UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., and AKORN INC., [1]
Petitioners,

v.

ALLERGAN, INC.,
Patent Owner.

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)

CORRECTED PATENT OWNER'S MOTION TO DISMISS FOR LACK OF JURISDICTION BASED ON TRIBAL SOVEREIGN IMMUNITY

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[1] 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. The word-for-word identical paper is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

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I. SUMMARY OF MOTION

The Saint Regis Mohawk Tribe ("Tribe"), a federally recognized, sovereign American Indian Tribe, is the owner of U.S. Patent Nos. 8,685,930, 8,629,111, 8,642,556, 8,633,162, 8,648,048, and 9,248,191 (hereinafter "Patents-at-Issue") that are at issue in these proceedings. The Tribe is a sovereign government that cannot be sued unless Congress unequivocally abrogates its immunity or the Tribe expressly waives it. Neither of these exceptions apply here. As Patent Owner, the Tribe is an indispensable party to this proceeding whose interests cannot be protected in its absence. Accordingly, the Tribe makes a special appearance before this Board to challenge the Board's jurisdiction over the Tribe and the Board's authority to adjudicate the status of the Tribe's property—the Patents-at-Issue. *See*, *e.g.*, *Friends of Amador Cty. v. Salazar*, 554 F. App'x 562, 564 (9th Cir. 2014) ("The Tribe made a special appearance to file a motion to dismiss based on the Appellants' failure and inability to join the Tribe as a required and indispensable party under Rule 19."). The Tribe does not otherwise submit to the jurisdiction of this Board. As a result, this proceeding must be dismissed.

II. THE SAINT REGIS MOHAWK TRIBE

The Tribe is a federally recognized Indian tribe with reservation lands in northern New York. EX. 2091 at 4. The Tribe's reservation was established by a federal treaty approved and ratified by the United States. EX. 2092. The Tribe's current

reservation constitutes 14,000 acres spanning Franklin and St. Lawrence Counties. The Tribe has over 15,600 enrolled tribal members, with approximately 8,000 tribal members 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. *See* https://www.srmt-nsn.gov/about-the-tribe.

But unlike other sovereign governments, the Tribe's ability to raise revenues through taxation is extremely limited. This is a problem faced by all American Indian Tribes as described by the National Congress of American Indians ("NCAI"):

> In general, tribal governments lack parity with states, local governments, and the federal government in exercising taxing authority. For example, tribes are unable to levy property taxes because of the trust status of their land, and they generally do not levy income taxes on tribal members. Most Indian reservations are plagued with disproportionately high levels of unemployment and poverty, not to mention a severe lack of employment opportunities. As a result, tribes are unable to establish a strong tax base structured around the property taxes and income taxes typically found at the local state government level. To the degree that they are able, tribes use sales and excise taxes, but these do not generate enough revenue to support tribal government functions.

EX. 2102 at 1.

In its "Tax Reform Briefing Paper," NCAI further highlights the problem:

> When Indian tribal governments undertake economic development efforts, one reality that almost all tribes confront is the lack of a tax base. Tribes are not able to impose property tax on trust lands, and imposing an income tax on reservation residents or the businesses that choose to locate on reservations is rarely feasible. Recent federal court decisions have compounded the "tribal tax gap" by permitting the imposition of state taxation on Indian lands, while limiting the ability of tribal governments to tax nonIndians.

EX. 2100 at 7.

These issues are compounded by barriers to access to capital. "Over 40% of Native people have limited or no access to mainstream financial services (one of the highest rates in the nation), a full 26.8 percent of American Indian and Alaska native households are underbanked (have a bank account but use alternative financial services), and an additional 14.5 percent are completely unbanked." EX. 2101 at 11.

Because of these disparities, 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.

As a result, the federal government has long supported efforts by tribes to achieve

economically self-sufficient and stable communities. In the Indian Self-Determination and Education Assistance Act, 25 U.S.C. § 5302(b), Congress stated the U.S. government policy:

> The Congress declares its commitment to the maintenance of the Federal Government's unique and continuing relationship with, and responsibility to, individual Indian tribes and to the Indian people as a whole through the establishment of a meaningful Indian self-determination policy … the United States is committed to supporting and assisting Indian tribes in the development of strong and stable tribal governments, capable of administering quality programs and developing the economies of their respective communities.

