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June 2, 2016

Commissioners Coppel and Chester
Productivity Commission
Email: intellectual.property@pc.gov.au

Dear Commissioners,

**PRODUCTIVITY COMMISSION INQUIRY INTO AUSTRALIA'S INTELLECTUAL PROPERTY ARRANGEMENTS:
DRAFT REPORT, April 2016**

I write in response to the above report.

Amgen Australia (Amgen) endorses the sentiments and comments made by our industry association, Medicines Australia. Like Medicines Australia, Amgen is very concerned about some of the recommendations from the Draft Report which appear to be at odds with the Government's innovation agenda.

In announcing the Government's innovation and science agenda¹, the Prime Minister noted that:

"this is a time when Australia's growth, when our living standards, when our incomes will be determined by the human capital, the intellectual capital that all of us have. By unleashing our innovation, unleashing our imagination, being prepared to embrace change, we usher in the ideas boom."

He also noted that:

"Australia is falling behind when it comes to commercialising good ideas and collaborating with industry. Australia consistently ranks last or second last among OECD countries for business research collaboration. Increasing collaboration between businesses, universities and the research sector is absolutely critical for our businesses to remain competitive. To commercialise an idea, a great invention, a great innovation, a great piece of research and then grow it into new sources of revenue, new jobs, new opportunities and new industries."

Intellectual property is a critical enabler for commercialising ideas.

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, capital will go elsewhere.

¹ Launch of the National Science and Innovation Agenda, Canberra December 7, 2015.

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 usable treatments for patients; i.e. successful commercialisation will not be achieved.

Intellectual property rights have been shown to be particularly important in the life sciences sector. The biotech and pharmaceutical industry regard IP rights as critical to protecting innovation. The fruits of IP also generate benefits to the whole economy.

The extensive contribution of biologic medicines to economic wealth and health has been recently documented in a report prepared for the Office of the Chief Scientist.² As this report notes, the economy would be 4.2% to 5.9% smaller if advances in the biological sciences sector over the past 30 years had not occurred, and the burden of disease would be 18-34% higher. Therefore, any measures which improve the operating environment for biological medicines are likely to deliver benefits to the economy.

As has been noted by a recent study³, countries that *“offer no or only minimal periods of biologics data exclusivity fail to cultivate an environment in which the latest biologics –based life sciences innovations can flourish. In so failing, these countries undermine their own potential to become havens of biomedical innovation.”*⁴ This report ranks Australia as having policies that do the least to support the global life sciences ecosystem.

The Productivity Commission (PC) approaches its discussion of IP from the position of Australia being a net importer of IP and its recommendations have the effect of weakening Australia’s intellectual property regime.

Amgen will confine its comments to recommendations associated with data exclusivity. In Amgen’s view, the Draft Report downplays the emerging issues around biologic medicines in relation to data protection/exclusivity.

The PC recommends that there should be no extension to the period of data protection. It believes that an extension to data protection from 5 to 12 years is not justified, because there is little evidence of a problem “despite claims of inadequate patent protection having been advanced for a decade” (p.14).

This approach fails to recognise that the off-patent market for biologics medicines is still emerging and is very early in its life.

The biosimilars market began in Europe just 10 years ago, and biosimilars are only well established in three therapy areas in Europe: Erythropoiesis Stimulating Agents (ESAs) for treating anaemia

² “The importance of Advanced Biological Sciences to the Australian economy” Report prepared by the Centre for International Economics for the Office of the Chief Scientist and the Australian Academy of Science, Jan 2016.

³ John Wu and Stephen Ezell.” How National Policies impact global biopharma innovation: a worldwide ranking” Information Technology and Innovation Foundation, April 2016.

⁴ As above, p.15

associated with chronic kidney disease and chemotherapy, Granulocyte-Colony Stimulating Factors (G-CSFs) for the prevention of infections following chemotherapy, and Human Growth Hormone.

In Australia, a total of nine biosimilars⁵ have been approved for use within the same therapeutic areas and are mostly hospital based products.

The regulatory standards for biosimilars of monoclonal antibodies are relatively recent. The first monoclonal antibody (Mab) biosimilar (to J&J's Remicade) was authorised in 2013 by the European Commission⁶ and in 2014 in Canada⁷ and Japan⁸.

