

Astrazeneca files patent lawsuit against Torrent for blockbuster drug, Crestor

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The UK-based drug major AstraZeneca has filed a Para IV patent infringement law suit against the Gujarat-based Torrent Pharmaceuticals and its US subsidiary for its alleged move to manufacture and sell the generic version of its blockbuster cholesterol-lowering drug, Crestor, before expiry of its patent.

The complaint against Torrent Pharma filed with the District Court of Delaware, US, is based on US Patents 6,858,618 ('618 patent) and 7,030,152 ('152 patent) for uses of rosuvastatin calcium for paediatric treatment of heterozygous familial hypercholesterolemia (HeFH) and for primary prevention of cardiovascular disease. According to AstraZeneca reports, the exclusivity rights provided by the '618 patent, as extended by applicable regulatory exclusivities, will expire on June 17, 2022, while the exclusive rights provided by the '152 patent will expire on April 2, 2018.

The Torrent Pharma has filed an Abbreviated New Drug Application (ANDA) with the US Food and Drug Administration (FDA) and has amended later to manufacture and market the generic version of the drug in US.

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 product reached US\$ 2.1 billion sales in US in 2009 and is expected to hit sales of around US\$ 4 billion by 2015 in this market. As per estimates reported by Thomson Pharma, a global pharmaceutical information solution provider, the global sales of Crestor are forecast to rise to US\$ 6.5 billion in 2013 from US\$ 4.5 billion in 2009.

Interestingly, Astrazeneca announced its first branded generic supply deal with Torrent, in March, 2010, for supply of 18 generic drugs in nine countries in the initial stage as part of its effort to increase presence in the emerging markets.

Astrazeneca, which has been in patent litigation fighting against several generic firms worldwide for past three years, has initiated a second wave of patent infringement actions based on the '618 and '152 patents, of late. In April 2010, the company filed nine new complaints against generic firms for alleged infringement of the patents in suit, including three Indian firms and their 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 company and its patent partner Shionogi, the company from which AstraZeneca acquired the patent in suit, received a shot in the arm when the District Court of Delaware ordered the the substance patent protecting Crestor (RE37,314 – the ‘314 patent) is valid and enforceable. The position of Astrazeneca and Shionogi, improved as the judgement has precluded the US FDA from issuing final approvals for the Abbreviated New Drug Applications (ANDAs) for generic versions prior to the expiration of the ‘314 patent in 2016, according to patent experts.

In 2007, AstraZeneca and Shionogi filed patent infringement suits against eight manufacturers (various parent or subsidiary entities of Apotex, Aurobindo, Cobalt, Mylan, Par, Sandoz, Sun and Teva) who had challenged the ‘314 substance patent. The ‘314 patent, which expires in 2016, covers rosuvastatin calcium, the active ingredient in Crestor. These suits were consolidated by order of the Judicial Panel on Multidistrict Litigation and tried in the US District Court, District of Delaware.