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Date :05 -03-2010

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Natco moves SC against Novartis drug

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Posted: Friday, Mar 05, 2010 at 0004 hrs IST

Updated: Friday, Mar 05, 2010 at 0004 hrs IST

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Part of the INTELLECTUAL PROPERTY Board decision said Novartis' Glivec was 'novel and inventive'

New Delhi: Natco Pharma has approached the Supreme Court challenging a part of the Intellectual Property Appellate Board's (IPAB) decision that said Swiss drug-maker Novartis' blood cancer drug Glivec (Imatinib Mesylate) was novel and inventive. The IPAB, in July last year, had denied patentability on cancer drug (Imatinib Mesylate) in the beta crystalline form under Section 3(d) of the amended Patents Act 1970 — under which a patent is granted only if a product proves to be more efficacious than the existing drug molecules.

However, it had given a favourable mention on novelty and innovation of Novartis' Glivec. However, the Supreme Court in September last has already issued notices to the Centre through ministry of industry and commerce, domestic drug-makers — Cipla, Ranbaxy Lab, Hetero Drugs, Natco Pharma and others — on a petition filed by Swiss drug major Novartis, challenging the denial of patent to its blood cancer drug, Glivec, in India.

Natco, in its appeal, has submitted that it had no option but to approach the Supreme Court as Novartis without seeking recourse to the Madras High Court had directly challenged the IPAB's decision before the apex court. Challenging the part of IPAB's decision that held the beta crystal of imatinib mesylate (Glivec) as novel and innovative, the local firm said the board ignored that the product claimed in the Indian Patent application was the same substance as claimed by the Swiss pharma firm in its own patent granted in the US in 1993. "The plea of selection patent raised by Novartis automatically leads to the logical conclusion that the beta crystal of imatinib mesylate was covered by the originating US patent of 1993 granted to the Swiss drug firm and an inventive step, if any, lies only in discovery of the advantageous properties of beta crystal; meaning thereby that beta crystal as such lacked novelty and inventive step," the petition stated.

Natco further said that the board erred in passing the impugned order even in view of its own finding that the Indian Patents Act did not provide for selection patents, and later also erroneously upheld novelty and inventive step of the beta crystal on the same very ground of 'selection patent.'

The legal wrangle over Glivec has been going on for sometime now after Novartis tried to prevent domestic drug-makers including Natco, Cipla, Hetero and Ranbaxy from making similar versions. Before the product.

patent regime became effective in the country in 2005, Glivec was the first pharmaceutical product to be given an exclusive marketing right in 2003 in the country. Pursuant to the patent office rejecting Novartis'

patent application on Glivec in 2006, Novartis has been contesting the rejection of its patent application and certain constitutional parameters that contributed to the rejection.

The Cancer Patients Aid Association is also fighting over prices as Novartis' Glivec as it costs over Rs 1 lakh a month, while local companies sell similar versions of the drug at Rs 10,000 a month.