

Tamiflu patent case: Favourable verdict for Natco in US

fe Bureau

Hyderabad, April 25: The United States Court of Appeals for the Federal Circuit has ruled in favour of Natco Pharma and its marketing and sales partner Alvogen against charges that the former infringed California-based Gilead Sciences' patent for its influenza drug Tamiflu.

Natco Pharma had filed an abbreviated new drug application (ANDA) with the US Food and Drug Administration (USFDA) for its generic version of Tamiflu, or oseltamivir phosphate, capsules. Gilead currently holds the patent for Tamiflu, which is valid till 2017, and the company had asked the court that the generic version of Tamiflu be blocked until its patent expires.

The case will now be taken up in the District Court of New Jersey, where Natco and Alvogen will continue to challenge the validity of the patent, Natco said in a state-

ment to stock exchanges. Tamiflu recorded sales of about \$495 million for the 12 months ended September 2013 in the US, according to IMS Health.

The court order said that Gilead Sciences owns US patent Nos. 5,763,483 and 5,952,375, which are directed to antiviral compounds and methods for their use. While the patents list the same inventors and the written descriptions disclose similar content, they do not claim priority to a common patent application and have different expiration dates.

Gilead sued Natco Pharma for infringement of the 483 patent after Natco filed a request with the Food and Drug Administration seeking approval to market a generic version of one of Gilead's drugs allegedly covered by the 483 patent. In response, Natco asserted that the 483 patent was invalid for obviousness type double patenting over Gilead's 375 patent.

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