

AstraZeneca sues Glenmark Generics in US for patent infringement of Crestor

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The Anglo-Swedish drug maker AstraZeneca Pharmaceuticals has filed a fresh Para IV patent infringement law suit against Glenmark Generics Inc, the North American division of Mumbai-based Glenmark Generics Ltd, in the US in June, 2010, for attempting to manufacture and sale of generic version of its blockbuster cholestrol-lowering drug, Crestor before expiry of patent validity.

The complaint filed with the US District Court for the District of Delaware explains that Glenmark Generics filed ANDA with the US Food and Drug Administration (FDA) to obtain approval for the commercial manufacture, use, importation, offer for sale and sale of rosuvastatin calcium (the active ingredient in Crestor) tablets in 5 mg, 10 mg, 20 mg and 40 mg dosage strengths, which are generic versions of Crestor tablets same strengths, in the US market. The company alleged that the move will violate its patent rights under US Patent No. RE37,314 ('314 patent) entitled Pyrimidine Derivatives, which is valid till April 2016.

According to the complaint, Glenmark has not asserted that its rosuvastatin calcium tablets are not covered by one or more claims of the '314 patent and that the said patent is unenforceable, but has filed a certification with the FDA alleging that the claims of the patent are invalid.

The validity of the '314 patent has been under question from 2007 and the decision on a litigation between AstraZeneca and seven generic competitors including the Indian drug firms Aurobindo Pharma and Sun Pharma are under consideration of the District Court of Delaware, according to reports. The full trial for these complaints were conducted by the Court between February and March, this year. Another litigation with Teva Pharmaceuticals is pending for decision since, in December 2009, the company failed in its attempt to attain summary judgement on allegations of inequitable conduct in the obtainment of the '314 patent.

Meanwhile, the Anglo-Swedish drug major has also initiated a second patent infringement actions involving Crestor in the District Court of Delaware by filing nine new complaints against companies including three Indian firms and their US subsidiaries - Aurobindo Pharma Ltd, Sun Pharmaceutical Industries Ltd and Glenmark Generics Ltd - along with Apotex Corporation, Cobalt Pharmaceuticals Inc, Par Pharmaceuticals, Sandoz Inc, Mylan Pharmaceuticals, and Teva Pharmaceuticals Inc, USA.

The new litigations are based on US Patents 6,858,618 ('618 patent) and 7,030,152 ('152

patent) which are respectively for uses of rosuvastatin calcium for primary prevention of cardiovascular disease and paediatric treatment of heterozygous familial hypercholesterolemia (HeFH). Among this, litigation against Glenmark Generics is the first patent infringement action by AstraZeneca for the product.

However, in March 2010, AstraZeneca, Shionogi (the company from which AstraZeneca acquired the patent under litigation), and the Aurobindo defendants submitted a stipulation and proposed order regarding Aurobindo Pharma Ltd's consent to jurisdiction and venue and the Plaintiffs' dismissal of action against Aurobindo Pharma USA Inc, which the Judge has signed the Order on 26 March 2010, says a latest report from AstraZeneca.

Crestor, claimed as one of the most effective lipid-lowering statins available in the market at present, is expected to be the most important sales driver for AstraZeneca in this decade. The company has reported US\$ 2.6 billion sales in US for the drug in 2009. The product is expected to reach sales of around US\$ 4 billion by 2015 in US. As per estimates reported by Thomson Pharma, the global sales of Crestor are forecast to rise to US\$ 6.5 billion in 2013 from \$4.5 billion in 2009.