# Allergan Makes Deal with Mohawk Nation to Avoid Patent Review Process

The tricks pharma companies use to protect endangered patents took an unexpected turn on Friday when Allergan transferred the rights to all of its patent on Restasis, a drug to treat chronic dry-eye, to the Saint Regis Mohawk tribe. The tribe will then grant Allergan exclusive licenses to the transferred patents. In exchange, the tribe will receive a $13.75 million upfront cash payment and up to $15 million in annual royalties from Restasis sales.

Allergan was facing both a federal lawsuit filed in Texas challenging the Restasis patents and an Inter Partes Review (IPR) challenge at the U.S. Patent and Trade Office (USPTO). An IPR allows a third-party (i.e. someone who does not own the patent) to challenge the patent at the USPTO based on either the novelty requirement of 35 U.S.C. § 102 or the non-obviousness requirement of 35 U.S.C. § 103.[1] Congress established the IPR process in 2012 to facilitate patent challenges by making them faster and more efficient than traditional court challenges. As a sovereign entity, however, the Mohawk tribe is not subject to proceedings within the USPTO. The Mohawk tribe then filed a motion to dismiss the IPR based on its sovereign status, although the transfer of IP would not affect the abbreviated new drug application (ANDA) patent litigations in the Texas federal court case.[2]

**What is the IPR and why does it matter?**

Congress passed the Leahy-Smith America Invents Act (AIA)[3] in 2011, after six years of hearings and negotiations.[4] Industry leaders and legislators recognized that the increasing number of patent challenges and the expense of patent litigation adversely affected innovation. Amongst other things, the law established a fast-track procedure within the (USPTO) that allows any petitioner to challenge the validity of an issued patent based on either If the USPTO grants the petition, the

USPTO's Patent Trial and Appeal Board (PTAB) will conduct an IPR proceeding and render a patentability decision.[5] Unlike in litigation, the PTAB does not presume validity for patents and it uses a preponderance standard instead of the more burdensome clear and convincing evidence standard used in district courts.[6] In addition, the time from petition to PTAB decision is usually less than two years, and IPRs are substantially cheaper than court proceedings due a more limited discovery.[7] As a result the of IPR, patents that do not meet appropriate standards of novelty and non-obviousness can be invalidated, allowing generic competitors to enter the market (pending FDA approval).

The actions by Allergan and the Saint Regis Mohawk tribe mark the latest in a series of attempts by patent holders to avoid the IPR process. The U.S. Court of Appeals for the Federal Circuit determined that state entities can use sovereign immunity to avoid proceedings in the USPTO.[8] The PTAB used this standard to dismiss three IPRs brought by Covidien LP against the University of Florida Research Foundation Inc. (UFRF) on the basis that the UFRF is an arm of the State of Florida and is entitled to sovereign immunity.[9]

**How does this deal affect Restasis prices?**

The six patents on Restasis expire in August 2024.[10] According to Allergan, the net revenues of Restasis' were $308.8 million in the first quarter of 2017.[11] A study by the IMS Institute for Healthcare Informatics found that prices for branded drugs fall 51% in the first year that a generic equivalent is released and 74% by the second year.[12] Using this data, Allergan could make *at least* $50 million in excess revenues on Restasis for every month that it delays generic competition.[13] On the other hand, patients will be forced to pay much higher prices for their drugs in the absence of a generic equivalent.

**What does this deal mean for pharmaceutical prices?**

If other pharmaceutical companies (or any patent holder) can avoid review by the

USPTO simply by transferring the rights to a patent to a Native American tribe, patent holders can completely thwart the intent of Congress when it established the IPR. Each month that a pharmaceutical company can delay entry of generic competition costs payers millions.

By virtue of its ability to protect brand-name drug revenues, transferring patent rights to a sovereign entity could become widespread practice. Other tactics used by drug companies to prevent competition cost the US health care system billions of dollars. For example, the FTC estimates that pay-for-delay agreements cost the health care system approximately $3.5 billion per year,[14] and a study by the Generic Pharmaceutical Association (GPhA) estimates that misuse of the Risk Evaluation and Mitigation Strategy (REMS) program at the FDA to delay entry of generics costs health care system $5.4 billion annually.[15]

Because competition is so effective at bringing down prices, manufacturers will use any legal means to prevent it. If Allergan and other drug companies are allowed to simply transfer patents to sovereign nations to avoid proceedings in the USPTO, the ultimate cost will be to patients and the US health care system.

[1] D. Christopher Ohly, *The America Invents Act: U.S.P.T.O. Implementation – Inter Partes and Post-Grant Review*, Md. Bar J., 45-4 (2012).

[2] Allergan Press Release. Available at: https://www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr.

[3] *Leahy-Smith America Invents Act of 2011*, Pub. L. No. 112-29, 125 Stat. 284 (codified as amended in scattered sections of 35 U.S.C.).

[4] Renoj Zachariah, *Fighting the Troll Toll: The Case for Judicial Review of the U.S.P.T.O. Director's Denial of A Petition to Institute an Inter Partes Review*, 38 Cardozo L. Rev. 2273, 2276 (2017)

[5] *Ibid*.

[6] See Zachariah for a discussion of: David Cavanaugh &amp|Chip O'Neill, Presentation: A Practical Guide to *Inter Partes* Review: Strategic Consideration for Pursuing *Inter Partes* Review in a Litigation Context (Nov. 21, 2013), Available at: http://www.wilmerhale.com/uploadedFiles/WilmerHale_Shared_Content/WilmerHale_Files/Events/WilmerHale-webinar-IPR1-20Jun13.pdf.

[7] Cyrus Morton, *IP: Do the New Patent Office Trials Actually Make Patent Litigation Cheaper?*, InsideCounsel Mag. (Feb. 5, 2014), Available at: http://www.insidecounsel.com/2014/02/05/ip-do-the-new-patent-office-trials-actually-make-p?slreturn=1497110939.

[8] Vas-Cath, Inc. v. Curators of Univ. of Mo., 473 F.3d 1376, 1382 (Fed. Cir. 2007).

[9] Paula Heyman and Catherine Garza *Sovereign Immunity Protects State-Funded Patent Owners from Post-Grant Proceedings* 29 No. 8 Intell. Prop. &amp|Tech. L.J. 25 (2017)

[10] *Ibid.*

[11] Joan McKenna. *Allergan's Restasis Sales Increase 3.4 Percent in Q1-2017*. May 12, 2017. https://market-scope.com/breaking-post/allergans-restasis-sales-increase-3-4-percent-in-q1-2017/.

[12] Price Declines after Branded Medicines Lose Exclusivity in the U.S. *IMS Institute for Healthcare Informatics.* January 2016. Available at: https://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Price_Declines_after_Branded_Medicines_Lose_Exclusivity.pdf.

[13] Revenue of 308.8 million per quarter means a revenue of 102.9 million per month. If revenue falls to between 26 and 49% because prices fall 51-74%, that means revenue falls to between 26.8 and 50.4 million or a loss of between 52 and 76 million per month.

[14] Federal Trade Commission. "Pay-for-delay: how drug company pay-offs cost consumers billions." Available at: https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-bi

llions-federal-trade-commission-staff.

[15] Brill, Alex "Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry." *Matrix Global Advisors.* July 2014. Available at: http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf.