APPENDIX

APPENDIX A

United States Court of Appeals
for the Federal Circuit

SAINT REGIS MOHAWK TRIBE,
ALLERGAN, INC.,
Appellants

v.

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

2018-1638, 2018-1639, 2018-1640, 2018-1641, 2018-1642, 2018-1643

IPR2016-01127,	IPR2016-01128,	IPR2016-01129,
IPR2016-01130,	IPR2016-01131,	IPR2016-01132,
IPR2017-00599,	PR2017-00576,	PR2017-00578,
IPR2017-00579,	IPR2017-00583,	IPR2017-00585
IPR2017-00586,	IPR2017-00594,	IPR2017-00596,
IPR2017-00598,	IPR2017-00600,	IPR2017-00601

Decided: July 20, 2018

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CHARLES R. MACEDO, Amster Rothstein & Ebenstein LLP, New York, NY, for amicus curiae Askeladden, L.L.C. Also represented by MARK BERKOWITZ, SANDRA A. HUDAK.

ANNA-ROSE MATHIESON, California Appellate Law Group, San Francisco, CA, for amicus curiae America's Health Insurance Plans.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, for amicus curiae The Association for Accessible Medicines. Also represented by JAIME ANN SANTOS; JEFFREY FRANCER, The Association for Accessible Medicines, Washington, DC.

MARIA AMELIA CALAF, Wittliff Cutter, Austin, TX, for amici curiae Software & Information Industry Association, L Brands, Inc., SAS Institute Inc., SAP America, Inc., Internet Association, Xilinx, Inc.

Before DYK, MOORE, and REYNA, *Circuit Judges*.
Opinion for the court filed by
Circuit Judge MOORE.

Concurring opinion filed by
Circuit Judge DYK.

MOORE, *Circuit Judge*.

Mylan Pharmaceuticals, Inc., petitioned for inter partes review ("IPR") of various patents owned by Allergan, Inc., relating to its dry eye treatment Restasis. Teva Pharmaceuticals USA, Inc., and Akorn, Inc. (together with Mylan, "Appellees") joined. While IPR was pending, Allergan transferred title of the patents to the Saint Regis Mohawk Tribe, which asserted sovereign immunity. The Board denied the Tribe's motion to terminate on the basis of sovereign immunity and Allergan's motion to withdraw from the proceedings. Allergan and the Tribe appeal, arguing the Board improperly denied these motions. We affirm.

BACKGROUND

This appeal stems from a multifront dispute between Allergan and various generic drug manufacturers regarding patents related to Allergan's Restasis product (the "Restasis Patents"), a treatment for alleviating the symptoms of chronic dry eye. In 2015, Allergan sued Appellees in the

Eastern District of Texas, alleging infringement of the Restasis Patents based on their filings of Abbreviated New Drug Applications. On June 3, 2016, Mylan petitioned for IPR of the Restasis Patents. Subsequently, Teva and Akorn filed similar petitions. The Board instituted IPR and scheduled a consolidated oral hearing for September 15, 2017.

Before the hearing, Allergan and the Tribe entered into an agreement Mylan alleges was intended to protect the patents from review. On September 8, 2017, a patent assignment transferring the Restasis patents from Allergan to the Tribe was recorded with the USPTO. The Tribe moved to terminate the IPRs, arguing it is entitled to assert tribal sovereign immunity, and Allergan moved to withdraw. The Board denied both motions.

Allergan and the Tribe appeal. We have jurisdiction pursuant 28 U.S.C. § 1295(a)(4)(A). Board decisions must be set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

ANALYSIS

As "domestic dependent nations," Indian tribes possess "inherent sovereign immunity," and suits against them are generally barred "absent a clear waiver by the tribe or congressional abrogation." *Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Okla.*, 498 U.S. 505, 509 (1991). This immunity derives from the common law, *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 58 (1978), and it does not extend to actions brought by the federal government, *see, e.g.*, *E.E.O.C. v. Karuk*

Tribe Hous. Auth., 260 F.3d 1071, 1075 (9th Cir. 2001); *United States v. Red Lake Band of Chippewa Indians*, 827 F.2d 380, 383 (8th Cir. 1987). Generally, immunity does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action. *See, e.g., Pauma v. NLRB*, 888 F.3d 1066 (9th Cir. 2018) (holding the NLRB could adjudicate unfair labor charges brought by the Board against a tribally-owned business operating on tribal land); *Karuk Tribe Hous. Auth.*, 260 F.3d at 1074 (holding tribe not immune in EEOC enforcement action); *cf. Fed. Power Comm'n v. Tuscarora Indian Nation*, 362 U.S. 99, 122 (1960) (holding that tribal lands were subject to takings by the Federal Power Commission). There is not, however, a blanket rule that immunity does not apply in federal agency proceedings. *Fed. Maritime Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743, 754–56 (2002)("FMC").

