Natco Pharma files India's first compulsory licence plea

Date: 2 August 2011

Source: The Economic Times

Link: http://m.economictimes.com/PDAET/articleshow/9462939.cms

NEW DELHI: Natco Pharma has applied for the country's first compulsory licence to sell a generic version of Bayer's patented medicine, a development whose outcome is expected to determine how global drug makers price their costly drugs in India.

In compulsory licensing, the government allows a generic firm to produce a patented product without the consent of the patent owner. It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property -TRIPS (trade-related aspects of intellectual property rights) Agreement.

Natco stated in its application that the German company's drug was unaffordable for the average Indian, a person familiar with the development said. PH Kurien, Controller General of Patents, said, "I understand they have filed the application."

Bayer's drug, Nexavar, which is used to treat liver and kidney cancer, costs about 2.85 lakh for a month's course. Natco said it can sell its generic version, sorafenib tosylate, for just 8,900 for the same course.

Local drug firms and health activists are pushing for liberal use of compulsory licensing, saying that innovator companies charge exorbitantly high prices for their medicines. "A favourable decision for Natco will open the floodgates and encourage other local firms to apply for compulsory licence for costly patented medicines," a senior industry said.

YK Sapru, chairman and CEO of Cancer Patients Aid Association (CPAA), said Natco's application, if approved, would be a big relief to those who can't afford Nexavar. There are an estimated 25 lakh cancer patients in India. A Natco spokesperson declined comment while Bayer did not respond to ET's email.

In December, Natco had sought a voluntary licence from Bayer for sorafenib tosylate that was refused. Indian laws allow a firm to apply for a compulsory licence only after the innovator company rejects the voluntary request.

Experts say the face-off is going to be a long drawn, as the loser will invariably challenge the decision in court. There are at least two other voluntary licence applications pending: Natco's with a GSK-Pfizer joint venture and Cipla's with US-based Merck & Co.

For Bayer, this is not the first challenge for Nexavar. Cipla has already launched its generic version without any permission and will have to pay penalty if the court rules in favour of Bayer in a pending patent case.

Although compulsory licensing allows a generic firm to legally make and sell the low-cost version, it has to pay some royalty, usually about 5% of sales. MNCs strongly oppose the use of this provision because it breaks their monopoly. They say such licensing is not a sustainable policy to address access of medicines as these products account for much less than 1% of Indian drug market.

Compulsory licensing provision has been used in countries such as Thailand, Brazil and South Africa.

In all these nations, the provision was used for HIV medicines, according to a commerce ministry discussion note on the use of such licences. India spends an estimated $35 billion in healthcare cost. Unlike most other countries, where such costs are state-funded or insured, 90% of Indians pay from their own pocket.

Keywords: Natco / Pharma / India / compulsory licence