Paper No. ___
Filed: October 13, 2017

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

PETITIONERS' OPPOSITION TO ST. REGIS MOHAWK TRIBE'S MOTION TO DISMISS

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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).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

RULES

PTAB

I. INTRODUCTION

A week before the scheduled hearing, Allergan announced it had made a deal with the St. Regis Mohawk Tribe ("the Tribe") to invoke tribal immunity as a shield against an adverse Board decision. Allergan and the Tribe justify the deal by claiming that *inter partes* review ("IPR") is "unfair" and a "kangaroo court."[2] But impugning the Board's integrity and Congress's considered decision to create IPRs cannot justify Allergan's purchase of the Tribe's immunity to circumvent the law and "reap a windfall at the public's expense." *Barona Band of Mission Indians v. Yee*, 528 F.3d 1184, 1187, 1190 (9th Cir. 2008). Their goal is to block public access to an alternative to Allergan's Restasis® product and perpetuate Allergan's monopoly profits, which they have already enjoyed for almost 15 years. EX1149 (Healthcare Organizations' Letter to Congress); EX1150 (Henry Waxman: Allergan's deal undermines Hatch-Waxman); EX1152; 35 U.S.C. §316(b).

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[2] EX1144; EX1145 at 1; *see also* EX1146 ("thorn in [Allergan's) side"); EX1147; EX1148. Allergan had no qualms embracing AIA review when it wanted to do so. After being accused of patent infringement in district court, Allergan filed an IPR and obtained a decision cancelling the claims. *See Allergan, Inc. v. 1474791 Ontario, Ltd.*, IPR2016-00102, Paper 61.

By purchasing immunity in an effort to protect its Restasis® patents from review, Allergan attempts to manipulate Board jurisdiction and subvert the very purpose of AIA reforms: to subject weak patents to scrutiny. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2139-40 (2016); EX1151. There is little doubt that Allergan's deal with the Tribe is a sham—the Tribe's interest ***as the purported patent owner*** amounts to a ***mere four days*** of Allergan's annual Restasis® sales. *See* EX1152 at 3, 8-10; EX1153 at 1-2. Legally and factually, the Tribe is not the effective owner.

The Tribe's theory for dismissal hinges on the false assumptions that the Tribe owns the patents and that the IPRs cannot proceed without them. Unsurprisingly, Allergan did not actually transfer to the Tribe any substantial rights to the patents protecting the Restasis® empire. The agreements show that Allergan retained all substantial rights, and it remains the owner under well-established patent law principles. Moreover, even if the Tribe could be considered an owner, its minimal interests (if any) are adequately represented by Allergan, the far more interested party, and an adequate remedy will issue with or without the Tribe's participation. The answer to the test used by the courts—"whether, in ***equity and good conscience***, the action should proceed among the existing parties" —is manifest: the Board's power over the patents was not destroyed by Allergan's eleventh-hour deal. Even if a valid assignment had taken place,

termination is not required because the Board has statutory and agency authority to proceed without further owner participation.

The Tribe's motion suffers numerous additional flaws and its assertion of tribal immunity is wrong. Further, Allergan and the Tribe overlook fundamental distinctions in this case from prior Board decisions on Eleventh Amendment immunity on which the Tribe relies. And, not to be overlooked, Allergan's abuse of the patent system runs contrary to established tribal immunity principles, and the assignment is facially void as a contrivance to thwart congressionally mandated review. The Tribe's motion should be denied.

II. ALLERGAN REMAINS THE PATENT OWNER

The Tribe's motion to dismiss these IPRs relies on Allergan's purported "assignment." But Allergan remains the owner, both practically and legally.

A. The Tribe Never Held All Substantial Rights

Even taking Allergan's agreements at face value, Allergan never transferred all substantial rights to the Tribe and it remains the effective owner today. An agreement's substance governs ownership, not the labels parties choose. *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 875 (Fed. Cir. 1991) ("[U]se of the term 'exclusive license'… [wa]s not dispositive" where agreements granted all substantial rights). To determine if a transaction is "tantamount to an assignment," this Board must evaluate both "the intention of the

parties" and "the substance of what was granted." *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1358-59 (Fed. Cir. 2010).

Courts have developed a non-exhaustive list of rights to evaluate if a transaction conveys "all substantial rights" and constitutes a true assignment, including the right to sue, exclusive use, sublicensing rights, allocation of licensing and litigation proceeds, licensing supervision, maintenance-fee payment, and alienability. *Id.* at 1360-61. When a transfer involves multiple documents executed simultaneously, courts read them together. *See, e.g.*, *FlowRider Surf, Ltd. v. Pac. Surf Designs, Inc.*, 2017 WL 2349031, at *1-4 (S.D. Cal. May 26, 2017); *Commander Oil Corp. v. Advance Food Serv. Equip.*, 991 F.2d 49, 53 (2d Cir. 1993). The Assignment and Exclusive License (EX2085–2087) ("Transaction Documents") make clear Allergan remains the sole effective owner.

