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HC rejects Bayer plea on Nexavar copycat

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NEW DELHI: The Delhi High Court (HC) on Tuesday dismissed an appeal by German drugmaker Bayer that sought to stop Cipla from obtaining a marketing approval from the country's drug regulator to launch a low-cost version of patented cancer drug Nexavar in India.

This ruling could pre-empt similar attempts by global pharma companies from getting a legal mandate to introduce patent linkage system in India. Under such a system, the local drug regulator cannot give marketing approval to copycat versions of drugs patented in India.

Amar Lulla, joint managing director of Cipla, said the company expects to launch the generic version of Nexavar within two months at less than half the price of Bayer's version. The medicine, used to treat renal cancer, cost Rs 2.85 lakh for a monthly dose of 120 tablets. However, if Cipla launches the drug, Bayer can move the court against the Mumbai-based company. If found guilty of patent infringement, Cipla may have to pay damages to the German patent holder.

The Delhi HC upheld an earlier ruling by the same court, which dismissed an appeal seeking to stop Indian generic companies to launch low-priced versions of patented drugs in India.

"The court does not find any ground having been made out to reverse the well reasoned judgment of learned single Judge in which we fully concur. The appeal is accordingly dismissed," a division bench of the Delhi HC comprising chief justice AP Shah and Justice Muralidhar said. It also rejected Bayer's contention that Cipla's generic drug was spurious.

The bench also ruled that drugs regulator Drug Controller General of India's (DCGI) powers and jurisdiction are circumscribed by the Drugs and Cosmetics Act 1940, and not by the Patents Act. "This is a historic judgement laying down the rules for access to generic drugs and impacts the entire drug industry. The ruling will also support India's stand at the World Trade Organisation against the ongoing seizures of drugs at ports in Europe," said Pratibha M Singh, who represented Cipla in the case.

The German firm hinted that it will appeal against the decision at the Supreme Court. "The company is disappointed and disagrees with the court's decision and will consider its legal options in this regard. We intend to defend the patent vigorously," a spokesman for Bayer India said.

Bayer had contested that since it holds the patent for Nexavar (chemical name sorafenib tosylate) which is valid for 20 years, DCGI cannot give marketing approval for Cipla's generic version. Indian patent law provides the patent holder exclusive marketing rights for 20 years with no competition from generic low-cost companies.

Cipla and patient groups, which are party to the case, argue that the DCGI's role is limited to ensuring the safety and efficacy of a drug. The innovator company can move the court to enforce its patent but cannot restrict DCGI from giving marketing approval. The DCGI also told the court it is not equipped to deal with validity of patents.

While rejecting its appeal last year, justice Ravindra Bhat of Delhi HC termed Bayer's contention as a speculative foray to tweak public policies.

Patient groups say restricting launch of a generic version delays the early introduction of low-cost drugs. "The court ruling will prevent delays in cancer patients getting access to less expensive, generic versions of patented drugs," said YK Sapru, chairperson of Cancer Patients Aid Association.