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## Sovereign Immunity for Rent: How the Commodification of Tribal Sovereign Immunity Reflects the Failures of the U.S. Patent System

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### **Cover Page Footnote**

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# Sovereign Immunity for Rent: How the Commodification of Tribal Sovereign Immunity Reflects the Failures of the U.S. Patent System

Katrina Grace Geddes\*

*Last year, a Fortune 500 pharmaceutical company attempted to rent the sovereign immunity of an American Indian tribe in order to shield its patents on a dry-eye drug from invalidation by generic competitors in inter partes review. Pharmaceutical firms are notorious for pursuing unconventional methods to extend the duration of their patents and, in this sense, the maneuver is unsurprising. The exploitation, however, of an historically disenfranchised community with limited economic opportunities is particularly unsettling. This Article will provide, firstly, a factual summary of the legal background of this case; secondly, a review of the February 2018 decision of the Patent Trial and Appeal Board (“PTAB”) to deny the application of tribal sovereign immunity in this case; thirdly, a review of the July 2018 decision of the U.S. Court of Appeals for the Federal Circuit, affirming the PTAB’s decision; fourthly, a discussion of the ways in which the precedent set by Allergan’s maneuver may adversely affect consumer welfare by undermining the process of inter partes review; fifthly, an analysis of the history of tribal sovereign immunity and how its exploitation in this case reflects the historic oppression of American Indians; and finally, strategies to deter such transactions from recurring in the future.*

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## I. FACTUAL BACKGROUND

Allergan’s dry-eye treatment Restasis® was approved in 2002, and its patents (issued in 1995 and 1999)<sup>1</sup> were set to expire in 2014. However, in 2013, Allergan obtained new patents claiming new uses of the drug, thereby extending patent protection to 2024.<sup>2</sup> In 2015, Allergan filed suit against Teva Pharmaceuticals, Akorn, and Mylan, alleging that each of the generic manufacturers had infringed their Restasis® patents by filing Abbreviated New Drug Applications (“ANDAs”) for bioequivalent drugs.<sup>3</sup> The defendants responded that the Restasis® patents were invalid on several grounds, and, in October 2017, the U.S. District Court for the Eastern District of Texas agreed that the patents were invalid for obviousness.<sup>4</sup> Allergan is appealing the court’s ruling, which will now be heard by the Court of Appeals for the Federal Circuit.<sup>5</sup>

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<sup>1</sup> U.S. Patent No. 5,474,979; U.S. Patent No. 5,981,607.

<sup>2</sup> See *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4803941, at \*10 (E.D. Tex. Oct. 16, 2017).

<sup>3</sup> *Id.* at \*13.

<sup>4</sup> *Id.* at \*65.

<sup>5</sup> Press Release, Allergan, U.S. District Court for the Eastern District of Texas Issues Adverse Trial Decision Concerning RESTASIS® (Cyclosporine Ophthalmic Emulsion) 0.05% Patents (Oct. 16, 2017), <https://www.allergan.com/news/news/thomson-reuters/u-s-district-court-for-the-eastern-district-of-tex> [<https://perma.cc/9QW3-2WDJ>]. An appeal

Meanwhile, on June 3, 2016, Mylan filed six inter partes review (“IPR”) challenges with the PTAB regarding the Restasis® patents,<sup>6</sup> and, on December 8, 2016, the PTAB granted its petitions to be heard. On September 8, 2017, less than a week before the oral hearing set for September 15, counsel for the Saint Regis Mohawk Tribe (“the Tribe”) contacted the PTAB to inform the Board that they had acquired the challenged patents and sought a motion to dismiss the proceedings based on the Tribe’s sovereign immunity.<sup>7</sup>

On September 8, 2017, the Tribe had entered into a patent assignment agreement with Allergan in which the latter had transferred to the former a set of U.S. patents and patent applications related to Restasis®.<sup>8</sup> On the same day, both parties also entered into a Patent License Agreement in which the Tribe granted Allergan “an ‘irrevocable, perpetual, transferable, and exclusive license’ under the challenged patents ‘for all FDA-approved uses in the United States.’”<sup>9</sup> In exchange, Allergan paid the Tribe \$13.75 million and promised \$15 million in royalties annually.<sup>10</sup> “The License Agreement expressly stated that the Tribe ‘will and shall assert its sovereign immunity in any Contested PTO Proceeding, including in the IPR Proceedings.’”<sup>11</sup>

In the media storm that followed this announcement, amicus briefs were filed before the PTAB by a variety of different commentators and interest groups. The Software Alliance highlighted the irrelevance of patent immunity to the preservation

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was filed on November 1, 2017. *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 18-1130 (Fed. Cir. Jan. 9, 2018).

<sup>6</sup> U.S. Patent No. 8,685,930; U.S. Patent No. 8,629,111; U.S. Patent No. 8,642,556; U.S. Patent No. 8,633,162; U.S. Patent No. 8,648,048; U.S. Patent No. 9,248,191.

<sup>7</sup> Elana Williams, Note, *Tribal Sovereign Immunity as a Defense in Overcoming IPR Challenges of Brand Name Pharmaceutical Patent Validity at PTAB—Effects on the Industry*, 18 J. Tech. L. & Pol’y 40, 57 (2018) at 48.

<sup>8</sup> *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, No. IPR2016-01127, at 5, 2018 WL 1100950, at \*2 (P.T.A.B. Feb. 23, 2018).

<sup>9</sup> *Id.* at 6.

<sup>10</sup> *Id.*

<sup>11</sup> Caleb A. Bates et al., *Sovereign Immunity and Inter partes Review*, KNOBBE MARTENS: BIOTECH. BLOG (Oct. 17, 2017), <https://www.knobbemartens.com/news/2017/10/sovereign-immunity-and-inter-partes-review> [<https://perma.cc/SDH2-Q9QW>].

of tribal sovereignty for self-governance,<sup>12</sup> while the Public Knowledge and the Electronic Frontier Foundation argued that IPR is a public-interest administrative proceeding with broader societal ramifications, unlike private litigation.<sup>13</sup> The Association for Accessible Medicines echoed these sentiments, calling on the PTAB to protect the public's paramount interest in containing patent monopolies within their legitimate scope.<sup>14</sup> On the other side, the Oglala Sioux Tribe called for greater respect for tribal decisions regarding revenue streams, economic development, and financial self-sufficiency.<sup>15</sup> Similarly, the Seneca Nation called for continued deference to Congress regarding the abrogation of tribal sovereign immunity.<sup>16</sup> The Native American Intellectual Property Enterprise Council emphasized the "vital support" offered by the patent assignment to "one of the groups in most need of economic and educational assistance in the United States."<sup>17</sup> Inventor advocacy organization U.S. Inventor, LLC emphasized that only Congress has the authority to qualify or limit tribal sovereign immunity,<sup>18</sup> and the National Congress of American Indians, the National Indian Gaming Association, and the United South and Eastern Tribes highlighted the shared common law origins of state and tribal sovereign immunity and the importance of deference to Congress regarding their abrogation.<sup>19</sup> Patent attorneys Luis Ortiz and Kermit Lopez emphasized that sovereign immunity is a core legal

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<sup>12</sup> Brief of BSA The Software All. as Amicus Regarding Applicability of Tribal Sovereign Immunity in IPR Proceedings at 5, *Mylan Pharm.*, No. IPR2016-01127.

<sup>13</sup> Brief of Pub. Knowledge and the Elec. Frontier Found. as Amici Collegii in Opposition to the Motion to Terminate at 2–3, *Mylan Pharm.*, No. IPR2016-01127.

<sup>14</sup> Brief of the Ass'n for Accessible Meds. as Amicus Curiae in Support of Petitioners at 2, *Mylan Pharm.*, No. IPR2016-01127.

<sup>15</sup> Brief of the Oglala Sioux Tribe as Amicus Curiae in Support of Corrected Patent Owner's Motion to Dismiss Based on Tribal Sovereign Immunity at 5, *Mylan Pharm.*, No. IPR2016-01127 [hereinafter Oglala Sioux Tribe Brief].

<sup>16</sup> Brief of the Seneca Nation as Amicus Curiae in Support of the Patent Owner, Saint Regis Mohawk Tribe at 2, *Mylan Pharm.*, No. IPR2016-01127.

<sup>17</sup> Brief of Native Am. Intellectual Prop. Enter. Council, Inc. as Amicus Curiae Regarding Patent Owner's Motion to Dismiss at 6, *Mylan Pharm.*, No. IPR2016-01127 [hereinafter NAIPEC Brief].

<sup>18</sup> Brief of U.S. Inventor, LLC as Amicus Curiae in Support of Patent Owner, the Saint Regis Mohawk Tribe at 5–6, *Mylan Pharm.*, No. IPR2016-01127.

<sup>19</sup> Brief of the Nat'l Cong. of Am. Indians et al. as Amici Curiae in support of Patent Holder the St. Regis Mohawk Tribe's Motion to Dismiss at 4, *Mylan Pharm.*, No. IPR2016-01127.

protection for American Indian tribes, and claimed that the PTAB “has no congressional imprimatur to determine whether tribal sovereign immunity applies in an IPR.”<sup>20</sup>

The case also received significant attention from non-legal stakeholders, including a coalition of prominent U.S. health care organizations, led by America’s Health Insurance Plans, American Hospital Association, and American College of Physicians. This coalition urged congressional leaders to “fully examine” Allergan’s “brazen attempt to circumvent U.S. law” that, if left unchallenged, could “represent the beginning of a lucrative business strategy at the expense of the public interest; thus jeopardizing timely access to lower-cost generic and biosimilar medicines.”<sup>21</sup> In March 2018, Senators Tom Cotton, Claire McCaskill, David Perdue, Joni Ernst, and Pat Toomey introduced the “Preserving Access to Cost Effective Drugs Act,” which would prevent patent holders from asserting sovereign immunity as a defense in any reexamination proceeding, including any appeal to the Patent Trial and Appeal Board, any inter partes review, any post-grant review, or any subsequent review of any of these proceedings by a U.S. court.<sup>22</sup> The bill has been referred to the Senate Judiciary Committee.<sup>23</sup>

On February 23, 2018, the PTAB delivered its decision denying the Tribe’s motion to terminate inter partes review on the basis of its tribal sovereign immunity. The Board held that “the Tribe has not established that the doctrine of tribal sovereign immunity should be applied to these proceedings. Furthermore, we determine that these proceedings can continue even without the Tribe’s participation in view of Allergan’s retained ownership interests in the challenged patents.”<sup>24</sup> The details of this judgment are elucidated in Section III. Following this decision, Allergan appealed to the U.S. Court of

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<sup>20</sup> Brief of Luis Ortiz and Kermit Lopez as Amicus Curiae in Support of Patent Owner’s Motion to Dismiss for Lack of Jurisdiction Based on Tribal Sovereign Immunity at 11, *Mylan Pharm.*, No. IPR2016-01127.

