

Depomed files second Para IV infringement suit against Lupin on Glumetza patent

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The US-based Depomed Inc has filed one more Para IV patent infringement suit against the Mumbai-based Lupin Pharmaceuticals and its US subsidiary alleging infringement of four patents on its anti-diabetic pill Glumetza in the District Court of Maryland. The action comes as a protective measure to block the generic major from obtaining manufacturing and marketing rights for generic version of the once daily drug.

The complainant, in its plea to the Court, alleges that Lupin's Abbreviated New Drug Application (A NDA) seeking approval from the US Food and Drug Administration (FDA) for manufacturing and marketing the generic version of the extended release metformin hydrochloride (marketed by Depomed under the brand name Glumetza) will infringe four patents owned by the originator.

Depomed holds US Patent Nos. 6,723,340 for Optimal Polymer Mixtures for Gastric Retentive Tablets, 6,635,280 for Extending the Duration of Drug Release Within the Stomach During the Fed Mode, 6,488,962 for Tablet Shapes to Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms, and 6,340,475 for Extending the Duration of Drug Release within the stomach during the Fed Mode. The patent exclusivity on Patent No 6,340,475 is set to expire in 2016, Patent No 6,488,962 will expire in 2020, Patent No 6,635,280 will expire in 2016 and Patent No 6,723,340 will expire in 2021.

Depomed, in November 2009, has filed a suit in the Northern District Court of California with plea to stop Lupin from launching the generic version in US. The second law suit is filed as a protective measure to preserve its rights and interests, given the possible consequence if Defendants succeeded with such unjustified action, according to the complaint. "Plaintiff expects that personal jurisdiction will be maintained in the Northern District of California and that the action will proceed in that forum, in which case this second action would be unnecessary," said the lawsuit.

Lupin, in its certification notice, said that the said US Patents listed in the FDA Orange Book for Glumetza by Depomed are invalid and/or will not be infringed by Lupin's commercial manufacture, use or sale of the products which are described in Lupin's ANDA.

Depomed received FDA approval for Glumetza, a long-acting, timed release, once daily version of metformin used to normalise blood sugar in patients with type II diabetes, last year. The once-a-day drug is claimed to reduce the amount of sugar produced in the liver and the amount of sugar absorbed in the body. The product, with the advantages from the currently available metformin drugs, is predicted to have huge market potential, especially in the 19 million type II diabetic population in US.

The company has signed an agreement with the California-based Santarus to market the drug in US, and as per the deal in which Santarus paid Depomed an up-front payment, while Santarus in turn will receive almost 75 to 80 per cent of the gross margin from sales of the drug. The product, launched in the market in the end of 2008, has been prescribed to around 79,000 patients till September, this year, with a growth of 20 per cent in market in mid 2009, according to market reports.