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Protecting Patents Through Tribal Sovereign Immunity: A Failed Experiment

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The Federal Circuit recently affirmed a Patent Trial and Appeals Board (PTAB) decision of first impression on whether an Indian tribe, which acquired an interest in patents previously owned by a pharmaceutical manufacturer, could intervene in and move to dismiss *inter partes* review proceedings (IPRs) on the basis of that tribe's sovereign immunity.[1] The PTAB ruled that tribal sovereign immunity did not warrant dismissal of the IPRs, and, in any event, the IPRs could proceed against the manufacturer because the manufacturer, not the tribe, was the true owner of the patents. The Federal Circuit affirmed, holding that tribal immunity did not bar IPRs.[2]

This novel case involves the Saint Regis Mohawk Tribe's (Tribe) acquisition of patents from Allergan for the blockbuster drug, Restasis®, which is prescribed to patients suffering from ocular inflammation associated with chronic dry eye disease. The facts underlying this action caught significant attention because of (1) the way in which the licensing deal between the Tribe and Allergan was structured, (2) the timing of the deal itself, and (3)

the perceived purpose of the deal. Quickly summarized, the deal was unusual because Allergan, the original owner of the Restasis patents, transferred its rights to those patents to the Tribe, and in exchange, the Tribe "licensed back" certain exclusive rights to Allergan, including the rights to commercialize the Restasis patents and prosecute infringement actions on the Restasis patents. For this licensing back of rights, Allergan was required to pay the Tribe $3.75 million each quarter.

The timing of the deal raised suspicions because, when it was executed, Allergan was embroiled in a two-front war over its Restasis patents. On one front, Allergan was prosecuting an infringement action against several prospective generic competitors in federal court, where a bench trial on the validity and infringement of the Restasis patent had just finished.[3] And on the other front, it was defending those same patents in IPRs brought by those same competitors. The IPRs, however, were particularly acute threats to Allergan's patents because even if Allergan settled with one or more of its generic competitors (e.g., by giving the generic a license to the patents in dispute), the PTAB could still continue its review and ultimately issue a decision cancelling the patents. This would permit other prospective competitors to enter the market upon receiving Food and Drug Administration (FDA) approval.

Lastly, some people suspected the deal was a sham and was only done for purposes of using the Tribe's tribal sovereign immunity to quash IPRs that threatened Allergan's Restasis patents and the monopoly profits it derived from Restasis sales. Allergan denied these contentions.

It is this last point—the avoidance of IPRs that could threaten Allergan's right to exclude competing generic products to Restasis—that raises the question: Can we expect to see more deals like the Allergan-Mohawk license? That is, will branded pharmaceutical manufacturers start assigning their rights to a tribe (or possibly another sovereign) and enter into concurrent licensing agreements, whereby the brand manufacturers hold significant rights to both commercialize the patent and defend it from would-be infringers, as a means of stalling generic entry and thwarting healthy competition that would lower prices for consumers?

For the reasons discussed in more detail below, this is unlikely to be a recurring issue. First, the Federal Circuit's ruling that tribal sovereign immunity does not apply to IPRs effectively ends the perceived benefit of such deals—to "rent" tribal immunity to avoid potentially adverse IPR rulings on suspect patents. Second, even if the Supreme Court were to reverse the Federal Circuit and hold that tribal immunity does apply, the PTAB's ruling would still jeopardize any such deal that did not provide the tribe with significant rights to the patents. Third, even a better-structured deal that provided something closer to joint patent ownership would have risks. Joint ownership will likely force a tribe into patent litigation with a brand manufacturer that wishes to take advantage of the Hatch-Waxman Act's 30-month regulatory stay on the approval of generic drug applications. In doing this, the tribe might expose itself to a potential waiver of its immunity not only in federal court, but also in IPRs, thereby limiting the value of any potential deal that contemplates the use of tribal immunity as a shield to IPRs.

District Court Restasis Patent Proceedings

Allergan received FDA approval to market Restasis in December 2002, and, since then, Restasis has generated billions in sales.[4] Several generic competitors filed Abbreviated New Drug Applications (ANDAs), seeking FDA approval of generic versions of Restasis. Each included "paragraph IV" certifications against each Restasis patent that Allergan listed in the FDA's Orange Book. By making these certifications, the generic manufacturers claimed that Allergan's patents were invalid, unenforceable, or not infringed.[5] As permitted under the Hatch-Waxman Act, Allergan sued each generic for patent infringement, with the first suit coming in August 2015 against Teva Pharmaceuticals, Akorn, Apotex, and Mylan Pharmaceuticals.[6]

In its complaint against these generic manufacturers, Allergan claimed that each generic ANDA infringed U.S. Patent Nos. 8,629,111; 8,633,162; 8,642,556; 8,648,048; and 8,685,930.[7] Each generic manufacturer answered and asserted affirmative defenses or counterclaims for, among other things, a declaration of non-infringement and invalidity of the asserted patents.[8]

As discovery proceeded and the matter approached trial, Allergan withdrew its claims of infringement on the '162 and '556 patents.[9] The parties agreed to try certain claims from the four remaining patents. In October 2017, after a week-long trial, the district court ruled that while the generics infringed the Restasis patents, they were ultimately invalid as obvious in light of prior art.[10]

