

ViiV, Vertex Sue Over Mylan's Bid To Market Generic Lexiva

By **Ben James**

Law360, New York (August 24, 2012, 1:13 PM ET) -- ViiV Healthcare Co. and Vertex Pharmaceuticals Inc. slapped Mylan Inc. with a patent infringement lawsuit in Delaware on Wednesday over Mylan's bid for U.S. regulatory approval to make and sell a generic version of the anti-HIV drug Lexiva.

North Carolina-based ViiV and Massachusetts-based Vertex said that Mylan infringed a patent owned by Vertex, and exclusively licensed to ViiV, when it submitted an abbreviated new drug application to the U.S. Food and Drug Administration seeking a green light for the manufacture, use and sale of generic fosamprenavir calcium tablets.

"If Mylan's infringement ... is not enjoined, ViiV and Vertex will suffer substantial and irreparable harm for which there is no adequate remedy at law," the complaint said.

Mylan alerted Vertex and ViiV Healthcare UK Limited that it had lodged ANDA No. 204060, which sought approval to market 700 milligram fosamprenavir calcium tablets, with the FDA in a July 9 letter, Wednesday's lawsuit said, adding that the plaintiffs believed Mylan intends to start making and selling its proposed generic as soon as it gets the FDA's permission.

Not only was filing that ANDA before the patent-in-suit's expiration an act of infringement, but Mylan will further infringe by making, selling and/or importing the proposed generic if it gets the chance, the plaintiffs said.

Mylan knew about the patent before lodging its ANDA, they added.

The plaintiffs want relief including a judgment saying that Mylan's ANDA submission infringed Vertex's patent, an order barring the FDA from approving the ANDA until the expiration of that patent and damages in the event that Mylan actually makes, sells or imports the proposed generic before the patent's expiration.

At issue is patent 6,436,989 — titled "Prodrugs of aspartyl protease inhibitors" — issued in 2002.

Lexiva is a protease inhibitor used to treat HIV infection.

ViiV Healthcare Co. is the U.S. arm of U.K.-based ViiV Healthcare, a joint venture of GlaxoSmithKline and Pfizer Inc., and focuses on HIV medications. GSK owns an 85 percent stake in ViiV, while Pfizer holds a 15 percent stake.

ViiV Healthcare UK and its U.S. unit also have litigation pending in the Delaware court against Teva Pharmaceutical Industries Ltd. over the HIV drug Epzicom, and Lupin Ltd. over the drug Trizivir. Both of those cases were filed in 2011.

A Mylan representative did not immediately respond to a call seeking comment on the suit Friday.

A U.S.-based ViiV representative could also not be immediately reached.

The plaintiffs are represented by Lisa Ferri, Brian Nolan and Richard McCormick of Mayer Brown LLP, and Brian Farnan and Michael Farnan of Farnan LLP.

The case is ViiV Healthcare Co. et al v. Mylan Inc. et al., case number 1:12-cv-01065, in the U.S. District Court for the District of Delaware.

--Editing by Jeremy Barker.

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