

Fed Circ. Won't Stay Immunity Ruling For Allergan's Appeal

By **Sophia Morris**

Law360 (November 14, 2018, 8:28 PM EST) -- The Federal Circuit on Tuesday said it wouldn't stay its ruling that sovereign immunity doesn't apply in inter partes reviews while Allergan PLC and the St. Regis Mohawk Tribe appeal to the U.S. Supreme Court.

Allergan and St. Regis had asked for a stay on Oct. 26, concerned that the Patent Trial and Appeal Board reviews for patents tied to the dry-eye medication Restasis would pick up again as they appealed the Federal Circuit's July decision. But a trio of generic drugmakers had said a stay was unnecessary, describing it as an extraordinary measure given that the motion only rehashes arguments the appeals court shut down and fails to show any "imminent irreparable injury."

The Federal Circuit did not offer any reasoning for its Tuesday decision.

In their bid for a stay, Allergan and St. Regis had said there is a tension between two of the Supreme Court's most high-profile patent decisions last year, *Oil States Energy Services v. Greene's Energy Group* and *SAS Institute v. Iancu*, regarding how they define the type of proceeding that IPRs fall under. Sovereign immunity can be used as a defense in adversarial, civil litigation but not in a federal enforcement proceeding, and Allergan and St. Regis say it's not clear how to categorize IPRs.

But Teva Pharmaceuticals USA Inc., Mylan Pharmaceuticals Inc. and Akorn Inc. shot back that the Federal Circuit has already handled this argument and determined IPRs to be an agency enforcement action when concerned with immunity.

"The 'tension' noted by the panel was not between *Oil States* and *SAS*, but in the 'hybrid' nature of inter partes review, which 'is neither clearly a judicial proceeding instituted by a private party nor clearly an enforcement action brought by the federal government,'" the brief said. "To the extent there is tension between *Oil States* and *SAS*, the panel correctly resolved that tension, reconciled the two decisions and reached the correct result."

Allergan and St. Regis then said they would be harmed without the stay since the IPR would likely start again, but the generics makers said there has been no proof that anything at the PTAB is picking up again so there is no "imminent and clear" threat.

This question of immunity falls into a larger infringement suit that Allergan was bringing against Teva, Mylan and Akorn, which wants to sell generic versions of Restasis. Those generic-drug makers fought back by asking the Patent Trial and Appeal Board to review the patents.

But the litigation switched gears in September 2017, when Allergan announced it had sold its patents to St. Regis. The drugmaker paid the tribe \$13.75 million to take ownership of the patents, with the promise of ongoing royalties. The tribe then licensed the patents back to Allergan for all U.S. Food and Drug Administration-approved uses, and it asserted sovereign immunity at the board — but lost. The appeal to the Federal Circuit followed.

Separately, a Texas federal court ruled in October 2017 that claims in several patents for Restasis were invalid. This ruling was affirmed Tuesday, with the Federal Circuit declining to restore those invalidated patent claims in a win for the generic drugmakers.

Representatives for Teva and St. Regis declined to comment. Representatives for the other parties did not immediately respond to requests for comment Wednesday.

The patents-in-suit are U.S. Patent Nos. 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 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 Dani Kass and Jeff Overley. Editing by Connor Relyea.