Mar
25
2013

Compulsory Licenses for pharmaceuticals: An inconvenient truth?

Editor

LSE's Sivaramjani Thambisetty discusses the legal and strategic implications for the pharmaceutical industry of the Indian decision to uphold the grant of the first compulsory license on a patented drug.

There are 25 makes of cars that sell for less than 300,000 rupees in India. So imagine the impossible annual expense of a drug for a rare cancer that costs as much as 12 of the most expensive of these cars. And then compare that to the cost of 100,000 rupees a year for a non-branded version of the same drug.

This wide gulf in pricing led earlier this month to the intellectual property appellate board (IPAB) in Chennai to uphold the grant of a compulsory license for the first time to a generic company that was producing the patented drug, Nexavar, at the lower cost. A compulsory license defeats the existence of a patent (in this case, owned by Bayer). On the one hand it raises the spectre of protectionist measures; on the other, the decision of the IPAB is in the best common law traditions—substantively reasoned and capable of methodological scrutiny. I selectively consider three aspects of the decision here: the articulation of public interest, which was the basis of the decision; the strategic implications for pharmaceutical companies with a presence in India; and the value of this decision in the context of keeping some of the world's poorest populations alive, if not healthy.

Which public, what interest?

Justice Prabha Sridevan's decision to uphold the grant of the compulsory license (CL) is largely based on a version of 'public interest' that is deeply controversial. What is reasonably affordable when it comes to the cost of a drug that treats severe diseases, in this case liver and kidney cancer? The legal context on which a partial consensus is possible is this: the TRIPS agreement allows for the grant of compulsory licenses. The CL can be granted in the public interest. And as per Indian law, the benefit of a patented invention must be available at a 'reasonably affordable' cost. The 'reasonably affordable' is not directly a condition under which a CL can be granted, but it is part of the general principles applicable to the working of patented inventions.

Considered by the judges as 'a marker', this principle led to the consideration of price as a factor of public interest. The public here is clearly Indian, and their purchasing power defined on average terms rather than the few who can presumably afford to pay the cost of a small car per month for an anti-cancer drug. On the inevitable appeals that will follow, a great deal of attention will be paid to whether 'reasonable affordability' amounts to an additional basis for the grant of a CL that is therefore incompatible with the TRIPs

agreement. Questions will also be raised about whether local assessments of affordability are just too subjective for an international trade regime built on 'universal (but minimal) standards of patent protection.

Bayer, the company whose patent was under threat, evidenced two kinds of arguments—that the pricing was in keeping with the price of the drug in other markets, and that pricing beyond the cost of production was justified by the costs of drug development in the pharmaceutical industry in general. Nexavar is designated an orphan drug under EU legislation, and therefore eligible for additional incentives right from the start of the research and development (R&D) process. These additional incentives are justified on the basis that the pharmaceutical industry would not otherwise be willing to invest in diseases that affect less than five in 10,000 people not globally, but in the EU. Patents themselves are granted in order to compensate for market failure—the notion that certain products will not reach the market but for the incentive effect of patents. Orphan drug designation ameliorates market failure even further.

The fundamental question here is whether pharmaceutical companies can continue their rent seeking behaviour in poor populations, when the drug was not developed with a view to alleviating the disease burden of those in developing countries. Another version of the same question would ask whether pharmaceutical companies can continue to claim that high prices for successful drugs are justified in order to cross-subsidise less successful drug discovery processes when only marginal quantities of global R&D is spent on targeting the disease burden in developing countries?

Bayer also claimed that the requirements of the local population were being met by a philanthropic Patient Assistance Programme (PAP). There is no legal obligation for Bayer to provide such assistance and consequently no legal authority to commit them to continuing such provision. Figures show that it had only imported 300 bottles of the drug in a month where a potential 16,000 were needed by the disease population in India. Bayer also claimed that the needs of the population were being met by another company that was producing the drug in infringement of Bayer's patent for 10 per cent of the cost at which Bayer was supplying the drug. This claim amounted to a spectacular own goal: for Bayer to claim that an infringing company was fulfilling the need was a tacit admission that it was not providing adequate supplies.

