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Bayer Battles Generic Yasmin Hopeful In Fed. Circ.

By **Christopher Norton**

Law360, Washington (December 07, 2011, 4:54 PM ET) -- Bayer Healthcare Pharmaceuticals Inc. sought to persuade the Federal Circuit on Wednesday that it has a valid case to block generics makers from introducing a version of its oral contraceptive Yasmin, saying its patent covers all uses of the drug.

In September 2010, a New York federal judge ruled in favor of Watson Laboratories Inc. and Sandoz Inc. in Bayer's Hatch-Waxman Act suit, saying the disputed claim of U.S. Patent 5,569,652 does not cover a use approved by the U.S. Food and Drug Administration.

Bayer argued in the lower court that a generic version of Yasmin would infringe the '652 patent, which Bayer said covered the principal use of the drug — pregnancy prevention — plus two additional uses, to reduce the symptoms of severe premenstrual symptoms and to treat acne.

But Watson and Sandoz argued, and the lower court agreed, that they were only seeking approval for the FDA-approved use of Yasmin — that is, contraception — and not the uses claimed in the '652 patent.

The district court's decision “sets a dangerous precedent” that runs counter to Federal Circuit holdings, FDA practice and the FDA's regulations in implementing the Hatch-Waxman Act, Bayer attorney Peter B. Bensinger Jr. told a three-judge appeals panel during oral arguments.

The court treated the FDA approval letter for the drug as relating solely to the indications noted, and that was in error, the lawyer said. It is significant that the letter says approval is based on the accompanying labeling materials for the drug, which include references to the other effects of the drug besides contraception, according to Bensinger.

The district court “avoided this factual evidence, as well as the FDA's interpretation of its own regulations,” Bensinger said.

The central question is whether FDA approval for use of the drug included all three uses at issue, or simply the contraceptive use, U.S. Circuit Judge S. Jay Plager said.

The district court did not give appropriate deference under the U.S. Supreme Court's Chevron USA Inc. v. Natural Resources Defense Council decision to the FDA's regulations implementing the Hatch-Waxman Act, Bensinger said. Those regulations don't limit drug approval to the indications section only, but refer to looking at all labeling material to find approved uses, he argued.

U.S. Circuit Judge William C. Bryson asked why it should be a problem when the method that the generics makers describe does not include the benefits of the other two noncontraceptive uses, and why there should be infringement if it is acceptable to prescribe the drug for contraceptive purposes but not the other two effects.

Judge Bryson questioned whether Bensinger was suggesting that any time other effects of a drug are described in its labeling material, that constitutes FDA approval for using the drug for those effects. FDA approval is not considered granted for potential drug side effects like heart attacks or strokes, he noted.

The FDA approved the drug in this case for the other two uses in addition to contraception, Bensinger argued in response. The other effects here should be considered approved because they can be beneficial, he said.

“Do you see the 600 pound gorilla in that corner? That's the FDA,” Circuit Judge S. Jay Plager told Bensinger, asking why it was not a party to the current appeal or to the underlying action, when the central question seemed to be what it did or did not approve, which no one seemed to have asked the agency.

The FDA's implementing regulations are sufficient to stand on their own, Bensinger replied.

Watson attorney Mark T. Jansen, arguing for the generics makers, said the FDA could not be considered to have granted approval for the two noncontraceptive effects. He also said, like Bensinger, that it was not necessary to hear from the FDA or have it present in the current case.

“You're attempting to squeeze through a very small hole in the Hatch-Waxman statute,” Judge Plager told Jansen. He asked Jansen whether it was valid for Bayer to sue under Hatch-Waxman rather than file a traditional infringement action.

The drug was not patented for contraception, and Bayer had to get a patent for the other uses, Jansen said.

The FDA's approval letter is the critical evidence of what the agency actually approved, and the other effects were noted for informational purposes only, not for approval for therapeutic use, he said.

Bayer can't win unless it can prove that the FDA approved all three uses and that the label instructed doctors to use the drug for all three, Jansen said.

Judges Pauline Newman, William C. Bryson and S. Jay Plager sat on the Federal Circuit panel.

Bayer is represented by Peter B. Bensinger Jr., Adam K. Mortara, Paul J. Skiermont, Sundeep K. Addy and Matthew R. Ford of Bartlit Beck Herman Palenchar & Scott LLP as well as by Lawrence D. Rosenberg of Jones Day.

Watson is represented by Mark T. Jansen, Gia L. Cincone, Cedric C.Y. Tan and Kristin M. Cooklin of Kilpatrick Townsend & Stockton LLP.

Sandoz is represented by Joseph A. Hynds and Steven M. Lieberman of Rothwell Figg Ernst & Manbeck PC.

The case is Bayer Schering Pharma AG v. Lupin Ltd., case number 2011-1143, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Eydie Cubarrubia.

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