

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.

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## 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,

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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.

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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

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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

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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.

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### 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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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.



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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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*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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*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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*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*



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)

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.

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)

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

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)

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).

IPR2016-01127 (8,685,930 B2); IPR2016-01128 (8,629,111 B2);  
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IPR2016-01131 (8,648,048 B2); IPR2016-01132 (9,248,191 B2)

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

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,

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)

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

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,

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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§ 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.



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)

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.

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)

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.

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)

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

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

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:

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)

**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

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)

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