In *FMC*, the Supreme Court considered whether state sovereign immunity precluded the Federal Maritime Commission from "adjudicating a private party's complaint that a state-run port ha[d] violated the Shipping Act of 1984." *Id.* at 747. In answering this question, the Court asked whether Commission adjudications "are the type of proceedings from which the Framers would have thought the States possessed immunity when they agreed to enter the Union." *Id.* at 756. It decided they were, given the FMC proceedings' "overwhelming" similarities with civil litigation in federal courts. *Id.* at 759. For example, the Court noted the procedural rules in the Commission's proceedings "bear a remarkably strong resemblance" to the rules applied in civil litigation, and the

discovery procedures were "virtually indistinguishable" from the procedures used in civil litigation. *Id.* at 757–58. The Court also distinguished the proceedings at issue from other proceedings in which the Commission had the authority to decide whether to proceed with an investigation or enforcement action. *Id.* at 768. In doing so, the Court recognized a distinction between adjudicative proceedings brought against a state by a private party and agency-initiated enforcement proceedings.

The Tribe argues that tribal sovereign immunity applies in IPR under *FMC*. It asserts that like the proceeding in *FMC,* IPR is a contested, adjudicatory proceeding between private parties in which the petitioner, not the USPTO, defines the contours of the proceeding. Appellees dispute this comparison, arguing that the Tribe may not invoke sovereign immunity to block IPR proceedings because they are more like a traditional agency action. They argue the Board is not adjudicating claims between parties but instead is reconsidering a grant of a government franchise. They also argue that even if the Tribe could otherwise assert sovereign immunity, its use here is an impermissible attempt to "market an exception" from the law and non-Indian companies have no legitimate interest in renting tribal immunity to circumvent the law. Appellees further argue the Tribe may not assert immunity because the assignment was a sham, and the Tribe waived sovereign immunity by suing on the patents.

Although the precise contours of tribal sovereign immunity differ from those of state sovereign immunity, the *FMC* analysis is

instructive. We hold that tribal sovereign immunity cannot be asserted in IPRs.

IPR is neither clearly a judicial proceeding instituted by a private party nor clearly an enforcement action brought by the federal government. It is a "hybrid proceeding" with "adjudicatory characteristics" similar to court proceedings, but in other respects it "is less like a judicial proceeding and more like a specialized agency proceeding." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2143–44 (2016). This tension was laid bare in two recent Supreme Court decisions decided on the same day.

In *Oil States Energy Services v. Greene's Energy Group, LLC*, 138 S. Ct. 1365 (2018), the Court emphasized the government's central role in IPR and the role of the USPTO in protecting the public interest. It held that IPR is a matter "which arise[s] between the Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments." 138 S. Ct. at 1373 (quoting *Crowell v. Benson*, 285 U.S. 22, 50 (1932)). It recognized that IPR is "simply a reconsideration of" the PTO's original grant of a public franchise, which serves to protect "the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope." *Id.* (quoting *Cuozzo*, 136 S. Ct. at 2144).

In contrast, in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the Court emphasized the adjudicatory aspects of IPR and the way in which it "mimics civil litigation." *Id.* at 1352; *see also id.* at 1353, 1355. It explained that Congress structured

IPR so that the petitioner, not the USPTO Director, "define[s] the contours of the proceeding." *Id.* at 1355. The Court contrasted the "party-directed, adversarial" IPR process, in which the Director is only given the choice of whether to institute IPR, with the "inquisitorial approach" established by the ex parte reexamination statute, under which the Director was given the authority to investigate patentability on his own initiative. *Id.*

Ultimately, several factors convince us that IPR is more like an agency enforcement action than a civil suit brought by a private party, and we conclude that tribal immunity is not implicated. First, although the Director's discretion in how he conducts IPR is significantly constrained, he possesses broad discretion in deciding whether to institute review. *Oil States*, 138 S. Ct. at 1371. Although this is only one decision, it embraces the entirety of the proceeding. If the Director decides to institute, review occurs. If the Director decides not to institute, for whatever reason, there is no review. In making this decision, the Director has complete discretion to decide not to institute review. *Oil States*, 138 S. Ct. at 1371 ("The decision whether to institute inter partes review is committed to the Director's discretion."). The Director bears the political responsibility of determining which cases should proceed. While he has the authority not to institute review on the merits of the petition, he could deny review for other reasons such as administrative efficiency or based on a party's status as a sovereign. *See Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364, 1372 (Fed. Cir. 2018) (en banc). Therefore, if IPR proceeds on patents owned by a tribe, it is because a politically accountable, federal official has authorized the institution of that

proceeding. *See Alden v. Maine*, 527 U.S. 706, 756 (1999) (contrasting suits in which the United States "exercise[s] . . . political responsibility for each suit prosecuted" in order to fulfill its obligation under the Take Care Clause with "a broad delegation to private persons to sue nonconsenting States"). In this way, IPR is more like cases in which an agency chooses whether to institute a proceeding on information supplied by a private party. In *FMC*, the Court recognized that immunity would not apply in such a proceeding. *FMC*, 535 U.S. at 768.

