protein medicines, vaccines (which can be made more effective through biotechnology), blood products such as clotting factors and specially targeted antibodies that interact with the immune system in very specific ways.

Using biotechnology, we can now replace proteins that are missing or lacking, use the body's own natural repair mechanisms to stimulate production of a deficient protein, use our knowledge of protein signaling to regulate processes that have gone wrong, and interact with the immune system in very specific ways to treat or prevent devastating diseases.

For example, damaged kidneys do not make enough of a protein called erythropoietin (EPO), which tells the bone marrow to increase red blood cell production. Using biotechnology, we can now use recombinant EPO to stimulate the production of red blood cells and treat chronic anaemia among very sick patients with chronic kidney disease. Before EPO was available, very little could be done to help these patients and treat the fatigue of anaemia.

Insulin is another example of a protein that helps to regulate a process in the body by functioning as a signal that a certain event should happen. Insulin is important in regulating overall metabolism by helping glucose to move out of the bloodstream and into muscles, where it is used for energy, or into the liver, where it is stored as fat for later use. Diabetes is a chronic disease in which a person has high blood sugar, either because the body does not produce enough insulin, or because cells do not respond to the insulin that is produced.

Yet another example is haemophilia which develops in children and adults who lack a type of protein called a "clotting factor," which helps the blood to clot after an injury—so their blood clots extremely slowly. People with haemophilia can suffer symptoms ranging from nose bleeds and excessive bruising to vision loss from bleeding into the eye, neurological problems, or even death from bleeding into critical areas such as the brain.

Biotechnology can help replace the missing clotting factor protein in children and adults with haemophilia. This alleviates the worry of parents, who fear the worst every time their child bumps a knee or falls down in the playground. Biotech clotting factors also allow adults with haemophilia to live richer, more rewarding lives.

There are still many devastating diseases which lack effective treatments or cures. With the completion of the Human Genome Project in 2003, we are on the leading edge of the biotech revolution that will produce treatments for scores of illnesses. It would be a mistake

at this exciting time in biotechnology research to do anything to inhibit innovation in this young and promising industry.

Amgen's pipeline is indicative of the many medicines which are being developed to address diseases previously untreated or poorly treated. It has more than 30 medicines in Phase 1 and 2 for such diseases as lupus, asthma, diabetes, cancer and its pipeline has been acknowledged to be one of the best in the industry. [1]

Excluding biological materials from being patentable inventions would deny Australian patients access to these promising new medicines.

2. Without patents, tomorrow's cures will not be developed

Strong protection of intellectual property – both patents and data – is the cornerstone of any research-intensive, innovation-driven industry.

A patent is a contract between the inventor and the government – in exchange for teaching the world about this new invention, the inventor has the right to exclude others from using the invention for a limited period of time. The patent does not guarantee that the inventor may market and sell, or that it will be successful if sold. It is simply a promise that, for a limited period of time, others will not benefit from the inventor's efforts without the inventor's permission.

Without adequate intellectual property protection, research and development will be greatly diminished. We know that incentives to invest - such as the ability to patent a medicine - are effective in stimulating innovation. Both paediatric studies and orphan drug development have been significantly stimulated by intellectual property protections put in place in the US and EU.

The biotech industry is very resource-intensive and companies must choose how to invest limited R&D resources. It takes, on average, 12 years and USD $1.2 billion to bring a biotech medicine to patients[2]. Success is the exception rather than the rule: 40% to 50% of candidates fail in Phase III studies.[3] The vast majority of biotechnology companies are not profitable today and are highly dependent on the flow of venture and investment capital to complete the research and development needed to bring their first product to the marketplace over a decade later.

Companies must make investment decisions on a regular basis, but so do venture capitalists who fund a great part of the research and development done by most biotech companies. Venture capitalists weigh the opportunity available to recover their investment with the already unlikely odds that a biotech company will be able to get a biologic product through

[1] Amgen received the "Best Biotechnology Pipeline" ranking from *R&D Directions* in its January 2011 issue.