The Allergan-Mohawk Deal

The Saint Regis Mohawk tribe is a federally recognized Indian tribe with reservations in New York. According to the IPR Tribe Decision, the tribe was approached by a law firm "to engage in new business activities related to existing and emerging technologies, which may include the purchase and enforcement of intellectual property rights, known as the 'Intellectual Property Project.'"[11]

In connection with this venture, the Tribe entered into a "Patent Assignment Agreement" (the "Assignment") with Allergan on September 8, 2017, whereby Allergan assigned to the Tribe a set of patents and patent applications related to Restasis. Further, under the Assignment, the Tribe would only waive its sovereign immunity for actions brought by Allergan arising from the Assignment, but the Tribe otherwise agreed that it "will not waive its or any other Tribal Party's sovereign immunity in relation to any *inter partes* review or any other proceeding in the United States Patent & Trademark Office or any administrative proceeding that may be filed for the purpose of invalidating or rendering unenforceable any Assigned Patents."[12]

Contemporaneous with the Assignment, Allergan and the Tribe entered into a "Patent License Agreement" (the "License"), in which the Tribe licensed back to Allergan an exclusive license to the Restasis patents for "all FDA-approved uses in the United States."[13] In addition, the License provided Allergan the first right to sue for patent infringement any competitor seeking to introduce "Generic Equivalents," which the parties defined as any "drug product that requires FDA approval for sale in the United

States," including those seeking ANDA approval for generic Restasis.[14] In exchange for these rights, Allergan was required to make an upfront payment of $13.75 million and fixed quarterly royalty payments of $3.75 million (or $15 million annually).[15]

Further, although the Tribe was the owner and licensor of the patents, its ability to commercialize and exploit the patents was very limited. For example, under the License, Allergan had the exclusive right to exploit and commercialize the licensed patents for *all FDA-approved uses* in the United States.[16] Further, the Tribe agreed that it "shall not directly or indirectly develop, market or *license any Competing Product*, or engage in . . . activities that would and/or are intended *to result in a Competing Product*."[17] A "Competing Product" under the License included not only "Generic Equivalents," but also "any product . . . that is developed . . . for any indication that includes or is the same as any indication for which any Licensed Product [including, but not limited to, Restasis] is approved by the FDA."[18] And apart from the royalty payments, the Tribe was not entitled to any proceeds from any commercialization of the patents, including, for example, royalties from Allergan's sales of Restasis.[19]

Criticism of the Assignment and License was quick. A few days following the announcement, Mylan, who was being sued by Allergan for infringing its Restasis patents, filed papers arguing that "Allergan is attempting to misuse Native American sovereignty to shield invalid patents from cancellation," and that Allergan had "admitted in other forums that [its] intent is to employ Native American sovereign immunity" in an attempt to "cut-off pending validity challenges with the Patent Office."[20] In response to the Allergan-Mohawk deal, bills were introduced in the Senate that sought to strip tribes of their tribal immunity for purposes of IPRs.[21]

The timing of the deal also was suspect. A patent trial on certain claims recently had concluded and a concurrent IPR concerning the same Restasis patents was well underway. After the parties notified the court of the deal, the court ordered, among other things, (a) limited, expedited discovery concerning the deal, (b) Allergan to describe what consideration it was given in exchange for the assignment of the Restasis patents to the Tribe, and (c) briefing on whether the Tribe should be added as a necessary party or whether the Assignment and License should be disregarded as shams.[22] In response to the court's order, the parties conducted limited discovery and submitted briefs on joinder of the Tribe. In its filings, Allergan conceded that the consideration for the assignment was the Tribe's sovereign immunity.[23]

In an opinion permitting joinder of the Tribe in the pending patent suit, Judge Bryson—a Senior Judge of the Federal Circuit who was presiding over the Restasis patent trial—expressed "serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed."[24] He further stated that "when faced with the possibility that the PTO would determine that [its Restasis] patents should not have been issued, Allergan has sought to prevent the PTO from reconsidering its original issuance decision. . . . If that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice."[25] Despite its reservations about the propriety of the deal, the court permitted joinder "in order to ensure that any judgment entered in this case will be protected against challenge on the ground that the proper parties were not all joined as plaintiffs[.]"[26]

The Restasis IPR Proceeding and Allergan-Mohawk Ruling

Restasis Generic Competitors Initiate IPRs

During the pendency of the patent litigation, the generic competitors, including Mylan, Teva, and Akorn, filed petitions before the PTAB requesting *inter partes* review of the Restasis patents.[27] In these petitions, the generic competitors argued that the Restasis patents were either obvious or anticipated in light of prior art and should be canceled.[28]

By way of brief background, IPRs were a product of the America Invents Act[29] and were intended to be a quicker and more efficient method through which patent challenges can be asserted and decided.[30] When a challenger files a petition for initiation of an IPR, the PTAB can commence an IPR if "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[31] If the PTAB commences an IPR and finds, by a preponderance of the evidence, that the challenged patent is invalid or should not have been issued, it can cancel the challenged patent.[32] A notable distinction between IPRs and federal court proceedings is that even if the patentee and the challenger settle their dispute, the PTAB can continue the IPR and reach a decision on whether the challenged patent should be canceled or otherwise modified.[33] Because a patent owner cannot necessarily avoid adjudication on the patent's validity in an IPR—and thus, the potential loss of the patent owner's ability to exclude competitors—even if the owner settles an unwanted challenge, IPRs pose a significant threat to patent owners. Further, such a determination has the potential to eviscerate a settlement previously reached.[34]

