

THE END OF LIPITOR

P A francis

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World's top pharmaceutical company, Pfizer Inc., stands to lose patent rights for its largest selling drug Lipitor in the US on November 30. That marks the end of a golden era for the US multinational. The global giant had already lost its basic product patent protection for Lipitor in Canada, Spain, Brazil, and Mexico last year. The company tried its level best to extend the basic patent rights for Lipitor for some time although these extensions were of short terms. Expiry of patent protection for the drug in November brings an end to these extensions of Pfizer's patent, originally set to end last year and then expected to expire in June this year. Pfizer, however, has the patent rights to Lipitor's crystalline and amorphous patents, which are expected to expire in 2016 and 2017. In July this year, Pfizer won a six-month extension from the EU for a chewable paediatric version of Lipitor for children aged 10 and older. EU patent protection for the new chewable Lipitor expires in May 2012. Pfizer's sales from Lipitor were on the decline for some time now. The company had the peak sales of \$12.9 billion from the cholesterol drug in 2006 which accounted for almost 27 per cent of the company's total sales that year. The sale has been on the decline since then and it fell to \$11.4 billion in 2009 and to \$10.7 billion last year. From now on, the drop in Lipitor sales for the company is going to be much steeper.

And on December 1, Ranbaxy Labs plans to start selling a generic version of Lipitor in the US market for the first time. The Indian company had to settle years of litigation against Pfizer way back in 2008 to win six months of exclusive marketing rights to sell the drug. By next year, an authorized generic version of Lipitor will also be in the market from Watson Pharmaceuticals. Watson has an exclusive supply agreement with Pfizer, which has agreed to manufacture and sell generic tablets to Watson for five years. Like Ranbaxy, a number of other drug companies have been trying to enter the market with generic products of Lipitor and fighting in courts. Pfizer had now resolved lawsuits with generic drug companies such as Mylan, Teva Pharmaceutical, and most recently, Dr. Reddy's Labs. In the years since settling with Ranbaxy, Pfizer has also resolved lawsuits with these generic companies looking to get into the market. Teva has settled with Pfizer in the US but two companies fought for some time about the selling of generic Lipitor in the UK. On October 7, the companies agreed that Teva would keep generic Lipitor off the UK market until Pfizer's patent in that country expired in May 2012. Whatever may be the outcome of the settlements with the generic companies, sales and profitability of Pfizer are going to take a big hit from next year. And there is no silver lining in the horizon for the world's largest pharmaceutical company despite its huge annual expenditure on new drug research.