

Drug cos seek compulsory licensing

Indian firms want WTO provision invoked which will allow them to make cheaper version of high-priced drugs

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Mumbai: Even as the government considers pricing patented drugs sold in India, local drug makers are exploring the possibility of using a controversial provision of the Trade Related Intellectual Property Rights (TRIPS) agreement of the World Trade Organization (WTO) that allows member countries to permit firms to make cheaper versions of such drugs.

Known as [compulsory licensing](#), this provision can be invoked by a country if a drug maker is willing to make and supply copies of patented drugs in a medical emergency or to export to least developed countries, which are yet to be covered by the TRIPS regime.

Setting off what could become a trend, Hyderabad-based cancer specialty company Natco Pharma Ltd has requested the government to grant it a compulsory licence for two high-cost drugs: Sutent, a renal cancer drug of Pfizer Inc., and Swiss drug maker F Hoffmann-La Roche Ltd's lung cancer medication, Tarceva. Both drugs are currently protected under global patents. "We have applied for granting compulsory licence for Erlotinib, the generic version of Tarceva, and Sunitinib (Sutent) to the government," Natco's chief operating officer Rajeev Nannapaneni said.

Cipla Ltd, one of the country's top three drug makers, has similar plans.

The target of compulsory licence requests are largely new cancer drugs already launched by multinational firms under patent protection. Often, these drugs are priced at the same level across the world. Tarceva, for instance, costs about Rs1.5 lakh for a month's treatment. Another cancer drug, Glivec, marketed by Novartis AG, is priced at Rs1.2 lakh for a five-week treatment cycle. Pfizer's Sutent, currently awaiting a patent grant in India, too, is likely to be priced on a par with the international price of \$4,000 for a six-week treatment cycle.

"The improved operating environment (IP and regulatory) in India has enabled Pfizer to rapidly bring Sutent to patients in India... Recognizing that affordability of cancer treatment can be a challenge, Pfizer has also developed a Sutent Patient Assistance Programme (SPAP)..." a Pfizer spokesperson said.

India has one of the widest compulsory licensing provisions in the world. The country's patent law provides for compulsory licences to be issued if the drug in question is not available in adequate quantities locally and also when the government feels the drug is not reasonably priced. It is in this context that Cipla is fighting a case in the Delhi high court to justify its plan to launch a low-cost version of Tarceva in the local market.

Cipla says it wants to sell the drug at Rs1,600 a tablet, one-third of its market cost. Natco wants to price it at about Rs1,000.

"Access to these medicines is a serious issue in a country like India if these are granted monopoly rights without merits. When generic companies can produce these drugs at one-third or one-fourth of the price, it should be encouraged," said Cipla chairman Yusuf K. Hamied.

In April, Union health minister Anbumani Ramadoss had asked Novartis to withdraw a patent litigation it is engaged in in India over Gli-vec and warned that the country should not be forced to "issue a compulsory licence" even though it had never issued one. Novartis has not withdrawn its case and Ramadoss has not taken any action yet.

Patent experts say there are several clauses in Indian patents law that local drug makers can use to push for compulsory licences. Patent holders, for instance, are not allowed to claim their product prices are high because they do not have manufacturing facilities in the country. In such a scenario, the government

can permit a local drug firm to make and sell the patented product at lower prices. Most of the patented drugs of multinational drug firms are imported today.

Next, said Shamnad Basheer, an associate at the Oxford Centre of Intellectual Property Studies, patent rules allow multinational pharmaceutical firms, when granted a patent, a lead time of three years to bring the prices of their drugs to a level that does not inhibit patient access to the drug. After three years, if the government is convinced that the use of the drug is limited because it is not affordably priced, it can issue a compulsory licence to a drug maker that promises to bring prices down. "As of today, this can certainly kick in for a number of pharmaceutical process patents that were granted more than three years back," Basheer said.

There is a third provision in the Indian Patents Act to enable a compulsory licence: if a globally patented drug was being manufactured in India prior to 2005 by a local drug maker, it, too, can be allowed a licence. Patents on drug products were allowed in India since January 2005, before which only processes to make drugs could be patented.

"India has some outstanding generic companies that can exploit compulsory licensing provisions. In countries like Nepal or Bhutan with no adequate manufacturing capacity, such compulsory licensing provisions may be of no use..." said Gopakumar Nair, chief executive of Gopakumar Nair Associates, a Mumbai intellectual property advisory firm.

According to the Doha Declaration of the WTO, compulsory licences to export to least developed nations have been made TRIPS-compatible. The rules mandate that the importing country must notify the WTO's council for TRIPS of the name and expected quantity of the product, verify that it has insufficient or no manufacturing capacity for the product, and confirm that it has granted or intends to grant a compulsory licence.

Still, in all these instances, it is the WTO member-country's responsibility to ensure and prove that its intent on compulsory licensing is in public interest. "In fact, it is widely thought that owing to the various preconditions, it is onerous to apply for and operate such a licence," said Basheer.

Late in 2006, Thailand issued a compulsory licence for Merck and Co.'s HIV/AIDS drug Efavirenz in a bid to cut growing health care costs. The Thai government then argued that products imported from India cost half that of Stocrin, Merck's branded treatment.

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