While the petitions were pending and shortly after the Allergan-Mohawk deal was finalized, Allergan and the Tribe moved to dismiss the IPRs on the grounds that the Tribe, as the owner of the patents-at-issue, was not subject to the jurisdiction of the PTAB due to tribal immunity.[35] The generic competitors opposed Allergan's dismissal motion, arguing alternatively that (1) tribal immunity did not bar IPRs, (2) the Allergan-Mohawk deal was a "sham," and (3) Allergan—not the Tribe—was the real patent owner and thus the IPR could proceed against Allergan without the Tribe.[36]

In light of the substantial public interest in the novel issues raised by the Allergan-Mohawk deal, the PTAB authorized third parties to file amicus briefs.[37] In total, the PTAB received over a dozen amicus briefs from a wide-ranging group of stakeholders, including academics, trade associations, and other Native American tribes and associations.[38]

The PTAB Rules Against Allergan and the Tribe

On February 23, 2018, the PTAB ruled on the dismissal motion, holding that (a) tribal immunity did not apply to IPRs and thus did not provide grounds for dismissal; (b) Allergan, not the Tribe,

was the real owner of the patents and thus the IPR could proceed against just Allergan; and (c) the Tribe was not an indispensable party. Like the Eastern District of Texas, the PTAB did not expressly rule on whether the License and Assignment were "sham[s]" or otherwise unlawful.[39]

Tribal immunity does not apply. As a threshold matter, the PTAB held that there was no binding authority on whether tribal immunity applied to IPRs. It distinguished Supreme Court precedent dealing with state sovereign immunity[40] and relied on another Supreme Court decision, which held that "'the immunity possessed by Indian Tribes is not co-extensive with that of the States.'"[41] Further, the PTAB noted that because there was "no statutory basis to assert a tribal immunity defense in *inter partes* review proceedings," it was reluctant to apply it here.[42]

In addition, the PTAB found that, consistent with existing precedent, "'general Acts of Congress apply to Indians . . . in the absence of a clear expression to the contrary.'"[43] The PTAB concluded that the Patent Act was a general act of Congress, which subjected all patents to the conditions and requirements of the Patent Act, including IPRs.[44]

The PTAB also distinguished IPRs from general litigation, where applying immunity would be more appropriate. Whereas in general litigation a private party may seek monetary or injunctive relief against the Tribe—and thus, would require a court to infringe tribal sovereignty—in an IPR "there is no possibility of monetary damages or an injunction as a 'remedy' against the Tribe. Rather . . . the scope of the authority granted by Congress to the Patent Office with respect to *inter partes* review proceedings is limited to assessing the patentability of the challenged claims."[45] IPRs' focus on the challenged patent itself, rather than the owner of the patent or any other interested party, is further confirmed by the fact that the PTAB can continue with an IPR without the patent owner appearing or even when the patent owner and patent challenger settle their dispute.[46]

Accordingly, the PTAB concluded that tribal immunity did not apply to IPRs.

Allergan was the owner of the patents. Next, the PTAB considered whether, even assuming tribal immunity applied, the IPRs could proceed without the Tribe. This inquiry essentially required the PTAB to determine whether the Tribe was the owner of the patents at issue in the proceedings. Again, the PTAB agreed with the generic petitioners, finding that notwithstanding the Assignment, because Allergan retained nearly all the rights to prosecute, enforce, exploit, and commercialize the patents, it was the de facto owner of the challenged patents.

The PTAB considered a nine-factor Federal Circuit test to determine whether rights under the challenged patent belonged exclusively to the Tribe, namely:

> (1) the nature and scope of the right to bring suit; (2) the exclusive right to make, use, and sell products or services under the patent; (3) the scope of the licensee's right to sublicense; (4) the reversionary rights to the licensor following termination or expiration of the license; (5) the right of the licensor to receive a portion of the proceeds from litigating or licensing the patent; (6) the duration of the license rights; (7) the ability of the licensor to supervise and control the licensee's activities; (8) the obligation of the licensor to continue paying maintenance fees; and (9) any limits on the licensee's right to assign its interests in the patent.[47]

The PTAB found that each of these factors favored a finding that Allergan was the true owner of the challenged patents and therefore the IPR could proceed without the Tribe. For example, despite the Assignment, Allergan possessed the "first right to sue" generic competitors seeking approval of generic Restasis for infringement of the "assigned" patents. The PTAB found the Tribe's "first right to sue for infringement unrelated to Generic Equivalents" as nothing more than "an illusory or superficial right to sue for infringement."[48] The second factor similarly favored a finding that Allergan owned the patents because Allergan had the "exclusive right to exploit the challenged patents 'for all FDA-approved uses in the United States[.]'"[49] The Tribe's rights to exploit were *de minimis* because it could not develop or help others develop a Competing Product—i.e., any pharmaceutical product that could conceivably compete for sales with Restasis.[50] Nor did the Tribe have a meaningful right to sublicense the Restasis patents to third parties (the third factor), obtain royalties from Allergan's commercial sales of Restasis (the fifth factor), or control how Allergan used or defended the patents (the seventh factor).[51]

