# University of Miami Law School University of Miami School of Law Institutional Repository

University of Miami Law Review

5-6-2019

# The Unlikely Duo That Shocked the Intellectual Property World and Why the Supreme Court Was the Chosen One to Restore Balance

Nicholas Dilts

Follow this and additional works at: https://repository.law.miami.edu/umlr

Part of the Intellectual Property Law Commons, and the Supreme Court of the United States

Commons

#### Recommended Citation

Nicholas Dilts, The Unlikely Duo That Shocked the Intellectual Property World and Why the Supreme Court Was the Chosen One to Restore Balance, 73 U. Miami L. Rev. 955 (2019)

Available at: https://repository.law.miami.edu/umlr/vol73/iss3/7

This Notes and Comments is brought to you for free and open access by University of Miami School of Law Institutional Repository. It has been accepted for inclusion in University of Miami Law Review by an authorized editor of University of Miami School of Law Institutional Repository. For more information, please contact library@law.miami.edu.

#### **NOTES & COMMENTS**

# The Unlikely Duo That Shocked the Intellectual Property World and Why the Supreme Court Was the Chosen One to Restore Balance

NICHOLAS DILTS\*

The United States Congress passed the Leahy Smith America Invents Act in 2011 in an effort to streamline the patent system and reduce patent litigation, allowing the United States to continue to be competitive globally. The Act enabled the U.S. Patent Office to facilitate patent challenges through an administrative process called inter partes review, an adversarial proceeding before the newly established Patent Trial and Appeal Board that was designed to be a cheaper and more efficient alternative for post-grant patent review than litigation in front of the federal district courts. In the years that followed, the Patent Trail and Appeal Board has earned a reputation for being notoriously trigger-happy in its invalidation of patents. This reputation

<sup>\*</sup> Articles and Comments Editor, *University of Miami Law Review*, Volume 73; J.D. Candidate 2019, University of Miami School of Law; B.A. 2016, University of Florida. I would like to thank Professor Andres Sawicki and Professor Sergio Campos, as well as Curtis Osceola, for their insight and guidance, without which this Comment would not have been possible. I would also like to thank the *University of Miami Law Review* for selecting my Comment for publication, and the Executive Board of Volume 73 for all of their dedication to my Comment and the Issue as a whole. Specifically, I am grateful to the extremely dedicated Megan Cheney and Elizabeth Montano for their detailed edits and feedback. Finally, I would like to thank my parents, Edward and Sandra Dilts, and my brother, Eric Dilts, the people I am absolutely blessed to have been stuck with. Your constant love and support, as well have the lessons you have imparted on me, enabled me to become the person I am today. I hope that I have made you proud and that I can continue to do so.

has encouraged patent holders to seek out ways to circumvent inter partes review in an effort to have their patents reviewed in front of the federal district courts, where they might stand a better chance. One such attempt was initiated by the global pharmaceutical company, Allergan, Inc., when it sold the rights to its Restasis eye drug to the Saint Regis Mohawk Tribe. The main components of the deal focused on a transfer of the Restasis ownership rights along with a yearly sum to the Tribe. In return, the Tribe licensed back the drug's production rights to Allergan and agreed to assert a tribal sovereign immunity defense in response to any inter partes review challenge, which would force the dispute into the federal district court forum.

The Allergan-Saint Regis deal threatened to have major impacts on the intellectual property world, the livelihoods of the federally recognized tribes, and the U.S. economy overall. The issues it presented involved an intersection of multiple types of law and begged a review of the patent review process, the state of the tribes today, and the scope of tribal sovereign immunity in today's day and age. Whether tribal sovereign immunity could be applied to an administrative action in post-grant patent review evolved into a battle at multiple forums. When the dust settled, the Patent Trial and Review Board had issued a decision that tribal sovereign immunity was not applicable and invalidated the Restasis patent—a decision that was affirmed by the United States Court of Appeals and the Supreme Court of the United States. This Comment discusses all of the angles in this case before advocating that the Supreme Court ultimately did not go far enough when it simply chose not to review the lower court's decision. Instead, the Court should have used this opportunity to limit tribal sovereign immunity in a way that implies a waiver of sovereign immunity for economic activities that take place off of tribal lands. This solution would simultaneously help to promote overall systemic and economic efficiency, as well as allow the tribes a better opportunity to participate in today's marketplaces—providing them with a more positive outlook for the future.

#### Introduction

In September of 2017, the pharmaceutical company Allergan, a leader in the industry, announced a deal that transferred the patent rights to one of their most valuable drugs, Restasis, to the Saint

Regis Mohawk Tribe.<sup>1</sup> Under the major terms of the deal, Allergan transferred the patent rights and \$13.75 million to the Tribe, who agreed to grant an exclusive license of those same rights back to Allergan for \$15 million a year in royalty payments throughout the patent's lifespan.<sup>2</sup> While this transaction looked like a very bad business deal on its face, the move created instant buzz within the legal community because of its potential impact on the future of the intellectual property world, the rest of the federally recognized tribes, and virtually all consumers within the United States.<sup>3</sup> So, why did Allergan choose to partner with a Native American tribe and why has the move garnered such attention? Because Allergan, with the assistance of the Saint Regis Mohawk Tribe, was in pursuit of a major pharmaceutical company's Holy Grail—immunity from review by the Patent Trial and Appeal Board's patent review process.<sup>4</sup>

Prior to the deal, the validity of Allergan's patent rights to their Restasis eye drugs had been challenged by several generic competitors looking to market their own, cheaper version of the drug. Normally, the U.S. Patent Office facilitates such challenges through an administrative process called inter partes review ("IPR") that entails an adversarial proceeding before the Patent Trial and Appeal Board ("PTAB" or "Board") rather than litigation before the federal district courts of the United States. While the IPR process was designed to be a cheaper and more efficient alternative for reviewing the validity of patents, it has drawn the ire of drug companies like Allergan that often find themselves before the Board as defendants. This is due to the companies' shared belief that presenting their patents for review in front of the Board is the intellectual property world's equivalent of sending their patent to the gallows. However, unlike its

<sup>&</sup>lt;sup>1</sup> Katie Thomas, *How to Protect a Drug Patent? Give It to a Native American Tribe*, N.Y. TIMES (Sept. 8, 2017), https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html.

<sup>&</sup>lt;sup>2</sup> *Id*.

<sup>&</sup>lt;sup>3</sup> *Id*.

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> Joe Mullin, *Apple Is Being Sued for Patent Infringement by a Native American Tribe*, ARS TECHNICA (Sept. 27, 2017, 8:11 AM), https://arstechnica.com/tech-policy/2017/09/apple-is-being-sued-for-patent-infringement-by-anative-american-tribe/.

<sup>&</sup>lt;sup>7</sup> *Id*.

<sup>&</sup>lt;sup>8</sup> See infra notes 29–31 and accompanying text.

predecessors that lost their patents following a PTAB review, Allergan strategically crafted a plan to bypass the Board's review, which began when the company ceded ownership of the Restasis patent to the Saint Regis Mohawk Tribe.

As the new owners, Saint Regis asserted a tribal sovereign immunity defense in front of the PTAB in an effort to shield the patent from the Board's review. 9 If such a defense were allowed, the PTAB would have been left without the jurisdiction required to render a decision on the patent's validity. <sup>10</sup> For Allergan, the deal would have enabled the company to defend their patent in a more agreeable forum—the federal district courts. For the Saint Regis Mohawk Tribe and the rest of the Native American tribes within the United States, the move provided a potential revenue stream and accompanying opportunities for a community that is in deep need. 11 For the rest of us, the ramifications of this deal and the extent of its potential effect on the U.S. economy were incalculable. The battle over Restasis evolved into one fought on multiple fronts, both in front of the PTAB and the federal courts.<sup>12</sup> In February of 2018, the PTAB rendered a decision against Saint Regis's use of the tribal sovereign immunity defense, saying that it did not apply in this case. 13 The Tribe appealed that decision, which was affirmed by the United States Court of Appeals for the Federal Circuit. 14 Allergan and the Tribe petitioned the Supreme Court of the United States for a review of the decision, but the Court denied their writ of certiorari, affirming the lower court's decision and putting an end to the case.<sup>15</sup>

<sup>&</sup>lt;sup>9</sup> Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe, No. IPR2016-01127, Paper 130, at 2 (P.T.A.B. Feb. 23, 2018); Thomas, *supra* note 1; Jason Rantanen, Saint Regis Mohawk Tribe, Allergan v. Mylan: *No Tribal Immunity for IPR*, PATENTLY-O (July 23, 2018) https://patentlyo.com/patent/2018/07/mohawk-allergan-immunity.html.

<sup>&</sup>lt;sup>10</sup> Thomas, *supra* note 1.

<sup>&</sup>lt;sup>11</sup> *Id*.

Rantanen, *supra* note 9.

<sup>&</sup>lt;sup>13</sup> *Id*.

<sup>&</sup>lt;sup>14</sup> Saint Regis Mohawk Tribe v. Mylan Pharm., 896 F.3d 1322 (Fed. Cir. 2018); Rantanen, *supra* note 9.

Lawrence Hurley, *U.S. Supreme Court Rejects Allergan Bid to Use Tribe to Shield Drug Patents*, REUTERS (Apr. 15, 2019, 9:41 AM), https://www.reuters.com/article/us-usa-court-allergan/us-supreme-court-rejects-allergan-bid-to-use-tribe-to-shield-drug-patents-idUSKCN1RR1FD.

The issue of whether tribal immunity from suit can be applied to an administrative action in patent review begs a review of the scope of tribal immunity, the effectiveness of the IPR process, and consideration of the impact a decision for either side will have going forward. This Comment argues that the correct course of action in this situation was to not only invalidate the Allergan-Saint Regis deal, but also amend the doctrine of tribal sovereign immunity as a whole—a task that could have been accomplished by the Supreme Court of the United States. Part I provides background information on IPR, tribal sovereign immunity, and the state of the tribes today in an effort to better understand the Allergan-Saint Regis deal. Part II analyzes the major issues posed by the Allergan-Saint Regis case and why the PTAB should not have ruled on the matter. Finally, Part III argues that the Supreme Court should have invalidated the deal and, in doing so, amended the doctrine of tribal sovereign immunity to imply a waiver of its protections for tribal commercial activities that occur off of the reservation.

#### I. BACKGROUND

A dive into the intricate and complex matters surrounding this issue warrants an overview of the background and legal positions that shaped the driving factors behind the Allergan-Saint Regis deal—current patent law, tribal sovereign immunity, and the state of Native American tribes in our country today.

