

NOVARTIS SUES DR REDDY'S OVER PATENT INFRINGEMENT

fe Bureau
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SWISS drug major Novartis has sued Dr Reddy's Laboratories (DRL) in an American court stating the Hyderabad-headquartered company's plan to market and sell its own version of the blockbuster cancer drug Gleevec (imatinib mesylate) would infringe Novartis' patent.

Novartis said in a Delaware federal court complaint that DRL's abbreviated new drug application (ANDA) would violate the patent for Gleevec issued in 2005. Novartis Pharmaceutical Corporation (NPC) holds an approved new drug application (NDA) for Gleevec tablets containing 100

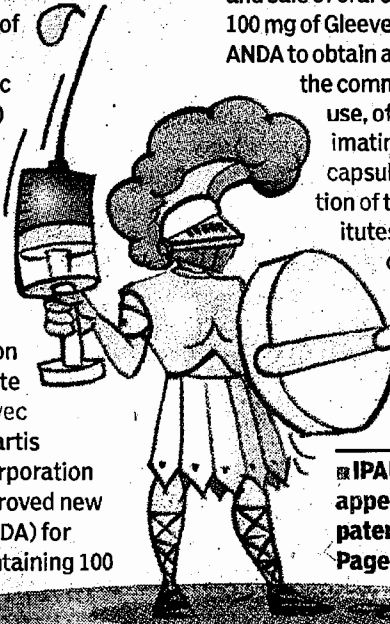
mg and 400 mg, which was approved by the US Food and Drug Administration on April 18, 2003.

On December 23, 2013, DRL notified Novartis that it had submitted an ANDA to the FDA seeking approval to engage in the commercial manufacture, use and sale of oral capsules containing 100 mg of Gleevec. "DRL's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell or sale of its imatinib mesylate ANDA capsules, prior to the expiration of the '051 Patent, constitutes infringement of one or more of the claims of that patent,"

Novartis said in a court order.

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Patent

Novartis...

"The '051 Patent is valid and enforceable and DRL has infringed one or more claims of the '051 Patent in violation of 35 USC; and DRL's making, using, selling, offering to sell or importing its imatinib mesylate ANDA capsules will infringe the '051 patent," Novartis said.

The patent and Novartis' new drug application, approved by the FDA in 2001, make it possible for Novartis to be the exclusive marketer and seller of Gleevec 50-mg and 100-mg capsules in the US.

However, Novartis has never been granted an original patent for Gleevec in India. In fact, in April 2013, the Supreme Court denied an appeal challenging the rejection of a patent for Gleevec, a life-saving medicine for certain forms of cancer, patented in nearly 40 countries including China, Russia, and Taiwan. Novartis filed a special leave petition with the Supreme Court in 2009 challenging the denial of the Gleevec beta crystal form patent on two grounds, based on of the Indian patent law.

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