

Indian co seeks compulsory nod for MNC's drug

Lee Pharma Wants Licence For AstraZeneca's Diabetes Drug

Rupali.Mukherjee
@timesgroup.com

Mumbai: A little-known Hyderabad-based pharma company has filed an application with the Patent Office to manufacture saxagliptin, a diabetes drug patented and marketed in the country by MNC AstraZeneca. This is the third compulsory licence application filed so far, in a bid to substantially bring down the cost of a key drug used in diabetes management.

Lee Pharma filed the application on June 29 to make a generic version of the patented drug, marketed as Onglyza, under Section 84 of the Patent's Act, 1970.

The first compulsory licence—Natco's application for Bayer's Nexavar, an anti-cancer drug—was successful, while the second—BDR's application for BMS' Dasatinib—was rejected by the Patent Office.

The domestic company, in the latest application, says that the drug is being sold by Astra Zeneca at Rs 41-45 per tablet, while the cost of importing is less than a rupee (0.80) per tablet. The cost of therapy per month amounts to nearly Rs 1,300, which is unaffordable to most diabetics in the country since over 75% are out-of-pocket expenses.

Lee plans to price saxagliptin 2.5 mg per unit at Rs 27, as against Rs 43.21 per unit of Astra Zeneca's Onglyza, while the 5 mg version cost per unit will be Rs 29, as against the MNC price of Rs 41.50, which would result in huge savings.

The application says nearly 80% of diabetics in

the country belong to low and middle-income groups, and that over 80% of diabetes deaths occur in low and middle-income countries like India. The domestic company has claimed that even after eight years of grant of patent, the drug is still not manufactured in the country, and is being imported, and that too in insufficient quantities, which does not meet the requirements of the country.

Under Section 84, a compulsory licence to manufacture a drug can be issued after three years of the grant



AFFORDABILITY PLEA

of patent on the particular product, which is not available at an affordable price.

Saxagliptin is covered by a patent granted in 2007 to Bristol-Myers Squibb, which assigned the monopoly rights to AstraZeneca, when the latter acquired its diabetes portfolio in February 2014. The drug is marketed as Onglyza in a standalone form and as Kombiglyze XR in a combination with another active ingredient.

To successfully obtain a CL under Section 84 of the Patents Act, an applicant needs to show that they have made efforts to negotiate a voluntary licence from the patentee for at least six months.

Patent / IPR