

**Nos. 18-1638, -1639, -1640, -1641, -1642, -1643**

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**In the United States Court of Appeals  
For the Federal Circuit**

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SAINT REGIS MOHAWK TRIBE and ALLERGAN, INC.,  
*Appellants,*

v.

MYLAN PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and AKORN,  
INC.,

*Appellees.*

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Appeal from: Patent and Trademark Office - Patent Trial and Appeal Board  
in *Inter Partes* Review Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129,  
IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00576,  
IPR2017-00578, IPR2017-00579, IPR2017-00583, IPR2017-00585,  
IPR2017-00586, IPR2017-00594, IPR2017-00596, IPR2017-00598,  
IPR2017- 00599, IPR2017-00600, IPR2017-00601.

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Saint Regis Mohawk Tribe	N/A	N/A
Allergan, Inc.	N/A	Allergan plc

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Federal Circuit: *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2018-1130

Eastern District of Texas: *Allergan, Inc. v. Deva Holding A.S.*, No. 2:16-cv-1447

April 18, 2018

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## INTRODUCTION

This case presents the question of whether a patent owner with sovereign immunity—the Saint Regis Mohawk Tribe (the “Tribe”)—may assert that immunity in an *inter partes* review (“IPR”) proceeding before the Patent Trial and Appeal Board (the “Board”).

The Board denied tribal immunity in the IPRs, even though it has repeatedly allowed state universities that own and license patents to assert sovereign immunity from IPRs. In so ruling here, the Board departed from Supreme Court precedent recognizing tribal immunity from suit, as well as this Court’s prior recognition that IPRs are adjudicatory proceedings.

The Board offered conclusory assertions rather than reasoned analysis to support its decision. For example, it insisted there was no “controlling precedent” to support tribal immunity (Appx10), despite the long history of Supreme Court decisions; it referred to “the recognized differences between the state sovereign immunity and tribal immunity doctrines” (*id.*), without explaining what those differences were or why they mattered; and it pointed to “other types of federal administrative proceedings” (Appx14), without addressing the Tribe’s showing that those proceedings were materially different from IPRs because they were agency *enforcement actions* (which IPRs, as adjudicatory proceedings between private parties, are not).

The Board then denied the motion to withdraw by the Tribe's licensee, Allergan, Inc. ("Allergan"), even though the Tribe owns the patents and retained substantial rights under its license to Allergan. The Board flouted this Court's decisions construing similar license agreements. The Board also failed to follow this Court's precedent in concluding that, even if the Tribe had sovereign immunity, and even if IPRs would ultimately prejudice the Tribe's interests, the IPRs could proceed in the Tribe's absence.

By Order of March 28, 2018, this Court stayed further proceedings before the Board, pending appeal. This Court should reverse the Board's decisions and dismiss the IPR proceedings.

### **STATEMENT OF RELATED CASES**

Some of the patents-in-suit are the subject of a separate appeal pending in this Court, No. 2018-1130. An additional district court case involving the same patents is pending in the Eastern District of Texas. *Allergan, Inc. v. Deva Holding A.S.*, No. 2:16-cv-1447-WCB.

### **JURISDICTIONAL STATEMENT**

The Tribe appeals from the February 23, 2018 decision of the Board denying dismissal based on sovereign immunity, Appx1-42, and Allergan appeals the Board's denial of its motion to withdraw. Appx43-48. The Combined Notice of Appeal was filed on February 28, 2018.



This Court has jurisdiction over the Tribe's appeal under 35 U.S.C. § 141(c) and 28 U.S.C. § 1295(a)(4)(A). A decision denying a motion to dismiss on sovereign immunity grounds is immediately appealable under the collateral order doctrine. *Univ. of Utah v. Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V.*, 734 F.3d 1315, 1319 (Fed. Cir. 2013).

The Court should exercise pendent jurisdiction over Allergan's appeal. The Court may exercise pendent appellate jurisdiction where an issue is "inextricably intertwined with [a] court's decision to deny" immunity or where review of the issue is "necessary to ensure meaningful review" of the denial of immunity. *Swint v. Chambers Cty. Comm'n*, 514 U.S. 35, 51 (1995); *see also Intel Corp. v. Commonwealth Sci. & Indus. Research Org.*, 455 F.3d 1364, 1369 (Fed. Cir. 2006) (exercising pendent appellate jurisdiction in sovereign immunity appeal).

Here the patent ownership issue is inextricably intertwined with the tribal immunity issue. Specifically, the question of who owns the patents is key to determining whether the Board can proceed despite the Tribe's immunity. Before the Board, Appellees acknowledged that Allergan's motion to withdraw (on the ground it was no longer the owner of the patents) was "inextricably tied to the Tribe's motion to dismiss." Appx3131. Before this Court, Appellees have argued there is no immunity bar because Allergan owns the patents. *See* Doc. 39, at 9-10 (Fed. Cir.).

In its Order of March 28, 2018, this Court recognized that both “[t]he Tribe and Allergan have appealed from the Board’s rejection of the Tribe’s sovereign immunity claim and motion to terminate proceedings and *all* issues raised therein.” Order at 2 (emphasis added). This Court explained: “[a]t this juncture, it appears that the *appeals* divested the Board of jurisdiction over *the aspects of the case* on appeal.” *Id.* (emphasis added).

### STATEMENT OF THE ISSUES

1. Whether the Board erred in holding that tribal immunity does not apply to IPR proceedings.
2. Whether the Board erred in holding that, even if the Tribe were entitled to assert immunity, the IPRs may proceed in the Tribe’s absence because Allergan is the “effective patent owner” of the patents-in-suit and the Tribe is not an “indispensable party.”

### STATEMENT OF THE CASE

#### A. Statement Of Facts.

1. **The Tribe Enters The Field Of Patent Licensing And Technology Transfer To Diversify Its Economy And Provide Support For Its Government Programs.**

The Tribe is a federally recognized Indian tribe with a federal reservation of 14,000 acres in a rural area of northern New York, along the Saint Lawrence River and the border with Canada. Appx1629, Appx1633 (1796 Treaty with the Seven

Nations of Canada, 7 Stat. 55). The Tribe has over 15,600 enrolled tribal members, with approximately 8,000 living on the reservation.

Like any sovereign government, the Tribe provides essential government functions such as education, policing, infrastructure, housing services, social services and health care. But unlike other sovereign governments, the Tribe's ability to raise revenues through taxation is extremely limited, and the Tribe must engage in commercial activities to generate revenue for governmental purposes. *See Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2043-44 (2014) (Sotomayor, J., concurring) (discussing impediments faced by tribes in generating revenue).

To overcome this economic disadvantage, the Tribe has taken steps to diversify its economy and foster jobs by investing in innovative businesses and various enterprises. The Tribe has a casino resort operated under federal law. But diversification is key to long-term economic viability, so the Tribe has sought other investment and business opportunities that are not tied to tourism. Looking to state universities, the Tribe created a technology and innovation center (the Office of Technology, Research and Patents ("Office")) to commercialize existing and emerging technologies. Appx1638-1639. All revenue generated by the Office will go into the Tribal General Fund and be used to address the chronically unmet needs of the Tribal community, such as housing, employment, education, health care, and cultural and language preservation.

## **2. Allergan Assigns Its Restasis® Patents To The Tribe.**

As part of its technology policy, the Tribe entered into an assignment and licensing agreement with Allergan for its Restasis® patents. Allergan sought to strengthen the defense of its intellectual property in IPR proceedings. Restasis® is FDA-approved to treat a condition known as “dry eye” by increasing a patient’s natural tear production. Appx24.

The assignment provides that “for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged,” Allergan, as the Assignor, “irrevocably conveys, transfers, and assigns to Assignee, and Assignee hereby accepts, all of Assignor’s right, title, p[r]erogatives, benefits, and interest in and to . . . the Assigned Patents.” Appx2556. Allergan and the Tribe recorded a short-form assignment with the PTO. Appx1796-1803.

In the license agreement, Allergan paid the Tribe the sum of \$13,750,000 and further agreed to pay quarterly royalties of \$3,750,000 until the patents expire or are rendered invalid by a nonappealable final judgment. Appx2580 (§§ 4.1, 4.2); Appx2593 (§ 9.1.1).

In return, the Tribe granted Allergan an exclusive field-of-use license limited to the use of “Licensed Products for all FDA-approved uses in the United States.” Appx2578-2579 (§ 2.1). “Licensed Products” are defined as products “approved by

the FDA for sale in the United States under, or otherwise relating or referring to” the Restasis® New Drug Applications (“NDAs”). Appx2576 (§1.33).

The Tribe retains all rights under the patents “not expressly granted” to Allergan. Appx2579 (§ 2.4). These retained rights include the right to practice the patents (subject to certain limitations)<sup>1</sup> in all other fields of use outside the Allergan license. For example, if the Tribe were to conduct clinical trials for a cyclosporin product and obtain FDA approval of the product without reference to or reliance on the Restasis® NDAs and with a different indication, it would be able to practice the patents and retain all rights in that product. The Tribe also retains the right to use and practice the patents for “research, scholarly use, teaching, education, patient care incidental to the foregoing [and] sponsored research” in connection with the FDA-approved use of Restasis®, as well as off-label uses. Appx2579 (§ 2.4).

There is a substantial potential market for cyclosporin products for uses other than dry eye. As reported in the REVIEW OF OPHTHALMOLOGY, “[i]n addition to its FDA-approved indications for the treatment of dry eye, Restasis has many off-label uses,” and “ophthalmologists are using it off-label to treat many conditions.” Appx2957. These off-label uses include treatment for conditions such as fungal

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<sup>1</sup> The Tribe may not develop a product relying on the Restasis® NDAs or qualifying as or competing with a “Licensed Product.” Appx2579 (§ 2.4); Appx2575 (§ 1.10 (defining “Competing Product”)).

infections, prevention of corneal transplant rejection, and management of post-corneal transplant glaucoma and cataracts. Appx2957-2963. In the words of Dr. Eric Donnenfeld, then an associate professor of ophthalmology at New York University Medical Center, “[t]here are opportunities for its use that we haven’t even explored yet.” Appx2962; *see also* Appx2964-2981 (article by Dr. Donnenfeld).

Although the license grants Allergan the right to enforce the patents against generic equivalents of Restasis®, the Tribe has the right to sue third parties in this field-of-use if Allergan declines to do so. Appx2582 (§ 5.2.2). Moreover, Allergan must consider the Tribe’s reasonable input when Allergan sues generic infringers in its field-of-use. *Id.*

With respect to any infringement outside of Allergan’s field-of-use, the Tribe retained the first right to enforce the patents against third parties. Appx2582-2583 (§ 5.2.3). The Tribe retains the proceeds from any such suit it brings. Appx2583 (§ 5.2.5). The Tribe also must preapprove any settlements relating to the patents-in-suit, even in Allergan’s field-of-use. Appx2583 (§ 5.2.4).

### **3. Controversy Over The Agreement.**

Allergan’s competitors and litigation opponents publicly criticized the transaction as a “sham” intended to avoid the IPR process. This argument has been made before in state university cases, and the Board has rejected it. For example, in *Covidien LP v. University of Florida Research Foundation Inc.*, IPR2016-01274,

the petitioner argued that extending sovereign immunity to IPRs would “do[] great harm to the patent system” by encouraging “entities whose patents are the subject of review . . . to assign them to a state entity, perhaps in exchange for an exclusive grant-back license.” Appx3360. The Board flatly rejected this argument as a basis to deny immunity in *Covidien* and held that the state university was entitled to assert sovereign immunity in an IPR. Appx1640-1679; *see also Reactive Surfaces Ltd., LLP*, IPR2017-00572, Appx1701-1719 (same); *Neochord, Inc. v. Univ. of Md.*, IPR2016-00208, Appx1680-1700. Chief Administrative Patent Judge David Ruschke has reiterated that IPR “is an adjudicatory proceeding of a federal agency from which state entities are immune.” Appx3372.

Nevertheless, opponents of tribal immunity lobbied Congress to the point where an oversight hearing was held,<sup>2</sup> and bills have been introduced in Congress to abrogate tribal immunity in IPRs.<sup>3</sup>

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<sup>2</sup> Hearing on Sovereign Immunity and the Intellectual Property System, House Oversight and Government Reform Subcommittee on Courts, Intellectual Property, and the Internet (Nov. 7, 2017).

<sup>3</sup> *See* S. 1948 - A bill to abrogate the sovereign immunity of Indian tribes as a defense in inter partes review of patents, <https://www.congress.gov/bill/115th-congress/senate-bill/1948/text> (Oct. 5, 2017); S. 2514 - PACED Act, <https://www.congress.gov/bill/115th-congress/senate-bill/2514/text> (March 7, 2018).

In response, the Tribe and Allergan made clear that they did nothing more than follow the model created by state universities. Appx2474-2529. As of 2012, U.S. colleges and universities had been assigned more than 75,300 patents by companies and other inventors. Appx2509. Moreover, universities are prolific patent licensors; some 4,350 university-licensed products are in the market, and approximately 5,000 active university-industry licenses are in effect.<sup>4</sup> The Tribe hopes one day to have a similar portfolio for licensing.

## **B. Procedural History.**

### **1. The Eastern District Of Texas Case.**

Allergan filed suit against Mylan, Teva, Akorn, and other parties in the Eastern District of Texas alleging infringement of its Restasis® patents before the Tribe became the patent owner. A week-long bench trial was held in front of Judge Bryson starting on August 28, 2017. Appx2092.

Shortly after the trial concluded but before any ruling, Allergan assigned the Restasis® patents to the Tribe and moved to join the Tribe as a co-plaintiff. Appx2092. The district court indicated “it was not required to decide whether the assignment . . . was valid,” but in *dicta* it criticized the business arrangement

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<sup>4</sup> Pam Baker, *The Positive Impact of Academic Innovations on Quality of Life*, THE BETTER WORLD REPORT, [http://www.betterworldproject.org/BetterWorldProject/media/Better-World-Reports/Documents/AUTM\\_BWR\\_2010\\_Positive\\_Impact\\_Academic\\_Innovations.pdf](http://www.betterworldproject.org/BetterWorldProject/media/Better-World-Reports/Documents/AUTM_BWR_2010_Positive_Impact_Academic_Innovations.pdf) (2010).



between the Tribe and Allergan. *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at \*4 (E.D. Tex. Oct. 16, 2017). That same day, the district court released findings of fact and conclusions of law that Mylan, Teva, and Akorn infringed all the asserted claims, that the Restasis® patents were not invalid for anticipation and not invalid for lack of enablement or improper inventorship, but that the asserted claims were invalid for obviousness. Appx2227-2228. That decision is the subject of a pending appeal to this Court, No. 2018-1130.

## **2. The *Inter Partes* Review Proceedings.**

Mylan, Akorn, and Teva filed their own IPR petitions against each of the six Restasis® patents. One week before the IPR hearing, the Tribe and Allergan finalized the aforementioned assignment and licensing agreements. Appx2556-2606. The Tribe made a special appearance in the IPR to assert its sovereign immunity, Appx1528, and the Board granted the Tribe's request to postpone the hearing and allow it to move to terminate the IPRs on the ground of its immunity. Appx1582. Allergan filed a motion to withdraw on the ground it was no longer the patent owner. Appx3107-3122.

The Board authorized *amici curiae* briefs on the issues raised by the Tribe. Appx3. Judge Ruschke noted that it was the "very first time that the board has authorized the filing of amicus briefs in any of [its] cases." Appx2617. Ultimately a total of fifteen amicus briefs were filed. Appx62-63.

On February 23, 2018, the Board issued its decision denying the Tribe's motion. The Board cited Supreme Court precedent establishing tribal immunity. Appx7. The Board nevertheless held, with little or no reasoned explanation, that state sovereign immunity is "distinguishable" from tribal immunity (without elaborating the relevant respects or their impact) (Appx8 n.4), an IPR "is not the type of 'suit'" to which tribal immunity applies (without defining what type of suit it is) (Appx16), and "we are not persuaded that the tribal immunity doctrine applies to our proceedings." Appx11.

In the alternative, the Board held that the IPR could proceed without the Tribe's participation because Allergan is the "effective patent owner" (Appx35), even though that term does not appear in the Patent Act or relevant regulations. The Board further held the Tribe was not an indispensable party because Allergan (purportedly) could represent its interest (Appx37), even though the Tribe is a sovereign and Allergan is a publicly traded company. The Board declined to find that the Allergan-Tribe agreement was a "sham" or "otherwise improper under the law." Appx35 n.11.

That same day, the Board denied Allergan's motion to withdraw and set April 3, 2018 as the date for the final hearing. Appx43-48.

## SUMMARY OF THE ARGUMENT

In the face of over a century of precedent holding that a tribe is not subject to suit in federal or state court absent waiver or abrogation, the Board held that there was no “statutory authority or controlling precedent” to permit the Tribe to invoke its immunity in an IPR. Appx10. This is a remarkable conclusion. The Board took a step that the U.S. Supreme Court has repeatedly held a court should not take—denying tribal sovereign immunity in an adjudication absent any explicit statement of congressional abrogation of immunity or clear tribal waiver.

The Board claimed lack of precedent, but the Supreme Court has repeatedly reaffirmed tribal immunity as settled law. It has also extended sovereign immunity principles to administrative adjudications in *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. 743, 754-756 (2002) (*FMC*), which the Board itself recognized in allowing state universities to assert sovereign immunity in IPR proceedings.

The Board denied tribal immunity by equating an IPR with an enforcement action initiated by a federal agency, but this Court has recognized that an IPR is a private adjudicatory action. It is a trial-like proceeding instituted and prosecuted by private parties.

The Board also erred in holding it could proceed with the IPRs in the Tribe’s absence because Allergan is the “effective patent owner” of the challenged patents.

Appx35. First, the Tribe is in fact the patent owner, and the Board lacked authority to invoke a concept—“effective patent owner”—that is absent from the Patent Act. Second, the Board erred in concluding that Allergan held “all substantial rights” under its license from the Tribe. The license, however, contains standard provisions, which this Court has held do *not* transfer “all substantial rights.”

The Board committed further legal error in holding that the Tribe is not an indispensable party and that the case could proceed without it. The Board failed to follow this Court’s decisions giving weight to sovereign interests and failed to recognize the significant prejudice to the Tribe if the IPRs were permitted to continue in its absence. However, if the Court finds that the Board erred in denying Allergan’s motion to withdraw, it would not even need to consider whether the Tribe was an indispensable party.

This Court should direct the dismissal of the IPR proceedings.

## **ARGUMENT**

### **STANDARD OF REVIEW**

This appeal presents legal questions that this Court reviews *de novo*. *Steuben Foods, Inc. v. Nestle USA, Inc.*, 884 F.3d 1352, 1355 (Fed. Cir. 2018). The Board’s decision rests on legal conclusions, and this Court need not review any disputed issues of material fact in order to reverse the Board. The Court reviews *de novo* decisions concerning sovereign immunity, *Univ. of Utah*, 734 F.3d at 1320, and

standing. *Alps South, LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1382 (Fed. Cir. 2015).