#### A. Patent Law and IPR

The Constitution of the United States grants the federal government the power to create and issue patents.<sup>16</sup> The owner of a patent can prevent all others from making, selling, or using their invention in the United States throughout the patent's lifespan, which is generally twenty years from the date the inventor filed his or her patent application.<sup>17</sup> The limits that define the areas protected by a patent are described in the patent's claims.<sup>18</sup> In order to obtain a patent, an

<sup>&</sup>lt;sup>16</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>&</sup>lt;sup>17</sup> 35 U.S.C. § 154(a)(2) (2012).

<sup>&</sup>lt;sup>18</sup> How Do I Read a Patent? - the Claims, BROWN & MICHAELS, http://www.bpmlegal.com/howtopat5.html (last visited Jan. 21, 2019).

applicant must prove that their invention is both novel<sup>19</sup> and nonobvious, meaning that the difference between the prior art and the claimed invention would not be obvious to a "person having ordinary skill in the art to which the claimed invention pertains."<sup>20</sup> From a policy standpoint, the U.S. patent system is functioning at its most optimal level when there is a balance between patent holders and market competition.<sup>21</sup> Allowing patent holders to have a monopoly over their invention for the duration of their patent incentivizes research and development that likely would not occur absent such protections, and thus, promotes innovation.<sup>22</sup> On the other side of the scale, "[c]ompetition stimulates innovation by fulfilling consumers' unmet needs or providing them new, better services."<sup>23</sup>

In 2011, Congress passed the Leahy Smith America Invents Act ("AIA"), establishing the PTAB.<sup>24</sup> The AIA gave the PTAB the ability to hold trials to challenge the validity of patents through several new post-grant proceedings, including the IPR.<sup>25</sup> Congress's purpose when it created the IPR was to present a method for challenging the validity of a patent that was a faster, cheaper alternative to litigation in the district courts.<sup>26</sup> To accomplish this goal, IPRs were designed as an adjudicative model (instead of examinational) that includes restricted discovery, statutory time limits, litigation time limits, and one level of appeal.<sup>27</sup> Additionally, the post-grant review of patents better enables the U.S. Patent and Trademark Office

<sup>&</sup>lt;sup>19</sup> 35 U.S.C. § 102(a)(1)–(2).

<sup>&</sup>lt;sup>20</sup> Id. § 103.

<sup>&</sup>lt;sup>21</sup> Stephanie A. Diehl, *Treating the Disease: A First Amendment Remedy for the Problem of Patent Trolls and Overbroad Business Methods*, 33 CARDOZO ARTS & ENT. L.J. 495, 499 (2015).

<sup>&</sup>lt;sup>22</sup> *Id*.

<sup>&</sup>lt;sup>23</sup> *Id*.

<sup>&</sup>lt;sup>24</sup> Kenneth J. Costa, *Patent System Manipulation: Hedge Funds Abusing IPR, Poor Patent Quality & Pharmaceutical Monopolies*, 35 CARDOZO ARTS & ENT. L.J. 177, 182 (2016).

<sup>&</sup>lt;sup>25</sup> *Id*.

Stacy Lewis & Tom Irving, Very Few Appreciated Just How Bad AIA Inter Partes Reviews (IPRs) Would Be for Patent Owners, Although IPR Denials Have Been, for Patent Owners, a Glimmer of Hope, 11 BUFF. INTELL. PROP. L.J. 28, 31 (2015).

<sup>&</sup>lt;sup>27</sup> *Id.* at 32–33.

("PTO") to weed out invalid or poor-quality patents while strengthening and validating the good patents that emerge from review unscathed.<sup>28</sup>

Early returns on the IPR process have sparked controversy and earned the PTAB a nickname, the "Death Squad," for its role in invalidating numerous existing patents.<sup>29</sup> Kenneth Costa presented several statistics that show just how beneficial the IPR process has been for petitioners:

In its first year of IPR, the PTAB granted 87% of petitions, and in its second year, it granted 76% of petitions. The overall claim cancellation rate, as of March 2014, was 96.4%. Thirty months into the creation of IPR, the overall claim cancellation rate was 80.9%.<sup>30</sup>

Numbers like these encourage generic drug companies and other third parties to challenge name-brand pharmaceutical corporations in front of the Board. In the eyes of many, pharmaceutical companies allegedly obtained these bad patents through abuse or manipulation of the patent approval process, part of a multitude of tactics employed by big pharma that allow the companies to artificially increase drug prices and keep competitors out of the market.<sup>31</sup>

On the other hand, numbers such as these encouraged patent holders to advocate that IPR is unfairly skewed to favor petitioners and unnecessary because an avenue to challenge patents already exists at the federal courts.<sup>32</sup> Opponents of this viewpoint argue that IPRs are fundamentally different from district court proceedings in

 $<sup>^{28}</sup>$   $\,$  157 Cong. Rec. S1380 (daily ed. Mar. 8, 2011) (statement of Sen. Grassley).

Rob Sterne & Gene Quinn, *PTAB Death Squads: Are All Commercially Viable Patents Invalid?*, IPWATCHDOG (Mar. 24, 2014), http://www.ipwatchdog.com/2014/03/24/ptab-death-squads-are-all-commercially-viable-patents-invalid/id=48642/.

<sup>&</sup>lt;sup>30</sup> Costa, *supra* note 24, at 183.

<sup>&</sup>lt;sup>31</sup> *Id.* at 184–86 (discussing pharmaceutical companies' ability to extend their patents through simple changes to the dosage, packaging, or slightly reformulating the drug to produce a "new" version and describing "pay-for-delay" schemes that pay generic drug companies to keep their generic version out of the market or buy a start-up rival).

Thomas, *supra* note 1.

ways that are favorable to the petitioners.<sup>33</sup> The main differences are identified as the "Big 3": (1) the PTAB applies a "broadest reasonable interpretation" claim construction,<sup>34</sup> while district courts use the "ordinary and customary meaning as would be understood by a person of ordinary skill in the art" framework developed in *Phillips v. AWH Co.*;<sup>35</sup> (2) the PTAB grants no presumption of validity for issued patent claims unlike the district court; and (3) the PTAB only requires a showing of unpatentability by preponderance of the evidence, which is a lower standard than the "clear and convincing evidence" standard used by the district courts.<sup>36</sup> Additionally, the PTAB is not bound by other administrative proceedings or judicial decisions, which means that an owner of a patent that a district court ruled was valid can later find themselves defending their patent's validity again in an IPR proceeding.<sup>37</sup>

With the deck stacked against them in IPR, patent holders certainly have an incentive to force any fight over the validity of their patents into the federal district courts where a patent's chances to survive are more favorable. Brent Saunders, the CEO of Allergan, explained that the motivation behind the deal with the Saint Regis Mohawk Tribe was "to avoid what he described as the 'double jeopardy' of having the same issue heard in two venues." In fact, the legal theory behind the Allergan-Saint Regis deal and the parties' attempt to block the PTAB's ability to review the Restasis patent via employment of the tribal sovereign immunity defense was motivated by recent PTAB decisions to dismiss cases based on the victorious party's state sovereignty protections prescribed to them under the Eleventh Amendment.<sup>39</sup>

<sup>&</sup>lt;sup>33</sup> See Lewis & Irving, supra note 26, at 58–59.

 $<sup>^{34}</sup>$  Id

<sup>&</sup>lt;sup>35</sup> Phillips v. AWH Corp., 415 F. 3d 1303, 1312–13 (Fed. Cir. 2005).

Lewis & Irving, supra note 26, at 58–59.

<sup>&</sup>lt;sup>37</sup> *Id.* at 60–61; *see* Katharine L. Neville, *PTAB Not Always Bound by Previous Court Decisions Regarding Patent Validity*, MARSHALL GERSTEIN IP: PTABWATCH (Dec. 4, 2017), https://www.ptabwatch.com/2017/12/ptab-not-always-bound-by-previous-court-decisions-regarding-patent-validity/ (explaining that it is legally permissible for the PTAB to arrive at different conclusions regarding patentability than an earlier court decision on the same patent due to differing standards of review and/or additional evidence presented).

Thomas, *supra* note 1.

<sup>&</sup>lt;sup>39</sup> See id.

#### B. Tribal Sovereign Immunity

Exploring the history of tribal sovereign immunity helps answer the complex questions posed by the Allergan-Saint Regis deal and presents the justification for the Supreme Court's authority to alter the doctrine. The first and only mention of the Native American tribes within the United States Constitution lies within the Indian Commerce Clause, which gives Congress the power to regulate commerce with the tribes. 40 In the past, courts consistently interpreted this as a grant to Congress of plenary and exclusive authority to legislate in regard to tribal affairs. 41 This reading is supported by the repeatedly relied upon characterization of Indian tribes as "domestic dependent nations"42 whose title as sovereigns stems from their status as self-governing nations that pre-existed the United States and its Constitution. 43 However, unlike state sovereign immunity from suit, which is codified in the Eleventh Amendment, 44 the Supreme Court independently created tribal immunity from suit as federal common law in *United States v. U.S. Fidelity & Guaranty* Company when it held that "Indian Nations are exempt from suit without congressional authorization."<sup>45</sup> The purpose of this immunity was grounded in "history" and the principle of comity, defined as a "proper respect for tribal sovereignty," that encourages harmonious relations between the United States and tribal governments.<sup>46</sup>

The federal courts' freedom to create common law can only be prescribed through an explicit or implicit grant from the Constitution or Congress.<sup>47</sup> While neither the Constitution nor Congress have explicitly regulated tribal sovereign immunity, Thomas P. McLish asserted that an implicit analysis of both led to the notion that the policies embodied within statutes Congress has passed that related to tribal affairs must serve as the basis for the federal court's

<sup>&</sup>lt;sup>40</sup> U.S. CONST. art. I, § 8, cl. 3.

<sup>&</sup>lt;sup>41</sup> See United States v. Lara, 541 U.S. 193, 200 (2004).

<sup>&</sup>lt;sup>42</sup> Cherokee Nation v. Georgia, 30 U.S. (5 Pet.) 1, 17 (1831); Okla. Tax Comm'n v. Citizen Band Potawatomi Tribe of Okla., 498 U.S. 505, 509 (1991).

Santa Clara Pueblo v. Martinez, 436 U.S. 49, 56 (1978).

<sup>&</sup>lt;sup>44</sup> U.S. CONST. amend. XI.

<sup>&</sup>lt;sup>45</sup> 309 U.S. 506, 512 (1940).

<sup>&</sup>lt;sup>46</sup> Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2045 (2014) (Sotomayor, J., concurring).