In *FMC*, the Federal Maritime Commission lacked the "discretion to refuse to adjudicate complaints brought by private parties," *FMC*, 535 U.S. at 764, and in federal civil litigation, a private party can compel a defendant's appearance in court and the court had no discretion to refuse to hear the suit. In both instances, absent immunity, a private party could unilaterally hale a sovereign before a tribunal, presenting an affront to the dignity of the sovereign. *See Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2042 (2014) (noting the need to consider the dignity of the Indian tribes as sovereigns); *FMC*, 535 U.S. at 760 ("The preeminent purpose of state sovereign immunity is to accord States the dignity that is consistent with their status as sovereign entities."). The Director's broad authority to not institute alleviates these concerns in the IPR context. It is the Director, the politically appointed executive branch official, not the private party, who ultimately decides whether to proceed against the sovereign.

Second, the role of the parties in IPR suggests immunity does not apply in these proceedings. Once IPR has been initiated, the Board may choose to

continue review even if the petitioner chooses not to participate. 35 U.S.C. § 317(a). The Director has also been granted the right to participate in appeals "even if the private challengers drop out." *Cuozzo*, 136 S. Ct. at 2144; *see also* 35 U.S.C. § 143 (granting the Director the right to intervene in appeals of Board decisions in IPRs). The Board has construed its rules to allow it to continue review even in the absence of patent owner participation. *See Reactive Surfaces Ltd. v. Toyota Motor Corp.*, IPR2017-00572, Paper 32 (PTAB July 13, 2017) (citing 37 C.F.R. §§ 42.108(c), 120(a)). This reinforces the view that IPR is an act by the agency in reconsidering its own grant of a public franchise.

Third, unlike *FMC*, the USPTO procedures in IPR do not mirror the Federal Rules of Civil Procedure. *See FMC*, 535 U.S. at 757–58. Although there are certain similarities, the differences are substantial. While the Federal Rules of Civil Procedure provide opportunities for a plaintiff to make significant amendments to its complaint, *see* Fed. R. Civ. P. 15, the Board has determined that in IPR a petitioner may only make clerical or typographical corrections to its petition, *see Nat'l Envtl. Prods. Ltd. v. Dri-Steem Corp.*, IPR2014-01503, Paper 11 (PTAB Nov. 4, 2014) (citing 37 C.F.R. § 42.104(c)). At the same time, a patent owner in IPR may seek to amend its patent claims during the proceedings, an option not available in civil litigation. 35 U.S.C. § 316(d). IPR also lacks many of the preliminary proceedings that exist in civil litigation. *See, e.g., Farmwald v. Parkervision, Inc.*, IPR2014-00946, Paper 13 (PTAB Jan. 26, 2015) (declining to conduct a Markman hearing). Moreover, in civil litigation and the proceedings at issue in *FMC*, parties have a host of discovery

options, including the use of interrogatories, depositions, production demands, and requests for admission. *FMC*, 535 U.S. at 758. In IPR, discovery is limited to "(A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice." 35 U.S.C. § 316(a)(5); *see also* 37 C.F.R. § 42.51. In *FMC*, the Court rejected the idea that sovereign immunity could be circumvented by merely moving a proceeding from an Article III court to an equivalent agency tribunal. *FMC*, 535 U.S. at 760. An IPR hearing is nothing like a district court patent trial. The hearings are short, and live testimony is rarely allowed. *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1270 n.2 (Fed. Cir. 2017) ("Very seldom do IPR proceedings have the hallmarks of what is typically thought of as a trial."). In IPR, the agency proceedings are both functionally and procedurally different from district court litigation. In short, the agency procedures in *FMC* much more closely approximated a civil litigation than those in IPR.

Finally, while the USPTO has the authority to conduct reexamination proceedings that are more inquisitorial and less adjudicatory than IPR, this does not mean that IPR is thus necessarily a proceeding in which Congress contemplated tribal immunity to apply. The Tribe acknowledged that sovereign immunity would not apply in ex parte or inter partes reexamination proceedings because of their inquisitorial nature. Oral Arg. at 6:30–8:10. The mere existence of more inquisitorial proceedings in which immunity does not apply does not mean that immunity applies in a different type of proceeding before the same agency. Notably, the Supreme Court in *Cuozzo* recognized inter partes reexamination and IPR have the same "basic

purposes, namely to reexamine an agency decision." 136 S. Ct. at 2144. While IPR presents a closer case for the application of tribal immunity than reexamination, we nonetheless conclude that tribal immunity does not extend to these administrative agency reconsideration decisions.

The Director's important role as a gatekeeper and the Board's authority to proceed in the absence of the parties convinces us that the USPTO is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant and protect the public interest in keeping patent monopolies "within their legitimate scope." *See Cuozzo*, 136 S. Ct. at 2144. The United States, through the Director, does "exercise . . . political responsibility" over the decision to proceed with IPR. *FMC*, 535 U.S. at 764 (quoting *Alden*, 527 U.S. at 756). The Tribe may not rely on its immunity to bar such an action. *See Miccosukee Tribe of Indians of Fla. v. United States*, 698 F.3d 1326, 1331 (11th Cir. 2012) ("Indian tribes may not rely on tribal sovereign immunity to bar a suit by a superior sovereign."). Because we conclude that tribal sovereign immunity cannot be asserted in IPR, we need not reach the parties' other arguments.