An indispensable-party determination under Rule 19 is reviewed for abuse of discretion, *Cloverleaf Standardbred Owners Ass’n, Inc. v. Nat’l Bank of Wash.*, 699 F.2d 1274, 1276-77 (D.C. Cir. 1983), although a “court by definition abuses its discretion when it makes an error of law.” *Koon v. United States*, 518 U.S. 81, 100 (1996).

**I. THE TRIBE’S SOVEREIGN IMMUNITY APPLIES TO *INTER PARTES* REVIEW.**

The Board acknowledged that “Indian tribes are ‘domestic dependent nations’” that “exercise ‘inherent sovereign authority.’” Appx7 (quoting *Bay Mills*, 134 S. Ct. at 2024, 2030). It conceded that, “[a]s a matter of federal law, an Indian tribe is subject to suit only where Congress has authorized the suit or the tribe has waived its immunity.” Appx7 (quoting *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 754 (1998)).

The Board cited these principles but failed to follow them. It opined that there was “no controlling precedent or statutory basis for the application of tribal immunity” in IPRs (Appx7 (heading)), ignoring the Supreme Court’s teaching that tribal immunity is “settled law” and “[t]he baseline position, [the Court has] often held, is tribal immunity; and ‘[t]o abrogate [such] immunity, Congress must ‘unequivocally’ express that purpose.’” *Bay Mills*, 134 S. Ct. at 2031 (citations

omitted); *see also, e.g., Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 58 (1978) (congressional waivers of sovereign immunity “cannot be implied but must be unequivocally expressed”) (citation omitted); *Puyallup Tribe, Inc. v. Dep’t of Game*, 433 U.S. 165, 172-73 (1977); *United States v. U.S. Fid. & Guar. Co.*, 309 U.S. 506, 512 (1940). Similarly, any waiver of sovereign immunity by the Tribe must be unequivocally expressed. *See, e.g., C & L Enters. Inc. v. Citizen Band Potawatomi Tribe of Okla.*, 532 U.S. 411, 418 (2001) (“to relinquish its immunity, a tribe’s waiver must be ‘clear’”). Waiver “cannot be implied on the basis of a tribe’s actions.” *Florida v. Seminole Tribe of Fla.*, 181 F.3d 1237, 1243 (11th Cir. 1999).

The Board opined that “*Board* precedent cautions against the application of non-statutory defenses in inter partes review proceedings.” Appx10 (emphasis added). But Board precedent is trumped by Supreme Court precedent, which has long recognized that tribal sovereign immunity applies to commercial activities, including off-reservation activities. Most recently, in *Bay Mills*, the Supreme Court explained that “a long line of precedents, concluding that ‘the doctrine of tribal immunity’—without any exceptions for commercial or off-reservation conduct—is settled law and controls this case.” 134 S. Ct. at 2036. In reaffirming these precedents, the Court expressly rejected the dissent’s concerns about private companies partnering with tribes in order to invoke immunity and avoid liability. *See id.* at 2036-39; *id.* at 2051-52 (Thomas, J., dissenting). Other courts have

likewise recognized the “broad interpretation of tribal sovereign immunity” in part based on “Congress’ desire to promote the goal of Indian self-government, including its overriding goal of encouraging tribal self-sufficiency and economic development.” *Breakthrough Mgmt. Grp., Inc. v. Chukchansi Gold Casino & Resort*, 629 F.3d 1173, 1183 (10th Cir. 2010) (citations omitted).

**A. Congress Has Not Abrogated Tribal Immunity In IPR Proceedings.**

The standard for congressional abrogation of tribal immunity is exacting: Congress must speak clearly and unequivocally. Congress did not expressly abrogate tribal sovereign immunity in the America Invents Act, or any other statute, for purposes of IPR. In fact, Congress did not mention tribes in any statute governing patents. *See Home Bingo Network v. Multimedia Games, Inc.*, No. 1:05-CV-0608, 2005 WL 2098056, at \*1 (N.D.N.Y. Aug. 30, 2005) (“Plaintiff points to no authority that Congress has expressly waived tribal immunity with respect to the enforcement of patents.”); *Specialty House of Creation, Inc. v. Quapaw Tribe*, No. 10-CV-371-GKF-TLW, 2011 WL 308903, at \*1 (N.D. Okla. Jan. 27, 2011) (noting “no authority that Congress has expressly abrogated tribal sovereign immunity with respect to the enforcement of patents”).

Indeed, legislation has been introduced in Congress to abrogate tribal immunity in IPRs, *see* n.3, *supra*. As the Supreme Court has observed, Congress’s consideration of legislative proposals restricting tribal sovereign immunity is a

powerful reason for other branches not to interfere. *See Bay Mills*, 134 S. Ct. at 2038-39. The proposals show that Congress understands that tribes currently possess immunity from IPRs and the decision is Congress's (not the Board's) to make.

The Board opined that since the Tribe is subject to patent laws, it must be subject to IPR proceedings. Appx10-11. But that is wrong: the mere fact that tribes are subject to a general law does not amount to a clear and unequivocal abrogation of immunity. "The fact that a general statute applies to tribes, however, does not mean that Congress has waived tribal sovereign immunity from private suits brought thereunder." *Specialty House*, 2011 WL 308903, at \*1-2 (tribe immune under patent laws); *see also Bassett v. Mashantucket Pequot Tribe*, 204 F.3d 343, 357 (2d Cir. 2000) ("the fact that a [copyright] statute applies to Indian tribes does not mean that Congress abrogated tribal immunity in adopting it").

Moreover, the Tribe's participation in the patent system may not be interpreted as a waiver. *See, e.g., Seminole Tribe of Fla.*, 181 F.3d at 1242 (tribe's participation in gaming activities under the IGRA did not result in waiver of immunity for enforcement by State); *Garcia v. Akwesasne Hous. Auth.*, 268 F.3d 76, 85 (2d Cir. 2001) (no abrogation even if participation in Native American Housing Assistance and Self-Determination Act).



**B. An IPR Is The Type Of “Suit” In Which Tribal Sovereign Immunity Applies.**

As a sovereign, the Tribe is entitled to assert its immunity from suit, whether in a civil action in court or in an adjudication brought by a private party against the Tribe before an administrative body. The Board stated that it “decline[d] the Tribe’s invitation” to hold tribal immunity applicable in IPRs. Appx10. But following binding precedent is not an “invitation” the Board was free to decline.

**1. An IPR Is A Contested Adjudicatory Proceeding Between Private Parties.**

The Board held that an IPR is not the “type of ‘suit’” triggering tribal immunity. Appx16. But its reasoning rested on shifting descriptions of IPRs that contradict this Court’s decisions. The Board insisted that it was “not adjudicating any claims in which Petitioners may seek relief from the Tribe” (Appx16) and distinguished an IPR from an interference proceeding on the ground that an interference is “contested.” Appx11 n.5. This Court’s decisions and the governing statutory and regulatory provisions make clear that IPRs are contested adjudicatory proceedings between private parties. Indeed, in cases involving state universities, the Board itself has agreed that IPRs are contested adjudicatory proceedings and therefore trigger sovereign immunity. Appx1658-1659, Appx1663, Appx1686, Appx3369, Appx3372.

This Court has characterized IPRs as “adjudicatory” proceedings. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) (noting “the adjudicatory context of an IPR”); *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1030 (Fed. Cir. 2016) (“Both the decision to institute and the final decision are adjudicatory decisions.”); *Merck & Cie v. Gnosis S.P.A.*, 820 F.3d 432, 434, 438 (Fed. Cir. 2016) (“adjudicative,” “court-like” proceedings).

In *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376, 1382 (Fed. Cir. 2007), this Court recognized the applicability of sovereign immunity in administrative adjudications and cited a number of factors to determine when an administrative proceeding “can indeed be characterized as a lawsuit.” *See id.* at 1382 (adverse parties, examination and cross examination, deposition discovery, and an impartial federal adjudicator).

All these factors are present in an IPR. In fact, the governing regulations define an IPR proceeding as a “trial” and a contested proceeding. 37 C.F.R. §§ 42.100(a) (“inter partes review is a trial”) and 42.2 (definition of trial as “contested case”). Like lawsuits, IPRs begin with the filing of a Petition—commonly by an alleged patent infringer—that asks the Board to cancel one or more claims of a patent on the ground that they were anticipated by or rendered obvious in view of identified prior art. 35 U.S.C. § 311(b). The Petitioner and Patent Owner then participate in an adversarial proceeding before the Board, taking discovery, engaging in motion

practice regarding evidence, and cross-examining fact and expert witnesses via depositions. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,757-68 (Aug. 14, 2012). Many of the procedural rules that govern the proceedings are based expressly on the Federal Rules of Civil Procedure. *E.g., id.* at 48,760-62.

Three Administrative Patent *Judges* hold a hearing, 37 C.F.R. § 42.70, and—in view of all the record evidence—issue a “final written decision” on whether the patent should be invalidated. 35 U.S.C. § 318(a). The regulations refer to this decision as a “judgment.” Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,766-67. The judgment may be appealed as of right only to this Court. 35 U.S.C. §§ 141(c), 319.

Accordingly, the House Report accompanying the enactment of the IPR provisions explained that they were intended to “convert[ ] inter partes reexamination from an examinational to an *adjudicative* proceeding.” H.R. Rep. No. 112-98, at 46 (2011) (emphasis added).

## **2. Tribal Sovereign Immunity Applies In Administrative Adjudications.**

In *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. at 754-756 (*FMC*), the Supreme Court found that an administrative proceeding before the FMC “walks, talks, and squawks very much like a lawsuit,” and held that a state could therefore invoke sovereign immunity before the FMC. *Id.* at 751. The Court opined that, as a sovereign, the state had the right not to be subject to the

indignity of having to “answer the complaints of private parties in federal courts.” *Id.* at 760. “The affront to a State’s dignity does not lessen when an adjudication takes place in an administrative tribunal as opposed to an Article III court. In both instances, a State is required to defend itself in an adversarial proceeding against a private party before an impartial federal officer.” *Id.* at 761; *see also id.* at 761 n.12 (likening “a complaint filed by a private party against a State with the FMC” to a “lawsuit brought by a private party against a State in federal court”).

The same logic applies to tribal immunity. An IPR is the type of contested adjudicatory proceeding that “walks, talks and squawks” like a lawsuit. Like a lawsuit in court, an adjudicatory action initiated by a private party before an administrative body such as the Board implicates the Tribe’s sovereign interests in avoiding suit without its consent. As the Supreme Court has explained in the context of tribal immunity, it is “inherent in the nature of sovereignty not to be amenable” to suit without consent. *Bay Mills*, 134 S. Ct. at 2030 (citation omitted). Indeed, the Court described this as one of “the core aspects of sovereignty that tribes possess.” *Id.* The Supreme Court has never drawn a distinction as to the type of forum in which tribal sovereign immunity may be asserted. *See id.* (federal court suit); *Kiowa Tribe*, 523 U.S. at 754 (state court suit); *Okla. Tax Comm’n v. Citizen Band Potawatomi Indian Tribe of Okla.* 498 U.S. 505, 509-10 (1991) (counterclaim in

federal court); *Puyallup Tribe*, 433 U.S. at 172-73 (state court action); *U.S. Fid. & Guar. Co.*, 309 U.S. at 511-12 (federal court counterclaim).

The Board declined to apply the *FMC* holding to the Tribe on the ground that the tribal immunity is not “co-extensive” with that of a state. Appx9. But the Board never explained the differences or why they dictated opposite results. The Board ignored the Supreme Court’s teaching that tribal immunity is the *same* “common-law immunity from suit” as those enjoyed by other “sovereign powers.” *Bay Mills*, 134 S. Ct. at 2030. Both tribal and state immunity are grounded in the same common-law principles. Appx1762-1773.

The Board claimed there is no statutory authority to assert an immunity “defense.” Appx10. But the Tribe does not need a statute to allow it to raise immunity because it is not a defense to liability. It is an inherent common-law right allowing a sovereign to avoid the indignity of being haled before a tribunal, a right that can be lost if a case goes to trial. *Burlington N. & Santa Fe Ry. Co. v. Vaughn*, 509 F.3d 1085, 1090 (9th Cir. 2007).

The Board also dismissed the application of *FMC* on the ground that there was no precedent specifically applying it to tribes. Appx8. This is irrelevant but also incorrect. Other boards to consider the question have agreed that tribes may assert immunity in administrative proceedings. *E.g., In the Matter of Jamal Kanj v. Viejas Band of Kumeyaay Indians*, No. 06-074, 2007 WL 1266963, at \*1 (Dept.

Labor Adm. Rev. Bd. April 27, 2007) (“Sovereign immunity from suit may be invoked not only in Article III courts, but also before court-like ‘federal administrative tribunals.’”) (citation omitted); *In the Matter of Tammy Stroud v. Mohegan Tribal Gaming Auth.*, Nos. 13-079, 14-013, 2014 WL 6850018, at \*3 (Dept. Labor Admin Rev. Bd. Nov. 26, 2014) (dismissal of claim on immunity grounds); *Alhameed v. Grand Traverse Resort & Casino*, 10 OCAHO 1126, 2008 WL 5638410, at \*4 (Dept. Justice Sept. 25, 2008) (tribe could assert immunity in administrative hearing seeking damages).<sup>5</sup>

The Board failed to ask the proper question: whether there was any legal basis for failing to follow the Supreme Court’s authoritative decision in *FMC* and this Court’s decision in *Vas-Cath*. The answer is “no.” The Board’s denial of immunity was based simply on its unwillingness “to hold for the first time that the doctrine of tribal immunity should be applied in inter partes review proceedings.” Appx10. But the Board’s unwillingness flies in the face of decades of precedent giving full recognition to tribal sovereign immunity.

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<sup>5</sup> The Board discounted these citations as not binding. Appx8. But these cases belie the Board’s conclusion that there were no precedents suggesting that *FMC* should be extended to a tribe in an adjudicatory administrative proceeding.

### C. An IPR Is Not An Agency Enforcement Action.

The Board also declined to recognize the Tribe's immunity in IPRs on the ground that tribes do not have immunity in "federal administrative proceedings" "used to enforce generally applicable federal statutes." Appx14. The Board conflated IPRs with other supposedly "similar" agency enforcement proceedings. Appx8. The Board failed to address the Tribe's point: IPRs are not agency-initiated, agency-prosecuted enforcement proceedings, as in the examples cited by the Board.

The key question is the identity of the party initiating and conducting the enforcement: a federal agency or a private litigant. *See Fla. Paralegic Ass'n v. Miccosukee Tribe*, 166 F.3d 1126, 1130 (11th Cir. 1999) ("[W]hether an Indian tribe is *subject* to a statute and whether the tribe may be *sued* for violating the statute are two entirely different questions.");<sup>6</sup> *Bales v. Chickasaw Nation Indus.*, 606 F. Supp. 2d 1299, 1302 (D.N.M. 2009) ("The issue of whether a statute of general applicability should apply to a tribe or tribal entity is distinct from the issue in this case, *i.e.*, whether a tribal entity enjoys sovereign immunity from suit.").

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<sup>6</sup> The Board sought to distinguish *Miccosukee* (although not any of the Tribe's other authorities) by noting that "there was no federal agency involved in that litigation." Appx15. That, of course, is just our point. There is no agency litigating here, either. The Board was structured as an impartial decision-maker, not as a prosecutor or enforcer.

Tribal sovereign immunity does not apply when the federal government brings an enforcement action against a tribe. *Fla. Paraplegic Ass’n*, 166 F.3d at 1135 (offering to a private litigant “an alternative method of enforcement” by having the U.S. enforce the statute because “[t]ribal sovereign immunity does not bar suits by the United States”).

An IPR does not fall into this exception because it is not an agency enforcement action. Nor does it resemble one. The United States does not bring suit. Instead, as noted previously (*see* pp. 19-21, *supra*), the Board adjudicates a dispute between two private parties—a patent owner and a petitioner. Indeed, “*inter partes*” literally means “between the parties.” As the Board explained in a case upholding immunity for a state university, “we are not persuaded that an *inter partes* review is an action brought by the federal government against a state.” Appx1655. Rather, the Board’s role is “not unlike that of the Commission in *FMC* to assess the merits of the arguments presented by the parties in an impartial manner.” Appx1655-1656 (citation omitted).

The statute does not delegate to the Board the authority to file an IPR petition, engage in investigations that would lead to filing a petition, or seek enforcement of patent laws by deciding on its own that a patent should be reviewed. Rather, a petitioner initiates the proceeding by filing a petition for review. 35 U.S.C. § 312; 37 C.F.R. § 42.101. The patent owner must be served with the petition in order for



the petition to be considered complete. 37 C.F.R. § 42.105. The patent owner may respond to the petition, 37 C.F.R. § 42.107, and if review is instituted, the patent owner may respond “in opposition.” 37 C.F.R. § 42.121. Once an IPR is initiated, the statute and regulations do not provide any role for the Board, the PTO, or any other federal officer to act as advocates in the proceedings, to add patent claims to an existing IPR, or to add prior art to that cited by the petition. The petitioner provides the evidence, including “affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions.” 35 U.S.C. § 312(a)(3)(B). The burden of proof is on the petitioner. 35 U.S.C. § 316(e).

The Board cited its ability to complete a case even if the patent owner fails to participate or even if the case is settled. Appx17-18. But this does not change the fact that the Board would have no proceeding to complete absent initiation by a petitioner and a finding that the petitioner has a reasonable likelihood to succeed on at least one claim. 35 U.S.C. § 314(a).

If the Patent Owner “abandons” the proceedings, the Board’s rules permit it—much like an Article III court—to avoid entirely any substantive ruling of patent validity and issue an “adverse judgment” against the Patent Owner, cancelling the Patent Owner’s claims. *See* 37 C.F.R. 42.73(b)(4); *Shire Develop. LLC v. Lucerne Biosciences, LLC*, IPR2014-00739, 2015 WL 4035976 (PTAB June 4, 2015).

The Board noted two reasons advanced by the Tribe for immunity from IPRs: lack of “agency-based prosecution” and absence of involvement by “a government attorney.” Appx14. The Board ignored the first reason and said the lack of a government attorney in an IPR “does not create a meaningful distinction.” Appx14-15. Yet, the first reason is dispositive and the second (absence of a government attorney) confirms the fundamental difference between an IPR and an agency enforcement action. Whether the enforcement is instituted and pursued by a private party is what matters in assessing the Tribe’s right to assert immunity because the Tribe has immunity against a private action. As the Supreme Court recognized in *FMC*, there is a key difference between a case brought by a private party *before* a federal agency and a case brought *by* a federal agency. *See* 535 U.S. at 760-61 (immunity applies in a situation where a sovereign “is required to defend itself in an adversarial proceeding against a private party before an impartial federal officer”).