<sup>&</sup>lt;sup>47</sup> Martha A. Field, *Sources of Law: The Scope of Federal Common Law*, 99 HARV. L. REV. 883, 895–96 (1986).

extension of tribal immunity from suit.<sup>48</sup> An examination of those statutes yielded McLish's conclusion that the current congressional policy "seeks to encourage tribal cultural autonomy, self-determination and economic security."<sup>49</sup> These policies present a framework for identifying the scope of tribal immunity that will be used in this Comment to assess the Allergan-Saint Regis deal.

Another useful guide for evaluating tribal sovereign immunity is past jurisprudence on the doctrine. In the past, courts accepted that any intent to abrogate tribal immunity must be unequivocally expressed by Congress. Outside of that, only a clear waiver of sovereign immunity by a tribe would suffice and that waiver may not be implied. The Supreme Court has emphasized stare decisis as controlling and that, outside of congressional action, any departure from the doctrine would demand "special justification." This reasoning has stood despite recent limitations on the overall doctrine of tribal sovereignty and a trend toward eliminating the other common law immunities from suit. Lately, the Court has declined to make an exception for commercial activities, even those occurring off tribal reservations, in the face of contentions that tribal business ventures have become so detached from tribal interests that immunity no longer makes sense in the commercial context. Throughout

<sup>&</sup>lt;sup>48</sup> See Thomas P. McLish, *Tribal Sovereign Immunity: Searching for Sensible Limits*, 88 COLUM. L. REV. 173, 181–89 (1988).

<sup>&</sup>lt;sup>19</sup> *Id.* at 184–89.

<sup>&</sup>lt;sup>50</sup> See, e.g., Okla. Tax Comm'n v. Citizen Band Potawatomi Tribe of Okla., 498 U.S. 505, 509 (1991) ("Suits against Indian tribes are thus barred by sovereign immunity absent a clear waiver by the tribe or congressional abrogation.").

Id.

<sup>&</sup>lt;sup>52</sup> Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2037 (2014).

<sup>&</sup>lt;sup>53</sup> See, e.g., In Defense of Tribal Sovereign Immunity, 95 HARV. L. REV. 1058, 1064–68 (1982) (describing several recent court decisions concerning assertions of tribal power over nonmembers and State taxation of tribal businesses located on the reservation as evidence of a narrowing of tribal sovereignty).

Kiowa Tribe of Okla. v. Mfg. Technologies, Inc., 523 U.S. 751, 754–56 (1998) (tribe entitled to immunity from suit on promissory note regardless of whether it was signed on or off the reservation); *Bay Mills*, 134 S. Ct. at 2034 ("[A] State lacks the ability to sue a tribe for illegal gaming when that activity occurs off the reservation."); *Potawatomi*, 498 U.S. at 511 (tribal convenience store operating on land not formally designated as "on reservation" exempt from state cigarette tax); Puyallup Tribe, Inc., v. Dep't of Game of the State of Wash., 433 U.S. 165, 170–73 (1977) (state could not exercise jurisdiction over Tribe to

these decisions, the Court has held that even in their own view of the merits, the courts will "defer to the role Congress may wish to exercise in this important judgment."<sup>55</sup>

Despite this apparent steadfastness, judicial support for the doctrine of tribal immunity has begun to waiver. In Puyallup Tribe, Inc. v. Department of Game of Washington, Justice Blackmun stated in his concurring opinion that the doctrine "may well merit re-examination in an appropriate case."56 Additionally, in Kiowa Tribe of Oklahoma v. Manufacturing Technologies, Inc., the majority opinion acknowledged the merits behind "doubt[ing] the wisdom of perpetuating the doctrine."57 In the recently decided Michigan v. Bay Mills Indian Community, tribal sovereign immunity narrowly emerged unscathed after four justices voted to curb the doctrine.<sup>58</sup> As a part of that decision, Justice Thomas wrote a powerful dissent that advocated for *Kiowa*'s overruling on the basis that the policy rationales for the immunity doctrine and deference to Congress do not apply to *Kiowa*'s "unjustifiable rule and its mounting consequences."<sup>59</sup> Thomas's reasoning in his dissent helped form the basis of this Comment's ultimate resolution in Part III that the Court should have amended tribal sovereign immunity to alleviate the problems the doctrine now poses for modern society.

#### C. Native American Tribes Today

Any discussion of tribal sovereign immunity and the Allergan-Saint Regis deal should consider the current economic position of Native American tribes in the United States today. In light of the congressional policy to promote tribal economic self-sufficiency, "tribal business operations are critical . . . because such enterprises in some cases 'may be the only means by which a tribe can raise revenues." On its face, the economy of American Indian tribes seems to be doing well, especially in the gambling industry where

assess penalties related to regulation of their fishing activities on or off the reservation).

<sup>&</sup>lt;sup>55</sup> *Kiowa*, 523 U.S. at 758.

<sup>&</sup>lt;sup>56</sup> *Puyallup*, 433 U.S. at 178–179 (Blackmun, J., concurring) (entertaining doubts of the doctrine's "continuing vitality").

<sup>&</sup>lt;sup>57</sup> *Kiowa*, 523 U.S. at 758.

<sup>&</sup>lt;sup>58</sup> *See Bay Mills*, 134 S. Ct. at 2024.

<sup>&</sup>lt;sup>59</sup> *Id.* at 2045–56 (Thomas, J., dissenting).

<sup>60</sup> *Id.* at 2043 (Sotomayor, J., concurring) (citation omitted).

gaming revenues have increased from \$8.5 billion in 1998 to \$27.9 billion in 2012.<sup>61</sup> Outside of the gambling industry, tribes have engaged in on-reservation commercial activities like "tourism, recreation, mining, forestry and agriculture" as well as expanded off-reservation to domestic and international ventures including cigarettes, foreign financing, national banks, cement plants, ski resorts, and hotels.<sup>62</sup>

Still, a look behind the curtain will reveal that the economic position of tribes is not what one might envision, especially when it comes to gaming revenue from casinos. 63 Only forty-two percent (42%) of the federally recognized Native American tribes in the United States operate gambling enterprises.<sup>64</sup> Of those facilities tribes are operating, twenty percent (20%) of them are raking in seventy percent (70%) of the total gaming revenues.<sup>65</sup> This casts a shadow over the popular idea that all American Indian tribes are lining their coffers with casino riches and reveals the darker reality a few tribes are profiting from gaming while many tribal governments struggle to find ways to bring in revenue for their constituents. These efforts have been complicated by federal laws and court decisions that have served to limit tribal sovereign immunity and broaden government jurisdiction over tribal reservations. 66 The Supreme Court has allowed states to impose taxes on cigarette sales to non-Indians, 67 non-Indian businesses, 68 and property owned by non-Indians<sup>69</sup> that are on Native American lands and normally would act

<sup>61</sup> *Id.* at 2050 (Thomas, J., dissenting).

<sup>62</sup> *Id.* at 2050–51.

<sup>&</sup>lt;sup>63</sup> See Gregory Ablavsky, *Tribal Sovereign Immunity and Patent Law*, WRITTEN DESCRIPTION (Sept. 13, 2017, 12:42 AM), https://writtendescription.blogspot.com/2017/09/tribal-sovereign-immunity-and-patent-law.html (stating that, contrary to popular belief, "Indian gaming revenue is spread very unevenly, with only a handful of well-situated tribes bringing in large sums").

<sup>&</sup>lt;sup>64</sup> Bay Mills, 134 S. Ct. at 2043 (Sotomayor, J., concurring).

<sup>65</sup> *Id*.

<sup>66</sup> See In Defense of Tribal Sovereign Immunity, supra note 53, at 1062–68 (describing what the author deems as "the demise of tribal immunity" based on legislative and judicial actions that limited tribal sovereign immunity).

<sup>&</sup>lt;sup>67</sup> See generally, Washington v. Confederated Tribes of the Colville Indian Reservation, 447 U.S. 134, 152–54 (1980).

<sup>&</sup>lt;sup>68</sup> See Ariz. Dep't of Revenue v. Blaze Constr. Co., Inc., 526 U.S. 32, 36–39 (1999).

<sup>&</sup>lt;sup>69</sup> See generally, Thomas v. Gay, 169 U.S. 264, 281–84 (1898).

as a revenue source for tribal governments. The effects have been further compounded by congressional acts such as the Dawes Act, which resulted in almost 150 million acres of American Indian reservation lands to be owned by non-Indians in an effort to encourage tribal assimilation within American society.<sup>70</sup>

As a result of these legal developments, tribal leaders face a tough choice—either subject individuals and businesses that choose to settle on reservation lands to double taxation or limit their tribe's own ability to generate revenue. 71 These funds could be used to assist constituencies that are in desperate need because Native Americans are still feeling the effects of hundreds of years of colonialization, violence, and persecution.<sup>72</sup> In the third quarter of 2014, the unemployment rate among Native Americans sat at 11%, which was about twice the national average of 6.2%. <sup>73</sup> Over one in four Native Americans lived in poverty at the time and their labor force participation rate (a statistic that measures the percentage of adults that are either working or looking for a job) was 61.6%—the lowest for all race and minority groups. 74 From an educational standpoint, 52% of the 14,217 Native American students that took the ACT in 2013 failed to meet any of the college readiness benchmarks in the exam's four core subjects.<sup>75</sup>

All of these factors likely contribute to the heightened level of criminal activity amongst American Indian peoples identified in a study conducted by the U.S. Department of Justice between the years of 1992 and 2002.<sup>76</sup> According to the study, the rate of violent victimization per 1,000 persons age twelve or older amongst American Indians was over twice the rate of any other race within the

<sup>&</sup>lt;sup>70</sup> Bay Mills, 134 S. Ct. at 2044 (Sotomayor, J., concurring).

Ablavsky, *supra* note 63.

<sup>72</sup> See id

<sup>&</sup>lt;sup>73</sup> Katharine Peralta, *Native Americans Left Behind in the Economic Recovery*, U.S. NEWS & WORLD REP. (Nov. 27, 2014, 7:00 AM), https://www.usnews.com/news/articles/2014/11/27/native-americans-left-behind-in-the-economic-recovery.

<sup>&</sup>lt;sup>74</sup> *Id*.

<sup>&</sup>lt;sup>75</sup> Allie Bidwell, *Are American Indian Students the Least Prepared for College?*, U.S. NEWS & WORLD REP.: DATA MINE (Mar. 13, 2014, 3:29 PM), https://www.usnews.com/news/blogs/data-mine/2014/03/13/are-american-indian-students-the-least-prepared-for-college.

<sup>&</sup>lt;sup>76</sup> U.S. Dep't of Justice, A BJS Statistical Profile, 1992–2002: American Indians and Crime (2004).

