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Compulsory licence for another cancer drug?

DIPP wants to know why generic version of Bristol-Myers Squibb's drug is needed

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After allowing an Indian firm to sell the generic, or copied, version of Bayer's anti-cancer drug Nexaver, the Centre is now considering doing the same for Dasatinib, made by US drug major Bristol-Myers Squibb (BMS) and sold under the brand name Sprycel.

Only, the Department of Industrial Policy and Promotion (DIPP) wants the Health Ministry to clarify the reason under which it wants approval.

If the Health Ministry can prove that denial of generic manufacture of this drug could lead to a national emergency or a situation of extreme urgency, the DIPP can allow its manufacture via a notification.

But if the Health Ministry wants the compulsory licence on the grounds that the patented version of the leukaemia drug is not affordable by the masses, then the approval of the Indian Patent Office is required. A month's dosage of BMS's patented medicine costs around ₹60,000.

Only one licence so far

India has granted only one compulsory licence – a permit to produce versions of patented medicines without the consent of the patent holder – so far. It has allowed Hyderabad-based Natco to sell a generic version of Bayer's anti-cancer drug, Nexaver.

The Nexaver licence was, however, granted by the Indian Patent Office, not the DIPP, as it was sought on the grounds of non-availability and high price of the patented drug.

Approaching the Indian Patent Office for a compulsory licence under the Patents Act (Section 84) is more complicated than getting it under the provision (Section 92 of the Act) where the Centre issues a notification. Generic manufacturers have to go to the Patent Office individually to seek a licence. In October 2013, the Patent Office had rejected the application of Mumbai-based BDR Pharmaceuticals to make a generic version of Dasatinib.

Following this, the Health Ministry approached the DIPP, asking it to grant a licence by issuing a notification. "We pointed out to the Health Ministry that as per the law, we can do so only when it can conclusively prove that denying it could lead to a public health crisis, or if it gives an undertaking that it wants it for public non-commercial use, where the medicines will be purchased by the Government," a DIPP official told *Business Line*.

The Health Ministry has to collate data on the number of patients suffering due to unavailability of the patented medicine to convince the Government that there are grounds to grant the compulsory licence to address a situation of public urgency or national emergency.

In case the Health Ministry wants the licence to be issued in order to bring down the price of the medicine and expand its reach, it has to be granted by the Controller of Patents, he added.

Health issues

- Approval can be given if Health Ministry can prove that denial of drug can lead to a national emergency
- Bristol-Myers Squibb's patented drug costs around ₹60,000 for a month's treatment
- Only Natco has been given a compulsory licence so far, to make Bayer's Nexaver

Patent.