



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 18-05-2010

News / Story reproduced with thanks:- **Financial Express**

### Lupin loses battle to launch antibiotic in US

Soma Das

Posted: Tuesday, May 18, 2010 at 2317 hrs IST

Updated: Tuesday, May 18, 2010 at 2317 hrs IST

Direct link to the News/Story:-

<http://www.financialexpress.com/news/Lupin-loses-battle-to-launch-antibiotic-in-US/620115/>

New Delhi: In a setback in the US market, India's fifth largest pharma company Lupin has lost the battle on antibiotic Levofloxacin against US-based Ortho Mcneil Pharma and Japanese drugmaker Daiichi Sankyo with the US Court of Appeals for Federal Circuit upholding the patent term extension granted to the innovator company on the drug.

The federal circuit upheld a judgement issued by a lower court (the District Court of New Jersey) which ruled in May 2009 that the patent term extension granted to Ortho McNeil-Janssen Pharmaceutical Inc by the US Patent and Trademark Office with respect to Levaquin (Levofloxacin, Patent number '407' ) is valid. This would prevent Lupin from launching and marketing the drug in the US market. This drug, an anti-microbial, has annual sales of \$1.4 billion in US alone.

"The district court enjoined Lupin from infringement during the extended term of the patent. We affirm the district court's judgment," said the Federal Circuit.

Interestingly, Lupin has already launched this drug in the Japan market in the third quarter of 2009, according to information available on Lupin's website.

According to a Religare Capital Market analyst FE spoke to, the news is not good for Lupin and the chances of a favourable judgement at the higher judiciary in the US appear slim after two courts at different level of hierarchy in US have upheld the concerned patent extension of Ortho Mcneil.

The company spokesperson refused to throw light on the matter, saying it is against the policy of the company to comment on patent litigation cases. However, industry watchers said that Lupin has the option to challenge this order and appeal against the judgement in higher US courts, something that the Indian drug firm is most likely to exercise if it has not filed an appeal already. In another ruling against generic drug manufacturer Mylan, the same patent had been upheld by a district court of US.

Originally, the concerned patent of Ortho Mcneil was about to expire in October 2008. In April 1998, the US FDA determined the regulatory review period for Levaquin, and in March 2000, the US patent office granted a patent term extension of 810 days with respect to the concerned patent, extending its term from October 1, 2008 to December 20, 2010.

Levofloxacin is a synthetic antibiotic of the fluoroquinolone drug class and is used to treat severe or life-threatening bacterial infections or bacterial infections that have failed to respond to other antibiotic classes.