United States.<sup>77</sup> Further, as offenders, American Indians had an arrest rate for alcohol violations that was twice the national rate, were investigated and convicted for a higher rate of violent crimes than all other races, and experienced an influx of gang activity within Indian communities.<sup>78</sup>

In light of these circumstances, it is not difficult to ascertain why the Saint Regis Mohawk Tribe and others like it, in an effort to overcome their economic and social disadvantages, might want to engage in this type of transaction with Allergan. The Saint Regis Tribe planned to use the revenues generated from Allergan's royalty payments and potential resulting deals with other companies to invest in the Tribe's "many unmet needs."<sup>79</sup> Other than Allergan, the Tribe has taken ownership of a technology company's patents that it expects will earn a significant amount of money through pursuit of infringement suits in federal court. 80 Saint Regis's tactic had already begun to gain traction within the tribal community, as MEC Resources, a company owned by the Mandan, Hidatsa, and Arkikara Nation, (otherwise known as the Three Affiliated Tribes) became a plaintiff in an infringement suit against Apple for a recently purchased patent that the company claims Apple's iPad 4 infringes upon. 81 Similar to Saint Regis, MEC Resources claimed sovereign immunity to avoid IPR by the U.S. Patent Office and sued Apple in federal court seeking royalty payments generated from the iPad's sales. 82 This additional action provides just a small illustration of the importance the PTAB and lawmakers' responses to Allergan's attempt to house its patents within the protective confines of tribal sovereign immunity has on both the intellectual property world and the broader American economy.<sup>83</sup>

#### II. ANALYSIS OF THE ALLERGAN-SAINT REGIS CASE

This Comment analyzes the two main points of contention in the case against Allergan and the Saint Regis Mohawk Tribe today. The

<sup>&</sup>lt;sup>77</sup> *Id.* at 4.

<sup>&</sup>lt;sup>78</sup> *Id.* at 17–21.

<sup>&</sup>lt;sup>79</sup> Thomas, *supra* note 1.

<sup>80</sup> Mullin, *supra* note 6.

<sup>81</sup> *Id* 

<sup>&</sup>lt;sup>82</sup> *Id*.

<sup>83</sup> See Thomas, supra note 1.

first, whether or not Saint Regis's sovereign immunity defense can apply to IPR, is the threshold question that must be answered because it can bar the PTAB from taking any action concerning the Restasis patent. Even if it were held that tribal sovereign immunity from suit does apply, the Allergan-Saint Regis deal could be voided if a court were to hold that the deal was a sham transaction. However, this Comment asserts that, because of the potential far-reaching ramifications that can result from a decision on this issue and the limited design of IPR, the PTAB was not the appropriate forum for adjudication on this matter. Instead, the Board should have refrained from deciding the case and deferred to the federal courts for guidance. At the federal level, the courts could have issued a proper ruling that would have had uniform application across the law to prevent schemes of the Allergan-Saint Regis deal's ilk in the future. Additionally, such a ruling would have allowed the Supreme Court of the United States the opportunity to address the growing problem created by tribal sovereign immunity's breadth.

#### A. The Saint Regis Mohawk Tribe Should Be Entitled to Assert a Sovereign Immunity Defense to the Institution of an IPR of Its Patent

The Supreme Court of the United States regards Native American tribes' immunity from suit as one of the core aspects of sovereignty that a tribe possesses.<sup>84</sup> In the past, the Court repeatedly dismissed any suit against a tribe that was without either an express authorization from Congress or an express waiver from the tribe.<sup>85</sup> The Court has also declined to make any exception to this tribal immunity notion for suits that arise from any of a tribe's commercial activities—even those that take place off of tribal lands.<sup>86</sup>

# 1. THE PTAB SHOULD HAVE VIEWED THIS CASE IN THE SCOPE OF ITS PRIOR STATE SOVEREIGN IMMUNITY DEFENSE DECISIONS AGAINST IPR

The issues presented in this case compare to prior PTAB decisions that addressed the applicability of state sovereign immunity

<sup>&</sup>lt;sup>84</sup> Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2030 (2014).

<sup>85</sup> Kiowa Tribe of Okla. v. Mfg. Technologies, Inc., 523 U.S. 751, 754 (1998).

<sup>86</sup> Id. at 760.

defenses in IPR proceedings. As an initial aside, a distinction between state and tribal sovereign immunity includes the fact that state sovereign immunity from suit is codified in the Eleventh Amendment and tribal sovereign immunity finds its roots in federal common law.<sup>87</sup> While these doctrinal differences make the PTAB decisions regarding state immunity non-binding, that should not disprove their relevance to the issue at hand. The Supreme Court has repeatedly characterized Indian tribes as "domestic dependent nations" in its decisions because, like the States, the tribes are separate governments located within the country and subject to the control of Congress.<sup>88</sup> In fact, the Supreme Court has accepted past arguments that tribal immunity from suit is in some senses more powerful than the States' immunities because the Native American tribes were not a party to the Constitutional Convention where each state surrendered their immunities from state-initiated suits.<sup>89</sup>

The Supreme Court strengthened state sovereign immunity from suit in *Federal Maritime Commission v. South Carolina State Ports Authority (FMC)* when it held that the immunity's protections extend to certain adjudicatory proceedings conducted before federal agencies. <sup>90</sup> According to the Court, the central purpose of a State's sovereign immunity is to give states the respect they are owed as joint sovereigns. <sup>91</sup> Similarly, the comity justification was the reasoning the Court attributed to its development of the tribal sovereignty doctrine. <sup>92</sup> Following *FMC*, the PTAB applied the Court's holding in its decisions to dismiss challenges against state institutions in IPR proceedings. <sup>93</sup>

While Saint Regis's use of a tribal sovereign immunity defense against IPR was uncharted territory for decision makers on the

<sup>87</sup> See supra notes 44–46 and accompanying text.

<sup>88</sup> See cases cited supra notes 41–43.

<sup>89</sup> See Blatchford v. Native Vill. of Noatak, 501 U.S. 775, 782 (1991).

<sup>&</sup>lt;sup>90</sup> Fed. Mar. Comm'n v. S.C. State Port Auth., 535 U.S. 743, 760 (2002).

<sup>&</sup>lt;sup>91</sup> *Id.* at 765 ("[T]he doctrine's central purpose is to 'accord the States the respect owed them as' joint sovereigns.").

<sup>&</sup>lt;sup>92</sup> See supra note 45 and accompanying text.

<sup>&</sup>lt;sup>93</sup> See generally Covidien LP v. Univ. of Fla. Research Found. Inc., No. IPR2016-1274, Paper 21 (P.T.A.B. Jan. 25, 2017); Neochord, Inc. v. Univ. of Md., No. IPR2016-208, Paper 28 (P.T.A.B. May 23, 2017); Reactive Surfaces Ltd. v. Toyota Motor Corp., No. IPR2016-1914, Paper 36 (P.T.A.B. July 13, 2017).

Board, the PTAB's past decisions in Covidien LP v. University of Florida Research Foundation, Inc., 94 Neochord, Inc. v. University of Maryland, 95 and Reactive Surfaces Ltd. v. Toyota Motor Corp. 96 presented an instructive framework the Board could have used in deciding the case. Instead, the Board chose to differentiate between the two types of sovereignty when it held that tribal immunity did not apply to IPR.<sup>97</sup> First, the Board referenced the Supreme Court's dicta in Kiowa that "the immunity possessed by Indian Tribes is not co-extensive with that of the States."98 Despite Saint Regis's attempts to apply the holding of FMC to the proceeding, the Board found that the Tribe had not presented any federal court or Board precedent to suggest that FMC should be applied to assertions of tribal sovereign immunity in similar federal administrative proceedings. 99 The Board further discussed tribal sovereignty's subjectivity to Congress's plenary control and the applicability of general Acts of Congress-such as the Patent Act and the IPR proceedings included within its scope—to American Indians. 100 Finally, the Board stated that because it claimed personal jurisdiction over only the challenged patents and not the patent owners themselves, the Board was outside the reach of the protections granted by tribal sovereign immunity.<sup>101</sup>

While the Board presented fair points when it explained the reasoning behind its decision, its logic does not exactly hold water. For

<sup>&</sup>lt;sup>94</sup> Covidien, No. IPR2016-1274, Paper 21, at 17–27 (applying *FMC* framework and finding that, considering the nature of IPR and the Board rules and procedures governing the review process, IPR resembled civil litigation sufficiently enough to find that Eleventh Amendment immunity barred IPR against an unconsenting state)

<sup>&</sup>lt;sup>95</sup> Neochord, No. IPR2016-208, Paper 28, at 12 (finding that the University could raise an Eleventh Amendment immunity defense in an IPR proceeding and granting University's motion to dismiss, terminating the review).

<sup>&</sup>lt;sup>96</sup> Reactive Surfaces, No. IPR2016-1914, Paper 36, at 6–11 (relying on the factors identified in *FMC* and dismissing Regents of the University of Minnesota from the action).

<sup>&</sup>lt;sup>97</sup> See generally Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe, No. IPR2016-01127, Paper 130, at 11–18 (P.T.A.B. Feb. 23, 2018).

<sup>&</sup>lt;sup>98</sup> *Id.* at 9 (quoting Kiowa Tribe of Okla. v. Mfg. Technologies, Inc., 523 U.S. 751, 756 (1998)).

<sup>&</sup>lt;sup>99</sup> *Mylan Pharm.*, No. IPR2016-01127, Paper 130, at 8.

<sup>100</sup> *Id.* at 11.

<sup>&</sup>lt;sup>101</sup> *Id.* at 16–17.

instance, the Board could have used the same personal jurisdiction over patents argument as an excuse to not apply state sovereign immunity protections in *Neochord*, *Covidien*, or *Reactive Surfaces* but it did not. Further, the fact that there was no precedent within the federal courts for applying *FMC* to tribal immunity does not mean that the Board should not apply it in such circumstance, only that the courts had not previously considered or decided such an application. It seems instead that the Board, in an understandable effort to comply with its ultimate mission to protect the public interest, made its decision first and then crafted the reasoning behind it later.

## 2. IPR: AN ADJUDICATORY ADMINISTRATIVE PROCEEDING SUBJECT TO TRIBAL SOVEREIGN IMMUNITY PROTECTIONS

In the past, whether or not proceedings conducted by federal agencies fell under the purview of sovereign immunity depended on the nature of the administrative proceeding and its similarities to civil litigation. The Court has noted some of the general similarities between the two:

[F]ederal administrative law requires that agency adjudication contain many of the same safeguards as are available in the judicial process. The proceedings are adversary in nature. They are conducted before a trier of fact insulated from political influence. A party is entitled to present his case by oral or documentary evidence, and the transcript of testimony and exhibits together with the pleadings constitute the exclusive record for decision. The parties are entitled to know the findings and conclusions on all of the issues of fact, law, or discretion presented on the record.<sup>103</sup>

Later, FMC was applied to a matter involving tribal sovereign immunity when the deciding court held that "tribes are entitled to no

<sup>&</sup>lt;sup>102</sup> Fed. Mar. Comm'n v. S.C. State Port Auth., 535 U.S. 743, 753–61 (2002) (comparing Federal Maritime Commission proceedings with civil litigation).

