

GSK Public policy positions

Patents & Access to Medicines in Developing Countries

The Issue

Despite improvements in recent years, millions of people in developing countries do not have access to even the most basic healthcare services, including safe and effective medicines. This is exacerbating a healthcare situation in which countries, many of which are those least able to cope, are hit with the double burden of infectious diseases, such as HIV/AIDS, tuberculosis (TB) and malaria, and the growing problem of non-communicable diseases (NCDs), such as diabetes, cardiovascular disease, respiratory conditions and cancers.

Poverty is the single biggest barrier to improving healthcare in the developing world. In many countries people do not have enough food, access to a clean water supply, hospitals or clinics in which to receive treatment, or healthcare professionals to care for them.

Nevertheless, there are some who continue to believe intellectual property, and patents in particular, are the reason why many millions of people are denied access to the medicines they need.

This paper provides some background on the importance of Intellectual Property (IP) to biomedical innovation; addresses some of the debate around whether patents can act as a barrier to access; and sets out possible solutions to the multi-faceted access challenge in developing countries.

GSK's Position

- Improving healthcare in the developing world presents a complex and multi-faceted challenge to the global community. It can only be addressed if the significant barriers that stand in the way of improved access are tackled as a shared responsibility by all sectors of global society – governments, international agencies, civil society, academic institutions, the pharmaceutical industry and others.
- GSK is committed to playing our part in addressing the healthcare challenges of the developing world by taking a flexible, responsible and, above all, sustainable approach. Our core business activity of developing and launching new medicines and vaccines significantly improves health and contributes to the achievement of the Sustainable Development Goals¹.
- We make a vital contribution to developing country healthcare through action in four areas²:
 1. flexible business models including preferential pricing of our medicines and vaccines;
 2. investing in research and development (R&D) that targets diseases predominantly affecting the developing world, including pursuing an open innovation strategy³;
 3. community investment activities and partnerships that foster effective healthcare; and,
 4. innovative partnerships and solutions to increase access, such as voluntary licensing.
- It is misleading and counter-productive to focus on patents in the access debate. Significant access problems exist even where no or few patents do – for example, about 95% of the 350+ drugs on the WHO Model List of Essential Medicines (EML) are not patent protected and yet the WHO says that 30% of the world's population do not have reliable access to these drugs.
- Patent protection stimulates and fundamentally underpins the continued R&D for new and better medicines for diseases, including those which occur in the developing world. Adequate therapies do not currently exist for many medical conditions, while many existing therapies could be improved. Market conditions must provide sufficient incentive to encourage research. Patents are a key incentive to the private sector to undertake the cost and risk of pharmaceutical development.
- GSK believes that the IP model reflected in the World Trade Organisation (WTO) Trade Related Aspects of IP Agreement (TRIPs) is indispensable and balanced. The IP-based R&D model has enabled the pharmaceutical industry to play a fundamental role in the development of nearly all the medicines available today. It has largely worked well and will continue to work well to promote innovation benefitting patients.
- We acknowledge that there are flexibilities within TRIPs that allow countries to address their public health needs. We reject the “one-size fits all” approach adopted by some involved in the TRIPs-related debate; approaches need to reflect a country's economic maturity. Of note, LDCs have secured an exemption from complying with TRIPs for pharmaceutical products until 2033, which we fully support. This means that IP should play no role in the lack of access to medicines in these countries.

¹ <https://www.gsk.com/media/5326/our-contribution-to-the-sdgs.pdf>

² For more information, please see <https://www.gsk.com/en-gb/responsibility/improving-health-globally/>

³ <https://www.gsk.com/en-gb/research/our-approach/open-innovation/diseases-of-the-developing-world/>

- We acknowledge that in the absence of a viable commercial market (e.g. for neglected tropical diseases), patents are not always a sufficient incentive. Under these circumstances, there is no single solution. We need to ensure a policy and financing environment where such global health discoveries are incentivised, developed and brought to patients using a model that shares the risk throughout the development life-cycle, and leverages the expertise of different partners involved in delivering healthcare. Some of the ways we seek to accelerate this are by pursuing public private partnerships, pooled approaches or open innovation models.

