

Patents body seeks Novartis feedback on Glivec EMR

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Mumbai, 28 June

The office of Controller of Patents & Designs has completed the first examination of patent application filed by multinational Novartis AG for its blockbuster drug Glivec (imatinib mesylate). The drug, which treats chronic myeloid leukemia, has a domestic market of about Rs 300 crore per annum.

The Hyderabad-based Nat-

co Pharma has, however, challenged the patent application by filing a pre-grant opposition in the Chennai Patent Office.

"The invention of the drug in question was made in 1993, and the Indian patent application merely claims a crystal form (Beta) version of the same substance and hence would not deserve consideration," said Adi Narayana, company secretary, Natco Pharma. Novartis India executives refused to comment

on the issue as the patent application has been filed by its parent.

The patent office has sent the first examination report (FER) to the company for clarifications on certain crucial aspects it has claimed in the application with regard to the date of invention and the novelty.

Following the patent office's FER, Novartis has now six months to revert back to the patent office on clarifications,

said a senior official from the Controller of Patents & Designs Office in Mumbai. Novartis AG, which was granted an exclusive marketing right (EMR) by the Controller of Patents in India in 2003, sells the drug at its international price of \$2,800 (around Rs 1,22,010) for a one year treatment.

Following the EMR, the five-odd local generic manufacturers of this product were forced to withdraw the product from the

market.

The players were Ranbaxy, Dr Reddy's Lab, Sun Pharma, Cipla, and Torrent Pharma.

Natco, which had challenged the EMR in the Delhi High Court, was, however, exempted from the stay order secured by Novartis against the generic players.

Natco's Veenat, the generic version of imatinib mesylate, costs Rs 10,000 for a one-year treatment.