This was an important milestone in the evolution of the biosimilars market as MAbs are more complex than the earlier biosimilar products, with more extensive differences in structure and function, with consequent implications for indications of use⁹. In Australia, the first monoclonal antibody biosimilar to be reimbursed was listed on the Pharmaceutical Benefits Scheme in December 2015, less than 6 months ago.¹⁰

The regulatory standards themselves are still evolving. In Australia, the regulatory pathway for biosimilars (the Similar Biological Medicinal Product pathway) was first used in 2010. The TGA's guidelines for the evaluation of biosimilars were revised and published in December 2015. Issues such as the naming of biosimilars and standards for interchangeability are yet to be settled. Given this, the PC's recommendation to rule out any increase in data protection is both premature and in conflict with the sentiments of a country which seeks to be innovative.

Patent rights and data protection are different intellectual property rights that play important but distinct roles in fostering medical innovation. This is particularly true for products that are difficult to develop and heavily regulated by the government. Although similar, patent rights and data exclusivity advance innovation in different ways.

- Patents protect the discovery – the molecule, or new way of making a product or method of administering it. A patent grants the innovator the right to exclude others from using the invention in exchange for teaching the public through the patent application how to make or use the invention. Innovation is advanced because the information is made public and others can learn from the discovery.
- Data protection protects the information (the data) submitted to the TGA by the innovator that proves the product is safe and effective and should be approved for marketing. This can include, for example, the results of clinical trials. Similar to a patent, data protection grants the owner, the right and the ability to prevent others from using – that is, relying on or referencing – the data. Without the assurance provided by data protection that others

⁵ Department of Health. *Implementation Framework: Biosimilar Awareness Initiative*. Version 2. Nov 2015, 4

⁶ "Hospira's Inflectra™ (infliximab) the first biosimilar monoclonal antibody to receive positive opinion from EMA's CHMP for rheumatoid arthritis, inflammatory bowel disease and plaque psoriasis", PR Newswire, Jun 28, 2013

⁷ "Subsequent entry biologics approved in Canada", GaBi Online, posted 31/01/2014

⁸ "Biosimilar infliximab receives approval in Japan and Turkey", GaBi Online, posted 08/08/2014

⁹ See for example. *Rapid comparison of a candidate biosimilar to an innovator monoclonal antibody with advanced liquid chromatography and mass spectrometry technologies*: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3180085/> or *The challenge of indication extrapolation for infliximab biosimilars*: <http://www.sciencedirect.com/science/article/pii/S1045105614000451>

¹⁰ From 1 December 2015, a biosimilar infliximab (Inflectra®) will be listed on the PBS for the same indications as Remicade®. <http://www.pbs.gov.au/info/general/biosimilars>, accessed May 31 2016

may not free-ride (for a set period of time) on the clinical trials conducted, it is unlikely anyone would invest millions of dollars and many years to conduct the clinical trials that are necessary to prove a product is safe and effective. Data protection, therefore, encourages companies to invest in the years of expensive, lengthy and uncertain development of essential information needed to take an invention from discovery to market.

Data protection is particularly important in the context of biosimilars¹¹ because of the scientific differences between biotechnology medicines (large molecules) and traditional small molecules. The assumption of patent infringement that is inherent in the generic drug model may not automatically apply in the case of biotechnology because the standard for biosimilar approval is “similarity” not “sameness”.

Biologic medicines are exponentially more complicated in size and structure than small molecule products, and it is technically impossible to make an identical copy of a biologic medicine. This is why the “copy” or follow on medicine is called “biosimilar”¹².

The regulatory standard for biosimilars i.e. similarity rather than sameness, has significant implications for the extent to which patents provide effective incentives for innovation. Requiring biosimilars to be only “similar” to the reference product causes an increased burden on the patent owner to show infringement and thus necessitates additional protections for innovators of biologic medicines through sufficient data protection periods and scope.

