

Allergan, Tribe Want PTAB Immunity Denial Reheard En Banc

By **Dave Simpson**

Law360 (August 20, 2018, 9:59 PM EDT) -- The Saint Regis Mohawk Tribe and Allergan PLC on Friday asked the Federal Circuit court to reconsider en banc its ruling last month that tribal sovereign immunity doesn't apply in reviews at the Patent Trial and Appeal Board, which rejected the drugmaker's attempt to shield patents for its dry-eye medication Restasis by transferring them to the Native American tribe.

The drugmaker and the tribe said that the Federal Circuit's decision cuts against several precedential decisions, and that the case presents an important question as to whether sovereign immunity can be used in inter partes reviews.

"The panel's reasoning effectively forecloses IPR immunity claims by any sovereign entity," the drugmaker and the tribe said. "Indeed, the United States described the immunity issue in this case as one of 'cross-cutting significance.'"

Last month, the appeals court, in a precedential opinion, affirmed the PTAB's decision that it has the authority to decide the validity of several patents that were challenged by generic drug companies and are now held by the Saint Regis Mohawk Tribe.

Writing for the three-judge panel, Federal Circuit Judge Kimberly A. Moore said inter partes reviews at the PTAB 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.

As such, "we conclude that tribal immunity is not implicated," the judge wrote.

The ruling is a setback for Allergan, which paid Saint Regis \$13.75 million in 2017 to take ownership of the patents, with the promise of ongoing royalties. The tribe licensed the patents back to the Allergan for all U.S. Food and Drug Administration-approved uses.

Allergan, which has already faced a public relations backlash and criticism from the U.S. Congress over the deal, has maintained that the tribe's status as a sovereign entity should insulate the patents from PTAB review.

The board rejected that argument in a February decision and said it could continue with reviews started in late 2016 based on challenges from Mylan Pharmaceuticals Inc. Teva Pharmaceuticals USA Inc. and Akorn Inc. are also part of the reviews, which were put on hold pending the Federal Circuit appeal.

During oral arguments in June, Judge Moore described IPRs as a “hybrid type of procedure” that in some ways resemble civil litigation but in other ways are more like a specialized agency proceeding. The question, the judge said, was on which side of the line do IPRs fall.

Deciding in July it was on the side of agency action, the judge emphasized that the director of the U.S. Patent and Trademark Office, of which the PTAB is a part, has broad discretion in deciding whether to review a challenged patent.

Judge Moore said that, in this way, IPRs are like cases in which an agency chooses to start a proceeding based on information provided by a private party. The U.S. Supreme Court has said that immunity doesn’t apply in such a proceeding, the judge wrote.

Another factor that weighed against the application of tribal immunity was the fact that the PTAB has the ability to continue with its review of a patent even if the patent owner drops out or chooses not to participate in the proceeding.

The patents at issue 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.

Saint Regis Mohawk Tribe 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 Miller, Dan L. Bagatell, Shannon Bloodworth, Charles Curtis, Andrew Dufresne and Brandon Michael White of Perkins Coie LLP and Jad Allen Mills, Steven William Parmelee and Richard Torczon of Wilson Sonsini Goodrich & Rosati.

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

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

The case is Saint Regis Mohawk Tribe et al. v. Mylan Pharmaceuticals Inc. et al., case numbers 18-1638, 18-1639, 18-1640, 18-1641, 18-1642 and 18-1643, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Matthew Bultman. Editing by Dipti Coorg.