AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

AusBiotech response to the Pharmaceutical Patents Review

(Background and Suggested Issues Paper, November 2012)

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Introduction

AusBiotech provides this submission in response to the Pharmaceutical Patents Review's Background and Suggested Issues Paper (November 2012). AusBiotech has a keen interest in the Australian patent system to the extent that is supports (or undermines) innovation, and its ability to provide appropriate incentives for companies to develop and bring new technologies to patients.

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.

Conventional wisdom dictates that a strong and reliable intellectual property and patent system is a standard requirement to attract sought-after foreign and domestic investment. For many biotechnology companies, patents are their only asset, from which they attract the investment necessary to develop biopharmaceutical products.

In response to the evaluation of "whether the system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively price pharmaceuticals, fostering innovation and supporting employment in research and industry" and the review of the "appropriateness of the extension arrangements for pharmaceutical patents," AusBiotech suggests that incentives are being eroded over time, thereby undermining innovation of bio-pharmaceuticals in Australia, and there is a good case for extending intellectual property protections to re-balance the system.

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.

Protection period too short

With intellectual property protections the foundation stone of innovation, AusBiotech is keen to see the Australian patent system for medicines and medical technologies harmonised with other key jurisdictions and provisions in countries that are Australia's key trading partners. Amongst the options to do this is the option to introduce longer initial patent periods or increase extension periods, which would provide greater certainty to industry and the government.

The patent term extension provisions were intended to provide a reasonable period of exclusivity after regulatory approval and 15 years has understood to be an effective protected period, since 1995. An analysis of data published by IP Australia, conducted by Davies Collison Cave (4 January 2013), shows only 53.22% of patent extensions have provided an effective 15 year provision from the date of the first "inclusion" of the product in the Australian Register of Therapeutic Goods. Almost half of the medicines received less than adequate market exclusivity. (http://www.davies.com.au/pub/detail/676/australian-pharmaceutical-patents-review-response-to-suggested-issues-paper)

The length of Government administrative and review processes prior to the listing of a device or medicine needs to be factored into what is seen as the reasonable exclusive period covered by a

patent. The extension is provided as a reasonable way of compensating patent owners for delays in the approval process, but the time for a product to actually reach the market, often means application via Australia's Pharmaceutical Benefits Scheme (PBS) reimbursement processes should also be factored in as it appears to be trending slower over time.

Patents on medicines in Australia have a five year data protection for clinical trial data submitted for regulatory approval, while most other industrialised countries offer eight to 12 years.

Pharmaxis, recently obtained reimbursement for the first new cystic fibrosis treatment in over 15 years, Bronchitol, which was discovered and developed in Australia. Pharmaxis CEO, Dr Alan Robertson said: "Government delays in approving funding have become a serious impediment to the introduction of new pharmaceuticals and this serves nobody well – not the patient with the disease, not the pharmaceutical company and not the government that has to pay for the treatments. These delays and the uncertainty add a lot of cost. They also mean the pharmaceutical company has a shorter time in which to recoup its investment in research and development. Paradoxically, the extended debate about the cost effectiveness of a product actually drives up the end cost of the product."

He goes on to say his relatively small company was left in limbo after it took more than 18 months for the Australian government to decide whether to reimburse Bronchitol after the Therapeutic Goods Administration (TGA) took only one year to review and approve the product as safe, effective and ready for marketing. (BioSpectrum Asia, October 2012)

A recent report from the UK Office of Health Economics (December 2012) reviewed research published over the last three decades, and confirmed what the industry has known anecdotally for some time: the costs and times of R&D are increasing.

The study shows an increase in costs from £125 million ($199 million) per new medicine in the 1970s to £1.2 billion ($1.9 billion) in the 2000s (both in 2011 prices). The R&D Cost of a New Medicine identified four factors contributing to increasing R&D costs: higher company out-of-pocket costs, up nearly 600 per cent over the period; lower success rates from clinical development as researchers tackle tougher therapeutic areas such as dementia and arthritis; increase in R&D time as science becomes more complex, from six years to 13.5 years; and increases in the cost of capital from 8% to 11%. In addition, time is needed to clear regulatory and reimbursement hurdles. (http://www.ohe.org/publications/article/the-rd-cost-of-a-new-medicine-124.cfm)

In Australia there has been a decade-long trend in increased delays, with the average time between a positive TGA recommendation and PBS listing increasing steadily from 13.6 months in 2000 to 34.2 months in 2009. Delays in the reimbursement approvals of medicines add to the erosion of patent protection and increase the total cost to the payer. It also increases uncertainty and discriminates against smaller companies (many of them Australian) as the company must have 18 months to two years' cash to survive the wait.

A study by the Australian Healthcare and Hospitals Association (November 2012) looked at applications for new medicines or for medicines to be used to treat new conditions approved in 2004 by the TGA and found that only 43% of these products were submitted for PBS listing within

two years, with an average 17-month delay from TGA approval of a product to consideration by the Pharmaceutical Benefits Advisory Committee (PBAC).

The analysis said that possible reasons for the delays included the cost of a major submission to the PBS - since 2010 the PBS has charged companies additional cost recovery fees of up to $19,500 per submission - particularly for medications with relatively small markets. A major PBS submission requires the collection of rigorous data on effectiveness and cost effectiveness. The time and resources required to prepare a PBAC submission means companies may choose not to apply for PBS listing and instead look for alternative ways of selling and marketing products and the need to negotiate on price with the pricing authority creates fewer incentives for pharmaceutical companies to apply for PBS listing. (http://ahha.asn.au/news/pbs-delays-need-industry-and-government-action)

Conclusion

The incentives to develop and patent innovative medicines in Australia are slowly eroding over time. This is caused by a raft of forces, including the trend towards medicines that target smaller patient groups (markets), increasing regulatory and reimbursement time, costs, complexity and uncertainty, increased cost and risks of clinical trials. There is also increasing uncertainly in policy, such as the process for Cabinet review of PBAC recommendations, which has been volatile in recent years, as well as continued reviews and comparative swift policy change and implementation.

New therapies (such as biologics) are demanding more time and investment due to the level of complexity and the data exclusivity period has not been reviewed in line with the industry-wide shift from small to large molecules.

If Australia is serious about becoming a knowledge-based economy, the case is strong for extended and increased periods of exclusive market access, as the pendulum has swung too far in the wrong direction – discouraging innovative companies. Many of the contributing factors are outside of the remit of IP Australia, but one way to re-balance is for consideration to be given to increasing the period of time companies have to recover their investment by ensuring a reasonable period of exclusivity.