Congress reaffirmed this policy in the Indian Financing Act, 25 U.S.C. § 1451:

> It is hereby declared to be the policy of Congress to provide capital on a reimbursable basis to help develop and utilize Indian resources, both physical and human, to a point where the Indians will fully exercise responsibility for the utilization and management of their own resources and where they will enjoy a standard of living from their own productive efforts comparable to that enjoyed by non-Indians in neighboring communities.

In 2013, a Presidential Executive Order recognized "a government-to-government relationship," the "tribe's inherent sovereignty," and the U.S.

government's policy "to promote the development of prosperous and resilient tribal communities" through "sustainable economic development, particularly energy, transportation, housing, other infrastructure, entrepreneurial, and workforce development to drive future economic growth and security." EX. 2093.

The economic disadvantages facing American Indian Tribes were also recognized by the Supreme Court in Justice Sotomayor's concurring opinion in *Michigan v. Bay Mills Indian Community*:

> A key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on federal funding. And tribal business operations are critical to the goals of tribal self-sufficiency because such enterprises in some cases "may be the only means by which a tribe can raise revenues." This is due in large part to the insuperable (and often state-imposed) barriers Tribes face in raising revenue through more traditional means.

134 S. Ct. 2024, 2043–44 (2014) (Sotomayor, J., concurring) (internal citations omitted).

To overcome these economic disadvantages, the Tribe took steps to diversify its economy with investments in innovative businesses and various enterprises to foster jobs and entrepreneurship. Looking to the business model already utilized by state universities and their technology transfer offices, the Tribe adopted a Tribal

Resolution endorsing the creation of a technology and innovation center for the commercialization of existing and emerging technologies. EX. 2094.

This new Tribal enterprise will be called the Office of Technology, Research and Patents and will be part of the Tribe's Economic Development Department. *See* https://www.srmt-nsn.gov/economic-development. The Office's purpose is to strengthen the Tribal economy by encouraging the development of emerging science and technology initiatives and projects, and promoting the modernization of Tribal and other businesses. The objective is to create revenue, jobs, and new economic development opportunities for the Tribe and its members. The Office will also promote the education of Mohawks in the fields of science, technology, engineering, and math.

All revenue generated by the Office of Technology, Research and Patents 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, healthcare, cultural and language preservation.

III. RELEVANT PROCEDURAL BACKGROUND

A. District Court Proceedings.

Allergan, Inc. ("Allergan") filed suit against Mylan, Teva, and Akorn in the Eastern District of Texas on August 24, 2015, alleging infringement of the Patents-at-Issue. A week-long bench trial was held in front of Judge Bryson in the Eastern

District of Texas starting on August 28, 2017. EX. 2098. At that trial, Mylan, Teva, and Akorn took full advantage of this opportunity by asserting numerous invalidity defenses under 35 U.S.C. §§ 102, 103, and 112. EX. 2099 at 13-17. The parties are currently engaged in post-trial briefing that will be filed on September 22, 2017.

B. PTAB Proceedings.

On June 3, 2016, Mylan Pharmaceuticals Inc. ("Mylan") filed six petitions for *inter partes* review against the Patents-at-Issue. IPR2016-01127; IPR2016-01128; IPR2016-01129; IPR2016-01130; IPR2016-01131; IPR2016-01132.

On January 6, 2017, Teva Pharmaceuticals USA, Inc. ("Teva") filed an additional six petitions for *inter partes* review against the Patents-at-Issue. IPR2017-00576; IPR2017-00578; IPR2017-00579; IPR2017-00583; IPR2017-00585; IPR2017-00586.

Also on January 6, 2017, Akorn Inc. ("Akorn") filed six more petitions for *inter partes* review against the Patents-at-Issue. IPR2017-00594; IPR2017-00596; IPR2017-00598; IPR2017-00599; IPR2017-00600; IPR2017-00601.

On March 31, 2017, each Teva and Akorn IPR proceeding was joined with the corresponding Mylan proceeding involving the same patent. *See*, *e.g.*, Paper Nos. 18 and 19 in IPR2016-01127.

