Intellectual property in medicines

Roche Australia (Pharmaceuticals) Policy Position

Summary

- Roche recognises the social contract inherent in medicines development: that companies are able to achieve a return on high-risk investments during a period of patent protection, after which time competition delivers savings to the community.
- Medicines development is expensive and risky, so intellectual property (IP) rights, consistent with global standards and agreements, are important for continued investment.
- A proper balance between driving savings from competition and encouraging continued innovation in medicines will improve health outcomes.
- As research does not always proceed in a linear way, some medicines are developed and registered for a particular use after patents have expired. In these circumstances, increasing Australia's "data exclusivity" term to align with other developed countries would provide a viable pathway for companies to develop medicines that are not protected by patents.

Background

Globally, Roche is one of the top ten investors in research and development[1]. Like all research-based companies, Roche relies heavily on intellectual property (IP) protection to be able to recoup long-term investments in research into new medicines and to pursue further innovations. To develop one medicine, it is estimated to cost over USD 1.4 billion (AUD 1.8 billion)[2].

In Australia, a patent prevents competitors from entering the market with the same or a similar product for a period of 20 years from when the patent application is filed. In the case of medicines, these competitor products are "generics" (same) or "biosimilars"[*] (similar). A possible extension of five years may be granted, recognising the impact of delays in securing approval by the Therapeutic Goods Administration (TGA) before being able to market a product[3]. Even with this extension, delays in reimbursement on the Pharmaceutical Benefits Scheme (PBS) may mean development costs are recouped over a shorter period than the original patent term of 20 years.

Roche position

Roche recognises the social contract inherent in medicines development: that companies are able to achieve a return on high-risk investments during a period of patent protection, after which time competition delivers savings to the community. It is important that there is a proper balance between driving savings from competition and encouraging continued innovation in medicines,

[*] Similar (but not identical) copies of medicines produced by biological means.

which will create the next generation of treatments for patients and drive improvements in health and non-health outcomes.

Once a patent expires and a generic or biosimilar competitor enters the market, the medicine continues to provide improved health benefits at a significantly reduced cost to government. However, without the initial introduction of a medicine, which depends on a company being able to achieve a return on investment, the full long-term value of the medicine may never be realised. IP incentives and enforceable rights, consistent with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), are important for continued investment in improving health outcomes.

Medicines are highly complex and are rarely a "one-time" innovation. The value of medicines may come from innovations in new methods of delivery, new formulations and new indications (uses). Improvements in medicines are sometimes disparaged as "evergreening". However, innovations such as oral or sub-cutaneous presentations of originally intravenously-administered medicines may drive greater efficiency of delivery in the healthcare system, improve compliance and be preferable to patients. In addition, these improvements in presentations are not introduced at a higher cost to government than the existing presentations. It is appropriate that these innovations are able to be patented, providing an incentive to deliver value to patients and the community, and not penalised with price reductions. This is consistent with the intent of the Strategic Agreement between the medicines industry and the Australian Government.

In case a generic competitor launches before patent expiry, and the originator, in good faith, believes it has a valid patent, it may choose to seek an interlocutory injunction to prevent launch of the competitor. Such injunctions are particularly important, given the listing of a generic competitor triggers the automatic application of mandatory PBS price reductions, the loss of market share, and unpredictable "price disclosure" outcomes. It can be challenging for an originator to be compensated appropriately if a competitor is allowed to launch and the originator's patent is ultimately upheld. Only a small proportion of injunctions granted by the Federal Court for PBS medicines have seen the patent later revoked[4].

In situations where an interlocutory injunction was granted but the patent was subsequently revoked, the Department of Health is seeking damages for the additional costs to the PBS from delayed generic entry. However, since the validity of the Department's claims has not yet been established, it is an uncertain situation for all parties. Roche considers that, in the interests of a stable operating environment, all stakeholders need to agree on a policy that balances the ability of originators to protect their IP, including through interlocutory injunctions, and the sustainability of the PBS. One potential option would be for greater use of notification to the originator sponsor that

a company intends to launch a generic medicine while a patent is still in place, which could allow resolution of issues prior to application of statutory price reductions.

Medical and scientific research does not always proceed in a linear way, and some medicines are developed and registered for a particular use after patents have expired. In these circumstances, "data exclusivity" provides some additional certainty around recouping risky investments. In Australia, data exclusivity means that another company (usually the manufacturer of a generic or biosimilar competitor) cannot rely on the data contained in the originator's evidence package to the regulatory authority for five years. This term is somewhat shorter than in similar jurisdictions, such as Canada, which offers eight years; the European Union, which offers ten years (with eight years of non-reliance on the originator's data) and up to 11 years for new uses with significant clinical benefit for patients; or the United States, which offers up to 12 years for biological medicines.

Data exclusivity and patent protection generally overlap and most Australian patents have an effective patent life exceeding data exclusivity by two years or more[5]. Increasing Australia's data exclusivity term to align with similar markets would therefore be unlikely to delay generic competition for medicines. Rather, the effect would be to increase the viability of those medicines that are not protected by patents, encouraging innovator companies to bring them to market and deliver additional clinical value and health outcomes to Australians.

Roche is concerned that without the correct IP incentives and enforceable rights, continued investment in improving health outcomes would not be sustainable. Roche therefore supports the maintenance of a strong, stable and predictable IP system in Australia.

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 24 September 2018 and entered into force the same day

Further reference

Pricing – Roche Australia (Pharmaceuticals) Policy Position

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[1] PricewaterhouseCoopers. 2017. "The 2017 Global Innovation 1000 study", retrieved from https://www.strategyand.pwc.com/innovation1000#VisualTabs1, 13/3/18

[2] Tufts Centre for the Study of Drug Development. 2014. "Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion", accessed from http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study, 13/3/18, converted at rate of 0.79 USD = 1 AUD

[3] IP Australia. "Types of patents", accessed from https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents/, 3/09/18

[4] Medicines Australia. 2013. "Submission to the Pharmaceutical Patents Review". Canberra, p12

[5] Harris T et al. 2013. "Pharmaceutical Patents Review Report". Canberra, p159