Simply put, the PTAB concluded that "[b]ecause Allergan remains the effective patent owner, . . . these proceedings can continue with Allergan's participation only, regardless of whether tribal immunity applies."[52]

Tribe was not an indispensable party. Lastly, the PTAB rejected the Tribe's argument that it was an indispensable party to the IPR—meaning that the proceeding could not continue without its participation. First, the PTAB concluded that to the extent the Tribe's joinder argument was based on Rule 19(b)—governing whether a court may proceed without joining a necessary party—it was untenable because (1) the Federal Rules of Civil Procedure do not apply to IPRs, and (2) there was no analogous procedural rule governing IPRs.[53]

Second, even if Rule 19(b) applied, the PTAB found that non-joinder of the Tribe was appropriate. Because Allergan and the Tribe had near identical interests in preserving the validity of the patent and would assert the same theories in defending the patentability of the challenged claims, Allergan's continued presence would limit any prejudice to the Tribe if it could not be joined.[54] By contrast, dismissing the IPRs *would* prejudice the petitioners because the "claims and patents litigated in the Eastern District of Texas are not co-extensive with the claims and patents challenged in these proceeding."[55] In addition, petitioners' burden of proof in the IPR for justifying cancellation (preponderance of the evidence) is different from that in federal court for showing invalidity (clear and convincing).[56] As a result, the PTAB concluded that the Tribe was not indispensable to the proceedings.

Federal Circuit Affirms PTAB Conclusion That Tribal Immunity Does Not Bar IPRs

Both the St. Regis Mohawk Tribe and Allergan appealed the PTAB's decision.[57] The Federal Circuit, *sua sponte*, expedited briefing and argument.[58] On July 20, 2018, the Federal Circuit affirmed the PTAB's ruling that tribal immunity does not bar IPRs.

After observing that tribal immunity is not a *per se* bar to federal agency action, the court noted that IPRs are neither purely independent administrative agency actions nor party-driven adversarial proceedings.[59] Rather, the court held that it is a "'hybrid proceeding' with 'adjudicatory characteristics' similar to court proceedings."[60] Recent Supreme Court decisions in *Oil States Energy Services v. Greene's Energy Group, LLC* and *SAS Institute Inc. v. Iancu* highlighted the hybrid nature of IPRs.[61]

Yet, the court identified four reasons that made IPRs more akin to an independent administrative action than an adversarial proceeding, which would trigger the application of tribal immunity. First, the court held that PTAB's Director "possesses broad discretion in deciding whether to institute review."[62] Indeed, the Director can decline to initiate proceedings for reasons unrelated to the merits of the petition—e.g., "administrative efficiency or a party's status as a sovereign."[63] This distinguishes IPRs from other administrative agency proceedings that adjudicate disputes between parties, such as those before the Federal Maritime Commission.[64] As a result, the Federal Circuit held that an "IPR is more like cases in which an agency chooses whether to institute a proceeding on information supplied by a private party."[65]

Second, the court held that the lack of continued participation by parties in IPRs, once initiated, also makes IPRs less like adjudicative proceedings. As the PTAB noted, the IPR can proceed even if the challenger declines to continue its participation.[66] Because there is no need for a private party to continue its participation, the court held that this "reinforces the view that IPR is an act by the agency in reconsidering its own grant of a public franchise."[67]

Third, the court held that the IPR procedures "do not mirror the Federal Rules of Civil Procedure."[68] For example, unlike federal court litigation, where a plaintiff is permitted to make significant amendments to its pleading, an IPR petitioner is only permitted to make "clerical or typographical corrections to its petition."[69] Similarly, many of the discovery procedures available to litigants in federal court (or similar administrative fora) are absent in IPRs. Discovery is limited to "(A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice."[70] Nor do hearings in IPRs have the "hallmarks of what is typically thought of as a trial": they "are short, and live testimony is rarely allowed."[71]

Fourth, the court held that the existence of other more "inquisitorial" procedures for patent challenges—e.g., *ex parte* or *inter partes* reexamination proceedings—does not mean that Congress intended tribal immunity to apply to IPRs.[72] Indeed, the Tribe acknowledged that tribal immunity would not bar such proceedings. And because *ex parte* and *inter partes* reexamination procedures share the same "basic purposes, namely to reexamine an agency decision," the Federal Circuit held that tribal immunity should not attach to IPRs.[73]

In sum, a majority of the Federal Circuit held that tribal immunity does not bar IPRs. Because it did so, the court declined to address the parties' other arguments, including whether the Allergan-St. Regis Mohawk deal was a sham.[74] It also explicitly left open "the question of whether there is any reason to treat state sovereign immunity differently."[75]

