



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 15-06-2010

News / Story reproduced with thanks:- [Thehindubusinessline](http://www.thehindubusinessline.com)

Dr Reddy's earnings may take a hit on US court order

Direct link to the News/Story:-

<http://www.thehindubusinessline.com/2010/06/15/stories/2010061551811200.htm>

Delay of 4 to 5 months likely in launch of generic version of drug.

Srividhya Sivakumar
BL Research Bureau

In an event that could morph into a temporary setback to drug maker Dr Reddy's Laboratories' growth plans, the US district court of New Jersey on Saturday granted the Sanofi-Aventis and Albany Molecular Research's motion for a preliminary injunction.

The motion, which was in relation to DRL's abbreviated new drug application to market the generic version of allergy drug Allegra D24, would now delay the launch of the generic by four to five months. Notably, DRL had received a sanction from the US Food and Drug Administration for the generic drug in March this year, following which Sanofi-Aventis and Albany Molecular Research had filed the motion.

Dr Reddy's has a FTF exclusivity position on the drug and was expected to launch generic Allegra by the first quarter of the fiscal. The imminent delay, therefore, would hold financial implications for the company and could affect analysts' estimates of its future earnings.

Estimated to have a market size of roughly over \$180 million, an at risk launch of the product on time would have yielded the company an earning of over Rs 7 a share in the current fiscal.

While DRL plans to appeal against the injunction, that it may not be able to launch the generic until such time there is a final legal resolution of the issue could trigger some mark down in its current-year earnings estimates.

The stock closed 3.6 per cent down for the day.

Though generic Allegra is vital to DRL's growth, with the company looking to drive its overall growth through a high-value (low-competition) opportunity every year for the next five years, the delay may only provide a temporary setback.

For one, DRL is the only FTF on Allegra D24 until now, and so it could well be in a position to extract maximum benefits if the company prevails in its appeal in the expected four-five months. Second, it has a strong product pipeline with over 73 pending abbreviated new drug applications, including 38 Para IVs and 12 FTFs.

Notably, launch of the generic version of GlaxoSmithKline's antithrombotic drug Arixtra (fondaparinux) is the other limited-competition opportunity that DRL may stand to benefit from in the near-term.

The timing of its launch is, however, subject to approval.