

NOVEMBER/DECEMBER 2017

DEVOTED TO
LEADERS IN THE
INTELLECTUAL
PROPERTY AND
ENTERTAINMENT
COMMUNITY

VOLUME 37 NUMBER 10

THE *Licensing*
Journal

Edited by Gregory J. Battersby and Charles W. Grimes



Patent Licensing

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Allergan and the Saint Regis Mohawk Tribe Enter Patent Agreement to Try Defend against IPR of RESTATIS® Patents

In a creative move to take advantage of recent Patent Trial and Appeal Board (PTAB) decisions regarding Sovereign Immunity, [see, e.g., *Covidien LP v. University of Florida Research Foundation*, IPR2016-01274 and *Neochord, Inc. v. University of Maryland*, IPR2016-2016-00208; *Reactive Surfaces LTD., LLP v. Toyota Motor Corp.*, IPR2017-00572] Allergan PLC announced that it will transfer six Orange Book (OB) listed patents for RESTATIS® to the Saint Regis Mohawk Tribe. [US Patent Nos. 8,629,111; 8,633,162; 8,642,556; 8,648,048; 8,685,930; and 9,248,191]; <https://www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr.>]

Allergan asserted the six patents, which are listed on the Food and Drug Administration's Orange Book (OB) of drugs approved or denied under Section 505 of the Federal Food, Drug and Cosmetic Act for interstate commerce within the United States of America, in infringement actions against Abbreviated New Drug Application (ANDA) filers Mylan,

Teva Pharmaceuticals, and others. Mylan, Teva, Argentum Pharmaceuticals, Famy Care Limited, and Akorn, Inc. have all filed *Inter Partes* Review (IPR) petitions against the six OB-listed patents. The IPRs involving Argentum, and Famy Care have been terminated by agreement of the parties pursuant to settlements. The IPR filed by Mylan is scheduled for Oral hearing on September 13, 2017, and trials on the IPRs filed by Teva and Akorn were instituted on March 31, 2017. Thus, this patent ownership change comes in the middle of ongoing IPR instituted trials.

The Saint Regis Mohawk Tribe is a sovereign tribal government, and Allergan and the Saint Regis Mohawk Tribe intend to assert the Saint Regis Mohawk Tribe's sovereign immunity as a defense in the pending IPR proceedings. Allergan states that the Saint Regis Mohawk Tribe will file motions to terminate the pending IPRs on the grounds that the Saint Regis Mohawk Tribe, as a sovereign entity, is immune from involvement in IPRs.

Under the disclosed terms of the deal, Allergan will transfer full ownership of the six OB-listed patents to the Saint Regis Mohawk Tribe, pay the Saint Regis Mohawk Tribe \$13.75 million, and Allergan will receive an exclusive license to the six OB-listed patents. The Saint Regis Mohawk Tribe also will be eligible to receive \$15 million in annual royalties.

This case can potentially limit or expand the reach of sovereign immunity as a defense in IPR. The PTAB's previous sovereign immunity decisions have been based on immunity under the Eleventh Amendment, which grants sovereign immunity to States, but is silent as to other sovereign entities. As the Saint Regis Mohawk Tribe is not a State, it may present different arguments to the PTAB than those relied on in previous sovereign immunity decisions. This could open the door to sovereign immunity as a defense to other sovereigns, such as foreign governments. It also will be interesting to see how the PTAB handles the motions to terminate where the ownership of the patents has changed specifically to take advantage of sovereign immunity.

Peter Law is an associate at Knobbe Martens in San Diego, CA. He has a degree in Chemical Engineering and worked as a nuclear engineer for six years before law school. Mr. Law works in many aspects of patent law including prosecution, licensing, strategic client counseling, and inter partes reviews.

Kerry S. Taylor, PhD is a partner at Knobbe Martens in San Diego, CA. He has been practicing since 1998 in areas including Inter Partes Reviews, patent litigation, patent prosecution, strategic planning and counseling relating to infringement and licensing issues, and intellectual property due diligence studies. Mr. Taylor received his doctorate degree in biochemistry and molecular biology from the University of Chicago.

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