<sup>21</sup> All. of Cmty. Health Plans et al., *Health Care Organizations Letter on Allergan Restasis*, ASS’N FOR ACCESSIBLE MEDS. 1, 3 (Oct. 10, 2017), <https://www.accessiblemeds.org/sites/default/files/2017-10/Health-Care-Organizations-Letter-on-Allergan-Restasis-10-10-17.pdf> [<https://perma.cc/9KFH-EJPT>].

<sup>22</sup> Preserving Access to Cost Effective Drugs Act, S. 2514, 115th Cong. (2018).

<sup>23</sup> See S.2514, 115th Cong. (as introduced in Senate, Mar. 7, 2018).

<sup>24</sup> *Mylan Pharm.*, No. IPR2016-01127, at 4, 2018 WL 1100950, at \*2.

Appeals for the Federal Circuit, which heard oral arguments on June 4, 2018.<sup>25</sup> During the hearing, the court explored the question of whether inter partes review represents a reconsideration of an administrative agency’s prior decision or whether it more closely resembles civil litigation between two private parties.<sup>26</sup> Jonathan Massey, representing Allergan, argued that inter partes review “bears all the trappings of a federal civil action” and therefore that tribal sovereign immunity should apply.<sup>27</sup> Eric Miller, for the defendants, argued that there were two critical features that distinguished IPR from civil litigation: firstly, how the process begins (the Director of the U.S. Patent and Trademark Office (“USPTO”) has discretion to deny an IPR petition, unlike the adjudicator in a civil suit); and secondly, how the process ends (in an IPR, the only possible outcome for the patentee is the cancellation of a public franchise issued by an administrative agency).<sup>28</sup> Miller argued that the consequence of the USPTO Director’s decision to initiate an IPR is not that the Tribe is hailed into court by a private party, but that “a politically accountable official at an executive branch agency has made a decision” to reconsider a prior agency action.<sup>29</sup>

Mark Freeman, representing the U.S. Department of Justice, agreed that “just because the petition . . . was begun by a petition by a private party that it was the private party’s cancellation of the patent.”<sup>30</sup> Freeman reiterated that “it’s the USPTO’s decision to reconsider [the grant of a patent],” and “because this is our decision, for which we are accountable, it is an act of the United States government, against which an Indian tribe does not have sovereign immunity.”<sup>31</sup> And for that reason, we would urge the court to hold that the Board correctly said this proceeding can proceed.”<sup>32</sup>

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<sup>25</sup> See Oral Argument, *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322 (Fed. Cir. 2018) (No. 2018-1638), [http://www.cafc.uscourts.gov/oral-argument-recordings?title=&field\\_case\\_number\\_value=18-1638&field\\_date\\_value2%5Bvalue%5D%5Bdate%5D=](http://www.cafc.uscourts.gov/oral-argument-recordings?title=&field_case_number_value=18-1638&field_date_value2%5Bvalue%5D%5Bdate%5D=) [https://perma.cc/5VH9-R9PQ].

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*



Although the court expressed skepticism at the oral arguments for both sides, it agreed that the “strongest argument” for the defendants was “the discretion of the [USPTO] director to initiate the proceeding or not.”<sup>33</sup> The court also made several references to the harmful precedent set by the “deliberate circumvention of the IPR process by buying sovereign immunity,” asking Massey, “many pharmaceutical or other companies could simply enter into the same type of transaction with an Indian tribe, where does that leave the IPR process?” Freeman also described the transaction as a “shell game” and encouraged the court to preserve the Board’s decision.<sup>34</sup>

On July 20, 2018, the U.S. Court of Appeals for the Federal Circuit handed down its judgment, affirming the PTAB’s decision to deny the Tribe’s motion to terminate inter partes review on the basis of its tribal sovereign immunity. The details of this judgment are explored in Section IV.

## II. DECISION OF THE PATENT TRIAL AND APPEAL BOARD

The Patent Trial and Appeal Board’s February 2018 decision can be summarized in four parts:

- There is no controlling precedent or statutory basis for the application of tribal immunity in inter partes review proceedings;
- Tribal immunity does not apply to inter partes review proceedings;
- These particular proceedings may continue with Allergan’s participation; and
- The Tribe is not an indispensable party.

With respect to its first assertion, the Board found that, although case law had established that state sovereign immunity can be exercised as a defense in adjudicatory proceedings before federal agencies,<sup>35</sup> the Tribe had failed to provide any federal court or Board

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<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> *See* Fed. Mar. Comm’n v. S.C. State Ports Auth., 535 U.S. 743, 743–44 (2002) (“State sovereign immunity’s preeminent purpose—to accord States the dignity that is consistent with their status as sovereign entities—and the overwhelming similarities between FMC

precedent suggesting that this principle should be extended to an assertion of tribal sovereign immunity in similar proceedings.<sup>36</sup> Furthermore, the Board highlighted statements by the Supreme Court that “the immunity possessed by Indian tribes is not coextensive with that of the States.”<sup>37</sup> Finally, the Board was reluctant to permit the application of non-statutory defenses in IPR proceedings.<sup>38</sup> In view of the differences between tribal and state sovereign immunity, the absence of relevant precedent, and the lack of statutory authority, the Board declined the Tribe’s request to invoke tribal sovereign immunity as a defense in the inter partes review.<sup>39</sup>

With respect to its second assertion, the Board exhibited strong deference to Congress with respect to the scope of applicability of federal laws to Indian tribes. The Ninth Circuit has stated that:

[A] federal statute of general applicability that is silent on the issue of applicability to Indian tribes will *not* apply to [Indian tribes] if: (1) the law touches “exclusive rights of self-governance in purely intramural matters”; (2) the application of the law to the tribe would “abrogate rights guaranteed by Indian treaties”; or (3) there is proof “by legislative history or some other means that Congress intended [the law] not to apply to Indians on their reservations . . . .”<sup>40</sup>

The Board found that, as none of these requirements had been met in this particular case, there was no basis for finding that the generally applicable America Invents Act was not applicable to

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adjudicative proceedings and civil litigation lead to the conclusion that the FMC is barred from adjudicating a private party’s complaint against a nonconsenting State.”).

<sup>36</sup> *Mylan Pharm.*, No. IPR2016-01127, at 8, 2018 WL 1100950, at \*3.

<sup>37</sup> *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 756 (1998); *see also* *Three Affiliated Tribes of the Fort Berthold Reservation v. Wold Eng’g*, 476 U.S. 877, 890 (1986).

<sup>38</sup> *Mylan Pharm.*, No. IPR2016-01127, at 10, 2018 WL 1100950, at \*4.

<sup>39</sup> *Id.*

<sup>40</sup> *Donovan v. Coeur d’Alene Tribal Farm*, 751 F.2d 1113, 1116 (9th Cir. 1985) (second alteration in original) (emphasis added) (quoting *United States v. Farris*, 624 F.2d 890, 893–94 (9th Cir. 1980)).

Indian tribes.<sup>41</sup> Furthermore, Indian tribes have generally “not enjoyed immunity in other types of federal administrative proceedings used to enforce generally applicable federal statutes.”<sup>42</sup>

With respect to its third assertion, the Board explained that reconsideration of the patentability of issued patents via inter partes review is possible “without regard to the identity of the patent owner” because the Board does not exercise personal jurisdiction over the patent owner.<sup>43</sup> It cannot restrain the patent owner from acting, nor compel it to act in any manner based on its final decision; the scope of the Board’s authority is limited to assessing the patentability of the challenged claims.<sup>44</sup> The patent owner cannot be compelled to appear as a party in the proceedings, and numerous inter partes reviews have proceeded to a final written decision without the patent owner’s participation.<sup>45</sup> Accordingly, the Board held that, even if the Tribe was entitled to assert immunity here, the proceedings could continue with the participation of Allergan, which did not enjoy such immunity, and which was, according to the Board, the “effective” patent owner.<sup>46</sup>

The Board pointed to statements by the Federal Circuit that the “party that has been granted all substantial rights under the patent is considered the owner regardless of how the parties characterize the transaction that conveyed those rights.”<sup>47</sup> Based on the terms of the license between Allergan and the Tribe, the Board found that Allergan was the effective patent owner in view of its possession of “all substantial rights” in relation to the patents, including the right to sue for infringement; the right to “indulge” any infringement; the right to make, use, and sell products or services under the patents; the right to sublicense; rights of reversion; the right to litigation or licensing proceeds; the right to control prosecution and other administrative proceedings; and the right to assign interests in the

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<sup>41</sup> *Mylan Pharm.*, No. IPR2016-01127, at 13, 2018 WL 1100950, at \*5.

<sup>42</sup> *Id.* at 14, 2018 WL 1100950, at \*5.

<sup>43</sup> *Id.* at 18, 2018 WL 1100950, at \*7.

<sup>44</sup> *Id.* at 16, 2018 WL 1100950, at \*6.

<sup>45</sup> *Id.* at 16–17, 2018 WL 1100950, at \*6.

<sup>46</sup> *Id.* at 35, 2018 WL 1100950, at \*13.