1. *Control of Litigation* One critical factor is who brings and controls litigation. *Mann*, 604 F.3d at 1361; *Vaupel*, 944 F.2d at 875. Allergan retains the "first right" to sue competitors and to "

." *Compare Mann*, 604 F.3d at 1361 and *FlowRider*, 2017 WL 2349031 at *6 ("first right, but not the obligation"), *with* EX2087 §5.2.2.

"This grant is particularly dispositive here because the ultimate question confronting [the Board] is whether [Allergan] can [act in the IPR] on its own or whether [the Tribe] must be joined as a party." *Vaupel*, 944 F.2d at 875.

In contrast to Allergan's expansive rights, the Tribe has only minor, contingent rights: it can take over commercially relevant litigation with Allergan's consent and provide "reasonable input"

Allergan's right to

renders these rights "nugatory." *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1251 (Fed. Cir. 2000); *see also Vaupel*, 944 F.2d at 875. Simply put, Allergan retained control over and commercially relevant infringement proceedings, and granted the Tribe only contingent, illusory rights to enforce the patents. This is compelling evidence that Allergan never transferred all substantial rights to the Tribe.

2. Exclusive Right to Make, Use, and Sell Restasis®. Allergan also retains the " rights to

"for all FDA-approved uses in the United States." EX2087 §§2.1, 3.1, 1.19, 1.33. Allergan also has

Allergan thus retains the "vitally important" right to exploit *all* claims of *all* patents for *all* FDA-approved purposes. *Mann*, 604 F.3d at 1360.

Allergan is not a mere field-of-use licensee. The Tribe's nominal rights—for research, scholarly use, teaching, education, and "incidental" patient care (EX2087 §2.4)—are window-dressing. The claims are limited to human use so any rights held by the Tribe for non-FDA approved uses are illusory. As recently as August 22, 2017, Allergan told the district court that all "the claimed uses are 'on-label.'" EX1154 at 0006 ("Using Restasis® to treat KCS and dry eye or to restore tearing are simply not off-label uses"). The Tribe's use rights are insubstantial because

Notably, the Tribe provides no evidence that it uses the patents at all. *See Azure Networks, LLC v. CSR plc*, 771 F.3d 1336, 1344 (Fed. Cir. 2014) (according little weight to nominal owner's right to make products because no evidence suggested it had such products), *vacated sub nom. CSR plc. v. Azure Networks LLC*, 135 S. Ct. 1845 (2015) (vacating claim construction); EX1145 at 1-2 (the Tribe informing members that it is investing no money to exploit the patents and that its only role will be to "hold the patents"). Again, the record shows Allergan retains all

substantial rights.

3. Right to Sublicense and Settle. Allergan retains "

Allergan's rights to settle litigation demonstrate that it remains the effective owner. *See Azure*, 771 F.3d at 1347 (exclusive license with substantial rights to sublicense and control litigation made licensee effective owner even where nominal assignee received a third of enforcement proceeds); *Speedplay*, 211 F.3d at 1251 (licensee's sublicensing right rendered licensor's nominal rights to sue and approve assignments insubstantial).

4. Duration of Rights. Allergan's

5. Proceeds from Commercial Litigation.

which is not a share in the recovery and does not amount to a substantial right. *See Flowrider*, 2017 WL 2349031, at *8. The Tribe's only real interest is monetary,

The Tribe's interest at most amounts to 1% of sales. EX1153 (reporting $15 million annual payment on $1.5 billion in annual sales). But "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 Vaupel*, 944 F.2d at 875.

6. Retention of Extensive Other Rights. Control over prosecution and payment of maintenance fees can "demonstrat[e] … the effective owner of the patent," *FlowRider*, 2017 WL 2349031, at *8, but these belong to Allergan.

Allergan can transfer or assign its rights to successor without the Tribe's consent. *Id.* §§2.1, 10.3, 7.2.8. These rights further confirm that Allergan is the real owner.

7. The Tribe's Obligation and Restrictions. The Tribe incurred many obligations and restrictions that confirm Allergan's status as owner.

—an extraordinary restriction on the supposed "assignee" and "owner."

Allergan may assign its interests to or successor. *Id.*

confirms that Allergan remains the owner. *See Calgon Corp. v. Nalco Chem. Co.*, 726 F. Supp. 983, 986 (D. Del. 1989) ("[T]he right to further assign patent rights is implicit in any true assignment."); *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) ("limits on … assignment rights weigh in favor of finding ... a transfer of fewer than all substantial rights in a patent").