Background

The Importance of Patents to the Pharmaceutical Industry

The risk factor: Patents are granted for products and processes which are new (i.e. not known) and inventive (i.e. not obvious) at the time they are applied for. They give their owner the exclusive right to manufacture and market the product for (usually) 20 years from the date of application. Developing an innovative pharmaceutical product or vaccine is a costly and risky activity. It requires:

1. the discovery of active substances suitable for treating or preventing the medical condition
2. developing them into formulations suitable for patients
3. satisfying the regulatory authorities in all countries where the product is to be sold that the product is safe and effective.

Approximately 5-10,000 compounds are synthesised for every one that comes to market. Those that show some type of potential medical activity undergo pre-clinical and, if this is successful, large-scale clinical testing before applications to approve the product are made. Substantial numbers, often thousands, of patients undergo clinical trials. Following approval, post-marketing surveillance of the product is required.

The complexity, length and uncertainty of the development phase, which includes the need to prove safety and efficacy before authorisation, means it can typically take 10-15 years from discovery of a novel compound to its launch, significantly eroding the 20 year patent term.

The cost factor: Pharmaceuticals operate in a uniquely high-risk business model. When a company like GSK chooses to invest significant sums to advance a potential medicine in its portfolio, we may not know for over ten years whether the asset will be approved by a regulatory authority like the FDA or EMA and we must wait even longer to know whether our predictions on market adoption were accurate. The FDA estimates the probability of a drug in development reaching the market at only 8%.

Furthermore, approximately 70% of the cost of bringing a product to market arises *after* discovery of the compound i.e. at the development stage. While public entities will often be involved in the discovery of a new compound, these later development costs will usually be borne by pharmaceutical companies. Recent data confirms that industry not only contributes the majority of global expenditure on pharmaceutical R&D (71%) but also performs 26% of basic pharmaceutical research. Many products which come to market also do not prove commercially successful.

Whilst the costs of R&D for different diseases and interventions may differ widely, Tufts University have estimated that the average cost of bringing a new pharmaceutical product to market (taking into account investment in products that don't make it to launch) is over \$2.5billion.

Companies would not incur the risk and cost of innovative R&D if, shortly after launch of their products, a copy could be launched by a competitor who had the advantage of not incurring development costs and risk and who had not invested in market preparation, including training healthcare professionals in use of the product.

A period of exclusivity is therefore needed to recoup the significant costs invested, to reward innovation, and to enable a return that allows re-investment in further R&D. Patents are a vital way of providing this incentive and reward. And the exclusivity afforded by a patent can serve to drive, not undermine, competition. Patented compounds from one company often compete with patented compounds from another, and generic products often compete with patented products. This is very much the situation in treatments for HIV/AIDS, for example.

The role of the public sector: While we acknowledge the contributions of others to innovation (for example the academic sector and public funders), the pharmaceutical industry has been fundamental to the development of all, or nearly all, the medicines we have today which benefit hundreds of millions of patients. Where a viable commercial market exists, the IP-based R&D system has led to virtually all the breakthroughs in medicines and vaccines over the last 50 years from vaccines, to antiretrovirals (ARVs) and hepatitis C treatments, to cancer and cardiovascular medicines. The patent system is the only system proven to be successful in incentivising biomedical innovation.

Limitations of IP: GSK acknowledges that in the absence of a viable commercial market, where the return on investment on R&D is too low to justify an adequate allocation of resources, patents are not always a sufficient incentive. Under these circumstances, we work to share the scientific and financial risks and our knowledge and expertise through Product Development Partnerships, pooled approaches, or open innovation models to help initiate and accelerate R&D.

GSK's Approach to Patents and Licensing

Patent filing: While patents stimulate and underpin continued investment in R&D, GSK believes being flexible with our patents can help address pressing health challenges in developing countries, without undermining the fundamental business model. We have been pursuing flexible models of IP management for many years and, in 2016, we announced an approach to filing patents, including any GSK medicines on the WHO's list of essential medicines, that reflects a country's economic maturity.

For Least Developed Countries (LDCs) and Low Income Countries (LICs), GSK no longer files patents for its medicines and we will not enforce those historic patents that we have in those countries. Generic companies can therefore manufacture and supply generic versions of GSK medicines in those countries.

