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AstraZeneca sues Lupin to protect patent rights of anti-ulcer drug, Nexium

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AstraZeneca, the Anglo-Swedish drug major, has filed a patent infringement lawsuit at the US District Court of New Jersey against the Mumbai-based Lupin Ltd and its US subsidiary to curb the latter's move to manufacture and market the generic version of its blockbuster acid reflux drug, Nexium.

In its complaint filed in October, the company alleged that Lupin has attempted to infringe its five US patents, with Patent Nos. 5,714,504 for compositions, 5,877,192 for method for the treatment of Gastric Acid-Related Diseases and production of medication using (-) Enantiomer of Omeprazole, 6,875,872 for compounds, 6,369,085 and 7,411,070 for form of S-omeprazole.

Lupin has filed Abbreviated New Drug Application (ANDA) to the US Food and Drug Administration (FDA) to market the generic version of 20 and 40 mg esomeprazole magnesium delayed-release capsules, marketed by AstraZeneca under the brand name – Nexium.

Lupin's notice letter contains Paragraph IV certifications for patents listed in the FDA Orange Book with reference to Nexium and in October 2009, the company has commenced patent infringement litigation against Lupin, explains the AstraZeneca officials in its annual financial statements. Nexium, the 'purple pill' that included in the top five top-selling drugs in retail pharmacies in US, has patent protection till May, 2014, as the earliest patent of the product will expire at that time. Patents on Nexium expire from 2014 to 2019, informs AstraZeneca.

Nexium is one of the major drugs used for the treatment of gastroesophageal reflux disease (GERD), which affects 20 per cent of the population in the United States affects 5 per cent to 7 per cent of the worldwide population.

The drug, which has recorded a sales of US$ 5.22 billion in 2007, is expected to reach US$ 5.6 billion with more than 40 per cent of the anti-ulcer market share in 2009, according to studies. In the first nine months of the current financial year, the company has received a revenue of US$ 3681 million from the product in the global market and out of this, US$ 2,118 million was from US. However, the revenue from the product has shown a downward turn this year, compared to the last year results, informs experts.

The company, in April, 2008, has settled a patent litigation on Nexium with Ranbaxy Laboratories in the District Court of New Jersey, which has been considered as a land mark settlement for any Indian pharma firm. As per the deal, Ranbaxy will be allowed to start marketing generic version of Nexium on May 27, 2014 and can formulate and supply the key ingredient of the product even by May 2010 to AstraZeneca. Of late, Atul

Sobti, chief executive officer of Ranbaxy informed media that the company will commence supply of the ingredient to the US-drug major from December 2009 or January 2010.