Altogether, any rights of the Tribe are at most a "minor derogation" and "d[o] not substantially interfere with the full use by [Allergan] of the exclusive rights under the patent…." *Vaupel*, 944 F.2d at 875. In reality, Allergan maintains

full control over these patents and retains more than 99% of the patent revenue.

B. The Sham Agreement Is No Barrier to *Inter Partes* Review

Allergan's deal with the Tribe is the latest in a long series of schemes to buy tribal immunity for dubious activities. *See Gingras v. Rosette*, Case No. 5:15-cv-101, 2016 WL 2932163, at *34 (D. Vt. May 18, 2016) (explaining "rent-a-tribe" schemes). Courts and agencies have the power and duty to prevent abuses of tribal immunity. *See Barona*, 528 F.3d at 1190 (refusing to extend an immunity "rooted in due respect for Indian autonomy, to provide tax shelters for non-Indian businesses"); *Cass Cnty. Joint Water Res. Dist. v. 1.43 Acres of Land*, 643 N.W.2d 685, 694-95 (N.D. 2002) (tribal immunity did not bar in-rem condemnation of off-reservation land transferred to block development).

Allergan's sham assignment does not alter the legal and economic reality that Allergan controls and principally benefits from the patents. The Tribe's attorney candidly admits exploiting immunity as an "arbitrage opportunity" given that "there's a huge value difference between patents which can be subject to IPRs and patents that are not." EX1148 at 1, EX1146, EX1145 at 2.

But creating an "arbitrage opportunity" for others is not the purpose of the tribal sovereign-immunity doctrine. Courts readily reject third-party abuse of tribal immunity to evade laws—and have specifically done so with the Tribe. *E.g., Dep't of Tax. & Fin. of N.Y. v. Milhelm Attea & Bros.*, 512 U.S. 61, 75-76 (1994)

(upholding State law to end Tribe-facilitated tax evasion); *Wash. v. Confed. Tribes of Colville Indian Reservation*, 447 U.S. 134, 136 (1980) (disallowing tribe-marketed "exemption from state taxation"); *Otoe-Missouria Tribe v. NY DFS*, 769 F.3d 105, 114, 116 (2d Cir. 2014) (a tribe "has no legitimate interest in selling an opportunity to evade [the] law" to a non-Indian). Allergan cannot buy a "legal loophole in the cloak of tribal sovereignty[.]" *Otoe-Missouria Tribe*, 769 F.3d at 114. Nor may it use tribal immunity to alter "the economic reality of a transaction … to reap a windfall at the public's expense." *Barona Band*, 528 F.3d at 1190.

Moreover, sham assignments made to destroy jurisdiction are ineffective when "the assignee was a strawman and had no real interest in the outcome of the case, although a good outcome would have had some economic value." *Attorneys Trust v. Videotape Computer Prods., Inc.*, 93 F.3d 593, 598 (9th Cir. 1996) (jurisdiction not affected); *cf. Kramer v. Caribbean Mills, Inc.*, 394 U.S. 823, 827-28 (1969) (jurisdiction not created through an assignment that was "a mere contrivance, a pretense, the result of a collusive agreement"). Courts police "manipulations of their jurisdiction with partial assignments which lack reality and amount to no change in the identity of the party with the real interest in the outcome of the case." *Attorneys Trust*, 93 F.3d at 597.

"[C]lassic elements of an assignment which does not affect jurisdiction"

include an assignee that "had no prior interest" in the matter prior to the assignment, an assignment timed to affect jurisdiction, "the assignee gave no consideration" apart from its role in the litigation, and the assignor retained significant control and most of the profits. *Id*. at 599; *see also Airlines Reporting Corp. v. S & N Travel, Inc.*, 58 F.3d 857, 863 (2d Cir. 1995) (facial collusion to affect jurisdiction shifts burden to show "a legitimate business purpose for the assignment"). These "classic elements" of a sham assignment are all present here. The question of "immunity" need not be reached because the assignment has all the "classic elements" of a sham that does not alter the Board's jurisdiction.

Indeed, the Tribe admittedly provided no consideration in return for the sham patent assignment apart from an unlawful promise to assert sovereign immunity in these or other IPRs. EX1151 at 2-3. Far from "good and valuable consideration" (EX2085), the promise amounts to "selling an opportunity to evade [the] law" and cannot be upheld. *Otoe-Missouria Tribe*, 769 F.3d at 114.

