A Strike against Pharma MNCs

The compulsory licence for Nexavar is only the beginning of a new battle over drug prices.

The grant of a compulsory licence (CL) to Natco Pharma, a relatively small Indian pharmaceutical company, to manufacture and sell the cancer drug sorafenib (Nexavar) has been rightly hailed as a major step forward for public health and the wider availability of life saving medicines.

The German pharmaceutical company Bayer holds the patent for Nexavar, which is used in the treatment of liver and kidney cancer, and the drug is sold in the Indian market at Rs 2.88 lakh for a month's supply of 120 tablets. Natco has said that it will supply the same quantity for Rs 8,880, a reduction of almost 97% in the price. There are said to be close to 1,00,000 patients in India with liver and kidney cancers who can benefit from this medicine but few, even among the rich, can possibly afford to spend Rs 34.5 lakh a year on it.

India's controller of patents, very rightly, took the stand that such pricing effectively places the medicine outside the reach of people and thus there was a need to allow its manufacture at relatively lower prices. In his order the controller noted that Bayer sold $934 million worth of Nexavar in 2010 globally but hardly any of these were sold in India due to its high price. He thus ordered the issue of a CL to Natco after noting, "The mandate of the law is not just [to] supply the drug in the market, but to make it available in a manner such that [a] substantial portion of the public is able to reap the benefits of the invention. If the terms are unreasonable, such as high cost, availability is meaningless." Bayer claimed an unbelievable $1.8 billion as the research and development cost of Nexavar but could show no data for this; it is likely that the development of this drug benefited significantly from public funds in the United States and Europe.

The importance of this decision cannot be stressed enough. Pharmaceutical multinational companies (MNCs) effectively control an $800 billion market of medicines and medical equipment and have been known to have significant financial and political power over governments and sovereign states to decide policy. Their power is evident from the fact that even relatively influential countries like South Africa have not yet invoked CLs to manufacture anti-HIV/AIDS medicines despite it being such a major public health issue. Brazil has managed to invoke only a couple of CLs; Thailand too has issued just a couple of such licences for manufacture of drugs under patent. This is the first time a CL has been used in India despite a legal provision being put explicitly on the statuette books in 2005. Indeed, India had an unwritten right under the 1994 Agreement on Trade-related Aspects of Intellectual Property Rights to use CLs to counteract unreasonable pricing behaviour of the patent owner. The non-use of the CL provision all these decades by a country which until 1993 believed in a flexible interpretation of patents is therefore surprising.

As doctors, lawyers and public health activists have pointed out, the Nexavar decision will hopefully lead to more Indian pharmaceutical companies coming forward to file CL applications which, in turn, should also compel foreign patent holders to market their drugs at lower prices. India's stance, assuming that this order is upheld by the higher judiciary where Bayer has decided to appeal, will also have a progressive impact on other countries in invoking CLs.

However, we need to realise that the grant of this CL is merely a small first step and much more needs to be done to provide access to medicines for all those who require it. First of all, even after this drastic price reduction, Nexavar will remain out of the reach of most Indians since they can ill afford to pay even Rs 8,880 for a month's supply. While the monopoly power of the patent holders should be fought and global treaties should not be treated as sacrosanct, we should not lose sight of the need to provide medicines and medical care to all, irrespective of their ability to pay. Good health is a right, not a commodity to be bought and sold.

Second, this decision of the controller of patents will be contested all the way to the Supreme Court. In general, pharmaceutical MNCs have been extremely proactive in blocking any loosening of their patent control in medicines. Any final ruling in favour of the patent holder, whether through a review of this order or in the Novartis Gleevac case, will be a huge reversal.

The third aspect to the issue which we need to take cognizance of is the slow but steady takeover of Indian pharmaceutical companies by the MNCs in different forms. Some of them, like Ranbaxy, have been bought over, but many Indian companies have entered into cash-rich deals with pharmaceutical MNCs through which they either manufacture medicines for them or the latter market their products

outside India. Such a trend in the Indian market puts definite limits on the power of the remaining Indian pharmaceutical companies to contest the foreign companies in pricing or patents. A further weakening of the relative power of the Indian pharmaceutical companies could undo any progress from episodic CLs.