

Novartis awaits Supreme Court verdict on Glivec patent case

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New Delhi: India's apex judicial body will today pass its verdict on historic seven-year legal battle involving Novartis' chronic myeloid leukemia drug, Glivec (known in Europe as Gleevec). The Supreme Court of India will rule on a landmark patent case involving the Swiss drugmaker, which has appealed that its investments be protected against Indian companies that are seeking to produce cheaper generic versions of several of its lifesaving medicines. It is estimated that while Glivec, which is also used in treating some other cancers, costs a patient about \$2,600 a month, its generic version was available in India for around \$175 per month.

Also read:

- All you need to know about Glivec
- Thoughts of Mr Ranjit Shahani, vice chairman and MD, Novartis India, on how Novartis has been determined to win the Glivec case on compulsory licensing

The legal case goes back to 2006 when Novartis' application for a fresh patent in India for its cancer drug Gleevec (imatinib mesylate) was rejected by the Indian patent office. The patent authority cited a legal provision in India's 2005 patent law, which aimed at preventing companies from getting fresh patents for making only minor changes to existing medicines (a practice infamously known as evergreening).

The drugmaker argued that the drug was a newer, more easily absorbed version that qualified for a fresh patent. The company filed an appeal, but India's patent appeals office turned it down in 2009 on the grounds the company was unable to show significant increase in efficacy of the drug. Novartis then approached the Supreme Court of India in August 2009, which heard arguments seeking to challenge the interpretation and application of India's patent law in the case.

The verdict of the case will have far-reaching consequences for the future availability of the drugs in India. The Novartis

verdict is important because it will determine whether India gets to limit patents to genuine new drugs, or whether drug companies get to "evergreen" their patents until eternity, simply by re-patenting a slightly modified version of a known substance. Western pharmaceutical companies have warned that a rejection of Novartis' application would discourage investment in research and innovation, and would hinder drugmakers' efforts to refine and improve their products.

India has come under intense scrutiny from pharma giants who say that India's 2005 Patent Act fails to guarantee the rights of pharma investors. The fact that Indian courts allowed Natco (a local drug manufacturer) to produce a generic version of Bayer's patented cancer drug Nexavar, to make the drug available to the public at an affordable price, has also made big pharma companies extremely anxious. Well, with regards to the Glivec case, Novartis will just have to keep its fingers crossed for now.