Allergan's purported assignment is also void because it undermines the AIA. "[F]ederal policy embodied in the law of intellectual property can trump even explicit contractual provisions." *Idaho Potato Comm'n v. M & M Produce Farm & Sales*, 335 F.3d 130, 137 (2d Cir. 2003). Allergan overtly seeks tribal immunity for private gain at public expense, which is no justification for extending tribal immunity to thwart a congressional mandate. *See Cuozzo Speed Techs., LLC v.*

Lee, 136 S. Ct. 2131, 2139-40 (2016) (recognizing the Board's "power to revisit and revise earlier patent grants" as an "important congressional objective" in the AIA). This sham assignment threatens to subvert a cornerstone of patent reform. Allergan's gambit threatens not just these IPRs, but the integrity of the patent system, encouraging others to follow the same "business plan." EX1147 at 3 (200 calls from interested parties); EX1155 (Allergan explaining "it creates a playbook for other cases down the road both for us and for others"); *Rates Tech. Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 172 (2d Cir. 2012) (voiding contract clause that would "significantly undermine the public interest in discovering invalid patents") (internal quotation omitted). Sovereign immunity does not require respect for an agreement designed to protect patents from review. The Tribe has not shown that a party "who has not chosen to deal with a tribe" is barred from seeking "relief for off-reservation commercial conduct." *Mich.* v. *Bay Mills Indian Cmty*, 134 S. Ct. 2024, 2036 n.8 (2014).

III. EVEN IF THE TRIBE WERE THE SOLE OR JOINT PATENT OWNER IT IS NOT AN INDISPENSABLE PARTY

The Tribe asserts (at 16-25) that the Board may not proceed without its participation and that Allergan is a mere "field-of-use licensee" that "lacks authority under the statutory scheme to participate." The Tribe is wrong—any rights retained by the Tribe are insufficient to make it indispensable, and this proceeding may continue without it.

A. Allergan Adequately Represents All Interests in the Patents

As discussed above, the Tribe holds no substantial rights in the patents. Even if the Tribe did hold any relevant interest through its sham agreements with Allergan, no rule categorically requires dismissal of an IPR in the absence of an interested sovereign, and Allergan can adequately represent any such interests as an existing party to the proceedings. In *Reactive Surface Ltd., LLP v. Toyota Motor Corp.*, Toyota and the University of Minnesota ("Minnesota") co-owned and had identical interests in the patent. Like the Tribe, Minnesota argued that "'the interests of the absent sovereign'… cannot be protected adequately by any remaining private-party defendants." IPR2017-00572, Paper 32 at 12-13. But the Board ***rejected*** "a rule under which the successful assertion of [state] sovereign immunity by one party requires a dismissal of the action against the remaining parties," finding that Toyota could adequately represent Minnesota's interests ***even though*** Toyota was not a sovereign entity. *Id.* at 14. The Board explained that the "rules contemplate proceeding with less than all the owners of challenged patent." *Id.* at 17. For example, the Board may "institute trial and proceed to a final written decision even in the absence of any preliminary response or response by the patent owner," and an "owner of a part interest" in a patent may "act to the exclusion" of another owner that cannot or will not participate or if it is "in the interests of justice to permit the owner of a part interest to act in the trial." *Id.* at 11-12 (citing

37 C.F.R. §§42.108(c), 42.74(a), 42.9(b)).

The Board should reach the same result here because Allergan holds substantial rights in the patents and the Tribe's rights are contingent and illusory. *See* Section II.A, *supra*. Even if some right allocated to the Tribe were a "substantial right," Allergan already has represented and can adequately represent all such interests. *See Reactive Surfaces*, IPR2017-00572, Paper 32 at 14-16.

The Tribe's contrary reliance on the statement in *NeoChord, Inc. v. Univ. of Md. Balt.*, IPR2016-00208, Paper 28 at 19, that any non-consenting sovereign patent owner that "has retained rights" is "a necessary and indispensable party" is misplaced. In *Reactive Surfaces,* the Board continued an IPR despite the absence of a sovereign state entity with substantial rights in the patent at issue. The same course is appropriate here.

The Tribe's reliance on *Neochord* should also be rejected because of Allergan's and the Tribe's blatant manipulation of jurisdiction. In *Neochord*, the Board considered the "interests of justice" and found "no indication" that the university had delayed asserting state sovereign immunity "for any tactical reasons." IPR2016-00208, Paper 28, at 15-16; 37 C.F.R. 42.9(b) ("interests of justice"). Here, by contrast, Allergan was the undisputed owner at each statutory opportunity for owner action, is and never was a sovereign, and entered into a transaction designed specifically to strip the Board of jurisdiction after the close of

evidence. 35 U.S.C. §§312(a)(5)), 313, 314(c), 315(b)), 316(a)(8)), 316(a)(9), 316(d)), 316(a)(10); Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48768 (2012) (no new arguments or evidence at oral hearing). Allergan's tactical delay allowed it to participate in the proceedings and then evaluate whether it liked the direction the IPRs were headed before deciding to pursue immunity.

