

Allergan, Tribe Want IPRs Blocked As They Turn To High Court

By Dani Kass

Law360 (October 26, 2018, 7:26 PM EDT) -- Allergan PLC and the St. Regis Mohawk Tribe on Friday urged the Federal Circuit to stay its ruling that the tribe can face inter partes reviews as it takes the case to the U.S. Supreme Court, arguing that if it has to sit through patent challenges in the interim, its “sovereign immunity would be irretrievably lost.”

The pair say there is a “substantial” question about whether tribes can invoke sovereign immunity during IPRs that the justices need to answer. There will be no harm done with a stay but significant harm without one, they argue.

“Once a sovereign entity is compelled to participate in an administrative adjudication (on pain of having its patents declared invalid in its absence), a core element of sovereign immunity is irrevocably lost,” Allergan and St. Regis said.

The motion lays out the basics of the appeal, including pointing to several Supreme Court cases it claims need to be interpreted. These include *Federal Maritime Commission v. S.C. State Ports Authority*, where the court held that “sovereign immunity extends to administrative systems of adversarial adjudication between private parties”; *Oil States Energy Services v. Greene’s Energy Group*, which upheld the legality of IPRs; and *SAS Institute v. Iancu*, which in part stated that IPRs are an “adversarial process ... that mimics civil litigation.”

These decisions matter because sovereign immunity can be used as a defense in adversarial, civil litigation, but not in a federal enforcement proceeding.

This question of immunity falls into a larger infringement suit that Allergan was bringing against Teva Pharmaceuticals USA Inc., Mylan Pharmaceuticals Inc. and Akorn Inc., which wanted to sell a generic version of Allergan’s dry-eye medication 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 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. 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, saying the reviews are more akin to an enforcement action than civil litigation. The pair again appealed, and on Oct. 22, the Federal Circuit denied a rehearing, either by the panel or en banc.

The patent owners now say that they will be harmed if they have to face an action they should be immune from, as it undercuts the very principle of sovereign immunity. Additionally, if the Supreme Court agrees with Allergan and St. Regis while the IPR is ongoing, then the PTAB will have to undo the ruling, which is a waste of judicial resources, Friday's motion states.

But if things are kept at status quo until the justices speak, then no one will be harmed, as the IPR will have been delayed but not blocked, Allergan and St. Regis said.

The motion notes that the Federal Circuit had previously stayed the IPRs in this case for the same reasons, and that this would merely be an extension of that ruling.

Representatives for Allergan, St. Regis and Teva declined to comment. Mylan and Akorn didn't immediately respond to requests for comment Friday.

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.

--Additional reporting by Matthew Bultman and Dave Simpson. Editing by Adam LoBelia.