In a concurrence, Judge Dyk agreed with the majority's holding, but wrote separately to provide additional context in the form of an extended discussion of the legislative history behind IPRs. Judge Dyk reasoned that this history "confirms that [IPR] proceedings are not adjudications between private parties" and "are fundamentally agency reconsiderations of the original patent grant"—"proceedings as to which sovereign immunity does not apply."[76]

Implications of the Allergan-Mohawk Deal

The Federal Circuit's holding that tribal immunity does not bar IPRs will likely end deals like those struck between Allergan and the St. Regis Mohawk Tribe—i.e., where a commercial entity attempts to "rent" the litigation immunities of a tribe or other sovereign. Although the Federal Circuit did not address the other arguments raised by the parties or comment on the applicability of state sovereign immunity to IPRs, should the Supreme Court take the case and reverse the Federal Circuit's ruling, there are additional reasons to believe that the Allergan-Mohawk deal may still be "one-and-done."

For starters, the way in which the Allergan-Mohawk deal was structured made its purpose fairly transparent. It appeared that Allergan was simply "renting" the Tribe's legal immunity to avoid adjudication on the validity of patents covering its billion-dollar drug. The deal gave no meaningful rights to the Tribe with respect to the patents Allergan assigned: The Tribe could not exploit or commercialize the patents; it could not sublicense them to those who could; it could not sue for infringement or control any litigation in connection with those patents; and it received no royalties for Allergan's exploitation or commercialization of the one product covered by those patents. As the PTAB found, the rights the Tribe did possess were simply "illusory" and Allergan, which possessed all meaningful rights in the patents, was the *de facto* owner.[77]

That said, pharmaceutical companies could structure deals that provide more substantive rights to Native American tribes (or even other sovereigns), such as co-equal rights to exploit, commercialize, and license the patents. Similarly, the parties could agree to a royalty structure that was contingent on the sales of any commercialization of a patent. A deal providing more substantive rights might pass muster with the PTAB and the courts. However, such a deal may not be a viable option because of the brand's desire to pursue patent infringement litigation as a first option to protect its drugs from generic competition.

To understand why this matters, take the following example: Assume that a branded pharmaceutical company enters into a co-license and development agreement with a Native American

tribe, whereby both parties have co-equal rights in the prosecution of certain patents and the commercialization of those patents. Through this arrangement, they develop a new drug; file a New Drug Application, which is approved; and jointly prosecute patents, which later issue. If a prospective generic competitor decides to file an ANDA with a paragraph IV certification, the branded pharmaceutical company and the tribe have a choice: sue within 45 days of receiving a paragraph IV notice to trigger an automatic 30-month regulatory stay on the FDA's approval of the ANDA, or do nothing and lose the stay, which would permit the FDA to approve the ANDA upon satisfaction of all regulatory requirements.[78]

Few brand manufacturers would pass on an automatic 2.5-year delay in generic competition—and continued monopoly sales—even if they had only a relatively small chance of winning an infringement trial. But in the case where a Native American tribe is a joint owner of the patent, litigation means both the brand manufacturer *and* the tribe must sue together.[79] By joining an infringement suit, the tribe might waive its immunity, at least as it relates to the claims asserted in the infringement litigation.[80] This waiver would apply not only to the federal court action where the tribe is a plaintiff, but also could potentially apply to any IPR proceeding.

Indeed, the PTAB has recently held that state sovereign immunity can be waived under such circumstances. In the context of whether a state university could avoid an IPR proceeding by virtue of state sovereign immunity, the PTAB recently held that the state university waived its sovereign immunity by initiating a federal court action on the same patents at issue in the IPR.[81] The PTAB reasoned that "[i]t would be unfair and inconsistent to allow a State to avail itself of the federal government's authority by filing a patent infringement action in federal court, but then selectively invoke its sovereign immunity to ensure that a defendant is barred from requesting an *inter partes* review of the asserted patent from a different branch of that same federal government."[82] This appears consistent with prevailing Federal Circuit authority, which has previously held that "'seriously unfair results' could obtain if a state were permitted to file suit in federal court seeking to enforce a right to ownership of patents arising from certain contractual agreements and conduct and, at the same, to claim immunity from liability for royalties or other compensation arising from those same contracts and conduct."[83] Although state sovereign immunity emanates from constitutional considerations—rather than common law principles barring suits against sovereigns that forms the basis of tribal immunity[84]—the same logic should apply if a Native American tribe initiated federal patent infringement litigation and then later had its patent(s) subjected to an IPR.

As both the PTAB and the Federal Circuit held in ruling against Allergan and the Saint Regis Mohawk Tribe, even though the mere filing of suit does not by itself waive a tribe's sovereign immunity to suit in other fora (e.g., another district court), IPRs are unlike suits in court because they can proceed to a decision on the propriety of the patent without an adversarial process. IPRs also serve the important public purpose of "'reexamin[ing] an earlier agency decision,' i.e., [to] take 'a second look at an earlier administrative grant of a patent,' and thereby 'help[] protect the public's paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.'"[85] Thus, permitting the use of sovereign immunity as both a sword and a shield would appear to be contrary to the spirit behind the IPRs, which has only been made more evident with recent legislative proposals to make that intent express.[86]

Under these circumstances, pharmaceutical companies may not view tribal immunity as particularly valuable if it can only be used defensively, and not offensively. Thus, there does not appear to be a particularly large incentive for pharmaceutical companies to enter into deals with Native American tribes in the hopes of using their immunity to shield patent challenges before the PTAB. And this was made all the more true by the Federal Circuit's recent decision.

