

GSK Public policy positions

Compulsory Licensing

The Issue

Compulsory licences (CLs) are widely recognised as one of the flexibilities of the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement. As the access to medicines debate has progressed over the years, it has been argued by some that widespread use of CLs could significantly help to alleviate the access crisis in developing countries. However, if anything, widespread compulsory licensing could exacerbate access problems, as well as undermine the much-needed R&D into new vaccines and therapies that society relies on the private sector to undertake. Far more effective solutions exist to the access challenge facing developing countries than the widespread use of CLs.

This paper sets out GSK's position on the role of CLs and why it is so important to the sustainability of biomedical research, to access and to public health, that CLs are used as an option of last resort.

GSK's Position

- **It is misleading and counter-productive to focus on IP protection as a significant barrier to access to medicines in the developing world.** Least Developed Countries (LDCs), for example, are not required to introduce patents for any medicines before the year 2033. This means that IP can play no role in the lack of access to medicines in these countries, so IP-based ideas such as CLs are extremely unlikely to help improve the access situation.
- **The root cause of the access challenge and the inability of developing countries to address their healthcare problems lies not with patents, but with a lack of funding, a lack of political will and inadequate healthcare infrastructure.** There are far more effective ways of tackling these problems than resorting to compulsory licensing which can have significant unintended consequences for long term investment and sustainable access.
- **All stakeholders, including the pharmaceutical industry, have a role to play in tackling these problems and addressing the access challenge.** GSK is taking an innovative, responsible and, above all, sustainable approach, one that is making real difference on the ground and has seen us top the ATM Index on five consecutive occasions. It comprises four key elements:
 1. new business models including preferential pricing of our medicines and vaccines;
 2. investing in R&D that targets diseases particularly affecting the developing world, including pursuing an open innovation strategy¹;
 3. community investment activities and partnerships that foster effective healthcare; and,
 4. innovative partnerships and solutions, such as voluntary licensing, particularly in the HIV area.
- **GSK acknowledges that CLs are one of the flexibilities in TRIPs; however there is too much at stake in terms of their impact on R&D investment, on generics' entry and quality and on the general investment environment, for their use to become standard practice.** They should be used sparingly and as an option of last resort.
- **Widespread use of CLs may contribute to a reduction in R&D.** Systematic use of CLs weakens the intellectual property (IP) system. The IP system underpins the ability of the private sector to undertake the R&D necessary to drive advances in treatments and vaccines for diseases of the developed and developing world. The more the IP system is weakened, the less R&D is likely. This was recognised by Switzerland, Japan and Korea who, when speaking at the WTO TRIPS Council, remarked that the use of CLs must not discourage innovation².

¹ <http://www.gsk.com/collaborations/tres-cantos.html>

² <https://www.ip-watch.org/2016/11/10/wto-members-discuss-un-high-level-report-medicines-access-declined-discuss/>

- **Excessive use of CLs may deny or delay patients' access to innovative products and undermine the introduction of good quality generic versions in the longer term.** Innovative companies are far more likely to launch products in markets with strong IP, rather than those with weak IP, including those characterised by excessive use or threat of CLs. Furthermore, if an innovative company does not register its own product for launch, launch of a generic alternative following patent expiry might also be prevented or delayed.
- **CLs can reduce incentives for Foreign Direct Investment, including technology transfer.** Excessive use of CLs is indicative of a weak IP system generally and can undermine the confidence of foreign investors across all industrial sectors.
- **The 31f Agreement on 'compulsory licences for export' reached by the WTO in December 2005 recognises the need for their use to be appropriate and measured.** It highlights, in particular, the importance of countries using CLs for export in "good faith", not as an instrument to pursue industrial or commercial policy objectives.

Background

Compulsory Licensing and TRIPs

TRIPs provides for minimum global standards of IP protection, including patent protection. These standards are to be introduced at different times, depending on the development classification of countries.

Patents are granted for inventions. They give exclusive rights to manufacture, use and sell the inventive product for a limited time, usually 20 years from the date of filing. The exclusive right given is an incentive to undertake the significant cost and risk associated with innovation and commercial development.

