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, cancer, respiratory diseases, and COVID-19. No other incentive mechanism for inventing 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 are important factors in incentivising medical innovation. Patents incentivise R&D investment by temporarily preventing any third party from using the result of that investment; they are granted for products or processes which are new (i.e. not known), useful and inventive (i.e. not obvious) at the time they are sought and require the inventor to publish the innovation. Regulatory data protection (RDP) protects the investment companies have made to meet regulatory requirements by temporarily granting exclusive right to rely upon the innovator's pre-clinical and clinical trial data to obtain marketing authorisation. Trade secrets rights protect an innovator's confidential expertise, technical knowledge and methods, as long as a company is taking all reasonable measures to safeguard this information.

Other forms of IP are also important to GSK; for example, trademark rights are used to clearly mark our products as being made by GSK and signify they will have the qualities associated with the company. They also distinguish our products from falsified ones, as part of our efforts to protect the safety of patients and people using GSK products. *(See our public policy on substandard and falsified medicines and vaccines)*

Some stakeholders believe that periods of exclusivity associated with IP prevent competition and impact affordability and patient access to medicines and vaccines. In this paper, we set out the core principles underpinning our position on IP, including how IP protections are a vital driver of innovation, economic growth and development, and are used in a responsible way, including as part of a holistic approach to widening access.

What is GSK's view?

- IP protections (especially patents, RDP & trade secrets) stimulate innovation and the development of future medicines and vaccines to get ahead of disease for patients. It is appropriate that IP rights are afforded to those that take on the risk, cost and complexity of translating research into effective, quality, medicines and vaccines and monitoring their ongoing safety.
- The cost of discovering and developing a new medicine has been estimated to be around $2.6 billion and take 10-15 years, with only 10% of compounds that enter clinical development successfully progressing to market[i]. IP frameworks give investors and companies confidence that any successful innovation will not be immediately copied and that companies will have the opportunity to recoup investment and generate potential returns. Returns can then be re-invested in further R&D and sustain the innovation cycle.
- Robust IP standards and frameworks enable the biopharma industry to invest in a country as well as partner with other companies and manufacturers, boosting economic development and creating highly skilled and productive jobs. The combined direct, indirect, and induced effects of the global pharmaceutical industry's contribution to the world's gross domestic product were $2,295 billion in 2022, and with the pharmaceutical industry's spending on R&D reflecting 30% of the sector's total gross value added, our industry invests substantially more in R&D compared to other R&D-intensive industries among countries of the Organisation for Economic Co-operation and Development (OECD)[ii].

- A competitive, quality generics and biosimilars market is an important part of the innovation cycle. The innovation and R&D within originator companies fuels the business model of generic and biosimilar companies. Generic and biosimilar competition increases patient choice and fulfils a market need such that innovative companies can focus resources on finding the next generation of treatments, funded by previously commercialised products.
- For the IP system to function effectively, it must be trusted. We believe a good IP system is one that contains rigorous checks and balances. These include a strong examination process for patent applications, a system to allow wrongly granted patents to be legally challenged, and strong regulatory data protection for innovators alongside patent protections
- IP protections can coexist with mechanisms to improve access to medicines. Effective protection and enforcement of IP supports the multi-stakeholder collaboration, information-sharing and knowledge transfer underpinning many major breakthroughs and access partnerships. We believe the root cause of access and health equity challenges are multifaceted; solving these challenges requires partnership working to ensure that innovation reaches patients.
- We support the 'Agreement on Trade-Related Aspects of Intellectual Property Rights' (TRIPS) and the 'Doha Declaration on TRIPS and Public Health' and the clarity these have given on the international rules around IP. We view the IP model reflected in TRIPS as indispensable and balanced.
- We acknowledge the flexibilities within TRIPS that allow the use of compulsory licences under certain circumstances. However, compulsory licences are not an effective means to increase sustainable access to innovative medicines or vaccines. Any mechanism that forcibly breaks IP protections to address crises in the short term pose long term public health risks, as it will destabilise the viability of any voluntary licence agreements and the innovation environment for life sciences more generally, which is necessary to drive advances in prevention, treatment and care.

Background

Our approach to patent filing and transparency

Since 2016 we have followed an approach to filing patents that is tailored to a country's economic maturity and fosters both innovation and sustainable access.

