

Times of India, Delhi

Monday 5th May 2014, Page: 15

Width: 20.94 cms, Height: 12.47 cms, 4r, Ref: pmin.2014-05-05.29.182

Govt mulls cancer drug patent waiver

Health Min Writes To DIPP On Ending Protection For Bristol-Myers' Dasatinib

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New Delhi: The health ministry has reopened the issue of waiving a global drug giant's patent rights for Dasatinib, a cancer drug, arguing the move is needed to deal with an "emergency". The latest development — which the ministry expects will go through — comes at a time when India has won a reprieve from the US over its intellectual property regime but is facing flak from the civil society, which is critical of the government "going soft" on affordability and availability of medicines for life-threatening diseases.

In a letter to the department of industrial policy and promotion (DIPP) last week, the health ministry has answered the concerns raised earlier and said the cost of the drug produced by pharmaceutical giant Bristol-Myers Squibb (BMS) will be met through gov-

MAKING IT AFFORDABLE

The health ministry has argued that Dasatinib patent waiver is needed to deal with an "emergency"

The ministry has assured that the cost of the drug produced by Bristol-Myers Squibb will be met through government schemes

Recently, India won a reprieve from the US over its IP regime but it is facing flak from civil society for "going soft" on affordability and availability of medicines for life-threatening diseases



ernment schemes. Many experts see BMS along with Pfizer at the forefront of the battle to get the US authorities to downgrade India's patent regime by a notch and open it to possible punitive action.

Officials in DIPP refused to comment on the latest move, but health ministry sources said they plan to use around half-a-dozen schemes to fund the cost of making the drugs available to patients for what

is called public non-commercial use and the position has been made clear in last week's letter. Dasatinib is used to treat chronic myeloid leukaemia.

If the move goes through, it will be the first instance of the government invoking emergency provisions in the law to waive the patent rights. So far, the compulsory licence provisions have been used by the Patents Office, which waived Bayer Corporation's patent rights over

Nexavar, a renal cancer drug, allowing Natco Pharma to manufacture and sell it at a fraction of the cost. Natco had offered to sell the medicine at Rs 8,800 for a month's therapy, compared to Bayer's Rs 2.8 lakh.

But unlike last time, this time the government will itself have to issue the compulsory licence, which is provided for in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Even in this case, the sources said, the government will have to hear the arguments put forward by BMS to "follow the principles of natural justice". Once the government issues its order, the Patents Office will be required to notify the availability of a compulsory licence for the drug and will be required to go through another round of hearing.

Initially, the health ministry was pushing for compulsory licence for three cancer

drugs, but had to drop plans for two of them.

Given the international scrutiny, the government is treading with caution and had earlier turned down health ministry's plea that the government issue a compulsory licence under section 84 of the Indian Patents Act on the grounds of affordability and had suggested an application be made with the Patents Office. DIPP is extra cautious over the issue as it will undergo the legal process and it does not want to be caught doing something which is against the law.

Last October, the Patents Office had rejected an application from BDR Pharma to make a generic version of BMS's Dasatinib, which is sold under the Sprycel brand. The proposal was rejected on the grounds that the Indian company did not make enough efforts to obtain a voluntary licence for the anti-cancer drug.

Patent

6/8