The distinction between an IPR and an agency enforcement action is underscored by comparing IPR to actual agency enforcement actions. Agencies such as the NLRB, OSHA, and the EEOC are expressly granted investigative and enforcement powers by statute. *See, e.g., EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071 (9th Cir. 2001); *N.L.R.B. v. Little River Band of Ottawa Indians Tribal Gov’t*, 788 F.3d 537 (6th Cir. 2015) (third party filed charge, case prosecuted by federal agency); *Menominee Tribal Enters. v. Solis*, 601 F.3d 669 (7th Cir. 2010)

(Department of Labor cited tribe for violations of OSHA); *Consumer Fin. Protective Bureau v. Great Plains Lending, LLC*, 846 F.3d 1049 (9th Cir. 2017) (CFPB sought to compel compliance with civil investigative demands agency issued to tribal entity).

The statute setting out the NLRB's enforcement role is instructive. Under 29 U.S.C. § 160(a), the Board is empowered "to prevent any person from engaging in any unfair labor practice." The Board has investigatory powers. 29 U.S.C. § 161. The Board's General Counsel has the authority to investigate and issue charges and complaints. 29 U.S.C. § 153(d).<sup>7</sup>

Other agencies follow a similar model. Once the agency concludes there is evidence to establish the law has been violated, the agency then moves against the party by filing a complaint before the respective board. The case is prosecuted by a federal government attorney, who is responsible for all aspects of proving the case such as discovery, developing expert testimony, calling witnesses and presenting arguments. The agency then issues its orders against the party brought before it. Third parties may intervene, but they do not enforce. *N.L.R.B. v. Fortune Bay Resort*

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<sup>7</sup> See also OSHA delegation, 29 U.S.C. § 657 (Secretary of Labor to make inspections and investigate using enforcement powers); EEOC delegation, 42 U.S.C. § 2000e-5 (commission empowered to prevent any person from engaging in unlawful employment practices and details for bringing charges).

*Casino*, 688 F. Supp. 2d 858, 875 (D. Minn. 2010) (private actions under the NLRB are available only in exceptional circumstances).

IPRs are meaningfully different from these schemes of agency enforcement. Accordingly, an IPR is not a suit or proceeding brought “by the United States,” and so the exception to tribal sovereign immunity applying to such actions does not apply here.

**D. The Board’s Claim That It Is Exercising Jurisdiction Only Over The Patent Is Wrong.**

The Board suggested that tribal sovereign immunity should not apply in IPRs because it “does not exercise personal jurisdiction over the patent owner.” Appx16. In the context of state universities, the Board has concluded the opposite. Appx1658 (“an *inter partes* review is an action against the patent owner”); *see also* Appx1691-1692, Appx1707-1708, 1638-40. But here, the Board said it was exercising jurisdiction “over the challenged patent” (Appx16), although it disclaimed *in rem* jurisdiction. Appx16-17 n.6. The Board cited no authority supporting such novel jurisdiction that is neither *in personam* nor *in rem*.

The Board’s conclusion that it is exercising jurisdiction over only the patent is incorrect. An IPR is directed at a specific party: “the patent owner,” as defined by statute. *See* Section II-B, *infra*. By rule, an IPR cannot begin until the patent owner is served with the petition. 37 C.F.R. §§ 42.105, 42.106. If the patent owner

is served and fails to respond, it may suffer an adverse judgment, just as in a court proceeding. 37 C.F.R. § 42.73(d)(3).

Moreover, the Board's decision does not adjudicate all rights and interests in the patent. Instead, Section 315(e) provides for estoppel that applies only to "[t]he petitioner in an *inter partes* review of a claim of a patent." See 35 U.S.C. § 315(e)(2). The petitioner remains free to challenge the validity of the patent on grounds that were not involved in the *inter partes* review proceeding. Parties not involved in the proceeding are free to raise precisely the same grounds as those raised in an *inter partes* review, either in another proceeding before the Board or before a district court.

The Board's conclusory assertion that it is exercising jurisdiction over only the patent is therefore incorrect.

**E. Tribes, Like All Sovereigns, Use Their Sovereignty And Immunity For The Economic Benefit Of Their Citizens.**

As explained above, opponents of the agreement between the Tribe and Allergan argue the deal should be greeted skeptically because the Tribe is using its sovereign immunity in a commercial transaction. But all sovereigns use their sovereignty to produce economic benefits for their citizens. For example, states make decisions to allow certain activities within their borders that are prohibited in other states. States may allow gambling to attract tourism dollars, permit high credit-card interest rates to attract financial services companies to set up in their state, or

offer tax benefits and favorable laws to lure businesses to the state. In all these examples, States exercise their sovereignty by enacting laws providing benefits to businesses to operate in a way that may not be permitted elsewhere, thereby incentivizing investment, generating tax revenues, and creating economic benefits for their citizens.

Sovereigns also use immunity to avoid liability in pending lawsuits. *E.g.*, *Oracle Am., Inc. v. Oregon Health Ins. Exch. Corp.*, 145 F. Supp. 3d 1018, 1042-43 (D. Or. 2015) (granting motion to dismiss on the pleadings on copyright claim in view of Eleventh Amendment immunity where defendant state-created public corporation's "rights, obligations and liabilities" were transferred to State of Oregon mid-case); *Maysonet-Robles v. Cabrero*, 323 F.3d 43, 51 (1st Cir. 2003) (upholding dismissal on immunity grounds even though assets of non-sovereign entity controlled by Puerto Rico were transferred in the middle of litigation to a sovereign entity created solely for the express purpose of asserting sovereign immunity to dismiss the lawsuit); *Kroll v. Bd. of Trs. of Univ. of Ill.*, 934 F.2d 904, 910 (7th Cir. 1991) (holding Board of Trustees may assert sovereign immunity after becoming a party during the pendency of the case); *Surprenant v. Mass. Tpk. Auth.*, 768 F. Supp. 2d 312, 318 (D. Mass. 2011)

(“It may seem unfair that an immunity defense that was not available to the MTA can be bestowed on the MassDOT as its successor by legislative fiat.”).<sup>8</sup>

The Tribe’s agreement with Allergan is similarly a permissible exercise of its sovereignty. Indeed, tribes (like states) have long used their sovereignty to foster economic development and generate revenue streams. For example, tribes are generally not subject to state law absent congressional permission. *McClanahan v. Ariz. State Tax Comm’n*, 411 U.S. 164, 171-72 (1973) (“State laws generally are not applicable to tribal Indians on an Indian reservation except where Congress has expressly provided that State laws shall apply.”). Even before the enactment of the Indian Gaming Regulatory Act, 25 U.S.C. § 2701, *et seq.*, non-Indian gaming companies were able to operate on reservations in partnership with tribes to build casino resort operations shielded from state law and regulations. *See, e.g., Seminole Tribe of Florida v. Butterworth*, 658 F.2d 310, 311 (11th Cir. 1981) (tribe partnered with private company to run high stakes bingo). The tribes benefited from this partnership because it generated income and job opportunities for their members. The non-Indian business partners benefited from being protected by the tribe’s sovereignty from the laws of the State in which they operated.

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<sup>8</sup> Companies also frequently engage in legal arrangements involving assignments and licensing of patents to protect royalty streams and patents rights, and to minimize litigation risk, for example, by incorporating in particular states.

The Supreme Court approved this economic development model in *California v. Cabazon Band of Mission Indians*, 480 U.S. 202 (1987), where the tribe sought to prohibit the State of California from enforcing its gambling laws against the tribe. The tribe argued that it was not subject to state law absent congressional consent. The Supreme Court agreed, affirming that “tribal sovereignty is dependent on, and subordinate to, only the Federal Government, not the States.” *Id.* at 207 (citation omitted). The Court recognized that the tribe was entitled to operate a bingo enterprise without interference from state law, even though the State warned that regulation was necessary to prevent infiltration by organized crime. *Id.* at 220-221. The Court took notice of the important federal interest in tribal self-sufficiency, federal policy encouraging tribal development of commercial enterprises that could lessen dependency on federal dollars, and the lack of any commercial resources available to the tribe, which required creation of other revenue sources. *Id.* at 221-22.

Today, under the Indian Gaming Regulatory Act, publicly-traded gaming corporations regularly partner with tribes to engage in gaming on tribal land under the aegis of tribal sovereignty, in states where those companies could not otherwise operate a casino under state law. The companies are, in effect, benefiting from the Tribe’s sovereignty.



The Tribe's agreement with Allergan is no different in principle from the policies adopted by other sovereigns to advance the economic benefit of their own citizens.

## **II. THE BOARD ERRED IN HOLDING THAT ALLERGAN WAS THE “EFFECTIVE PATENT OWNER” AND DENYING ITS MOTION TO WITHDRAW**

The Board held that, even if tribal immunity applied, the IPR could proceed without the actual Patent Owner—the Tribe—because Allergan was the “effective patent owner.” Appx35, Appx37, Appx44. That term appears nowhere in the relevant statutes or regulations. The Board reached its conclusion by applying this Court's “all substantial rights” test, which is used to determine, not the proper participants in an IPR, but whether a licensee is effectively the “patentee” for purposes of standing to sue for infringement. The test permits a licensee to pursue an infringement action without joining the actual patent owner as a co-plaintiff. *Int'l Gamco, Inc. v. Multimedia Games, Inc.*, 504 F.3d 1273, 1276 (Fed. Cir. 2007). The Board's approach was legal error.

### **A. The Board's Determination That Allergan Is The “Effective Patent Owner” Is Irrelevant Because That Term Has No Legal Significance Under The IPR Statutes.**

The IPR statutes and regulations repeatedly state that an IPR proceeds against “the patent owner.” 35 U.S.C. §§ 313, 314(c), 315(a)(2), 316(a)(8), 316(a)(9), 316(d), 317(a), 317(b). No statute or regulation authorizes the Board to proceed

with an IPR against the “effective” patent owner in the absence of the *actual* patent owner—let alone one that is entitled to sovereign immunity. Moreover, when Congress wished to refer to a wider group of entities in the IPR provisions, it used broader language. *E.g.*, 35 U.S.C. § 315(b) (“the petitioner, real party in interest, or privy of the petitioner”). These differences in statutory text are presumed to carry different meanings. *Russello v. United States*, 464 U.S. 16, 23 (1983).

The salient issue is thus the identity of “the patent owner”—not the “effective patent owner.” Rather than end its inquiry there, the Board looked to the definition of “patentee” and this Court’s case law interpreting “patentee” in the context of determining whether a licensee can proceed with an infringement action without joining the patent owner. But, as the Board implicitly acknowledged, neither the IPR statutes nor regulations use the term “patentee.” Appx19 n.7.

Under this Court’s case law interpreting “patentee,” the Court has held that a grant of “all substantial rights” is sufficient to create standing to sue for infringement. *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1320 (Fed. Cir. 2009). But standing to sue is governed by its own statutory policies and provisions. *See* 35 U.S.C. §§ 271, 281. For example, prudential standing requirements are designed to avoid “multiple suits and multiple liabilities against an alleged infringer for a single act of infringement.” *A123 Sys., Inc. v. Hydro-Quebec*,

626 F.3d 1213, 1217 (Fed. Cir. 2010). That policy has no application when determining the entities to be involved in an IPR.

The Board erred by applying the test governing standing in infringement suits. The concept of an “effective patent owner” is irrelevant in IPR proceedings. The Tribe is the patent owner here.

**B. Allergan Is Not The “Effective Patent Owner” Because The Tribe Did Not Convey All Substantial Rights In The Patents.**

Even if the standing-to-sue test applied, the Board failed to follow this Court’s precedent. The Board improperly emphasized the broad conveyance of rights from the Tribe to Allergan under the agreement and failed to give sufficient weight to the substantial rights retained by the Tribe under the plain terms of the license. *See Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1132 (Fed. Cir. 1995) (“Although the agreement effected a broad conveyance of rights to [the licensee], [the licensor] retains substantial interests under the . . . patents.”).

The Tribe retains multiple substantial rights—and therefore did not transfer all substantial rights to Allergan, including:

1. The Tribe grants Allergan a field-of-use license and retains the remaining field, including the primary right to practice the patents as to products that are unrelated to Restasis® and its approved indication.
2. The Tribe retains a primary right to enforce the patents as to products that do not require FDA approval.

3. The Tribe retains a secondary right to enforce the patents against Generic Equivalents to Restasis<sup>®</sup>, if Allergan declines to initiate such an action.
4. The Tribe retains significant rights in the prosecution and settlement of any litigation that Allergan initiates.

Because the Tribe retains these rights, the Board erred in concluding Allergan is the “effective patent owner.” Indeed, the license here closely tracks licenses held by this Court *not* to transfer “all substantial rights.” The Board’s reasoning, if permitted to stand, will improperly convert countless licenses into assignments.

**1. Allergan Is A Field-Of-Use Licensee And Therefore Does Not Possess “All Substantial Rights.”**

This Court’s precedent “establishes a clear rule for cases involving licenses with field of use restrictions.” *Alps S.*, 787 F.3d at 1384. “[A] field-of-use license” does “not transfer[] all substantial rights to the patents to” the licensee. *A123 Sys.*, 626 F.3d at 1217; *see also Int’l Gamco*, 504 F.3d at 1278 (“[T]his court’s prudential standing requirement compels an exclusive licensee with less than all substantial rights, *such as a field of use licensee*, to join the patentee before initiating suit.” (emphasis added)).

In this case, the Tribe granted Allergan an “exclusive (including with regard to Licensor) license . . . under the Licensed Patents to Exploit Licensed Products for all FDA-approved uses.” Appx2578-2579 (§ 2.1). The Tribe further limited

“Licensed Products” to products “approved by the FDA . . . under, or otherwise relating or referring to [Allergan’s NDAs covering Restasis®].” Appx2576 (§ 1.33). The Tribe retains the rights to the remaining field. Appx2579 (§ 2.4).

Thus, subject to certain limitations, the Tribe may practice the patents to develop a cyclosporin product and seek FDA approval for uses other than dry eye. *See pp. 7-8, supra.* This would include conducting clinical trials and obtaining FDA approval of products without reference to or reliance on the Restasis® NDAs and with a different indication. *See pp. 7-8, supra.* In addition, the Tribe has the right to use and practice the patents for “research, scholarly use, teaching, education, patient care incidental to the foregoing [and] sponsored research” in connection with the FDA-approved use of Restasis®, as well as off-label uses. Appx2579 (§ 2.4).

The Board dismissed the Tribe’s retained rights because it concluded they were unimportant as a practical matter. Appx27-28. This Court has charted a different course. Rather than attempting to weigh the relative importance of the two fields or predict how and when the licensor might practice in the field, this Court looks to the license’s terms. *See, e.g., Alps South*, 787 F.3d at 1383 (relying on field-of-use restriction in license without assessing relative importance of patents outside license’s field of prosthetic products); *A123*, 626 F.3d at 1217-18 (relying on field-of-use restriction in license instead of assessing commercial prospects of remaining

field; even license to “a significant portion of the field of technology” is insufficient to confer “all substantial rights”).

In any event, the uncontroverted record evidence establishes the Tribe’s retained field of use is not insubstantial. Indeed, there is a significant potential market for cyclosporin products for uses other than dry eye. Appx2957 (“In addition to its FDA-approved indications for the treatment of dry eye, Restasis has many off-label uses,” including treatment of fungal infections in certain patients, prevention of corneal transplant rejection, and management of post-corneal transplant glaucoma and cataracts); *see also* p. 8, *supra*. The Tribe has the opportunity—partnering with physicians, research institutions, pharmaceutical companies, and others—to use its patent rights to explore and develop cyclosporin emulsions in commercially significant ways.

Under this Court’s precedent, Allergan does not possess “all substantial rights.”

**2. The Tribe Retains The Right To Enforce The Patents Outside Allergan’s Field Of Use.**

In applying the “all substantial rights” test, this Court has frequently recognized that “the nature and scope of the exclusive licensee’s purported right to bring suit, together with the nature and scope of any right to sue purportedly retained by the licensor, is the most important consideration.” *Alfred E. Mann Found. v. Cochlear Corp.*, 604 F.3d 1354, 1361 (Fed. Cir. 2010); *see also Aspex Eyewear, Inc.*

*v. Miracle Optics, Inc.*, 434 F.3d 1336, 1342 (Fed. Cir. 2006) (“A key factor” is “right to sue for infringement”).

In this case, the right to enforce the patents does not rest solely with either the Tribe or Allergan. As the Board recognized, “per the terms of the License, the Tribe retains the first right to sue for infringement unrelated to Generic Equivalents.” Appx22. Thus, the Tribe has the first right to file infringement suits apart from third parties seeking to market a generic product for which Allergan’s Restasis® is listed as the reference drug. Appx2582-2583 (§ 5.2.3) (detailing the Tribe’s right to enforce the patents against infringements other than “Generic Equivalents”); Appx2576 (§ 1.23 (defining “Generic Equivalent”)). To conduct such enforcement, the Tribe need not seek Allergan’s prior consent; it need only provide Allergan with notice and consider Allergan’s reasonable input. Appx2582-2583 (§ 5.2.3). Otherwise, the Tribe has complete discretion to decide on litigation strategy and tactics. *Id.* (“Licensor shall retain control of the prosecution of such Infringement, including the response to any defense or defenses of any counterclaim . . . .”). Finally, the Tribe is entitled to the proceeds of any such lawsuit, after reimbursement of costs and expenses. Appx2583 (§ 5.2.5).

The Board nevertheless discounted the Tribe’s right as “illusory” because, in the Board’s estimation, “any viable infringement allegation for the challenged patents would have to necessarily be limited to drug products that require FDA

approval,” and would fall within Allergan’s right to enforce the patents. Appx22. The Board’s reasoning is inconsistent with this Court’s precedent. *See Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 978-79 (Fed. Cir. 2005) (holding that licensor maintained ownership, despite retaining the right to sue only *noncommercial* accused infringers, while the licensee had sole right to sue *commercial* infringers).

Moreover, the Board incorrectly discounted actual evidence of a recently announced product that illustrated the Tribe’s right to enforce the patents. Appx22-23. Specifically, Imprimis Pharmaceuticals, Inc. has announced plans to launch a cyclosporine product like Restasis®. Appx2535-2536. Because the Imprimis product is a compound-based product, Imprimis has no intention of seeking FDA approval. *Id.* The Board did not deny that the Tribe would have the first right to bring and control any lawsuit involving such a non-FDA approved product. Instead, the Board disregarded this actual example substantiating the Tribe’s right to enforce by imposing an unprecedented burden on the Tribe to establish that “the composition of Imprimis’s non-FDA-approved cyclosporine product . . . could reasonably be alleged to infringe any of the challenged patents.” Appx23. But the Board is neither authorized nor equipped to decide even *actual* infringement questions, as the Government conceded during oral argument in *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*. Tr. of Oral Arg. at 61, No. 16-712 (Nov. 27, 2017).



*A fortiori*, satellite trials on hypothetical infringement actions are not within the Board’s purview. Moreover, in this case the Board never permitted the development of a factual record on the *Imprimis* issue.<sup>9</sup>

Finally, the Board misinterpreted the sublicense language as “giv[ing] Allergan ‘full power to end any proceeding—even one the Tribe wants to pursue—simply by granting a sublicense.’” Appx30 (citation omitted). But Allergan may grant a sublicense only in its field-of-use. Appx2579 (§ 2.3 (sublicensing limited to license granted in § 2.1)). The licensee in *Mann* possessed the power to grant sublicenses, and this Court nonetheless held that it did not hold “all substantial rights.” 604 F.3d at 1362.

