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Purdue Pharma sues Lupin following Para IV filing on controlled release painkiller drug

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The US-based Purdue Pharma Products LP and its UK-based partner Napp Pharmaceutical Group Ltd has filed a para IV patent infringement suit against the Mumbai-based Lupin Ltd and its US subsidiary for the latter's move to manufacture and market the generic version of the narcotic painkiller drug Ultram ER.

In a complaint filed with the US District Court for the District of Delaware, Purdue alleged that Lupin has attempted to infringe US patent with patent nos. 6,254,887 (`887) for controlled release tramadol, issued on July 3, 2001, and 7,074,430 (`430) for controlled release tramadol tramadol [sic] formulation, issued on July 11, 2006. Lupin has filed abbreviated new drug application (ANDA) with the US Food and Drug Administration (FDA) seeking approval to manufacture and market tramadol hydrochloride controlled-release tablets, 100 mg, 200 mg, and 300 mg, according to the complaint.

The complaint against Lupin is filed at a time when a similar case on the same product is under consideration of the US Court of Appeals for the Federal Circuit, as the originator companies failed on a suit against Par Pharmaceuticals, last year. In August 14, 2009, the US District Court of Delaware has ruled in favor of US-based generic drugmaker Par Pharmaceuticals Inc in a patent-infringement case against Purdue Pharma related to tramadol.

The judgment was to permit Par to market its generic formulation of Ultram ER in the US, on condition that it receive final regulatory approval from the USFDA. Par, in November, 2009, announced that it has received approval from the drug regulator for 100 mg and 200 mg tablets of generic tradmol extended release. The patent '887, issued on July 3, 2001 is expected to expire on July 10, 2016 whereas the '430 will have validity till March 6, 2021, according to available information.

Considering the number of cases pending on the tradmol extended release patents and the current status of its litigation against Par Pharma, Purdue and other plaintiffs could either request to add the case against Lupin with the other pending cases under the Judicial Panel on Multidistrict Litigation (MDL Panel) conceived to centralize five previously-filed tradmol cases in the Delaware Court or has to wait until a final decision of the appeal in the Par case is issued by the Court of Appeals, explains experts.
Even though the Par case is pending, Purdue has filed the litigation to close any chances of entry of a generic equivalent to Ultram ER before its patent expiry. Under the Hatch-Waxman Act, the patent holder should file infringement suit against the generic company within 45 days after receipt of the latter's notice to trigger a 30-month stay during which the FDA cannot approve the generic company's ANDA.

The patent for tradmol controlled release is owned by two Canada-based firms, Biovail and Labopharm, which are in collaboration with Purdue to sell the drug in US. Biovail's revenue for Ultram ER was US$ 81.9 million in 2008 and US$ 37.2 million in the first half of 2009, according to reports. Purdue and Napp Pharma are the lawful owners of all rights to the two patents, including all right to sue and to recover for past infringement.