For non-G20 Lower Middle Income Countries (LMICs), GSK may file for patents but will offer licences to allow supplies of generic versions of our medicines as described below. For other countries, GSK continues to seek patent protection in accordance with our commercial strategy at any given time.

Patent portfolio 'transparency': GSK is committed to making information about our current and future patent portfolio more freely available. We are founding participants in Pat-INFORMED (*Patent Information Initiative for Medicines*) which is a programme developed by a number of global research-based biopharmaceutical companies with support from the World Intellectual Property Office (WIPO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). It was launched in 2017 to facilitate access to medicine patent information⁴. Being more transparent about which patents are held in which countries will make it easier for procurement agencies to understand any patent issues that might be relevant to their plans.

Voluntary licensing: When few generic options exist within a particular therapy area, GSK may consider allowing generic manufacturers to produce and supply versions of our patented medicines in an agreed territory under a voluntary licence. This can increase the availability of the medicines and contribute to better supply security.

Our approach to licensing is evident in HIV/AIDS, where GSK began offering voluntary licences for our ARVs in 2001. Our HIV portfolio transitioned to ViiV Healthcare – a new specialist HIV company with GSK, Pfizer and Shionogi Limited as shareholders in 2009. Since then ViiV has expanded its approach to licensing both directly with generic manufacturers as well as indirectly via the Medicines Patent Pool⁵. For more detail regarding ViiV Healthcare's approach to voluntary licensing, please [click here](#).

Voluntary licences are not always suitable and will only have an impact when certain conditions exist, including but not limited to: 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; and products are easy to manufacture and administer and do not require complex, capital-intensive facilities.

In non-G20 LMICs GSK is prepared to grant licences, subject to any third-party consents that may be needed, to allow supplies of generic versions of our medicines for a period of 10 years. We will seek a small royalty on sales in those countries. This offer applies even for those countries that move out of LMIC status due to increased economic growth during this period.

⁴ <https://www.wipo.int/pat-informed/en/>

⁵ <https://medicinespatentpool.org/>

GSK and the TRIPs Agreement

The TRIPs Agreement established minimum standards of IP protection with which WTO Members have to comply. Some provisions, such as a minimum 20-year patent term and the principle of non-discrimination for any field of technology, are clearly mandated by the Agreement. A number of TRIPs provisions, however, can be implemented in a variety of different but nonetheless TRIPs-compliant ways. Examples include:

- How to apply the “exhaustion” principle whereby a patent holder is considered to have exhausted their patent rights once they market their patent-protected product. TRIPs allows for national, regional or international exhaustion; governments are free to decide which they apply. Regional exhaustion, for example, exists within the EU.
- What grounds to set for compulsory licencing (CLs) whereby a third party can copy a patented product without the consent of the patent owner. Under certain conditions, CLs are permitted by TRIPs; however, governments are not obliged to legislate for them. Reasons most commonly cited by governments for granting a CL are a failure by the owner “to work the patent” i.e. failing to supply the product.
- Whether or not to allow “early working” (Bolar type) provisions whereby other parties are free to conduct studies, research and tests in preparation for drug regulatory approval and other related acts, such as manufacturing, prior to patent expiry.
- What level of protection to afford the regulatory data compiled by a company at considerable cost and submitted to government authorities in order to obtain product approval. While TRIPs requires that unpublished data be protected against disclosure and unfair commercial use, it does not specify a minimum period of protection. Many countries offer between 5 and 12 years protection from local approval for new chemical entities.

While we do not believe that the flexibility permitted under TRIPs is quite as extensive as some claim, TRIPs undoubtedly allows WTO members some flexibility in implementation, to address their own particular social and economic welfare concerns. As a result, some laws are implemented in ways which are more supportive of innovation conducted by the pharmaceutical industry than others.

Of note, LDCs have secured an exemption from complying with TRIPs for pharmaceutical products until 2033, which we fully support. This means that IP should play no role in the lack of access to medicines in these countries.

Patents as a ‘Barrier to Access’

The most commonly cited criticism of patents as a barrier to access is that they prevent generic competition and enable higher pricing than is affordable. GSK acknowledges that price is a factor in affordability and that affordability is a component of access. We also acknowledge that patents can be a factor affecting price. However, clearly, this can only have an impact when patents exist.

