AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

AusBiotech response to the

Productivity Commission Issues Paper: Compulsory Licensing of Patents

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To: Productivity Commission
Compulsory Licensing of Patents
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AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), food technology and agricultural, environmental and industrial biotechnology sectors; working on behalf of members for more than 25 years to provide representation to promote the global growth of Australian biotechnology.

Introduction

AusBiotech provides this submission in response to the Productivity Commission's discussion paper on its review into compulsory licensing in the patents system, in which it examines whether and how to ensure access to patented technology, while maintaining the patent incentive to create and protect new technologies.

Please find following AusBiotech's comments, based on feedback from its membership, which includes biotechnology companies, ranging from start-ups to mature multinationals, research institutes and universities, and specialist service professionals. In addition, AusBiotech has reviewed the joint submission made by the Institute of Patent and Trade Mark Attorneys (IPTA) and the Australian Federation of Intellectual Property Attorneys (FICPI Australia), and would like to indicate its general agreement with the submission. Salient points from the IPTA and FICPI submission are included below.

Technology neutral IP laws

The Government said in announcing the review that it "was prompted by concern about a perception that patents over genetic technologies, or a perceived lack of licences to use these patents in Australia, unreasonably restricts or delays patient access to medical advice based on the latest diagnostic tests."

AusBiotech supports technology neutral IP laws and welcomes the note in the discussion paper that "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" and the note in the terms of reference that "compulsory licensing is also relevant to a number of other areas, including climate change mitigation and alternative energy technologies, food security, and standard essential patents."

AusBiotech agrees with IPTA and FICPI (point 56), which "supports the decision of the majority of the Senate Legal and Constitutional Affairs Legislation Committee on the gene patents issue. The general issues which were raised in respect of gene patents are also raised in respect of alternative energy and other climate change mitigation technologies, food and certain essential patents…it believes that the *Patents Act* should be technology neutral and that there should be no industry specific provisions or at least any more industry specific provisions."

Striking the balance

AusBiotech welcomes the Commission's cognisance of the importance of striking a balance between incentives for industry and researchers to invest in research, development and innovation and on the other hand affordable and equitable access to technologies, including healthcare.

As IPTA and FICPI note (point 14) "compulsory licence regime is, in a sense, a balancing act between the long term interests of the public, inventors and investors and the short term interests of the public. Any dealing with the short term interests of the public should not detract from the overall long term goal of the system which is to encourage investment in research and development. In assessing the compulsory licensing provisions, IPTA and FICPI submit that the assessment must take place in the wider context of what the system delivers in the long term."

IPTA and FICPI said (point 57): "The danger in responding to the emotion charged debate in relation to gene patents by amending the compulsory licensing provisions to accommodate access to patents in relation to the use of particular gene sequences for diagnostic and other healthcare reasons runs

the risk that, in the long term, investment in research and the commercialisation of research in the healthcare area will be substantially reduced… if investors are not able to recoup their investment in successful and failed projects because a compulsory licence is obtained in respect of a successful innovation, there will be less incentive to invest and less money for investment."

AusBiotech agrees and believes that uncertainty in the patent system caused by an increase in the issuing of compulsory licences will affect access to technologies in the longer term by substantially reducing the incentive to innovate and to invest in innovation and commercialisation. An uncertain or unbalanced situation will increase risk, and in all likelihood flow-on to decrease benefits for the community in withdrawn products. The Abbot Laboratories experience in Thailand is a case in point in the IPTA and FICPI submission. The Thai government compulsorily licensed a HIV medication, which prompted Abbot Laboratories to withdraw 7 product applications. IPTA and FICPI (point 61) also notes the following example:

> India is another country which has issued a compulsory licence for a pharmaceutical product in circumstances which did not take due account of the significant research and development costs associated with the commercialisation of a pharmaceutical product. In that case a compulsory licence was granted to an Indian generic company, Natco Pharma Ltd, to produce a generic version of Bayer's drug, Nevaxar (sorefanib) which is used to extend the lives of patients with advanced liver or kidney cancer. The compulsory licence was granted on the basis that the price at which the drug was offered by Bayer was much more than general members of the public could afford. The generic company, who did not have to expend the money associated with the research and development of the product, was able to produce the product and offer it for a price much lower than the Bayer's price. On this basis the compulsory licence was granted. This decision, which is under appeal, is considered to have set a dangerous precedent in India, and will likely have an adverse effect on the availability of new medicines in India. It also confirms the perceived negative attitude in India to research-based pharmaceutical companies, and sends a strong message that India would prefer to "free ride" on the research and expenditure of others than contribute to this effort through subsidising the cost of medicines to the general public.

