Our position on
Intellectual Property

What is the issue?

Intellectual Property (IP) underpins the system that has led to transformational medical breakthroughs in areas including HIV, diabetes, cancer, cardiovascular disease, and COVID-19. No other mechanism for developing new medicines or vaccines has been shown to stimulate these levels of innovation, which in turn has benefitted patients.

There are various forms of IP protection that can be applied to medicines. Patents are granted for products which are new (i.e. not known) and inventive (i.e. not obvious) at the time they are sought. They give their owner the exclusive right to manufacture and market the product, usually for 20 years from the date of application. Regulatory data protection (RDP) is another form of IP, which grants companies the exclusive right to rely upon data they have generated and submitted (proprietary pre-clinical and clinical data) to regulatory authorities to obtain marketing authorisation for their products.

These protections promote competition and the development of future medicines, as investors have confidence the innovation created will not be immediately copied. This is particularly important given the risk and cost associated with medicine R&D. The return can then be re-invested in further R&D to generate the next generation of medicines and vaccines.

While the IP system has generated cutting-edge treatments, some stakeholders believe that IP is a barrier to affordability and patient access to medicines and vaccines, particularly in low-income countries. We believe that IP protections can be used in a responsible way, as part of a holistic approach to widening access.

In this paper, we set out the core principles underpinning our position on IP and the approach we take to patents and licensing – for example, being flexible with patents in lower income settings.

What is GSK's view?

- IP protections are the foundation for the success of the current system of innovation. The cost of discovering and developing a new medicine has been estimated to be around $2.6 billion[i]. Around 80-90% of candidates fail, and those that are successful require roughly 15 years to develop[ii]. This innovation ecosystem only works with a stable IP framework in place. Capital would not be raised or invested without IP providing some protection and potential for return.
- A competitive, quality generics market is an important counterbalance to patented innovation. Following patent expiry, generic competition can reduce prices and encourage originator companies to further innovate, funded by previously patent-protected products. This counterbalance is an important part of any healthcare model and we support an efficient and competitive generics market.
- IP protections can coexist with mechanisms to improve access to medicines. We believe the root cause of healthcare challenges in developing countries is multifaceted. Solving access challenges requires partnership working to ensure that innovation reaches patients.
- For the IP system to function effectively, we must use it responsibly. We believe a good IP system is one that contains rigorous checks and balances. These include a strong examination process for patent applications and a system to allow wrongly granted patents to be legally challenged.

- Transparency about which patents are held in which countries is important for procurement agencies to understand IP issues relevant to their plans. We are committed to making information about our current and future patent portfolio more freely available.
- We acknowledge the role of compulsory licenses as one of the flexibilities in TRIPs, and the importance of improving access to medicines and vaccines in Low-Income Countries (LICs). However, we believe more focus is needed on the underlying challenges for access. As the protections granted by IP are necessary to incentivise investment in R&D, there is a risk that widespread use of compulsory licenses could undermine future innovation.
- RDP is a critical intellectual property right for the pharmaceutical industry. It provides an important incentive for innovation and protection of investment where there is little or no patent protection.

Our approach to patents and licensing

Patent filing

In 2016 we announced an approach to filing patents where we are the marketing authorisation holder for medicines on the WHO's list of essential medicines that reflects a country's economic maturity:

- We no longer file patents for our medicines, or enforce historic patents, in Least Developed Countries (LDCs) and LICs. Generic companies can manufacture and supply generic versions of our medicines in those countries.
- For non-G20 Lower Middle-Income Countries (LMICs), we may file for patents but we are open to offering licences to allow supplies of generic versions of our medicines where we believe this will enable access. For other countries, our approach to seeking patent protection will be in accordance with our commercial strategy.
- ViiV Healthcare, a specialist HIV company - with GSK as majority shareholder - has a description of circumstances in which voluntary licenses will be considered in their policy briefing on access to medicines.

Voluntary licensing

In our view, voluntary licences are more feasible to implement when:

- products are in a therapy area where there are limited suitable alternative products available;
- policies and funding are in place to support the purchase of the licensed products at volumes that are attractive and sustainable for generic producers;
- products are easy to manufacture and administer and do not require complex, capital-intensive facilities; and
- clear demand forecasts are available to support generic and third-party investments to build appropriate manufacturing capacity and ensure sustainability.