Legally, failure to 'work' the patented invention is one of the conditions on which a compulsory license may be granted. In this case while the IPAB seemed to note that it may not be feasible for a company with a small patient base to manufacture the product locally in every country where it holds a patent, it held that if a company is relying on import alone to satisfy the 'working' condition it must be on a commercial scale. The IPAB seemed to take Bayer's reliance on the infringer's presence and the patient assistance programme as an admission that the importation was therefore not on a commercial scale. Both of these circumstances are interesting albeit contested, extensions to an entrenched debate that has seen 'working' of an invention defined across a spectrum from local manufacturing that draws investment and increases local capability to mere importation of the product to supply the market.

The price of failure in the pharmaceutical industry

Figures based on different studies put the cost of producing a marketable drug between US$43.4 million and US$4 billion. Some of the difference is accounted for by whether or not the figures compensate for all the drugs that fail at different stages of a long process of research, standardisation and safety approval. The pharmaceutical industry's preferred number rests largely on the DiMasi study, which puts it at around US$800 million. Clearly, understanding how estimates can vary so much requires a fine-grained understanding of the constructed nature of R&D costs and warrants a closer look at the source and verifiability of figures.

For a number of decades the pharmaceutical industry has lobbied governments for incentives and concessions on the basis of claims around the risk and cost involved in producing a commercially

successful drug. As a direct result most jurisdictions in developed countries have seen patents being granted for lower levels of inventiveness, to mere variations in dosage regimes, extension of patent terms through supplementary protection certificates, exclusivity to drug safety information and orphan drug incentives. The real expense that these regulatory measures are compensating for is the expense of failure. In which other industry would such a staggering amount of waste be tolerated? Yet the pharmaceutical industry is successful enough and safe enough to draw investments from universal investors (including the Universities Superannuation Scheme).

These measures have infantilised the pharmaceutical industry. By responding to demands to increase incentives, we have created an industry that is set in its ways and finds no need, reason or incentive to change its practices. The strategic implications of the Indian decision for the pharmaceutical industry seem clear. Take market segmentation and differential pricing seriously. Take local 'affordability' seriously. Factor in social responsibility. These are all measures that would be common to mature and responsible corporate strategies in other sectors, but regulatory incentives in developed countries for the pharmaceutical industry have greatly distorted the ability of this industry to respond to a diverse range of challenges. (Here and here.)

Furthering legal pluralism

Irrespective of the outcome of this case on appeal, the decision of the IPAB plays a crucial role in building up alternative and legitimate legal narratives around TRIPS and the ability to meet the public health needs of populations in all parts of the world. Despite the explicit legal grounds to grant compulsory licenses, they have been used relatively rarely in developing countries. There are many poorly reasoned and inadequately articulated fears that have prevented their wider use: fears that a CL will be seen as protectionist and incompatible with the TRIPS agreement; fear that it will chill foreign direct investment; or fear that a CL will draw the kind of political pressure and sanctions that were common prior to the TRIPs agreement. These fears appear in many cases to trump the reasonable legal conditions that have to be met in all cases where CLs are granted as well as widespread precedents from developed countries where CLs are used to tackle anti-competitive measures. (For instance, see here and here.)

Thailand, Brazil, Malaysia, Indonesia and now India have all granted CLs for drugs. The significance of the decision in India is that it is plugged into a systematic approach to the question of patent rights for pharmaceutical innovation. A pharmaceutical innovation may be thought of as incremental, substantial or radical according to the significance of the unmet health need it addresses. There is however, a growing gulf between product novelty and inventiveness in the law and the social value of pharmaceuticals measured through health outcomes. The Indian patent act has defined inventiveness to exclude incremental innovations in drugs that evidence little 'therapeutic efficacy' – itself a contested term. The Supreme Court in India is due to give its verdict on the constitutionality and TRIPS compatibility of this provision. Decisions like the IPAB's in *Bayer v Natco* bring legitimate lines of reasoning into the mainstream of legal developments and will make it that much harder to dismiss the right to life of patients in poorer countries.

Sivaramjani Thambisetty is an intellectual property lawyer who teaches and researches on patent law, emerging technologies, innovation and legal institutions.

Declaration of interest: Siva is a member of Universities Superannuation Scheme. The scheme has a responsible investment policy since 1999.

This entry was posted in Development, Health and tagged affordability, patent, pharmaceutical, TRIPS, WTO. Bookmark the permalink.