

## **Purdue Pharma sues Sun Pharma following Para IV patent filing on pain killer drug**

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The US based Purdue Pharma products LP and its partner Napp Pharmaceutical Group Ltd have filed a patent infringement petition against Sun Pharmaceuticals and its US arms following a para IV certification filed by the latter to manufacture and market generic version of the former's pain killer - Ryzolt - tramadol hydrochloride extended-release drug.

Purdue Pharma and Napp Pharmaceutical, in a complaint filed in the District Court of Delaware, alleged that the defendants' move to launch the generic version will infringe the US patents, under Patent Nos. 6,254,887 for controlled release tramadol, and 7,074,430 controlled release tramadol tramadol [sic] formulation. The complaint is filed against Sun Pharmaceutical Industries Ltd, Sun Pharmaceutical Industries Inc, Sun Pharma Global FZE and Caraco Pharmaceutical Laboratories Ltd. The patents mentioned are valid till May 2014, claims the company. Ryzolt, the tramadol hydrochloride extended-release pills, were launched in the US by Canada-based Labopharm along with marketing partner Purdue earlier this year.

Of late, Sun Pharma applied for an Abbreviated New Drug Application (ANDA) with the US FDA for approval to market 100, 200 and 300 mg generic versions of Ryzolt. In the end of September, Labopharm announced that the company has received notice from Sun Pharma Global FZE advising that Sun Pharma has submitted ANDA applications with the US FDA.

Labopharm explains that Sun's ANDA includes a paragraph IV certification to obtain approval to manufacture, use, or sell its generic versions before the expiration of Patent Nos. 5,591,452, 6,254,887 and 6,607,748. US Patent Nos. 5,591,452 and 6,254,887, which are owned by Purdue Pharma Products L.P., Labopharm's marketing and distribution partner in the US. Labopharm's one patent, with US Patent No. 6,607,748 on tramadol hydrochloride extended-release, is valid till 2020.

In another litigation on the same drug, In August, 2009, a court in Delaware ruled in favour of US-based generic drug maker Par Pharmaceuticals Inc in a patent-infringement case against Purdue Pharma related to tramadol. Purdue Pharma Products LP initiated a patent-infringement litigation against Par Pharmaceutical Companies, Inc. relating to Ultram ER, tramadol hydrochloride extended-release tablets. The patents-in-suit are owned by Purdue and were licensed to Ortho-McNeil, Inc, the marketer of Ultram ER.

The court judged in favour of Purdue and against Par on the issue of infringement and rejected Par's claim that the patents were unenforceable for inequitable conduct. Purdue

Pharma, in September, has appealed against the August decision that invalidated Purdue's patents for the painkiller and cleared the way for Par Pharmaceuticals to market a generic version of the once-daily drug.

During the 12-month period ending September 2008, the tramadol products accounted for more than US\$ 650 million in sales in the US even as the overall chronic painkiller market had sales of about US\$ 4 billion in the same period, according to the originator firm.