None of the cases on which the Tribe relies held that an owner may manipulate Board jurisdiction through a post-institution assignment. In each case an original assignee asserted state sovereign immunity. *Covidien LP v. Univ. of Fla. Research Found.*, IPR2016-01274, Paper 21 at 3; *Neochord*, IPR2016-00208, Paper 28 at 2; *Reactive Surfaces*, IPR2017-00572, Paper 32 at 2-3. By contrast, the Tribe is not the original assignee. In fact, Allergan waited months after *Covidien* to engage with the Tribe, after all evidence and argument had been submitted. *NeoChord*'s equitable analyses favor proceeding with this IPR.

In short, this IPR should continue without the Tribe regardless of any interest the Tribe claims to have in the patents. The Tribe's interests are insubstantial and illusory, and in any event, Allergan may remain a party to this proceeding and can adequately represent those interests going forward.

B. Even Under Federal Rule of Civil Procedure 19, the Tribe Is Not Required or "Indispensable"

No rule or precedent governing IPR proceedings mandates dismissal if the Tribe does not become a party. The Board has noted that IPR proceedings have no

direct analogue to Fed. R. Civ. P. 19, and its "more restrictive [indispensability]" standards do not specifically apply in IPR proceedings. *Reactive Surfaces*, IPR2017-00572, Paper 32 at 15-17 & n.2. The Board has considered F.R.C.P. 19 precedent by analogy but, even under that Rule, these proceedings may continue without the Tribe.

Rule 19(a) deems a party "required" only if complete relief cannot be accorded without the party, if the party's absence would impair its ability to protect an interest it claims in the subject matter of the action, or if the party's absence would leave an existing party subject to a substantial risk of multiple or inconsistent obligations. Only when such a required party cannot be joined must a court consider Rule 19(b)—whether, "in equity and good conscience," the case should proceed absent the required party. By its nature, the analysis is "a pragmatic and equitable determination[.]" *City of Lincoln City v. U.S. Dep't of Interior*, 229 F. Supp. 2d 1109, 1114 (D. Or. 2002).

The Tribe is neither required nor indispensable. Regardless of whether it joins as a party, the Board can afford complete relief among the existing parties and there is no risk of inconsistent obligations because patentability is the sole issue under review and the Board can cancel claims without the Tribe. As Allergan was the sole owner when all evidence and argument were submitted, the Tribe's absence at this late stage does not "as a practical matter impair or impede" the

Tribe's ability to protect its asserted interests in the patents.

Nor is the Tribe indispensable. Rule 19(b) serves two purposes in an infringement context. First, it protects the alleged infringer from multiple lawsuits. *Aspex Eyewear Inc. v. Miracle Optics Inc.*, 434 F.3d 1336, 1343 (Fed. Cir. 2006). Infringement is not at issue in IPRs. Second, it "prevent[s] a party with lesser rights from bringing a lawsuit that may put the licensed patent at risk of being held invalid or unenforceable in an action that did not involve the patentee." *Id.* Here, Allergan has already adequately represented the owner's interests and may continue to do so. Indeed, as explained above, Allergan designed the Transaction Documents to retain full control.

Allergan can fully represent any ownership interests the Tribe may have. The Tribe's main interest—fixed, quarterly royalties—is more than adequately represented by Allergan, which stands to realize 100-fold more revenue ($375 million versus $3.75 million) every quarter. EX1153 at 1; *Commonwealth v. Think Finance, Inc.*, No. 14-cv-7139, 2016 WL 183289, at *5-8 (E.D. Pa. Jan. 14, 2016) (rejecting claim of tribal indispensability in suit concerning "rent-a-tribe" scheme in which tribe acted as "nominal lender" for payday lending operation managed and controlled by non-Indians). The Tribe urges (at 22-23) it would be unduly prejudiced if the IPRs proceed without it because Allergan is allegedly a mere "field-of-use licensee" and cannot adequately represent its interests in the patents.

As shown above, that is simply false: Allergan is far more than a mere field-of-use licensee.

The Tribe asserts (at 22) that claim construction positions "might" serve Allergan's interests differently than the Tribe's or that the Tribe might "desire to not risk the validity of the Patents-at-Issue." But Allergan placed the claims at risk in the Texas litigation and completed all claim construction briefing before it made this transaction. Moreover, Allergan, not the Tribe, retains control over the Texas litigation, and patent prosecution. EX2087 §§5.1.1, 5.2.2, 5.3. The Tribe knowingly assumed any risk that Allergan might urge claim constructions that "conflict with the Tribe's interests in subject matter not licensed to Allergan."

