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Compulsory Licensing of Patents
Productivity Commission
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Dear Commissioner

Productivity Commission Review – Compulsory Licensing of Patents

Thank you for the opportunity to provide comment for consideration by the Productivity Commission during the inquiry into Compulsory Licensing of Patents in Australia.

Pfizer is the nation's leading pharmaceutical company, employing 1,500 Australians. In addition to our innovative and generic medicines, we have animal health, hospital, consumer and nutrition businesses, with high quality export manufacturing facilities in New South Wales, Victoria and Western Australia. Pfizer is one of the world's largest investors in medical research and development.

Pfizer Australia is a member of Medicines Australia, the peak body representing innovative pharmaceutical manufacturers.

We believe the interests of inventors (and their ability to protect their inventions through intellectual property (IP) are interdependent with the positive economy-wide impacts, including the effects on other businesses, consumers, and the broader Australian community (including social impacts).

Strong intellectual property rights which include patents, trademarks, copyright, and data exclusivity, underpin a company's ability to invest in R&D and commercialise innovative healthcare solutions. There must be predictability in the opportunity for a company to recoup this investment in bringing new and innovative medicines to patients. This should not be challenged unfairly by other companies who bear no initial risk or research investment but seek to profit from these advances via speculative patent challenges. We compete in a global economy and we must have an operating environment which remains world class to ensure we continue to attract investment and opportunity to Australia.

The medicines industry in Australia attracted approximately $1 billion in R&D investment in 2010-11, the third largest by area, behind financial services and mining. Exports of pharmaceutical and medicinal products were just over $4 billion in 2011-12, a increase of 7% on the previous year. The Australian pharmaceutical industry employs over 14,000 individuals as part of a highly skilled professional workforce which provides support for medicines from discovery until well after market launch. In 2011 the investment in clinical trials was $450 million, which allowed around 18,000 Australians patients to participate.

It is essential to recognise the world class access to innovative medicines we enjoy, including access to medicines such as insulin; monoclonal antibodies for rheumatoid arthritis and cancer treatment; biotherapeutics that depend on gene technology, including vaccines and human growth factors is largely due to the Australian IP system.

Health and medical research and innovation brings not only better health to so many Australians, it lifts the quality of the healthcare services and builds our global competitive advantage. One in four medicines approved was a medical breakthrough using a newly discovered molecule, unique to any other currently used to combat disease. It takes the testing of 10,000 molecules, 15 years and more than $1 billion to get one medical breakthrough from microscope to medicine. Health and medical research continues to generate improvement not only in our health but also increases in productivity and our GDP.

The greatest barriers to access are not patents and other forms of intellectual property rights. The challenges we see in ensuring Australian consumers have equitable and sustainable access to our innovative medicines are broad and include regulation and reimbursement hurdles. Genetic testing allows some new medicines to be very accurately targeted in patients most likely to derive a benefit. This also means we can avoid treating patients who will not benefit from a targeted treatment thereby reducing their potential exposure to harm. The real issue in delaying access to patients is the long and uncertain pathway to equitable access, not the IP issues.

The cost in developing and the time taken in shepherding these medicines through the regulatory and reimbursement process is already a significant factor when deciding to invest. Weakening patent laws will not increase consumer access to new technology, it will reduce the likelihood of companies making the investment to bring it to Australian patients.

The issues paper notes: *While this inquiry was largely initiated in response to past debates about the patenting of genes, the focus of the inquiry is on the application of compulsory licensing rather than gene patents (p.2, Issues Paper).* The concerns around gene patenting in Australia and the limitations on access to innovative healthcare have shown to be unfounded. While critics of our system are genuine in their beliefs, extensive debate, inquiries and reviews have ultimately endorsed Australia's existing arrangements and those of our trading partners. Genes cannot be patented, as they are discoveries and not inventions. To consider whether there should be a link between compulsory licensing and access to gene technology is not appropriate in Australia. There is ongoing access to innovative diagnostic testing and medicines in Australia.

