Affordable Medicine: A big step forward

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India's long struggle to ensure access to affordable medicines for its people recently took a positive and interesting turn. In early March 2012, just before he demitted office, Controller of Patents P. H. Kurien passed an order on an application filed by Hyderabad headquartered Natco Pharma requesting a license to produce a cancer drug (Sorafenib Tosylate), the patent for which is held by German pharmaceuticals and chemicals giant Bayer. Bayer produces and markets the drug under the brand name Nexavar, which is used in the treatment of patients diagnosed as being in the advanced stages of affliction with liver or kidney cancer. Having failed to obtain a voluntary license for manufacture from Bayer, Natco had filed an application under Section 84 of the Indian Patents Act, which specifies the conditions under which a "Compulsory License" (CL) may be issued to a producer other than the patentee. Compulsory Licencing (CL) involves providing an agent, other than the holder of the patent for a product or process, the permission to produce or market that product without the consent of the patent holder.

Before 2005, when India amended its Patents Act to recognise product patents, Natco or any other Indian pharmaceutical company would not have needed such permission. All it needed to do was demonstrate that it had access to a process technology different from that used by Bayer to produce Sorafenib. This encouraged the growth of an industry producing a large number of on-patent (and off-patent) drugs and marketing them at prices much lower than those charged by the original patentees. The net result was the well-documented facts that drug prices in India were among the lowest in the world, and that despite these low prices there was no shortage of essential drugs in the country.

However, once India signed into the Uruguay Round world trade agreement, which included an agreement on Intellectual Property Rights (IPR), India's Patent Act, 1970 had to be amended thrice in 1999, 2002 and 2005, to bring it in line with the agreement on Trade-Related Intellectual Property Rights (TRIPS). These changes not only replaced the Chapter on CLs, but culminated in the recognition of product patents. Inasmuch as the latter prevented Indian firms from producing a patented product (unless the technology was voluntarily licensed by the patent holder) and gave the patent holder a monopoly right to produce the product, there was a danger that prices would rule high and if sought to be regulated or controlled could lead to inadequate availability.

The TRIPS agreement was to the disadvantage of less-industrialised developing countries like India, which had registered few patents, including in a crucial area like pharmaceuticals. However, the TRIPs agreement did provide a few windows of opportunity for governments to intervene to rein in prices in support of needy patients in their countries. Crucial among them was the right (subject to conditions) that the agreement granted governments to resort to "compulsory licensing" on grounds such as public interest, anti-competitive conduct, or need for non-commercial government use. It was that right that the clauses on CL in the revised Patent Act sought to interpret.

An issue of significance is what constitutes "public interest". In principle, the right of the government to resort to compulsory licencing can be invoked when the patent holder does not

work the patent or does so in a manner that is inimical to the public interest, leading to "unreasonable prices", inadequate technological progress, or inability to deal with public health or other emergencies. However, the TRIPs agreement did require that the patentee should be notified about possible violations and the prospect of issue of a CL and that negotiations held with the patentee to resolve the issue if possible.

In the case of pharmaceuticals this right to issue a CL was strengthened under pressure from the developing countries and civil society activists in the Doha ministerial declaration of 2001. The Declaration on the TRIPS Agreement and Public Health of 2001, affirmed the power of WTO Members "to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" and held that agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all."

In India these flexibilities became a matter for debate before the revision of the Patents Act was legislated to make it TRIPs compliant, leading to major advances. One of those advances was the stipulation that CL can be invoked also in instances were the patented product is not just reasonably priced (say, relative to costs), but reasonably priced and affordable. According to section 84 of the Indian Patents Act: " At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely: (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India."

What was unclear was how the presence or absence of such grounds for action was to be assessed. Remarkably, after India amended its Patents Act to make it TRIPS compliant and recognise product patents, the government had not till now exercised the right to compulsory licencing even once, which would have helped clarify matters. This is despite the fact that in a crucial public health-related area like drugs and pharmaceuticals the transition to the new regime made a considerable difference to both availability and affordability.

