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Deccan Herald, Delhi Monday 5th May 2014, Page: 15 Width: 4.21 cms, Height: 17.35 cms, a4, Ref: pmin.2014-05-05.38.132

Amarin files patent case against DRL

HYDERABAD, PTI: Dublinbased Amarin Pharma has filed a patent infringement case against Dr Reddy's Laboratories alleging that the latter is attempting to come out with generic versions of its patented drug Vascepa.

Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (=500 mg/dL) hypertriglyceridemia. Amarin alleged that the Indian drug maker's Abbreviated New Drug Application (ANDA), seeking to market the generic version, would infringe the patent of Vascepa on 16 counts.

"A permanent injunction restraining and enjoining DRL and its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing any product that infringes the...Patents, including the product described in ANDA No. 205616," Amarin requested the court.

According to a pharma industry expert, the lawsuit was filed under the provisions of the Hatch-Waxman Act, resulting in a stay of final FDA approval of the ANDA by Dr. Reddy's until the expiry of the patents or final resolution of the matter before the court, whichever occurs sooner, subject to any other exclusivities.

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