<sup>47</sup> *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000); *see also* *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1358–59 (Fed. Cir. 2010).

patents.<sup>48</sup> The Board found that the recordation of Allergan's assignment of the patents to the Tribe at the USPTO only created "a rebuttable presumption regarding ownership."<sup>49</sup> The Board held that this presumption had been overcome, and that the proceedings could continue with Allergan's sole participation, as the "effective patent owner," regardless of whether tribal immunity applied.<sup>50</sup>

This conclusion led the Board to its fourth and final assertion, that the inter partes review proceedings need not be terminated because the Tribe was not an indispensable party. The Board held that the Tribe would not "be significantly prejudiced in relation to the merits of the patentability challenges in these proceedings" if it did not participate based on its tribal immunity because Allergan, as the effective patent owner, would be able to "adequately represent any interests the Tribe may have in the challenged patents."<sup>51</sup> Notably, the briefing and evidence on the substantive patentability issues at stake in these proceedings were completed before the Tribe's involvement.<sup>52</sup> Accordingly, the Board concluded that the Tribe had failed to show that it was entitled to assert tribal immunity in these proceedings, that it was not an indispensable party to the proceedings, and that the proceedings could continue with Allergan as the effective patent owner.<sup>53</sup> The Board denied the Tribe's motion to terminate the IPR proceedings.<sup>54</sup>

### III. DECISION OF THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

In an opinion delivered on July 20, 2018, Judge Moore distinguished this case from the facts of *Federal Maritime Commission v. South Carolina State Ports Authority* ("FMC"),<sup>55</sup> in which the Supreme Court held that state sovereign immunity

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<sup>48</sup> *Mylan Pharm.*, No. IPR2016-01127, at 20–35, 2018 WL 1100950, at \*8–13.

<sup>49</sup> *Id.* at 34, 2018 WL 1100950, at \*13.

<sup>50</sup> *Id.* at 35, 2018 WL 1100950, at \*13.

<sup>51</sup> *Id.* at 37–38, 2018 WL 1100950, at \*14.

<sup>52</sup> *Id.* at 38, 2018 WL 1100950, at \*14.

<sup>53</sup> *Id.* at 40, 2018 WL 1100950, at \*15.

<sup>54</sup> *Id.*

<sup>55</sup> *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327–28 (Fed. Cir. 2018) (citing *Fed. Mar. Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743, 764 (2002)).

precluded the Federal Maritime Commission from adjudicating a private party's complaint against a state-run port. What differentiated *FMC* from the present case, Moore reasoned, was that Commission adjudications bear "overwhelming" similarities to federal civil litigation between private parties, whereas IPR "is more like an agency enforcement action than a civil suit brought by a private party."<sup>56</sup> Judge Moore identified four characteristics that distinguished IPR from adjudication between private parties. First, the USPTO Director possesses broad discretion in deciding whether to institute review and this "embraces the entirety of the proceeding."<sup>57</sup> Accordingly, if IPR "proceeds on patents owned by a tribe, it is because a politically accountable, federal official has authorized the institution of that proceeding."<sup>58</sup> In contrast, the Federal Maritime Commission has no discretion to refuse to adjudicate complaints brought by private parties, meaning that a private party could "unilaterally hale a sovereign before a tribunal, presenting an affront to the dignity of the sovereign."<sup>59</sup> Secondly, following the initiation of an IPR, the Board may proceed with review even if the petitioner chooses not to participate, demonstrating IPR's higher purpose of permitting a federal agency to reconsider the grant of a public franchise. Judge Moore found *Cuozzo Speed Techs* and *Oil States* to be particularly persuasive in this regard, echoing their obiter that "IPR is 'simply a reconsideration of' the PTO's original grant of a public franchise, which serves to protect 'the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope.'"<sup>60</sup>

The third factor identified by Judge Moore to distinguish IPR from private adjudication was the difference between the Federal Rules of Civil Procedure and USPTO procedures in IPR.<sup>61</sup> Civil litigation allows plaintiffs to significantly amend their complaints, and to employ a host of discovery options including interrogatories,

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<sup>56</sup> *Id.* at 1327.

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 1328.

<sup>60</sup> *Id.* at 1327 (quoting *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1373 (2018)).

<sup>61</sup> *Id.* at 1328.

depositions, production demands, and requests for admission.<sup>62</sup> IPR petitioners may only make clerical or typographical corrections to their petitions, and discovery is limited to the deposition of witnesses submitting affidavits or declarations and “what is otherwise necessary in the interest of justice.”<sup>63</sup> IPR hearings are short and rarely permit live testimony, differentiating them substantially from civil litigation hearings. The final factor identified by Judge Moore to distinguish IPR from private adjudication was the similarity between IPR and the other “administrative agency reconsideration decisions” issued by the USPTO, namely *ex parte* and *inter partes* reexamination.<sup>64</sup> The Tribe had acknowledged in oral argument that sovereign immunity would *not* apply in these proceedings due to their inquisitorial nature, and Judge Moore reasoned that IPR’s slightly less inquisitorial nature did not preclude it from also being an administrative agency reconsideration decision.<sup>65</sup>

Judge Moore concluded that, in instituting an IPR, the USPTO “is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant and protect the public interest in keeping patent monopolies ‘within their legitimate scope.’”<sup>66</sup> Accordingly, the Tribe could not rely on its immunity to bar such an action. Judge Dyk, in his concurring opinion, also emphasized the important public function of IPR in improving patent quality and restoring public confidence in the presumption of patent validity by giving the USPTO “a second look at an earlier administrative grant of a patent.”<sup>67</sup> Judge Dyk provided a painstaking account of the legislative history of IPR to illustrate its similarities with *ex parte* and *inter partes* reexamination, seizing also on the Tribe’s concession in oral argument that sovereign immunity would not apply in either proceeding. Judge Dyk emphasized the enormous

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<sup>62</sup> *Id.*

<sup>63</sup> *Id.* at 1328 (citing 35 U.S.C. § 316(a)(5) (2012)).

<sup>64</sup> *Id.* at 1329.

<sup>65</sup> Oral Argument, *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322 (Fed. Cir. 2018) (No. 2018-1638), [http://www.cafc.uscourts.gov/oral-argument-recordings?title=&field\\_case\\_number\\_value=18-1638&field\\_date\\_value2%5Bvalue%5D%5Bdate%5D=](http://www.cafc.uscourts.gov/oral-argument-recordings?title=&field_case_number_value=18-1638&field_date_value2%5Bvalue%5D%5Bdate%5D=) [https://perma.cc/5VH9-R9PQ].

<sup>66</sup> *Id.* (citing *Cuozzo*, 136 S. Ct. at 2144).

<sup>67</sup> *Id.* at 1335 (quoting *Cuozzo*, 136 S. Ct. at 2144).

responsibility of the USPTO (“the USPTO receives over 600,000 applications a year”) and its extremely limited resources, leading to a lack of public confidence in the patent system and subsequent judicial skepticism about patent validity.<sup>68</sup> Reexamination, Judge Dyk explained, was designed to restore faith in the presumption of patent validity which many courts had come to treat as coextensive with a presumption of administrative correctness.<sup>69</sup> Ex parte reexamination was introduced in 1980 “to use the motivation and resources of third parties to improve the accuracy of the USPTO’s patent process,” followed closely by inter partes reexamination in 1999.<sup>70</sup> The participation of third parties in these processes was designed not to simulate an adjudication between private parties, Judge Dyk explained, but to leverage the vigilance of competitors in the field seeking to invalidate an allegedly defective patent, as well as their greater access to relevant prior art resources.<sup>71</sup>

In detailing this legislative history, Judge Dyk sought to show that the eventual replacement of inter partes reexamination with, among other things, inter partes review represented a change in name rather than a change in substance. While IPR has some features similar to civil litigation, Judge Dyk explained,

[A]t its core, it retains the purpose and many of the procedures of its reexamination ancestors, to which everybody agrees sovereign immunity does not apply. Inter partes review is an administrative proceeding designed to improve patent quality by giving the USPTO “a second look at an earlier administrative grant of a patent.”<sup>72</sup>

For these reasons, Judge Dyk concluded, like its predecessors ex parte and inter partes reexamination, IPR is an agency reconsideration that enlists third-party assistance and “in such a reexamination proceeding, sovereign immunity does not apply.”<sup>73</sup>

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<sup>68</sup> *Id.* at 1331–32.

<sup>69</sup> *Id.* at 1333.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.* at 1335 (citing *Cuozzo*, 136 S. Ct. at 2144).

<sup>73</sup> *Id.*

The court affirmed the PTAB's decision denying the Tribe's motion to dismiss IPR on the basis of tribal sovereign immunity.<sup>74</sup>

It is important to note that the court confined its decision to tribal sovereign immunity alone. With respect to state sovereign immunity, the court stated that, "[w]hile we recognize there are many parallels, we leave for another day the question of whether there is any reason to treat state sovereign immunity differently."<sup>75</sup> Both Judges Moore and Dyk, however, made reference to the Supreme Court's obiter in *FMC* that state sovereign immunity "would *not* bar the Commission from 'institut[ing] its own administrative proceeding against a state-run port,' even if that proceeding were prompted by 'information supplied by a private party.'"<sup>76</sup> Accordingly, whether states can continue to claim immunity from IPR after this decision remains to be seen. Arguably, the reasoning laid out by the Federal Circuit for barring tribal sovereign immunity in IPR should compel a similar result for state sovereign immunity, but this issue remains unresolved for now.

#### IV. CONSUMER WELFARE LOSS

The quid pro quo of the patent system lies in the public disclosure of a useful invention in exchange for a time-limited monopoly on the development, sale, and distribution of this invention. The temporal restriction is important because, while this monopoly exists, not all members of the public will be able to access the patented invention at monopoly prices. The patent's expiry is critical for the entry of generic competitors selling the invention at more affordable prices. In the exclusive pursuit of profit, however, many patentees have attempted to extend their statutory monopolies beyond their rightful term. Pharmaceutical patentees, in particular, are notorious for their attempts to extend the duration of their patents through evergreening, pay-for-delay agreements, and other anticompetitive schemes.<sup>77</sup> The unlawful extension of monopoly

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<sup>74</sup> *Id.* at 1322.

<sup>75</sup> *Id.* at 1329.

<sup>76</sup> *Id.* at 1330 (citing *Fed. Mar. Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743, 768 (2002))(emphasis added).