About 95% of the 350+ drugs on the WHO Model List of Essential Medicines (EML) are not patent protected and yet the WHO says that 30% of the world’s population do not have reliable access to these drugs. First line treatments for killer diseases like malaria and TB are available as generic products at very low cost, and yet many people are denied access to them. A 2012 study found that 22% of the products on the WHO’s EML (17th version) are indicated for NCDs and that none of these medicines have patentability issues that could prevent their generic production. Significant access problems therefore exist even where no or few patents do.

Despite this, many people see re-writing intellectual property rules or expanding local manufacture, as a panacea for addressing access issues. However, India provides a good case study as to why this is too simplistic. Until recently, India had no IP protection for pharmaceutical products and had seen the creation of the most developed generics industry in the world. And yet, access to essential medicines for those in need in India remains a significant challenge, with – according to the WHO’s 2017 Global Monitoring Report – lower service coverage than Botswana, Kenya, Libya, Namibia and Swaziland.

Patents can in fact be an engine for access and local innovation. Innovative companies are more likely to launch their products more quickly in markets with strong patent protection, thereby accelerating access for patients. Further, by encouraging launch of innovative products, patents can help to support capacity building and information exchange with local healthcare professionals; they can support launch of local generics, at the appropriate time, by facilitating reliance on the innovator’s local regulatory dossier to demonstrate the generic product is equivalent; and they can encourage local innovation by new companies and generic companies, particularly SMEs, whose principal markets, especially in early years, tend to be domestic. A strong patent system therefore supports more rapid access to, and wider diffusion of, both innovative and generic products, creates competition and drives the next cycle of innovation.

Improving Access in Developing Countries

There are many significant barriers to access to medicines and vaccines in the developing world. The problem is rooted in poverty, which results in an inability to pay for even the lowest-priced medicines, including generics. Another key factor is a chronic under-investment in healthcare infrastructure which has led to a lack of clinics and hospitals, poor distribution networks, low numbers of trained healthcare providers, and high levels of patient illiteracy. According to the WHO, a per capita spend on healthcare of at least US\$34 per year is required to provide a basic healthcare infrastructure. Current expenditure on health by many sub-Saharan African countries is well below this. Significant additional external funding is essential for medicines and development of the infrastructure needed to deliver them.

Other factors that impede access are taxes and tariffs that raise prices unnecessarily, and cultural factors such as stigma and discrimination.

Addressing these barriers is a complex and multi-faceted problem. There is no simple answer. The challenges can only be properly addressed through partnership between developed and developing country governments, international organisations, civil society, the industry and charitable organisations.

- *Sustained funding:* Developed world governments provide much needed resources for healthcare in the developing world through bilateral arrangements and support for multilateral organisations, such as the Global Fund to Fight AIDS, TB and Malaria and Gavi, the Vaccine Alliance. This has been key in the global response to access and such investment should be sustained. Additional domestic resources must also be mobilised to complement this.
- *Greater political commitment:* Governments should remove import tariffs that raise prices; prioritise healthcare in national budgets to deliver as much money as possible to reinforce the funding coming from donors; and drive out inefficiencies in the procurement, storage, prescribing and use of drugs. The 2016 Lancet Commission on Essential Medicines concluded that while between \$13 to \$25 per capita is required to finance a basic package of essential medicines, in 2010, the majority of LICs and 13 out of 47 MICs spent less than \$13 per capita on pharmaceuticals.
- *Capacity building and retention of healthcare workers:* Resources are needed to provide the infrastructure – hospitals, clinics, distribution networks – and human capital which will ensure that medicines reach patients.
- *Price and product diversion:* Developed and MICs must undertake not to use the preferential prices offered to LDCs and LICs as benchmarks for their domestic drug prices. And, along with developing countries, they should act to prevent diversion of preferentially-priced products from the patients who need them into countries with wealthier populations.
- *Strategic guidance and support:* International organisations such as the WHO have an important role to play in providing strategic guidance and technical assistance to countries. In doing so, they should be aware of and acknowledge the central role of patents in fostering innovation for healthcare products. Likewise, Non-Governmental Organisations (NGOs) and civil society play an important role in delivering healthcare to some of the poorest people who otherwise would have no access to healthcare services.

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