On September 8, 2017, Allergan, Inc. assigned all six Patents-at-Issue in this case to the Tribe. EX. 2086; EX. 2103. The Tribe concurrently granted back an exclusive

limited field-of-use license. EX. 2087. The Tribe immediately filed an updated Mandatory Notice to reflect that the Tribe is the Patent Owner. Paper No. 63 in IPR2016-01127. The Tribe then sought and received the Board's permission to file this motion. Paper No. 76 in IPR2016-01127.

IV. ARGUMENTS AND AUTHORITY

A. The Tribe Possesses Immunity From Suit.

As a federally recognized, sovereign Indian Tribe, the Tribe has inherent sovereign immunity. EX. 2091 at 4. The Federal Government and the U.S. Supreme Court have long recognized that Indian tribes are "distinct, independent political communities." *Worcester v. State of Ga.*, 31 U.S. 515, 519 (1832).

As such, the Tribe "possess[es] the same common-law immunity from suit traditionally enjoyed by sovereign powers." *Bay Mills*, 134 S.Ct. at 2030. The Supreme Court has repeatedly reaffirmed the doctrine of Indian tribal sovereign immunity. *Kiowa Tribe of Okla. v. Mfg. Techs. Inc.*, 523 U.S. 751, 754 (1998); *Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Okla.*, 498 U.S. 505, 510 (1991) ("*Potawatomi I*"); *Santa Clara Pueblo v. Martinez,* 436 U.S. 49, 58 (1978); *Puyallup Tribe, Inc. v. Dep't of Game*, 433 U.S. 165, 172-73 (1977); *U.S. v. U.S. Fid. & Guar. Co.*, 309 U.S. 506, 512 (1940). The Tribe's status as a sovereign that is immune from suit is firmly established.

"[A]bsent a clear waiver by the [T]ribe or congressional abrogation," all suits

against the Tribe are barred by its sovereignty. *Potawatomi I,* 498 U.S. at 509.

Congress may abrogate a tribe's immunity from suit by statute. *Santa Clara*, 436 U.S. at 58; *Ransom v. St. Regis Mohawk Educ. and Cmty. Fund, Inc.,* 86 N.Y.2d 553, 560 (1995). But congressional waiver cannot be implied; it "must be unequivocally expressed." *Santa Clara,* 436 U.S. at 58.

Similarly, waiver by the Tribe must also be unequivocally expressed. *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 Florida*.,181 F.3d 1237, 1243 (11th Cir. 1999); *Santa Clara*, 436 U.S. at 58. "There is a strong presumption against waiver of tribal sovereign immunity." *Demontiney v. U.S. ex rel. Dept. of Interior, Bureau of Indian Affairs,* 255 F.3d 801, 811 (9th Cir. 2001).

The burden of proof is on the Petitioner to establish that the Tribe's immunity has been abrogated or waived. *See Williams v. Poarch Band of Creek Indians*, 839 F.3d 1312, 1317 (11th Cir. 2016) (party asserting claim against tribe bears burden of proving waiver of immunity).

Thus, because Petitioners cannot show that Congress has "unequivocally" authorized this suit or that the Tribe has clearly and expressly waived its immunity, this action must be dismissed.

1. Congress has not unequivocally abrogated the Tribe's sovereign immunity.

Congress has not "unequivocally expressed" a waiver of tribal sovereign immunity for IPRs. "In 'determining whether a particular federal statute waives tribal sovereign immunity, courts should tread lightly in the absence of clear indications of legislative intent.'" *Osage Tribal Council ex rel. Osage Tribe of Indians v. U.S. Dep't of Labor*, 187 F.3d 1174, 1181 (10th Cir. 1999). "Congress abrogates tribal immunity only where the definitive language of the statute itself states an intent either to abolish Indian tribes' common law immunity or to subject tribes to suit under the act." *Florida Paraplegic, Ass'n, Inc. v. Miccosukee Tribe of Indians of Florida,* 166 F.3d 1126, 1131 (11th Cir. 1999).

Congress knows how to expressly abrogate Tribal sovereign immunity. *Osage Tribal Council*, 187 F.3d at 1181 (holding that Congress clearly and explicitly waived tribal immunity in Safe Drinking Water Act); *Blue Legs v. U.S. Bureau of Indian Affairs*, 867 F.2d 1094, 1097 (8th Cir. 1989) (holding text and history of Resource Conservation and Recovery Act "clearly indicates congressional intent to abrogate the Tribe's sovereign immunity").

