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Bayer drags Cipla to SC over anti-cancer drug patent

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<http://www.financialexpress.com/news/bayer-drags-cipla-to-sc-over-anticancer-drug-patent/584075/>

New Delhi: German drug major Bayer AG on Wednesday approached the Supreme Court seeking protection for its drug Nexavar even as Cipla's plea for marketing approval for Sorafenib, the generic version of its kidney cancer drug, is pending with the regulatory authorities.

A Bench headed by Justice Dalveer Bhandari has posted the matter for hearing on February 26. Bayer Corporation and Bayer Polychem (India) Ltd has sought to restrain the drug regulator from granting Cipla Ltd permission to sell generic version of Bayer's patented anti-cancer drug Nexavar, which costs Rs 2.85 lakh for a monthly dose of 120 tablets.

Bayer alleged that if Cipla's generic Sorafenib was granted marketing rights, then it would be seen as a spurious drug under Section 17B of the Drugs and Cosmetics Act as it was the genuine patent holder and owner of Sorafenib Tosylate. It would amount to infringement of its patent, the German major said.

Alleging Cipla was a "habitual infringer" and the high court "ought to be taken cognizance of," Bayer said the Indian maker "openly defies and flouts the exclusive rights granted to patentees...its modus operandi is to reverse engineer patented products, taking advantage of R&D carried out by others."

Challenging the impugned Delhi High Court judgement, it alleged that more and more Indian generic firms were now applying for marketing approval for generic versions of drugs covered by patents prior to expiration or invalidation of patents, which was "violative of product patent regime that India ushered in effective January 1, 2005 and therefore, it is necessary that petition raising questions of public importance is adjudicated upon and is settled by an authoritative pronouncement by the apex court. "

Under the patent laws, a patent holder has exclusive marketing rights for 20 years with no competition from generic companies.

The high court had rejected Bayer's plea and had imposed Rs 6.75 lakh penalty on it saying "speculative" petition had delayed the approval of generic drugs in the domestic market.

The high court erred in observing that the issue of patent linkage requires a policy decision to be taken by the government as much as by necessary implication of the relevant provisions of the Drugs & Cosmetics Act, 1940 and the Patents Act, 1970, the legislature does provide for the patent linkage, it said.

Bitter pill

- A Bench headed by Justice Dalveer Bhandari has posted the hearing to Feb 26
- Bayer alleged that Sorafenib would be seen as a spurious drug under Section 17B
- It would also amount to infringement of its patent

The German drug giant said the high court failed to appreciate that the two statutes in question read together have an inbuilt provision of "patent linkage".

"Section 2 of the Drugs & Cosmetics Act 1940 read with Section 48 of the Patents Act 1970, evidently provides the concept of patent linkage. By virtue of Section 2 of the 1940 Act, the Drug Controller needs to ensure that his decision on the grant of marketing approval should not derogate from any other law for the time being in force, Section 48 of the 1970 Act, in the present case," the petition said.