<sup>77</sup> Gregory H. Jones et al., *Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 *BLOOD J.* 1398, 1398 (2016).



pricing has significant adverse effects on consumer welfare; “approximately one in five Americans do not fill prescriptions because of prohibitive cost.”<sup>78</sup> Pay-for-delay agreements are estimated to cost U.S. taxpayers, insurance companies, and consumers approximately \$3.5 billion per year.<sup>79</sup> Generic drugs, on the other hand, have saved the U.S. health care system almost \$1.5 trillion between 2004 and 2013.<sup>80</sup> The Federal Trade Commission estimates that within one year of market entry, authorized generics sell for 15% of the price of brand name equivalents, generating significant cost savings for consumers.<sup>81</sup>

One of the primary ways in which generic manufacturers can actively ensure that patent terms are not unlawfully extended is by challenging weak patents at the USPTO.<sup>82</sup> The IPR process was designed to provide an efficient and affordable venue for generic firms to contest the patents held by brand-name pharmaceutical firms without recourse to expensive and lengthy litigation.<sup>83</sup> Under this system, introduced with the America Invents Act in 2012, any third party (not just a competitor in the same market) can petition the USPTO for review of a patent on the basis that it fails to meet the requirements for patentability.<sup>84</sup> By relocating patent disputes before an administrative body rather than a judge or jury, IPR was intended to reduce the time, cost, and uncertainty of patent litigation.<sup>85</sup> Although any third party can file a petition,<sup>86</sup> the scope of the inquiry is limited to the validity of the patent, not any

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<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at 1399.

<sup>80</sup> *Id.* at 1398.

<sup>81</sup> Complaint and Jury Trial Demand at 13, *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.* (E.D.N.Y. May 16, 2018) (No. 1:18-cv-02907), 2018 WL 2252507, at \*7.

<sup>82</sup> Jones et al., *supra* note 77, at 1401.

<sup>83</sup> *Inter Partes Review*, USPTO, <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review> (last visited Feb. 25, 2019) [<https://perma.cc/XL2U-ASK5>].

<sup>84</sup> See 35 U.S.C. § 311(a) (2012); Brian T. Apel, Note, *An Administrative Meter Maid: Using Inter Partes Review and Post-Grant Review to Curb Exclusivity Parking Via the “Failure to Market” Provision of the Hatch-Waxman Act*, 114 MICH. L. REV. 107, 115 (2015).

<sup>85</sup> Apel, *supra* note 84, at 115.

<sup>86</sup> 35 U.S.C. § 311(a) (2012).

allegations of infringement,<sup>87</sup> and a final decision must be issued within a year.<sup>88</sup> In contrast, the median time to trial in patent litigation is two and a half years.<sup>89</sup> Additionally, the threshold for initiating an IPR (“reasonable likelihood” that the petitioner will prevail)<sup>90</sup> is higher than that required for district court litigation (a “short and plain statement” showing entitlement to relief),<sup>91</sup> reducing the likelihood of frivolous petitioning creating a backlog of cases.<sup>92</sup> Once the IPR has been instituted, however, proof of invalidity only requires a preponderance of the evidence,<sup>93</sup> rather than the “clear and convincing” evidence required by the district court to overcome the presumption of validity.<sup>94</sup> Additionally, unlike in federal courts, claims are given the “broadest reasonable construction in light of the specification” (meaning they are more likely to overlap with prior art),<sup>95</sup> and there is no presumption of validity. IPRs are estimated to incur fees of approximately \$300,000 to \$500,000 due to their limited duration and scope, whereas patent litigation can require several million dollars.<sup>96</sup> Finally, the institution of an IPR is often successfully utilized by defendants to seek a stay of any co-pending infringement litigation relating to the same patent, thereby freezing district court litigation costs.<sup>97</sup>

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<sup>87</sup> 35 U.S.C. § 311 (b) (2012). The scope of discovery is also limited relative to that permitted in the district court. *Compare* 35 U.S.C. § 316(a)(5), *with* FED. R. CIV. P. 26(b)(1).

<sup>88</sup> 35 U.S.C. § 316(a)(11).

<sup>89</sup> Apel, *supra* note 84, at 125.

<sup>90</sup> 35 U.S.C. § 314(a) (2012).

<sup>91</sup> FED. R. CIV. P. 8(a)(2).

<sup>92</sup> Apel, *supra* note 84, at 124.

<sup>93</sup> 35 U.S.C. § 316(e).

<sup>94</sup> *See* 35 U.S.C. § 282(a) (2012) (presumption of validity); *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 97 (2011) (“Under the Federal Circuit’s reading of § 282, a defendant seeking to overcome [the presumption of patent validity] must persuade the factfinder of its in-validity defense by clear and convincing evidence.”).

<sup>95</sup> 37 C.F.R. § 42.100(b) (2018).

<sup>96</sup> Apel, *supra* note 84, at 125–26.

<sup>97</sup> Matthew Rizzolo et al., *Shielded by Sovereignty: The Implications for Patentees of Covidien v. University of Florida Research Foundation and its Progeny*, 45 *AIPLA Q.J.* 593, 601–02 (2017).

Illustrating its popularity, over 7,573 IPRs were filed between 2012 and 2018.<sup>98</sup>

The ability to invalidate patents prior to the end of their term is critical to ensuring that invalid patents do not deter market entry, distort innovation, reduce competition, decrease consumer welfare,<sup>99</sup> and undermine public confidence in the patent bargain. While the grant of a patent creates a presumption of validity, it is capable of being rebutted. The Hatch–Waxman framework deliberately introduced incentives for generic manufacturers to challenge the validity of brand name patents, for example, by obviating the need to repeat safety and efficacy tests when filing an Abbreviated New Drug Application (“ANDA”) demonstrating bioequivalence to an approved drug.<sup>100</sup> ANDA applicants must demonstrate that no patent would be infringed by the granting of the ANDA either because (i.) no patent exists; (ii.) the patent has expired; (iii.) the patent will soon expire; or (iv.) the patent is invalid.<sup>101</sup> Hatch-Waxman incentivized patent challenges under paragraph IV by granting 180 days of market exclusivity to generic manufacturers who successfully challenged patents under this process (the so-called “first filer” advantage).<sup>102</sup>

Accordingly, Elana Williams argues that Allergan’s attempt to unlawfully extend its Restasis® monopoly by avoiding invalidation through IPR is “exactly what Congress in enacting the Hatch-Waxman Act sought to avoid.”<sup>103</sup> Generic competitors “must be allowed to enter the market through Congressionally created mechanisms such as IPR in order to provide consumers with low-cost options to the medications they desperately need.”<sup>104</sup> Weaponizing tribal sovereign immunity to shield corporate

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<sup>98</sup> Patent Trial & Appeal Bd., *Trial Statistics: IPR, PGR, CBM*, U.S. PAT. & TRADEMARK OFF. 3 (Feb.2018), [https://www.uspto.gov/sites/default/files/documents/trial\\_statistics\\_20180228.pdf](https://www.uspto.gov/sites/default/files/documents/trial_statistics_20180228.pdf) [<https://perma.cc/MEZ8-7FHL>].

<sup>99</sup> Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 114 (2006).

<sup>100</sup> Apel, *supra* note 84, at 109, 111–12.

<sup>101</sup> Apel, *supra* note 84, at 112–13.

<sup>102</sup> Apel, *supra* note 84, at 109.

<sup>103</sup> Elana Williams, Note, *Tribal Sovereign Immunity as a Defense in Overcoming IPR Challenges of Brand Name Pharmaceutical Patent Validity at PTAB—Effects on the Industry*, 18 J. TECH. L. & POL’Y 40, 57 (2018).

<sup>104</sup> *Id.* at 58.

monopoly power from generic competition has significant anticompetitive effects, including a welfare loss for consumers. It inflates the probabilistic value of Allergan's patents beyond that created by the initial grant of market exclusivity by artificially eliminating sources of competition, in this case, generic firms.<sup>105</sup> By shielding weak patents from potential invalidation through inter partes review, Allergan is extending its market monopoly beyond its rightful limits, thereby maintaining price inflation and harming consumers who cannot afford Restasis® at current prices.

In a separate judgment accompanying his invalidation of Allergan's Restasis® patents for obviousness, U.S. Circuit Judge William Bryson criticized Allergan's assignment of its patents to the Tribe: "[w]hat Allergan seeks is the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits through the administrative mechanism for canceling invalid patents."<sup>106</sup> Judge Bryson expressed concern that Allergan's strategy would be adopted by other pharmaceutical firms also seeking to shield their patents from administrative review: "[i]f that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice. In short, Allergan's tactic, if successful, could spell the end of the PTO's IPR program, which was a central component of the America Invents Act of 2011."<sup>107</sup> Judge Bryson compared Allergan's patent assignment to abusive tax shelter transactions, in which courts have "looked behind the face of the transactions to determine whether the transactions have economic substance or are simply a method of gaming the . . . system to generate benefits that were not intended to be available."<sup>108</sup>

A coalition of American health care organizations expressed similar concern at the harm posed by Allergan's transaction to consumer welfare:

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<sup>105</sup> Cecilia (Yixi) Cheng & Theodore T. Lee, *When Patents Are Sovereigns: The Competitive Harms of Leasing Tribal Immunity*, 127 *YALE L.J. F.* 848, 852 (2018).

<sup>106</sup> *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at \*2 (E.D. Tex. Oct. 16, 2017).

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at \*3.

The actions taken by Allergan to ensure that patients and payors do not benefit from timely generic competition to Restasis® is an alarming new example of the steps that brand name drug companies will take to put profits above the public interest . . . . If left unchallenged, this potentially precedent-setting transfer of patents to Native American tribes to avoid lawful review of these government-granted monopolies may represent the beginning of a lucrative business strategy at the expense of the public interest, thus jeopardizing timely access to lower-cost generic and biosimilar medicines.<sup>109</sup>

Dallas-based lawyer Michael Shore, who brokered the Allergan-Tribe assignment, however, has been candid about his desire to “destroy the IPR process” by creating sufficient loopholes to compel congressional review.<sup>110</sup> On a Teleforum podcast aired in January 2018, he explained his intention to carve out such a loophole that “anyone can go to a sovereign, whether it’s a state sovereign or a tribal sovereign, and get in a time machine and go back to 2011,” prior to the introduction of the America Invents Act.<sup>111</sup> His motivation, he explained, was to make the IPR system “more fair” by eliminating the “huge arbitrage in value between sovereigns and non-sovereigns.”<sup>112</sup> Shore believes that the IPR process “grossly favors infringers,” to the detriment of patent holders. He describes the “insanity” of a process in which “no patent is presumed valid, no matter how much you’ve invested in it, no matter how much work you’ve done on it.”<sup>113</sup> He argues that the introduction of the IPR process has “literally destroyed” the U.S. patent system, and he is simply trying to “take us back to a time when we had the number one innovative economy in the world.”<sup>114</sup> Shore believes that the invalidation of patents through district court litigation is preferable

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<sup>109</sup> All. of Cmty. Health Plans et al., *supra* note 21, at 3.

