

Emergency Clause Won't Be Invoked To Waive Patent On BMS' Dasatinib Govt cautious on cancer drug IPRs

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New Delhi: Amid heightened scrutiny of the intellectual property regime, the government has decided to tread with caution on a compulsory licence for a cancer drug to ensure that its decision is in line with the legal provisions.

While compulsory licensing, which entails waiver of patent under extreme situations, for three cancer drugs was being pushed by the health ministry, the issue is now limited to Dasatinib, a medicine to treat a type of cancer of the white blood cells, for which Bristol-Myers Squibb (BMS) holds a patent.

Sources said that the commerce and industry ministry recently wrote to the health ministry, rejecting the plea that the government should issue a compulsory licence under section 92 of the Patents Act. Using this provision, the government can only waive the BMS's patent rights in case of a national emergency or a circumstance of extreme urgency which was not the case at the moment.

There is a third possibility as well, which is to suspend the rights for public non-commercial use in special circumstances, including public health crisis. In fact, the Patents Act has list-

> The commerce & industry ministry is said to have pointed out that availability of patented drugs at affordable prices should not be dealt by the government but the Patent Office, which is an independent agency

> US pharma lobby has already raised the heat over the bid to grant compulsory licences on patented cancer drugs in India



> Trade disputes between India and the US have escalated in the recent past over subsidies and job losses in the US

TRADE TIFF TO BLAME?

ed AIDS, HIV, tuberculosis, malaria and other epidemics as examples.

Sources said that in case of Dasatinib, this provision may be used but then the health ministry has to clearly show that it has the budget to procure the medicine and supply it under a plan for cancer patients. "You can't expect a manufacturer to sell the medicine below cost," said a source.

Sources said that the commerce & industry ministry has pointed out that availability of patented drugs at affordable prices, which is being cited by the health ministry for granting a patent waiver, should not be dealt by the government. In fact, the health ministry was recently told that section 84 of

the Patents Act clearly stipulates that compulsory licence can be issued if a "patented invention is not available to the public at a reasonably affordable price".

But the government does not have powers under the law to suspend patent rights on the grounds of affordability. The law only allows the Patent Office, which is an independent agency, to issue a compulsory licence. Last October, the Patent 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.

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