<u>Existing provisions work and 'Raising the Bar'</u>

AusBiotech supports safeguards that are readily-accessible and adequate in their reach to ensure all Australians have access to beneficial technologies and are protected against a patent owner who, in the course of exercising their patent rights, may act unethically or unreasonably in granting a license to a medicine, test or technology.

These safeguards currently exist in 'crown use' and compulsory licensing provisions and their lack of use – only three applications have ever been made in Australia - suggests they are rarely required. All three were based on a perceived unmet reasonable requirement of the Australian public and none were granted. These provisions should be and are available for exceptional circumstances. The system is working as it should. Provisions are not so accessible as to cause uncertainty to patent holders, but allow an independent review, and this situation is appropriate in a country that seeks to encourage innovation.

Any recommendation that lowered the threshold to gain in the short-term, would do so at the expense of long term benefits to the community in access to new innovations at a micro level and to Australia's productivity at a macro level. The threat of compulsory licensing adds additional risk for biotechnology research and development, and the potential threat of government confiscation of patents to address national or global problems would make it difficult for companies to pursue development of products that hold much promise, but are risky endeavours.

For many biotechnology companies, patents are their only asset, from which they attract the investment necessary to develop biotechnology products. If there is a threat of compulsory licensing is increased, not only will investors have to factor the inherent risk of failure, they will also need to consider whether a product or a technology stands a risk of being nationalised by the Federal Government.

The IPTA and FICPI submission carries a quote from the Deputy Assistant Attorney General of the Anti-Trust Division of the US Department of Justice, Makan Delrahim, who said: "When uncertainty increases, innovation often decreases, which is exactly the opposite of what should be the long term goal of competition law…There are important policy reasons to cause us to be cautious when considering a compulsory licensing remedy. The most important of these is the concern that an improperly designed compulsory licence can stifle innovation."

Government investment contributes to research and development, but cannot alone fund the millions of dollars required to develop a biotech food, health or environmental product. The private sector funds double the Government's contribution in Australia. The threat of compulsory licensing may reduce investor confidence in the industry, and may stifle development of new biotech agricultural products and other products, if the system was deemed to be unfair or unreasonable, or not taking into account wider commercial issues.

AusBiotech has no issue with protecting the community from inappropriate monopolistic behaviours, however, the tests applied must be reasonable and the companies concerned treated fairly in terms of compensation.

During the many reviews and inquires related to gene patents over the past decade, AusBiotech has also supported a 'research use' exemption to be enshrined in the law, based on the understanding that this would provide clarity and certainty to researchers as well as ameliorating concerns about access for research purposes. This exemption has now been delivered with the recent changes to the intellectual property system provided in the *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*. The legislation began to take effect in April 2012 and will not be fully phased in until mid-2013. While in its very early phase, the legislation directly addresses the articulated concerns about in appropriate monopolistic behaviours impacting research. Its impact cannot be assessed until it has had a reasonable period of functioning.

<u>Compulsory licensing in healthcare</u>

The inclusion of 'gene patent' debate in this review and the comments of Bradbury and Dreyfus in launching this review that "Of concern to government is a perception that patents over genetic technologies, or a perceived lack of licences to use these patents in Australia, unreasonably restricts or delays patient access to medical advice based on the latest diagnostic tests," is of note. Its inclusion suggests that making compulsory licenses or acquisitions easier to obtain – effectively lowering the bar - may be seen by some as a suitable response to the gene patent debate.

AusBiotech does not agree that compulsory licenses, acquisitions or crown use provisions are appropriate 'tools' to use to gain access to new gene-based technologies and supports the use of other regimes if price is the issue. This would be an acute response to a specific, short-term challenge and not a panacea for the most controversial matters in healthcare.

For example, a pricing system in the style of the Pharmaceutical Benefits Scheme (PBS) is a mechanism that gives the Government a framework for controls over pricing of medicines and to a large extent the market itself. In a listing and negotiation process, innovative developers take lower prices on their products than would be afforded in a free market system in exchange for access to

the Australian market. To use a compulsory acquisition instead would need to add value not already available via the PBS.

Conclusion

AusBiotech support the ongoing technology neutral treatment of intellectual property in Australia and appreciates the Commission's attention to striking a balance between immediate access to technologies and the innovation system that enables them to be accessible to the community in the short, medium and long term. The current system of safeguards appears to be working well and the "Raising the Bar" legislation is expected to provide certainty that was previously lacking. We also note that compulsory acquisition still requires that a company be compensated for its development of intellectual property and is not the answer to a debate in which the proponents talk about access but in reality potentially seek to free-ride another's research and development investment.