**3. The Tribe Retains The Right To Enforce The Patents Within Allergan’s Field-Of-Use, If Allergan Declines To Pursue A Potential Infringer.**

The Tribe also retains the right to sue third parties in Allergan’s field-of-use if Allergan declines to do so. Appx2582 (§ 5.2.2). And once that right vests, the

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<sup>9</sup> The Board opined the Tribe would not be able to license the *Imprimis* product because it would qualify as a “Competing Product” under the license. Appx23-24. The Board’s determination was improper, given the absence of a factual record before it on the nature of the *Imprimis* product (which the Board itself noted in opining that it lacked evidence to determine whether the *Imprimis* product was infringing, Appx23). Regardless, the Tribe’s ability to enjoin or collect damages from a company like *Imprimis* are substantial rights, even if the Tribe were unable to grant a license, which is only one potential settlement strategy.

Tribe has complete discretion to decide what trial strategy and tactics to employ. *Id.*<sup>10</sup> The Tribe is entitled to keep the proceeds from any suit it initiates, after the deduction of costs and expenses. Appx2583 (§ 5.2.5). The same is true in Contested PTO proceedings, where if Allergan elects not to defend the licensed patents, the Tribe “may conduct and control the defense of any such claim, suit, or proceeding.” Appx2583-2584 (§ 5.3).

This Court has previously determined that similar secondary rights to sue were substantial. In *Mann*, for example, this Court held that, even when a licensor’s right to sue does not vest until the licensee decides not to sue, it nevertheless prevents a licensee from receiving “all substantial rights.” 604 F.3d at 1362; *see also AsymmetRx*, 582 F.3d at 1321 (licensor retained ownership where license provided “if [licensee] elects not to exercise its right to sue, [licensor] has the right to bring its own infringement action”); *Abbott*, 47 F.3d at 1132 (licensor did not lose ownership even where exclusive licensee was given right of first refusal in suing alleged infringers). This case is actually easier than *Mann*, because the license agreement in that case lacked a time limit within which the licensee was required to

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<sup>10</sup> The Board noted that the Tribe cannot initiate a case within Allergan’s field-of-use without Allergan’s consent. Appx24. But neither can Allergan initiate a case outside its field-of-use without the Tribe’s consent. Appx2583 (§ 5.2.3). The provisions are reciprocal and in both instances provide that consent is “not to be unreasonably withheld, conditioned, or delayed.” *Id.*

make its decision as to whether to sue. 604 F.3d at 1363. Here, by contrast, Allergan must make its decision within ninety days. Appx2582 (§ 5.2.2).

**4. The Tribe Enjoys Substantial Rights In Connection With Allergan’s Litigation Decisions.**

The license agreement also grants the Tribe substantial checks on Allergan’s exercise of control over infringement litigation initiated by Allergan. When the Tribe agrees to join a Hatch-Waxman action, the Tribe joins to protect its own interests, not leaving those to Allergan: “Licensor consents to join as a party . . . to protect the interests of the Tribe.” Appx2582 (§ 5.2.2). Moreover, even when Allergan initiates an infringement action, it must consult with the Tribe concerning strategy and consider the Tribe’s reasonable input. *Id.*

More importantly, Allergan cannot settle such litigation without the Tribe’s written consent. Appx2583 (§§ 5.2.4, 5.3). *See Sicom*, 427 F.3d at 979 (licensee did not have “all substantial rights” where it did not have the right to settle litigation without the prior written consent from licensor). Thus, contrary to the Board’s view, Allergan’s right to sublicense does not alter the extent to which the Tribe controls Allergan’s ability to settle lawsuits. Allergan’s right to issue a sublicense to settle its own infringement cases is restricted because the Tribe must consent to any settlement. Accordingly, the Tribe has veto power over any sublicenses that Allergan may offer in settlement. Hence, Allergan’s ability to grant sublicenses is

“fettered,” *Mann*, 604 F.3d at 1362, confirming that it does not hold “all substantial rights.”

**5. The Board Disregarded The Additional Substantial Rights Retained By The Tribe Under The License.**

In addition to the important rights discussed above, the Tribe also retains the right to defend the validity of the Patents-at-Issue if Allergan declines to do so. Appx2582-2583 (§§ 5.2.2, 5.3). This is an important right, given that the Eastern District of Texas found the asserted claims of the patents-at-issue invalid as obvious. If Allergan had chosen not to appeal the district court decision (and thereby avoid paying additional royalties to the Tribe, Appx2580 (§ 4.2)), the Tribe’s right to defend the validity of the patents would have protected its right to future royalty payments.

The Tribe retains another key right: “sole and exclusive control over the means and manner in which its sovereign immunity is asserted or waived.” Appx2581 (§ 5.1.2). The license agreement provides that the Tribe “shall assert its sovereign immunity in any Contested PTO Proceedings” (Appx2583-2584 (§ 5.3)), effectively taking the control of the proceedings away from Allergan, unless the PTAB casts away the Tribe’s immunity.<sup>11</sup>

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<sup>11</sup> The Board noted that the Tribe agreed not to assert its sovereign immunity in the Eastern District of Texas Litigations. Appx25. But the Tribe voluntarily assented to this provision, confirming its ability to control its assertion of immunity.

**6. The Board Misapplied The Remaining Factors Of The “All Substantial Rights” Test.**

The remaining factors cited by the Board do not diminish the substantial rights obtained by the Tribe or change the outcome of the “all substantial rights” test. While Allergan acquired certain rights under the license that are “perpetual” and “irrevocable,” Appx31, *see also* Appx2578-2579 (§ 2.1), Appx2593 (§ 9.1.1), this Court has recognized that exclusive, permanent, and irrevocable field-of-use licenses may nevertheless transfer less than “all substantial rights.” For example, in *International Gamco*, this Court cited with approval a Fifth Circuit decision concluding that an “exclusive, *irrevocable*, royalty-free license” regarding certain oil drilling technology did not transfer all substantial rights because “the grant of a right of a limited use is a mere license.” 504 F.3d at 1278 (emphasis added) (quoting *Etherington v. Hardee*, 290 F.2d 28, 28-29 (5th Cir. 1961)). Similarly, the licensee in *Mann* possessed its exclusive right to exploit the patents for their full term, but the Court nevertheless found the licensor’s retained secondary right to sue sufficiently substantial to require the licensor’s presence in infringement suits. 604 F.3d at 1362-63. In *Abbott*, the agreement was to remain in effect for the life of the patents unless the licensee decided to terminate it earlier, but the licensor’s retained limited right to make and use the patented inventions and secondary right to sue were sufficiently substantial to require the licensor’s presence in infringement suits. 47 F.3d at 1132.

The Board next looked to the rights of the parties to litigation or licensing proceeds, noting that the Tribe would not receive “a portion of the proceeds from any of Allergan’s commercially relevant litigation or licensing activities,” although the Tribe would be entitled to reimbursement of its costs. Appx31-32. But the Board did not deny that the Tribe keeps the proceeds from any suit it initiates under the Agreement (Appx2583 (§ 5.2.5)), as well as any proceeds from any of its own licensing activities. The allocation of proceeds under the license agreement does not disturb the substantial rights held by the Tribe. Moreover, the “proceeds” from litigation initiated by Allergan, to which the Board pointed, are entirely hypothetical. In the Hatch-Waxman context, a brand manufacturer is primarily seeking to obtain *injunctions* against generic ANDA applicants to prevent them from launching infringing products.

Finally, the Board noted that the Tribe relinquished its right to assign its ownership of the patents to third parties. Appx33. This is not an unusual provision. Licensors in other cases have provided the same term, and this Court has held in such cases that they have not transferred “all substantial rights.” *E.g., Abbott*, 47 F.3d at 1132. Indeed, a restriction on assignment is typically the nature of an exclusive license, to which the Tribe agreed by contract. It was, understandably, a critical and necessary component of the deal for Allergan. Moreover, the Board gave short shrift to the fact that Allergan may not assign its rights (except to an

Affiliate or “successor”) without the Tribe’s prior written consent. Appx2594 (§ 10.3). This Court has described a restriction on the right to assign as a “fatal reservation” preventing a licensee from obtaining “all substantial rights.” *Sicom*, 427 F.3d at 979 (citation omitted); *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) (“limits on a transferee’s assignment rights weigh in favor of finding that an agreement constitutes a transfer of fewer than all substantial rights in a patent”).

**7. The Tribe Holds More Substantial Rights Than Licensors This Court Has Recognized As Retaining Substantial Rights.**

Although the Tribe granted numerous valuable interests to Allergan under the terms of the license agreement, the license agreement reserved substantial rights in the patents for the Tribe. That conclusion is strongly supported by this Court’s precedent.

For example, in *Abbott*, this Court held a licensee did not receive “all substantial rights” where the licensor “retained a limited right to make, use, and sell products embodying the patented inventions, a right to bring suit on the patents if [the licensee] declined to do so, and the right to prevent [the licensee] from assigning its rights under the license to any party other than a successor in business.” 47 F.3d at 1132. As explained in the preceding sections, the Tribe retained rights beyond those retained by the licensor in *Abbott*. By virtue of the field-of-use license, the Tribe retained rights to use the patented inventions. In addition, not only did the

Tribe retain a secondary right to sue—like the licensor in *Abbott*—but the Tribe also retained a substantial *primary* right to sue outside the context of Generic Equivalents. As the Court in *Abbott* explained: “Those retained rights are the sort that are commonly held sufficient to make a patent owner who grants an exclusive license a necessary party to an infringement action brought by the licensee.” 47 F.3d at 1132.

Similarly, in *AsymmetRx*, the Court acknowledged that the license “effected a broad conveyance of rights” to the licensee, but nevertheless acknowledged that the licensor retained substantial interests in the patents that prevented the licensee from being the effective patentee. 582 F.3d at 1320. Indeed, the rights retained by the licensor in *AsymmetRx* parallel some of the rights that the Tribe retained: (i) the licensor retained the right to use the patents for academic or research purposes, *see id.*; *see also* Appx2579 (§ 2.4); (ii) the licensor retained a secondary right to sue if the licensee elects not to, *see AsymmetRx*, 582 F.3d at 1320-21; *see also* Appx2582 (§ 5.2.2); and (iii) even in suits initiated by the licensee, the licensee is obligated to consider the input from the licensor on trial strategy, *see AsymmetRx*, 582 F.3d at 1321; *see also* Appx2582 (§ 5.2.2). Importantly, the Tribe holds rights beyond those retained by the licensor in *AsymmetRx*. For example, as discussed above, the Tribe retained a primary right to sue for infringement outside of Allergan’s field of use



(Appx2582-2583 (§ 5.2.3)) and, in the case of suits initiated by Allergan, a right to veto any proposed settlement (Appx2583, § 5.2.4).

Accordingly, under the Court’s precedent, the Tribe retained the rights cited in *Abbott* and *AsymmetRx*, plus more. Allergan did not receive “all substantial rights” to the patents and cannot be dubbed the “effective patent owner.”

The Tribe also retained more rights than the University of Maryland did in *Neochord, Inc. v. University of Maryland*, IPR2016-00208, Appx1680-1700, where the Board held that Maryland did not grant “all substantial rights” (and that the proceedings could not go forward in its absence), because the state “retain[ed] the right to sue a third party for infringement if [the licensee] fails to do so.” Appx1698. This right tracks the secondary right to sue that the Tribe retained in this case, and should compel the same result here. But the Tribe additionally retained the *primary* right to sue for infringement outside the context of Generic Equivalents. Despite this additional substantial right, the Board concluded in this case that the Tribe did not retain all substantial rights. The Board was plainly wrong.

\* \* \*

Accordingly, even if the “effective patent owner” case law applied to IPR proceedings (and it does not), Allergan is not the effective patent owner under this Court’s precedent because it did not receive “all substantial rights.”

### **III. THE TRIBE IS AN INDISPENSABLE PARTY IN THE IPRS AND THE BOARD CANNOT PROCEED IN ITS ABSENCE.**

The Board should have granted Allergan's motion to withdraw and dismissed the IPR. But even if the Board correctly identified Allergan as an "effective owner" for purposes of IPR proceedings, the Board still should have dismissed the IPR because the Tribe is a necessary and indispensable party.

#### **A. The Board's Decision Conflicts With The Supreme Court's Decision In *Pimentel*.**

In *Republic of Philippines v. Pimentel*, 553 U.S. 851 (2008), the Supreme Court considered the application of Rule 19 to a foreign sovereign entity.<sup>12</sup> Referring to cases involving joinder of the United States, the Court concluded that "the holdings were clear": "A case may not proceed when a required-entity sovereign is not amenable to suit[.] . . . [W]here sovereign immunity is asserted, and the claims of the sovereign are not frivolous, dismissal of the action must be ordered where there is a potential for injury to the interests of the absent sovereign." *Id.* at 867.

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<sup>12</sup> Rule 19(b) provides that courts determining whether a party is indispensable to a proceeding must consider (1) the extent to which a judgment rendered in the party's absence might prejudice that party or the existing parties; (2) the extent to which any prejudice could be lessened or avoided; (3) whether a judgment rendered in the party's absence would be adequate; and (4) whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder.

*Pimentel* expressed concern over the failure of the lower courts to give proper weight to the “compelling claim of sovereign immunity.” 553 U.S. at 869. Citing *Pimentel*, this Court has also recognized that “sufficient weight” must be given to the prejudice to a sovereign who is absent based on a claim of immunity. *A123 Sys. Inc.*, 626 F.3d at 1221.

Courts have recognized this compelling factor as applied to tribes. When a tribe is immune from suit, there is “very little need for balancing Rule 19(b) factors because immunity itself may be viewed as the compelling factor.” *White v. Univ. of Cal.*, 765 F.3d 1010, 1028 (9th Cir. 2014) (internal quotations omitted).

*Klamath Tribe Claims Committee v. United States*, 106 Fed. Cl. 87, 95 (2012), *aff’d* 541 F. App’x 974 (Fed. Cir. 2013), applied *Pimentel*, finding the case “stands for the proposition that where a sovereign party should be joined in an action, but cannot be because of sovereign immunity, the entire case must be dismissed if there is the potential for the interests of the sovereign to be injured.” Tribes are entitled to heightened deference, just like other foreign and domestic sovereigns. *Klamath*, 106 Fed. Cl. at 96 (“As subsequent cases confirm, this rationale applies to domestic sovereigns, *i.e.*, States and Indian nations, as much as it does to foreign sovereigns, *e.g.*, the Philippines”). *Accord Mesa Grande Band of Mission Indians v. United States*, 121 Fed. Cl. 183, 191 (2015); *Center for Biological Diversity v. Pizarchik*, 858 F. Supp. 2d 1221, 1228 (D. Colo. 2012).

Under this weighted sovereignty test, the requirement to dismiss the suit “is mandated by the policy of tribal immunity . . . [and] turns on the fact that society has consciously opted to shield Indian tribes from suit without congressional or tribal consent.” *Enter. Mgmt. Consultants, Inc., v. United States*, 883 F.2d 890, 894 (10th Cir. 1989) (quoting *Wichita & Affiliated Tribes of Okla. v. Hodel*, 788 F.2d 765, 777 (D.C. Cir. 1986)).

Nearly every court that has considered the impact of tribal immunity in a Rule 19 analysis has concluded dismissal is warranted because of the weight given to a tribe’s sovereign interest in its government authority, its property, or in a contract.<sup>13</sup>

The Board suggested the Tribe could avoid any harm to its interests by appearing voluntarily in the IPR. *See* Appx45 (“In order to allow the Tribe to represent its interests in these proceedings before the Board and in any appeals, we will allow the Tribe to continue participating as a patent owner along with

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<sup>13</sup> *See, e.g., Fluent v. Salamanca Indian Lease Auth.*, 928 F.2d 542, 547 (2d Cir. 1991) (affirming the lower court’s finding of “the paramount importance accorded the doctrine of sovereign immunity under Rule 19”); *Am. Greyhound Racing, Inc. v. Hull*, 305 F.3d 1015 (9th Cir. 2002); *Dawavendewa v. Salt River Project Agric. Improvement & Power Dist.*, 276 F.3d 1150 (9th Cir. 2002); *Lomayaktewa v. Hathaway*, 520 F.2d 1324 (9th Cir. 1975), *cert. denied*, 425 U.S. 903 (1976); *Tewa Tesuque v. Morton*, 498 F.2d 240 (10th Cir. 1974), *cert. denied*, 420 U.S. 962 (1975); *Kescoli v. Babbitt*, 101 F.3d 1304 (9th Cir. 1996); *Quileute Indian Tribe v. Babbitt*, 18 F.3d 1456, 1460 (9th Cir. 1994); *N. Arapaho Tribe v. Harnsberger*, 660 F. Supp. 2d 1264 (D. Wyo. 2009); *Vann v. Salazar*, 883 F. Supp. 2d 44, 49-51 (D.D.C. 2011); *Jamul Action Comm. v. Chaudhuri*, 200 F. Supp. 3d 1042, 1050 (E.D. Cal. 2016).

Allergan.”). This type of Hobson’s choice, requiring the Tribe to forgo immunity or risk injury to its interests, is exactly what sovereign immunity is intended to prevent.

**B. The Board Misapplied The Rule 19 Factors And Failed To Follow Controlling Precedent Of This Court.**

The Board, having incorrectly concluded that *Pimentel*’s compelling interest assessment had no application in a Rule 19 evaluation, determined that the Tribe would not be prejudiced if the IPR went forward because the Tribe and Allergan’s interests are “identical,” and therefore Allergan could adequately represent the Tribe’s interest. Appx37.

The Board’s reasoning fails to follow this Court’s decision in *A123*, which assessed the interests of a sovereign patent owner and a field-of-use licensee under the first and second Rule 19 factors—the extent to which a judgment rendered in the party’s absence would prejudice that party, and whether that prejudice could be lessened. The *A123* Court was careful to accord appropriate weight to the sovereign interest, as required by *Pimentel*. See 626 F.3d at 1221. This Court held that proceeding without the sovereign posed a significant risk of prejudice because the sovereign could lose its rights “despite the fact that it had no opportunity to defend its interests in the litigation.” *Id.* The Court also found the prejudice could not be ameliorated, due to a lack of adequate representation. This Court noted that, even though the owner and licensee “undoubtedly share[d] the same overarching goal of defending the patents’ validity,” one was a “field-of-use licensee” and the other a

sovereign owner of the patents. *Id.* at 1221 (distinguishing *Dainippon, Screen Mfg. Co. Ltd. v. CFMT, Inc.*, 142 F.3d 1266 (Fed. Cir. 1998) (where the absent nonsovereign party wholly owned the patent owner holding company)).

*A123* governs here. The Board noted that the Tribe “has not sought to introduce new claim constructions in this proceeding that would differ from Allergan’s.” Appx39. Neither did the sovereign in *A123*. In both cases, the sovereign has retained a substantial interest in the patents, separate and apart from the rights granted to the licensee, and there is no connection between the field-of-use licensee and the sovereign patent owner that would suggest the licensee can adequately protect the sovereign’s interests. They are not co-owners and they have no other business relationship.

