



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

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As discussed in [Part I](#) of this two-part Sidebar, on September 8, 2017, 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's (PTO's) Patent Trial and Appeal Board (PTAB). While [Part I](#) provides background on the Allergan-Saint Regis deal and tribal sovereign immunity, this post explores the potential immediate and long-term outcomes of this deal, analyzes the arrangement in the broader contexts of patent law and sovereign immunity, and highlights the unresolved questions it raises.

What Happens Next?

The Allergan-Saint Regis deal was reached within the context of several factors that could terminate the Restasis Patents, which are set to expire in August 2024 after which others may use the underlying drug inventions without regard to the expired patents. First, ongoing litigation in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.* (case number 2:15-CV-1455-WCB) could result in the invalidation of some or all of the Restasis Patents' claims, a decision that could then be appealed to the [U.S. Court of Appeals for the Federal Circuit](#) (Federal Circuit). While [Allergan has asserted](#) that its deal with the Tribe does not affect this litigation, [commentators](#) have stated that, "[as a matter of law, it is not clear why that would be so.](#)" As discussed below, there are seemingly several issues that the Allergan-Saint Regis deal may raise in the district court litigation or possibly on appeal. Second, in the pending inter partes review (*Mylan Pharm. Inc. v. Allergan, Inc.*, case number IPR2016-01127), the PTAB could determine that some or all of the Restasis Patents' claims are invalid for failure to meet the [Patent Act's requirements for patentability](#). However, the PTAB may not reach the patent validity issues if it grants the Tribe's [motion to dismiss based on tribal sovereign immunity](#), thereby ending the proceedings.

How Does Tribal Sovereign Immunity Differ from State Sovereign Immunity?

The PTAB's decisions in the inter partes reviews involving patents owned by the [University of Florida](#) and the [University of Maryland](#), both of which were terminated on *state* sovereign immunity grounds,

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may serve as precedent upon which the PTAB could similarly dismiss the challenge to the Restasis Patents, albeit on *tribal* sovereign immunity grounds. During a [hearing on September 11, 2017](#), however, Mylan—a generic drug manufacturer involved in both the judicial and the PTO proceedings—indicated it would raise several objections to the Tribe’s motion to dismiss. Similarly, in a [letter to the district court](#), Mylan stated that it “will vigorously oppose this transparent delay tactic before the [PTAB].” Mylan could rely on the differences between tribal and state sovereign immunity discussed [here](#). In addition, during the [hearing on September 11](#), Mylan asserted that this case “is totally non-analogous to any of the 11th Amendment cases even if those sorts of cases apply because in all of those cases, the state entity was the pre-existing owner of the intellectual property.” One potential similarity between tribal and state sovereign immunity, however, is that the [initiation of a lawsuit](#) under some circumstances constitutes a [waiver of sovereign immunity](#). In this regard, the Allergan-Saint Regis deal would arguably not affect the district court litigation because Allergan commenced the litigation.

Who is the Real Party in Interest?

Issues related to the real party in interest could also be brought to bear in both the judicial and the PTAB proceedings. Specifically, in litigation contesting patents, which are owned by one entity (here, the Tribe), but licensed exclusively to a manufacturer of a product (here, Allergan, manufacturer of Restasis), who is the real party in interest? The Supreme Court recently addressed the issue of the real party of interest in [Lewis v. Clarke](#), a negligence action against a tribal employee wherein the Court held: “in a suit brought against a tribal employee in his individual capacity, the employee, not the tribe, is the real party in interest and the tribe’s sovereign immunity is not implicated.” Although this case arose in an entirely different context, it suggests that the identity of the real party in interest has implications for the availability of sovereign immunity. Notably, on October 6, 2017, the [district court ordered briefing](#) as to “whether the Tribe should be added as a co-plaintiff or whether the assignment transaction should be disregarded as a sham.” In deciding this issue, the court may examine whether the Allergan-Saint Regis deal changes who should be considered the real party in interest for purposes of this litigation. If the district court were to decide that the agreement was a [sham transaction](#), Mylan could then use the court’s holding to oppose the Tribe’s motion to dismiss before the PTAB.

Relatedly, in the [University of Maryland](#) case, the PTAB found that the University remained an indispensable party in an inter partes review even though it granted an exclusive license to its patent to a third party, because it had retained certain patent rights under the licensing agreement. By contrast, in a subsequent case involving a patent jointly owned by the University of Minnesota and Toyota, the PTAB granted the University’s motion to dismiss on sovereignty immunity grounds, in part, finding that the inter partes review could proceed without the University. Specifically, in [Reactive Surfaces Ltd. v. Toyota Motor Corp.](#), the PTAB relied on Federal Circuit precedent in concluding that “when the absent sovereign party and a remaining party have identical ‘interests in the asserted patents,’ the remaining party adequately represents the interests of the absent sovereign party.” During the [hearing on September 11](#), Allergan confirmed that, despite the Tribe’s intervention, it will not be withdrawing from the PTAB proceedings. Thus, relying on [Reactive Surfaces](#), Mylan asserted “if Allergan remains, the [T]ribe can be dismissed and the proceeding can continue without it.” How the district court and the PTAB rule on these issues remains to be seen.

What Rights Were Transferred?