In sum, while the Allergan-Mohawk deal was unusual and generated significant attention, the gambit was short-lived—particularly in light of the Federal Circuit's ruling that tribal immunity is no bar to IPRs. Further, even better-structured deals that provide Native American tribes more meaningful rights in the patents are not likely to be a recurring issue because the value of an infringement lawsuit significantly outweighs the potential defensive value of the tribe's tribal immunity.

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1 *See Mylan Pharms. Inc. v. Saint Regis Mohawk Tribe*, No. IPR2016-01127, et al. (P.T.A.B. Feb. 23, 2018) (hereinafter the "IPR Tribe Decision").

2 *St. Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F.3d 1322 (Fed. Cir. 2018), *reh'g en banc denied* (Fed. Cir. Oct. 22, 2018) (hereinafter the "Federal Circuit Decision").

3 *See Allergan, Inc. v. Teva Pharms. USA, Inc*., No. 2:15-cv-01455, 2017 U.S. Dist. LEXIS 170825 (E.D. Tex. Oct. 16, 2017).

4 Restasis had approximately $1.49 billion in sales in 2016 and $676.4 million in sales in the first half of 2017. *See* Jonathan Stempel, *Shire Sues Allergan in U.S. Over Dry Eye Drug*, Reuters, Oct. 2, 2017, https://reut.rs/2xOQNkO.

5 *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.95.

6 *See* Compl., *Allergan, Inc. v. Teva Pharms. USA, Inc.,* No. 2:15-cv-01455 (E.D. Tex. Aug. 24, 2015). Allergan later sued InnoPharma and TWi Pharmaceuticals for infringement of the Restasis patents. *See* Compl., *Allergan, Inc. v. InnoPharma, Inc.*, No. 1:15-cv-00815 (D. Del. Sept. 14, 2015); Compl., *Allergan, Inc. v. InnoPharma, Inc.*, No. 2:15-cv-01504 (E.D. Tex. Sept. 8, 2015); Compl., *Allergan, Inc. v. TWi Pharms*., Inc., No. 1:16-cv-00620 (D. Del. July 20, 2016).

7 *See, e.g.*, Compl., *Allergan, Inc. v. Teva Pharms. USA, Inc.,* No. 2:15-cv-01455 (E.D. Tex. Aug. 24, 2015). In the suit against TWi, Allergan also alleged infringement against the 9,248,191 patent.

8 *See* Answers, *Allergan, Inc. v. Teva Pharms. USA, Inc.,* No. 2:15-cv-01455 (E.D. Tex.) at (Nos. 30 (Mylan), 33 (Apotex), 40 (Teva), and 41 (Akorn)).

9 *Allergan, Inc. v. Teva Pharms. USA, Inc.,* No. 2:15-cv-01455 (E.D. Tex. Oct. 16, 2017) (ECF No. 523 at 29, *citing* ECF Nos. 457, at 73-74; 492, at 4; 494, at 34 n.4).

10 *Allergan, Inc. v. Teva Pharms. USA, Inc.,* No. 2:15-cv-01455 (E.D. Tex. Oct. 16, 2017) (No. 523).

11 IPR Tribe Decision at 5 (internal quotations and citation omitted).

12 *Id.* at 5-6 (internal quotations and citation omitted).

13 *Id.* at 6 (internal quotations and citation omitted).