Allergan has no duty to the Tribe. Allergan is a publicly traded company owned by shareholders and controlled by a board of directors with a fiduciary duty to its shareholders. When a party “has a ‘broad obligation’ to serve many people, that party generally does not share a sufficient interest with an absent tribe” to represent it. *Union Pac. R.R. Co. v. Runyon*, 320 F.R.D. 245, 252 (D. Or. 2017).

In contrast, the Tribe is a sovereign nation, with a sovereign territory, whose Tribal Council is answerable to its tribal members. The Tribe has a responsibility for governing and raising revenue for its government operations. The validity of the

patents is important to the Tribe's governance and to generate revenue, jobs, and economic opportunities for its members.

Most importantly, the Tribe, as a sovereign, has unique interests such that no other party can adequately represent it. "The Tribe's interest ... in its sovereign right not to have its legal duties judicially determined without consent" is an interest that Allergan simply cannot protect. *See Enter. Mgmt. Consultants*, 883 F.2d at 894 (United States could not sufficiently protect tribe's interest in its immunity); *Rosales v. United States*, 73 F. App'x 913, 914 (9th Cir. 2003) (same).

Thus, the first two factors support a finding that the Tribe is indispensable. Moreover, the Board cannot fashion an adequate judgment absent the Tribe. The patents are the Tribe's property, and the IPR will affect the validity of those patents, creating more than enough impact on the Tribe to make it an indispensable party. *See Quileute Indian Tribe*, 18 F.3d at 1460 (potential for tribe to lose property interest renders tribe indispensable); *Jamul Action Comm. v. Chaudhuri*, 200 F. Supp. 3d 1042, 1050 (E.D. Cal. 2016) ("[T]he Tribe's interests in its status, its sovereignty, its beneficial interests in real property, and its contractual interests cannot be adjudicated without its formal presence.").

Finally, the district court case in Texas (now on appeal) provides an adequate forum to adjudicate the issues of patent validity relevant to Appellees that the IPRs would address. The Board's conclusion otherwise is directly contrary to this Court's

holding in *A123*, which found that a separate district court case in which the sovereign had waived its immunity and was subject to counterclaims was an adequate forum. 626 F.3d at 1222. The Board did not even mention *A123* with respect to this issue. Appx39; compare *Univ. of Utah*, 734 F.3d at 1327 (fourth factor not met because the alternative forum was unlikely to be available).

Accordingly, the Board failed to follow this Court's precedent demonstrating the Tribe is an indispensable party in whose absence the IPRs cannot proceed.



## CONCLUSION

This Court should reverse the Board's decision and direct the dismissal of the IPR proceedings.

Dated: April 18, 2018

Respectfully submitted,

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# **ADDENDUM**

<b>Document</b>	<b>Appx Page Nos.</b>
Decision Denying the Tribe's Motion to Terminate	Appx1-42
Conduct of the Proceedings	Appx43-48

[Trials@uspto.gov](mailto:Trials@uspto.gov)

Tel: 571-272-7822

Paper No. 127

Entered: February 23, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS  
USA, INC., and AKORN INC.

Petitioners,

v.

SAINT REGIS MOHAWK TRIBE,

Patent Owner.

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Case IPR2016-01127 (8,685,930 B2); Case IPR2016-01128 (8,629,111 B2);  
Case IPR2016-01129 (8,642,556 B2); Case IPR2016-01130 (8,633,162 B2);  
Case IPR2016-01131 (8,648,048 B2); Case IPR2016-01132 (9,248,191 B2)

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Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and  
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PER CURIAM.

DECISION

Denying the Tribe's Motion to Terminate  
*37 C.F.R. §§ 42.5, 42.72*

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<sup>1</sup> Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. This Decision addresses issues that are the same in the identified cases. Paper numbers and exhibits cited in this Decision refer to those documents filed in IPR2016-01127. Similar papers and exhibits were filed in the other proceedings.

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

## I. INTRODUCTION

Based on petitions filed by Mylan Pharmaceuticals, Inc. (“Mylan”), we instituted these *inter partes* review proceedings on December 8, 2016. *See, e.g.*, IPR2016-01127, Paper 8 (Decision on Institution). At the time of institution, the undisputed owner of the patents being challenged in these proceedings was Allergan, Inc. (“Allergan”). *Id.* at 1. On March 31, 2017, we granted motions joining Teva Pharmaceuticals USA, Inc. (“Teva”) and Akorn Inc. (“Akorn”) (collectively with Mylan, “Petitioners”) as parties in each of these proceedings. Paper 18 (Teva); Paper 19 (Akorn). In each proceeding, Allergan filed Patent Owner Responses and Petitioners filed Replies. Paper 16; Paper 34. A consolidated oral hearing for these proceedings was scheduled for September 15, 2017. Paper 59.

On September 8, 2017, less than a week before the scheduled hearing, counsel for the Saint Regis Mohawk Tribe (“the Tribe”) contacted the Board to inform us that the Tribe acquired the challenged patents and to seek permission to file a motion to dismiss these proceedings based on the Tribe’s sovereign immunity. In view of the Tribe’s purported ownership and alleged sovereign immunity, we suspended the remainder of the Scheduling Order (Paper 10), authorized the Tribe to file a motion to terminate, and set a briefing schedule for the parties. Paper 74. Pursuant to this authorization, the Tribe filed “Patent Owner’s Motion to Dismiss<sup>[2]</sup> for Lack of

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<sup>2</sup> We note that we authorized the Tribe to file a motion to terminate the proceedings, and not a motion to dismiss. Paper 74, 3. Because the Tribe did not own the patents at issue at the time we instituted *inter partes* review,

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

Jurisdiction Based on Tribal Sovereign Immunity” on September 22, 2017. Paper 81 (“Motion” or “Mot.”). On October 13, 2017, Petitioners filed an opposition to the Tribe’s motion to terminate (Paper 86, “Opposition” or “Opp’n”). On October 20, 2017, the Tribe filed a reply to Petitioners’ opposition (Paper 14, “Reply”).

In view of the public interest and the issue of first impression generated by the Tribe’s Motion, we authorized interested third parties to file briefs as *amicus curiae*. Paper 96. We received amicus briefs from the following third parties: The Oglala Sioux Tribe (Paper 104); Public Knowledge and the Electronic Frontier Foundation (Paper 105); Legal Scholars (Paper 106); Askeladden LLC (Paper 107); DEVA Holding A.S. (Paper 108); The High Tech Inventors Alliance (Paper 109); The Seneca Nation (Paper 110); Native American Intellectual Property Enterprise Council, Inc. (Paper 111); Software & Information Industry Association (Paper 112); U.S. Inventor, LLC (Paper 113); The National Congress of American Indians, National Indian Gaming Association, and the United South and Eastern Tribes (Paper 114); Luis Ortiz and Kermit Lopez (Paper 115); The Association for Accessible Medicines (Paper 116); BSA | The Software Alliance (Paper 117); and James R. Major, D.Phil. (Paper 118).

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a motion for termination of these proceedings, rather than dismissal, is the appropriate process under our rules. *See* Paper 63 (Patent Owner’s Updated Mandatory Notice, filed September 8, 2017, informing the Board that the Tribe had taken assignment of the patents-in-suit); 37 C.F.R. § 42.72 (“The Board may terminate a trial without rendering a final written decision, where appropriate.”); *id.* § 42.2 (defining “trial” as beginning after institution). Thus, notwithstanding the title of the Tribe’s paper, we refer to the Tribe’s motion as a “motion to terminate” rather than a motion to dismiss.

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

Further pursuant to our authorization, the Tribe and Petitioners filed responses to the amicus briefs. Paper 119; Paper 121.

Additionally, in light of the Board's recent rulings in *Ericsson Inc. v. Regents of the University of Minnesota*, Case IPR2017-01186 (PTAB Dec. 19, 2017) (Paper 14) ("*Ericsson*"), and *LSI Corp. v. Regents of the University of Minnesota*, Case IPR2017-01068 (PTAB Dec. 19, 2017) (Paper 19) ("*LSI*"), we authorized the Tribe and Petitioners to file supplemental briefs on the applicability of litigation waiver to the Tribe's claim of sovereign immunity. Paper 125; Paper 127.

Upon consideration of the record, and for the reasons discussed below, we determine 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. The Tribe's Motion is therefore *denied*.

## II. FACTUAL BACKGROUND

### A. *The Tribe*

The Tribe is a federally recognized Indian tribe with reservation lands in New York. Ex. 2091, 4. According to the Tribe, the current reservation spans 14,000 acres in Franklin and St. Lawrence Counties. Mot. 1–2. The Tribe further states that there are over 15,600 enrolled tribal members, of which approximately 8,000 tribal members live on the reservation. *Id.* at 2.

The Tribe provides services such as education, policing, infrastructure, housing services, social service, and health care for its members. *Id.* But the Tribe notes that its ability to raise revenue through

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

taxation and to access capital through banking is limited. *Id.* at 2–3. Thus, the Tribe states that “a significant portion of the revenue the Tribe uses to provide basic governmental services must come from economic development and investment rather than taxes or financing.” *Id.* at 3.

Accordingly, on June 21, 2017, the Tribe adopted a Tribal Council Resolution endorsing the creation of a “technology and innovation center for the commercialization of existing and emerging technologies,” called the Office of Technology, Research, and Patents. Ex. 2094, 1. The Tribal Council Resolution states that the Tribe was approached by the law firm Shore Chan DePumpo LLP “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.’” *Id.* The purpose of the Intellectual Property Project is “to promote the growth and prosperity of the Tribe, the economic development of the Tribe, and to promote furthering the wellbeing of the Tribe and its members.” *Id.*

### *B. The Transactions Between Allergan and the Tribe*

Pursuant to its new business venture, the Tribe entered into a Patent Assignment Agreement, effective as of September 8, 2017, with Allergan. Ex. 2086 (“Assignment”). In the Assignment, Allergan assigned to the Tribe a set of U.S. patents and patent applications, including the challenged patents in these proceedings, related to Allergan’s “Restasis” drug. Ex. 2086, 13–15 (Exhibit A); Ex. 1157, 1. Aside from a limited waiver of its sovereign immunity for actions brought by Allergan relating to the Assignment, the Tribe represents that “it has not and will not waive its or



IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

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.” Ex. 2086 § 12(i).

On the same day, the Tribe and Allergan also entered into a Patent License Agreement (“License”) in which the Tribe granted back to Allergan “an irrevocable, perpetual, transferable and exclusive license” under the challenged patents “for all FDA-approved uses in the United States.” Ex. 2087 § 2.1. Additionally, Allergan is granted the first right to sue for infringement with respect to “Generic Equivalents,” while the Tribe has the first right to sue for infringement unrelated to such Generic Equivalents. *Id.* §§ 5.2.2, 5.2.3. In exchange for the rights granted in the License, Allergan paid the Tribe a nonrefundable and noncreditable upfront amount of \$13.75 million. *Id.* § 4.1. During the royalty term of the License, Allergan will also pay the Tribe a nonrefundable and noncreditable amount of \$3.75 million each quarter (\$15 million annually). *Id.* § 4.2. The License also specifies the rights and obligations as between Allergan and the Tribe concerning the maintenance and prosecution of the challenged patents, as well as in administrative proceedings before the PTO. *Id.* §§ 5.1.1, 5.3.<sup>3</sup>

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<sup>3</sup> We address the relevant provisions of the License in further detail below in our analysis of whether Allergan has retained ownership of the challenged patents. *See infra*, § IV.C.

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

### III. LEGAL BACKGROUND

Indian tribes are “domestic dependent nations” that exercise “inherent sovereign authority.” *Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2030 (2014) (“*Bay Mills*”) (quoting *Oklahoma Tax Comm’n v. Citizen Band Potawatomi Tribe of Okla.*, 498 U.S. 505, 509 (1991)). “As a matter of federal law, an Indian tribe is subject to suit only where Congress has authorized the suit or the tribe has waived its immunity.” *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 754 (1998). A tribe’s sovereignty, however, “is of a unique and limited character.” *United States v. Wheeler*, 435 U.S. 313, 323 (1978). “It exists only at the sufferance of Congress and is subject to complete defeasance.” *Id.*

### IV. ANALYSIS

#### A. *There Is No Controlling Precedent or Statutory Basis for the Application of Tribal Immunity in Inter Partes Review Proceedings*

The Tribe’s Motion presents an issue of first impression. Relying upon the Supreme Court’s decision in *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. 743 (2002) (“*FMC*”), the Tribe seeks to terminate these proceedings on the basis of its tribal sovereign immunity (“tribal immunity”). Mot. 14. As noted by the Tribe, the Supreme Court in *FMC* “held that *State* sovereign immunity extends to adjudicatory proceedings before federal agencies that are of a ‘type . . . from which the Framers would have thought the *States* possessed immunity when they agreed to enter the Union.’” *Id.* (citing *FMC*, 535 U.S. at 734, 754–56) (emphasis added). The Tribe further relies upon certain prior Board decisions applying *FMC*’s holding with respect to state sovereign immunity

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 IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
 IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

in the context of *inter partes* review proceedings. *Id.* (citing *Covidien LP v. Univ. of Fla. Research Found. Inc.*, Case IPR2016-01274 (PTAB Jan. 25, 2017) (Paper 21) (“*Covidien*”); *Neochord, Inc. v. Univ. of Md.*, Case IPR2016-00208 (PTAB May 23, 2017) (Paper 28) (“*Neochord*”); *Reactive Surfaces Ltd, LLP v. Toyota Motor Corp.*, Case IPR2016-01914, (PTAB July 13, 2017) (Paper 36) (“*Reactive Surfaces*”)).<sup>4</sup>

The Tribe and its supporting *amici*, however, have not pointed to any federal court or Board precedent suggesting that *FMC*’s holding with respect to state sovereign immunity can or should be extended to an assertion of tribal immunity in similar federal administrative proceedings. Rather, the Tribe cites certain administrative decisions of other federal agencies to assert that “[t]he principal [sic] that sovereign immunity shields against adjudicatory proceedings has been extended to tribes.” Mot. 15–16. We are not bound by those agency decisions, but even those decisions do not squarely address the issue. For instance, in *In re Kanj v. Viejas Band of Kumeyaay Indians*, the Department of Labor Administrative Review Board stated that “[n]othing in existing sovereign immunity jurisprudence indicates

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<sup>4</sup> More recently, expanded panels in the Board’s *Ericsson* and *LSI* decisions also addressed the applicability of the state sovereign immunity doctrine in the context of *inter partes* review proceedings. *Ericsson*, slip op. at 5; *LSI*, slip op. at 4–5. The parties each filed a supplemental brief addressing those decisions. Paper 125 (Petitioner); Paper 127 (Tribe). Although we have considered the reasoned opinions and analyses set forth in each of the prior Board decisions (and the parties’ respective arguments concerning the decisions), for the reasons stated herein, we find the issue raised in these proceedings concerning tribal immunity to be distinguishable from the prior cases addressing state sovereign immunity.

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

that tribes cannot invoke sovereign immunity in administrative adjudications such as this,” but ultimately rested its decision on the basis that Congress abrogated tribal immunity from Clean Water Act whistleblower complaints. 2007 WL 1266963, at \*2–3 (DOL Adm. Rev. Bd. Apr. 27, 2007). The Tribe also cites a single state court decision to support its argument for the application of *FMC* in these proceedings. Mot. 15 (citing *Great Plains Lending, LLC v. Conn. Dep’t of Banking*, No. HHBCV156028096S, 2015 WL 9310700, at \*4 (Conn. Super. Ct. Nov. 23, 2015)). However, insofar as that state court decision only addressed whether tribal immunity may be invoked before a *state* agency, we find that it is even less relevant to the question of whether tribal immunity may be invoked in *federal* administrative proceedings such as ours.

In this regard, the Supreme Court has stated that “the immunity possessed by Indian Tribes is not co-extensive with that of the States.” *Kiowa*, 523 U.S. at 756; *see also Three Affiliated Tribes of Fort Berthold Reservation v. Wold Eng’g*, 476 U.S. 877, 890 (1986) (“Of course, because of the peculiar ‘quasi-sovereign’ status of the Indian tribes, the Tribe’s immunity is not congruent with that which the Federal Government, or the States, enjoy.”). Lower courts have, therefore, not always considered Supreme Court precedent concerning state sovereign immunity to be applicable in the context of tribal immunity. *See Bodi v. Shingle Springs Band of Miwok Indians*, 832 F.3d 1011, 1021 (9th Cir. 2016) (declining to extend *Lapides v. Bd. of Regents of the Univ. Sys. of Ga.*, 535 U.S. 613 (2002), concerning waiver of state’s sovereign immunity based on litigation conduct, to tribal immunity); *Contour Spa at the Hard Rock, Inc. v.*

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IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

*Seminole Tribe of Fla.*, 692 F.3d 1200, 1201 (11th Cir. 2012) (same).

Indeed, the Tribe itself has relied upon these latter cases to argue that the litigation waiver doctrine applicable to states should not apply to its assertion of tribal immunity in these proceedings. *See* Paper 127 (Patent Owner’s Supplemental Brief on Litigation Waiver), 2.

Furthermore, Board precedent cautions against the application of non-statutory defenses in *inter partes* review proceedings. *See Athena Automation Ltd. v. Husky Injection Molding Sys. Ltd.*, Case IPR2013-00290, slip op. at 12–13 (PTAB Oct. 25, 2013) (Paper 18) (precedential) (declining to deny petition based on equitable doctrine of assignor estoppel in view of statutory language of 35 U.S.C. § 311(a)). There is no statutory basis to assert a tribal immunity defense in *inter partes* review proceedings. *See id.* at 13 (contrasting § 311(a) with 19 U.S.C. § 1337(c) in which Congress provided explicitly that “[a]ll legal and equitable defenses may be presented” in International Trade Commission (ITC) investigations).

“There are reasons to doubt the wisdom of perpetuating the [tribal immunity] doctrine.” *Kiowa*, 523 U.S. at 758. In view of the recognized differences between the state sovereign immunity and tribal immunity doctrines, and the lack of statutory authority or controlling precedent for the specific issue before us, we decline the Tribe’s invitation to hold for the first time that the doctrine of tribal immunity should be applied in *inter partes* review proceedings.

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IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

*B. Tribal Immunity Does Not Apply to Inter Partes Review Proceedings*

Having considered the arguments of the parties and *amici*, we are not persuaded that the tribal immunity doctrine applies to our proceedings.<sup>5</sup> We start with the recognition that an Indian tribe’s sovereignty is “subject to the superior and plenary control of Congress.” *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 58 (1978). Furthermore, as noted by the Supreme Court, “general Acts of Congress apply to Indians . . . in the absence of a clear expression to the contrary.” *Fed. Power Comm’n v. Tuscarora Indian Nation*, 362 U.S. 99, 120 (1960); *see also id.* at 116 (stating “it is now well settled . . . that a general statute in terms applying to all persons include Indians and their property interests”).

