

Fed. Circ. OKs Teva's Patent Win Over Allergan Colitis Drug

By **Tiffany Hu**

Law360 (December 12, 2018, 7:19 PM EST) -- Teva Pharmaceuticals USA Inc. scored a win on Wednesday when the Federal Circuit affirmed an Eastern District of Texas ruling that the generics maker did not infringe Allergan USA's patent for the ulcerative colitis drug Delzicol, paving the way for Teva to get approval on the generic version of the drug.

In a one-line order, the appellate panel summarily affirmed U.S. District Judge Rodney Gilstrap's decision that Teva could not have infringed the patent for Allergan's branded Delzicol drug because the film composition of Teva's drug capsule is different from Allergan's. Mylan Pharmaceuticals Inc., which was named as a defendant in the suit, has since settled out of the case, according to court records.

The appellate panel heard oral arguments earlier this month, with the judges seeming wary of Allergan's claim that Teva infringed its patent by making a generic in a gel capsule just like the branded medication, which Allergan said was key to what the generics makers had allegedly infringed.

The panel had appeared particularly skeptical of the role Allergan said water played as a capsule gelling agent, saying that characterization didn't appear anywhere in the lower court record.

"It feels just a little too vague for me," Circuit Judge Raymond T. Chen had told an Allergan lawyer, referring to the use of water in creating the capsule's outer film.

Despite Allergan's contention that it was clear from the evidence that water gelled the film used in the drug capsules, even if it had not been characterized as a gelling agent in earlier proceedings, the panel remained unmoved and affirmed the lower court decision.

At the center of the dispute is the capsule used to hold Allergan's Delzicol drug and the patent covering the capsule. In its lawsuits, Allergan alleged that Teva and Mylan were unlawfully seeking U.S. Food and Drug Administration approval to market and sell generic versions of Allergan's Delzicol drug in violation of its patent.

In October 2017, Judge Gilstrap adopted the magistrate judge's conclusion that the Teva and Mylan capsules did not have the same outer composition as the patent at issue, though he put off ruling on counterclaims by the generics makers seeking to invalidate the patent, saying that dispute involves different facts and legal theories and could be taken up at a later date.

Further, having the court move forward and determine the validity of Allergan’s patent “would likely be unnecessary and counterproductive” because the U.S. Patent and Trademark Office had already set in motion an inter partes review of the asserted claims, the judge said at the time.

Circuit Judges Kimberly A. Moore, Jimmie V. Reyna and Raymond T. Chen sat on the panel for the Federal Circuit.

The patent-in-suit is U.S. Patent No. 6,649,180.

Counsel for both parties declined to comment Wednesday.

Allergan is represented by Michael N. Kennedy, Jeffrey B. Elikan, Jeremy D. Cobb, Philip S. May and David S. Denuyl of Covington & Burling LLP.

Teva is represented by John Christopher Rozendaal, Michael E. Joffre, Chandrika Vira, William H. Milliken and Daniel J. Ritterbeck of Sterne Kessler Goldstein & Fox PLLC.

The case is Warner Chilcott US LLC v. Teva Pharmaceuticals USA Inc., case number 18-1241, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Christopher Cole and Bonnie Eslinger. Editing by Haylee Pearl.