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3 December 2015

Intellectual Property Arrangements Inquiry
Productivity Commission
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Via email: intellectual.property@pc.gov.au

To whom it may concern

Inquiry into Australia's Intellectual Property Arrangements

Thank you for providing Pfizer Australia with the opportunity to make a submission to the Productivity Commission's *Inquiry into Australia's Intellectual Property Arrangements* ("the Inquiry"). Pfizer Australia strongly supports the Inquiry and welcomes the Government's interest in encouraging public policy debate in this area.

Pfizer Australia is one of Australia's leading providers of prescription medicines and consumer health products. We deliver medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. A number of our products are manufactured right here in Australia across our four high-tech, advanced manufacturing facilities. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer and manufacturer.

Pfizer Australia's submission (Attachment 1) argues that a strong, stable and predictable intellectual property system is critical to fostering local pharmaceutical innovation, productivity and competitiveness. In this way, it is the cornerstone of increased access to life-changing and life-saving medicines for Australian patients. We do this by drawing from our own experience in the Australian market to explore three themes outlined in the issues paper: patents, enforcing intellectual property rights, and regulatory issues.

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia. As an active member of MA, Pfizer was involved in the preparation of MA's detailed submission to this inquiry, and we encourage the Productivity Commission to carefully consider the evidence, analysis and recommendations presented within.

Thank you again for the opportunity to contribute to this Inquiry. Pfizer Australia is available at any time to provide further information.

Yours sincerely

David Gallagher



ATTACHMENT 1

Submission to the Productivity Commission's Inquiry into Australia's Intellectual Property Arrangements



Key Recommendations

- Recommendation 1:** Government should ensure that any changes to intellectual property legislation do not weaken provisions in Australia's current pharmaceutical patent framework nor run contrary to any existing international agreement.
- Recommendation 2:** Government should maintain the current term of patent extension in order to allow patent holders to recoup a valuable portion of a patent term that is lost due to lengthy regulatory processes.
- Recommendation 3:** Government should implement an effective notification system, in line with Australia's obligations under the AUSFTA, that allows patent holders to defend their intellectual property in a timely manner and without causing unnecessary delays to generic market entry.
- Recommendation 4:** Government should reconsider its policy of pursuing damages against innovative pharmaceutical companies and instead use existing legislation available for those cases which are brought in bad faith.
- Recommendation 5:** Government should consider twelve (12) years of data protection for biological medicines.
- Recommendation 6:** Government should consider providing additional market exclusivity for innovative advances.



I. Patents

Recommendation 1

Government should ensure that any changes to intellectual property legislation do not weaken provisions in Australia's current pharmaceutical patent framework nor run contrary to any existing international agreement.

The extent to which a country benefits from IP depends on the country's relative strengths and factors such as infrastructure, political stability, and respect for the rule of law. It is widely recognized that where countries have strong and effective IP protection regimes in place, there is a significant connection between increased incentives for local innovation, and the transfer of technologies that foster local innovation and economic growth.ⁱ A strong intellectual property system also serves to foster an innovative culture and provides incentives for technology transfer and foreign direct investment.

Developing innovative medicines is expensive and carries a high degree of risk. Recent estimates suggest it takes an average of 10-15 years and can cost up to \$2 billion to develop and bring a single new medicine to market.ⁱⁱ Globally, approximately 7,000 medicines are in development and patents play a critical role in providing incentives for continuing to innovate and pursue discovery of cures for patients, including in Australia.ⁱⁱⁱ Most medicines require several years following marketing approval, sometimes decades, before they recoup their substantial investments in research and development.^{iv}

A strong and effective patent regime helps attract investments in the inherently risky, costly, complex and lengthy R&D and regulatory process. Pfizer fully agrees with the issue paper's statement that the patent system drives innovation across the innovative pharmaceutical industry.^v It is equally important to underscore the importance of incremental innovation. Incremental innovation can include reformulating a medicine to encourage compliance with treatment regimens or increasing a medicine's shelf-life and heat stability to ensure the medicine is effective in different environments. Without this form of innovation in the pharmaceutical sciences, many of the medicines we have today (and their delivery forms) would not exist.

To this end, Pfizer Australia urges Government to refrain from implementing any changes that would weaken Australia's pharmaceutical patent system, stifle innovation, including incremental innovation, or run counter to its commitments under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement).