<sup>110</sup> *New Frontiers for Tribal Immunity: Patents, Pharmaceuticals, and the PTAB*, THE FEDERALIST SOCIETY (Jan. 30, 2018), <https://fedsoc.org/events/new-frontiers-for-tribal-immunity-patents-pharmaceuticals-and-the-ptab> [<https://perma.cc/5YZX-JJGU>].

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

to the IPR process because of the legal protections that exist for patentees: the ordinary person skilled in the art standard, a jury, a presumption of validity, the ability to cross-examine expert testimony, and a “clear and convincing evidence” standard.<sup>115</sup>

Shore’s arguments echo Allergan’s defense of its transaction as protection against the “double jeopardy” of fielding both federal lawsuits and IPR proceedings.<sup>116</sup> Ironically, however, in 2016, at a time when pharmaceutical firms were facing heightened media, political, and regulatory scrutiny (largely thanks to the public antics of “pharma bro” Martin Shkreli),<sup>117</sup> Allergan publicly committed to a “social contract” with patients, which promised that Allergan would “not engage in price gouging actions or predatory pricing,” would “enhance access” for patients, and would limit annual price increases in line with inflation.<sup>118</sup> Whatever goodwill was generated by this social contract was quickly consumed by the media storm that followed the announcement of the Allergan-Tribe transaction in 2017. Public shifts in the access policies of pharmaceutical firms seem more closely tied to swings in public sentiment than underlying changes in corporate policy; particularly those tied to the generation of profit for shareholders. Resultingly, consumer welfare continues to weather significant losses.

In November 2017, Restasis® purchasers filed an antitrust suit against Allergan, claiming damages for its anticompetitive conduct.<sup>119</sup> The class action claims that,

In the absence of Allergan’s unlawful actions,  
generic Restasis® would have been available by

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<sup>115</sup> *Id.*

<sup>116</sup> Sy Mukherjee, *Botox Maker Allergan’s CEO Defends Selling Drug Patents to Native American Tribe to Thwart Rivals*, *FORTUNE* (Sept. 9, 2017), <http://fortune.com/2017/09/09/allergan-drug-patents-native-american/> [<https://perma.cc/5FSY-5YS3>].

<sup>117</sup> *See, e.g.*, Andrew Pollack & Matthew Goldstein, *Martin Shkreli All but Gloated Over Huge Drug Price Increases, Memos Show*, *N.Y. TIMES* (Feb. 2, 2016), <https://www.nytimes.com/2016/02/03/business/drug-makers-calculated-price-increases-with-profit-in-mind-memos-show.html> [<https://perma.cc/JC7W-B3GX>].

<sup>118</sup> Brent Saunders, *Our Social Contract with Patients*, *ALLERGAN: CEO BLOG* (Sept. 6, 2016), <https://www.allergan.com/news/ceo-blog/september-2016/our-social-contract-with-patients> [<https://perma.cc/4VJ5-ABCK>].

<sup>119</sup> Class Action Complaint & Jury Trial Demand, *FWK Holdings, LLC v. Allergan, Inc.*, No. 2:17-cv-00747 (E.D. Tex. 2017).

May 17, 2014 and direct purchasers would have purchased the less expensive generic. FWK Holdings, LLC and the proposed class have paid hundreds of millions of dollars in overcharges as a result of Allergan's anticompetitive scheme.<sup>120</sup>

Six months later, a similar suit was brought against Allergan by four major U.S. retailers: Walgreen Co., Kroger, Albertsons and HEB. The antitrust action alleges that Allergan's anticompetitive conduct (including the patent assignment to the Tribe) "had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Restasis® from generic competition," with the effect that the plaintiffs were "compelled to pay, did pay, and continue to pay, artificially inflated prices for their [Restasis] requirements" and have incurred "substantial injury to their business and property in the form of overcharges."<sup>121</sup> These lawsuits reflect the ripple effects of the Allergan-Tribe transaction, not just in terms of the harm to consumers (reduced access to affordable medicines) but also in terms of the anticompetitive effects on purchasers and retailers.

#### V. HISTORY OF ECONOMIC OPPRESSION OF AMERICAN INDIAN TRIBES

Allergan's attempt to protect \$1.4 billion<sup>122</sup> in annual sales of a blockbuster drug by renting a legal protection designed for a historically disenfranchised community represents a new frontier in abuses of the patent system. Perhaps more disturbingly, however, it reflects the limited utility of this legal protection to a community with insufficient economic opportunities.

Tribal sovereign immunity, like that of states, finds its roots in the common law. The doctrine developed out of the "international public law doctrine of nation-state sovereign immunity," and the

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<sup>120</sup> Class Action Complaint & Jury Trial Demand at 3, *FWK Holdings, LLC v. Allergan, Inc.*, 2017 WL 5513947 (E.D. Tex.) (No. 2:17-cv-00747).

<sup>121</sup> Complaint and Jury Trial Demand, *supra* note 81, at 37 para. 109, 39 paras. 115–16.

<sup>122</sup> Allergan, Plc, *Annual Report: 2017 Form 10-K*, ALLERGAN 59 (Feb. 16, 2018), <https://allergan-web-cdn-prod.azureedge.net/actavis/actavis/media/allerganinvestors/financial-information/proxy-materials/10-k-2017> [<https://perma.cc/42F5-34ZX>].

need to protect the dignity of sovereigns, as well as their treasuries.<sup>123</sup> The United States Supreme Court first formally recognized tribal sovereign immunity in the early twentieth century in cases involving the Cherokee Nation, the Choctaw Nation, and the Creek Nation.<sup>124</sup> In these early cases, judicial recognition of the sovereignty of Indian tribes often referenced as “indicators” of sovereignty their political organization, independent legislatures, exclusive territorial domain, treaties with the United States, distinct political community, and written laws and constitutions.<sup>125</sup> Prior to the formation of the United States, the British Crown had interacted with Indian tribes as foreign sovereigns for the purposes of commercial trade, negotiation, diplomacy, and treaty-making.<sup>126</sup> Even after Congress changed its policy from diplomacy to regulation in 1871, Indian tribes retained the sovereignty inherent in their status as self-governing peoples predating the U.S. Constitution.<sup>127</sup> In its current form, the boundaries of tribal sovereign immunity lie where tribes have consented to being sued or Congress has unequivocally expressed<sup>128</sup> its intent to abrogate the scope of the immunity.<sup>129</sup> State sovereign immunity arises from the states’ inherent sovereignty prior to ratification of the U.S. Constitution and is affirmed by the Eleventh Amendment.<sup>130</sup> Tribal

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<sup>123</sup> William Wood, *It Wasn’t an Accident: The Tribal Sovereignty Immunity Story*, 62 *AM. U. L. REV.* 1587, 1610, 1615 (2013); see also Andrea M. Seielstad, *The Recognition and Evolution of Tribal Sovereign Immunity Under Federal Law: Legal, Historical, and Normative Reflections on a Fundamental Aspect of American Indian Sovereignty*, 37 *TULSA L. REV.* 661, 662–63 (2002).

<sup>124</sup> Wood, *supra* note 123, at 1622–23; see, e.g., *United States v. U.S. Fid. & Guar. Co.*, 309 U.S. 506 (1940); *Turner v. United States*, 248 U.S. 354 (1919).

<sup>125</sup> See Wood, *supra* note 123, at 1627–28.

<sup>126</sup> Seielstad, *supra* note 123, at 684.

<sup>127</sup> *Id.* at 686.

<sup>128</sup> *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 58–59 (1978).

<sup>129</sup> Ryan Seelau, *In Defense of Tribal Sovereign Immunity: A Pragmatic Look at the Doctrine as a Tool for Strengthening Tribal Courts*, 90 *N.D. L. REV.* 121, 138–39 (2014).

<sup>130</sup> *Alden v. Maine*, 527 U.S. 706, 713 (1999) (“We have . . . sometimes referred to the States’ immunity from suit as ‘Eleventh Amendment immunity.’ The phrase is convenient shorthand but something of a misnomer, for the sovereign immunity of the States neither derives from, nor is limited by, the terms of the Eleventh Amendment. Rather, as the Constitution’s structure, its history, and the authoritative interpretations by this Court make clear, the States’ immunity from suit is a fundamental aspect of the sovereignty which the States enjoyed before the ratification of the Constitution, and which they retain today (either literally or by virtue of their admission into the Union upon an equal footing with



sovereign immunity, however, receives no constitutional protection. As a result, both Congress and the Executive Branch have played a greater role in defining the contours of tribal immunity.<sup>131</sup> Yet, Gregory Ablavsky argues that the justifications for sovereign immunity “apply with as much or greater force in the tribal context” than they do in the state context.<sup>132</sup> When compared to U.S. states, Native nations continue to have substantially less capital and less capacity to raise capital through taxation.<sup>133</sup> More than 26% of American Indians and Alaskan Natives lived in poverty in 2016, the highest of any racial group.<sup>134</sup> In these circumstances, the function of sovereign immunity to protect sovereign treasuries from the financial burden of litigation increases in importance.

Recent decisions of the PTAB, however, reflect preferential treatment of state sovereign immunity when used to shield patents owned by state universities from inter partes review. In May 2017, the PTAB granted the University of Maryland’s motion to terminate IPR proceedings on the basis of its sovereign immunity as an “arm of the State of Maryland.”<sup>135</sup> Four months earlier, the PTAB had dismissed another IPR proceeding due to the Florida Research Foundation’s sovereign immunity.<sup>136</sup> The PTAB’s willingness to dismiss IPR petitions for patents owned by state sovereigns was precisely what motivated Michael Shore to broker the Allergan-Tribe transaction in the belief that tribal immunity would receive similar treatment.<sup>137</sup> The basis for the PTAB’s differential treatment

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the other States) except as altered by the plan of the Convention or certain constitutional Amendments.”); see also Gregory J. Wong, *Intent Matters: Assessing Sovereign Immunity for Tribal Entities*, 82 WASH. L. REV. 205, 209 (2007).

