

Restasis Patent Redo Bid 'Inappropriate,' Fed. Circ. Told

By **Tiffany Hu**

Law360 (February 15, 2019, 6:33 PM EST) -- The row over Allergan Inc.'s controversial deal to sell patents on the dry-eye drug Restasis to a Mohawk tribe to avoid the Patent Trial and Appeal Board continues, as generic makers on Thursday blasted Allergan's "inappropriate" bid for the Federal Circuit to reconsider its decision upholding the invalidity of its patents.

Teva Pharmaceuticals USA Inc., Mylan Inc. and Akorn Inc., which are all developing generic versions of Restasis, filed a response urging the full Federal Circuit to deny the en banc petition by Allergan after a three-judge panel in November summarily affirmed a lower court decision that found claims in several Restasis patents invalid for obviousness.

The petition for rehearing, which was filed by Allergan and the St. Regis Mohawk Tribe in December, contended that the panel ruling is an expansion of the so-called "blocking patent" doctrine, which generally does not allow a company to use commercial success as an indicator of nonobviousness if the company owns a patent that would block others from competing with it.

Here, Allergan had argued, the panel barred not only evidence of commercial success but also evidence of a long-felt need for the dry-eye treatment, a decision that contradicts the appellate court's precedent by categorically applying the doctrine and failing to conduct a fact-specific analysis, the company said. If left to stand, the panel's decision "threatens innovation and is problematic in any form," according to the December petition.

Teva and the others on Thursday shot back in their response that the panel's one-line affirmance did not create a circuit precedent and did not address the doctrine or any part of the district court's opinion, thus making rehearing of the present case improper.

Instead, the affirmance "applied black-letter obviousness law to case-specific disputed questions of fact," the generic-drug companies wrote. "It is hard to imagine a more inappropriate candidate for rehearing en banc."

In any case, they argued, the district court had correctly applied precedent to the case, noting that Allergan's petition addressed the same issues regarding blocking patents in another Federal Circuit case known as *Acorda Therapeutics v. Roxane Laboratories*, which the court refused to rehear last month.

"By Allergan's own logic, the petition here deserves the same fate," the generics argued.

The patent claims relate to clinical research that found a greater benefit to patients from a lower concentration of Restasis' active ingredient, cyclosporine. Allergan had called that a "surprising clinical finding" that the district court failed to properly consider when deciding to invalidate the claims.

Akorn, Mylan and Teva had jointly pushed back on that argument, telling the Federal Circuit in January 2018 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 in October 2017, had found that Allergan had "substantially overstated" improvements in effectiveness when comparing different cyclosporine formulations.

Allergan transferred the patents in question to the St. 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 last 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.

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

Counsel for the parties did not immediately respond to requests for comment Friday.

Allergan is represented by Jonathan E. Singer, Susan E. Morrison, Robert M. Oakes and Deanna J. Reichel of Fish & Richardson PC. The St. Regis Mohawk Tribe is represented by Michael W. Shore, Christopher L. Evans and Joseph F. DePumpo of Shore Chan DePumpo LLP.

Mylan is represented by Douglas H. Carsten, Wendy Devine and Christina E. Dashe of Wilson Sonsini Goodrich & Rosati PC.

Teva is represented by John C. Rozendaal, Michael E. Joffre, R. Wilson Powers III, Pauline M. Pelletier and William H. Milliken of Sterne Kessler Goldstein & Fox PLLC.

Akorn is represented by Michael R. Dzwonczyk and Mark Boland of Sughrue Mion PLLC.

The case is Allergan Inc. et al. v. Teva Pharmaceuticals USA Inc. et al., case number 18-01130, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Jeff Overley. Editing by Haylee Pearl.