<sup>&</sup>lt;sup>103</sup> Butz v. Economou, 438 U. S. 478, 513 (1978) (internal citations omitted).

less dignity than states with regard to their immunity from administrative action."<sup>104</sup> By this logic, if IPRs were found to be adjudicatory proceedings, then the Saint Regis Mohawk Tribe's sovereign immunity defense would stand.

While Congress originally presented IPR as a quicker and less expensive alternative to district court litigation, a closer look at IPRs—similar to the reviews conducted in the aforementioned line of Eleventh Amendment state sovereign immunity cases—reveals similarities like those that prompted the Court to accept the sovereign immunity defense in FMC. Indeed, Congress specifically identified a shift from an examinational to an adjudicative model as the justification for this alternative when it created the AIA post-grant proceedings. 105 These regulations instructed the Director of the Patent and Trademark Office to create a review process that carried many of the same features as civil litigation, such as discovery, protective orders, the right to an oral hearing, and sanctions for abuse of process or discovery. 106 Like the pleadings in civil litigation proceedings, IPR proceedings are initiated when a person who is not the owner of the patent files a petition for a review of the validity of an existing patent's claims. 107 In their petition, the petitioner must identify the real parties in interest, the claims challenged and the grounds for challenging, along with all relevant documents required for support of their assertions and ultimately carries the burden of proving their assertions. 108

Like civil pleadings, the petition can be met with a preliminary response by the post-institution patent owner that sets reasons a review should not be instituted.<sup>109</sup> This is followed by a later response that can be filed after IPR has been instituted and addresses the claims asserted by the petitioner and the petitioner's accompanying right to file a reply.<sup>110</sup> During discovery, parties may seek a motion for authorization (which authorizes a party to acquire a subpoena from the district court) to compel testimony or produce documents,

<sup>&</sup>lt;sup>104</sup> Great Plains Lending, LLC v. Conn. Dep't of Banking, No. HHBCV156028096S, 2015 WL 9310700, at \*4, (Conn. Super. Ct. 2015).

<sup>&</sup>lt;sup>105</sup> 157 CONG. REC. S1376 (daily ed. Mar. 8, 2011).

<sup>&</sup>lt;sup>106</sup> 35 U.S.C. § 316(a) (2012).

<sup>&</sup>lt;sup>107</sup> *Id.* § 311(a).

<sup>&</sup>lt;sup>108</sup> *Id.* §§ 312, 316(e).

<sup>&</sup>lt;sup>109</sup> *Id.* § 313.

<sup>&</sup>lt;sup>110</sup> 37 C.F.R. §§ 42.120, 42.23 (2018).

which is subject to the Federal Rules of Civil Procedure.<sup>111</sup> Like subpoenas, any evidence provided during the IPR is also governed by the Federal Rules of Evidence.<sup>112</sup> The Director appoints a three-member panel comprised of administrative patent judges from the PTAB to oversee the proceeding.<sup>113</sup> Ultimately, the PTAB issues a final decision on the patentability of any claim challenged by the petitioner.<sup>114</sup>

Additional differences exist between an Article III proceeding and IPR conducted by the PTAB other than those previously identified in Part I. 115 As mentioned previously, IPR involves a re-assessment of the PTO's original grant of a patent unlike the classic "suit" to which tribal sovereign immunity is traditionally applied. 116 While an IPR proceeding's parameters are defined by a private party, it is up to the broad discretion of the Director of the PTO whether to initiate the review.<sup>117</sup> Additionally, the procedures involved in IPR do not mirror the Federal Rules of Civil Procedure. No monetary or injunctive relief is involved in the review of the patent's claims, just the validity of the patent itself. 118 Further, to comport with the ultimate mission of a faster alternative to district court litigation, the duration of the proceedings is limited to one year, with an additional allowance of six months for good cause. 119 Discovery is also limited unless the parties agree to additional discovery or the PTAB grants a motion. 120 Finally, the PTO can continue to review a patent and render a final decision in the event a petitioner is no longer a party to the review.<sup>121</sup>

Despite IPR's adjudicatory characteristics, the Federal Circuit Court of Appeals, in its review of the PTAB's decision, found these differences to be substantial enough to hold that tribal immunity did

```
111 Id. § 42.52; 35 U.S.C. § 24.
```

<sup>&</sup>lt;sup>112</sup> 37 C.F.R. § 42.62.

<sup>&</sup>lt;sup>113</sup> 35 U.S.C. § 6(a).

<sup>114</sup> *Id.* § 318(a); 37 C.F.R. § 42.73.

See supra notes 33–37 and accompanying text.

See supra note 101 and accompanying text.

See Oil States Energy Services v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1371 (2018) (describing the IPR process).

<sup>&</sup>lt;sup>118</sup> See 35 U.S.C. § 318.

<sup>&</sup>lt;sup>119</sup> 37 C.F.R. § 42.100.

<sup>&</sup>lt;sup>120</sup> *Id.* § 42.51.

<sup>&</sup>lt;sup>121</sup> 35 U.S.C. § 317(a).

not extend to administrative agency reconsideration decisions of this kind. 122 However, this Comment respectfully disagrees with this decision and argues that the differences between an Article III proceeding and IPR do not prevent a decision maker from labeling IPR as an adjudication in front of an administrative tribunal. As the Fourth Circuit wrote and the Supreme Court echoed in *FMC*, where the proceeding "walks, talks, and squawks very much like a lawsuit" placing that proceeding "within the Executive Branch cannot blind us to the fact that the proceeding is truly an adjudication."123 In the past. States have been shielded regardless of whether the petitioner prayed for relief in the form of monetary damages or any other kind of relief due to the dignity the state's sovereign status commanded. 124 Further, the Federal Circuit Court of Appeals interestingly chose not to apply FMC because it found that the agency procedures in that proceeding were much closer to civil litigation than those used in IPR, <sup>125</sup> although the PTAB itself clearly did not share the same sentiment when it applied the *FMC* framework to its prior state immunity decisions.

Additionally, application of the tribal sovereign immunity defense comports with the Supreme Court's use of comity as a justification for sovereign immunity and the congressional policy to promote Native American tribe's cultural autonomy, self-actualization, and economic self-sufficiency. Adjudication and invalidation of the Restasis patents would eliminate a potential line of revenue and societal development not just for the Saint Regis Mohawk Tribe, but for all of the tribes in the United States that could follow Saint Regis's lead and make deals with other companies like Allergan. In respect to legal precedent, comity, and Congress, any member of the courts or PTAB tasked with evaluating Saint Regis's motion should have found that—barring other considerations—the tribal sovereign immunity defense applies to IPR and subsequently shields a patent owned by the Saint Regis Mohawk Tribe from review.

<sup>&</sup>lt;sup>122</sup> Saint Regis Mohawk Tribe v. Mylan Pharm., 896 F.3d 1322, 1329 (Fed. Cir. 2018).

<sup>&</sup>lt;sup>123</sup> Cruise S.C. State Ports Auth. v. Fed. Mar. Comm'n, 243 F.3d 165, 174 (4th Cir. 2001), *aff'd*, 535 U.S. 743 (2002).

<sup>&</sup>lt;sup>124</sup> Fed. Mar. Comm'n v. S.C. State Port Auth., 535 U.S. 743, 765 (2002).

<sup>&</sup>lt;sup>125</sup> Saint Regis Mohawk Tribe, 896 F.3d at 1327–29.

See supra notes 46–49 and accompanying text.

#### B. The Validity of the Allergan-Saint Regis Deal

While tribal sovereign immunity should apply to an IPR proceeding, an opportunity exists for a decision maker to bypass the immunity issue entirely. This arises in the event that Allergan's assignment of the Restasis patent rights to the Saint Regis Mohawk Tribe were deemed to be a sham. If so, the decision maker could hold that Allergan was the true owner of the patent, dismiss the Tribe as a party to the proceeding, and evaluate the validity of the patent claims. Historically, parties have made attempts to affect the jurisdiction of the courts through assignments by name only. 127 *Kramer v. Caribbean Mills, Inc.*, 128 the leading case on this kind of jurisdiction tampering, set forth a two-prong test that evaluates (1) whether there was nominal or no consideration involved in the deal; and (2) the interest that the assignor retained after the deal was made. 129

Later cases developed factors to consider the impropriety or collusiveness of an assignment, which include the following: whether there were good business reasons for the assignment; whether the assignee had a prior interest in the item or instead coincided with the litigation; what was the consideration given by the assignee; whether the assignment was partial or complete; and was there an admission that the motive was to affect jurisdiction. Using these factors, an assignment can be rendered ineffective following a decision maker's determination that the assignee was not the real party in interest but "a strawman [who] had no real interest in the outcome of the case, although a good outcome would have had some economic value." 131

Similarly, tribal immunity has been used as a tool in schemes to avoid taxation and other kinds of government interference in the past. Following those instances, judiciaries have maintained that

<sup>&</sup>lt;sup>127</sup> Attorneys Tr. v. Videotape Comput. Prods., Inc., 93 F.3d 593, 595 (9th Cir. 1996).

<sup>&</sup>lt;sup>128</sup> Kramer v. Caribbean Mills, Inc., 394 U.S. 823 (1969).

<sup>&</sup>lt;sup>129</sup> See id. at 827–29; Haskin v. Corporacion Insular de Seguros, 666 F. Supp. 349, 353–54 (D.P.R. 1987).

<sup>&</sup>lt;sup>130</sup> Attorneys Tr., 93 F. 3d at 595–96.

<sup>&</sup>lt;sup>131</sup> Id. at 598.