<sup>131</sup> Seielstad, *supra* note 123, at 675.

<sup>132</sup> *New Frontiers for Tribal Immunity: Patents, Pharmaceuticals, and the PTAB*, *supra* note 110.

<sup>133</sup> Seelau, *supra* note 129, at 140.

<sup>134</sup> U.S. Census Bureau, *American Indian and Alaska Native Heritage Month: November 2017*, PROFILE AM. FACTS FOR FEATURES 5 (Oct. 6, 2017), <https://www.census.gov/content/dam/Census/newsroom/facts-for-features/2017/cb17-ff20.pdf> [<https://perma.cc/8VFD-JY2R>].

<sup>135</sup> See *NeoChord, Inc. v. Univ. of Md., Balt.*, No. IPR2016-00208, at 4 (P.T.A.B. May 23, 2017).

<sup>136</sup> See *Covidien LP v. Univ. of Fla. Research Found. Inc.*, Nos. IPR2016-01274, IPR2016-01275, IPR2016-01276, at 3 (P.T.A.B. Jan. 25, 2017).

<sup>137</sup> See Gregory Ablavsky & Lisa Larrimore Ouellette, *Selling Patents to Indian Tribes to Delay the Market Entry of Generic Drugs*, 178 JAMA INTERNAL MED. 179, 179 (2018).

of state and tribal immunity remains unclear; the Board referred to statements by the Supreme Court that “the immunity possessed by Indian Tribes is not coextensive with that of the States,”<sup>138</sup> and argued that lower courts, therefore, have “not always considered Supreme Court precedent concerning state sovereign immunity to be applicable in the context of tribal immunity.”<sup>139</sup> The PTAB then referred to obiter from *Kiowa* (“[t]here are reasons to doubt the wisdom of perpetuating the [tribal immunity] doctrine”) and “the recognized differences between the state sovereign immunity and tribal immunity doctrines” (without further elucidation) before denying the Tribe’s motion to dismiss the IPR proceedings.<sup>140</sup>

Some distinguishing characteristics between *Covidien*, *NeoChord*, and the present case may be illustrative. Firstly, at the time that the IPR was originally initiated, the relevant patents in *Covidien* and *NeoChord* were already owned by a sovereign, unlike the present case, in which ownership changed hands after the IPR had already been instituted, clearly for the purpose of dismissing the proceedings.<sup>141</sup> Secondly, Eleventh Amendment immunity is considered a valid defense to adjudicative administrative proceedings brought by a private party,<sup>142</sup> and tribal immunity does not enjoy such constitutional protection.<sup>143</sup> Thirdly, the unique fiduciary relationship between the federal government and Indian “domestic dependent nations”<sup>144</sup> has been held to bar the invocation of sovereign immunity. The Ninth Circuit has noted that “tribal immunity is generally not asserted in administrative proceedings because tribes cannot impose sovereign immunity to bar the federal

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<sup>138</sup> *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 756 (1998).

<sup>139</sup> *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, No. IPR2016-01127, at 9, 2018 WL 1100950, at \*4 (P.T.A.B. Feb. 23, 2018).

<sup>140</sup> *Id.* at 10, 2018 WL 1100950, at \*4.

<sup>141</sup> *Williams*, *supra* note 103, at 56.

<sup>142</sup> *Fed. Mar. Comm’n v. S.C. State Ports Auth.*, 535 U.S. 743, 760 (2002) (“Given both this interest in protecting States’ dignity and the strong similarities between FMC proceedings and civil litigation, we hold that state sovereign immunity bars the FMC from adjudicating complaints filed by a private party against a nonconsenting State. Simply put, if the Framers thought it an impermissible affront to a State’s dignity to be required to answer the complaints of private parties in federal courts, we cannot imagine that they would have found it acceptable to compel a State to do exactly the same thing before the administrative tribunal of an agency.”).

<sup>143</sup> *Williams*, *supra* note 103, at 56.

<sup>144</sup> *Cherokee Nation v. Georgia*, 30 U.S. 1, 14 (1831).

government from exercising its trust obligations,” and that “tribal sovereignty does not extend to prevent the federal government from exercising its superior sovereign powers.”<sup>145</sup> The significance of these differences has yet to be tested; the U.S. Court of Appeals for the Federal Circuit explicitly confined its decision to tribal sovereign immunity alone, and left the differential treatment of state sovereign immunity “for another day.”<sup>146</sup>

Certainly, the policy reasons for denying the application of sovereign immunity that has been “rented” by private corporations to avoid administrative review should apply equally to state sovereigns. As the Oglala Sioux Tribe argued in its amicus brief, comparing the role of the University of Florida Research Foundation to that of the Tribe in this case, “[b]oth merely took an assignment of the patent or patents in question for purposes of monetizing the patents through licensing and generating royalty revenue.”<sup>147</sup> Indeed, Michael Shore has expressed his intent, if Congress limits tribal immunity in inter partes review, to shift patent portfolios to state universities (e.g. underfunded historically black colleges) to exploit their state sovereign immunity.<sup>148</sup> Faced with the same concerns regarding corporate abuse of the patent system, the technical differences between state and tribal sovereign immunity do not seem to justify disabling tribal immunity in inter partes review while preserving that of states.<sup>149</sup>

In fact, the differential treatment of state and tribal immunity in these circumstances suggests a broader delegitimization of this core legal protection for tribal communities. William Wood argues that the Supreme Court’s mischaracterization of the development of tribal sovereign immunity “almost by accident” in *Kiowa*<sup>150</sup> has triggered a broader jurisprudential trend of delegitimizing tribal

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<sup>145</sup> *Quileute Indian Tribe v. Babbitt*, 18 F.3d 1456, 1459 (9th Cir. 1994).

<sup>146</sup> *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1329 (Fed. Cir. 2018). *See supra* Part IV.

<sup>147</sup> Oglala Sioux Tribe Brief, *supra* note 15, at 12.

<sup>148</sup> Adam Davidson, *Why is Allergan Partnering with the St. Regis Mohawk Tribe?*, NEW YORKER (Nov. 20, 2017), <https://www.newyorker.com/magazine/2017/11/20/why-is-allergan-partnering-with-the-st-regis-mohawk-tribe> [<https://perma.cc/M25M-25Q6>].

<sup>149</sup> *See generally* Ablavsky & Ouellette, *supra* note 137.

<sup>150</sup> Wood, *supra* note 123, at 1589–90 (citing *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 752 (1998)).

sovereign immunity, in which lower federal courts and state supreme courts are more willing to “carve out exceptions to the doctrine” and “make their own policy judgments about whether immunity should apply—and to tip the balance against upholding immunity.”<sup>151</sup> In *TTEA v. Ysleta del Sur Pueblo*,<sup>152</sup> for example, the Fifth Circuit noted that *Kiowa* provided reasons to “doubt the wisdom” of perpetuating tribal sovereign immunity, and held that this immunity “did not bar an action seeking declaratory and injunctive relief against the tribe.”<sup>153</sup> Wood argues that exceptions to the application of tribal sovereign immunity have similarly been carved out by courts in California and Oklahoma on the basis of *Kiowa* obiter.<sup>154</sup> *Kiowa*’s criticism of the “wisdom of perpetuating the doctrine” of tribal immunity,<sup>155</sup> Wood claims, has encouraged lower courts to place limitations on tribal immunity despite its longstanding congressional recognition.<sup>156</sup>

Certainly, the PTAB’s February decision to deny the operation of tribal sovereign immunity in inter partes review significantly curtails the operability of a core legal protection for American Indians, with unpredictable consequences. Retaining meaningful control over whether sovereign immunity is waived or invoked can have a significant impact on the capacity and legitimacy of tribal court systems, as well as the scope of their jurisdiction.<sup>157</sup> Preserving tribal immunity allows tribes to strengthen and develop their own legal systems, for example, by reincorporating traditional norms which may have been removed through the colonization of tribal justice systems (e.g. alternative dispute resolution mechanisms, such as peacemaker courts, and internal grievance procedures).<sup>158</sup> Immunity from suit remains a core legal protection and should not be lightly curtailed. As Andrea Seielstad reiterates, tribal immunity “derives its existence from the presumed and long-recognized

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<sup>151</sup> Wood, *supra* note 123, at 1591.

<sup>152</sup> 181 F.3d 676 (5th Cir. 1999).

<sup>153</sup> Wood, *supra* note 123, at 1599 (citing *TTEA v. Ysleta del Sur Pueblo*, 181 F. 3d 676 (5th Cir. 1999)).

<sup>154</sup> *Id.* at 1602–03.

<sup>155</sup> *Kiowa Tribe*, 523 U.S. at 758.

<sup>156</sup> See Wood, *supra* note 123, at 1662.

<sup>157</sup> Seelau, *supra* note 129, at 133.

<sup>158</sup> Seielstad, *supra* note 123, at 771.

inherent sovereignty of Indian nations. The doctrine is not easily disturbed, and interpretive deviations from the general rule should be cautiously undertaken.”<sup>159</sup> Any challenge to such immunity must confront a “longstanding inter-branch jurisprudential legacy” that has “consistently endorsed a federal policy and jurisprudence protective of tribal immunity.”<sup>160</sup> While the PTAB’s anxiety to preclude abuses of the patent system is understandable, abrogating tribal sovereign immunity without congressional oversight is not the solution.

Interestingly, in *Covidien*, the PTAB had earlier dismissed the argument that immunizing patents owned by sovereigns would have “harmful and far-reaching consequences,” as invalid patents would stand simply because they were assigned to sovereign entities.<sup>161</sup> The Board was unpersuaded that “an application of sovereign immunity to inter partes review [would] do violence to the patent system” and stated that “there is no evidence that the harm to the patent system, described by the Petitioner, will come to pass, let alone exists as a basis to divest States of sovereign immunity.”<sup>162</sup> Yet, less than a month later, the Board handed down a very different decision in which it denied the application of tribal immunity to inter partes review on the basis of seemingly trivial differences between state and tribal immunity.<sup>163</sup> It is possible that the media storm and public outrage which followed the announcement of the Allergan-Tribe transaction may have contributed to a shift in perception of the social utility of immunizing patents held by sovereigns, but this remains speculation.

