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PTAB Mostly Rejects Lupin's AIA Review Of HIV Drug Patent

By **Vin Gurrieri**

Law360, New York (July 14, 2015, 6:25 PM ET) -- The Patent Trial and Appeal Board has partially nixed Lupin Limited's bid for an America Invents Act review of certain claims of a patent covering the anti-HIV drug Lexiva, saying that the patent owner's evidence of secondary considerations for certain key claims overcame Lupin's evidence of obviousness.

While the board accepted Lupin's request to institute an inter partes review on certain claims of Vertex Pharmaceuticals Inc.'s U.S. Patent Number 6,436,989 — which covers Lexiva — it refused to review claims that focus on fosamprenavir, the active ingredient in the drug, and its use to treat HIV infection, according to the June 9 decision.

The panel found Lupin "has not demonstrated a reasonable likelihood of prevailing" on those particular claims.

While Lupin had sought to review claims 1-12 of the '989 patent, the board instituted an IPR only for claims 1 of the '989 patent, which encompass both fosamprenavir and other compounds, as well as dependent claims 4-9.

The ’989 patent — titled “Prodrugs of aspartyl protease inhibitors” — was issued in 2002 and is directed to prodrugs of HIV aspartyl protease inhibitors, pharmaceutical compositions of those inhibitors, and methods of treating HIV infections in mammals.

Prodrugs generally are inactive compounds that convert to an active form in the body.

As part of its ruling, the PTAB said it was swayed by objective evidence of nonobviousness presented by Vertex to overcome Lupin's obviousness contentions for the surviving claims.

“The evidence shows, for example, that fosamprenavir … has improved pharmacokinetics, reduced gastrointestinal side effects, and different resistance profile as compared to its parent drug, amprenavir,” the board said.

Based on the evidence, the board found that “the development of HIV protease inhibitors prodrugs was not at all predictable, but produced compounds with varying degree of effectiveness.”

The board noted, however, that Vertex's evidence of secondary considerations is specific to fosamprenavir. Since claim 1 of the patent encompasses more compounds than just fosamprenavir,

there is a reasonable likelihood that Lupin will prevail on its assertion that the claim is obvious over two prior art references, it said.

“Accordingly, we credit patent owner’s evidence of nonobviousness only for the subject matter of claims 2 and 3,” the board said. “Patent Owner’s evidence of nonobviousness is not commensurate to the scope of claim 1.”

The panel also instituted a review of claims 4-8 due to their dependency from claim 1, and claim 9 because it does not require treatment of HIV infection, as claims 10-12 do.

No underlying litigation currently exists between Lupin and Vertex involving the '989 patent, according to court documents. Vertex had previously asserted the patent in a suit **it filed in 2012** against Mylan Inc., which had sought U.S. regulatory approval to make and sell a generic version of Lexiva. The case settled shortly after a trial began.

While the HIV treatment covered by the '989 patent was developed by Vertex, it is marketed by ViiV Healthcare Co.

Counsel for Vertex declined comment Tuesday, and attorneys for Lupin were not immediately available.

Administrative Patent Judges Lora M. Green, Sheridan K. Snedden and Robert A. Pollock sat on the panel for the PTAB.

The patent-in-suit is U.S. Patent Number 6,436,989.

Lupin was represented by Stephen R. Auten and Richard T. Ruzich of Taft Stettinius & Hollister LLP.

Vertex was represented by Lisa Ferri, Brian Nolan, Neil DuChez and Jonathan Kim of Mayer Brown LLP.

The case is Lupin Limited v. Vertex Pharmaceuticals Inc., case number IPR2015-00405, before the Patent Trial and Appeal Board.

--Editing by Emily Kokoll.
