



UPDATE: All Eyes on Allergan: Drug Company's Unprecedented Move Raises Questions for Patent and Drug Law (Part I)

Updated March 16, 2018

UPDATE 2, 3/16/2018: On February 23, 2018, the [Patent Trial and Appeal Board \(PTAB\)](#) [denied](#) the Saint Regis Mohawk Tribe's motion to terminate the inter partes proceedings based on tribal sovereign immunity, holding (1) the doctrine of tribal sovereign does not apply to PTAB proceedings and (2) the proceedings could continue "without the Tribe's participation in view of Allergan's retained ownership interests in the challenged patents." Appeals have been filed with the [U.S. Court of Appeals for the Federal Circuit](#) with respect to both (1) the U.S. District Court for the Eastern District of Texas's decision invalidating the Restasis Patents (discussed in [UPDATE 1](#) below) and (2) the PTAB's denial of the motion to terminate (Federal Circuit docket numbers 18-1130 and 18-1638, respectively).

UPDATE 1, 10/19/2017: In the latest development in a series of events that has [surprised many](#), on October 16, 2017, the U.S. District Court for the Eastern District of Texas issued [an opinion and final judgment](#) in Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., invalidating the Restasis Patents for failure to meet the [Patent Act's](#) "non-obvious" requirement for patentability. In tandem with the issuance of this judgment, the court issued a [second opinion](#) granting Allergan's motion to join the Saint Regis Mohawk Tribe (the Tribe) as co-plaintiff based on the court's concern that if it "decline[d] to join the Tribe as a co-plaintiff and it is later determined that the Tribe is a valid owner of the patents, any judgment entered by the Court could be subject to challenge on the ground that the owner of the patents was not a party to the action."

Allergan's motion had been opposed by defendant Mylan—a generic drug manufacturer—who also raised the issue of whether the Allergan-Saint Regis deal constituted a "sham" transaction. Just last week, the district court issued [an order](#) requesting briefs that address "whether the Tribe should be added as a co-plaintiff or whether the assignment transaction should be disregarded as a sham." The Order indicated that the briefs were due on October 13, 2017 at 2:00 p.m., after which "the Court [would] determine by the close of business on October 13 whether a hearing will be needed," which, if necessary, would be held on October 16. Instead of ruling on that particular issue, the court invalidated the Restasis Patents that day, resolving the entire case.

Furthermore, although the court stated it was "not required to decide whether the assignment of the patent rights from Allergan to the Tribe was valid in order to resolve the question whether to add the

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Tribe as a co-plaintiff,” the court included a lengthy critique of the nature of the Allergan-Saint Regis deal in its [opinion](#). Citing the Second Restatement on Contracts, the court stated: “sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities. It is not an inexhaustible asset that can be sold to any party that might find it convenient to purchase immunity from suit. Because that is in essence . . . what the agreement between Allergan and the Tribe does, the Court has serious reservations about whether the contract between Allergan and the Tribe should be recognized as valid, rather than being held void as being contrary to public policy.”

Allergan reportedly will be appealing these decisions, an appeal that would be heard by the [Federal Circuit](#), as noted in [Part II](#).

The original post from October 12, 2017, is below.

In a move that took many in the [pharmaceutical and patent fields by surprise](#), brand-name drug manufacturer Allergan, Inc. [announced](#) that it assigned its rights to six patents covering its dry-eye drug Restasis (Restasis Patents) to the Saint Regis Mohawk Tribe (Tribe). The company seemingly intends to benefit from the Tribe’s sovereign immunity in a patent validity challenge pending before the U.S. Patent and Trademark Office (PTO). Allergan’s move was perhaps [an effort to manage the ticking clock](#) on the Restasis Patents, all of which expire in August 2024. The Allergan-Saint Regis deal, however, has broader implications across industries if the validity of issued patents can no longer be challenged before the PTO. For instance, [commentators have](#) speculated as to whether other drug companies will similarly seek to transfer their patents to entities that can claim sovereign immunity in order to render their patents incontestable, which could, in turn, affect [drug pricing](#).

