

Compulsory Licenses

The Issue

Compulsory licenses (CLs) are widely recognised as one of the flexibilities of the TRIPs Agreement which can help to prevent and address abuse of patents by innovators. As the access to medicines debate has developed over the years, the potential role of CLs in helping to alleviate the access crisis in the developing world has been afforded increasing attention. However, for GSK, as patents are not a barrier to access, their nullification 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 to prevent abuse of patents 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.
- GSK welcomed the 31f Agreement reached by the WTO in December 2005. It allows for a workable solution for compulsory licencing for export but maintains respect for Intellectual Property. It strikes a balance in ensuring that GSK, and others, can invest in R&D for badly needed new vaccines and medicines for patients in the developing world, whilst allowing for compulsory licencing of patents where this is necessary to protect public health.
- CLs may impede rather than facilitate greater access. Innovative companies are less likely to launch products in markets with weak IP systems as copyists 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. 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. Their excessive use is indicative of a weak intellectual property system generally and can undermine the confidence of foreign investors across all industrial sectors.

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 (i.e. things that are not known and not obvious at the date they are applied for). They give exclusive rights to manufacture, use and sell the inventive product for a minimum period of 20 years. The exclusive right given is an incentive to undertake the cost and risk associated with innovation.

The Doha Declaration and 31f

The exclusive rights conferred by patents can be the subject of exceptions. For example, use of the invention by a third party without the consent of the patent owner can be authorised by Governments under a Compulsory License. CLs are permitted by TRIPs provided certain conditions, specified in Article 31 TRIPs, are complied with.

Until recently, there had been one issue relating to Article 31 which attracted considerable global, namely that provision that any production under a compulsory licence should be predominantly for the domestic market. That meant that country A could not issue a compulsory licence 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.

Paragraph 6 of the Doha Declaration on TRIPs and Public Health, issued by the WTO Ministers at their meeting in Doha in November 2001, referred to this issue (aka Article 31f). It called upon the TRIPs Council of the WTO to find a solution for those countries with insufficient or no manufacturing capacities in the pharmaceutical sector who could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. The TRIPs Council comprises all WTO members and is responsible for monitoring the operation of the agreement, and, in particular, how members comply with their obligations under it

The "31f Agreement"

In December 2005, the 149 countries of the WTO reached a consensus regarding how to amend the TRIPs Agreement to allow the granting of compulsory licenses for export.

It is often argued that the 31f agreement created a number of obstacles that poor countries and generic manufacturers will find difficult to overcome. Indeed, many point to the lack of compulsory licences issued under the agreement since 2003 as evidence of its ineffectiveness. Clearly, however, the WTO's 149 country membership would not have agreed to the proposal if it had been overly bureaucratic and the agreement's provisions, such as the anti-diversion measures, actually act *in full accordance with* the interests of poor countries by ensuring that badly needed medicines are not diverted to wealthier markets.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

The fact that the 31f agreement has not been used more often has less to do with its provisions than with the facts that:

1. The main problem of lack of access is not related to IP so an IP-based solution will not provide the answer;
2. Most essential medicines are not patented, although where some essential medicines do have patents, voluntary licences have been granted to generic companies in Africa. GSK has granted 8 such licences and our licensees are now selling more ARVs in Africa than we are ourselves;
3. Countries wishing to import generic versions of patented medicines can do so from India without needing a compulsory licence to export because the majority of medicines are not patented in India; and
4. Evidence suggests that developed world generic companies may not be able to compete on a cost basis with those in the developing world.

Patents and Access to Essential Medicines

Some have argued that full implementation of the TRIPS agreement will lead to higher prices for essential medicines and that access will, therefore, be reduced. However, 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 developing countries' inability to address their healthcare problems does not lie with the patenting system and their ability or otherwise to grant compulsory licenses. 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 such access. 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. The real reason for inadequate access to essential medicines therefore 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.
- It costs on average almost \$1.2 billion to bring a drug to market
- Only one of every 3 drugs which reach the market is profitable.

Although the public sector has had a role 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.

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Drugs are generally easy and cheap to copy. Industry estimates suggest that it usually costs less than \$2 million, including cost of capital employed, to bring a copy 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. It is primarily relatively small private markets in developing countries which provide the commercial viability for the presence of research based companies in those markets. To undermine this commercial viability by use of CL will serve as a disincentive for companies to expand their activities (or even remain) in these markets.

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.

Intellectual Property and Economic Development

There is substantial evidence that inward investment increases as the patent system is strengthened. For example:

- In 1988, Canada restricted laws which allowed automatic compulsory licences of pharmaceuticals and abolished them in 1993. Inward investment by the pharmaceutical industry into Canada increased from Can\$106 million in 1987 to Can\$504 million in 1993 to Can\$1.16 billion in 2002.
- Pharmaceutical industry investment in Mexico and Brazil increased significantly after each country strengthened their IPR in the early 1990s. However, the IPR Decree introduced by the Brazilian Government in 1999 and increasingly erratic implementation of IPRs so shook the pharmaceutical industry's confidence in Brazil's IP framework, that a marked tailing off in investment and drop in employment numbers can be traced from the beginning of 1999.

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GlaxoSmithKline's Position

Weak patent protection for pharmaceutical products can also contribute towards a “brain drain” of scientific talent. For example, India’s own trade association OPPI estimated that more than 15% of scientists working for US pharmaceutical companies in the US are of Indian origin. This “brain drain” in itself impacts development. Similarly, in the 1960s, only 16% of Korean scientists and engineers with doctorates from the US returned to Korea. However, when Korea’s patent laws were strengthened in the 1980s, some 60% returned.

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