

Fed. Circ. Clears Perrigo's Generic Pepcid In Patent Case

By Ryan Davis

Law360 (February 28, 2019, 8:13 PM EST) -- The Federal Circuit ruled Thursday that Perrigo Co.'s generic version of the antacid Pepcid Complete does not infringe a patent owned by Boston's Brigham and Women's Hospital, ruling the evidence doesn't show the generic provides the "immediate" heartburn relief the patent requires.

The appeals court affirmed a decision by U.S. District Judge Rya W. Zobel of Massachusetts, who granted judgment as a matter of law to Perrigo and overturned a jury's verdict that the company infringed and should pay \$10.2 million.

The judge found that "immediate" heartburn relief means that it starts within five to 10 minutes of ingesting the drug. The case hinged on whether clinical evidence showed that Pepcid Complete itself provides relief that quickly, since Perrigo's version has the same ingredients and dosages. The Federal Circuit found that it did not, so Perrigo's generic cannot infringe.

"We agree with the district court that Brigham failed as a matter of law to prove that Perrigo's product meets the claimed limitation of providing immediate relief from episodic heartburn within 5–10 minutes," the appeals court said, adding that "the court did not err in concluding that the infringement verdict and damages award could not stand."

The dispute over Perrigo's generic Pepcid Complete has a lengthy history. Brigham and Women's licenses patents to Johnson & Johnson for use in the drug, and Perrigo notified the hospital of its plans to launch a generic version in 2004.

The hospital notified J&J that the generic would infringe its patent, but J&J declined to file suit over it. Instead, it sued Perrigo over a different patent and lost when that patent was found invalid, leading Perrigo to launch its generic version in 2008.

The hospital itself filed the instant suit against Perrigo in 2013, a year after its patent expired. The jury **found in 2016** that the hospital's patent was infringed and rejected Perrigo's contention that it was invalid. However, on post-trial motions, Judge Zobel ruled in favor of Perrigo and found that the patent was not infringed and is invalid.

The Federal Circuit only addressed infringement in its opinion, noting that while there is generally a strong public interest in resolving patent validity, that interest is minimal in this case because the

hospital's patent expired in 2012 and can't be asserted against others.

The court then analyzed whether a clinical study showed that Pepcid Complete, and by extension, Perrigo's version, provides immediate heartburn relief and concluded it does not.

"At most, the study suggests that Pepcid Complete might provide immediate and sustained relief; such speculative data, however, cannot sustain Brigham's burden of proof," the court ruled.

The court rejected the hospital's argument that since the study showed the drug provided adequate relief within 15 minutes, that necessarily meant that relief started within five to 10 minutes. It ruled that since the number of patients who felt relief in five to 10 minutes was not measured or even estimated in the study, it cannot be used to prove infringement.

Finally, the court said the hospital could not rely on testimony from Dr. M. Michael Wolfe, the inventor of the patent, that he took Perrigo's generic product after the suit was filed and felt heartburn relief within five to 10 minutes.

"This uncorroborated, conclusory, and interested testimony is insufficient to carry Brigham's burden of proof and to sustain the jury verdict," the court said.

Jeffrey Gargano of Morgan Lewis & Bockius LLP, an attorney for Perrigo, said the appeals court "found that Brigham's evidence was insufficient to show immediate relief as claimed, and no reasonable jury could have found otherwise."

An attorney for the hospital could not immediately be reached for comment Thursday.

The patent-in-suit is U.S. Patent Number 5,229,137.

Judges Alan Lourie, Kathleen O'Malley and Kara Farnandez Stoll sat on the panel for the Federal Circuit.

The hospital is represented by James Bollinger, Timothy Heaton, Phoenix Pak, Gerald Porter, Lindsay Henner and Douglas Salyers of Troutman Sanders LLP.

Perrigo is represented by Jeffrey Gargano of Morgan Lewis & Bockius LLP and Peter Siavelis of Barnes & Thornburg LLP.

The case is Brigham and Women's Hospital Inc. et al. v. Perrigo Co., case number 2017-1950, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Kelly Duncan.

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