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SC dismisses Bayer plea against generic drug

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Mumbai: In a move which will bring cheer to patients and generic companies pursuing affordable treatments, the Supreme Court on Friday dismissed Bayer's appeal on the compulsory licence (CL) issued on kidney and cancer drug, Nexavar. The Supreme Court set aside the special leave petition filed by the MNC in October against the Bombay high court's decision upholding the CL on Nexavar, legal sources told **TOI**.

In 2012, while issuing the country's first CL, the government had allowed Hyderabad-based Natco Pharma to make and sell a patented cancer drug at a fraction of the price charged by Germany's Bayer.

The development, which concludes the legal proceedings on India's first-ever CL, should encourage more companies to come forward with affordable versions of their drugs, legal experts say. After the first CL got into a series of litigation, most domestic firms have shied away from pursuing the route and, hence, from offering affordable treatments.

Over the last two years, Bayer has unsuccessfully challenged the order before the Intellectual Property Appellate Board (IPAB), and later at the Bombay high court. "The fear in minds' of generic companies while pursuing plans to challenge MNCs is now over," Gopakumar Nair, a patent expert and intellectual property, said. He added more companies may now go ahead.

Bayer's appeal was on a compulsory licence issued on kidney and cancer drug, Nexavar. SC's move will cheer patients and generic cos pursuing affordable treatments

The grant of CL to Natco for Nexavar (Sorafenib) and the litigation around it is the first of its kind in India. Sorafenib is a crucial drug for patients with kidney and liver cancer. Bayer's drug Nexavar is priced at at Rs 2.84 lakh per patient per month, while Natco's corresponding version was substantially lower Rs 8,800.

When contacted, a Bayer spokesperson said: "We are disappointed with the decision of the Supreme Court. We are analyzing the order and will determine any future course of action afterwards."

Finding little merit in Bayer's submission, the bench comprising Justices Ranjan Gogoi and Rohinton Nariman on Friday asked its counsel Sudhir Chandra facts about the company's research and development spend.

On the challenge to royalty rate which was determined, Justice Nariman enquired why Bayer had not made available the research and development expenses on the drug, which would have been the best evidence to arrive at a reasonable rate of royalty. Chandra said it was impossible to provide an exact amount as 98% costs accrue from failed drugs.

The bench opined that in absence of any evidence supplied by Bayer, Natco's affidavit stating that all R&D costs have been recouped within the first year itself can be taken into account.

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