

Fed. Circ. Clips Exela Appeal In Ofirmev Infringement Row

By **Vin Gurrieri**

Law360, New York (March 23, 2015, 5:28 PM ET) -- The Federal Circuit on Monday upheld a Delaware federal judge's ruling that Exela Pharma Sciences LLC and two related entities flouted two Cadence Pharmaceuticals Inc. patents covering the injectable pain reliever Ofirmev by planning a generic version of the drug.

In a precedential opinion, a three-judge panel affirmed a November 2013 ruling by U.S. District Judge Leonard P. Stark that Cadence's U.S. Patent Numbers 6,028,222 and 6,992,218 were infringed and that the '218 patent was not shown by Exela to be invalid.

The panel said that it has "affirm[ed] the district court's finding of infringement" and that Exela "has not proven that the asserted claims of the '218 patent are obvious."

Cadence had filed suit in August 2011 alleging Exela had filed Abbreviated New Drug Applications seeking to make a generic version of Ofirmev, plans that also constituted infringement of the '222 and '218 patents which protect the branded pain reliever.

The patents-in-suit are held by a French company called SCR Pharmatop — a co-plaintiff in Cadence's suit — which exclusively licensed them to Bristol-Myers Squibb Co. Bristol-Myers, in turn, granted an exclusive sub-license of the '222 and '218 patents to Cadence, according to court documents.

Ofirmev, approved by the U.S. Food and Drug Administration in 2010 for treatment of mild to moderate pain and fever, or for treatment of moderate to severe pain in conjunction with opioid painkillers, was the first injectable acetaminophen available in the U.S.

In November 2013, Judge Stark concluded after a seven-day bench trial that Cadence proved by a preponderance of the evidence that both patents had been infringed and that Exela could not prove by clear and convincing evidence that both patents were invalid.

In March 2014, Exela filed an opening brief to the Federal Circuit challenging the lower court's construction of certain claim terms pertaining to the two patents as well as the lower court's findings pertaining to infringement and validity. Exela, however, did not appeal the lower court's decision that the '222 patent was valid, according to court documents.

In its ruling Monday, the panel said Exela's appeal regarding the '222 patent turns on claim construction and that Judge Stark properly construed a disputed claim term. As a result, since the panel rejected

Exela's proposed claim construction on which it based its appeal, the panel affirmed Judge's Stark's finding that the patent was infringed.

In regards to the '218 patent, the panel determined that there was no clear error in the district court's finding of infringement under the doctrine of equivalents, and also affirmed the lower court's finding that the patent was infringed based on its construction of the so-called "vacuum stoppering step" claim term.

The panel also rejected Exela's argument that it was able to show by clear and convincing evidence that the asserted claims of the '218 patent were invalid as obvious, saying the lower court correctly found that the '218 patent was not obvious in light of the '222 patent and other prior art.

In addition to Exela Pharma Sciences, the appeal also named as appellants Exela PharmSci Inc. and parent company Exela Holdings Inc.

Mallinckrodt PLC, which acquired Cadence in February 2014, said in a statement that it "is pleased with the court's decision and will continue to vigorously enforce the company's intellectual property rights relating to Ofirmev."

Attorneys for Exela were not immediately available for comment Monday.

On the panel were Circuit Judges Jimmie V. Reyna, Evan J. Wallach and Richard Linn.

The patents-in-issue are U.S. Patent Numbers 6,028,222 and 6,992,218.

Cadence is represented by Kenneth G. Schuler, Marc N. Zubick, Emily C. Melvin, Stephen P. Swinton, Darryl H. Steensma, Richard P. Bress, Gabriel K. Bell and Parker M. Tresemer of Latham & Watkins LLP. SCR Pharamtop represented by Charles A. Weiss of Holland & Knight LLP.

Exela is represented by Jeffrey S. Ward and Wendy M. Ward of Merchant & Gould PC as well as C. Edward Polk and Satish Chintapalli of Polk & Chintapalli PLLC.

The case is Cadence Pharmaceuticals Inc. et al. v. Exela Pharma Sciences LLC et al., case number 2014-1184, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Daniel Siegel and Ryan Davis. Editing by Kelly Duncan.