See generally Barona Band of Mission Indians v. Yee, 528 F.3d 1184 (9th Cir. 2017) (devising contract to render construction materials purchased by non-Indian subcontractor exempt from state sales taxes); Otoe-Missouria Tribe v. N.Y. State Dep't of Fin. Services, 769 F.3d 105 (2d Cir. 2014) (payday lending

federal Indian law does not authorize tribes to market their immunities and exemptions to businesses that normally would take their activities elsewhere. <sup>133</sup> As such, the validity of the Allergan-Saint Regis transaction can be properly judged following a determination of the "real party in interest," which involves an examination of the economic substance of the deal to reveal the party that would truly be affected by any remedy. <sup>134</sup>

## 1. ALLERGAN WAS THE REAL PARTY IN INTEREST IN THE ALLERGAN-SAINT REGIS DEAL

Evaluation of whether the Allergan-Saint Regis deal was a bonafide transaction begs consideration of the "real party in interest" in light of the *Kramer* sham test and its accompanying factors. <sup>135</sup> "[T]he fact that a patent owner has retained a right to a portion of the proceeds of the commercial exploitation of the patent . . . does not necessarily defeat what would otherwise be a transfer of all substantial rights of the patent. "<sup>136</sup>

Allergan announced its deal to assign the rights to its Restasis drug patents to the Saint Regis Mohawk tribe on September 8, 2017—following the start of proceedings in federal district courts and the petition for IPR made by Mylan Pharmaceuticals. Previously, Saint Regis had no involvement in the development or commercialization of the drug. The terms of the agreement entailed the Tribe's grant of an exclusive license of the Restasis patents back to Allergan to practice the patents in the United States for all uses approved by the Food Drug Administration ("FDA") without any reversionary rights on behalf of the Tribe. The Tribe stood to receive \$13.5 million up front and \$15 million in annual royalty payments from Allergan for Restasis sales over the patents' remaining

schemes); Washington v. Confederated Tribes of the Colville Indian Reservation, 447 U.S. 134, 152–54 (1980) (marketing exemption from statewide cigarette tax).

<sup>&</sup>lt;sup>133</sup> Colville, 447 U.S. at 155.

<sup>&</sup>lt;sup>134</sup> Lewis v. Clarke, 137 S. Ct. 1285, 1290–92 (2017).

<sup>135</sup> *Id.*; see supra note 129 and accompanying text.

<sup>&</sup>lt;sup>136</sup> Propat Int'l Corp. v. RPost, Inc., 473 F.3d 1187,1191 (Fed. Cir. 2007).

<sup>&</sup>lt;sup>137</sup> Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4619790, at \*1 (E.D. Tex. Oct. 16, 2017).

See id.; see also Thomas, supra note 1 ("[T]he Mohawk tribe played no role in developing the drug.").

<sup>&</sup>lt;sup>139</sup> Allergan, 2017 WL 4619790, at \*3-\*4.

duration.<sup>140</sup> Additionally, Allergan had the first right to sue for any infringement that relates to a generic equivalent as well as the right to grant any further sublicenses.<sup>141</sup> The Tribe retained all of the other rights to the patent's practice outside of the aforementioned FDA-approved uses, including the right to use the patents for research, education, and other non-commercial uses as well as the first right to sue third parties in matters not related to Restasis bioequivalents.<sup>142</sup>

Despite assigning the patent rights to Saint Regis, Allergan retained complete control over the sales of the Restasis drug—a matter of chief importance to the company. As part of that exclusive licensing agreement for a drug that generates sales of \$1.5 billion dollars a year, the Tribe was slated to be paid one percent (1%) of those earnings in royalties. During court proceedings, Allergan stated that the "consideration for the assignment of the patents to the Tribe was the Tribe's promise not to waive its sovereign immunity with respect to IPR or other administrative action in the PTO related to the patents." Renting immunity from the Tribe in order to continue enjoying the monopolistic protections a patent provides without having to subject said patents to reconsideration of their validity by the PTO does not amount to a legitimate business purpose. 147

The issue presented is analogous to a prior case before the California Supreme Court, where tribal entities were running a payday loan business, and the Court observed that the formal agreements made between the tribes and lending entities did not hide the fact that the tribes retained no operational control over the businesses and received only a small percentage of the ventures' profits before

<sup>&</sup>lt;sup>140</sup> *Id.* at \*1.

<sup>&</sup>lt;sup>141</sup> See id. at \*4.

<sup>142</sup> *Id.* at \*4.

Thomas, *supra* note 1 ("A. Robert D. Bailey, the chief legal officer of Allergan, said . . . 'It's one of our most valuable products, so we can't wait."").

Michael Erman & Tamara Mathias, *Allergan Assuages Shareholder Fears over Losing Restasis Patent*, REUTERS (Nov. 1, 2017, 7:26 AM), https://www.reuters.com/article/us-allergan-results/allergan-assuages-shareholder-fears-overlosing-restasis-patent-idUSKBN1D14HV.

Thomas, *supra* note 1.

<sup>&</sup>lt;sup>146</sup> Allergan, 2017 WL 4619790, at \*2.

<sup>&</sup>lt;sup>147</sup> See Airlines Reporting Corp. v. S & N Travel, Inc., 58 F.3d 857, 862–63 (2d Cir. 1995) (facial collusion to affect jurisdiction shifts the required burden to showing "a legitimate business purpose for the assignment").

holding that the tribes could not assert immunity.<sup>148</sup> Allergan's use of formalities to divert attention from the transaction's hollowness amounted to little more than an illusion. Once someone is able to move past the smoke and mirrors of the deal, it is easy to see that the Saint Regis Mohawk Tribe provided no real consideration in making this deal and identify Allergan as the real party in interest.

## 2. LEGAL PRECEDENT AND THE PUBLIC INTEREST CATERED TOWARD INVALIDATION OF THE AGREEMENT

Transactions similar to the Allergan-Saint Regis deal have been historically disregarded when they run contrary to the policies underlying relevant laws. 149 Originally, Congress developed the patent system as a way to spur innovation by incentivizing research and development that would not normally occur absent some form of protection. 150 IPR was later introduced as a way to re-examine an earlier agency decision to issue a patent that in retrospect should not have been issued. 151 By doing so, the government can better protect the delicate balance between incentivizing development and creating monopolies that the patent process naturally created and comport with the public's "paramount interest in seeing that patent monopolies . . . are kept within legitimate scope." <sup>152</sup> Allergan benefited from the patent system's protections, made billions off of the Restasis patent, and then sought to continue doing so without honoring the system's limitations that were built in as safeguards. 153 IPR emerged as a threat to the existence drug companies have built as they engaged in a system of abusive tactics aimed at manipulating markets, suppressing the competition, and charging higher prices to

<sup>&</sup>lt;sup>148</sup> See People ex rel. Owen v. Miami Nation Enter., 386 P.3d 357, 376–79 (Cal. 2016).

<sup>&</sup>lt;sup>149</sup> Allergan, 2017 WL 4619790, at \*3 (comparing the circumstances surrounding the Allergan-Saint Regis deal to tax shelter schemes that were labeled as sham transactions and disregarded when held to be against public policy).

<sup>&</sup>lt;sup>150</sup> See Costa, supra note 24, at 181.

<sup>&</sup>lt;sup>151</sup> Cuozzo Speed Technologies, LLC v. Lee, 136 S. Ct. 2131, 2144 (2016).

<sup>&</sup>lt;sup>152</sup> *Id.*; Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234 (1892) (discussing the importance "to the public that competition should not be repressed by worthless patents."); Megan M. La Belle, *Patent Litigation, Personal Jurisdiction, and the Public Good*, 18 GEO. MASON L. REV. 43, 51 (2010) (stating that an invalid patent "reduces the overall value of patent protection and undermines the public's confidence in the patent system at large").

<sup>&</sup>lt;sup>153</sup> Allergan, 2017 WL 4619790, at \*2.

the public.<sup>154</sup> The Allergan deal received so much attention because, assuming its strategy to purchase "a legal loophole in the cloak of tribal sovereignty"<sup>155</sup> were successful, the company would have provided a blueprint for patent owners across all industries to undermine the entire patent system and, subsequently, the American markets.<sup>156</sup> Prior instances like this have inspired the Court to state that public welfare demands the PTO to not sit idly by in the face of wrongly issued patents and deceptive tactics.<sup>157</sup>

While the federal courts have traditionally looked to congressional policies that promote the tribes and emphasized respect of tribal sovereignty, they have also been keen to prevent the tribes' abuse of those protections in an effort to "alter the economic reality of a transaction . . . to reap a windfall at the public's expense." <sup>158</sup> Following the decisions made in regard to tribal proliferation of payday lending and tax evasion schemes, the Second Circuit Court of Appeals made a very clear statement: tribes do not have a "legitimate interest in selling an opportunity to evade the law" to non-Indians. 159 In fact, this case is very similar to Washington v. Confederated Tribes of the Colville Indian Reservation, which went before the Supreme Court. 160 There, the Court approved Washington's application of a statewide cigarette tax to the tribe's on-reservation cigarette sales to non-Indians, stating that the principles behind Native American law did not "authorize Indian tribes thus to market an exemption from state taxation to persons who would normally do their business elsewhere." 161 Like in Colville, although the result of invalidation of the Allergan-Saint Regis deal eliminates the potential for tribal commerce with other companies looking to shield their

<sup>&</sup>lt;sup>154</sup> See Costa, supra note 24, at 184–91.

Otoe-Missouria Tribe v. N.Y. State Dep't of Fin. Services, 769 F.3d 105, 114 (2d Cir. 2014).

<sup>&</sup>lt;sup>156</sup> Allergan, 2017 WL 4619790, at \*2.

Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 246 (1944) (explaining that a wrongly issued patent does not solely concern those private parties but "[t]he public welfare demands that the agencies of the public justice be not so impotent that they must always be mute and helpless victims of deception and fraud").

<sup>&</sup>lt;sup>158</sup> Barona Band of Mission Indians v. Yee, 528 F.3d 1184, 1190 (2017).

<sup>&</sup>lt;sup>159</sup> *Otoe-Missouria*, 769 F.3d at 114–116.

Washington v. Confederated Tribes of the Colville Indian Reservation, 447
 U.S. 134 (1980).

<sup>&</sup>lt;sup>161</sup> *Id.* at 155.

patents, the market for these types of assignments only existed in the first place because of Saint Regis's claimed exemption of immunity. 162

# 3. WEIGHT SHOULD HAVE BEEN ACCORDED TO SAINT REGIS'S SUBSTANTIAL RIGHTS CLAIMS AND ITS INTEREST AS AN INDISPENSABLE PARTY

Although the FDA-approved sales of Restasis are the main part of the patent's worth to Allergan, that does not preclude the Tribe from showing the substantiality of the rights they retained after granting the exclusive-license in the Restasis patents to Allergan. If the Tribe could show that it retained substantial rights in those patents, Saint Regis would then be a necessary party to the action and thus, the validity of any PTAB decision made concerning the validity of the Restasis patent or Allergan-Saint Regis deal with only Allergan present would be subject to challenge. 163 Aside from the royalties stemming from the exclusive license, it was argued at the Texas district court that Saint Regis's retained right to sue third parties not related to Restasis bioequivalents and the right to practice the Restasis patents for research, education, and other non-commercial uses were substantial, prompting a decision by the court to join Saint Regis as a plaintiff. 164 This sentiment was not echoed by the PTAB, which dismissed Saint Regis from the action under the reasoning that Allergan had at least an identical, if not increased, interest in defending the validity of the Restasis patent. 165 This Comment argues that decision was a mistake.