Part I of this two-part Sidebar provides background on the Allergan-Saint Regis deal and tribal sovereign immunity. [Part II](#) then explores the potential immediate and long-term outcomes of the deal, before analyzing the arrangement in the broader contexts of patent law and sovereign immunity, while highlighting the unresolved questions it raises.

The Allergan-Saint Regis Deal

The Allergan-Saint Regis deal is comprised of two separate transactions. First, Allergan and the Tribe entered into a [patent assignment agreement](#) on September 8, 2017, under which Allergan assigned “all of [its] right, title and interest in, to and under the [Restasis] Patents.” In turn, the Tribe agreed that it “will not waive its sovereign immunity . . . in relation to any *inter partes review* or any other proceeding in the [PTO].” [Inter partes reviews](#), administrative proceedings created by the [Leahy-Smith America Invents Act](#), allow any person (other than the patent holder) to challenge a patent’s validity based on earlier patents or printed publications (the so-called “prior art”) that disclose the claimed invention. (For more on these types of proceedings, and patent law generally, see this [CRS Report](#)). Second, the Tribe concurrently granted to Allergan an [exclusive field-of-use license](#) limited to “all FDA-approved uses in the United States” in exchange for a payment of [\\$13.75 million and eligibility for annual royalties of \\$15 million](#). While the Tribe reportedly already owns [certain technology patents](#), this appears to be the Tribe’s first deal involving pharmaceutical patents.

Notably, at the time the Allergan-Saint Regis deal was reached, the Restasis Patents were the subject of proceedings pending in federal court and before the PTO. Specifically, on August 24, 2015, Allergan filed suit in the U.S. District Court for the Eastern District of Texas (*Allergan, Inc. v. Teva Pharm. USA, Inc.*, case number 2:15-CV-1455-WCB) against several generic drug manufacturers. Allergan alleged patent infringement based on the generic drug manufacturers’ applications to the U.S. Food and Drug Administration for approval to market generic versions of Restasis under certain provisions of the Drug Price Competition and Patent Term Restoration Act (i.e., the [Hatch-Waxman Act](#)). Several of the defendants raised counterclaims alleging that the Restasis Patents are invalid. A [five-day trial](#) as to the

validity of the Restasis Patents ended on September 1, 2017, and a decision is forthcoming. Interestingly, when Allergan [informed the court of the deal](#), it stated that it did “not anticipate that [the patent] assignment will have any impact on the litigation or the issues before the Court, other than [Allergan] expects to join the Tribe as a co-plaintiff.”

In addition, between June 3, 2016 and January 6, 2017, three generic drug manufacturers petitioned the PTO for inter partes reviews of the Restasis Patents to determine whether some or all of the patents’ claims are invalid for failure to meet the [Patent Act’s requirements for patentability](#). A trial before the PTO’s Patent Trial and Appeal Board (PTAB) was scheduled for September 15, 2017 in the consolidated case (*Mylan Pharm., Inc. v. Allergan, Inc.*, case number IPR2016-01127), and the statutory deadline for completion of the review (i.e., the PTAB’s issuance of a final written decision) is December 8, 2017. After the Allergan-Saint Regis deal was [announced](#) on September 8, however, the PTAB held a [hearing on September 11](#) to determine the effects of the deal on its proceedings. The Tribe then filed a [motion to dismiss based on tribal sovereign immunity](#), postponing further proceedings concerning the validity of the Restasis Patents. If granted, the Tribe’s motion would end the proceedings. The [PTAB has indicated](#) that it will likely hear oral arguments before issuing a decision on the sovereign immunity issue.

