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AstraZeneca sues Sun Pharma in us court

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Sun had challenged the patent on Nexium IV in the US market.

Multinational drug maker AstraZeneca has sued Sun Pharmaceuticals Industries for challenging the patent on its ulcer drug brand, Nexium IV, in the US market.

Patent experts said the UK-based drugmaker filed two lawsuits against Sun Pharma and its US subsidiary on February 26 in a federal court in Trenton, New Jersey, and on March 1 in Detroit, US.

Nexium (Esomeprazole Magnesium) is the largest selling drug for AstraZeneca, with global sales of close to \$5 billion (Rs 22,907 crore). The drug had sales of \$2.84 billion (Rs 13,011 crore) in the US market in 2009, said sources.

"As a matter of policy, we do not comment on our patent litigation strategy," said a Sun Pharma spokesperson.

Nexium was approved by the US Food and Drug Administration (FDA) in 2005. Its patents are valid in the US till 2014.

Earlier, the company had sued Indian drug makers like Ranbaxy Laboratories, Lupin Ltd and Dr Reddy's Laboratories for infringing the patents.

Ranbaxy had entered into an out of court settlement with AstraZeneca following its takeover by Daiichi Sankyo, and had agreed not to launch the product in the US before 2014. Israel-based generic drugmaker Teva Pharmaceutical also had entered into a similar out of court settlement.

Earlier, AstraZeneca had sued several generic drug makers, including many Indian generic companies, for challenging patents of other versions of Nexium.

Such litigation is common in the US, the largest drug market in the world, with sales of \$280 billion (Rs 12.8 lakh crore).

According to the US rules for generic drug sales, the innovator drug company has to sue the generic challenger within 45 days to trigger an automatic ban on approval for generic substitutes for the next 30 months or till the court decides the litigation. Such marketing applications (abbreviated new drug applications or ANDAs) filed with the FDA challenging the patents are certified as Para IV applications, by US rules.

Meanwhile, in an another patent litigation, Japanese drug major Takeda Pharmaceuticals sued another Indian company, Aurobindo Pharma, for infringing the patent on Actosplus Met, an oral drug combination to treat type II diabetes. Takeda and its US arm recently filed the case with the US District Court for the Southern District of New York, said sources.