

Fed. Circ. Rejects Bid For PTAB Tribal Immunity Rehearing

By Dani Kass

Law360 (October 22, 2018, 9:52 PM EDT) -- The full Federal Circuit on Monday said it won't reconsider a panel's ruling that tribes can face Patent Trial and Appeal Board scrutiny, likely paving the way for one of the court's closest-watched cases to head to the U.S. Supreme Court.

The Federal Circuit shot down a request by Allergan PLC and the St. Regis Mohawk Tribe to rehear the immunity issue that has eclipsed an infringement case over patents covering the dry-eye medication Restasis. As is common, the Federal Circuit didn't explain why both the unanimous three-judge panel and full court turned down the rehearing request.

"The St. Regis Mohawk Tribe is disappointed with this morning's decision by the Federal Circuit to deny our petition for a rehearing," the tribe said in a statement. "We continue to maintain that the court's decision declaring an [inter partes review] an action of the United States" — which nullifies a tribe's immunity — "is not supported by the statute. In light of today's order, our legal department is currently considering our options."

One of the generic-drug makers accused of infringing the patent, Teva Pharmaceuticals USA Inc., declined to comment. Representatives for Allergan and the other generic-drug makers — Mylan Pharmaceuticals Inc and Akorn Inc. — didn't immediately respond to requests for comment Monday.

Allergan first sued generic-drug makers Mylan, Teva and Akorn in Texas federal court, accusing them of infringing its patents with their planned Restasis generics. The litigation switched gears in September 2017, when Allergan announced a controversial deal with St. Regis, wherein it paid the tribe \$13.75 million to take ownership of the patents, with the promise of ongoing royalties, and the tribe licensed the patents back to Allergan for all U.S. Food and Drug Administration-approved uses.

Not long after the infringement litigation was filed, the generic-drug makers had asked the PTAB to review the validity of the patents. After the sale, Allergan tried to claim immunity from the inter partes review, but the PTAB shot the drugmaker down in February and said it must face the patent challenge. Allergan and St. Regis appealed, but the Federal Circuit upheld the PTAB's decision in July.

Writing for the three-judge panel, Federal Circuit Judge Kimberly A. Moore said that IPRs are more akin to a traditional enforcement action from a federal agency, as opposed to a civil lawsuit in which tribal immunity would generally apply, so immunity doesn't apply.

Allergan and St. Regis — backed by seven states and two state universities — asked the court for another go in August, in part pointing to recent Supreme Court decision *SAS Institute v. Iancu*, wherein Justice Neil Gorsuch remarked that IPRs were an “adversarial process” that “mimics civil litigation.”

The three generic-drug makers pushed back, calling on a high court decision released the same day as *SAS*: *Oil States v. Greene’s Energy*. There, the justices made clear that IPRs are not equivalent to lawsuits even though they borrow “court-like procedures,” the companies said.

“There is no ‘looks like test’ to determine if agency action is the equivalent of a common-law suit,” the companies wrote, adding that “an IPR ‘remains a matter of public rights, one between the government and others,’ not a determination of one party’s liability to another.”

The patents-in-suit are U.S. Patent Numbers 8,685,930; 8,629,111; 8,642,556; 8,633,162; 8,648,048; and 9,248,191.

Allergan is represented by Jonathan Massey of Massey & Gail LLP, and Thomas Brugato, Jeffrey B. Elikan, Robert Allen Long Jr. and Alaina Marie Whitt of Covington & Burling LLP.

St. Regis is represented by Michael W. Shore, Alfonso Chan, Joseph F. DePumpo and Christopher L. Evans of Shore Chan DePumpo LLP, and Marsha K. Schmidt.

Mylan is represented by Eric D. Miller, Charles G. Curtis Jr., Andrew T. Dufresne, Shannon M. Bloodworth, Brandon M. White and Dan L. Bagatell of Perkins Coie LLP, and by Steven W. Parmelee, Jad A. Mills and Richard Torczon of Wilson Sonsini Goodrich & Rosati PC.

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

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

The case is *St. Regis Mohawk Tribe et al. v. Mylan Pharmaceuticals Inc. et al.*, case number 18-1638, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Matthew Bultman and Dave Simpson. Editing by Michael Watanabe.