The exclusive rights conferred by patents can be the subject of limitations. For example, use of the invention by a third party without the consent of the patent owner can be authorised by governments under a CL. CLs are permitted by TRIPs provided certain conditions specified in Article 31 TRIPs, are complied with. Reasons most commonly cited by governments in recent years for granting a CL are a failure by the owner to work the patent i.e. failing to register the product or making it inaccessible through excessive pricing.

Patents and Access to Essential Medicines

More than 90% of drugs on the WHO Essential Drugs List (EDL) are not patent protected and yet the WHO says that 2 billion of the world's population do not have regular access to these drugs. Many of these people are concentrated in the poorer parts of Africa and South-East Asia, where often 50% of the population lack access to these products.

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. And in India, where for years there were no patents for medicines and where there are numerous generic medicine producers, access to medicines is as big a problem as it is in many parts of Africa. Where patents do not exist, the access challenge must logically be related to barriers other than IP.

The Importance of Strong IP to the Pharmaceutical Industry

Strong patent protection is needed to incentivise the high risk and high cost of developing new pharmaceuticals as it creates the conditions under which industry can generate the returns needed to fund R&D. The cost, time and risk involved bringing a product to market is significant:

- Safety and efficacy requirements mean it takes between 8 and 12 years to bring a product to market, and the vast majority of this time passes while the 20 year patent term is running. Returns on the investment, therefore, usually only begin relatively late in the patent term, thus reducing the effective period of patent protection in which adequate returns can be obtained.

- For every 10,000 compounds that are tested for pharmaceutical activity, only 3 reach the market. And only one in every 3 drugs which reach the market is profitable.
- Allowing for failure (more than 90% of the compounds that enter clinical trials fail to demonstrate sufficient safety and efficacy to gain regulatory approval), it costs on average almost \$1.2 billion on research and development to bring a drug to market.
- We believe that over use of CLs for medicines could have significant unintended consequences. The journey from concept to finished medicine can take up to 25 years. If there is significant uncertainty about returns being available for successful, value-adding products at the end of that period, companies, would be less willing to invest the significant levels of funding required to research and develop new medicines. Innovation would be endangered for patients around the world.

Although the public sector has a crucial role to play in the initial discovery of some drugs, most are invented by the private sector. Further, the post-invention proof of safety and efficacy (by far the most expensive and risky part of the development process) is almost without exception undertaken by, and at the risk to and cost of, the private sector.

CLs and Access to Innovative Medicines

To create a market for a product in a particular country involves cost and effort. Innovative companies are far more likely to launch products in markets with strong IP, rather than those with weak IP. In such cases, patients in countries characterised by excessive use or threat of CLs could be deprived innovative products either temporarily or altogether.

Further, in some countries, it is only possible to launch generic products if there is a local approval of the innovative product which the generic company can “piggy back” on. The generic company may have to show that its product is essentially similar to the locally marketed innovative product. If the innovative company does not register its own product for launch, launch of a generic product might be prevented or delayed.

The Doha Declaration and the 31f Agreement

One issue relating to Article 31 of TRIPS which attracted considerable attention some years ago was the requirement in Article 31f that any production under a CL should be *predominantly* for the *domestic* market. That meant that countries with no manufacturing capacity would struggle to benefit from a CL; they would need to rely on countries with manufacturing capacity to issue a CL predominately for their own domestic use and to then access part of that capacity.

In December 2005, the 149 countries of the WTO reached a consensus regarding how to amend the TRIPS Agreement to allow the granting of CLs to address the needs of countries with inadequate manufacturing capacity. The amendment permits the granting of CLs for export to countries in response to requests from another country providing that, amongst other issues, adequate measures are put in place to prevent diversion of the product to other (more lucrative) countries/markets.

The new system has been used extremely infrequently. This is not because, as some have argued, it is unworkable; rather it is because the main problem of lack of access is not related to IP, so an IP-based (CL) solution will not provide the answer.

November 2017