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Fed. Circ. Won't Restore Allergan's Restasis Patent Claims

By **Jeff Overley**

Law360 (November 13, 2018, 9:07 PM EST) -- The Federal Circuit on Tuesday declined to restore invalidated patent claims for Allergan Inc.'s dry-eye drug Restasis, delivering a fresh boost to proposed generics of the blockbuster eye-drop medicine.

In a one-word judgment, the appeals court affirmed an October 2017 ruling that found claims in a quartet of Restasis patents to be invalid for obviousness. The Federal Circuit's nonprecedential judgment on Tuesday is a win for Akorn Inc., Mylan Inc. and Teva Pharmaceuticals, which are all developing copycat versions of Restasis.

More broadly, Tuesday's ruling marks a setback for the brand-name drug lobby. Trade group Pharmaceutical Research and Manufacturers of America has argued that invalidation of the Restasis patent claims would deter drugmakers from "dedicating meaningful resources to improving upon existing therapies which already enjoy patent protection."

The patent claims relate to clinical research that found a greater benefit for patients from a lower concentration of Restasis' active ingredient, cyclosporine. In a brief at the Federal Circuit, Allergan called that a "surprising clinical finding" that a federal judge failed to properly consider when deciding to invalidate the claims.

Akorn, Mylan and Teva jointly pushed back on that argument, telling the Federal Circuit in January that Allergan's arguments about surprising results were based on "cherry-picked data points" and "statistical manipulation."

"In reality, the Restasis formulation performed precisely the way a skilled artisan would have expected during clinical trial," the trio of generic-drug makers asserted.

U.S. Circuit Judge William C. Bryson, who invalidated the patent claims after a trial last year, found that Allergan had "substantially overstated" improvements in effectiveness when comparing different cyclosporine formulations.

Allergan transferred the patents in question to the Saint Regis Mohawk Tribe and licensed them back in an effort to stymie generic-drug rivals by seeking cover under tribal sovereign immunity. The Federal Circuit this year rejected that maneuver in a separate case that may be headed to the U.S. Supreme Court.

Restasis earned $1.4 billion last year, making it a lucrative target for generics. Numerous companies are developing Restasis generics, but no such copycats have yet won approval from the U.S. Food and Drug Administration.

Representatives of Allergan, Akorn, Mylan, Teva and PhRMA had no immediate comment on Tuesday.

The patents-in-suit are U.S. Patent Numbers 8,629,111; 8,648,048; 8,685,930; and 9,248,191.

U.S. Circuit Judges Sharon Prost, Jimmie Reyna and Todd M. Hughes sat on the panel for the Federal Circuit.

Allergan is represented by Jonathan Singer, Juanita Brooks, Susan Morrison, Robert Oakes, Deanna Reichel and Joseph Herriges of Fish & Richardson PC. The Saint Regis Mohawk Tribe is represented by Christopher Evans and Michael Shore of Shore Chan DePumpo LLP.

Teva is represented by J.C. Rozendaal, Michael Joffre, R. Wilson Powers III, Pauline Pelletier and William Milliken of Sterne Kessler Goldstein & Fox. Mylan is represented by Douglas Carsten, Christina Dashe and Wendy Devine of Wilson Sonsini Goodrich & Rosati. Akorn is represented by Michael Dzwonczyk and Mark Boland of Sughrue Mion PLLC.

The case is Allergan Inc. et al. v. Teva Pharmaceuticals USA Inc. et al., case number 18-1130, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Aaron Pelc.