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Fed. Circ. Says Tribal Immunity Doesn't Apply In IPR

By **Matthew Bultman**

Law360 (July 20, 2018, 11:55 AM EDT) -- The Federal Circuit on Friday ruled tribal sovereign immunity doesn't apply in reviews at the Patent Trial and Appeal Board, rejecting an attempt from Allergan PLC to shield patents for its dry-eye medication Restasis by transferring them to a Native American tribe.

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 St. 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 where tribal immunity would generally apply.

As such, "we conclude that tribal immunity is not implicated," Judge Moore wrote.

The ruling is a setback for Allergan, which paid St. 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 public relations backlash and criticism from Congress over the deal, has maintained 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.

"This win is a victory in our ongoing efforts to stop patent abuses by brand companies and to help drive access to more affordable medicine," Mylan CEO Heather Bresch said in a statement.

Allergan said it does not comment on pending litigation. Brendan White, the communications director for St. Regis, said the tribe was disappointed with the ruling.

"The tribe is reviewing the decision and consulting with our attorneys," he said.

During oral arguments last month, 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 which side of the line IPRs fall.

Deciding Friday 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 apart, 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 director’s important role as a gatekeeper and the board’s authority to proceed in the absence of the parties convinces us that the USPTO is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant,” the court wrote.

“The tribe,” it added, “may not rely on its immunity to bar such an action.”

In a concurring opinion, Circuit Judge Timothy B. Dyk said the purpose of an IPR is to allow the USPTO to take a second look at an issued patent and fix its mistakes. This is similar to the re-examination procedures that pre-date IPRs and “to which everyone agrees sovereign immunity does not apply.”

The appeals court was careful to note that it was not weighing in on the issue of state sovereign immunity. In contrast to tribal protections, the PTAB has said that state immunity can be a defense in IPRs. That issue is currently before the Federal Circuit in a separate case.

“While we recognize there are many parallels, we leave for another day the question of whether there is any reason to treat state sovereign immunity differently,” the court wrote.

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.

Circuit Judge Jimmie V. Reyna joined Judges Moore and Dyk on the Federal Circuit panel.

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 by 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 by 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.

--Editing by Rebecca Flanagan and Emily Kokoll.

Correction: An earlier version of this story misstated the law firm of one of Mylan's attorneys. The error has been corrected. The story has also been updated with more information on the case and to include comment.