What is clear is that without an extended data protection period, other companies would be able to piggyback on the innovator’s clinical data “for free” in the circumstances where the current 5-year term of data protection has expired and the originator patent has been “designed around”. The potential for “design around” exists because of the exceedingly complicated size and structure of biologic medicines.

The justification for an improved data protection regime also exists because of the manner in which biologic medicines, particularly in cancer, are developed.

In cancer research, it is often the case that the initial TGA registration generally focuses on late-stage disease or one particular cancer tumour. Research and development activities for early-stage or adjuvant therapies or different cancers typically occur much later in time. In fact, on average, a biologic that has been on the market for six years is expected to have another two additional indications approved after those first six years.¹³

¹¹ A biosimilar is an off patent medicines which reaches the market by referencing the data of an originator (reference) product, in a similar fashion to generic medicines

¹² A biosimilar is an off patent medicines which reaches the market by referencing the data of an originator (reference) product, in a similar fashion to generic medicines

¹³ The Boston Consulting Group, “Continued Development of Approved Biological Drugs” (Dec. 2007).

Therefore, the need to encourage research and development of new therapies, especially in the oncology area where there is unmet clinical need, does not cease with the initial approval of a biologic. Indeed, data protection is also critical to providing the necessary incentive to research, develop, test and obtain TGA approval for new indications and other important developments emerging from existing biologics.

An example of the issue aims to demonstrate this point:

If we assume that the initial indication for which a molecule is registered is breast cancer, the period of data protection will cover the molecule for the next 5 years. If at year 4, clinical trials justify an expanded indication of head and neck cancer, data protection for this expanded indication will essentially only be for 1 year. If at year 6, clinical trials justify a further expanded indication of prostate cancer, the data generated by these latest clinical trials will receive no protection.

This speaks to the need for longer periods for, and scope of, data protection.

Australia's data protection system is one of the weakest in the developed world. The current term of data protection is 5 years, which is well behind most other OECD countries who offer between 8-12 years of data protection, as well as extensions for new indications.

Extending data protection in Australia will have many benefits including:

- Bringing the Australian data protection regime into line with leading OECD nations
- Improving Australia's attractiveness as a destination for foreign investment
- Supporting the local biotech sector

Amgen would urge the Productivity Commission to change its view on this issue, given that this is an emerging component of the pharmaceutical market, and for which the future of medical intervention is still evolving. Without a substantial period of data protection, the incentive to find new and novel uses for therapies will be significantly diminished.

Yours sincerely,

James Priour
Managing Director, Australia and New Zealand

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics expertise to strive to solutions that improve health outcomes and dramatically improve people's lives.

A biotechnology pioneer since 1980, Amgen has grown to be one of the world's largest independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen was established in Australia 1991 and its corporate headquarters are located in North Ryde, Sydney, New South Wales. It currently markets eleven products in Australia for the treatment of cancer, kidney disease, bone disease and other serious illnesses. It employs around 160 highly skilled people in Australia, one third of whom are engaged in the R&D side of the business. Many are science based graduates.

Amgen has a proud history of clinical trial activity in Australia. Clinical research actually started here four years before Amgen had established offices in Australia: In 1987 early development work in the area of supportive treatment for cancer patients was carried out at The Royal Melbourne Hospital with phase I and II clinical trial work for Neupogen[®], (which helps reduce the incidence of infection in patients undergoing certain cancer chemotherapy).

Amgen's clinical research activity in Australia:

- Contributes disproportionately to Amgen's global clinical trial effort by being in the top ten countries for active clinical studies and in the top five for interventional studies. At any one time, Amgen Australia is involved in over 25% of interventional studies in Amgen's global clinical trial program.
- Consistently contributes 2-3% of patients to the global pool of studies in which the affiliate participates.
- Involves on average two First in Human (FIH) studies every year.
- Has a high level of clinical trial activity in Phase 1 and 2 trials – almost half of Amgen's activity is in this early phase research which provides Australian patients and clinicians with early access to new medicines.

In 2015, Amgen Australia conducted 62 different clinical studies at over 347 sites, involving almost 1645 patients trialling Amgen's innovative medicines.

Amgen Australia invests around A\$30-35 million in local research and development annually, which represents around 12% of its sales – this is very high compared with the industry average.