Congress also knows how to specifically abrogate sovereign immunity in the context of the patent laws. For example, Congress explicitly waived the immunity of the United States for patent infringement claims in 28 U.S.C. § 1498(a). And Congress tried, but failed, to waive state sovereign immunity for patent infringement

claims in 35 U.S.C. § 296; s*ee Florida Prepaid Postsecondary Education Expense Bd. v. College Savings Bank*, 527 U.S. 627, 635-36 (1999) (holding that Congress lacked power to abrogate State's immunity in the Patent Remedy Act).

Congress did not expressly abrogate tribal sovereign immunity in the America Invents Act, or any other statute, for purposes of the *inter partes* review process. *See* EX. 2095: *Covidien LP v. Univ. of Fla. Research Found. Inc.*, Case IPR 2016-01274, Paper 21 (Jan. 25, 2017) ("*Covidien*") ("Petitioner does not point to, and we do not find there is, an unequivocal express intent by Congress in the AIA to abrogate immunity for the purposes of *inter partes* review."). In fact, tribes are not mentioned 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); *see also* 35 U.S.C. §§ 311-319.

Nor can the Tribe's participation in the patent system be interpreted as an abrogation or waiver. *See e.g.*, *Seminole Tribe of Florida*, 181 F.3d at 1242-1243 ("Tribe did not expressly and unequivocally waive its immunity from this suit by electing to engage in gaming under IGRA."); *see Xechem Int'l, Inc. v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 382 F.3d 1324, 1331 (Fed. Cir. 2004) ("[T]he argument

must be rejected that a state's entry into the patent system is a constructive waiver of immunity for actions in federal court against the state under the patent law."); *Bassett v. Mashantucket Pequot Tribe*, 204 F.3d 343, 357-358 (2d Cir. 2000) ("[T]he fact that a statute applies to Indian tribes does not mean that Congress abrogated tribal immunity in adopting it."); *Garcia v. Akwesasne Housing Authority*, 268 F.3d 76, 85-86 (2d Cir. 2001) (same).

Thus, Congress has not expressly and unequivocally abrogated the Tribe's immunity for purposes of *inter partes* review.

2. The Tribe has not unequivocally and expressly waived its immunity to these proceedings.

Just like congressional abrogation, waiver of sovereign immunity by the Tribe must be clear, express, and unequivocal. *Potawatomi I,* 498 U.S. at 509. No waiver can be implied based on the Tribe's actions. *Seminole Tribe of Florida*, 181 F.3d at 1243. Contractual "waiver may only be found if the clause unequivocally and expressly indicates the [Tribe's] consent to waive its sovereign immunity." *Pan Am. Co. v. Sycuan Band of Mission Indians,* 884 F.2d 416, 418 (9th Cir. 1989).

In fact, it is black letter law that waiver of the Tribe's sovereign immunity cannot be implied. In *Kiowa,* the Supreme Court was asked to limit the scope of tribal immunity in the commercial context but it declined to do so noting:

> The petitioner there asked us in [*Potawatomi I*] to abandon or at least narrow the doctrine because tribal

> businesses had become far removed from tribal self-governance and internal affairs. We retained the doctrine, however, on the theory that Congress had failed to abrogate it in order to promote economic development and tribal self-sufficiency.

523 U.S. at 757.

The Supreme Court recently reaffirmed this holding. When asked to scale back tribal immunity on policy grounds, the Court expressly held that only Congress can "determine whether or how to limit tribal immunity." *Bay Mills*, 134 S.Ct. at 2037. The Supreme Court noted that Congress had "considered several bills to substantially modify tribal immunity in the commercial context" but that ultimately Congress decided to keep tribal immunity intact. *Id.* at 2038-2039. Accordingly, the Supreme Court held that it "would scale the heights of presumption" for it to "replace Congress's considered judgment with our contrary opinion." *Id.* at 2039.

