

Celgene, Novartis sue Sun Pharma on Para IV infringement of its extended release ADHD drug, Focalin

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The US-based Celgene Corporation and the Swiss pharma major Novartis AG have filed a Para IV patent infringement suit against the US subsidiary of the Mumbai-based Sun Pharmaceuticals Industries Ltd with the District Court of New Jersey for allegedly attempting to manufacture and sell the generic version of extended release Focalin, used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Celgene Corp, the patent holder for the drug and Novartis Pharma, which has the exclusive license for the product from the former, alleged that by filing Abbreviated New Drug Application (ANDA) with the US Food and Drug Administration (FDA), seeking approval to market generic dexmethylphenidate hydrochloride (the key ingredient in Focalin) tablets in 2.5 mg, 5 mg, and 10 mg dosage strengths prior to the expiration of Focalin XR's patents, Sun Pharma has attempted to infringe the patent rights owned by the complainants.

The dispute is on the patent rights approved to the complainants through US Patent Nos. 5,908,850 ('850) for method of treating Attention Deficit Disorders with D-Threo methylphenidate, 6,355,656 ('656) and 6,528,530 ('530), both for Phenidate drug formulations having diminished abuse potential. As per available reports, the first patent for Focalin XR is expected to expire in 2015.

The companies allege that Sun's ANDA contains information showing that its proposed generic dexmethylphenidate hydrochloride tablets are bioequivalent to the patented Focalin products, have the same active ingredient, the same route of administration and strength along with having the same, or substantially the same, dosage form and the same indication and usage mentioned in Focalin.

The complainants urged the Court to enjoin the FDA from issuing approvals for Sun's ANDA for the drug. The complaint adds that the Sun Pharma does not deny that its proposed generic product as described in the ANDA will, if allowed on the market, infringe the claims of the '850 and '530 patents and though Sun has presented a non-infringement argument relating to the '656 patent, it only addresses five of the patent's 40 claims.

In February, 2010, Celgene and Novartis has settled patent infringement lawsuits filed against Teva Pharmaceuticals USA on Focalin XR. Both the companies have filed four lawsuits against Teva between 2004 and 2007, alleging infringement of Focalin patent.

In the current year itself, the companies have settled similar lawsuits with KV Pharmaceutical Co and IntelliPharmaCeutics Corporation after filing patent infringement suits in the US District Court of New Jersey. However, the terms of settlement on all these lawsuit settlements are undisclosed. Focalin and the Focalin XR had US sales of approximately US\$ 350 million, in 2008.