14 *Id.* at 21. The License also provides the Tribe with the first right to sue in connection with infringement "unrelated to . . . Generic Equivalents." *Id.* at 6.
15 *Id.* at 6.
16 *Id.* at 26.
17 *Id.* at 23 (internal quotations and citation omitted) (emphasis in original).
18 *Id.* at 23 & n.8 (internal quotations and citation omitted).
19 *Id.* at 31.
20 *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 15-cv-01455 (E.D. Tex. Sept. 11, 2017) (ECF No. 481, at 1-2).
21 S. 1948, 115th Cong. § 1(b) (2017) ("Notwithstanding any other provision of law, an Indian tribe may not assert sovereign immunity as a defense in a review that is conducted under chapter 31 of title 35, United States Code."); Press Release, Sen. Tom Cotton, *Cotton, Colleagues Introduce the PACED ACT Preserving Access to Cost Effective Drugs Act* (Mar. 7, 2018), https://www.cotton.senate.gov/?p=press_release&id=901 (Senators Tom Cotton, Claire McCaskill, Pat Toomey, Joni Ernst, and David Perdue introduced the "Preserving Access to Cost Effective Drugs Act", which "restores the power of Patent and Trade[mark] Office and federal courts, and the International Trade Commission to review patents regardless of sovereign immunity claims made as part of sham transactions.").
22 *See Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 15-cv-01455 (E.D. Tex. Sept. 11, 2017) (ECF Nos. 503, 509).
23 *See id*. (ECF Nos. 510, 511, 513, 514).
24 *Id.* (ECF No. 522, at 4).
25 *Id.*
26 *Id.* (ECF No. 522, at 10).
27 *See* IPR Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00576, IPR2017-00594, IPR2017-00578, IPR2017-00596, IPR2017-00579, IPR2017-00598, IPR2017-00583, IPR2017-00599, IPR2017-00585, IPR2017-00600, IPR2017-00586, and IPR2017-00601.
28 *See, e.g., Teva Pharms. USA, Inc. v. Allergan, Inc*., No. IPR2017-00578 (P.T.A.B. Jan. 6, 2017) (Paper No. 3) (Teva's petition for cancellation of the '111 patent); *Teva Pharms. USA, Inc. v. Allergan, Inc.*, No. IPR2017-00576 (P.T.A.B. Jan. 6, 2017) (Paper No. 4) (Teva's petition for cancellation of the '930 patent).
29 Pub. L. No. 112-29, 125 Stat. 284 (2012).
30 *See* WilmerHale, *A Practical Guide to* Inter Partes Review: *Strategic Considerations for Pursuing Inter Partes Review in a Litigation Context*.
31 35 U.S.C. § 314(a).
32 *See* 35 U.S.C. §§ 311, 316.
33 *See* 35 U.S.C. § 317; 37 C.F.R. § 42.74; *Microsoft Corp. v. Global Techs., Inc.*, No. IPR2016-00663 (P.T.A.B. June 2, 2017) (Paper 33) (entering adverse judgment and final written decision where no legally recognized patent owner made an appearance).
34 Many pharmaceutical patent settlements contain provisions that permit the competitor to enter immediately upon a final judicial determination of invalidity.
35 *See* IPR2016-01127 (Paper No. 81).
36 *See, e.g.,* IPR2016-01127 (Paper No. 87).
37 IPR2016-01127 (Paper No. 96).
38 The amicus brief filers included: The Oglala Sioux Tribe (Paper No. 104); Public Knowledge and the Electronic Frontier Foundation (Paper No. 105); Legal Scholars (Paper 106); Askeladden LLC (Paper No. 107); DEVA Holding A.S. (Paper No. 108); The High Tech Inventors Alliance (Paper No. 109); The Seneca Nation (Paper No. 110); Native American Intellectual Property Enterprise Council, Inc. (Paper No. 111); Software & Information Industry Association (Paper No. 112); U.S. Inventor, LLC (Paper No. 113); The National Congress of American Indians, National Indian Gaming Association, and the United South and Eastern Tribes (Paper No. 114); Luis Ortiz and Kermit Lopez (Paper No. 115); The Association for Accessible Medicines (Paper No. 116); BSA | The Software Alliance (Paper No. 117); and James R. Major, D.Phil. (Paper No. 118).
39 *See* IPR Tribe Decision at 35, n.11.
40 *See Fed. Maritime Comm'n v. S.C. State Ports Auth*., 535 U.S. 743 (2002).
41 IPR Tribe Decision at 9 (quoting *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 756 (1998)).
42 *Id.* at 10.
43 *Id.* at 11 (quoting *Fed. Power Comm'n v. Tuscarora Indian Nation*, 362 U.S. 99, 120 (1960)).
44 IPR Tribe Decision at 11.
45 *Id.* at 16.
46 *Id.* at 17 (citing *Microsoft Corp. v. Global Techs., Inc.*, No. IPR2016-00663, (P.T.A.B. June 2, 2017) (Paper No. 33) (entering judgment on patent where no patent owner appeared) and 37 C.F.R. § 42.74(a); 35 U.S.C. § 317(a), which both permit the PTAB to proceed to determination even if no petitioner remains in the *inter partes* review).
47 IPR Tribe Decision at 20 (quoting *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1342 (Fed. Cir. 2014)).
48 IPR Tribe Decision at 22.
49 *Id.* at 27.
50 *Id.* at 28.
51 *Id.* at 29, 31, 32.
52 *Id.* at 35.
53 *Id.* at 36 (citing 37 C.F.R. §§ 42.1-42.123).
54 IPR Tribe Decision at 37.
55 *Id.* at 39.
56 *Id*.
57 *See* IPR2016-01127 (Paper No. 133) (notice of appeal).
58 *See St. Regis Mohawk Tribe v. Mylan Pharms. Inc*., No. 18-1638, ECF No. 42 (Fed. Cir. Mar. 28, 2018).
59 Federal Circuit Decision at 1326.
60 Id. at 1326 (*quoting Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2143-44 (2016)).
61 Federal Circuit Decision at 1326-27 (*comparing Oil States Energy Servs. v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1373 (2018) (IRPs are "simply a reconsideration of" the PTO's original grant, which serves to protect "the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope") *with SAS Inst. Inc. v. Iancu,* 138 S. Ct. 1348, 1348 (2018) (noting the adversarial aspects of an IPR and the way it "mimics civil litigation")).
62 Federal Circuit Decision at 1327 (*citing Oil States*, 138 S. Ct. at 1371).
63 Federal Circuit Decision at 1327 (*citing Wi-Fi One, LLC v. Broadcom Corp*., 878 F.3d 1364, 1372 (Fed. Cir. 2018) (en banc)).
64 In *Federal Maritime Comm'n v. South Carolina Ports Auth.*, 535 U.S. 743 (2002), the Supreme Court held that South Carolina's sovereign immunity barred it being hauled into proceedings before the Federal Maritime Commission by a private party.
65 Federal Circuit Decision at 1327.
66 IPR Tribe Decision at 17.
67 Federal Circuit Decision at 1328.
68 *Id.*
69 *Id.* (*citing Nat'l Envt'l Prods. Ltd. v. Dri-Steem Corp*., IPR2014-01503, Paper 11 (PTAB Nov. 4, 2014)).
70 Federal Circuit Decision at 1328 (*quoting* 35 U.S.C. § 316(a)(5)).
71 *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1270 n.2 (Fed. Cir. 2017).
72 Federal Circuit Decision at 1329.
73 *Id.* (*quoting Cuozzo*, 136 S. Ct. at 2144).
74 Federal Circuit Decision at 1329.
75 *Id.*
76 *Id.* (Dyk, J. concurring).
77 IPR Tribe Decision at 20.
78 *See* Maryll Toufanian, & Martin Shimer, *Hatch-Waxman 101*, at 9, Presentation at Regulatory Education for Industry (REdI): Generic Drugs Forum (Apr. 22-23, 2015), https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM445610.pdf.
79 Courts have long held that "[a]n action for infringement must join as plaintiffs all co-owners." *Ethicon, Inc. v. U.S. Surgical Corp*., 135 F.3d 1456, 1467 (Fed. Cir. 1998) (*citing Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891)). *See also Isr. Bio-Eng'g Project v. Amgen, Inc.,* 475 F.3d 1256, 1264-65 (Fed. Cir. 2007) ("Where one co-owner possesses an undivided part of the entire patent, that joint owner must join all the other co-owners to establish standing. . . . Absent voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing.") (citations omitted).

