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Pfizer, Actavis End Patent Fight Over Generic Lipitor

By Zach Winnick

Law360, Los Angeles (October 12, 2011, 3:13 PM ET) -- A Delaware federal judge on Tuesday dismissed pharmaceutical giant <u>Pfizer Inc.</u>'s patent infringement suit against Iceland-based Actavis Group HF over a generic version of anti-cholesterol drug Lipitor, after the parties announced they had reached a settlement.

Tuesday's dismissal ends one of a series of patent suits brought by Pfizer over abbreviated new drug applications for generic Lipitor. Terms of the settlement were not immediately available.

New York-based Pfizer lodged a complaint alleging patent infringement in August 2010, after Actavis filed an ANDA seeking federal approval to market atorvastatin calcium tablets, sold under the brand name Lipitor, before a patent covering the drug expires in January 2017.

The asserted patent, U.S. Patent Number 5,969,156, covers crystalline forms of atorvastatin and hydrates, which are useful hypolipidemic and hypocholesterolemic agents, according to patent documents. It was issued in 1999 and assigned to Warner-Lambert Co., which Pfizer acquired in 2000.

The '156 patent was later reviewed by the U.S. Patent and Trademark Office, which issued a reexamination certificate in September 2006.

Pfizer says it holds an approved new drug application covering atorvastatin calcium formulations, including 10-milligram, 20-milligram, 40-milligram and 80-milligram dosage strengths.

Actavis notified Pfizer in June that it was seeking to make generic Lipitor in 10-milligram, 20-milligram and 40-milligram dosage strengths, and asserted that Pfizer's patent was not infringed by the proposed ANDA, according to the complaint.

Actavis filed an answer and counterclaims in September 2010, seeking a declaration that it had not infringed the '156 patent and that the patent is invalid.

Actavis sought similar declarations with respect to two additional Pfizer patents, U.S. Patent Numbers 5,686,104 and 6,126,971, which cover stable formulations of an oral pharmaceutical for treating hypercholestereolemia or hyperlipidemia.

Pfizer and Actavis filed a joint motion to dismiss the litigation on Monday, saying they had reached an Oct. 7 agreement resolving the claims between the parties and asking the court to dismiss the action without prejudice.

U.S. District Judge Leonard P. Stark signed off on Tuesday, dismissing the case

In an apparent drafting error, the joint motion seeking dismissal filed Monday refers to an agreement between Pfizer and Dr. Reddy's Laboratories Ltd.

Pfizer, which has sued numerous generics makers over Lipitor, settled a similar lawsuit against Dr. Reddy's in August. Dr. Reddy's is not a party to the present suit.

In 2009, Pfizer fired off similar infringement suits against Mylan Pharmaceuticals Inc., Kremer Urbans LLC and Apotex Inc.

A representative for Actavis declined to comment Wednesday. Representatives for Pfizer did not immediately respond to requests for comment.

The patents-in-suit are U.S. Patent Numbers 5,969,156; 5,686,104 and 6,126,971.

The plaintiffs are represented by Rudolf E. Hutz, Jeffrey B. Bove, Mary W. Bourke and Daniel C. Mulveny of Connolly Bove Lodge & Hutz LLP.

The defendants are represented by Stamatios Stamoulis and Richard C. Weinblatt of Stamoulis & Weinblatt LLC, and Steven M. Coyle, Anne Maxwell and Andrew Ryan of <u>Cantor Colburn LLP</u>.

The case is Pfizer Inc. et al. v. Actavis Group HF et al., case number 1:10-cv-00675, in the U.S. District Court for the District of Delaware.

--Additional reporting by Erin Coe and Megan Leonhardt. Editing by John Quinn.

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