

Fed. Circ. Urged Not To Stay Immunity Ruling For Appeal

By Dani Kass

Law360 (November 6, 2018, 5:38 PM EST) -- A trio of generic-drug makers have urged the Federal Circuit not to stay its ruling that sovereign immunity doesn't apply in inter partes reviews, arguing that Allergan PLC and the St. Regis Mohawk tribe haven't proven the U.S. Supreme Court would have a reason to take up their case or overturn the decision.

Allergan and St. Regis haven't shown that there is any kind of circuit conflict or tension in interpreting Supreme Court precedent that the justices need to hear, Teva Pharmaceuticals USA Inc., Mylan Pharmaceuticals Inc. and Akorn Inc. said Monday. Additionally, this case won't be a good vehicle to test the Eleventh Amendment, as that doesn't apply to tribes, the brief states.

"Although appellants intend to petition for a writ of certiorari, there is no reason to believe the Supreme Court is likely to grant review, let alone reverse," the generic-drug companies said. "The panel and concurring opinions were comprehensive, thoughtful, and correct."

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 decision. But the generic-drug makers said there is no need for this "extraordinary" measure, as the motion only rehashes arguments the Federal Circuit shut down and fails to show any "imminent irreparable injury."

For example, Allergan and St. Regis 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.

But Teva, Mylan and Akorn said 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 states. "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."

The generic-drug makers also pointed to the fishy nature of the deal between Allergan and St. Regis to prove the high court won't hear it, calling the deal "an impermissible abuse of trial sovereign immunity." Allergan sold its patents to St. Regis and then licensed them back to sell Restasis, hoping to get out of having to face IPRs.

"It is unlikely that the justices will vote to exercise discretionary review in support of appellants' transparent effort to destroy the PTAB's jurisdiction through a sham patent-assignment-and-exclusive-license-back transaction," the drugmakers said.

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

While Allergan and St. Regis had argued that a stay would keep things at the status quo, since the Federal Circuit had allowed a stay once before, the generic-drug makers said that status quo has "fundamentally changed" now that the appeals court has made its ruling.

Allergan and Teva declined to comment. Representatives for each of the remaining parties didn't immediately respond to requests for comment Tuesday.

This question of immunity falls into a larger infringement suit that Allergan was bringing against Teva, Mylan and Akorn, which wanted 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 the St. Regis deal. 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.

Allergan and St. Regis appealed to the Federal Circuit, but a three-judge panel upheld the board's decision in July. The pair again appealed, and on Oct. 22, the Federal Circuit denied a rehearing, either by the panel or en banc.

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 Steven W. Parmelee, Jad A. Mills and Richard Torczon of Wilson Sonsini Goodrich & Rosati PC.

Teva is represented by J.C. Rozendaal, Michael E. Joffe, 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.

--Editing by Connor Relyea.