Unquestionably, tribal governments have been placed in a position where they must undertake innovative methods to generate rev-

<sup>&</sup>lt;sup>162</sup> See id. at 157.

See Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4619790, at \*3 (E.D. Tex. Oct. 16, 2017).

<sup>164</sup> Id. at \*4 (adopting the "safer course of joining the Tribe as a co-plaintiff, while leaving the question of the validity of the assignment to be decided in the IPR proceedings").

<sup>&</sup>lt;sup>165</sup> Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe, No. IPR2016-01127, Paper 130, at 37–39 (P.T.A.B. Feb. 23, 2018).

enue in order to serve their constituents and improve their communities. 166 For the Saint Regis Mohawk Tribe, the Allergan deal alone—and the yearly royalties it offered—provided a substantial boost to their annual budget of \$50 million. 167 In addition to Allergan, the Tribe hired a firm to vet patents from other companies and refer them to the Tribe along with recommendations for potential business uses. 168 While the Tribe planned to use those patents in infringement litigation at the federal courthouse, it also opened an Office of Technology, Research and Patents whose purpose is to encourage research and development in the fields of science and technology. 169 Further, the Office hopes to foster education of Mohawk children in the fields of science, technology, engineering and math in an effort to create revenue, jobs, and new economic development opportunities. 170 This lends credence to the notion that the rights retained by the Tribe in the Allergan deal were not empty. The Tribe would have had no need for the Office if its purpose was to sit idly by and cash the Restasis royalty checks it receives from Allergan. Instead, the Tribe viewed this line of business as a way to truly help its people. This is primarily why—after examination and consideration of all the relevant documents—the judge at the district court considered the question of whether Saint Regis had retained any substantial patent rights to be a close one.<sup>171</sup>

Further, importance can also be assigned to the accepted premise that the Tribe is an indispensable party in any proceeding that will evaluate their contractual agreement with Allergan.<sup>172</sup> Courts have previously held that a "[t]ribe's interests in its status, its sovereignty,

See supra Section I.C.; Ablavsky, supra note 63 ("Tribal leaders are understandably anxious to make deals that will bring much-needed jobs and money to places that have long lacked both.").

Thomas, *supra* note 1.

<sup>&</sup>lt;sup>168</sup> Id

<sup>&</sup>lt;sup>169</sup> SRMT Office of Technology, Research and Patents Information, SAINT REGIS MOHAWK TRIBE, https://www.srmt-nsn.gov/\_uploads/site\_files/OTRAP-Website-Blurb.pdf (last visited Mar. 24, 2019).

<sup>&</sup>lt;sup>170</sup> *Id*.

Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4619790, at \*4 (E.D. Tex. Oct. 16, 2017).

Lomayaktewa v. Hathaway, 520 F.2d 1324, 1325 (9th Cir. 1975) ("No procedural principle is more deeply imbedded in the common law than that, in an action to set aside a lease or a contract, all parties who may be affected by the determination of the action are indispensable.").

its beneficial interests in real property, and its contractual interests cannot be adjudicated without its formal presence."<sup>173</sup> Like the prejudiced tribe in *Lomayaktewa v. Hathaway*, the Saint Regis Tribe had significant property interests at stake in its rights to ownership of the patents and subsequent royalty streams from the license agreement with Allergan, as well as its ability as a sovereign to enter into valid contracts.<sup>174</sup>

Further, it is unlikely that Allergan was able to adequately capture the interests of the Saint Regis Tribe in any adjudication over the validity of the contract and the substantiality of the patent rights the Tribe retained post-license. As a company, Allergan's main obligations are to its shareholders. On the other hand, the Tribe is uniquely responsible for the best interests of its Native American citizens and furthering its economic development in order to benefit its community. As such, the Tribe's ability to represent itself in these proceedings touched the congressional policy interests of cultural autonomy, self-determination, and economic self-sufficiency. 175 In light of these considerations, it would have been reasonable for a decision maker to come to the conclusion that the Tribe would be prejudiced if a final judgment on the Restasis patent and the validity of the Allergan-Saint Regis agreement was rendered without the Tribe's presence at an adjudication to which it consented to be a party.

## C. The PTAB Should Have Issued a Stay and Deferred to the Federal Courts for Guidance

The PTAB chose to bypass rendering a decision on the validity of the Allergan-Saint Regis transactions when it held both that the Tribe was not entitled to assert its immunities at their proceedings and that it was not an indispensable party. Instead, it arrived at that decision by differentiating tribal sovereign immunity from that of

<sup>&</sup>lt;sup>173</sup> Jamul Action Comm. v. Chaudhuri, 200 F. Supp. 3d 1042, 1049 (E.D. Cal. 2016); 25 U.S.C. § 4301 (2012) ("Indian tribes retain the right to enter into contracts and agreements to trade freely.").

<sup>174</sup> Lomayaktewa, 520 F.2d at 1326–27 (holding that Tribe's royalties under a lease and the impact the lease's cancellation would have on the community were sufficient to support a finding of prejudice and indispensability).

Enter Mgmt. Consultants, Inc. v. United States, 883 F.2d 890, 894 (10th Cir. 1989) ("The Tribe's interest [is] in its sovereign right not to have its legal duties judicially determined without consent.").

the states, emphasizing the existence of their jurisdiction over patents themselves, and holding that under the deal's terms Allergan remained the effective owner of the Restasis patent so the proceedings could continue absent participation of the Tribe. However, after consideration of the circumstances, an alternate decision to stay proceedings at the PTO and allow the case to play out in the federal courts was the best course of action for all of the stakeholders that stand to be affected by this issue.

Adjudicating issues that either have potential to or affirmatively do involve tribal sovereignty submerge the Board in an evaluative inquiry of tribal motivations and the policies that surround the idea of tribal economic development.<sup>177</sup> This is an arena that requires vastly different expertise than what is required to evaluate those patent challenges based on prior art and obviousness over which Board members have been granted statutory jurisdiction.<sup>178</sup> In light of this, the potential of the Board's decision to inappropriately affect Native American sovereignty—a complex doctrine that has received heavy congressional and judicial attention—and the ripple effects that decision may produce should have encouraged the PTAB to tread with caution.<sup>179</sup>

Procedurally, the design of IPR restricts the Board's ability to properly decide on this issue. To start, the compressed time schedule<sup>180</sup> and limited discovery afforded to parties<sup>181</sup> in IPR may be efficient for review of patent validity disputes between two parties, but this issue merits a full inquiry and discovery process that would

<sup>&</sup>lt;sup>176</sup> Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe, No. IPR2016-01127, Paper 130 (P.T.A.B. Feb. 23, 2018).

<sup>&</sup>lt;sup>177</sup> See Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2043 (2014) (Sotomayor, J., concurring).

<sup>&</sup>lt;sup>178</sup> See 35 U.S.C. §§ 311(b), 103 (2012).

<sup>179</sup> See Greene v. McElroy, 360 U.S. 474, 507 (1959) (absent explicit authorization from Congress, decisions of "great constitutional import and effect" are outside an administrator's decision-making authority); see also King v. Burwell, 135 S. Ct. 2480, 2489 (2015) (holding that the Internal Revenue Service was not equipped to address questions that involved profound "economic and political significance" stemming from the Affordable Care Act).

<sup>&</sup>lt;sup>180</sup> See 37 C.F.R. § 42.100 (2018).

<sup>&</sup>lt;sup>181</sup> *Id.* § 42.51 (covering mandatory disclosures, routine discovery and production of additional documents); *id.* § 42.52 (discussing procedure for compelling testimony and production).

likely stretch the time-pressed PTAB thin. Any decision on this momentous issue carries the potential of far-reaching ramifications and therefore, anything less than a complete factual determination may prejudice all parties involved. Additionally, the decision reached by the PTAB on the Allergan-Saint Regis deal is not likely to be binding, given that the PTO rarely labels opinions as precedential for all other future patent validity reviews in front of the PTAB. Uniform and consistent action by the PTO in regard to tribal patent assignments and immunity defenses is required to avoid serial assertions and challenges to sovereign immunity that themselves could undermine the patent validity review process. 183

The PTAB decision on a matter of this much importance was hasty given the fact there were actions pending in other forums that could drastically impact both IPR and tribal sovereign immunity. Shortly after the announcement of the Allergan-Saint Regis deal, Senator Claire McCaskill introduced a bill that would abrogate Indian Tribes' ability to assert a sovereign immunity defense in IPR. 184 Any mention of State sovereign immunity assertions is noticeably absent from the bill, meaning its passage is unlikely because it would do little to eliminate the threat of assertions of sovereign immunity at the PTAB and carries with it the opportunity for Native Americans to assert that they have been discriminated against. 185 Still, the bill shows that lawmakers on Capitol Hill are cognizant of the matter and serves as an indicator that Congress—the preeminent authority on Indian affairs—is considering abrogation of tribal sovereign immunity.

Saurabh Vishnubhakat, *Precedent and Process in the Patent Trial and Appeal Board*, PATENTLYO (May 10, 2016), https://patentlyo.com/patent/2016/05/precedent-process-patent.html (discussing the designation of five opinions as precedential in 2016 and the rarity of the designation since only three had been given the label in the prior twenty-two months).

<sup>&</sup>lt;sup>183</sup> See Mullin, supra note 6 (describing how the Allergan-Saint Regis strategy of transferring patents to Native American tribes could result in a reshaping of the intellectual property landscape as patent holders would transfer their whole patent portfolios to tribes).

<sup>&</sup>lt;sup>184</sup> S. 1948, 115th Cong. (2017).

Gene Quinn, Senator McCaskill Introduces Bill to Abrogate Native American Sovereign Immunity, IPWATCHDOG (Oct. 5, 2017), http://www.ipwatchdog.com/2017/10/05/senator-mccaskill-legislation-abrogate-native-american-sovereign-immunity/id=88975/.