As knowledge of genetics has grown – particularly with the publication of the Human Genome in 2001 – the number of patents on individual genes has dropped sharply. This is because the threshold for 'novelty' and 'inventiveness' at the heart of the patent system is now very much higher than it was when the first gene patents were issued. As patent offices worldwide have gained experience with genetic technologies, the patents now granted are much more specific to the biotechnologies than the early broader patents. Since the patent term is 20 years from the date when the priority application is filed, the majority of the early, broad patents are nearing the end of their patent life.

Pfizer supported the development and implementation of the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*, which represents the culmination of a systematic and wide-ranging review of IP rights in Australia.

These reviews took into consideration not only the current environment but also a long-term strategic view to future trends across all technologies.[1] The Raising the Bar Bill raises patentability standards and strengthens research use exemptions. This strengthening of the legislation is an essential element for ensuring Australians have continued access to innovative medicines which are central to the future health and productivity of our nation.

The issues paper raises the BRCA1 and BRCA2 case, the unique example used by those who have previously sought wholesale change to Australia's regulatory system. A business decision by a single patent holder, since reversed, is not evidence that Australia's entire patent system is fundamentally flawed. As we urged the Senate Committee to consider, the vast majority of patents on genetic material and technology at work in Australia have not limited research or access to healthcare. Currently the Australian Government Medical Services Advisory Committee is considering many applications from companies for genetic testing of patients to allow equitable access to targeted therapy.

There are already sufficient legislative mechanisms in place which provide a safeguard for those instances where one company owns the IP on an innovative medicine, for example, but for whatever reason are unable to commercialise the product. As stated by the Commission: *Patent licensors may enter into a licensing arrangement for a number of reasons. For instance, the licensor may lack the capability to manufacture the invention themselves, or they may lack the capacity to supply customers in different geographic regions. Alternatively, they may be unable to scale their existing production facilities to meet increased demand for their invention, or they may wish to transfer the risk for the manufacture and marketing of the invention to another party. In such cases, licensing of the patent may be an appropriate solution. (p.4).*

To guard against issues such as *reputational damage if the invention is implemented poorly (p.5)* company interests are protected through the strength of the contractual agreement between the two parties involved and the responsibility is not with IP Australia. These are contractual commercial arrangements and not intellectual property matters.

Compulsory Licensing
Overall, we do not believe compulsory licensing of patented inventions is a sustainable or viable course of action to address any challenges to the equitable access of healthcare in Australia. As noted, proposals to promote the use of compulsory licenses could inhibit technological development in the pharmaceutical sector in Australia and thereby undermine efforts to make medicines and other products widely available to patients. In fact, many governments and experts share the view that compulsory licenses should be used only in exceptional circumstances – and only as a *last resort*.

The use of compulsory licensing therefore is rarely the best policy option and cannot be a suitable tool to addressing issues with access. The key to ensuring that issues with equitable access to innovative healthcare solutions in Australia are addressed is a working partnership with all stakeholders, including the innovative biopharmaceutical industry, who are more than ready to partner with the Australian government and other stakeholders to address these long-term issues in a meaningful way. An active compulsory licensing policy will not be helpful in promoting such partnerships.

In relation to the specific questions raised by the Commission:

[1] Previous consultation included the Senate Community Affairs Inquiry into 'Gene Patents' (November 2010); the Australian Government's Advisory Council on Intellectual Property (IP) report *'Review of Patentable Subject Matter'(February 2011); and* the Australian Law Reform Commission (ALRC) 2004 report *'Genes and Ingenuity: Gene Patenting and Human Health'*. Currently, the Legal and Constitutional Affairs Committee is conducting an inquiry into *Patent Amendment (Human Genes and Biological Materials) Bill 2010*, to which Pfizer provided a submission.