Because of this precedent, waiver of tribal sovereign immunity cannot be premised on policy concerns, fairness, or the unique circumstances of a case. No court has ever found a waiver of tribal sovereign immunity based on equitable or policy concerns and it would be unprecedented for the Board to do so. *Ute Distrib. Corp. v. Ute Indian Tribe*, 149 F.3d 1260, 1267 (10th Cir. 1998) ("the Supreme Court has refused to find a waiver of tribal immunity based on policy concerns, perceived inequities arising from the assertion of immunity, or the unique context of

a case").

There is no express waiver here. To the contrary, the Tribe stated in both the Assignment Agreement and License Agreement that it "has not and will not waive its … sovereign immunity in relation to any *inter partes* review." EX. 2086 at §12(i); EX. 2087 at §10.8.9. Nor did the Tribe "waive its sovereign immunity through the mere act of succeeding a corporation that is … not entitled to sovereign immunity." *See Amerind Risk Mgmt. Corp. v. Malaterre*, 633 F.3d 680, 686 n.7 (8th Cir. 2011).

Thus, the Tribe has not and will not waive its immunity to these proceedings.

B. The Tribe's Sovereign Immunity Applies to all Adjudicatory Proceedings, Including IPR.

Sovereign immunity applies to all adjudicatory proceedings, including IPRs. In *Fed. Mar. Comm'n v. S.C. State Ports Auth.,* 535 U.S. 743, 754–756 (2002) ("*FMC*"), the Supreme Court 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."

Applying *FMC*, the Board has correctly held in three well-reasoned opinions that IPRs are adjudicatory proceedings to which sovereign immunity applies. EX. 2095: *Covidien*; EX. 2096: *Neochord, Inc. v. Univ. of Md. et al*, Case IPR2016-00208, Paper 28 (May 23, 2017) ("*Neochord*"); EX. 2097: *Reactive Surfaces Ltd, LLP v. Toyota Motor Corp.*, Case IPR2016-01914, Paper 36 (July 13, 2017) ("*Reactive*").

The Federal Circuit has not considered the issue in the context of IPRs but it has repeatedly characterized IPRs as adjudicatory proceedings. *SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016) ("IPR proceedings are formal administrative adjudications."); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016) ("As the PTO concedes, however, that burden-shifting framework does not apply in 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."). And the Federal Circuit has also held that administrative interference proceedings at the USPTO "can indeed be characterized as a lawsuit." *see also Vas-Cath, Inc. v. Curators of Univ. of Missouri*, 473 F.3d 1376, 1382 (Fed. Cir. 2007).

The principal that sovereign immunity shields against adjudicatory proceedings has been extended to tribes. *See In the Matter of Jamal Kanj v. Viejas Band of Kumeyaay Indians,* 2007 WL 1266963, *1 (DOL Adm. Rev. Bd. Apr. 27, 2007) ("Sovereign immunity from suit may be invoked not only in Article III courts, but also before court-like 'federal administrative tribunals.'"); *See also Great Plains Lending, LLC v. Conn. Dep't of Banking*, No. HHBCV156028096S, 2015 WL 9310700, at *4 (Conn. Super. Ct. Nov. 23, 2015) ("Applying *Federal Maritime Commission*, the court first acknowledges that tribes are entitled to no less dignity than states with regard to their immunity from administrative action.").

Tribes have successfully raised sovereign immunity in many different administrative settings. *See*, *e.g.*, *In the Matter of Tammy Stroud v. Mohegan Tribal Gaming Authority*, 2014 WL 6850018, at *2-3 (DOL Admin Rev. Bd. Nov. 26, 2014) (dismissal of claim on immunity grounds); *Alhameed v. Grand Traverse Resort & Casino,* 10 OCAHO 1126 (DOJ Exec Office for Hearing Review Sept. 25, 2008) (tribe could assert immunity in administrative hearing); *In the Matter of Private Fuel Storage*, 56 N.R.C. 147, 159 (Oct. 1, 2002) ("All parties appear to share the common ground that, as a general rule, federal agencies and adjudicators lack power to oversee sovereign Indian tribal matters.").

Thus, tribal sovereign immunity applies to *inter partes* review proceedings.

C. This Case Cannot Proceed Without the Tribe.

This case cannot proceed without the Tribe because (1) the Tribe is an indispensable party under both the Board's identity-of-interests test first articulated in *Neochord* and the four factor test for Federal Rule of Civil Procedure 19 and (2) Allergan, as a field-of-use licensee, lacks authority under the statutory scheme to participate in these proceedings.