Recommendation 2

Government should maintain the current term of patent extension in order to allow patent holders to recoup a valuable portion of a patent term that is lost due to lengthy regulatory processes.

Pfizer Australia applauds the Government for maintaining five years of patent term extension to address the shrinking effective patent life^{vi} for pharmaceutical innovations.

Following in the footsteps of other advanced economies around the world, the Australian Government introduced patent term extension provisions for pharmaceuticals in 1998 to:

- Compensate pharmaceutical patent holders for the delays in obtaining regulatory approval for new products
- Provide an effective patent life more in line with that available to inventions in other fields of technology
- Create a patent regime for pharmaceuticals in line with Australia's competitors.^{vii}

Patent term extension is based on a doctrine of fairness. If there are delays in obtaining regulatory approval for new products, patent holders ought to be compensated. Without the modest and partial restorations of marketing exclusivity provided by patent term extensions, innovators would have less incentive and justification to make the substantial R&D investments needed to sustain the pharmaceutical innovation process. Patent term extension therefore represents an appropriate and necessary recognition by governments of the increasingly heavy burden



of expense and risk incurred by innovators as a result of government requirements imposed during the R&D and regulatory review process.

Therefore, we applaud Government for its implementation of the 5-year term and for its fair and balanced approach that ensures that products in Australia are afforded the same extended patent life consistent with that in other major jurisdictions. We caution against any legislative provisions that would further reduce this term and therefore stifle innovation.

II. Enforcing Intellectual Property Rights

Pfizer Australia supports adequate and effective protection of intellectual property rights for the innovative pharmaceutical sector. The enforcement of patents is fundamental to their effectiveness in recouping pharmaceutical R&D investment, and thus providing an incentive for further investment in the future. Based on Australia's existing IP framework, there are currently two areas that we urge Government to address as soon as possible:

(a) Notification Provisions

Recommendation 3

Government should implement an effective notification system, in line with Australia's obligations under the AUSFTA, that allows patent holders to defend their intellectual property in a timely manner and without causing unnecessary delays to generic market entry.

Under the current Australian system, innovative pharmaceutical companies do not receive notification of a generic company's intention to enter the market with a product that may infringe a valid and enforceable patent. Patent holders like Pfizer Australia are only able to access this information once the generic product has been registered on the Australian Register of Therapeutic Goods (ARTG). While in recent years Government has introduced quicker publication of new products on the ARTG website, this does not provide adequate notice of a potentially infringing product.

Enforcement systems are only effective for pharmaceutical patents if they provide for early resolution of patent disputes, before an infringing product is launched on the market. Effective notification provisions are an important part of a strong patent system. This is particularly important to help avoid confusion in the marketplace caused by having infringing products marketed and then withdrawn, which can adversely affect patients. In addition, the generic market entry triggers a number of mandatory and irreversible price cuts for innovator products listed on the Pharmaceutical Benefits Scheme (PBS) and also results in market share erosion. An effective notification system would allow the timely resolution of legitimate patent disputes, making it easier for both innovators and generics to make better-informed and more efficient investment decisions. The resulting R&D investment would stimulate increased development of new cures and treatments, which in turn would lead to improved health outcomes and wellbeing of patients.

Pfizer Australia urges Government to implement a fair and effective notification system, in line with Australia's obligations under the Australia–United States Free Trade Agreement (AUSFTA), so that patent holders are able to defend their intellectual property in a timely manner without causing unnecessary delays to generic market entry. Similar provisions were also included in the recently released Trans-Pacific Partnership Agreement text. At the very least, the TGA should be required to notify the patent holder that they have received a patent certificate before beginning to register the generic product.

(b) Damages Claims

Recommendation 4

Government should reconsider its policy of pursuing damages against innovative pharmaceutical companies and instead use existing legislation for cases which are brought in bad faith.