The technology transfer offices of public universities are reportedly concerned that the trendline of recent cases, namely, the PTAB’s February decision and the Federal Circuit’s July decision, may ultimately sprout federal legislation which abrogates all sovereign immunity before the PTAB, thereby “crippling” the innovation spurred by the Bayh-Dole Act and imposing significant

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<sup>159</sup> *Id.* at 704.

<sup>160</sup> *Id.* at 772.

<sup>161</sup> *Covidien LP v. Univ. of Fla. Research Found. Inc.*, Nos. IPR2016-01274, IPR2016-01275, IPR2016-01276, at 25 (P.T.A.B. Jan. 25, 2017).

<sup>162</sup> *Id.* at 26–27.

<sup>163</sup> *Mylan Pharmaceuticals Inc. v. Saint Regis Mohawk Tribe*, No. IPR2016-01127-01132, at 9–10 (P.T.A.B. Feb. 23, 2018).

financial burdens on state universities as they are forced to defend themselves before inter partes review.<sup>164</sup> If the financial burdens of sovereigns were to legitimately influence a decision to shield them from inter partes review, however, surely the dire financial circumstances of American Indian tribes would be more compelling. A small community in upstate New York with an annual budget of only \$50 million to support 13,000 people,<sup>165</sup> the Saint Regis Mohawk Tribe had already agreed to hold supercomputer patents for SRC Labs as part of its economic diversification strategy.<sup>166</sup> SRC Labs had transferred its patents to the Tribe in August 2017 in order to use tribal immunity as a shield from counter-challenge through inter partes review. In October 2017, the Tribe filed lawsuits against Microsoft and Amazon for infringement of these patents.<sup>167</sup>

The Tribe's willingness to rent its sovereign immunity to patent holders in exchange for upfront payments reflects the financial strain of a legacy of colonial oppression of American Indians through federal policy and judicial decisions.<sup>168</sup> The effective promotion of tribal self-sufficiency, sovereignty, and political self-determination relies in large part on economic independence from federal funds. And despite popular misconceptions, Indian gaming revenue is unevenly distributed and largely insufficient.<sup>169</sup> Of the 562 federally recognized Indian Nations, less than half operate gaming facilities.<sup>170</sup> And on the thirtieth anniversary of the Indian

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<sup>164</sup> *BIO 2018: Allergan-Tribe Deal Just the Start, says Former USPTO Director*, LIFE SCI. INTELL. PROP. REV. (Aug. 6, 2018), <https://www.lifesciencesipreview.com/news/bio-2018-allergan-tribe-deal-just-the-start-says-former-uspto-director-2909> [<https://perma.cc/2HKS-DKW3>].

<sup>165</sup> Oglala Sioux Tribe Brief, *supra* note 15, at 7.

<sup>166</sup> Aaron Mak, *Native American Tribe Helping Supercomputer Company Sue Amazon and Microsoft*, SLATE (Oct. 19, 2017, 12:25 PM), [http://www.slate.com/blogs/future\\_tense/2017/10/19/a\\_native\\_american\\_tribe\\_is\\_helping\\_a\\_supercomputer\\_company\\_sue\\_amazon\\_and.html](http://www.slate.com/blogs/future_tense/2017/10/19/a_native_american_tribe_is_helping_a_supercomputer_company_sue_amazon_and.html) [<https://perma.cc/7RQP-EMV8>].

<sup>167</sup> Meg Tirrell, *Mohawk Tribe Sues Microsoft, Amazon for Patent Infringement*, CNBC (Oct. 18, 2017, 1:54 PM), <https://www.cnbc.com/2017/10/18/mohawk-tribe-sues-microsoft-amazon-for-patent-infringement.html> [<https://perma.cc/A2NP-TA9F>].

<sup>168</sup> See Venida S. Chenault, *Indigenous Gaming: Economic Resources for Social Policy Development in First Nations Country*, 1 INDIGENOUS NATIONS STUD. J. 95, 96 (2000).

<sup>169</sup> Oglala Sioux Tribe Brief, *supra* note 15, at 6.

<sup>170</sup> *2018 Annual Report*, NAT'L INDIAN GAMING ASS'N 25 (Apr. 30, 2018), <https://online.flippingbook.com/view/236925/> [<https://perma.cc/K94T-G3VK>].

Gaming Regulatory Act,<sup>171</sup> billions of dollars in gaming revenue have failed to systematically reduce tribal poverty levels (the median poverty rate for gaming tribes in Washington, Oregon, Idaho, and Alaska actually increased over 2000-2010 from 25% to 29%, despite \$19 billion in gaming revenue), and there is evidence of an inverse correlation between per capita payments and poverty reduction.<sup>172</sup> Additionally, taxation revenue from businesses located on Indian reservations has been crowded out by parallel state taxation powers.<sup>173</sup> Dual taxation forces tribes to reduce their tax rates or forfeit tax revenue altogether in order to maintain market pricing, yet the threat of double taxation continues to frighten investors away.<sup>174</sup> Despite tribal taxation powers representing “an essential attribute of Indian sovereignty,”<sup>175</sup> tribes’ ability to generate taxation revenue or offer tax incentives to stimulate economic activity has been sharply curtailed by “flexible preemption analysis” decisions.<sup>176</sup> Naturally, in these circumstances, tribes seeking additional revenue streams to support the needs of their members are more willing to “rent” their sovereign immunity for financial reward. The Saint Regis Mohawk Tribe has acknowledged that the upfront payment of \$13.75 million followed by quarterly royalty payments of \$3.75 million from Allergan will allow it “to address some of the chronically unmet needs of the Akwesasne community, such as housing, employment, education, healthcare, cultural and language preservation.”<sup>177</sup>

Interestingly, the Tribe’s participation in this transaction has also been justified, not only by its significant economic needs, but by the long history of unlawful appropriation of Native American inventions in the United States. The Native American Intellectual Property Enterprise Council, in its amicus brief to the PTAB,

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<sup>171</sup> Alan P. Meister et al., *Indian Gaming and Beyond: Tribal Economic Development and Diversification*, 54 S.D. L. REV. 375, 375 (2009).

<sup>172</sup> W. Gregory Guedel, *Sovereignty, Economic Development, and Human Security in Native American Nations*, 3 AM. INDIAN L.J. 17, 36, 37 (2014).

<sup>173</sup> See Oglala Sioux Tribe Brief, *supra* note 15, at 6.

<sup>174</sup> F. Michael Willis, *The Power to Tax Economic Activity in Indian Country*, 28 NAT. RESOURCES & ENV’T 1, 2 (2014).

<sup>175</sup> *Merrion v. Jicarilla Apache Tribe*, 455 U.S. 130, 137 (1982).

<sup>176</sup> Willis, *supra* note 174, at 4.

<sup>177</sup> *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, No. IPR2016-01127, at 31, 2018 WL 1100950, at \*12 (P.T.A.B. Feb. 23, 2018).

justified the assignment of Restasis® patents to the Tribe on the basis that

Appropriation and outright theft of Native American inventions and ideas without attribution has occurred for hundreds of years. The curing of rubber, the game of Lacrosse, tortillas, potato chips, root beer, and innumerable planting, cultivation, crossbreeding, and cooking techniques and inventions were all Native American in origin, yet the Tribes saw little or no benefits aside from occasional lip service.<sup>178</sup>

Framing Allergan's patent assignment as a form of intergenerational equity (when in fact its only purpose was to protect Allergan's Restasis® revenue) suggests an alarming form of vigilante justice that should not be encouraged. Denying U.S. patients access to affordable generic medicines in order to remedy the historical deprivation of intellectual property rights to Native American tribes seems like a misguided attempt to correct one wrong by committing another. Justifying abuse of the patent system "in order to overcome significant historical disadvantages"<sup>179</sup> faced by Native American tribes is misdirected and unsustainable. Certainly, the U.S. government should be doing more to compensate Indian tribes for centuries of oppression, discrimination, and resource appropriation, but back-door vigilantism by means of crippling inter partes review is not an appropriate remedy.

Understanding the motivation for tribal participation in this transaction does not diminish its effect on consumer welfare and the underlying patent bargain. In granting patent rights, society agreed to provide inventors with a time-limited monopoly in return for the release of information concerning socially beneficial innovation. The financial needs and historical suffering of American Indians, while important, have no bearing on this bargain. For this reason, inter partes review cannot and should not be manipulated to serve extraneous objectives while there continue to exist alternative (and more appropriate) means of achieving them.

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<sup>178</sup> NAIPEC Brief, *supra* note 17, at 3.

<sup>179</sup> *Id.*, at 6.



## VI. LOOKING FORWARD

The harms caused by the commodification of sovereign immunity for corporate profit (including the loss to consumer welfare and the narrowing of tribal immunity) demonstrate that sustainable solutions are needed for the future. Identifying the optimal solution, however, is extremely difficult. Scholars at Yale argue that patent assignments that make no economic sense *but for* their anticompetitive purpose (in this case, shielding patents from invalidation by generic competitors) should be subject to antitrust scrutiny.<sup>180</sup> Cheng and Lee argue that bringing an antitrust suit to challenge an anticompetitive patent assignment would be a “natural extension” of *FTC v. Actavis*, in which the Supreme Court held that antitrust law can apply to reverse payment agreements between brand name and generic pharmaceutical manufacturers.<sup>181</sup> The “no economic sense” test, they argue, would capture the most egregious anticompetitive conduct without unduly eroding sovereign immunity, or chilling legitimate patent transfers.<sup>182</sup> This would prevent abuse of the patent system by prohibiting anticompetitive patent assignments without touching the question of sovereign immunity.