In this case we are only deciding whether tribal immunity applies in IPR. While we recognize there are many parallels, we leave for another day the question of whether there is any reason to treat state sovereign immunity differently.

CONCLUSION

For the foregoing reasons, the decision of the Board is *affirmed*.

AFFIRMED

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SAINT REGIS MOHAWK TRIBE,
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v.

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2018-1638, 2018-1639, 2018-1640, 2018-1641, 2018-1642, 2018-1643

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00599, PR2017-00576, PR2017-00578, IPR2017-00579, IPR2017-00583, IPR2017-00585 IPR2017-00586, IPR2017-00594, IPR2017-00596, IPR2017-00598, IPR2017-00600, IPR2017-00601

DYK, *Circuit Judge*, concurring.

I fully join the panel opinion but write separately to describe in greater detail the history of inter partes review proceedings, history that

confirms that those proceedings are not adjudications between private parties. While private parties play a role, inter partes reviews are fundamentally agency reconsiderations of the original patent grant, proceedings as to which sovereign immunity does not apply.

As the panel makes clear, it is well established that tribes cannot assert sovereign immunity in proceedings brought by the federal government.[1] This understanding is reflected in *Federal Maritime Commission v. South Carolina State Ports Authority* (*"FMC"*), which dealt with a proceeding conducted by the Federal Maritime Commission adjudicating a private party's claim that a state-run port had violated a federal statute in which the private party sought monetary and injunctive relief. 535 U.S. 743, 747–49 (2002). "[T]he only duty assumed by the FMC, and hence the United States, in conjunction with [the] private complaint [was] to assess its merits in an impartial manner." *Id.* at 764.

The Supreme Court held that state sovereign immunity barred the FMC from adjudicating the complaint, but noted that it would not bar the FMC from "institut[ing] its own administrative proceeding against a state-run port," even if that proceeding

[1] See *Washington v. Confederated Tribes of Colville Indian Reservation*, 447 U.S. 134, 154 (1980) (holding that tribal sovereignty is "dependent on, and subordinate to" the Federal Government); *Pauma v. NLRB*, 888 F.3d 1066, 1078–79 (9th Cir. 2018) (holding that tribal immunity does not preclude a proceeding brought "on behalf of the NLRB, an agency of the United States, to enforce public rights"); *NLRB v. Little River Band of Ottawa Indians Tribal Gov't,* 788 F.3d 537, 555 (6th Cir. 2015).

were prompted by "information supplied by a private party." *Id.* at 768. Private parties, the Court explained, "remain perfectly free to complain to the Federal Government about unlawful state activity and the Federal Government [remains] free to take subsequent legal action." *Id.* at 768 n.19.

Under *FMC*, it is clear that sovereign immunity cannot bar agency denial of an original patent application filed by a sovereign entity or, consequently, agency reconsideration of an original patent grant. Such reconsideration simply does not involve agency adjudication of a private dispute, but rather agency reconsideration of its own prior actions.

At oral argument, counsel for the tribe acknowledged that sovereign immunity would not apply in either ex parte or inter partes reexamination proceedings, and even suggested that the USPTO could continue to provide post-grant review of tribe-owned patents by simply converting the inter partes reviews to ex parte reexaminations. Oral Arg. 6:30–7:08, 54:48–55:15. But inter partes review is not fundamentally different from other reexamination procedures. Rather, inter partes review is a direct successor to ex parte and inter partes reexamination. It shares many of the same procedural features and is designed to address the same problems. And like the reexaminations from which it descends, it is fundamentally agency reconsideration, assisted by third parties, rather than agency adjudication of a private dispute.

Post-grant administrative review of issued patents is a relatively new feature of the patent system. It was first enacted in 1980 to address

longstanding concerns about the reliability of the original examination process. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 603 (Fed. Cir. 1985). Before reexamination procedures, once a patent was issued, "there was no way the PTO or private persons could have forced . . . patents back into the examination phase against [the patent owner's] will." *Id.* at 601.[2] This was problematic because the USPTO—then and now—is an agency with finite resources that sometimes issues patents in error. Currently, for instance, the USPTO receives over 600,000 applications a year. U.S. Patent & Trademark Office, *Performance & Accountability Report* 169 tbl.2 (2017). Patent examiners receive roughly 22 hours to review each application, an amount of time that 70% of examiners report as insufficient. *See* U.S. Gov't Accountability Office, GAO-16-490, *Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity* 10, 25–26 (2016). And the USPTO struggles to attract and retain examiners with the technical competence required to understand the inventions being reviewed and to perform sufficiently thorough prior art searches. *See* U.S. Gov't Accountability Office, GAO-16-479, *Patent Office Should Strengthen Search Capabilities and Better Monitor Examiners' Work* 28–29 & n.50 (2016).

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[2] The USPTO did have the authority to reissue patents to cure errors in the original. *See Grant v. Raymond*, 31 U.S. 218, 244 (1832); *see also* 35 U.S.C. § 251. However, reissue proceedings could only be initiated at the request of the patentee, so they were of limited use in ensuring patent quality. *See Russell E. Levine et. al.*, *Ex Parte Patent Practice and the Rights of Third Parties*, 45 Am. U. L. Rev. 1987, 2008 (1996).

