GSK Public policy positions

Compulsory Licenses

The Issue

Compulsory licenses (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 the developing world. However, undermining the effectiveness of patents via CLs would not help to address the access crisis. 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.

GSK's Position

– GSK acknowledges that compulsory licenses (CLs) are one of the flexibilities in TRIPs and that their sparing use can be appropriate. However, as the DG of the WHO, Margaret Chan, acknowledged in January 2007, "We have to find a right balance for compulsory licenses. We can't be naïve about this. There is no perfect solution for accessing drugs in both quality and quantity". Compulsory licensing is an option not a solution.

– 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 that is essential if we are to see 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. Widespread use of CLs may, therefore, contribute to a reduction in R&D.

– Innovative companies are less likely to launch products in markets with weak IP systems as generic companies are more likely to undermine the returns in those markets. Without local launch of the innovative product, generic companies may not be able to obtain "piggy back" approvals to sell their products. And even if they do, they rarely provide the post-launch product support, education and surveillance which innovators provide. Excessive use of CLs may, therefore, deny or delay patients' access to innovative products and undermine the introduction of good quality generic versions in the longer term.

– CLs can reduce incentives for Foreign Direct Investment, including technology transfer. Their excessive use is indicative of a weak intellectual property system generally and can undermine the confidence of foreign investors across all industrial sectors.

– GSK welcomed the 31f Agreement reached by the WTO in December 2005 as a reasonable compromise. It provides a workable solution for compulsory licensing for export in the rare cases where this is needed to address healthcare crises in countries without manufacturing capacity.

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.

Patents and Access to Essential Medicines

It is misleading and counter-productive to focus on intellectual property protection as a significant barrier to access to medicines in the developing world. The root cause of the inability of developing countries to address their healthcare problems does not lie with the patenting system and their ability or otherwise to grant CLs. More than 95% of drugs on the WHO Essential Drugs List (EDL) are not patent protected and yet the WHO says that one third of the world's population do not have regular access to these drugs. According to the WHO, in the poorer parts of Africa and South-East Asia, 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. The problem of access to medicines cannot be blamed on patents when the medicines are not patented.

The real reason for inadequate access to essential medicines lies not with patents, but with a lack of funding, a lack of political will and inadequate healthcare infrastructure.

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 huge:

- 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.

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.

Drugs are generally easy and cheap to copy. Industry estimates suggest that it costs $2-3 million to bring a copy of a small molecule product to market. Generic companies generally (and understandably) focus their efforts on copying very successful innovative drugs at the end of patent protection. Therefore, companies which do not bear the risk and cost of drug development can, without doubt, sell drugs at a profit more cheaply than those that do incur the risk and cost of development.

CLs and Access to Innovative Medicines

To create a market for a product in a particular country involves cost and effort. If an innovator believes that a CL will be granted once the market has been created, it might not launch its product at all or might delay launch. In such cases, patients in the country concerned are deprived of the innovative product either altogether or temporarily.

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.

CLs and Local Health Infrastructure

CLs reduce the profitability of the local operating companies of innovative pharmaceutical organisations, particularly in developing countries where the commercial environment for companies is already challenging. Innovative companies provide employment, medical services and product support to these markets. It is innovative companies who educate local medical staff about the benefits and dangers of the products concerned and thereby contribute to the local health infrastructure, particularly in the poorest countries. These services are rarely provided to any significant degree by generic companies. CL, therefore, risks undermining local infrastructure in these markets.

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 compulsory licence should be *predominantly* for the *domestic* market. That meant that country A could not issue a CL only to supply country B. So if country B had no capacity to manufacture pharmaceuticals, it may not be able to take advantage of the compulsory licensing safeguards in TRIPS.

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 only been used once. 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.

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