1. The Tribe is an indispensable party under the Board's identity-of-interests test.

This Board does not have the option of proceeding in the absence of the Tribe because Allergan and the Tribe do not have identical interests, and Allergan cannot represent the Tribe in its absence. EX. 2087; s*ee Neochord* at 19 (citing *A123 Sys.*

Inc. v. Hydro-Quebec, 626 F.3d 1213, 1217 (Fed. Cir. 2010)); *see Reactive* at 15 (citing *A123 Sys.*, 626 F.3d at 1221).

In *A123 Sys.*, the Federal Circuit noted the lack of identical ownership as a basis to find indispensibility, stating "a patent should not be placed at risk of invalidation by the licensee without the participation of the patentee." *A123 Sys.*, 626 F3d at 1221. This holding was followed by the Board in both *Neochord* and *Reactive* and underpins the Board's identity-of-interests test. *See Neochord* at 19; *Reactive* at 15.

In *Reactive*, the Board assessed the identity of interests of the parties to determine whether the case could go forward in the absence of a sovereign co-owner of the patents. The Board found that identity of interests is at its highest when "the parties at issue are patent owners, when all of the patent owners except the absent sovereign are present in the action, and when all of the present patent owners are represented by the same legal counsel." *Reactive* at 15. That is not the case here. Allergan is not a co-owner and the Tribe is represented by its own independent counsel. Paper 63 in IPR2016-01127.

Moreover, the Tribe transferred to Allergan less than "substantially all" rights to the Patents-at-Issue. *See Neochord* at 18-19; *A123 Sys.*, 626 F.3d at 1217. The Tribe granted Allergan a field-of-use license limited to "all FDA-approved uses in the United States." EX. 2087 at § 2.1. The Tribe retained all other fields of use, "including the right to use and practice the Licensed Patents for research, scholarly

use, teaching, education, patient care incidental to the forgoing, sponsored research for itself and in collaborations with Non-Commercial Organizations." *Id.* at § 2.4.

The Tribe also retained the first right to sue third parties outside of Allergan's field-of-use for infringement. *Id.* at § 5.2.3. The Tribe has the right to sue third parties in Allergan's field-of-use if Allergan declines to do so. § 5.2.2. And the Tribe keeps the proceeds from any such suit. *Id.* at § 5.2.5 Allergan must consider the Tribe's reasonable input when Allergan sues infringers in its field-of-use. *Id.* at § 5.2.2. The Tribe also must pre-approve all settlements relating to the Patents-at-Issue. *Id.* at § 5.2.4.

Additionally, Allergan must pay the Tribe quarterly royalties of $3,750,000 for its field-of-use license. *Id.* at § 4.2. Allergan may not assign its rights (except to a successor) without the Tribe's prior written consent. *Id.* at § 10.3. And the Tribe may control the prosecution and maintenance of the Patents-at-Issue if Allergan elects not to. *Id.* at § 5.1.3.

Therefore, the Tribe has retained far greater rights to the Patents-in-Suit than the University of Maryland retained in *Neochord*, where the Board held that the University was an indispensable party. *Neochord* at 19.

While the different interests of Allergan and the Tribe should be a sufficient basis to find that this proceeding cannot proceed in the Tribe's absence, courts also "generally afford sovereigns 'heightened protection' if a lawsuit poses 'a potential

of injury to the sovereign's interest.'" *Klamath Tribe Claims Comm. v. United States*, 106 Fed. Cl. 87, 95 (2012), *aff'd sub nom.* 541 F. App'x 974 (Fed. Cir. 2013).

The Tribe, as a sovereign nation, has a duty to its government and its members. It has a duty to protect its sovereignty, economic interests, and the integrity of the Tribe as a Nation. The royalties the Tribe will receive from Allergan are an important part of the Tribe's economic diversification strategy. Specifically, these royalties 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.

The Board cannot strip the Tribe of this critical revenue stream in the Tribe's absence. *See Jamul Action Committee 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.").