Here, Congress has enacted a generally applicable statute providing that *any* patent (regardless of ownership) is “subject to the conditions and requirements of [the Patent Act].” 35 U.S.C. § 101; *see also* 35 U.S.C. § 261 (“*Subject to the provisions of this title*, patents shall have the attributes of personal property.”) (emphasis added). Congress has further determined that those requirements include *inter partes* review proceedings. *See* 35 U.S.C. §§ 311–319. In this regard, Congress has given the Patent Office

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<sup>5</sup> Our analysis herein is specific to the applicability of tribal immunity in *inter partes* review proceedings, in which the Board assesses the patentable scope of previously granted patent claims, and does not address contested interference proceedings, which necessarily involve determining the respective rights of adverse parties concerning priority of inventorship. *Cf. Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376, 1382 (Fed. Cir. 2007).

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statutory authorization both *to grant* a patent limited in scope to patentable claims and *to reconsider* the patentability of those claims via *inter partes* review. *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1289 (Fed. Cir. 2015) (noting that Congress granted the Patent Office “the authority to correct or cancel an issued patent” by creating *inter partes* review). Moreover, these proceedings do not merely serve as a forum for the parties to resolve private disputes that only affect themselves. Rather, the reconsideration of patentability of issued patent claims serves the “important public purpose” of “correct[ing] the agency’s own errors in issuing patents in the first place.” *Id.* at 1290. Indeed, as the Supreme Court has explained, a “basic purpose[]” of *inter partes* review is “to reexamine an earlier agency decision,” i.e., 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.’” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016) (internal citations omitted).

Courts have recognized only limited exceptions when a generally applicable federal statute should not apply to tribes. For example, the Ninth Circuit has stated:

A federal statute of general applicability that is silent on the issue of applicability to Indian tribes will not apply to them 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.

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IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

*Donovan v. Coeur d'Alene Tribal Farm*, 751 F.2d 1113, 1116 (9th Cir. 1985) (quoting *U.S. v. Farris*, 624 F.2d 890, 893–94 (9th Cir. 1980)). We find that none of these exceptions apply to our statutory authority over these proceedings. That is, *inter partes* review proceedings do not interfere with the Tribe's "exclusive rights of self-governance in purely intramural matters." *Id.*; see also *San Manuel Indian Bingo & Casino v. NLRB*, 475 F.3d 1306, 1312–13 (D.C. Cir. 2007) ("*San Manuel*") (stating "when a tribal government goes beyond matters of internal self-governance and enters into off-reservation business transaction with non-Indians, its claim of sovereignty is at its weakest") (citing *Mescalero Apache Tribe v. Jones*, 411 U.S. 145, 148–49 (1973)); *NLRB v. Little River Band of Ottawa Indians Tribal Gov't*, 788 F.3d 537, 550 (6th Cir. 2015) ("*Little River Band*") ("The tribes' retained sovereignty reaches only that power 'needed to control . . . internal relations[,] . . . preserve their own unique customs and social order[, and] . . . prescribe and enforce rules of conduct for [their] own members.'") (quoting *Duro v. Reina*, 495 U.S. 676, 685–86 (1990)). We are also unaware of any basis to conclude either that *inter partes* review proceedings "abrogate rights guaranteed by Indian treaties," or that Congress did not intend the proceedings to apply to Indians based on the legislative history of the America Invents Act. See *Donovan*, 751 F.2d at 1116.

Consistent with the foregoing, 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 government from exercising its trust obligations," and that "tribal sovereignty does not extend to prevent the federal government from exercising its superior sovereign



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powers.” *Quileute Indian Tribe v. Babbitt*, 18 F.3d 1456, 1459 (9th Cir. 1994). As such, Petitioners and some of their supporting *amici* have pointed out that Indian tribes have not enjoyed immunity in other types of federal administrative proceedings used to enforce generally applicable federal statutes. *See, e.g.*, Paper 109, 5; Paper 117, 5–6; Paper 121, 12; *Consumer Fin. Prot. Bureau v. Great Plains Lending, LLC*, 846 F.3d 1049, 1058 (9th Cir. 2017) (permitting Consumer Financial Protection Bureau to bring enforcement proceeding against tribal lending entities); *Little River Band*, 788 F.3d at 555 (permitting National Labor Relations Board (“NLRB”) proceeding against tribal casino); *Menominee Tribal Enters. v. Solis*, 601 F.3d 669, 674 (7th Cir. 2010) (permitting Occupational Safety and Health Act proceeding against tribe’s sawmill operation); *cf. EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1075, 1081 (9th Cir. 2001) (determining that although tribe did not enjoy immunity from federal agency inquiry, the Age Discrimination in Employment Act did not apply to a tribal authority’s “intramural” dispute with a tribe member).

The Tribe seeks to distinguish the above cases on the basis that each of the prior administrative proceedings against a tribe involved “agency-based prosecution” in which a government attorney was “responsible for all aspects of proving up the case, such as discovery, developing expert testimony, calling witnesses and presenting arguments.” Paper 119, 9–10. *Inter partes* review proceedings do not involve a separate government party that “prosecutes” the case before the Board. *See* 37 C.F.R. § 42.2 (defining “party” to include petitioner and patent owner). Nonetheless, we are not persuaded that the lack of involvement of a government attorney at this stage

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creates a meaningful distinction such that tribal immunity should apply to these proceedings. As recognized by the Tribe, agency proceedings may be initiated based on third-party complaints filed against a tribal entity. Paper 119, 9–10. But, moreover, the third party may be permitted to intervene in such proceedings and participate beyond just the initial role of filing the complaint. *See San Manuel*, 475 F.3d at 1312–13 (permitting NLRB proceeding against tribal casino based on complaint filed by labor union, where labor union continued to participate as intervenor). Accordingly, a private entity’s continued involvement as a party in a federal administrative proceeding does not necessarily entitle a tribal entity to assert its immunity in that proceeding.

The Tribe also contends that “while the federal government has the authority to enforce a law of general applicability against a tribe, private citizens do not have the authority to enforce such laws absent abrogation of immunity.” Paper 119, 8–9 (citing *Fla. Paralegic Assoc. v. Miccosukee Tribe of Indians of Fla.*, 166 F.3d 1126 (11th Cir. 1999) (“*Miccosukee*”). *Miccosukee* did not involve a federal administrative proceeding, but rather a private right of action brought in federal district court against a tribal employer under the Americans with Disabilities Act. 166 F.3d at 1127 (“We hold that Congress has not abrogated tribal sovereign immunity with respect to this statute so as to allow a private suit against an Indian tribe.”). To be clear, there was no federal agency involved in that litigation. As such, we find the *Miccosukee* decision to be of minimal relevance to the question of whether tribal immunity may be invoked in federal administrative proceedings such as these proceedings.

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The doctrine of tribal immunity has been described as “the common-law immunity from suit traditionally enjoyed by sovereign powers.” *Santa Clara Pueblo*, 436 U.S. at 58. We determine that an *inter partes* review proceeding is not the type of “suit” to which an Indian tribe would traditionally enjoy immunity under the common law. *Cf. Bonnet v. Harvest (U.S.) Holdings, Inc.*, 741 F.3d 1155, 1159 (10th Cir. 2014) (determining that subpoenas served directly on a tribe can trigger tribal immunity based on a definition of “suit” that includes “legal proceedings, at law or in equity” or “judicial process,” which “comports with the core notion of sovereign immunity that in the absence of governmental consent, the courts lack jurisdiction to ‘restrain the government from acting, or to compel it to act’”) (quoting *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 704 (1949); *Belknap v. Schild*, 161 U.S. 10, 16 (1896)). In these proceedings, we are not adjudicating any claims in which Petitioners may seek relief from the Tribe, and we can neither restrain the Tribe from acting nor compel it to act in any manner based on our final decisions. Indeed, there is no possibility of monetary damages or an injunction as a “remedy” against the Tribe. Rather, as discussed above, 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.

Furthermore, the Board does not exercise personal jurisdiction over the patent owner. At most, the Board exercises jurisdiction over the challenged patent in an *inter partes* review proceeding.<sup>6</sup> The Tribe cannot

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<sup>6</sup> Several *amici* supporting Petitioners have asserted that *inter partes*

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be compelled to appear as a party in these proceedings. 37 C.F.R. §§ 42.108(c) (requiring the Board to take a preliminary response into account in deciding whether to institute trial only “where such a response is filed”), § 42.120(a) (“A patent owner *may* file a response to the petition addressing any ground for unpatentability not already denied.”) (emphasis added). In this regard, a patent owner’s participation is not required, and *inter partes* reviews have proceeded to a final written decision under 35 U.S.C. § 318(a) even where the patent owner has chosen not to participate. *See, e.g., Microsoft Corp. v. Global Techs., Inc.*, Case IPR2016-00663 (PTAB June 2, 2017) (Paper 35) (entering adverse judgement and final written decision where no legally recognized patent owner made an appearance); *Old Republic Gen. Ins. Group, Inc. v. Owner of U.S. Patent No. 6,519,581*, Case IPR2015-01956 (PTAB Apr. 18, 2017) (Paper 39) (entering final written decision without participation by the patent owner).

Finally, if the parties to an *inter partes* review settle their dispute, the Board may continue to “independently determine any question of jurisdiction, patentability, or Office practice.” 37 C.F.R. § 42.74(a); *see also*

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reviews are *in rem* proceedings, which are not subject to sovereign immunity. *See, e.g.,* Paper 105, 13; Paper 109, 12–13; Paper 116, 10. We are unaware of any controlling precedent holding that *inter partes* reviews are *in rem* proceedings, and we need not characterize these proceedings as *in rem* in order to reach our conclusions here. We recognize that the Supreme Court will consider whether “a court’s exercise of *in rem* jurisdiction overcome[s] the jurisdictional bar of tribal sovereign immunity when the tribe has not waived immunity and Congress has not unequivocally abrogated it.” *Upper Skagit Indian Tribe v. Lundgren*, 138 S. Ct. 543 (Mem.) (2017). But we do not consider a state court’s *in rem* jurisdiction over tribal land in a quiet-title action to bear on the issues presented here.

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35 U.S.C. § 317(a) (permitting the Board to “proceed to a final written decision” even “[i]f no petitioner remains in the *inter partes* review”). The Board has undertaken this process in situations where parties have settled in an advanced stage of the proceeding. *See, e.g., Yahoo! Inc. v. CreateAds L.L.C.*, Case IPR2014–00200 (PTAB Feb. 26, 2015) (Paper 40); *Blackberry Corp. v. MobileMedia Ideas LLC*, Case IPR2013-00016 (PTAB Dec. 11, 2013) (Paper 31). The Board’s authority to proceed without the parties’ participation underscores its independent role in ensuring the correctness of granting patentable claims.

In view of the above, we conclude that reconsideration of the patentability of issued claims via *inter partes* review is appropriate without regard to the identity of the patent owner. We, therefore, determine that the Tribe’s assertion of its tribal immunity does not serve as a basis to terminate these proceedings.

*C. These Proceedings May Continue with Allergan’s Participation*

Even assuming *arguendo* that the Tribe is entitled to assert immunity, termination of these proceedings is not warranted if we can proceed with another patent owner’s participation. *See Reactive Surfaces*, slip op. at 11–17 (determining that *inter partes* review proceeding could continue notwithstanding a state university’s assertion of sovereign immunity because a private entity had an ownership interest in the challenged patent); *but see Neochord*, slip op. at 18–19 (determining that a state university was an indispensable and necessary party to the proceeding and dismissing on sovereign immunity grounds because the university had retained substantial rights under the license agreement). Here, Petitioners contend that the

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proceedings can continue because Allergan is the true owner of the challenged patents. For the reasons explained below, we agree with Petitioners that these proceedings may continue with Allergan as the “patent owner.”<sup>7</sup>

It is well settled that “[w]hether a transfer of a particular right or interest under a patent is an assignment or a license does not depend upon the name by which it calls itself, but upon the legal effect of its provisions.” *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891). As such, the Federal Circuit has held 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.” *Speedplay, Inc. v. Bebob, 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) (“*Mann*”) (“A patent owner may transfer all substantial rights in the patents-in-suit, in which case the transfer is tantamount to an assignment of those patents to the exclusive licensee.”).

“To determine whether an exclusive license is tantamount to an assignment, we ‘must ascertain the intention of the parties [to the license agreement] and examine the substance of what was granted.’” *Mann*, 604 F.3d at 1359. However, “[t]he parties’ intent alone is not dispositive” in this inquiry. *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1342 (Fed. Cir. 2014) (vacated on other grounds). Rather, in making this determination,

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<sup>7</sup> Although “patent owner” is not defined in the statute, the Patent Act defines “patentee” to include “successors in title.” 35 U.S.C. § 100(d).

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courts have assessed both the rights transferred and the rights retained under the license agreement, including:

(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.

*Id.* at 1343; *see also Mann*, 604 F.3d at 1360–61 (identifying similar factors).

Based on the terms of the License between Allergan and the Tribe, we determine that the License transferred “all substantial rights” in the challenged patents back to Allergan. We address the relevant factors below.

#### *1. Right to Sue for Infringement*

First and foremost, we must consider the nature and scope of the right to enforce the challenged patents as allocated between Allergan and the Tribe. Petitioners contend that the License gave Allergan (not the Tribe) primary control over “commercially relevant infringement proceedings,” and the Tribe was granted “only contingent, illusory rights to enforce the patents.” Opp’n 4–5. We agree with Petitioners.

“[T]he most important consideration” in a determination of whether a license transfers all substantial rights in a patent is “the nature and scope of the exclusive licensee’s purported right to bring suit, together with the nature and scope of any right to sue purportedly retained by the licensor.” *Mann*,

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
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604 F.3d at 1361; *see also Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1342 (Fed. Cir. 2006) (stating that, in determining whether an agreement results in a transfer of ownership, a “key factor has often been where the right to sue for infringement lies”); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 875 (Fed. Cir. 1991) (“*Vaupel*”) (stating the grant of the right to sue can be “particularly dispositive” in an ownership determination). The right to sue that is granted or retained in an agreement cannot merely be “illusory” or otherwise rendered meaningless. *See Speedplay, Inc.*, 211 F.3d at 1251 (finding that licensor’s secondary right to sue was “illusory” due to licensee’s sub-licensing rights). As a corollary to the right to sue, it is also important to determine whether the purported owner has a right to “indulge” any infringement of the transferred patents by others. *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1132 (Fed. Cir. 1995) (“[A]lthough [the licensee] has the option to initiate suit for infringement, it does not enjoy the right to indulge infringements, which normally accompanies a complete conveyance of the right to sue.”).

With regard to enforcement of the challenged patents, the License provides that “Allergan shall have the first right, but not the obligation, to control and prosecute” infringement that relates to a “Generic Equivalent.” Ex. 2087 § 5.2.2. “Generic Equivalent” is defined in the License as a drug product that requires FDA approval for sale in the United States, including those products covered by an Abbreviated New Drug Application (ANDA) for which Allergan’s Restasis product is the listed reference drug. *Id.* § 1.23. The claims of the challenged patents are directed to pharmaceutical compositions and methods used to treat dry eye, keratoconjunctivitis sicca,



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and/or increase tear production in human eyes. Each of the challenged patents is listed in the FDA's "Orange Book." Ex. 1069. As such, we find that any viable infringement allegation for the challenged patents would have to necessarily be limited to drug products that require FDA approval, i.e., Generic Equivalents. Indeed, to date, the only district court proceedings in which the challenged patents have been alleged to be infringed are in Hatch-Waxman litigations against companies seeking to market FDA-approved generic versions of Restasis. *See* Papers 2 and 6 (identifying related matters).

We recognize that, per the terms of the License, the Tribe retains the first right to sue for infringement unrelated to Generic Equivalents. Ex. 2087 § 5.2.3. The Tribe contends that in order to conduct such an enforcement campaign, it need only provide Allergan with notice and consider Allergan's reasonable input, but otherwise has complete discretion to decide what trial strategy and tactics to employ in such litigation. Reply 2. The Tribe asserts that this retained primary right to sue is not merely "illusory" because third-party Imprimis Pharmaceuticals, Inc. ("Imprimis") recently "announced plans to launch a compounded-based non-FDA-approved cyclosporine product to compete directly with Restasis," and "[i]f this product infringes the Patents-at-Issue, the Tribe will have the first right to bring and control an infringement suit and retain the proceeds." *Id.* (citing Ex. 2111; 2087, § 5.2.5).

Based on the record before us, we find that the Tribe has not retained anything more than an illusory or superficial right to sue for infringement of the challenged patents. With respect to its only example of a potential

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infringement action that could be initiated by the Tribe (as opposed to Allergan) under Section 5.2.3 of the License, the Tribe has not pointed to any evidence concerning the composition of Imprimis's non-FDA-approved cyclosporine product for us to assess whether that product could reasonably be alleged to infringe any of the challenged patents. Moreover, Allergan has sued Imprimis under the Lanham Act and California's Unfair Competition Law on the basis that the relevant products sold by Imprimis properly require FDA approval. *See Allergan, USA, Inc. v. Imprimis Pharmaceuticals, Inc.*, No. 8:17-cv-01551-DOC-JDE, Order Denying Defendant's Motion to Dismiss (C.D. Cal. Nov. 14, 2017).

But even if the Tribe could theoretically bring an infringement suit against Imprimis or others for any products that do not require FDA approval, the terms of the License do not allow the Tribe to "indulge" the possibility of infringement by any such products that would compete directly with and/or have the same treatment indication as Restasis. Specifically, the License indicates that the Tribe "shall not directly or indirectly develop, market or *license any Competing Product*, or engage in or license activities that would and/or are intended *to result in a Competing Product*." Ex. 2087 § 2.4 (emphasis added). A "Competing Product" is defined in the License to not only include any "Generic Equivalent," but also "any product . . . that is developed . . . for any indication that includes or is the same as any indication for which any Licensed Product<sup>[8]</sup> is approved by the FDA." *Id.*

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<sup>8</sup> "Licensed Product" is defined as "any product, including an authorized generic, approved by the FDA for sale in the United States under, or otherwise relating or referring to, NDA No. 050790 and/or No. 021023,

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§ 1.10; *see also* Paper 118, 3–4 (*Amicus Curiae* Brief of James R. Major, D. Phil.). Because Imprimis’s announced product, like Restasis, was developed to treat dry eye (Ex. 2111), it falls within the License’s definition of a “Competing Product” that the Tribe may not further license under the challenged patents. We find this to be a significant limit on the Tribe’s right to sue or indulge infringements (by granting licenses) for the challenged patents, regardless of whether the Imprimis products at issue are Generic Equivalents. As such, the “Competing Product” language in the License effectively limits the Tribe’s ability to license *any* product that treats dry eye disease.