In some disease areas few therapy options exist, and the only medicines available may still be under patent protection with no generic alternatives. In these circumstances, we may allow generic

manufacturers to produce and supply versions of our patented medicines in non-G20 LMICs under a voluntary licence. This can increase the availability of the medicines and contribute to better supply security. We may seek a small royalty on sales in some countries. This applies even for countries that move out of LMIC status due to increased economic growth.

Our approach to licensing is evident in HIV and AIDS where we began offering voluntary licences for antiretrovirals in 2001. ViiV Healthcare licenses directly with generic manufacturers and indirectly via the Medicines Patent Pool[iii].

Patent portfolio transparency

We are committed to making information about our current and future patent portfolio more freely available. For example, we are founding participants in Pat-INFORMED (*Pat*ent *In*formation *In*itiative *for Med*icines), a programme facilitating access to medicine patent information.[iv] Greater transparency about which patents are held in which countries makes it easier for procurement agencies to understand patent issues relevant to their plans.

Compulsory licensing

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes minimum standards for the regulation of IP in World Trade Organization (WTO) member nations. TRIPS includes a provision on the use of compulsory licensing in limited situations. This is when a government allows the use of an invention by a third party without the consent of the patent owner.

We support the IP model reflected in TRIPs and view it as indispensable and balanced. We also recognise the flexibilities within TRIPs that allow the use of compulsory licenses under certain circumstances. This flexibility was originally provided for the domestic manufacturing of medicines and vaccines. To address the needs of countries with inadequate local manufacturing capacity, the Doha declaration included an allowance for the use of a compulsory license for export from countries with greater manufacturing capabilities.

It is important to note, however, that least developed countries are not required to enforce IP rights for medicines before the year 2033. It follows, therefore, that IP can play no role in the lack of access to medicines in these countries. As the protections granted by IP are necessary to incentivise investment in R&D, there is also a risk that widespread use of compulsory licenses could undermine future innovation.

We believe the root cause of healthcare challenges in developing countries is multifaceted and includes a lack of funding, political will and inadequate healthcare infrastructure. In most circumstances, there are more effective solutions to overcome these barriers and to increase access than the use of compulsory licenses. As a life sciences company, we focus on our science, as this is where we believe we can make the greatest contribution. We then partner with others who have the right capability, geographic reach and local knowledge, particularly in lower income countries, to address these barriers. By working in partnership, we aim to identify sustainable solutions to ensure our innovation reaches patients.

Regulatory data protection

Companies invest in and submit significant amounts of proprietary pre-clinical and clinical data to regulatory authorities to obtain marketing authorisation for their products. Regulatory Data Protection

(RDP) grants those companies the exclusive right to manage the use of the submitted data for a set time. Following this, generic manufacturers are permitted to rely upon the same data to obtain approval of their "abbreviated" applications.

RDP and patents are two critical intellectual property rights for the pharmaceutical industry; however, they are different forms of protection. Specifically, RDP protects the enormous scientific and financial investment needed to generate quality, safety and efficacy data required by regulatory authorities. RDP is particularly important in certain circumstances:

- where patent protection may not be available;
- where patent enforcement systems are inadequate; or
- where the patent term has been eroded by a long development process.

This may only become clear well into the development phase or after launch of the product. RDP is, therefore, an incentive for innovation and protection of investment where there is little or no patent protection.

RDP is not a monopoly right like a patent and does not prevent a competitor generating their own clinical data.

GSK agrees that to enable generic competition while avoiding repetitive animal testing and human trials, competitors should be able to draw upon the originator's data. However, direct or indirect reliance upon the originator's data should be prohibited for a reasonable period as a matter of fairness. Many countries offer between five and ten years RDP from local approval. We believe a ten-year period of exclusivity is appropriate for new products; and welcome the 12-year period extended to biologics in the US.

Conclusion

Ultimately, medicines and vaccines are difficult and expensive to develop. The science is complex, with high risk of failure. We keep investing, however, because the system works and it brings huge benefit to patients and society, alongside financial returns to our business. These in turn finance the R&D into the next generation of innovative medicines and vaccines - and the cycle continues. Intellectual property protection enables this innovation cycle. We are committed to helping to ensure our medicines reach patients, and more detail is provided in our policy position on access to medicines.

[i] IFPMA The pharmaceutical industry and global health Facts and Figures 2021
[ii] Ibid
[iii] https://medicinespatentpool.org/
[iv] https://www.wipo.int/pat-informed/en/