Most importantly, the Tribe has an interest in protecting its immunity. "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. *Enter. Mgmt. Consultants Inc v. United States*, 883 F.2d 890, 894 (10th Cir. 1989) (the U.S. could not sufficiently protect a tribe's interest in its immunity); EX. 2087 at § 5.1.2 ("Licensor shall have sole and exclusive control over the means and

manner in which its sovereign immunity is asserted or waived.").

By contrast, Allergan owes a fiduciary duty to its shareholders, not the Tribe. 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*, No. 3:17-cv-00038-AA, 2017 WL 923915, at *5 (D. Or. Mar. 8, 2017).

2. The Tribe is an indispensable party under F.R.C.P. 19.

As this Board explained in *Reactive*, the Federal Rules of Civil Procedure do not apply. However, the four factors set forth in Rule 19(b) have served as a touchstone for analyzing whether a proceeding may move forward without a non-consenting sovereign party. The four factors are: (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 can be lessened or avoided by protective provisions in the judgment, the shaping of relief, or other measures; (3) whether a judgment rendered in the person's absence will be adequate; and (4) whether the plaintiff will have an adequate remedy if the action is dismissed for non-joinder. *A123 Sys.,* 626 F.3d at 1220. Three of these factors weigh heavily in favor of prohibiting this case from proceeding in the Tribe's absence, and the fourth is, at worst, neutral.

a. Significant weight must be given to the Tribe's sovereignty.

Preliminarily, the Board must afford significant weight to the Tribe's

"compelling claim of sovereign immunity." *See Republic of Philippines v. Pimentel*, 553 U.S. 851, 869 (2008) (holding that the lower courts erred in their analysis of Rule 19(b)'s first factor by "not accord[ing] proper weight to the compelling claim of sovereign immunity"). In *Pimentel*, the Supreme Court 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." *Id.*at 867; *see also Mesa Grande Band of Mission Indians v. United States*, 121 Fed. Cl. 183, 191 (2015). This rule holds even if there is no alternative forum. *Pimentel*, 553 U.S. at 872.

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 quotes omitted). There is a "strong policy that has favored dismissal when a court cannot join a tribe because of sovereign immunity." *Klamath Tribe Claims Comm.,* 106 Fed. Cl. at 95. That "[t]he dismissal of this suit is mandated by the policy of tribal immunity. … turns on the fact that society has consciously opted to shield Indian tribes from suit without congressional or tribal consent." *Enter. Mgmt. Consultants, Inc.*, 883 F.2d at 894; s*ee also Am. Greyhound Racing, Inc. v. Hull,* 305 F.3d 1015, 1024-25 (9th Cir. 2002).

The Tribe's sovereignty must be given significant, if not dispositive, weight.

b. The Tribe will be prejudiced if the case proceeds in its absence.

Under the first factor, the Tribe would be significantly prejudiced if the Board were to allow the case to continue. In *University of Utah v. Max-Planck-Gesellschaft Zur Forderun-der Wissenschaften*, 734 F.3d 1315,1327 (Fed. Cir. 2013), the Federal Circuit held a sovereign party was not indispensable largely based on its conclusion that the remaining party could represent the sovereign's interest thereby mitigating prejudice.

As explained above, while Allergan and the Tribe share "the same overarching goal of defending the patents' validity," their interests are not identical. *A123 Sys.*, 626 F.3d at 1221. Allergan is a field-of-use licensee. EX. 2087 at § 2.1 (license limited to "FDA-approved" field of use). Claim constructions that might serve its interests in obtaining infringement judgments against Petitioners may conflict with the Tribe's interests in subject matter not licensed to Allergan and may also conflict with the Tribe's desire to not risk the validity of the Patents-at-Issue. *See A123 Sys.*, 626 F.3d at 1221.

And the Tribe has a significant property interest (the patents and royalty stream) at stake which cannot be adjudicated in its absence. *See Jamul Action Committee*, 200 F. Supp. 3d at 1050; *Quileute Indian Tribe v. Babbitt*, 18 F.3d 1456, 1460 (9th Cir. 1994) (potential for tribe to lose property interest renders tribe indispensable).