The Tribe also emphasizes that it has the right to enforce the challenged patents for infringement in Allergan’s “exclusive field-of-use” (i.e., related to Generic Equivalents) in the event Allergan declines to initiate such an infringement action. Reply 2–3 (citing Ex. 2087 § 5.2.2). However, the Tribe’s rights with regard to an infringement action concerning Generic Equivalents not only depend upon Allergan’s primary choice as to whether or not to sue for such infringement, but also require Allergan’s written consent for the Tribe to both initiate *and* settle any such action. *See* Ex. 2087 § 5.2.2 (“[U]pon Allergan’s written consent (such consent not to be unreasonably withheld, conditioned or delayed), Licensor may prosecute such Infringement Action at its sole cost and expense.”); *id.* § 5.2.4 (“[T]he prosecuting Party must obtain the other Party’s written consent to any

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including any supplements, amendments or replacement applications relating to any of the foregoing.” Ex. 2087 § 1.33. This includes, but is not limited to, Allergan’s Restasis product. Ex. 2033; Ex. 2034.

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settlement (such consent not to be unreasonably withheld, conditioned or delayed).”). Moreover, contrary to the Tribe’s contention that it “has complete discretion to decide what trial strategy and tactics to employ” in litigation once its right to sue vests (Reply 3), a “Cooperation” provision in the License requires the Tribe to consult with Allergan as to strategy and consider in good faith any comments with respect to such an infringement action. Ex. 2087 § 5.2.4. Indeed, at least in the pending “E.D. Texas Litigations” where the Tribe was recently joined as a party,<sup>9</sup> the Tribe’s ability to control critical trial strategy is limited insofar as the Tribe is expressly precluded from even asserting its sovereign immunity as a claim or defense. *Id.* § 5.2.2.

All in all, we find that several License terms significantly limit the Tribe’s right to sue for infringement of the challenged patents. This stands in contrast to prior cases where a licensor’s retained right to sue was “otherwise unfettered” when compared to the restricted rights transferred to a licensee. *Cf. Mann*, 604 F.3d at 1362 (determining that licensor’s secondary right to sue was “unfettered” once that right vested because licensor could “decide whether or not to bring suit, when to bring suit, where to bring suit, what claims to assert, what damages to seek, whether to seek

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<sup>9</sup> “E.D. Texas Litigations” include *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2:15-cv-1455 (E.D. Tex.) and other district court proceedings in the U.S. District Court for the Eastern District of Texas. Ex. 2087, 31 (Schedule 1.17). Although the Tribe was recently joined as a discretionary party, the district court specifically indicated that its “decision to permit joinder of the Tribe does not constitute a ruling on the validity of the assignment of the Restasis patents or the Tribe’s status as a ‘patentee.’” Ex. 1163, 9.

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injunctive relief, whether to settle the litigation, and the terms on which the litigation will be settled”); *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 979 (Fed. Cir. 2005) (determining that transfer of the right to sue for commercial infringement did not result in all substantial rights conveyed because, *inter alia*, licensee did not have the right to settle litigation, grant sublicenses, or assign its rights under the agreement without the licensor’s prior approval).

2. *Right to Make, Use, and Sell Products or Services Under the Patents*

Under the License, Allergan is granted “an irrevocable, perpetual, transferable and exclusive (including with regard to Licensor) license” under the challenged patents to “Exploit [i.e., “make, have made, use, offer to sell, sell import, or otherwise exploit”] Licensed Products *for all FDA-approved uses in the United States.*” Ex. 2087 §§ 1.19, 1.33, 2.1 (emphasis added). Furthermore, with regard to development, commercialization, and regulatory activities, the License provides:

**3.1 In General.** During the Term, Allergan (by itself or through its Affiliates or its or their sublicensees) shall have the sole and exclusive right in the United States, at its sole cost and expense, to Exploit Licensed Products under the Licensed Patents, including to: (a) develop (or have developed); (b) manufacture (or have manufactured); (c) commercialize (or have commercialized); and (d) prepare, submit, obtain, and maintain approvals (including the setting of the overall regulatory strategy therefor), and conduct communications with the Governmental Entities with respect to, Licensed Products.

*Id.* § 3.1.

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Despite this broad grant of rights, the Tribe characterizes Allergan as merely a limited “field-of-use” licensee, whereas the Tribe retained the right to use and practice the patents for all other fields of use. Mot. 17–18 (citing Ex. 2087 §§ 2.1, 2.4). Petitioners disagree with that characterization, and assert that “any rights held by the Tribe for non-FDA approved uses are illusory.” Opp. 6. We again agree with Petitioners.

Because the claims of the challenged patents are directed to pharmaceutical compositions and methods used to treat human medical conditions, we find Allergan’s exclusive right to exploit the challenged patents “for all FDA-approved uses in the United States” to be a substantial right. Ex. 2087 § 2.1. In *A123 Systems, Inc. v. Hydro-Quebec*, the Federal Circuit found that an exclusive license that transferred a “significant portion of the field of technology” covered by the patents was still “less than a complete grant of rights” because “not *all* fields of technology described and claimed in the patents” were transferred to the licensee. 626 F.3d 1213, 1218 (Fed. Cir. 2010) (emphasis in original). However, unlike the transfer of rights at issue in *A123 Systems*, the record in these proceedings does not persuasively show that there are in fact any commercially relevant ways to practice the challenged patents that would not require FDA approval in the U.S., and thereby fall outside the scope of the exclusive rights granted to Allergan. Based on the current record, we find Allergan’s right to exploit the patents for “all FDA-approved uses” is effectively co-extensive with the scope of the claimed inventions. We, therefore, do not find Allergan’s exclusive rights to be limited in any meaningful sense.

Nonetheless, the Tribe asserts that it has retained “the right to use and

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practice the Licensed Patents for research, scholarly use, teaching, education, patient care incidental to the forgoing [sic], sponsored research for itself and in collaborations with Non-Commercial Organizations.” Mot. 17–18 (citing Ex. 2087 § 2.4). But the Tribe’s own right to practice and license the challenged patents is significantly limited insofar as the Tribe “shall not directly or indirectly develop, market or license any Competing Product or engage in or license activities that would and/or intended to result in a Competing Product,” regardless of whether such a “Competing Product” requires FDA approval. Ex. 2087 § 2.4. Moreover, even within the scope of the rights nominally retained under the License, the Tribe has not pointed to any record evidence showing that it is currently engaged in any commercial or non-commercial activities in a manner that practices that challenged patents or plans to engage in such activities in the future. To the contrary, in an “FAQ” document available on the Tribe’s official website, the Tribe has informed its members that it “is not investing any money in this [patent] business” and that “[i]ts only role is to hold the patents, get assignments, and make sure that the patent status with the US Patent Office is kept up to date.” Ex. 1145. *See Azure Networks*, 771 F.3d at 1344 (finding licensor’s right to practice the patent “has little force as [licensor] does not make or sell any products, . . . and the evidence on record suggests that [licensor] will not make or sell any products in the future”).

Even if the Tribe intends to engage in such activities, we do not find any non-commercial rights retained for the challenged patents to be substantial. In *AsymmetRx, Inc. v. Biocare Medical, LLC*, the licensor (Harvard College) retained the right to make and use “p63 antibodies”

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covered by the licensed patents “for its own academic research purposes, as well as the right to provide the p63 antibodies to non-profit or governmental institutions for academic research purposes,” but the court further pointed out that “Harvard retained a great deal of control over aspects of the licensed products within the commercial diagnostic field, such as requiring [licensee] AsymmetRx to meet certain commercial use, availability, and FDA filing benchmarks;” and “specifying that manufacture had to take place in the United States during the period of exclusivity.” 582 F.3d 1314, 1320 (Fed. Cir. 2009). As such, the Federal Circuit did not rely upon only the licensor’s retained non-commercial rights, and identified other license terms that restricted the licensee’s commercial rights in concluding that not all substantial rights were transferred. *Id.* at 1321 (“While any of these restrictions alone might not have been destructive of the transfer of all substantial rights, their totality is sufficient to do so.”). Such additional restrictions are not present in this case. The terms of the License do not allow the Tribe to control Allergan’s (or any other licensee’s) commercial activities with regard to the challenged patents.

### 3. *Right to Sublicense*

A third factor to take into account is the scope of the licensee’s right to sublicense. Here, the License “grants Allergan all licenses and other rights (*including sublicense rights relating to any Generic Equivalent*) under the Licensed Patents *related, necessary or useful for Allergan to settle any Infringement Actions under Section 5.2* or to comply with its obligations, or to exercise its rights under, any Prior Settlement Agreement.” Ex. 2087 § 2.1 (emphasis added). The License further provides:



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**2.3 Permitted Sublicensing.** Allergan shall have the right to grant sublicenses, through multiple tiers of sub licensees, under the license granted in Section 2.1, to its Affiliates and other Persons, including sublicenses for the purpose of settling any dispute or proceeding pertaining to the Licensed Patents, or to comply with Prior Settlement Agreements.

*Id.* § 2.3.

The Tribe asserts that “Allergan can only grant a sub-license in its limited field-of-use.” Reply 3. As discussed above, however, Allergan’s “field-of-use” extends to “all FDA approved uses” and, therefore, its sublicensing rights are also not limited in any commercially meaningful way. Furthermore, we agree with Petitioners that these provisions give Allergan “full power to end any proceeding—even one the Tribe wants to pursue—simply by granting a sublicense.” Opp’n 7. In particular, the License allows Allergan to grant a sublicense to others for the purpose of settling “any Infringement Actions under Section 5.2” or “any dispute or proceeding pertaining to the Licensed Patents.” Ex. 2087 §§ 2.1, 2.3. *See Speedplay*, 211 F.3d at 1251 (determining that licensee could render licensor’s retained right to sue “nugatory by granting the alleged infringer a royalty-free sublicense”). The Tribe has not pointed to any License terms that allow it to veto or otherwise control the terms of sublicenses that may be granted by Allergan.

#### *4. Reversionary Rights in Patents*

The rights granted to Allergan under the License are “perpetual” and “irrevocable,” and the License will continue to be in force either until the challenged patents expire or until all the claims are rendered invalid in a

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non-appealable final judgement. Ex. 2087 §§ 2.1, 9.1.1. As such, the Tribe does not have *any* reversionary rights in the challenged patents. *Cf. Azure Networks*, 771 F.3d at 1347 (finding that, with respect to two-year reversionary interest, “[s]uch short patent term life following expiration, coupled with the rolling renewal cycle that can extend to the end of the patent’s term, provides another indicator that [licensor] transferred all substantial rights to the patent”); *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1378 (Fed. Cir. 2000) (finding that license agreement temporally limited to an initial two-year period, but which could be renewed for successive one-year periods until patent expired, did not deprive the licensee of standing to maintain an infringement suit in its own name).

#### *5. Right to Litigation or Licensing Proceeds*

Under the License, the Tribe receives an upfront payment of \$13,750,000 followed by quarterly royalty payments of \$3,750,000. Ex. 2087 §§ 4.1, 4.2. The License, however, does not allow the Tribe to receive a portion of the proceeds from any of Allergan’s commercially relevant litigation or licensing activities. *Id.* § 5.2.5 (following reimbursements for costs, any remaining proceeds from litigation “shall be retained by the Party that has exercised its right to bring the Action”).

Nonetheless, the Tribe asserts that the royalties it will receive from Allergan are an important part of the Tribe’s “economic diversification strategy,” which will allow “the Tribe to address some of the chronically unmet needs of the Akwesasne community, such as housing, employment, education, healthcare, cultural, and language preservation.” Mot. 19. We recognize that the additional revenue that the Tribe is entitled to receive

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under the License may well serve these important needs. However, “a financial interest . . . without more does not amount to a substantial right.” *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1351 (Fed. Cir. 2016); *see also Propat Int’l Corp. v. RPost, Inc.*, 473 F.3d 1187, 1191 (Fed. Cir. 2007) (“[T]he fact that a patent owner has retained a right to a portion of the proceeds of the commercial exploitation of the patent, . . . does not necessarily defeat what would otherwise be a transfer of all substantial rights in the patent.”).

*6. Obligation to Pay Maintenance Fees and Right to Control Prosecution and Other PTO Proceedings*

The License provides Allergan with the primary right, but not the obligation, to prosecute and maintain the challenged patents, as well as the responsibility for any “Administrative Proceedings” before the PTO. Ex. 2087 § 5.1.1. The Tribe itself is not obligated to pay any maintenance fees.

With respect to “Contested PTO Proceedings” in particular, which include these *inter partes* review proceedings, the License provides that “[a]s between the Parties, Allergan shall have . . . the first right, but not the obligation, to defend and control the defense of the validity, enforceability and patentability of the Licensed Patents in such Contested PTO Proceeding.” *Id.* § 5.3; Schedule 1.31 (identifying “IPR Proceedings” to include current proceedings). The same provision indicates that the Tribe “shall cooperate in the defense of any such Contested PTO Proceeding” and “shall assert its sovereign immunity in any Contested PTO Proceeding,

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including in the [current] IPR Proceedings,”<sup>10</sup> but nonetheless “Allergan shall retain control of the defense in such claim, suit or proceeding.” *Id.* § 5.3. The Tribe may conduct and control the defense in any Contested PTO Proceeding only in the event that Allergan elects not to defend the challenged patents in such a proceeding. *Id.* We find this last provision to be particularly relevant given that the question before us is whether these proceedings may continue only with Allergan’s participation. The License itself allows for that possibility since Allergan has retained the primary right to defend the challenged patents in these proceedings.

#### *7. Right to Assign Interests in Patents*

The License does not allow the Tribe to freely assign its interests in the challenged patents. In particular, among various other restrictions placed on the Tribe, the License provides that the Tribe shall not, without Allergan’s prior written consent, “take or fail to take any action, or enter into any agreement that would result in the transfer” of the challenged patents to any third party or “Component of Licensor,” which includes Tribe-owned companies or other related entities. Ex. 2087 § 7.2.8; *see also id.* § 1.11 (defining “Component of Licensor” to mean “any company, corporation, enterprise, authority, division, subdivision, branch or other agency, instrumentality or other government component of Licensor”). Furthermore,

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<sup>10</sup> The Tribe’s obligation to assert its sovereign immunity in “Contested PTO Proceedings” stands in contrast to the License’s provision concerning other types of “Administrative Proceedings,” in which the Tribe “shall have sole and exclusive control over the means and manner in which its sovereign immunity is asserted or waived.” Ex. 2087 § 5.1.2.

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the Tribe may not cause the imposition of any lien on, or the grant of any license or other right in or to, the challenged patents without Allergan's prior written consent. *Id.* § 7.2.8. By contrast, Allergan may assign its interests to any affiliate or successor without the Tribe's consent. *Id.* § 10.3.

We find these provisions to be significant restrictions on the Tribe's purported ownership rights. "The right to dispose of an asset is an important incident of ownership, and such a restriction on that right is a strong indicator" of whether a license agreement transferred all substantial rights under the patent. *Propat*, 473 F.3d at 1191; *see also Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) (stating "limits on ... assignment rights weigh in favor of finding ... a transfer of fewer than all substantial rights in a patent").

In sum, upon considering the relevant License terms, we find that Allergan obtained all substantial rights in the challenged patents. The Tribe points out that Allergan executed an assignment of the challenged patents to the Tribe, and this assignment was recorded at the PTO. Reply 5; Ex. 2085; Ex. 2086; Ex. 2103. As recognized by the Tribe, however, a recordation of a patent assignment only creates a rebuttable presumption regarding ownership. *See SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1328 (Fed. Cir. 2010) ("The recording of an assignment with the PTO is not a determination as to the validity of the assignment," but "creates a presumption of validity as to the assignment and places the burden to rebut such a showing on one challenging the assignment"). For the foregoing reasons, we determine that the presumption associated with the recorded assignment of the challenged patents has been overcome in this case.

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Because Allergan remains the effective patent owner, we determine that these proceedings can continue with Allergan’s participation only, regardless of whether tribal immunity applies to the Tribe.<sup>11</sup>

*D. The Tribe Is Not an Indispensable Party*

The Tribe contends that it is an “indispensable party” to these proceedings under Federal Rule of Civil Procedure 19(b).<sup>12</sup> Mot. 20–24; Reply 10–12. In *Republic of Philippines v. Pimentel*, the Supreme Court

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<sup>11</sup> In reaching this conclusion, we do not comment on whether the License and the other agreements between the Tribe and Allergan constitute a “sham” transaction, nor do we need to decide whether the agreements are otherwise improper under the law. Opp’n 10–13.

<sup>12</sup> Rule 19(b) of the Federal Rules of Civil Procedure provides that “[i]f a person who is required to be joined if feasible cannot be joined, the court must determine whether, in equity and good conscience, the action should proceed among the existing parties or should be dismissed.” It goes on to state four “factors for the court to consider” in making that determination:

- (1) the extent to which a judgment rendered in the person’s absence might prejudice that person or the existing parties;
- (2) the extent to which any prejudice could be lessened or avoided by:
  - (A) protective provisions in the judgment;
  - (B) shaping the relief; or
  - (C) other measures;
- (3) whether a judgment rendered in the person’s absence would be adequate; and
- (4) whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder.

Fed. R. Civ. P. 19(b).

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held that “[a] case may not proceed when a required-entity sovereign is not amenable to suit . . . where sovereign immunity is asserted, and the claims of the sovereign are not frivolous, dismissal of the action must be ordered where there is a potential for injury to the interests of the absent sovereign.” 553 U.S. 851, 867 (2008) (“*Pimentel*”). Relying upon *Pimentel*, the Tribe and some supporting amici argue that a non-frivolous assertion of tribal immunity is itself a “compelling factor” that requires dismissal because the Tribe is an indispensable party that cannot be joined in these proceedings. Mot. 21; *see also* Paper 106 (*Amici* Scholars), 5 (asserting that “once a tribunal recognizes that an assertion of sovereign immunity is ‘not frivolous,’ it is ‘error’ for the tribunal to proceed further to address the merits” (citing *Pimentel*, 553 U.S. at 864)); Paper 110 (*Amici* Seneca Nation), 4–5, 8–10 (arguing for *Pimentel*-like joinder analysis and asserting that Tribes have been held to be indispensable parties in other contexts).

We are not persuaded by these arguments. First, the Federal Rules of Civil Procedure do not apply to *inter partes* review proceedings. The specific rules for our proceedings do not have an analogous requirement for joinder of indispensable parties. *See generally* 37 C.F.R. §§ 42.1–42.123. Nonetheless, we recognize that the Board has previously found “instructive the Federal Circuit’s analysis under Rule 19(b)(1) . . . regarding the identity of interests between present and absent patent owners.” *Reactive Surfaces*, slip op. at 15 n.2. But even if we were to consider Rule 19(b) and case law analyzing that Rule, we do not find the Tribe to be an indispensable party.

*Pimentel* involved a claim to foreign sovereign immunity in federal interpleader litigation concerning disputed claims to money that had been

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stolen from the foreign sovereign. 553 U.S. at 851, 865–67. As such, we find it distinguishable from the circumstances presented in these proceedings. Since *Pimentel* was decided, the Federal Circuit has considered at least twice the issue of whether to dismiss litigation in the absence of a sovereign defendant. In both of those decisions, the court considered the proper application of the Rule 19(b) factors rather than dismissing the case based solely on a defendant’s non-frivolous assertion of sovereign immunity. See *Univ. of Utah v. Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V.*, 734 F.3d 1315, 1326 (Fed. Cir. 2013) (determining that state university was not an indispensable party in a proceeding to correct inventorship because university’s interests were adequately represented by other defendants); *but see A123 Sys.*, 626 F.3d at 1121–22 (determining that “three of the four Rule 19(b) factors weigh in factor of holding [state university] to be an indispensable party”). Accordingly, we do not find that the Tribe’s mere assertion of tribal immunity requires automatic termination of these proceedings.