In considering the enactment of reexamination, Congress was well aware of constraints on the accuracy of initial examination and the adverse effects of the issuance of bad patents. The Senate report on patent reexamination emphasized that the USPTO faced "a situation where a limited staff is trying to cope with a constantly increasing workload and is under pressure to make speedy determinations on whether or not to grant patents." S. Rep. No. 96-617, at 8 (1980); *see also Patent Reexamination: Hearing on S. 1679 Before the Comm. on the Judiciary*, 96th Cong. 3 (1980) (statement of Sen. Bayh) (characterizing the USPTO as "an understaffed and overworked office trying to handle an ever increasing workload."). The USPTO Commissioner testified that these resource constraints led to uncertainty in the patent system "because pertinent prior patents and printed publications . . . often are discovered only after a patent has issued and become commercially important." S. Rep. No. 96-617, at 9 (1980). The Commissioner also explained that

> The main reason reexamination is needed is because members of the public interested in the validity of a patent are sometimes able to find pertinent prior patents and printed publications not known or available to the PTO. . . .
>
> The patent owner's competitors will devote great effort and expense to invalidating a patent that affects their business. They can afford to look for documentary evidence of unpatentability in library collections,

> technical journals and other sources not within the PTO's search file. Because of budgetary and time constraints, the examiner's search seldom extends beyond the PTO's 22 million document collection.

Industrial Innovation and Patent and Copyright Law Amendments: Hearing on H.R. 6033, H.R. 6934, H.R. 3806, and H.R. 2414 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the H. Comm. on the Judiciary, 96th Cong. 576 (1981) (statement of Sidney A Diamond, Commissioner of Patents and Trademarks).[3] In short, given the high volume of applications and the USPTO's manpower limitations, pre-grant patent examination was—and still is—an imperfect way to separate the good patents from the bad. Resource constraints in the initial examination period inevitably result in erroneously granted patents.[4]

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[3] *See also* Thomas E. Popovich, *Patent Quality: An Analysis of Proposed Court, Legislative, and PTO—Administrative Reform—Reexamination Resurrected* (Part I), 61 J. Pat. Off. Soc'y 248, 269 (1979) (concluding that the issuance of low quality patents was attributable to the USPTO's failure to discover and adequately to consider the most relevant prior art and that patent reform should be directed at these failures).

[4] *See* U.S. Gov't Accountability Office, GAO-16-490, *Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity* 25 (2016) (reporting that "examiners' time pressures are one of the central challenges for patent quality"); *see also* Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 Stan. L. Rev. 613, 652–53 (2015) (finding increased patent grant rates correlated with increased resource strain on the USPTO); Shawn P. Miller, *Where's the Innovation: An Analysis of the*

As a result of these problems, there was a perception that the public lacked confidence in the patent system, which in turn contributed to judicial skepticism about the USPTO's work. *See* S. Rep. No. 96-617, at 3, 14 (1980). Indeed, "judicial opinions and commentaries from the time" evince "a fundamental lack of trust in the competency of the PTO to discover sources of relevant prior art and apply them properly under the statutory standards, particularly in the context of a confidential ex parte examination process." Mark D. Janis, *Rethinking Reexamination: Toward A Viable Administrative Revocation System for U.S. Patent Law*, 11 Harv. J.L. & Tech. 1, 9–10 (1997). This lack of confidence led to an undermining of the presumption of patent validity, as "many courts treated the presumption of validity as coextensive with the presumption of administrative correctness." *Id.* at 12.

Some kind of reexamination procedure was therefore desirable, particularly as to issues of anticipation and obviousness where prior art has always played a central role. "After reexamination," the Commissioner testified, "the presumptive validity of the patent as it leaves the reexamination process will be enhanced. The court will have greater confidence that the patent claims are of exactly the right scope and that any unpatentable original claims have been canceled." *Industrial Innovation and Patent and Copyright Law Amendments: Hearing on H.R. 6033, H.R. 6934, H.R. 3806, and H.R. 2414 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the H. Comm. on*

Quantity and Qualities of Anticipated and Obvious Patents, 18 Va. J.L. & Tech. 1, 45 (2013) (estimating that 28% of issued patents would be invalidated as anticipated or obvious).

the Judiciary, 96th Cong. 580–81 (1981) (statement of Sidney A Diamond, Commissioner of Patents and Trademarks). Reexamination would allow the USPTO to cure its own errors, thereby improving patent quality, bolstering the presumption of patent validity, and restoring the public's and the judiciary's confidence in the USPTO.

In 1980, Congress enacted the Reexamination Act and created ex parte reexamination, the first post-issuance proceeding to review patent validity. *See* Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015 (1980). A request for ex parte reexamination could be filed by "any person at any time," including the patent owner, a third party, or the Director of the USPTO. 35 U.S.C. § 302 (1980). If the request raised "a substantial new question of patentability" based on prior art, the USPTO would grant the request and conduct reexamination. *Id.* at § 303(a). The USPTO would then cancel any claim of the patent determined to be unpatentable. *Id.* at § 307.