A related issue is the nature of the rights that Allergan actually transferred to the Tribe in the patent assignment, and received from the Tribe in the licensing agreement. [One commentator](#) has asked: “Is it credible . . . that the pharma company has given the [T]ribe a completely free hand to use the patents in any way that it wishes? If it hasn’t, are the restrictions that have been imposed enough for Mylan and others to argue that Allergan continues to exercise *de facto* control over them and that, for this reason,

sovereign immunity should not apply?” Patent rights are sometimes characterized as a [bundle of sticks](#) with each stick representing a separate right—the right to sell the patent, to sue for infringement, to practice the invention, to license the patent, etc. And in patent law you can transfer some of these rights while retaining others. So, in short, did Allergan transfer its full bundle of rights to the Tribe through the patent assignment? If not, the more rights Allergan retained, the less likely it is that a court would find a patent assignment occurred for certain purposes, such as [standing to sue](#). That is, if Allergan [remains, in effect, the patentee](#), is the Tribe’s sovereign immunity available?

As noted, Mylan has characterized the Allergan-Saint Regis deal as a [“sham” transaction](#) and will likely continue to question the propriety of the deal both before the district court and the PTAB. For instance, during the [hearing on September 11](#), Mylan argued that, under [35 U.S.C. § 261](#), “when you accept a patent, you accept it with strings attached. . . . Congress actually expressly reserves that any ownership is taken subject to the provisions of the patent code. One of those provisions is amenability to [inter partes reviews]. So the [T]ribe . . . went into this with eyes open.” Similarly, [in a letter to the court](#) opposing the joinder of the Tribe, Mylan characterized the Allergan-Saint Regis deal “as nothing less than a transparent, last minute attempt to shield the patents-in-suit from inevitable cancellation.”

For its part, the [Tribe counters](#) that it “transferred to Allergan less than ‘substantially all’ rights to the [Restasis] Patents” by granting to “Allergan a field-of-use license limited to ‘all FDA-approved uses in the United States,’” while “retaining all other fields of use, ‘including the right to use and practice the Licensed Patents for research, scholarly, use, teaching, education, [and] patient care.’” Thus, the Tribe believes it remains indispensable to the PTO proceedings. But, if so, would the Tribe be similarly indispensable to the district court litigation? That question is currently [under consideration by the court](#).

What Are the Broader Implications for Patent Law?

At a broader level, the continued viability of inter partes review proceedings is currently in question. On June 12, 2017, the Supreme Court granted certiorari in [Oil States Energy Services v. Greene’s Energy Group](#) on the sole question as to “[w]hether inter partes review—an adversarial process used by the [PTO] to analyze the validity of existing patents—violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.” Thus, the Court could potentially strike down the PTO’s patent invalidation proceedings as unconstitutional. As such, the outcome of this case could arguably diminish some of the [concerns](#) raised by the Allergan-Saint Regis deal, such as companies forging alliances with entities claiming sovereign immunity to shield their patents from invalidation during PTO proceedings.

What Are the Options for Congress?

While the pending judicial and administrative proceedings discussed above could affect the issues raised by the Allergan-Saint Regis deal, Congress could also take action. Patent reform appears to be of perennial interest to Congress. (For a discussion of Congress’s patent reform efforts, see this [CRS Report](#)). For instance, as in past sessions, during the 115th Congress, Members of Congress proposed a number of reforms to the PTO’s proceedings in the [Support Technology and Research for Our Nation’s Growth and Economic Resilience Patents Act of 2017](#) (the STRONGER Patents Act). For example, the bill would align the PTAB’s patent claim construction standard with that used in federal court; would require that the PTAB’s findings of patent invalidity be proved by clear and convincing evidence, as they are in district court; and, with regard to standing in PTO proceedings, the bill would limit potential petitioners to only those individuals and enterprises who have demonstrated an adverse interest in the challenged patent. And [Allergan has cited](#) the “disadvantage that ‘inter partes review’ creates for biopharma innovators and the patients they serve” as one reason it entered into the deal with the Tribe.

The Allergan-Saint Regis deal has also brought increased attention to the topic of tribal sovereign immunity generally. As [one commentator](#) has pointed out, “[m]any scholars are not fans of sovereign immunity in general, and their hackles may be raised still further by what may seem like tribes renting their immunity.” Such criticisms have seemingly led to various [congressional responses](#). For instance, in a [letter](#) to the Senate Judiciary Committee dated September 27, 2017, four Senators requested that the Committee [initiate an investigation](#) into the Allergan-Saint Regis deal. Others have responded with legislative fixes. On October 5, 2017, for instance, “[a] [bill to abrogate the sovereign immunity of Indian tribes as a defense in inter partes review of patents](#)” was introduced in the Senate.

While Congress could enact legislation to abrogate tribal sovereign immunity in the context of patent invalidity proceedings, possibly alleviating the concerns some have raised, such arrangements may improve a tribe’s economic conditions. Indeed, as one commentator notes, “[Tribal leaders](#) are understandably anxious to make deals that will bring much-needed jobs and money to places that have long lacked both.” With regard to the Allergan-Saint Regis deal, the [Saint Regis Mohawk Tribal Council](#) released the following statement: “This is a viable and sound opportunity for the Saint Regis Mohawk Tribe to enter into the patent, technology and research sector as part of our overall economic diversification strategy. We realize that we cannot depend solely on casino revenues and, in order for us to be self-reliant, we must enter into diverse business sectors to address the chronically unmet needs of the Akwesasne community; such as housing, employment, education, healthcare, cultural and language preservation.” These considerations could weigh against imposing legislative restrictions on the Tribe’s sovereign immunity.

In sum, while much remains murky after the announcement of the Allergan-Saint Regis deal, over the coming months, the PTAB (if the PTO proceedings are not dismissed on sovereign immunity grounds) or the district court will likely resolve whether the Restasis Patents are valid through 2024. Concurrently, when it issues its *Oil States* decision, the Supreme Court will likely resolve whether PTO inter partes review proceedings can be used to challenge patents. At the same time, congressional action—on tribal sovereign immunity and/or PTO proceedings, including changes to inter partes review procedures—is, as always, a possibility.

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