Alternatively, bipartisan legislation has been proposed that would strip both states and tribes of sovereign immunity in inter partes review. The Preserving Access to Cost Effective Drugs Act (the “PACED Act”), introduced in March 2018 by Senators Cotton, McCaskill, Perdue, Ernst, and Toomey, would amend title 35 of the United States Code to provide that “a patent owner may not assert sovereign immunity, including the sovereign immunity accorded to an Indian tribe” in derivation, reexamination, inter partes review, and post-grant review proceedings (and federal reviews thereof), but “only to the extent permitted under the 11th amendment to the Constitution of the United States.”<sup>183</sup> Whether such statutory language would be sufficient to abrogate state sovereign

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<sup>180</sup> Cheng & Lee, *supra* note 105, at 851.

<sup>181</sup> *Id.* at 864.

<sup>182</sup> *Id.* at 871.

<sup>183</sup> Preserving Access to Cost Effective Drugs Act, S. 2514, 115th Cong. §§ 135(g), 305(b), 316(f), 326(f) (2018).

immunity,<sup>184</sup> or whether the actual effect of the PACED Act would be to exclusively penalize tribes while permitting states to continue invoking immunity, remains to be seen. The Bill has been referred to the Senate Judiciary Committee.

An alternative solution, suggested by Greg Ablavsky and Lisa Ouellette, would be to encourage states to waive immunity in inter partes review by making the receipt of federal research funds conditioned upon such a waiver.<sup>185</sup> Given the importance of federal funding to the continuity of university-based research and development, this incentive could be persuasive. Jennifer Polse, focusing on patent infringement proceedings in federal court, originally argued that conditioning the receipt of federal research funds on the waiver of sovereign immunity in patent suits would ensure that federal funds are not used to violate federal patent law.<sup>186</sup> According to Polse, obtaining a waiver from states in this manner is the only way to hold state universities accountable for patent infringement after *Florida Prepaid II* effectively “close[d] the door to future legislative attempts to abrogate state immunity from suit for patent infringement.”<sup>187</sup> Importantly, to avoid triggering the doctrine of unconstitutional conditions (in which the significant financial inducement of a federal research grant may effectively coerce states into giving up their constitutional rights),<sup>188</sup> a modified solution would be to withhold only a percentage of federal research funds from states which refuse to waive their immunity in inter partes review.<sup>189</sup>

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<sup>184</sup> See *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 44 (1996) (“Congress may abrogate the States’ sovereign immunity if it has ‘unequivocally expresse[d] its intent to abrogate the immunity’ and has acted ‘pursuant to a valid exercise of power.’”). See generally Note, *Reconciling State Sovereign Immunity with the Fourteenth Amendment*, 129 HARV. L. REV. 1068 (2016).

<sup>185</sup> Ablavsky & Ouellette, *supra* note 137, at 179–80.

<sup>186</sup> Jennifer Polse, Comment,  *Holding the Sovereign’s Universities Accountable for Patent Infringement after Florida Prepaid and College Savings Bank*, 89 CALIF. L. REV. 507, 507 (2001).

<sup>187</sup> *Id.* at 519.

<sup>188</sup> See *South Dakota v. Dole*, 483 U.S. 203, 211 (1987) (“Our decisions have recognized that in some circumstances the financial inducement offered by Congress might be so coercive as to pass the point at which ‘pressure turns into compulsion.’”) (quoting *Charles C. Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937)).

<sup>189</sup> Polse, *supra* note 186, at 534.

In its departure from its intended purpose, the monetization of tribal sovereign immunity clearly reflects the desperate state of tribal finances.<sup>190</sup> Accordingly, a more sustainable means of discouraging anticompetitive patent transfers would involve identifying alternative revenue streams for American Indian tribes. As aforementioned, tribal taxation revenue has been severely decimated by the threat of double taxation due to increasingly generous judicial interpretations of state taxation powers. If, however, Congress were to grant immunities from state tax in specific contexts (as it did with gaming under the Indian Gaming Regulatory Act),<sup>191</sup> it would significantly bolster tribal revenue streams on a sustainable, long-term basis.<sup>192</sup> Natural resource development represents a significant revenue stream for many tribes, and there exists tremendous potential to generate renewable energy through wind and solar power.<sup>193</sup> Indian lands hold an estimated 535 billion kWh/year of wind and 17,600 billion kWh/year of solar-energy potential.<sup>194</sup> Yet harnessing this energy requires capital-intensive technologies and non-Indian investment, which again raises the specter of double taxation.<sup>195</sup> Tribes do not enjoy the renewable energy tax credits, accelerated depreciation allowances, and loan guarantees that make renewable energy projects profitable for investors.<sup>196</sup> Additionally, as tribes are generally excluded from regional transmission line planning, transmission lines often skirt tribal lands, and the cost of relocating

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<sup>190</sup> As U.S. Circuit Judge William Bryson stated in his 2017 opinion invalidating Allergan's Restasis® patents, "sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities. It is not an inexhaustible asset that can be sold to any party that might find it convenient to purchase immunity from suit." 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>191</sup> 25 U.S.C. § 2710(d)(4) (1988).

<sup>192</sup> Willis, *supra* note 174, at 4.

<sup>193</sup> Heather J. Tanana & John C. Ruple, *Energy Development in Indian Country: Working Within the Realm of Indian Law and Moving Towards Collaboration*, 32 UTAH ENVTL. L. REV. 1, 2 (2012).

<sup>194</sup> *Id.*

<sup>195</sup> *Id.* at 11.

<sup>196</sup> *The New Energy Future in Indian Country: Confronting Climate Change, Creating Jobs, and Conserving Nature*, NAT'L WILDLIFE FED'N 16 (2010), [https://www.nwf.org/~media/PDFs/Global-Warming/Reports/03-23-10\\_NWF\\_TribalLands\\_LoRes.ashx](https://www.nwf.org/~media/PDFs/Global-Warming/Reports/03-23-10_NWF_TribalLands_LoRes.ashx) [<https://perma.cc/H4XQ-A3NK>].

or extending these lines closer to tribal lands would be prohibitive.<sup>197</sup> Renewable energy investment, therefore, represents a significant source of untapped tribal revenue and employment. If Congress were to establish immunities from state tax for renewable energy developments, this exemption would significantly bolster tribal revenue streams and obviate the need to monetize sovereign immunity.<sup>198</sup> Discouraging imitation of the Allergan-Tribe transaction “requires more than a stopgap narrowly focused on the use of tribal sovereign immunity in inter partes review proceedings challenging drug patents.”<sup>199</sup> It requires sustainable, long-term solutions which address the root causes that motivate these transactions, namely, serious financial need.

A more compelling but likely less feasible solution would be to return title to Indian land to tribes under a new status that confers permanent jurisdiction and full taxation powers.<sup>200</sup> The U.S. government’s ownership of Indian land (held in trust for tribes)<sup>201</sup> means that tribes cannot sell, lease, develop, or mortgage their land without the express approval of the U.S. government, which unreasonably burdens and hinders tribal entrepreneurship and economic development.<sup>202</sup> In addition to erecting significant bureaucratic barriers to economic growth, the trust status of Indian resources “freezes” tribal assets in a pre-capitalist state.<sup>203</sup> The Indian Trust Asset Reform Act, for example, allows participating tribes to assume responsibility for the management of trust assets according to tribal standards, notwithstanding federal regulations.<sup>204</sup>

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<sup>197</sup> *Id.*

<sup>198</sup> See Willis, *supra* note 174, at 10–11.

<sup>199</sup> Ablavsky & Ouellette, *supra* note 137, at 180

<sup>200</sup> Gavin Clarkson & Alisha Murphy, *Tribal Leakage: How the Curse of Trust Land Impedes Tribal Economic Self-Sustainability*, 12 J.L. ECON. & POL’Y 177, 190 (2016).

<sup>201</sup> The allotment of tribal lands formed part of a policy of forced assimilation—based on the belief that communal landholding was an obstacle to Indian “civilization”—and ultimately produced the General Allotment Act of 1887. See *id.* at 186; see also Monte Mills, *New Approaches to Energy Development in Indian Country: The Trust Relationship and Tribal Self-Determination at (Yet Another) Crossroads*, 63 FED. LAW. 50, 51 (2016) (“The allotment of tribal lands resulted in tribes losing more than 90 million acres . . . and resulted in fractured ownership patterns of both the surface and subsurface estates on the remaining lands.”).

<sup>202</sup> Clarkson & Murphy, *supra* note 200, at 181.

<sup>203</sup> *Id.*, at 188.

<sup>204</sup> Mills, *supra* note 201, at 56.

This step, although small, could represent the start of a “new approach to tribal self-determination that would allow for greater tribal authority and flexibility in the management of trust assets, including surface and potentially subsurface resources for energy development.”<sup>205</sup> Greater legislative creativity and courage could significantly alter the pattern of tribal engagement with their resources and reclaim the control and self-determination that has been denied them for centuries. This paper is not the appropriate place to discuss the incredibly complex and controversial issues relating to tribal land held in trust by the United States. Suffice to say that, rather than narrowing the scope of an important legal protection for American Indian tribes, a more effective deterrent to future imitations of the Allergan-Tribe transaction would be to significantly buttress the economic opportunities afforded to American Indian communities in a sustainable and meaningful fashion.

## VII. CONCLUSION

Although the optimal resolution of the issues raised herein remains unclear, two conclusions may be drawn from the foregoing discussion. Firstly, pharmaceutical firms should not be permitted to rent sovereign immunity (state or tribal) in order to extend their patent monopolies beyond their lawful terms, to the detriment of U.S. consumers. The effective functions of inter partes review should be preserved in order to maintain consumer access to affordable generic medicines. Secondly, the willingness of the Saint Regis Mohawk Tribe to rent its sovereign immunity in return for lump-sum payments reflects the dire financial circumstances of many Indian tribes and the economic legacy of centuries of oppression. These financial needs should be addressed, not by curtailing the scope of an already limited legal protection, but by identifying sustainable, long-term sources of tribal revenue that would obviate the financial need to engage in anticompetitive patent assignments with pharmaceutical firms. Unless and until Congress acts to reverse centuries of economic oppression of American Indians, these transactions will continue to be lucrative for tribes,

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<sup>205</sup> Mills, *supra* note 201, at 56–57.

and U.S. consumers will continue to suffer a lack of access to affordable medicines.