The objective of reexamination was to "strengthen[] investor confidence in the certainty of patent rights by creating a system of administrative reexamination of doubtful patents," H.R. Rep. No. 96-1307, pt. 1, at 3 (1980), and to "permit efficient resolution of questions about the validity of issued patents without recourse to expensive and lengthy infringement litigation," *id.* at 4. In particular, reexamination aimed to use the motivation and resources of third parties to improve the accuracy of the USPTO's patent process. *See* S. Rep. No. 96-617, at 2 (1980) (explaining that reexamination "will help to restore confidence in the effectiveness of our patent system by efficiently bringing to the PTO's attention relevant [prior art] materials that are

missing or have been overlooked."). "The problem," the Senate report concluded, "is to insure that the patent examiner has the materials needed for a complete examination and patent reexamination will help to get these materials before him." *Id.* at 3.

Nevertheless, ex parte reexamination had several limitations with the result that it was rarely used. H.R. Rep No. 106-464, at 133 (1999). First and foremost, a "third party challenger had no role once the proceeding was initiated while the patent holder had significant input throughout the entire process." S. Rep. No. 110-259 at 18 (2008). Additionally, there was no right for a requestor to appeal the USPTO's reexamination decision either administratively or in court. *Id.* at 19.

In light of these deficiencies, Congress sought to introduce a new system that would make reexamination more effective and broaden its use. H.R. Rep 106-464 at 133 (1999). In 1999, it enacted a new procedure, known as inter partes reexamination, adding to the 1980 Reexamination Act's ex parte option. Act of Nov. 29, 1999, Pub. L. No. 106-113, 113 Stat. 1501 (1999). Inter partes reexamination allowed a third party to file a request for reexamination based on prior art, and if a substantial new question of patentability was raised, the USPTO would grant the request and proceed with reexamination. 35 U.S.C. § 312 (2002). Unlike ex parte reexamination, however, inter partes reexamination allowed third party requesters to participate in the process by providing that "[e]ach time that the patent owner files a response to an action on the merits from the Patent and Trademark Office, the third-party requester shall have one opportunity to file written comments addressing

issues raised by the action of the Office or the patent owner's response thereto." *Id.* at § 314. It also permitted a requester to appeal an examiner's determination that the reexamined patent is valid to the Board of Patent Appeals and Interferences. "The participation by third parties [was] considered vital" to the goal of "improving patent quality and validity" because "in many circumstances they [would] have the most relevant prior art available and incentive to seek to invalidate an allegedly defective patent." H.R. Rep. 107-120, at 4 (2001).

Over the next few years, Congress revised inter partes reexamination in an attempt to make it more effective. In 2002, the procedure was amended to allow requests based solely on prior art already considered by the USPTO, Pub. L. 107-273, §13105, 116 Stat. 1758, 1900 (2002), and to provide the same appellate review opportunities to patentees and third-party requesters. *Id.* at § 13202, 116 Stat. 1899–1906. Ultimately, however, both ex parte and inter partes reexamination were less widely used than Congress had hoped, and had features that made them "troublesomely inefficient and ineffective as a truly viable alternative for resolving questions of patent validity." S. Rep. No. 110-259 at 19 (2008).

It was against this background that, in 2011, Congress enacted the Leahy–Smith America Invents Act, which replaced inter partes reexamination with new post-grant review procedures, such as inter partes review, covered business method review, and post-grant review, while retaining ex parte reexamination. *See* Pub. L. No. 112-29, § 6, 125 Stat. 284, 299–304 (2011). Inter partes review in particular was designed to improve upon the inter partes reexamination process. *Cuozzo Speed Techs.,*

LLC v. Lee, 136 S. Ct. 2131, 2137 (2016).[5] Similar to reexamination, the purpose behind creating inter partes review was to "improve patent quality and restore confidence in the presumption of validity." H.R. Rep. 112-98, pt. I, at 48 (2011).

Inter partes review, like inter partes reexamination, begins with a third party's filing a petition challenging the validity of one or more claims in a patent on the basis of prior art. The USPTO may institute review if the petitioner demonstrates a "reasonable likelihood that [it] would prevail" in the dispute, rather than instituting if it demonstrates a "substantial new question of patentability," as was the case in reexamination. *See* 35 U.S.C. § 314(a). Like inter partes reexamination, the third party remains involved throughout the proceeding, but inter partes review can include discovery and an oral hearing in addition to written comments. It is conducted before the Patent Trial and Appeal Board rather than an examiner. § 316(c).

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[5] The proceedings created by the AIA continued Congress' efforts to channel the work of third party challengers in order to help the USPTO achieve its mission. *See* H.R. Rep. No. 112-98, pt. I, at 39–40 (2011) (characterizing post-grant proceedings as "a more efficient system for challenging patents that should not have issued"). Indeed, the AIA also expanded the role of private parties in the pre-grant examination process. Previous USPTO procedure allowed third parties to submit prior art patents and other printed publications of potential relevance to a pending examination but did not allow explanations of "why the prior art was submitted or what its relevancy might be." *Id.* at 48–49. In an effort to better capitalize on the assistance of third parties, the AIA removed this restriction and provided a mechanism for third parties to explain the relevance of prior art they bring to the USPTO's attention. *Id.* at 49.