Being the first in itself makes the Nexavar judgement historic. But there is more to the judgement than its pioneering character. It is the grounds on which the Controller of Patents accepted Natco's application and rejected Bayer's opposition that are also pathbreaking. One important ground was the assessment whether reasonable public requirement was being met with regard to the supply of Nexavar through importation. Noting that: (i) over the years, Bayer had imported the drug in volumes that could have treated only a small fraction (a little above 2 per cent) of those who could be credibly assessed as requiring the drug; (ii) that there were years in which no imports were made; and, (iii) that the company was relying only on the import route and not on local production to work the patent, the Controller General had concluded that in a physical sense Bayer was not working the patent. It was not meeting the condition that "the reasonable requirements of the public with respect to the patented invention" were being satisfied.

He also rejected the argument that these circumstances with respect to supply of Nexavar had to be judged in the context of the fact that Cipla, another domestic generic pharmaceuticals manufacturer, has without licence been marketing Sorafenib in India at a price much lower than

that charged by Bayer. Bayer has filed an infringement suit against Cipla which is pending in the courts. In the circumstances, the Controller General argued that this could not be an excuse for Bayer not ensuring adequate supply of Nexavar.

A second important conclusion of the Controller is that the failure to meet demand adequately was partly because the product was priced such that it was unaffordable. While Natco's counsel had referred to research findings on reasonable estimates of R&D costs and the per capita incomes of the poor in India to argue that the product was unreasonably priced, the judgement itself focuses on the issue of unaffordability. Even when assessing this the fundamental issue was not the fact that Nexavar was being priced at around Rs. 2.8 lakh for a month's dosage of 120 tablets, when Cipla was supplying the drug at Rs. 30,000 for a month's treatment and Natco was promising the same quantum at Rs. 8,800 if granted a license. Rather, starting from the fact that the sale of Nexavar over the previous four years was only equivalent to a fraction of the public's estimated requirement of this life-extending treatment, Controller Kurian concluded that the drug "was not bought by the public due to only one reason, i.e. its price was not reasonably affordable to them." This is an important precedent, since it lays down a condition for assessing affordability. If enough of a patented drug that was crucial for the public was not being actually consumed, it must reflect the fact that a significant share of patients are not able to afford the drug at the price at which it can be sold. That does warrant invoking the right to issue a CL.

Finally, the judgement examines the issue of whether the patent was being fully worked in India, given that it was only being imported and not manufactured in the country. Counsel for Bayer referred to the fact that the phrase "manufactured in India' was dropped from the Patents Act when it was amended in 2002, to argue that local manufacture was not required to establish "working of a patent". Moreover, Bayer's counsel argued, cost effective scales of production of the drug were far above India's requirement. This precluded local manufacture, in which quality control was also difficult to ensure. Not accepting this argument but recognising that the Act does not define the phrase "worked in the territory of India", the judgement turns to international conventions and the fact that the issue of local manufacture though removed from one context when the Indian Patents Act was amended was incorporate in another clause (84(1)(c)).

There are three points the judgement makes here. The first is that while importation rather than local manufacture is not a ground for forfeiture of a patent, a country may use the discretionary powers it has when framing patent legislation to make it a ground for invoking the right to compulsory licensing. Second, the understanding of working the patent in the relevant conventions does not imply working the patent on a "commercial scale". And, finally but most importantly, "mere importation cannot amount to working of a patented innovation". According to the judgement, "a patentee is obliged to contribute to the transfer and dissemination of the technology, national and internationally, so as to balance rights with obligations. A patentee can achieve this by either manufacturing the product in India or by granting a license to any other person for manufacturing in India." This conclusion too, if sustained, is a precedent with implications that go far beyond this case and product.

On these grounds the Controller of Patents issued an order giving Natco the right to manufacture and sell a generic version of Sorafenib Tosylate, subject to pricing it at Rs 8800 for a monthly dose of 120 tablets and paying Bayer a 6% royalty on net sales.

As noted earlier, this judgement does mark a whole new phase in India's journey to fashion a patenting regime that would ensure access to affordable medicines to its people. It is bound to be a precedent that would be quoted in a range of other cases and products. This is not because this is the first instance of grant of a CL, which itself is important. The failure to resort to compulsory licensing thus far was not because of lack of global precedent. In fact, developed countries such as Canada, the United Kingdom and Italy and developing countries such as Brazil, Thailand, Malaysia, South Africa and Kenya have resorted to such licencing in the case of drugs and pharmaceuticals. Very clearly ideology and international pressure had held back the system. Controller General Kurian has initiated the process through which India can free itself of such fears and exercise its legitimate rights and options. The nation owes him much.

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