Additionally, the constitutionality of the entire patent review process was recently argued in front of the Supreme Court<sup>186</sup> in what became one of two landmark patent decisions issued by the Court in 2018.<sup>187</sup> A prospective lame-duck PTAB issuing a decision on the Allergan-Saint Regis patent rights is contrary to public interest and carries the potential of being the final nail in PTAB's coffin, since any perception by the Court that the Board overstepped its authority could tip the scales and result in PTAB's invalidation. In 2018, Allergan initiated an infringement action in the Eastern District of Texas against the generic drug companies.<sup>188</sup> At the conclusion of the proceedings, the Court joined the Saint Regis Mohawk Tribe as a co-plaintiff but left the question as to the assignment's validity to be decided in the IPR proceedings where it had already been presented.<sup>189</sup>

In light of all of the aforementioned factors, the clear, best course of action by decision makers on the Board was to stay the inter partes proceedings and allow for the issues that precede any validity assessment of the Restasis patents to be adjudicated by the federal district court. In doing so, the PTAB would have simultaneously comported with judicial precedent<sup>190</sup> and been released from the burden of potentially abrogating a Tribe's sovereign immunity absent authority. A case at the federal court level represented the best chance to render a correct decision following an opportunity to compile a complete factual record and develop legal reasoning that comprehend the multitude of factors at play. It also presented an opportunity

<sup>&</sup>lt;sup>186</sup> Jeff John Roberts, *The Supreme Court's Blockbuster Patent Case: What You Need to Know*, FORTUNE (Nov. 27, 2017), http://fortune.com/2017/11/27/supreme-court-patents/.

Renee C. Quinn & Steve Brachmann, *Supreme Court Issues Much Anticipated* Oil States *and* SAS *Decisions*, IPWATCHDOG (Apr. 24, 2018), http://www.ipwatchdog.com/2018/04/24/supreme-court-issues-much-anticipated-oil-states-sas-decisions/id=96302/.

<sup>&</sup>lt;sup>188</sup> Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4619790, at \*1 (E.D. Tex. Oct. 16, 2017).

<sup>&</sup>lt;sup>189</sup> *Id.* at \*4.

Republic of the Philippines v. Pimentel, 553 U.S. 851, 867 (2008) ("A case may not proceed when a required-entity sovereign is not amenable to suit. . . . [W]here sovereign immunity is asserted, and the claims of the sovereign are not frivolous, dismissal of the action must be ordered where there is a potential for injury to the interests of the absent sovereign.").

for the courts to properly address the growing issue of overbroad tribal immunity protections.

These decisions would establish precedent for other courts and administrative decision makers, like the PTAB, to use when facing this issue in the future. Indeed, the PTAB did just that when it used the Supreme Court's ruling in *FMC* to guide its subsequent decisions concerning the applicability of state sovereign immunity to its own IPR proceedings. <sup>191</sup> Instead, the Board eschewed these broader implications when it made a decision that viewed the Allergan-Saint Regis issue through the narrow scope of applicability to its own proceedings.

## III. THE SUPREME COURT SHOULD HAVE SEIZED THE OPPORTUNITY TO AMEND THE DOCTRINE OF TRIBAL SOVEREIGN IMMUNITY

This Comment argues that the PTAB erred when it chose to make its decision on the applicability of tribal immunity to IPR proceedings and Saint Regis's dispensability as a party—a close call in its own right and one that does not address the issue of tribal sovereign immunity's overbroad protections. True, the decision was appealed and affirmed at the U.S. Court of Appeals for the Federal Circuit, but the court also chose not to address the larger tribal sovereign immunity issues in the case and restricted the scope of its review to the Board's decision and reasoning. The Allergan-Saint Regis deal itself—specifically, the threats it posed on the federal patent system and U.S. markets—indicates that the doctrine of tribal immunity has grown to levels that are inconsistent with the congressional policies that underlie it.

Ideally, Congress would address this issue as Congress possesses the power to intervene and legislate over common law. Unfortunately, Congress has failed to take an official stance on the matter. As such, the responsibility for amending tribal sovereignty falls on the Supreme Court. The federal courts' standard for reviewing administrative agency decisions of this kind requires the decisions be set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." In the past, this has

See supra notes 92–96 and accompanying text.

Saint Regis Mohawk Tribe v. Mylan Pharm., 896 F.3d 1322 (Fed. Cir. 2018).

<sup>&</sup>lt;sup>193</sup> 5 U.S.C. § 706 (2012).

occurred following a court's finding that the agency failed to consider a relevant and important factor in making its decision. This would seemingly provide an avenue for the Court to consider the larger impacts that the Allergan-Saint Regis deal would potentially have on American Indian communities and the doctrine of tribal sovereign immunity as a whole, if the Court elected to do so.

As Justice Thomas detailed in his *Bay Mills* dissenting opinion, the doctrine of tribal immunity was a common law creation of the Supreme Court and the Court bears the fault for failing to properly define the immunity's scope. <sup>195</sup> Until Congress does so, "it is up to [the Supreme Court] to correct [its] errors." <sup>196</sup> On the basis of stare decisis, when prior decisions have become unworkable or time has exposed their shortcomings, the public interest demands that precedent be overruled. <sup>197</sup> In *Kiowa*, the Supreme Court extended the doctrine of tribal sovereign immunity to bar suits arising from tribal commercial activities that occurred off of the tribal reservation. <sup>198</sup> While the Court narrowly reaffirmed the *Kiowa* decision on the grounds of comity, stare decisis, and deference to Congress's plenary power over the tribes in *Bay Mills*, Justice Kagan left the door open for a change when she said a special justification would be needed to "overcome all these reasons for this Court to stand pat." <sup>199</sup>

Allergan and Saint Regis had expressed that they were working on a petition of certiorari to the Supreme Court for a ruling on the matter. Saint Regis's use of tribal immunity in an attempt to create a loophole in the U.S. patent system that would pose a threat to the U.S. economy seems to satisfy that "special justification" requirement and, if so, provided the perfect opportunity for the Court to

Dep't of State v. Coombs, 482 F.3d 577, 581 (D.C. Cir. 2007).

<sup>&</sup>lt;sup>195</sup> Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2049–50 (2014) (Thomas, J., dissenting).

<sup>&</sup>lt;sup>196</sup> *Id.*; see Exxon Shipping Co. v. Baker, 554 U.S. 471, 507 (2008) ("[I]f, in the absence of legislation, judicially derived standards leave the door open to outlier punitive-damage awards, it is hard to see how the judiciary can wash its hands of a problem it created, simply by calling quantified standards legislative.").

<sup>&</sup>lt;sup>197</sup> Bay Mills, 134 S. Ct. at 2051.

<sup>&</sup>lt;sup>198</sup> Kiowa Tribe of Okla. v. Mfg. Technologies, Inc., 523 U.S. 751, 758, 760 (1998).

<sup>199</sup> Bay Mills, 134 S. Ct. at 2036 (majority opinion).

Dani Kass, *Allergan, St. Regis Drop 2 Short-Lived Restasis IP Suits*, LAW 360 (Jan. 3, 2019, 8:20 PM), https://www.law360.com/articles/1115088/allergan-st-regis-drop-2-short-lived-restasis-ip-suits.

accept the petition in order revisit the *Kiowa* line of cases. Instead, the Court opted for the easy way out when it denied Allergan and Saint Regis's petition and affirmed the Federal Circuit's ruling—a move that succeeded at striking the Allergan-Saint Regis deal but avoided ruling on the stickier issue of the scope of tribal sovereign immunity.<sup>201</sup>

Rather than absolute immunity from suit that can only be waived by Congress or a tribes' explicit consent, the Court should have amended the doctrine of tribal sovereign immunity to imply a waiver of a tribe's immunity in commercial activities that take place off of the reservation. This would not have changed the ultimate outcome of the PTAB's decision. Alternatively, while the application of the PTAB decision is limited only to IPR proceedings, this hypothetical solution fashioned by the Supreme Court would have created a precedent that could be uniformly applied by other courts and administrative agencies around the country.

Further, the implied waiver would have been able to comport with the congressional policy behind tribal sovereign immunity encouragement of tribal cultural autonomy, self-determination, and economic security. A slight abrogation of tribal sovereign immunity in this fashion would not threaten the tribes' cultural activities because it only relates to business and could actually serve to foster tribal economic development. Additional evidence of an implied waiver's alignment with Congress's intent can be found in the Indian Reorganization Act. 202 There, Congress allowed tribes to bifurcate into governmental entities and corporate entities, thus creating two distinct legal entities.<sup>203</sup> As Thomas McLish explained, this allowed for tribal corporations to waive immunity in order to better participate in normal business activities while still protecting the tribal government from suit.<sup>204</sup> McLish continued to explain that this indicates that Congress "did not intend all commercial activity by the tribes to be immune" and that tribal governments choosing to not use the Act's corporate provisions or to act independently from that

Hurley, supra note 15.

<sup>&</sup>lt;sup>202</sup> Indian Reorganization Act, 25 U.S.C. §§ 461–479 (2012).

<sup>&</sup>lt;sup>203</sup> *Id.* at §§ 476–477.

McLish, *supra* note 48, at 189–90 (explaining that despite the legislation, Courts have continued to recognize immunity where the tribal governments "acted commercially through a subordinate economic enterprise.").

tribal corporation to engage in commercial activities "should not be immune from suits arising from their commercial dealings."<sup>205</sup> This makes sense given the potential windfall a blanket immunity from suit presents for tribes and any associated business partners such as Saint Regis and Allergan.

A decision to imply such a waiver would have served to alleviate any potential market inefficiencies unintentionally created as a result of the continued proliferation of Native American commercial activity. An implied waiver of immunity from suit for off-reservation commercial activities would enable tribal businesses to compete effectively in today's markets, as businesses or lenders that were previously reluctant to commercially engage in business with the tribes due to their sovereign immunity would no longer have to worry. Today, the expansion of tribal commercial activities and the associated disputes that have occurred as a result seem to indicate some sort of sensible tribal immunity waiver that can both serve the best interests of the tribes and promote market efficiency.

#### **CONCLUSION**

The Supreme Court originally fashioned tribal sovereign immunity as federal common law with the best of intentions. As the years have passed and the world has changed, the Court's deference to Congress and stare decisis have allowed the doctrine's breadth to grow past the sensibility of the policies that underlie it to a point where the public interest is threatened. The PTAB was unfit to properly review the sovereign immunity issue that the deal between Allergan and the Saint Regis Mohawk Tribe presents because, at best, the Board's invalidation of the deal serves as only a Band-Aid solution. As Congress has failed to properly address the matter, the Supreme Court should have exercised the power it possesses to amend tribal sovereignty and imply a waiver of immunity from suit for a tribe's commercial activities that occur off of tribal lands. This

 $<sup>^{205}</sup>$  *Id* 

<sup>&</sup>lt;sup>206</sup> Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2051 (2014) (Thomas, J., dissenting) (illustrating how tribal immunity hampers State's ability to protect their own citizens and enforce their laws against tribal businesses).

<sup>&</sup>lt;sup>207</sup> McLish, *supra* note 48, at 189.

would have represented an equitable solution for all stakeholders involved and thus, would have restored balance to the intellectual property world and the public at large.