In inter partes review, the federal agency tasked with patent examination of patent applications takes a "second look" at its own decision to issue a patent. As the Supreme Court concluded in *Cuozzo*:

> [T]he purpose of [inter partes review] is not quite the same as the purpose of district court litigation. The proceeding involves what used to be called a reexamination (and, as noted above, a cousin of inter partes review, ex parte reexamination, 35 U.S.C. § 302 et seq., still bears that name). The name and accompanying procedures suggest that the proceeding offers a second look at an earlier administrative grant of a patent. Although Congress changed the name from "reexamination" to "review," nothing convinces us that, in doing so, Congress wanted to change its basic purposes, namely, to reexamine an earlier agency decision.

136 S. Ct. at 2144*; see also Patlex*, 758 F.2d at 604 (explaining that ex parte reexamination's "purpose is to correct errors made by the government, to remedy defective governmental (not private) action, and if need be to remove patents that should never have been granted.").

While inter partes review has some features similar to civil litigation, *see SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1352 (2018), at its core, it retains the purpose and many of the procedures of its reexamination ancestors, to which everybody agrees sovereign immunity does not apply. Inter

partes review is an administrative proceeding designed to improve patent quality by giving the USPTO "a second look at an earlier administrative grant of a patent." *Cuozzo*, 136 S. Ct. at 2144; *see also Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) ("The primary distinction between inter partes review and the initial grant of a patent is that inter partes review occurs after the patent has issued.").

As the panel describes, significant features of the system confirm that inter partes review is an agency reconsideration rather than an adjudication of a private dispute and does not implicate sovereign immunity. Inter partes review brings to bear the same agency expertise as exists in initial examination. There is no requirement that a third party petitioner have any interest in the outcome of the proceeding, much less Article III standing. *See* 35 U.S.C. § 311(a). Upon receiving a petition, the Director has complete discretion regarding whether to institute review. § 314; *Oil States*, 138 S. Ct. at 1371. The inter partes review procedures limit discovery, typically preclude live testimony in oral hearings, and do not mirror the Federal Rules of Civil Procedure. § 316(a)(5); *see also* 37 C.F.R. §§ 42.51, 42.70; *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1270 n.2 (Fed. Cir. 2017). And if the third party settles, the proceeding does not end, and the USPTO may continue on to a final written decision. § 317(a). The USPTO may intervene to defend its decisions on appeal, whether or not the third party petitioner remains in the case. § 143; *Cuozzo*, 136 S. Ct. at 2144. It does not involve exercise of personal jurisdiction over the patent holder or adjudication of infringement. The only possible adverse outcome is the cancelation of

erroneously granted claims. Notably, the Supreme Court has held that "adversarial proceedings" that do not involve the exercise of personal jurisdiction do not necessarily raise sovereign immunity concerns. *See Tenn. Student Assistance Corp. v. Hood,* 541 U.S. 440, 448 (2004) (bankruptcy).

These features distinguish inter partes review from the proceeding in FMC and bolster the view that it is, like ex parte and inter partes reexamination, an executive proceeding that enlists third-party assistance. As the panel concludes, in such a reexamination proceeding, sovereign immunity does not apply.

APPENDIX B

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Paper No. 129
Entered: February 23, 2018

UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND
APPEAL BOARD

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

v.

SAINT REGIS MOHAWK TRIBE,
Patent Owner.

Case IPR2016-01127 (8,685,930 B2);
Case IPR2016-01128 (8,629,111 B2);
Case IPR2016-01129 (8,642,556 B2);
Case IPR2016-01130 (8,633,162 B2);
Case IPR2016-01131 (8,648,048 B2);
Case IPR2016-01132 (9,248,191 B2)[1]

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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. This Decision addresses issues that are the same in the identified

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

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

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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.

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[2] for Lack of 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

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[2] 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, 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.

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). 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 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 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, 5.3.3.[3]

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.*

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[3] 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.

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 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*")).[4]

[4] 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 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 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

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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.

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. 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.

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.[5]

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[5] 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).

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 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.'

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 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 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. Paraplegic 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.

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.[6] The

[6] Several *amici* supporting Petitioners have asserted that *inter partes* 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

Tribe cannot 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* 35 U.S.C. § 317(a)

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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.

(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 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."[7]

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. Bebop, 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

[7] 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).

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, 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*, 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, keratoconjuctivitis sicca, 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 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[8] is approved by the FDA." *Id.* § 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

[8] "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, 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.

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 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,[9] the Tribe's ability to control critical trial

[9] "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

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 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).

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.

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.

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 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" 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:

> **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 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 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, but nonetheless[10] "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

[10] 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.

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, 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.

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.[11]

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).[12] Mot. 20–24;

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[11] 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.