Tribal Sovereign Immunity

As characterized by the Supreme Court in *Michigan v. Bay Mills Indian Community*, Native American tribes are considered “domestic dependent nations” with “inherent sovereign authority.” Accordingly, tribes possess “[common-law immunity](#) from suit traditionally enjoyed by sovereign powers” as “a necessary corollary to Indian sovereignty and self-governance.” Thus, tribes are immune from suit *unless* (1) Congress has [expressly abrogated](#) their sovereign immunity or (2) a tribe has [expressly waived](#) its immunity. Consequently, the courts have dismissed suits against tribes involving, inter alia, alleged [patent](#) and [copyright](#) infringement, [gaming](#), [payday lending](#), and [third-party debt collection](#) on sovereign immunity grounds.

Sovereign immunity, moreover, generally exists in judicial proceedings in the courts, as well as in adjudicative proceedings before administrative agencies. As the Supreme Court explained in *Federal Maritime Commission v. South Carolina State Ports Authority*, “if the Framers thought it an impermissible affront to a State’s dignity to be required to answer the complaints of private parties in federal courts, we cannot imagine that they would have found it acceptable to compel a State to do exactly the same thing before the administrative tribunal of an agency.” In the context of inter partes reviews, on January 25, 2017, the PTAB declined to initiate a proceeding involving a patent owned by the University of Florida on *state* sovereign immunity grounds in *Covidien LP v. University of Florida Research Foundation, Inc.* The PTAB’s decision relied explicitly on an opinion issued in [parallel district court litigation](#) in *University of Florida Research Foundation, Inc. v. Medtronic PLC* (case number 1:16CV183-MW/GRJ), wherein the Northern District of Florida dismissed patent counterclaims against the University on sovereign immunity grounds six months before the PTAB decided the issue. [Allergan has acknowledged](#) that the PTAB’s decision in the *University of Florida* case was the impetus for the Allergan-Saint Regis arrangement.

Four months after the PTAB issued its decision in the *University of Florida* case, the PTAB dismissed an inter partes review involving a patent owned by the University of Maryland based on state sovereign immunity grounds in *Neochord, Inc. v. University of Maryland, Baltimore*. And in a third decision issued in July 2017, *Reactive Surfaces Ltd. v. Toyota Motor Corp.*, the PTAB similarly dismissed the University of Minnesota from an inter partes review proceeding. As discussed [extensively here](#), the line of decisions involving universities issued by the PTAB over the past nine months may have a measurable impact on patent law going forward, particularly by incentivizing non-sovereign-entity patent holders to insulate their patents from invalidation proceedings through strategic alliances with entities claiming sovereign immunity.

The pending inter partes review of the Restasis Patents appears to be the first time the PTAB has had to consider dismissal based on *tribal*, as opposed to *state*, sovereign immunity. Significantly, tribal sovereign immunity differs from state sovereign immunity. While state sovereign immunity finds its source in the [Constitution's Eleventh Amendment](#), tribal sovereign immunity "is subject to the [superior and plenary control of Congress](#)" and may be abrogated through legislation so long as legislation doing so "unequivocally express[es] that purpose." In *Bay Mills*, for example, the Supreme Court examined a provision of the Indian Gaming Regulatory Act (IGRA), 25 U.S.C. § 2710(d)(7)(A)(ii), and concluded that "IGRA partially abrogates tribal sovereign immunity in § 2710(d)(7)(A)(ii) The provision . . . authorizes a State to sue a tribe to 'enjoin a class III gaming activity located on Indian lands and conducted in violation of any Tribal-State compact.'" By contrast, after Congress attempted to abrogate *state* sovereign immunity for purposes of the Patent Act, the Supreme Court struck down the statutory provisions in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, holding that Congress lacked the power to compel states to surrender their sovereign immunity for purposes of patent infringement suits.

For a detailed discussion of the potential immediate and long-term outcomes of the Allergan-Saint Regis deal, as well as an analysis of the arrangement in the broader contexts of patent law and sovereign immunity, proceed to [Part II](#) of this post.

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