The Tribe contends (at 23-24) that its potential injury cannot be mitigated because "[t]he Board's judgment is binary: the claims are patentable or not patentable." In any event, expected pecuniary loss to the Tribe, which has made no investment in creating or commercializing the patents, does not justify termination. *Otoe-Missouria Tribe*, 769 F.3d at 116 n.8 (courts "weigh[] a tribe's sunk costs in a venture, not their potential future earnings," in determining the substantiality of the tribal interests); *see also Lewis v. Clark*, 127 S. Ct. 1285 (2017) (tribal immunity no bar against tort suit against tribal employee even though judgment would be satisfied from tribal treasury); *Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V.*, 734 F.3d 1315, 1324-25 (Fed. Cir. 2013)

(absent sovereign not indispensable to correction of inventorship suit under Rule 19 even though loss of inventorship would impact sovereign's treasury); *Luminara*, 814 F.3d at 1351 (financial interest not a substantial right); *SourceOne Global Partners, LLC v. KGK Synergize, Inc.*, No. 08-C-7403, 2009 WL 1346250, at *4 (N.D. Ill. May 13, 2009) (denying absent sovereign's motion to dismiss under Rule 19).

The Tribe argues (at 20) that adequacy of remedy is one of the factors in a Rule 19 analysis, but the Tribe fails to address it substantively. This factor strongly favors continuation of the proceedings as the Board can afford complete relief without requiring any action by the Tribe. *Univ. of Utah*, 734 F.3d at 1324-25.

The Tribe contends (at 24) that Petitioners have an adequate remedy in the Texas litigation if these proceedings are dismissed. But the Tribe ignores the fact that only a small subset of claims from these proceedings are still at issue in the Texas litigation. It also ignores the fact that IPRs evaluate ***patentability*** under a preponderance of the evidence standard, whereas district courts evaluate ***validity*** under a clear-and-convincing evidence standard. And unlike in district court, Administrative Patent Judges with technical expertise and extensive experience in patent law make the decision rather than lay judges and juries. 35 U.S.C. §6(a). The Tribe and Allergan may view district court litigation to be an adequate substitute for IPRs, but Congress plainly concluded otherwise in adopting the AIA.

Finally, ***every*** case the Tribe cites (at 19-23) finding a tribe to be indispensable involved disputes that were closely tied to the tribe itself, its reservation and reservation resources, or tribal members. As discussed above, that is not the case here.

C. *Pimentel* and Its Progeny Do Not Require Dismissal

The Tribe insists (at 13) that the Board may not consider "equitable or policy concerns, fairness, or the unique circumstances of a case." But the Supreme Court has recognized that the decision whether to proceed in an action absent a sovereign party under Rule 19 must be "based on equitable considerations," requires evaluation of a "non-exclusive" list of "case-specific" factors, and ultimately turns on "[t]he balance of equities." *Philippines v. Pimentel,* 553 U.S. 851, 862–63, 873 (2008). As discussed above, the balance of equities strongly favors continuation.

The Tribe relies heavily on *Pimentel* in arguing it is an "indispensable party" and that this Board lacks ***any*** jurisdiction absent the Tribe's acquiescence. But *Pimentel* involved a claim of ***foreign*** sovereign immunity in federal interpleader litigation dealing with disputed claims to money that allegedly had been stolen from the Philippines and in which the litigation arose from "events of historical and political significance for the Republic and its people." *Id.* at 865-67. This case could not be more different.

To begin with, the Tribe is a "domestic ***dependent*** nation" that is fully

subject to substantive federal law, including the U.S. patent system; "comity concern[s] between co-equal sovereigns" are not present here. *See, e.g., 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 (D. Colo. Jan. 4, 2013) (rejecting tribal immunity arguments because "virtually all public and private activity on Indian lands would be immune from any oversight under the government's environmental laws"). Furthermore, these patents have no historical connection to the Tribe, which was a stranger to these proceedings until September 8, 2017, when it accepted these patents and lots of cash in exchange ***for nothing*** other than a promise to assert sovereign immunity here.

IV. IPRS ARE NOT SUBJECT TO TRIBAL IMMUNITY

The sole purpose of an IPR is to review patent compliance with patent laws, not to compel a party to act. 35 U.S.C. §§ 311(b); 318(b). A petition starts the process, but the Board alone determines whether to institute review, and can enter judgment without any party participation. § 317(a). Board action on patent claims does not compel any action from an owner or interfere with any core sovereign interest of the Tribe. *Cf. Colville*, 447 U.S. at 162 (seizing untaxed cigarettes en route to tribe was not an unnecessary intrusion "on core tribal interests"). The Board has jurisdiction to decide the fate of these patents regardless of its power over the Tribe. *Cf. Cnty. of Yakima v. Yakima Indian Nation*, 502 U.S. 251, 264-70