Applying the traditional Rule 19(b) factors here, we find that Allergan has at least an identical interest to the Tribe—if not *more* of an interest as the effective patent owner for the reasons discussed above—in defending the challenged patents. Thus, we do not find that the Tribe will be significantly prejudiced in relation to the merits of the patentability challenges in these proceedings if it chooses not to participate based on its alleged tribal immunity because Allergan will be able to adequately represent any interests



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the Tribe may have in the challenged patents.<sup>13</sup> *Cf. Reactive Surfaces*, slip op. at 15 (“The adequacy of that representation is even stronger when the parties at issue are patent owners, [and] when all of the patent owners except the absent sovereign are present in the action.”). In this regard, we note that the briefing and evidence on the substantive patentability issues were completed even before the Tribe’s involvement in these proceedings. *See, e.g.*, Paper 10 (Scheduling Order); Paper 16 (Patent Owner Response submitted by Allergan). Other than oral argument, the record in these proceedings is closed.

The Tribe asserts that “while Allergan and the Tribe share ‘the same overarching goal of defending the patents’ validity,’ their interests are not identical” because Allergan’s claim constructions “may conflict with the Tribe’s interests in subject matter not licensed to Allergan and may also conflict with the Tribe’s desire not to risk the validity of the” challenged patents. Mot. 22 (citing *A123 Sys.*, 626 F.3d at 1121). However, the Tribe

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<sup>13</sup> We recognize that the Tribe’s continued entitlement to receive royalty payments under the License depends upon the challenged patents being upheld in these proceedings. *See* Ex. 2087 § 1.45 (defining “Royalty Term” as a period ending when there ceases to be any “Valid Claim” of the challenged patents). The Tribe identifies the royalty stream as a “significant property interest . . . which cannot be adjudicated in its absence.” Mot. 22. However, we do not find that this incidental financial interest in the outcome of these proceedings is sufficient to render the Tribe an indispensable party. *See Liberty Mut. Ins. Co. v. Treesdale, Inc.*, 419 F.3d 216, 230 (3d Cir. 2005) (“The ‘interest’ relating to the subject matter of the action that makes an absent party a party needed for just adjudication must be a legally protected interest, not merely a financial interest or interest of convenience.”) (citing 3A, Moore’s Federal Practice ¶ 19.07–1(2)).

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has not sought to introduce new claim construction positions in these proceedings that would differ from Allergan's positions already made of record. Accordingly, our final judgment in these proceedings, i.e., a determination on the patentability of the challenged claims, would be the same regardless of whether Allergan or the Tribe continues to participate. *See* Mot. 24 ("The Board's judgment is binary: the claims are patentable or not patentable.").

Finally, we disagree with the Tribe that, if we terminate these proceedings in view of the Tribe's alleged sovereign immunity, Petitioners will still have an adequate remedy in the co-pending district court cases. *Id.* The claims and patents litigated in the Eastern District of Texas are not co-extensive with the claims and patents challenged in these proceedings. *See* Ex. 1165 (Final Judgment in district court proceeding declaring subset of challenged claims invalid under 35 U.S.C. § 103). Moreover, by statute, *inter partes* review proceedings involve a different evidentiary standard for unpatentability determinations (preponderance of the evidence) than the district court's invalidity determinations (clear and convincing evidence). *See* 35 U.S.C. § 316(e).

We, therefore, determine that the Tribe is not an indispensable party, and that we may continue with these proceedings without the Tribe's participation.<sup>14</sup>

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<sup>14</sup> Courts have also recognized a "public rights" exception to the requirement of joinder of otherwise indispensable parties. *See Nat'l Licorice Co. v. NLRB*, 309 U.S. 350, 363 (1940) ("In a proceeding . . . narrowly restricted to the protection of public rights, there is little scope or need for

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IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

## V. CONCLUSION

For the foregoing reasons, we determine that the Tribe has not established that it is entitled to assert its tribal immunity in these *inter partes* review proceedings. We further determine that these proceedings may continue with Allergan as the patent owner, and that the Tribe is not an indispensable party to these proceedings.

Accordingly, based on the foregoing, it is:

ORDERED that the Tribe's Motion to Terminate is *denied*.

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the traditional rules governing the joinder of parties in litigation determining private rights.”); *see also S. Utah Wilderness All. v. Kempthorne*, 525 F.3d 966, 969 n.2 (10th Cir. 2008) (“We note that Movants as private lessees were not indispensable parties to the district court proceedings because SUWA’s action against BLM fell within the ‘public rights exception’ to joinder rules, most notably Fed. R. Civ. P. 19.”); *Diné Citizens Against Ruining Our Env’t v. U.S. Office of Surface Mining Reclamation & Enf’t*, No. 12-CV-1275-AP, 2013 WL 68701, at \*3–\*6 (D. Colo. Jan. 4, 2013) (distinguishing *Pimentel* and applying public rights exception despite claim of tribal immunity). The Federal Circuit has recognized that *inter partes* review proceedings involve an adjudication of public rights. *MCM Portfolio*, 812 F.3d at 1293. The issue is also before the Supreme Court in *Oil States Energy Services LLC v. Greene’s Energy Group, LLC*, No. 16–712, 137 S. Ct. 2293, 2017 WL 2507340 (June 12, 2017).

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Paper No. 128  
Entered: February 23, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS  
USA, INC., and AKORN INC.  
Petitioners,

v.

SAINT REGIS MOHAWK TRIBE and ALLERGAN, INC.,  
Patent Owners.

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Case IPR2016-01127 (8,685,930 B2); Case IPR2016-01128 (8,629,111 B2);  
Case IPR2016-01129 (8,642,556 B2); Case IPR2016-01130 (8,633,162 B2);  
Case IPR2016-01131 (8,648,048 B2); Case IPR2016-01132 (9,248,191 B2)

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Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and  
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

ORDER  
Conduct of the Proceedings  
*37 C.F.R. § 42.5*

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<sup>1</sup> Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601, have respectively been joined with the captioned proceedings. This Order addresses issues that are the same in the identified cases. Paper numbers and exhibits cited in this Order refer to those documents filed in IPR2016-01127.

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

*Allergan's Motion to Withdraw*

Pursuant to our authorization, Allergan, Inc. (“Allergan”) filed a motion to withdraw from these proceedings. Paper 126 (“Motion” or “Mot.”). Petitioners filed an opposition to Allergan’s Motion. Paper 128 (“Opposition” or “Opp’n”).

Allergan seeks to withdraw from these proceedings on the grounds that it has ceased to be an owner of the six patents involved in these proceedings in view of its agreements with the Saint Regis Mohawk Tribe (“the Tribe”). Mot. 4–5. Petitioners contend that the “ownership question, however, is a fundamental dispute that has been extensively briefed in connection with the Tribe’s pending Motion to Dismiss.” Opp’n 1. Petitioners further contend that Allergan is at least a joint owner as a result of the agreements with the Tribe, and that Allergan has already taken all actions authorized to be taken by the patent owner under our rules and governing statute. *Id.* at 2–3. Additionally, Petitioners contend that Allergan’s request to withdraw should be construed as an abandonment of these proceedings, and thus a request for adverse judgement under 37 C.F.R. § 42.73(b)(4). *Id.* at 4–5.

As set forth in our Decision Denying the Tribe’s Motion to Terminate, we determine that Allergan remains an effective “patent owner” of the challenged patents in these proceedings based on the terms of its License Agreement with the Tribe. Paper     , 18–34. Accordingly, we find that the basis for Allergan’s request to withdraw does not hold true. We decline, however, to construe the request to withdraw as a request for adverse judgment insofar as the ownership question was not settled at the time

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IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

Allergan filed its Motion. In this regard, we recognize that the Tribe may still claim an ownership interest in the challenged patents in a subsequent appeal to the Federal Circuit. In order to allow the Tribe to represent its interests in these proceedings before the Board and in any appeals, we will allow the Tribe to continue participating as a patent owner along with Allergan. Allergan and the Tribe shall coordinate their efforts going forward, and shall file joint papers in these proceedings unless otherwise authorized by the Board. The caption for this Order and subsequent orders and decisions in these proceedings will reflect both Allergan's and the Tribe's status as the named "Patent Owners."

*Remaining Schedule*

In view of our Decision Denying the Tribe's Motion to Terminate, we will resume the schedule for these proceedings and proceed to a final written decision. The parties had previously submitted requests for oral hearing pursuant to 37 C.F.R. § 42.70(a). Papers 47 and 48. Accordingly, an oral hearing has been tentatively scheduled for April 3, 2018. Within five (5) business days after entry of this Order, the parties shall meet and confer and notify the Board via email whether this hearing date is acceptable to the parties or, if not, the parties shall provide the Board with several mutually acceptable dates for a hearing. Any proposed hearing dates shall be no later than April 6, 2018. We will consider the proposed hearing dates and enter a revised Hearing Order with the new date for the hearing, subject to the availability of hearing rooms at the Board.



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IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

In order to provide ourselves with sufficient time to consider the arguments presented, we will also adjust the time to enter our final written decisions in these proceedings to June 6, 2018.

ORDER

Accordingly, based on the foregoing, it is:

ORDERED that Allergan's Motion to Withdraw is *denied*;

FURTHER ORDERED that the Tribe may continue participating as a patent owner along with Allergan. Allergan and the Tribe shall coordinate their efforts going forward, and shall file joint papers in these proceedings unless otherwise authorized by the Board. The caption for these proceedings shall reflect both Allergan's and the Tribe's status as "Patent Owners";

FURTHER ORDERED that an oral hearing has been tentatively scheduled for April 3, 2018;

FURTHER ORDERED that within five (5) business days after entry of this Order, the parties shall meet and confer and notify the Board via email whether April 3, 2018, is acceptable to the parties for a hearing, or, if not, the parties shall provide the Board with several mutually acceptable dates for a hearing no later than April 6, 2018; and

FURTHER ORDERED that the time to enter final written decisions in these proceedings is adjusted to June 6, 2018.

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IPR2016-01129 (8,642,556 B2); IPR2016-01130 (8,633,162 B2);  
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# **STATUTORY ADDENDUM**

<b>Statute</b>	<b>Page Nos.</b>
35 U.S.C. § 311. INTER PARTES REVIEW.	1
35 U.S.C. § 312. PETITONS.	2
35 U.S.C. § 313. PRELIMINARY RESPONSE TO PETITION.	3
35 U.S.C. § 314. INSTITUTION OF INTER PARTES REVIEW.	4
35 U.S.C. § 315. RELATION TO OTHER PROCEEDINGS OR ACTIONS.	5-6
35 U.S.C. § 316. CONDUCT OF INTER PARTES REVIEW.	7-9
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**35 U.S.C. § 311. INTER PARTES REVIEW.**

(a) IN GENERAL.—Subject to the provisions of this chapter, a person who is not the owner of a patent may file with the Office a petition to institute an inter partes review of the patent. The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review.

(b) SCOPE.—A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.

(c) FILING DEADLINE.—A petition for inter partes review shall be filed after the later of either—

- (1) the date that is 9 months after the grant of a patent; or
- (2) if a post-grant review is instituted under chapter 32, the date of the termination of such post-grant review.

**35 U.S.C. § 312. PETITIONS.**

(a) REQUIREMENTS OF PETITION.—A petition filed under section 311 may be considered only if—

(1) the petition is accompanied by payment of the fee established by the Director under section 311;

(2) the petition identifies all real parties in interest;

(3) the petition identifies, in writing and with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim, including—

(A) copies of patents and printed publications that the petitioner relies upon in support of the petition; and

(B) affidavits or declarations of supporting evidence and opinions, if the petitioner relies on expert opinions;

(4) the petition provides such other information as the Director may require by regulation; and

(5) the petitioner provides copies of any of the documents required under paragraphs (2), (3), and (4) to the patent owner or, if applicable, the designated representative of the patent owner.

(b) PUBLIC AVAILABILITY.—As soon as practicable after the receipt of a petition under section 311, the Director shall make the petition available to the public.

**35 U.S.C. § 313. PRELIMINARY RESPONSE TO PETITION.**

If an inter partes review petition is filed under section 311, the patent owner shall have the right to file a preliminary response to the petition, within a time period set by the Director, that sets forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirement of this chapter.



**35 U.S.C. § 314. INSTITUTION OF INTER PARTES REVIEW.**

(a) THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

(b) TIMING.—The Director shall determine whether to institute an inter partes review under this chapter pursuant to a petition filed under section 311 within 3 months after—

(1) receiving a preliminary response to the petition under section 313; or

(2) if no such preliminary response is filed, the last date on which such response may be filed.

(c) NOTICE.—The Director shall notify the petitioner and patent owner, in writing, of the Director's determination under subsection (a), and shall make such notice available to the public as soon as is practicable. Such notice shall include the date on which the review shall commence.

(d) NO APPEAL.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

**35 U.S.C. § 315. RELATION TO OTHER PROCEEDINGS OR ACTIONS.**

**(a) INFRINGER'S CIVIL ACTION.—**

**(1) INTER PARTES REVIEW BARRED BY CIVIL ACTION.—**An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.

**(2) STAY OF CIVIL ACTION.—**If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for inter partes review of the patent, that civil action shall be automatically stayed until either—

(A) the patent owner moves the court to lift the stay;

(B) the patent owner files a civil action or counterclaim alleging that the petitioner or real party in interest has infringed the patent; or

(C) the petitioner or real party in interest moves the court to dismiss the civil action.

**(3) TREATMENT OF COUNTERCLAIM.—**A counterclaim challenging the validity of a claim of a patent does not constitute a civil action challenging the validity of a claim of a patent for purposes of this subsection.

**(b) PATENT OWNER'S ACTION.—**An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).

(c) JOINDER.—If the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

(d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

(e) ESTOPPEL.—

(1) PROCEEDINGS BEFORE THE OFFICE.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

(2) CIVIL ACTIONS AND OTHER PROCEEDINGS.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

**35 U.S.C. § 316 CONDUCT OF INTER PARTES REVIEW.**

(a) REGULATIONS.—The Director shall prescribe regulations—

(1) providing that the file of any proceeding under this chapter shall be made available to the public, except that any petition or document filed with the intent that it be sealed shall, if accompanied by a motion to seal, be treated as sealed pending the outcome of the ruling on the motion;

(2) setting forth the standards for the showing of sufficient grounds to institute a review under section 314(a);

(3) establishing procedures for the submission of supplemental information after the petition is filed;

(4) establishing and governing inter partes review under this chapter and the relationship of such review to other proceedings under this title;

(5) setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to—

(A) the deposition of witnesses submitting affidavits or declarations; and

(B) what is otherwise necessary in the interest of justice;

(6) prescribing sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding;

(7) providing for protective orders governing the exchange and submission of confidential information;

(8) providing for the filing by the patent owner of a response to the petition under section 313 after an inter partes review has been instituted, and requiring that the patent owner file with such response, through affidavits or declarations, any additional factual evidence and expert opinions on which the patent owner relies in support of the response;

(9) setting forth standards and procedures for allowing the patent owner to move to amend the patent under subsection (d) to cancel a challenged claim or propose a reasonable number of substitute claims, and ensuring that any information submitted by the patent owner in support of any amendment entered under subsection (d) is made available to the public as part of the prosecution history of the patent;

(10) providing either party with the right to an oral hearing as part of the proceeding;

(11) requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c);

(12) setting a time period for requesting joinder under section 315(c); and

(13) providing the petitioner with at least 1 opportunity to file written comments within a time period established by the Director.

(b) **CONSIDERATIONS.**—In prescribing regulations under this section, the Director shall consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter.

(c) PATENT TRIAL AND APPEAL BOARD.—The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

(d) AMENDMENT OF THE PATENT.—

(1) IN GENERAL.—During an inter partes review instituted under this chapter, the patent owner may file 1 motion to amend the patent in 1 or more of the following ways:

(A) Cancel any challenged patent claim.

(B) For each challenged claim, propose a reasonable number of substitute claims.

(2) ADDITIONAL MOTIONS.—Additional motions to amend may be permitted upon the joint request of the petitioner and the patent owner to materially advance the settlement of a proceeding under section 317, or as permitted by regulations prescribed by the Director.

(3) SCOPE OF CLAIMS.—An amendment under this subsection may not enlarge the scope of the claims of the patent or introduce new matter.

(e) EVIDENTIARY STANDARDS.—In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.

**35 U.S.C. § 317. SETTLEMENT.**

(a) IN GENERAL.—An inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed. If the inter partes review is terminated with respect to a petitioner under this section, no estoppel under section 315(e) shall attach to the petitioner, or to the real party in interest or privy of the petitioner, on the basis of that petitioner’s institution of that inter partes review. If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).

(b) AGREEMENTS IN WRITING.—Any agreement or understanding between the patent owner and a petitioner, including any collateral agreements referred to in such agreement or understanding, made in connection with, or in contemplation of, the termination of an inter partes review under this section shall be in writing and a true copy of such agreement or understanding shall be filed in the Office before the termination of the inter partes review as between the parties. At the request of a party to the proceeding, the agreement or understanding shall be treated as business confidential information, shall be kept separate from the file of the involved patents, and shall be made available only to Federal Government agencies on written request, or to any person on a showing of good cause.

**35 U.S.C. § 318. DECISION OF THE BOARD.**

(a) FINAL WRITTEN DECISION.—If an inter partes review is instituted and not dismissed under this chapter, the Patent Trial and Appeal Board shall issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under section 316(d).

(b) CERTIFICATE.—If the Patent Trial and Appeal Board issues a final written decision under subsection (a) and the time for appeal has expired or any appeal has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

(c) INTERVENING RIGHTS.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes review under this chapter shall have the same effect as that specified in section 252 for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, before the issuance of a certificate under subsection (b).

(d) DATA ON LENGTH OF REVIEW.—The Office shall make available to the public data describing the length of time between the institution of, and the issuance of a final written decision under subsection (a) for, each inter partes review.



**35 U.S.C. § 319. APPEAL.**

A party dissatisfied with the final written decision of the Patent Trial and Appeal Board under section 318(a) may appeal the decision pursuant to sections 141 through 144. Any party to the inter partes review shall have the right to be a party to the appeal.

**PROOF OF SERVICE**

I hereby certify that on April 18, 2018, I electronically transmitted this **Brief for Appellants** to the Clerk of the Court using the Court's ECF system. I further certify that all counsel of record for Appellees are being served with a copy of this Brief by electronic means via the Court's ECF system.

/s/ Marsha K. Schmidt  
Marsha Kostura Schmidt

**CERTIFICATE OF COMPLIANCE WITH RULE 32(A)**

1. This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 13,380 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14 point font.

Dated: April 18, 2018

Respectfully submitted,

*/s/ Marsha K. Schmidt*  
Marsha Kostura Schmidt