PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

**Financial Express, Delhi**
**Tuesday 9th September 2014, Page: 6**
**Width: 17.74 cms, Height: 17.10 cms, a4, Ref: pmin.2014-09-09.34.34**

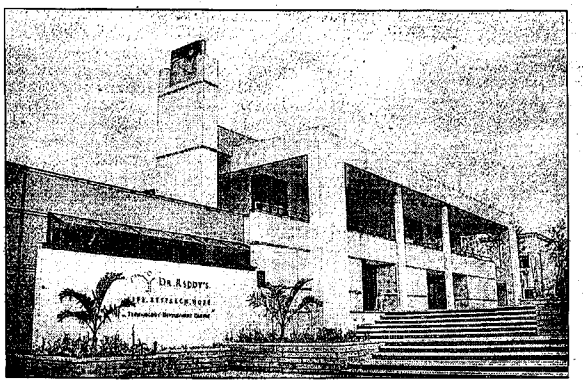
# Novartis drags DRL to US court for patent violation

**fe Bureau**
Hyderabad, Sept 8

SWITZERLAND-BASED Novartis AG and Novartis Pharmaceuticals Corporation (NPC) have sued Dr Reddy's Laboratories in a the United States' District Court for the District of Delaware for a patent infringement action on the drug Gleevec.

The action relates to an Abbreviated New Drug Application (ANDA) filed by DRL with the United States Food and Drug Administration (US FDA) for approval to market generic versions of Novartis' Gleevec, which is used as a targeted therapy for treating certain types of leukaemia. Gleevec is one of the best selling drugs of Novartis clocking sales revenues worth over $4 billion.

"Upon information and belief, this court also has personal jurisdiction over DRL Inc and DRL Ltd because they have been sued previously in this district, did not challenge this Court's assertion of personal jurisdiction over them, and availed themselves of this forum by seeking affirmative relief in this jurisdiction by answering complaints and asserting counterclaims for the purpose of litigating a patent infringement dispute in at least fifteen cases since 2004," the court said. This includes cases against Teijin Ltd, Genzyme Corporation, Pfizer Inc, Fresenius Kabi USA LLC, among others.



**The action relates to an Abbreviated New Drug Application filed by DRL with the US FDA for approval to market generic versions of Novartis' Gleevec, used as a targeted therapy for treating certain types of leukaemia**

NPC holds an approved New Drug Application (NDA) for Gleevec tablets for 100 mg and 400 mg Imatinib mesylate, which was approved by the FDA on April 18, 2003. Novartis AG has two patents 051 and RE932 and NPC is an exclusive licensee to this drug.

In its letter dated July 16, DRL notified Novartis that it had submitted ANDA to the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, offer to sell or sale of tablets containing 100 mg and 400 mg of Imatinib mesylate. DRL stated that its drug are bioequivalent to Novartis' 100 mg and 400 mg Imatinib mesylate Gleevec tablets. As said in the notice, DRL's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale prior to the expiration of the 051 patent and the RE932 patents. DRL notified Novartis that its ANDA contained a "paragraph IV certification" and termed the 051 and RE932 patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale.

"DRL had notice of the 051 patent and the RE932 patent at the time of its infringement. Novartis will be substantially and irreparably damaged and harmed if DRL's infringement is not enjoined. Novartis does not have an adequate remedy at law," the order said.

Patent