(1992) (in-rem power to tax land not contingent on jurisdiction over landowners); *Anderson & Middleton Lumber Co. v. Quinault Indian Nation*, 929 P.2d 379, 385 (Wash. 1996) (sale of property to Tribe was "of no consequence" because jurisdiction was not *in personam*, but *in rem*); *Lundgren v. Upper Skagit Indian Tribe*, 389 P.3d 569, 573 (Wash. 2017) (immunity does not bar *in rem* proceeding to quiet title), *modified*, 2017 Wash. LEXIS 619 (Wash. June 8, 2017); *Cass Cnty.*, 643 N.W.2d at 694-95 (same for condemnation proceeding); *see also* EX1152 at 7-9. The Patent Office's power to apply estoppel against "an application" or patent with the same written description as that involved in an IPR judgment (37 C.F.R. 42.73(d)(3)) is also *in rem*, not *in personam*, jurisdiction.

Furthermore, 35 U.S.C. §261 provided the Tribe with notice that patents only have "the attributes of personal property" to the extent they comply with *all* of title 35, including chapter 31. By recording its transaction under § 261, and taking advantage of the section's provisions, the Tribe acknowledged USPTO jurisdiction over these patents. The Tribe cites decisions holding ***tribes*** immune from ***private suits*** (at 11, 15-16), but these decisions do not make tribally owned ***patents*** immune from *USPTO* review. Moreover, tribal immunity does not apply to an instituted IPR because it is a Federal action in a Federal licensing program. EX1145 at 1 (Tribe: patents are time-limited Federal licenses); *EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071, 1075 (9th Cir. 2001) (tribe may not assert

immunity against Federal agency). Petitioner's provision of Congressionally-authorized assistance to the Board by filing the petition and presenting argument and evidence does not destroy the Patent Office's ability to proceed against the patents. Accordingly, the Board can and should proceed to a final decision on patentability regardless of the Tribe's participation.

V. THE TRIBE FAILS TO JUSTIFY DISMISSAL

The Tribe must justify the relief it seeks, 37 C.F.R. § 42.20(c), and show Board jurisdiction to grant it, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998); *Reactive Surfaces*, IPR2017-00572, Paper 32 at 11 (movant must establish "that this proceeding should be terminated rather than continuing in the absence of the Regents"). The Board is a statutory creation, so its authority must come from its enabling statute. *Vastfame Camera, Ltd. v. ITC*, 386 F.3d 1108, 1112 (Fed. Cir. 2004); *Civil Aeronautics Bd. v. Delta Air Lines, Inc.*, 367 U.S. 316, 322 (1961) (agency can only do what Congress permits). The Tribe has not identified any statutory authority to dismiss for tribal immunity. 37 C.F.R. § 42.23(b).

The Board can only dismiss an instituted review "under this chapter" (chapter 31 of title 35); otherwise, the "Board shall issue a final decision with respect to the patentability of any patent claim challenged…." 35 U.S.C. §318(a). Chapter 31 authorizes dismissals for other reasons, not tribal immunity. 35 U.S.C.

§315(d) (multiple proceedings); § 316(a)(6) (sanction); § 317 (settlement). An agency cannot elevate common law doctrine over its enabling statute. *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001) ("[A federal agency] has no constitutional or common law existence or authority, but only those authorities conferred upon it by Congress."); *cf.* EX1156 (common law does not control patent system). Prior Board opinions addressing state sovereign immunity did not consider the Board's power to decide immunity, much less abrogate Section 318(a). The Tribe invites the Board to create (not fill) a gap in a comprehensive patent reform that Congress painstakingly legislated. The Board must adhere to the statute and reject this invitation.

VI. CONCLUSION

For the foregoing reasons, the Tribe's motion should be dismissed or denied.

Respectfully submitted,

Dated: October 13, 2017

/ Steven W. Parmelee /
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Reg. No. 31,990