Further, it has been held that if a contract or lease is to be voided, all parties are deemed indispensable to avoid prejudice. *U.S. ex rel. Hall v. Tribal Development Corp*., 100 F.3d 476, 479 (7th Cir. 1996). "No procedural principle is more deeply imbedded in the common law than that, in an action to set aside a lease or a contract, all parties who may be affected by the determination of the action are indispensable." *Lomayaktewa v. Hathaway*, 520 F.2d 1324, 1325 (9th Cir.1975). A finding that the Patents-at-Issue are invalid will, in effect, terminate the Tribe's License Agreement with Allergan because its term ends if the claims of the Patents-at-Issue are "rendered invalid in a non-appealable final judgment." EX. 2087 at § 9.1.1.

So the Tribe has a direct interest in the validity of its patents and it will be directly impacted if this Board proceeds to the merits of this action. The Tribe has a direct interest in the royalties related to these patents and cancellation would significantly impact the Tribe's business interest and more broadly, its efforts at economic development to benefit its community. *Lomayaktewa,* 520 F.2d at 1326-27 (Tribe's interest in royalties under lease and potential for cancellation that would impact tribal community was sufficient to support finding of prejudice and indispensability).

c. Injury to the Tribe cannot be mitigated.

The conclusion that the Tribe is indispensable is strongly supported by the second factor because these prejudices to the Tribe cannot be mitigated by protective

provisions in the judgment. The Board's judgment is binary: the claims are patentable or not patentable. There is nothing to mitigate.

d. The Petitioners have an adequate remedy in District Court.

Finally, the fourth factor also weighs heavily against proceeding without the Tribe because the Petitioners have an adequate remedy if this action is dismissed for non-joinder. The Petitioners can and have challenged the validity of the Patents-at-Issue in a recently completed five-day bench trial in the Eastern District of Texas. Petitioners challenged the validity of the Patents-at-Issue based on improper inventorship, anticipation, obviousness, obviousness-type double patenting, and lack of enablement. EX. 2097. Those grounds are more extensive than the grounds available in these proceedings, which is limited to invalidity "under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b). Petitioners have had and will continue to have their day in district court. The Tribe will not assert sovereign immunity in the Eastern District of Texas case. EX. 2087 at §5.2.2. So dismissing this case does not deprive Petitioners of an adequate remedy; it only deprives them of multiple bites at the same apple.

3. Allergan lacks authority under the statutory scheme to continue to participate in these proceedings.

Allergan lacks authority under the statutory scheme to continue to participate in these IPRs. In an IPR proceeding, the authorizing statutes and regulations identify

only two classes of allowable participants: patent owners and petitioners. *See* 35 U.S.C. §§ 311-319 (petitioners and patent owners only parties authorized to take any actions); *and* 37 C.F.R. §§ 42.100-41.123 (same). Allergan is no longer a member of either class, so it is not authorized to continue to participate in these proceedings under the applicable statutes and regulations. Unlike constitutional standing in the federal courts, administrative standing is determined solely by the language of the statutes and regulations authorizing the administrative hearing, and not by Article III. *See Coach Servs., Inc. v. Triumph Learning LLC*, 668 F.3d 1356, 1376 (Fed. Cir. 2012) ("[F]or an agency such as the PTO, standing is conferred by statute."); *Ritchie v. Simpson*, 170 F.3d 1092, 1095 (Fed. Cir. 1999) ("[T]he starting point for a standing determination for a litigant before an administrative agency is not Article III, but is the statute that confers standing before that agency."); *Koniag, Inc., Vill. of Uyak v. Andrus*, 580 F.2d 601, 614 (D.C. Cir. 1978) (same).

V. CONCLUSION

These consolidated proceedings must be dismissed because the Patent Owner, Saint Regis Mohawk Tribe, is an indispensible, non-consenting sovereign. The Tribe has retained substantial rights in the Patents-at-Issue, its interests cannot be adequately represented by its field-of-use licensee, Allergan, and Allergan lacks authority to continue to participate in these IPRs. Therefore, the Board must dismiss these proceedings.

Dated: September 22, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4) and 42.205(b), the undersigned certifies that on September 22, 2017, a complete and entire copy of *Saint Regis Mohawk Tribe's Motion to Dismiss for Lack of Jurisdiction Based on Tribal Sovereign Immunity and Exhibits 2091-2103* were provided, via electronic service, to the Petitioner by serving the correspondence address of record as follows:

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