

AstraZeneca sues Lupin for 'infringing on' drug patent

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New Delhi: Anglo-Swedish drug giant AstraZeneca has sued the Mumbai-based pharma company Lupin Ltd in the US District Court of New Jersey charging it of infringing the innovator's patent coverage by attempting to manufacture and market anti-ulcer drug Nexium (esomeprazole magnesium), one of the top five blockbuster drugs globally. The drug is indicated in case of gastroesophageal reflux disease. The innovator has objected to all the five filings that Lupin has made in its Abbreviated New Drug Application (ANDA) to the US Food and Drug Administration (US FDA) to market the generic version of Nexium with strength 20 and 40 mg.

The drug is projected to clock over \$5.5 billion globally this financial year. Of this, the company has already garnered \$3.6 billion in the first nine months of the current financial year with a revenue of \$2.1 billion from the US market only. The drug clocked sales worth \$5.22 billion in 2007, and commands over more than 40% of market share in the anti-ulcer category in 2009. Nexium is one of the most important drugs used for the treatment of gastroesophageal reflux disease (GERD), which affects 20% of the population in the United States around 6% of the global population making the market size of the drug very lucrative for the generic companies. A Lupin spokesperson Fe spoke to refused to comment on the litigation aspects of the specific case but said that litigations related to patent busting form necessary part of any generic player's portfolio.

AstraZeneca had settled a patent litigation on Nexium with the Daiichi Sankyo owned second largest domestic drug maker Ranbaxy Laboratories last year in April. According to the settlement, Ranbaxy could market the generic version of Nexium starting middle of 2014. However, the Gurgaon-based pharma firm would start supplying the key raw material of the drug to AstraZeneca starting next year. AstraZeneca has patent protection for Nexium till May, 2014, the year when first of the product's patents is set to expire. Other patents related to Nexium would expire between 2014 to 2019.

Lupin has a steady record of patent settlements and has managed to settle four such cases in the last two years. These include patent settlements with Wyeth for antidepressant Effexor XR and Hatch-Waxman litigation relating to Desloratadine, a generic version of Schering-Plough's Clarinex tablets in the recent past.

Source-Financial Express

<http://www.financialexpress.com/news/AstraZeneca-sues-Lupin-for-infringing-on-drug-patent/539873/>