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Justices Urged To Turn Down PTAB Tribal Immunity Case

By **Tiffany Hu**

Law360 (March 7, 2019, 1:58 PM EST) -- A trio of generic-drug companies asked the U.S. Supreme Court on Wednesday not to hear Allergan Inc. and the St. Regis Mohawk tribe's suit over whether tribal immunity applies at the Patent Trial and Appeal Board, saying the court should wait for a case in which the patents at issue are actually owned by a tribe.

In July, the Federal Circuit correctly found that inter partes reviews are federal agency actions not barred by tribal sovereign immunity, according to the brief filed by Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA Inc. and Akorn Inc. But even if tribal immunity in IPRs were an issue that could be examined by the high court, the present case does not warrant such review because the patents at issue are only "nominally" owned by the tribe, they said.

According to Wednesday's brief, the parties orchestrated a deal in which Allergan assigned the patents to the St. Regis Mohawk tribe in exchange for its promise not to waive immunity. But the tribe's ownership of the patents was in name only, as Allergan later paid millions of dollars for exclusive license of the patents, making the case a "deeply tainted one," the companies said.

"The court should wait for a case in which the patents at issue are actually owned by a tribe, instead of by a private pharmaceutical company that has attempted to misappropriate tribal sovereign immunity to evade its obligations under federal law and preserve its patent monopoly," the brief says.

In January, Allergan and the St. Regis Mohawk tribe filed a petition for certiorari to the Supreme Court, saying the Federal Circuit strayed from high court precedent about how patent reviews are characterized.

Namely, the appellate court misinterpreted the Supreme Court's decisions in Oil States v. Greene's Energy Group and SAS Institute v. Iancu by finding that inter partes reviews are primarily agency enforcement actions in which immunity doesn't apply, according to the petition. IPRs are akin to adversarial, civil litigation, in which immunity does apply, Allergan and the St. Regis Mohawk tribe said.

"The Federal Circuit erroneously opined that this court's decisions in Oil States and SAS 'laid bare ... tension' regarding the supposedly 'hybrid' nature of IPRs. But there is no such 'tension' and no conflict in this court's decisions," the petition says. "Neither SAS nor Oil States referred to IPRs as a 'hybrid proceeding.' The only conflict is between the Federal Circuit's holding and this court's precedent, and with the decisions of other lower courts that have faithfully followed this court."

Mylan and the others fired back in Wednesday's brief, saying the Federal Circuit's decision does not conflict with precedent. Oil States found IPRs constitutional and SAS held that PTAB has full discretion on whether to institute review but must address each challenged claim before doing so, and the panel had properly considered the two cases together, they said.

"SAS did emphasize the adversarial characteristics of IPRs, and petitioners rely heavily on this language," the generics makers wrote. "But Oil States made clear that IPRs are not equivalent to common law suits between private parties even though they borrow 'courtlike procedures' and 'use terms typically associated with courts.'"

Allergan and St. Regis are leading this fight because of a September 2017 deal they entered, wherein Allergan handed over several patents for the dry eye medication Restasis to the tribe, which then licensed them back. They claimed those patents are immune from scrutiny.

A Texas federal judge, the Federal Circuit and PTAB have all said the tribal immunity argument doesn't hold up and the patents can be reviewed and, at times, invalidated.

In the district court case this appeal sprang from, Allergan accused Mylan, Teva and Akorn of infringing its patents with their proposed Restasis generics. After a bench trial, Senior U.S. Circuit Judge William C. Bryson in 2017 said immunity doesn't apply and invalidated claims from four patents.

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.

Counsel for the parties did not immediately respond to requests for comment Thursday.

Mylan is represented by Charles G. Curtis Jr., Andrew T. Dufresne, Shannon D. 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.

Allergan is represented by Jonathan Massey of Massey & Gail LLP, and Robert Allen Long Jr., Jeffrey B. Elikan, Thomas Brugato and Alaina Marie Whitt of Covington & Burling LLP.

The St. Regis Mohawk tribe is represented by Michael W. Shore, Alfonso Chan, Christopher L. Evans and Joseph F. DePumpo of Shore Chan DePumpo LLP, and Marsha K. Schmidt.

The case is St. Regis Mohawk Tribe et al. v. Mylan Pharmaceuticals Inc. et al., case number 18-899, in the Supreme Court of the United States.

--Additional reporting by Dani Kass. Editing by Stephen Berg.