80 Although the Supreme Court in *Oklahoma Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Oklahoma*, 498 U.S. 505, 510 (1991), held that the mere filing of a suit does not waive an Indian tribe's sovereign immunity, other cases have affirmed the narrow principle that "'when the sovereign sues it waives immunity as to claims of the defendant which assert matters in recoupment-arising out of the same transaction or occurrence which is the subject matter of the government's suit.'" *Jicarilla Apache Tribe v. Andrus,* 687 F.2d 1324, 1344 (10th Cir. 1982) (citation omitted). *See also, e.g., Flandreau Santee Sioux Tribe v. Gerlach*, 162 F. Supp. 3d 888, 894 (D.S.D. 2016) (when a tribe brings suit, tribal immunity waived for counterclaims sounding in recoupment) (*citing Berrey v. Arasco, Inc*., 439 F.3d 636, 643 (10th Cir. 2006)); *Buchwald Capital Advisors, LLC for Greektown Litig. Trust v. Sault Ste. Marie Tribe of Chippewa Indians*, 584 B.R. 706, 717 (E.D. Mich. 2018) (recognizing the "narrow recoupment exception could apply to Indian tribes") (*citing Andrus*, 687 F.2d at 1344).

81 *See Ericsson Inc. v. Regents of the Univ. of Minn.,* No. IPR2017-01186, et al. (P.T.A.B. Dec. 19, 2017) (Paper No. 14, at 9) (*citing Lapides v. Bd. of Regents of Univ. Sys. of Ga.,* 535 U.S. 613, 619-20 (2002)).

82 *Ericsson, Inc.*, IPR2017-01186 (Paper No. 14, at 8-9).

83 *Regents of the Univ. of New Mexico v. Knight*, 321 F.3d 1111, 1125 (Fed. Cir. 2003). However, a few years later in 2007, the Federal Circuit in *Tegic Communications Corp. v. Board of Regents of Univ. of Texas Sys.*, 458 F.3d 1335 (Fed. Cir. 2007), upheld a state university's immunity from plaintiff's declaratory judgment action because the declaratory judgment action was brought in a different district court from the one where the university was prosecuting an infringement action against other parties. But later that year, the Federal Circuit cautioned that *Tegic* did not "draw a bright-line rule whereby a State's waiver of sovereign immunity can never extend to a separate action *simply because* the action involves the same parties and same subject matter." *Biomedical Patent Mgmt. Corp. v. Cal. Dep't of Health Servs.,* 505 F.3d 1328, 1339 (Fed. Cir. 2007) (emphasis in original). Whether the Federal Circuit will read *Tegic* to bar IPR petitions against state institutions prosecuting parallel infringement actions in federal court is an open question.

84 *Compare Michigan v. Bay Mills Indian Cmty*., 134 S. Ct. 2024, 2030 (2014) ("Among the core aspects of sovereignty that tribes possess . . . is the common-law immunity from suit traditionally enjoyed by sovereign powers") (quotes omitted) *with Principality of Monaco v. Mississippi,* 292 U.S. 313, 322-23 (1934) ("There is also the postulate that States of the Union, still possessing attributes of sovereignty, shall be immune from suits, without their consent, save where there has been a surrender of this immunity in the plan of the [Constitutional] [C]onvention") (quotes and citation omitted). *See also* U.S. Const., amend. XI ("The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.").

85 IPR Tribe Decision at 12 (*quoting Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016)).

86 *See supra* note 21.