Pharma MNCs ask DCGI to liaison with patent offices

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Mumbai, Mar 19: In the backdrop of Wednesday's Delhi High Court verdict that allowed Cipla to manufacture and sell a patented cancer drug in India, multinational pharma companies plan to urge the Drug Controller General of India (DCGI) to improve its co-ordination with patent offices across the country. Cipla has been granted marketing approval for Erlotinib, copycat version of Roche's Tarceva, as DCGI was not aware that Roche had been granted patent for Tarceva, MNCs argue.

Dismissing the injunction filed by Swiss major Hoffmann La Roche, the Delhi High Court allowed Cipla to manufacture and sell a generic version of the Roche's cancer drug, Tarceva, in India.

Tapan Ray, director general, Organisation of Pharmaceuticals Association of India (OPPI), the body for MNC having presence in India, told FE, "In Cipla's case, the DCGI has given the marketing approval without cross checking whether any product patents have been granted over the drug.

DCGI gave the marketing approval to Cipla while the patent for Erlotinib had been granted to Roche by Delhi patent office one year back." The marketing application that is submitted to the DCGI must contain the details of whether any patent application has been granted over the same molecule," he added. The Swiss major had been granted patent for Erlotinib hydrochloride by Controller General of Patents, Trademarks and Designs, New Delhi in February 2007.

"This is a procedural flaw. When the DCGI comes to know the product patent has been granted over the same molecule, the DCGI must ask the generic player to withdraw the drug from the market. We have already brought the issue in DCGI's notice. However, we want to reinforce in the backdrop of Delhi HC verdict," they said.

However, Gopakumar Nair, Mumbai-based patent attorney, points out that the MNCs' demands are not viable. "In US, there is a requirement for orangebook listing of patent before applying for the marketing approval of a drug. But in India there is no law to insist that DCGI should be aware of the patents granted before."

The Orange Book with the US FDA contains the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. The data is updated concurrently with the publication of the annual edition or cumulative supplements.

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