[2] Tufts Center for the Study of Drug Development, "Average Cost to Develop a New Biotechnology Product is $1.2 Billion" (Nov. 9, 2006), *available at* http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69 . Currently, the cost to develop a new biological therapy - at USD$1.2 billion - is an increase of three times what it cost to develop a drug back in 1984. Only 10% of potential drug candidates reach the human trial phase. Only a small portion of that 10% actually reach the market and only two out of ten marketed drugs ever produce revenues that match or exceed R&D costs.

[3] *See* "Deconstructing De-risking," *BioCentury* (June 7, 2004) (discussing risks associated with biotechnology research and development).

the rigorous regulatory approval process. Intellectual property is the primary way innovators are assured an opportunity to try to recover the resources that they invest in research and development. If intellectual property protection is inadequate to ensure an opportunity to recover the investment, venture capitalists will go elsewhere.

Without capital investment, universities will be unable to license their basic research discoveries to biotech companies, which, in turn, will not be able to invest in the long research and development process needed to convert that basic research into meaningful and useable treatments for patients.

Patents have been shown to be particularly important in the health sector. The biotech and pharmaceutical industry regard patents as critical to protecting innovation. Several studies over the years have demonstrated the important role patents play in these sectors. A recent paper by several professors at the Berkeley School of Law, University of California, found that there were "substantial differences between the health-related sectors (biotechnology and medical devices), in which patents are more commonly used and considered important, and the software and Internet fields, in which patents are reported to be less useful." [4]
These studies reinforce earlier work which indicated that 65% of pharmaceutical inventions would not have been brought to market without patent protection in contrast to the 8% of innovations made in other industries.[5]

A ban on patenting biological materials would interfere with the ability of biotech companies to attract or invest the capital needed to fund further research and development.

3. The proposed Bill will send negative signals about the Australian operating environment with disastrous impacts on inward R&D investment and clinical trial activity.

Amgen has a proud history of clinical trial activity in Australia. Clinical research actually started here three years before Amgen had established offices in Australia: in 1987 the early development work for Neupogen® (supportive treatment for cancer patients) was carried out in Royal Melbourne Hospital.

Amgen Australia invests around AUD$30-35 million in local research and development annually, representing around 15% of its sales.

Through its significant clinical presence Amgen conducts on average two First in Human (FIH) studies every year and almost half of its clinical trial activity is in early phase research.

Amgen Australia also contributes disproportionately to the global clinical trial effort. It consistently contributes around 7-10% of patients to Amgen's global pool of studies in which the affiliate participates and is amongst the highest contributing countries to clinical trial activity in the Amgen world.

[4] *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 1255.

[5] Edwin Mansfield, "Patents and Innovation: An Empirical Study," *Management Science*, February 1986, 173-181.

In 2010, we conducted 62 different studies at over 370 sites, involving some 1200 patients trialling Amgen's innovative medicines.

This activity would be unlikely to occur if the proposed Bill becomes law. This is because a strong and effective intellectual property regime is critical for a knowledge-based company such as Amgen.

Without patent protection for our biological medicines, we would be unwilling to sell our therapeutics in the Australian market. Without a sustained sales presence, it would be difficult to maintain a clinical trial presence knowing that Australian patients trialling Amgen medicines would never be able to access them.

A loss of clinical trial activity in Australia by Amgen and similarly affected biotech companies will lead to, among other things:

- Patients losing early access to innovative therapies;
- Investigators and hospitals losing resources (including funding for many study site personnel) and opportunities to conduct medical research; and
- Loss of significant investment dollars, resulting in extensive job losses across the medical research and biotech community.

Had this Bill been law over the past 10 years, thousands of Australian patients would not have been able to access Amgen's revolutionary medicines used in the treatment of cancer and kidney disease.

4. The proposed Bill is all-encompassing and will have devastating consequences for the biotech sector

The stated purpose of the Bill is "to advance medical and scientific research and the diagnosis, treatment and cure of human illness and disease by enabling doctors, clinicians and medical and scientific researchers to gain free and unfettered access to biological materials, however made, that are identical to such materials as they exist in nature"[6].

However, the scope of the Bill will mean it detrimentally impacts many of the medicines in Amgen's past and future pipeline, not to mention the adverse impact on every other biotechnology company.

