

## Generic Cos. Tell Fed. Circ. Not To Halt PTAB Restasis IPRs

By **Matthew Bultman**

*Law360 (March 26, 2018, 7:52 PM EDT)* -- The Patent Trial and Appeal Board should be allowed to proceed with its review of patents covering Allergan PLC's Restasis medication, generic-drug makers said Friday, urging the Federal Circuit not to reward the drug company for its "misappropriation" of tribal immunity.

Mylan Inc. and other generics makers who challenged the patents in inter partes review said the court should deny a bid from Allergan and the Saint Regis Mohawk Tribe to stay the reviews while they appeal a PTAB decision finding tribal sovereign immunity doesn't apply in IPRs.

Allergan transferred six patents to the tribe in a controversial licensing deal last year. The generic companies argued the stay request was the latest step in an "unprecedented" effort to prevent the board from reaching a final decision about the validity of those patents.

"This court should not undermine the integrity of IPRs ... and reward appellants' manipulative tactics and misappropriation of tribal sovereign immunity by granting a stay," Mylan, along with Teva Pharmaceuticals USA Inc. and Akorn Inc., wrote in a brief.

The generic companies' filing came one day after the PTAB said it planned to move forward with the reviews, despite arguments from Allergan and the Saint Regis tribe that the appeal had divested the board of its jurisdiction to proceed to a final decision about the patents' validity.

The PTAB said that while the tribe may be entitled to an immediate appeal of its decision regarding the applicability of tribal immunity in IPRs, review could continue with only Allergan — the "true owner" of the patents.

"Because we do not find that our conclusion regarding Allegan's ownership is a proper 'appealable decision,' we do not find that the filing of the [notice of appeal] has divested the board of jurisdiction to proceed to a final written decision," the board wrote.

Oral arguments are currently set for April 3, with a final decision on the validity of the patents due by early June.

Allergan transferred the patents to the Saint Regis Mohawk in September as part of an agreement in which the tribe would license them back for all U.S. Food and Drug Administration-approved uses. In

return, the tribe was paid \$13.75 million, with the promise of ongoing royalties.

Allergan and the tribe contend tribal immunity shields the patents from PTAB review and asked the Federal Circuit to weigh in after the board rejected their arguments in a decision last month. They have also asked that the reviews be paused until the appeals court has a chance to rule.

In their Friday filing, Mylan and the other generic companies said the licensing deal was a sham, calling it an “undisguised trade of money for sovereign immunity.” That alone makes a stay inappropriate, they contend.

The companies also pushed back on the idea that the tribe would be irreparably harmed if the IPRs are completed, arguing the PTAB’s validity decisions will be same whether it is the tribe or Allergan that continues to participate. They also noted the board’s final decisions can be appealed.

“Even if the tribe had substantial rights in the patents, no claims will be cancelled until after appellate review and Allergan’s contractual payments will continue ‘until all claims of the licensed patents are rendered invalid in a non-appealable final judgment,’” the generic makers wrote. “The tribe thus faces no irreparable harm if the board completes its task.”

Allergan and the Saint Regis Mohawk are separately appealing an October ruling from a judge in a parallel district court infringement case against generics companies that found claims in some of the same Restasis patents were invalid.

An attorney for the tribe could not immediately be reached for comment. Counsel for Mylan has declined to comment on the case.

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.

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

Allergan is represented at the Federal Circuit by Jonathan Massey of Massey & Gail LLP.

Mylan is represented at the Federal Circuit 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, Will 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 v. Mylan Pharmaceuticals Inc. et al., case number 18-1638, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Marygrace Murphy.