

DCGI's plan on patent linkage gets HC booster

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NEW DELHI: The Delhi High Court (HC) has directed the drug controller general of India (DCGI) not to give marketing or manufacturing permission to generic drugmakers for drugs that have already been granted patent in India. The court gave this order last month while preventing Hyderabad-based drug company Hetero Drugs from manufacturing or selling its low-cost version of Bristol-Myers Squibb's (BMS) patented Leukemia drug, Dasatinib.

In its ex parte interim injunction order, the court said: "It is expected that the DCGI while performing statutory functions will not allow any party to infringe any laws and if the drug for which the approval has been sought by Hetero Drugs is in breach of the patent of BMS, the approval ought not to be granted to Hetero."

The order added that Hetero should restrain from manufacturing, selling, distributing, advertising, exporting, offering for sale that would directly or indirectly infringe upon BMS's drug Dasatinib. The next hearing will be held next month.

ET had reported last May that the DCGI was planning to link marketing approval to patents. Indian generic companies had strongly opposed such a policy while patent experts said the DCGI does not have the mandate to do so but the court order could bolster the DCGI's initiative.

Patent expert and professor in intellectual property Shamnad Basheer said the Delhi HC's decision has transgressed existing laws and regulations, besides giving legal mandate to the DCGI to link marketing approval with patents. "The order contravenes the Drug and Cosmetics Act under which the mandate of the DCGI is limited to examining the safety and efficacy of drugs," he added.

Indian Pharmaceutical Association's (IPA) secretary general DG Shah said the order grants unlimited data exclusivity to the patent holder as the HC has asked Hetero not to pursue its marketing application. The order also invalidates the bolar expression of the Indian patent law which allows generic companies to pursue regulatory process of patented drugs to expedite the launch of their own drugs. They can even 'launch their drugs at risk'.

Global discovery drugmakers who have been demanding to link patent with marketing approvals alleging generic companies of infringing on their patents has welcomed the order.

Organisation of Pharmaceutical Producers of India (OPPI) director general Tapan Ray said: "OPPI has been trying to impress upon the need of 'patent linkage' to the government, since quite sometime. In April last year, the DCGI acceded to our request. Unfortunately, due to some reason, this assurance did not get translated into reality. We are delighted to know about this Delhi HC order, specially at a time when we are still discussing this issue with the government."

It may be recalled that there has been a few cases where Indian generic drug companies launched their low-cost versions of patented drugs in India, notably Cipla's launch of Roche's patented drugs Tarceva and Valcyte. Roche has dragged Cipla to court in both the cases and is awaiting the final order.

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