

No Need To Reconsider Immunity At PTAB, Fed. Circ. Hears

By **Matthew Bultman**

Law360 (September 19, 2018, 7:32 PM EDT) -- Mylan Pharmaceuticals Inc. and other generic-drug companies challenging Allergan PLC patents for dry-eye medication Restasis urged the full Federal Circuit on Tuesday not to reconsider an earlier decision that tribal sovereign immunity doesn't apply in reviews at the Patent Trial and Appeal Board.

The generics makers argued the three-judge panel's July ruling was "fully consistent" with U.S. Supreme Court and Federal Circuit precedent and correctly pointed out the differences between civil litigation — where tribal immunity generally applies — and inter partes review at the PTAB.

"The panel correctly recognized that an IPR is not a private suit against a patent holder but instead a mechanism by which a federal agency may reconsider its own grant of a public franchise," Mylan, Teva Pharmaceuticals USA Inc. and Akorn Inc. said.

The companies also suggested that Allergan and the St. Regis Mohawk tribe, which now holds the Restasis patents, exaggerated the impact of the panel's ruling when they argued it could also subject state-owned patents to PTAB review.

"The panel expressly did not decide those broader questions," the companies wrote, adding that questions about state immunity "can and will be addressed in other cases."

The brief comes almost a month after Allergan and St. Regis filed a petition for en banc rehearing.

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

Allergan believes tribal sovereign immunity should shield the patents from PTAB reviews that were brought by Mylan.

The board rejected that argument, as did the Federal Circuit panel. Ruling tribal immunity doesn't apply in IPRs, the appeals court emphasized 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.

"In this way, IPR is more like cases in which an agency chooses whether to institute a proceeding on

information supplied by a private party,” the court wrote, adding the U.S. Supreme Court has “recognized that immunity would not apply in such a proceeding.”

Seeking a rehearing, Allergan and St. Regis pointed to, among other things, the Supreme Court’s recent opinion in *SAS Institute v. Iancu*, where Justice Neil Gorsuch remarked that IPRs were an “adversarial process” that “mimics civil litigation.”

Mylan and the generic makers responded Tuesday by pointing to a second Supreme Court decision that came out the same day as *SAS Institute*, *Oil States v. Greene’s Energy*. In that case, the justices made clear that IPRs are not equivalent to lawsuits even though they borrow “court-like procedures,” the companies said.

“There is no ‘looks like test’ to determine if agency action is the equivalent of a common-law suit,” the companies wrote, adding that “an IPR ‘remains a matter of public rights, one between the government and others,’ not a determination of one party’s liability to another.”

Earlier this month, several states and two universities — the University of Minnesota and the University of New Mexico — filed briefs supporting Allergan and St. Regis’ bid for a rehearing.

The University of Minnesota is in the midst of its own appeal challenging the PTAB’s determination that state sovereign immunity, which the board has said applies in IPRs, can be waived when an infringement lawsuit is filed over the disputed 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.

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

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.

The case is *Saint 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 Adam LoBelia.