In 2012, the Australian Government initiated court proceedings to recover damages from innovative pharmaceutical companies in cases where patents on PBS-listed medicines had been revoked. The damages sought by the Government relate to the PBS savings the Government may have achieved through the statutory price reduction and price disclosure process if a generic product had entered the market, but for an interlocutory injunction. There is currently no equivalent undertaking to compensate a patent holder, or to restore the patent holder's price, if a generic product is listed on the PBS and subsequently found by the courts to have infringed a valid patent and required to cease supply. This policy was introduced retrospectively, without notice or consultation, and appears to be inconsistent with World Trade Organization (WTO) rules.^{viii}

This is a short-sighted public policy which erodes intellectual property rights by significantly increasing the cost and risk borne by innovative pharmaceutical companies in defending their patents. Government intervention in legal proceedings involving the same patent the Government has granted results in uncertainty for businesses and unfairly penalizes inventors who have sought to defend their legitimate patent rights, which later proved to be unsuccessful. When an innovator receives a granted patent, there is a presumption of validity, and it is this presumption that provides a level of certainty that is required to engage in costly R&D activities. Continued application of this policy could significantly impact Australia's ability to attract local and foreign investment in pharmaceutical research and development.

To uphold the strength and stability of Australia's intellectual property system, Pfizer Australia urges Government to:

- Reconsider its policy of pursuing damages against innovative pharmaceutical companies following the loss of patent proceedings and discontinue all existing claims for damages in cases where patent enforcement proceedings and requests for interlocutory injunctions are brought in good faith.
- Utilise existing legislative measures that are already available to the Commonwealth if it is found that a patent case has not commenced in good faith, has little prospect of success or has been conducted with unreasonable delay (such as those outlined in Section 26c of the *Therapeutic goods Act 1989* and/or within Australia's antitrust laws).
- Implement an effective notification system (as addressed in Notification Provisions above) so that patent holders are able to defend their intellectual property in a timely manner and without causing unnecessary delays to generic market entry.

III. Regulatory Issues

Recommendation 5

Government should consider twelve (12) years of data protection for biological medicines.

Data protection, also referred to as data exclusivity, plays a unique but vital role in protecting intellectual property rights, as well as encouraging R&D investment and follow-on innovation in the Australian pharmaceutical industry. Data protection provides a minimum protection to innovators during which time no unauthorized third party can rely on the data submitted by the innovator for regulatory approval. This exclusivity helps recognize the extensive time, effort, and cost of clinical studies required to ensure that medicines are safe and effective for patients, and it allows biopharmaceutical manufacturers the opportunity to recover some of the costs associated with launching and introducing a new drug into the market.

Data protection is particularly important for innovative biological medicines due to the differences between a biologic and a traditional small molecule medicine. Due to the complexities of biological medicines and the differences that can result in a product made by a different manufacturer, a biosimilar is not an exact copy of an innovator's biological medicine. Due to the evolving nature of patent law surrounding biologic medicines, they are at a greater risk of imitation. Thus, data protection provides an important incentive for continued R&D. For example, a biosimilar may be analogous enough to rely on originator data (after the mandated period of data exclusivity expires) but different enough to not infringe a patent, leading to patent workarounds. In this case, data exclusivity would be necessary to protect intellectual property and the substantial investments of the company.



In the case of oncology, new indications for existing compounds are approved relatively late in patent life. Many oncology drugs, for example, have been shown to work in a wide variety of indications. It is often the largest patient population that is included in the data package when a product is first brought to market. Without suitable data protection, many other indications that require extensive clinical research while the drug is in the market may be missed. Ultimately, this means that patients from smaller population subgroups, with less common cancers, could miss out on access to potentially life-changing and life-saving medicines.

Strong data protection provisions also encourage innovative pharmaceutical companies to conduct clinical trials in Australia. Clinical trials play an important role in not only fostering innovation in Australia, but also helping Australia realise the social and economic benefits of that innovation by:

- Providing patients with early access to novel therapies
- Saving Australian taxpayers millions of dollars each year in hospital and PBS costs
- Creating highly skilled and high-paying jobs for Australians
- Encouraging collaboration between healthcare, education, research and industry sectors
- Building expertise in current international best-practice in the medical and medical research community
- Attracting substantial national and overseas research dollars.

Despite the obvious benefits of data protection, Australia's data protection provisions are still in their infancy. The standard term of data protection in Australia is five years, compared to twelve 12 years of data protection for biologics in the U.S. and ten (10) years of data protection for biologic products in the European Union. The recent finalisation of negotiations under the Trans-Pacific Partnership Agreement to which Australia is a party, include provisions for eight years of data protection for biological medicines or, alternatively, effective market protection for a period that delivers a "comparable outcome" of eight years comprised of a legislated five (5) year period plus "other measures".