How might compulsory licensing be utilised to address the specific concerns related to genes, food security, climate change mitigation and alternative energy technologies, and standard essential patents? Is compulsory licensing the most effective means to address these concerns? Should the compulsory licensing provisions be altered to specifically address issues related to genes, food security, climate change mitigation and alternative energy technologies, and standard essential patents? What are the advantages/disadvantages of altering the provisions in such a way? Would maintaining a more general (technology neutral) approach be preferable?

We do not support any change to compulsory licensing specific to the matter of genes. The current IP provisions, including the options for licensing, are more than adequate to address any concerns which can be raised regarding access to innovative healthcare, from diagnosis to treatment. We reiterate that the issue of lack of access to the BRCA1 and BRCA2 diagnostic tests were commercial issues not related to IP, and were ultimately resolved. There are currently sufficient avenues through licensing, technology transfer arrangements, Crown use provisions and research exemptions to ensure equitable access to diagnostics and medicines for treatment and research in Australia. Any change to the current status would send a major signal for consideration during investment decisions and would likely result in less investment and reduced access if Australia is seen as an unpredictable market.

After extensive examination of the issues and broad community and international consultation on the matter, the previous inquires and reports recommended strengthening of current IP legislation and application. The Raising the Bar Bill does this. There was never a recommendation for wholesale change and there has been no indication that a change in the compulsory licensing provisions would prevent the isolated incident which arose with the BRCA1 and BRCA2 genes. Pfizer's position since the inquiry in 2009[2] is unchanged and is reflected in the findings of the Australian Government's Advisory Council on Intellectual Property[3]:

> *"We have found that no persuasive case has been made to introduce a specific exclusion to prevent the patenting of human genes and genetic products. Accordingly, we do not recommend the introduction of such a specific exclusion.*
>
> *"No case has been made for the abolition of the current specific exclusion preventing the patenting of human beings and biological processes for their generation. It should be retained."*

The changes implemented with the Raising the Bar Bill[4] ensure legislative provisions protect commercial and trade interests whilst ensuring a robust research environment, including the strengthening of enforceability of IP rights in Australia. Current IP provisions are in line with Australia's prominent and principled position in the protection of intellectual property rights, as a signatory of the TRIPS Agreement (Agreement on Trade Related Aspects of Intellectual Property Rights) and as a member of the World Intellectual Property Organisation (WIPO). In fact, if there was consideration that enabling compulsory licensing on grounds other than those outlined in the TRIPS Agreement, it would be seen to be going back on the Australian Government's

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[2] *"We do not believe that there are fundamental problems with Australia's patents system covering gene technology. Although there have been a small number of high-profile cases concerning gene patents, these need to be balanced against the large number of cases where patents are working as they are intended to – creating incentives to harness knowledge of genetic science and improve human health. Our advice to the Senate Committee is that Australia's patent laws – and IP Australia – work well for the Australian community, the research community, and for investors.* Pfizer Australia, Submission to the Senate Community Affairs Committee Inquiry into Gene Patents, pg 2

[3] Australian Government's Advisory Council on Intellectual Property (IP): Review of Patentable Subject Matter, pg 60, February 2011.

[4] To address concerns raised around gene patenting stifling access to biological material for research purposes the Bill specifically includes amendments to strengthen the enforceability of the current legal provisions to ensure that scientists are free to conduct research on patented inventions, so long as it is for the purpose of investigating the patented invention, allowing access for research purposes (*Schedule 2- Free access to patented inventions for regulatory approvals and research, Section 119C.*).

international commitment to uphold and encourage innovation. Such a policy shift to the country would be minimal – if at all – in terms of improving access to modern medicines.

However, it would send a strong negative to companies considering investments here. In such a scenario, our country could lose its hard earned credibility as a nation which fosters innovation and respects international laws and commitments.

For these reasons and those outlined in our previous submission we strongly urge the Commission to recognise that the current compulsory licensing provisions are appropriate to ensure access to innovative healthcare in Australia.

Yours sincerely

John Latham