

Covid drug: Natco eyes patent waiver

Files Plea To Produce Arthritis Medicine That Can Be Used With Remdesivir

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In the first instance of a pharma company taking the compulsory licensing (CL) route to launch a Covid drug in India, Hyderabad-based Natco Pharma has filed for a waiver of patent rights to manufacture rheumatoid arthritis drug Baricitinib. The CL, if granted, will help in improving the accessibility and affordability of the drug, bringing its price down substantially.

The USFDA had last November granted emergency authorisation for Baricitinib in combination with Remdesivir.

At present, a limited quantity of the patented drug is available in the country, and that too, at an exorbitant price (see graphic). The patent is held by Incyte Holdings, with a licence to Eli Lilly, which markets the drug under the Olumiant brand name. The application has been filed under Section 92 of the Patents Act, which can be invoked by the Centre due to a national emergency, circumstances of extreme urgency or in case of public non-commercial use.

In its application, Natco has cited the unmet medical needs due to the lack of supply and affordability in light of the grave and life-threatening national public health emergency caused by the second Covid wave as the main grounds for seeking the CL. Under the World Trade Organization TRIPS Agreement, CLs are legally recognised means to overcome barriers in accessing affordable medicines. Under the rules, governments allow a company to manufacture a patented drug without the consent of the innovator firm. In 2012, Natco became the first company to get a compulsory licence in India, which was related to a cancer drug called Nexavar.

Natco's move is expected to force the government to examine the application carefully given that former PM Manmohan Singh had pointed to the flexibility available under the law, although his reference was in the context of ramping up vaccination. The application puts pressure on the US drug maker, analysts said. It has only two choices — either give a voluntary

licence or sue Natco for the patent, which could result in a public backlash given the soaring Covid case load and death toll in India.

In its application, Natco has urged the Controller General of Patents to grant it a CL to manufacture and market Baricitinib, both as bulk API (active pharmaceutical ingredient) and finished dosage only for Covid treatment in India till the pandemic prevails. It is also willing to pay a 7% royalty on net profits from Baricitinib sales to the patent-holder.

Making its case, Natco's application said Olumiant is not manufactured in India — less than 9,000 tablets were imported in 2019 and 2020.

“The tablets of Olumiant imported through 2020 by Lilly would serve at best to meet the needs of only approximately 600 patients,” Natco said in its application, a copy of which was reviewed by **TOI**.