To harmonise an important element of the Australian intellectual property system with international best practice, Pfizer Australia strongly urges Government to increase the term of data protection in Australia to twelve years for biological medicines.

Recommendation 6

Government should consider providing additional market exclusivity for innovative advances.

In order to encourage paediatric drug development and testing, the Government should consider granting additional market exclusivity to companies that conduct paediatric clinical studies on their marketed products and develop valuable information about the safety and effectiveness of their product in children. The U.S., for example, grants an additional 6 months of exclusivity, Pfizer is involved in a number of programs supporting paediatric uses of our medicines and we encourage policies that incentivize continued research and development in this area.

We also encourage the Government to consider allowing additional market exclusivity for antibiotics. There has been a significant decline in the development of new antibiotics over the last 30 years.^{ix} This decline is a real issue given increasing levels of resistance to existing antibiotics. In Australia, some types of infections (such as golden staph and gonorrhoea) are already resistant to multiple antibiotics.^x The World Health Organisation has warned that antibiotic resistance is one of the greatest threats to human health today.^{xi} Without access to effective antibiotics, infections that were once easily treatable may become lethal again. If left unchecked, antibiotic resistance could lead to an estimated 10 million deaths a year worldwide by 2050.^{xii}

Pfizer Australia acknowledges that addressing antibiotic resistance is a complex problem that requires global agreement on a multifaceted solution. As a first step, however, towards addressing supply issues in Australia, we urge Government to consider offering incentives around antibiotic R&D. In the U.S., for example, the *Generating Antibiotics Incentives Now Act* (GAIN) grants companies an additional five (5) years of market exclusivity if they develop an antibiotic intended for a qualified infectious disease.



Pfizer Australia also encourages Government to consider providing periods of exclusivity for drugs that cover new formulations, new combinations, new indications, new populations (e.g. paediatrics) and new dosage forms to encourage the follow-on innovation that can maximise the clinical benefit of medicines. In the U.S., for example, new use or new formulation exclusivity provides three (3) years of marketing exclusivity.

ⁱ Park, W. and D.C. Lippoldt, "Technology Transfer and the Economic Implications of the Strengthening of intellectual Property Rights in Developing Countries," OECD Trade Policy Working Papers, No. 62, OECD Publishing, 2008.

ⁱⁱ "Cost of Developing a New Drug," Nov. 2014 Tufts CSDD & School of Medicine

ⁱⁱⁱ Adis R&D Insight Database. Accessed 2015.

^{iv} Grabowski, G. (2008). Follow-on Biologics: Data Exclusivity and the Balance between Innovation and Competition. *Nature Reviews Drug Discovery*, 7, pp. 479-488.

^v Hall, B. and Harhoff, D. (2012, January). *Recent Research on the Economics of Patents* (No, 17773). National Bureau of Economic Research Working Paper. Retrieved from <http://www.nber.org/papers/w17773.pdf>

^{vi} The 'effective patent life' is defined as the period of time between a product's introduction to the market and the patent's expiration date.

^{vii} Commonwealth of Australia. Senate. (1998). *Parliamentary debates (Official Hansard)*. Retrieved from <http://www.aph.gov.au>

^{viii} See Article 50 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

^{ix} Spellberg, B., et al. (2008). The epidemic of antibiotic-resistance infections: A call to action for the medical community from the infection disease society of America. *Clinical Infection Disease*, 46, pp. 155-164.

^x NPS Medicine Wise. (2015). Antibiotic Awareness Week 2015. Retrieved from: http://www.nps.org.au/about-us/what-we-do/campaigns-events/antibiotic-awareness-week?utm_medium=vanity-url&utm_source=15-09-07&utm_campaign=aaw&utm_content=aaw

^{xi} World Health Organisation. (2014). WHO's first global report on antibiotic resistance reveals serious, worldwide threat to public health. Retrieved from: <http://www.who.int/mediacentre/news/releases/2014/amr-report/en/>

^{xii} NPS Medicine Wise. (2015). *Antibiotic Awareness Week 2015 Campaign Toolkit [Brochure]*. Retrieved from: http://www.nps.org.au/__data/assets/pdf_file/0019/312319/antibiotic-awareness-week-toolkit.pdf