We do not file patents or enforce historic patents for our medicines or vaccines in Least Developed Countries (LDCs, as designated by the United Nations), Low Income Countries (as designated by the World Bank) and in the majority (above 80%) of Lower Middle Income Countries (LMICs, as designated by the World Bank). Other companies can manufacture and supply generic versions of our products in those countries. Filing strategies for in-licensed/partnered assets are determined by all parties; we encourage a tailored approach where possible.

Where we do file for patents in LMICs, we are open to exploring the use of licences to allow supplies of generic versions of our medicines where we believe this is appropriate or will boost supply capacity to support sustainable access. In particular, for our Global Health portfolio, we take a partnership approach and work with organisations who bring complementary capabilities to ensure that our innovations achieve maximum health impact at scale in lower income countries. *(See our Global Health commitment for more)*

For other countries, our approach to seeking patent protection will be in accordance with our commercial strategy.

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

Our view on voluntary licensing

A voluntary licence is an authorisation given by a patent holder to another manufacturer, allowing the licensee to produce a patented product, as if it were a generic. The licence usually sets quality requirements and defines the markets in which the licensee can sell the product.

Voluntary licences are most effective when they pose a viable commercial proposition for a generic manufacturer. For example for products:

- with strong demand forecasts and procurement funding mechanisms in place to support the purchase of the licensed products at attractive and sustainable volumes;
- with low cost of goods and that do not require complex, capital-intensive manufacturing processes;
- in a therapy area where there are limited suitable, alternative products available.

Voluntary arrangements help build the trusted framework and relationship needed to reassure innovators that they can share their intellectual property without misappropriation by that partner. They also enable the originator to identify the most appropriate partners with proven ability to meet the highest standards on quality, as well as a strong track record on issues such as environmental sustainability, labour and human rights, and ethics and compliance.

While voluntary licences may not enable broader access in all circumstances, they have clearly demonstrated a significant and sustainable impact in tackling the global HIV epidemic in appropriate settings. GSK began offering voluntary licences for antiretrovirals in 2001; today, ViiV Healthcare partners with the UN-backed Medicines Patent Pool (MPP)[iv] as well as directly with generic manufacturers to license its medicines *(See ViiV Healthcare's access to medicine policy for more).*

Our view on regulatory data protection

Companies invest in and submit significant amounts of proprietary pre-clinical and clinical data regarding quality, safety and efficacy 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 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 temporarily prohibited for a period as a matter of fairness; this period should be adequate to reflect the enormous scientific and financial investment needed to generate quality, safety and efficacy clinical data for regulatory authorities. Many countries offer between five and ten years RDP from local approval. We believe a ten-year period of data exclusivity is appropriate for new products and welcome the 12-year period provided to biologics in the US.

Specifically, 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.

Access challenges are multifaceted

While TRIPS obligations apply to all WTO member countries, it is important to note that Least Developed Countries are not required to enforce TRIPS Agreement IP rights for medicines and vaccines before July 2034. Generic or biosimilar supply could be realised in these markets, without infringing the rights of patent holders. However, these are often challenging markets in which to commercialise products – for innovator and generic companies.

We believe the root cause of access and health equity challenges are multifaceted, and that IP is not a barrier to access. An estimated 2 billion people around the world have no access to the medicines listed as essential by the WHO, of which 90% are off-patent[v]. In India, 50-80% of the population has limited access to essential medicines[vi], even with a domestic medicines manufacturing presence. Operational barriers to access include inadequate healthcare infrastructure or distribution networks and low numbers of trained healthcare providers. Access also depends on procurement practices, the strength of national regulatory authorities and health coverage.

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[i] https://www.ifpma.org/initiatives/alwaysinnovating-pharmaceutical-industry-facts-figures/
[ii] https://www.ifpma.org/initiatives/alwaysinnovating-pharmaceutical-industry-facts-figures/
[iii] https://www.wipo.int/pat-informed/en/
[iv] https://medicinespatentpool.org/
[v] https://accesstomedicinefoundation.org/news/is-the-generics-industry-stepping-up-on-access-to-medicine-new-analysis-spotlights-actions-of-5-major-companies#:~:text=Of%20the%20medicines%20classed%20as,%2C%20tuberculosis%2C%20malaria%20and%20HIV
[vi] https://www.researchgate.net/publication/353551874_Essential_Medicines_Research_in_India_Situation_Analysis