If the concern which underpins the Bill is about access to biological materials for research purposes then the solution to this is already provided for in the proposed Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 which contains a statutory provision clarifying researchers' freedom to conduct experiments without infringing patents. Amgen fully supports such a research exemption.

If the concern is about the granting of patent rights to human genes, it is based on a misunderstanding of the patenting process. Patents do not provide any rights to a person or the genes in his or her body. Instead, patents are granted on "isolated" genes and gene products that have real-world applicability. When a gene sequence is isolated by human ingenuity to a free-standing artificial environment in which its function and usefulness to mankind as part of a technology are described, it then deservedly becomes eligible to be

[6] Explanatory Memorandum, Patent Amendment (Human Genes and Biological Materials) Bill 2010, 2

patented. It is because of the ability to patent this innovation that biotech companies are able to commit to costly and high risk development of novel therapies.

Many human diseases have their roots in our genes. Modern biotechnology relies in large part on using gene-based inventions to make medicines because it is either impossible or uneconomical to make them in other ways.

Amgen's pioneering work with erythropoietin revolutionised the treatment of anaemia. Normally, when blood oxygen levels are low, or when someone has lost blood in an injury, erythropoietin is produced and released by the kidneys. Erythropoietin (EPO) is a protein which tells the bone marrow to increase red blood cell production. People with kidney failure, in addition to all of their other complications, do not make enough erythropoietin in their kidneys, and as a result they have fewer red blood cells than normal.

EPO is produced in a select few cell types in the body. It is highly regulated – it is only switched on during particular limited windows of time. The existence of endogenous EPO was postulated in 1906 and confirmed in 1953. By 1975 it was known that small amounts of EPO were excreted by the kidneys.

An object of Amgen's invention was to produce biologically active EPO in sufficient quantities for therapeutic use. The problem was that no one knew the sequence of the DNA encoding for EPO.

Using biotechnology, we can now produce therapeutic doses of EPO to stimulate the production of red blood cells and treat chronic anaemia among very sick patients with chronic kidney disease. Before Amgen's product became available, very little could be done to help these patients and treat the fatigue of anaemia- a significant proportion of renal patients on dialysis would need to have regular blood transfusions. Amgen's research and development of the EPO agent (ultimately licensed to Janssen Cilag in Australia) virtually eliminated the need for such transfusions.

Amgen considers that the focus of the Bill on biological materials is discriminatory, could lead to many unintended consequences in a technically complex and fast moving segment of biomedical research, and represents bad policy. Rather than legislating areas of technology that can or cannot be patented, we believe the better policy is to give effect to broad rules of patentability and allow the courts to sort out issues as new technologies emerge.

Conclusion

It is Amgen's view that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 will have the effect of preventing many innovative new medicines reaching Australian patients; and sending negative signals about the Australian operating environment with disastrous impacts on inward R&D investment and clinical trial activity.

Amgen therefore requests that the Senate Committee recommend the Bill be rejected.

About Amgen

A biotechnology pioneer since 1980, Amgen was one of the first companies to realise the new science's promise by bringing safe and effective biological medicines from lab, to manufacturing plant, to patient, and is now a leading human therapeutics company in the biotechnology industry.

Amgen's protein-based therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, osteoporosis and other serious illnesses.

Amgen is and will remain a leader in developing the next generation of biological medicines for these conditions.

Amgen began in Australia, 1991 and now has a presence in every major capital city.

It employs around 160 highly skilled people in Australia, of which around 50% are engaged in the R&D side of the business. Many are science based graduates.

Amgen invests more than 15% of its Australian sales - or around $AUD35 million - in the discovery and development of new therapies, making it one of the largest R&D investors in this sector in Australia.

Amgen began clinical research work in Australia in 1987 before it officially opened here in 1991. In the early days it carried out phase I and II clinical trial work for Neupogen®, (which helps reduce the incidence of infection in patients undergoing certain cancer chemotherapy).

Today, it attracts a disproportionately high share of the global corporation's clinical trial activity. Approximately half of its Australian clinical research activity is in early phase 1 or 2 trials.