LIST OF EXHIBITS

Exhibit No.	Description
1001	The Patent (U.S. Patent No. 8,685,930; 8,629,111; 8,642,556; 8,633,162; 8,648,048; or 9,248,191 to Acheampong *et al.*, in IPR2016-01127 – IPR2016-01132, respectively)
1002	Declaration of Dr. Mansoor Amiji
1003	*Curriculum Vitae* of Dr. Mansoor Amiji
1004	File History (U.S. Patent No. 8,685,930; 8,629,111; 8,642,556; 8,633,162; 8,648,048; or 9,248,191 to Acheampong *et al.*, in IPR2016-01127 –01132, respectively)
1005	File history of U.S. Patent Application No. 10/927,857, filed on August 27, 2010 to Acheampong *et al.*
1006	U.S. Patent No. 5,474,979 to Ding *et al.*, filed May 17, 1994
1007	Sall, K., *et al.*, *Two Multicenter, Randomized Studies of the Efficacy and Safety of Cyclosporine Ophthalmic Emulsion in Moderate to Severe Dry Eye Disease*, 107 OPHTHALMOL. 631 (2000)
1008	Acheampong, A., *et al.*, *Cyclosporine distribution into the conjunctiva, cornea, lacrimal gland, and systemic blood following topical dosing of cyclosporine to rabbit, dog, and human eyes*, 2 LACRIMAL GLAND, TEAR FILM, AND DRY EYE SYNDROMES 1001 (1998)
1009	U.S. Patent No. 5,578,586 to Glonek *et al.*, filed February 4, 1994
1010	U.S. Patent No. 5,981,607 to Ding *et al.*, filed January 20, 1998
1011	Kaswan, R., *Intraocular Penetration of Topically Applied Cyclosporine* 20 TRANSPL. PROC. 650 (1988)
1012	Kunert, K., *et al.*, *Analysis of Topical Cyclosporine Treatment of Patients with Dry Eye Syndrome* 118 ARCH OPHTHALMOL 1489 (2000)
1013	Physicians' Desk Reference for Ophthalmic Medicines (1999)

1014	Turner, K., *et al*., *Interleukin-6 Levels in the Conjunctival Epithelium of Patients with Dry Eye Disease Treated with Cyclosporine Ophthalmic Emulsion* 19 CORNEA 492 (2000)
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1023	Complaint; *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Apotex, Inc., Apotex Corp., Akorn, Inc., Mylan Pharmaceuticals Inc., and Mylan Inc.*, No. 2:15-cv-01455
1024	Approved Drug Products with Therapeutic Equivalence Evaluations (34th Ed.) (2014) (Excerpts)

1025 (IPR2016-01127)	File history of U.S. Patent No. 8,629,111 to Acheampong *et al*. (Exhibit Number Reserved in IPR2016-01128, -01129, -01130, & -01131)
1025 (IPR2016-01132)	Complaint; *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Apotex, Inc., Apotex Corp., Akorn, Inc., Mylan Pharmaceuticals Inc.*, No. 2:15-cv-01455 (Exhibit Number Reserved in IPR2016-01128, -01129, -01130, & -01131)
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1035	PROTECTIVE ORDER MATERIAL - Transcript of June 1, 2017 Deposition of Rhett Schiffman, M.D., M.S.Sc.
1036	PROTECTIVE ORDER MATERIAL - Transcript of June 7, 2017 Deposition of Thorsteinn Loftsson, Ph.D.

1037	Transcript of June 20, 2017 Deposition of John D. Sheppard, M.D., M.S.Sc.
1038	PROTECTIVE ORDER MATERIAL - Transcript of June 22, 2017 Deposition of Mayssa Attar, Ph.D.
1038	REDACTED - Transcript of June 22, 2017 Deposition of Mayssa Attar, Ph.D.
1039	PROTECTIVE ORDER MATERIAL - Declaration of Andrew F. Calman, M.D.
1040	PROTECTIVE ORDER MATERIAL - Declaration of Daniel A. Bloch, Ph.D.
1041	PROTECTIVE ORDER MATERIAL - Declaration of Ivan T. Hofmann
1042	*Curriculum Vitae* of Andrew F. Calman, M.D.
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1133	Declaration of Anna G. Phillips in support of Petitioner's Motion for *Pro Hav Vice* Admission
1134	June 5, 2017 Email Regarding Deposition Requests
1135	July 6, 2017 Email Regarding Patent Owner's Sur-reply
1136	July 21, 2017 Email Regarding New Arguments and Evidence in Patent Owner's Sur-reply
1137	Transcript of Telephonic Hearing Held Monday, 11 September 2017, in IPR2016-01127; IPR2016-01128; IPR2016-01129; IPR2016-01130; IPR2016-01131 and IPR2016-01132
1138	Declaration of Shannon M. Bloodworth in support of Petitioner's Motion for Pro Hac Vice Admission
1139	Declaration of Charles G. Curtis, Jr. in support of Petitioner's Motion for Pro Hac Vice Admission
1140	Declaration of Jennifer A. MacLean in support of Petitioner's Motion for Pro Hac Vice Admission
1141	Declaration of Eric D. Miller in support of Petitioner's Motion for Pro Hac Vice Admission
1142	Declaration of Benjamin S. Sharp in support of Petitioner's Motion for Pro Hac Vice Admission

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CERTIFICATE OF SERVICE

This is to certify that I caused to be served true and correct copies of the foregoing Petitioners' Opposition to the Tribe's Motion to Dismiss and Exhibits 1144-1162 on this 13th day of October, 2017, on Allergan, Inc. and the St. Regis Mohawk Tribe as follows:

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