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 five 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 2.0 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. In the case of one Roche medicine for breast cancer, the time to government subsidisation has meant that the exclusive period in Australia has been just 15 years[4].

Roche balances its need to secure a reasonable return with the importance of providing access to healthcare in the world's poorest countries. For that reason, we do not file for new patents or enforce existing patents in the world's least developed (UN definition) and low income (World

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

Bank definition) countries. We also do not file or enforce patents for HIV medicines in sub-Saharan African countries, including South Africa.

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, which will create the next generation of treatments for patients and drive improvements in health and non-health outcomes. Roche is concerned by initiatives that devalue IP, based only on delivering savings, such as the 5% price reduction for all products that have been on the F1 formulary of the PBS (i.e. with no generic or biosimilar competitor) for more than five years.

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 as well as being 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.

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 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. Since 2007, only two of 20 injunctions granted by the Federal Court for PBS medicines have seen the patent later revoked[5].

In those 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 in the case of 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[6]. 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 value to Australians. "Repurposing" medicines for new uses still requires significant investment and risk, and may not be viable without IP protection.

Another area of policy discussion in recent years has been patents on medicines or diagnostics that are derived from naturally-occurring molecules such as gene sequences or proteins, sometimes inaccurately referred to as "gene patents". The debate on this topic has been confused by a perception that companies have the ability to patent something that occurs in the natural environment (and is therefore not different from nature). However, naturally occurring compounds must first be isolated from nature and when produced (e.g. by biotechnological means) are often different in structure. In addition, in order to be patentable, either the structure and/or its process of isolation and/or its production must not be "obvious" to be patentable. Patents can only be granted where there has been an "inventive step" in the development of a treatment or diagnostic.

This has been confirmed by the 2015 High Court decision on the BRCA genes for risk of breast and ovarian cancer[7]. Many new medicines and diagnostics that benefit Australian patients depend on research based on naturally-occurring substances[8]. A broad ban on patents of any natural biological substances could discourage innovation and limit Australian's access to the benefits of medical research.

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 31 May 2016 and entered into force the same day

Further reference

Pricing – Roche Australia (Pharmaceuticals) Policy Position

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