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भारत सरकार

Financial Express, Delhi
Tuesday 15th April 2014, Page: 6
Width: 12.45 cms, Height: 22.83 cms, a4, Ref: pmin.2014-04-15.35.76

Novartis takes DRL to court in US over cancer drug patent

fe Bureau
Hyderabad, April 14

SWISS drug major Novartis AG has sued Dr Reddy's Laboratories in the United States District Court for the District of Delaware for infringing a patent covering its drug Gleevec.

The company said this was action for patent infringement arising under the patent laws of the US. The action relates to an Abbreviated New Drug Application (ANDA) filed by DRL with the United States Food and Drug Administration (USFDA) for approval to market generic versions of Novartis' Gleevec 100 mg Imatinib Mesylate capsules. Gleevec is used in the treatment of myeloid leukemia.

Earlier, Novartis had filed a similar suit against Dr Reddy's in February for infringing an US patent No. 6,894,051. This patent was legally issued on May 17, 2005 to inventors Jürg Zimmerman, et al. Later, the 2005 patent was assigned to Novartis AG and Novartis Pharmaceuticals Corporation is an exclusive licensee. However, on March 26, Novartis again filed an infringement of US patent No. RE43,932, a crystal modification of a N-phenyl-2-pyrimidineamine derivative, processes for its manufacture and its use, which was issued January 15, 2013.

Novartis holds approved NDA for Gleevec tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003. In its action, DRL stated it will not assert lack of personal service or lack of personal jurisdiction as a defense, a court order said.

DRL notified Novartis that it had submitted ANDA to the FDA of the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use and sale of oral capsules containing 100 mg of imatinib mesylate oral capsules, 100 mg base. In its notice letter, DRL notified Novartis that its ANDA contained a "paragraph IV certification" and that in DRL's opinion, the RE932 patent is invalid, unenforceable or will not be infringed by the manufacture, use, sale, or offer to sell of DRL's Imatinib Mesylate ANDA capsules.

The court order said that 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 RE932 patent, constitutes infringement of one or more of the claims of that patent.

As per available reports, sales of Gleevec totalled more than $1.8 billion in 2013, but the patent protecting the active principle will expire on January 4, 2015 while the patent protecting the beta crystal form of the active principal ingredient will expire on May 23, 2019.

Incidentally, 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.

Lupin recalls two lots of antibiotic drug in US

Drug major Lupin is voluntarily recalling 9,210 bottles of its antibiotic drug Suprax, used to treat bacterial infections, in the US market, according to the USFDA. As per the information available on the USFDA website, Lupin is recalling two lots of Suprax as the "product did not meet specification in total impurities at the nine-month stability station". The company is recalling 4,038 bottles of Suprax in the first lot and 5,172 bottles of the drug in the second lot in the US market, it added. *PTI*

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