[12] 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;

Reply 10–12. In *Republic of Philippines v. Pimentel*, the Supreme Court held that "[a] case may not proceed when a required-entity sovereign is not amenable to suit . . . where sovereign immunity is asserted, and the claims of the sovereign are not frivolous, dismissal of the action must be ordered where there is a potential for injury to the interests of the absent sovereign." 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).

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(2) the extent to which any prejudice could be lessened or avoid 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).

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 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 the Tribe may have in the challenged patents.[13] *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

[13] 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)).

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 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.[14]

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

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[14] 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 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).

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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APPENDIX C

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Paper No. 132
Entered: February 23, 2018

UNITED STATES PATENT AND
TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND
APPEAL BOARD

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

v.

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

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)

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)

[1]

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

PAULRAJ, *Administrative Patent Judge*.

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

Allergan's Motion to Withdraw

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

Allergan seeks to withdraw from these proceedings on the grounds that it has ceased to be an owner of the six patents involved in these

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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. This Order addresses issues that are the same in the identified cases. Paper numbers and exhibits cited in this Order refer to those documents filed in IPR2016-01127.

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

As set forth in our Decision Denying the Tribe's Motion to Terminate, we determine that Allergan remains an effective "patent owner" of the challenged patents in these proceedings based on the terms of its License Agreement with the Tribe. Paper 130, 18–34. Accordingly, we find that the basis for Allergan's request to withdraw does not hold true. We decline, however, to construe the request to withdraw as a request for adverse judgment insofar as the ownership question was not settled at the time Allergan filed its Motion. In this regard, we recognize that the Tribe may still claim an ownership interest in the challenged patents in a subsequent appeal to the Federal Circuit. In order to allow the Tribe to represent its interests in these proceedings before the Board and in any appeals, we will allow the Tribe to continue participating as a patent owner along with Allergan. Allergan and the Tribe shall coordinate their efforts going forward, and shall file joint papers in these proceedings

unless otherwise authorized by the Board. The caption for this Order and subsequent orders and decisions in these proceedings will reflect both Allergan's and the Tribe's status as the named "Patent Owners."

Remaining Schedule

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

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

ORDER

Accordingly, based on the foregoing, it is:

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

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

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

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

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

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APPENDIX D

NOTE: This order is nonprecedential.

United States Court of Appeals
for the Federal Circuit

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

v.

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

2018-1638, -1639, -1640, -1641, -1642, -1643

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00599, PR2017-00576, PR2017-00578, IPR2017-00579, IPR2017-00583, IPR2017-00585 IPR2017-00586, IPR2017-00594, IPR2017-00596, IPR2017-00598, IPR2017-00600, IPR2017-00601

ON MOTION

PER CURIAM.

O R D E R

In this case, Saint Regis Mohawk Tribe notified the Patent Trial and Appeal Board that it had acquired the patents at issue in these *inter partes* reviews from Allergan, Inc. and moved to terminate all proceedings based on the Tribe's sovereign immunity. The Board rejected the Tribe's claim of sovereign immunity, found that the proceedings could continue against Allergan, and declined to stay proceedings. The Board has scheduled a final hearing for April 3, 2018. The Tribe and Allergan have appealed from the Board's rejection of the Tribe's sovereign immunity claim and motion to terminate proceedings and all issues raised therein, and have moved for this court to stay all proceedings before the Board pending their appeals. The appellees oppose the motion. This court *sua sponte* expedited briefing on the merits and scheduled oral argument for June 2018.

Upon consideration thereof,

IT IS ORDERED THAT:

Appellants' motion for a stay is granted until the day after oral argument in June 2018. At this juncture, it appears that the appeals divested the Board of jurisdiction over the aspects of the case on appeal, *see Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56, 58 (1982); *Princz v. Fed. Republic of Ger.*, 998 F.2d 1 (D.C. Cir. 1993) (appeal from denial of motion to dismiss on grounds of sovereign immunity divests district court of jurisdiction over entire case); *Apostol v. Gallion,* 870 F.2d 1335 (7th Cir. 1989); accord *In re Graves*, 69 F.3d 1147, 1149 (Fed. Cir. 1995), and that exclusive jurisdiction to resolve the threshold issue of whether these proceedings must be terminated vests in this court,

and that the Board may not proceed until granted leave by this court. The stay shall remain in effect until the day after oral argument in the appeals in June 2018. The court will address whether the stay shall remain in effect or whether it will be lifted at that time based on further consideration of the merits of the appeals.

FOR THE COURT

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

s19

APPENDIX E

NOTE: This order is nonprecedential.

United States Court of Appeals
for the Federal Circuit

SAINT REGIS MOHAWK TRIBE,
ALLERGAN, INC.,
Appellants

v.

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

2018-1638, 2018-1639, 2018-1640, 2018-1641, 2018-1642, 2018-1643

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00599, PR2017-00576, PR2017-00578, IPR2017-00579, IPR2017-00583, IPR2017-00585 IPR2017-00586, IPR2017-00594, IPR2017-00596, IPR2017-00598, IPR2017-00600, IPR2017-00601

ON PETITION FOR REHEARING EN BANC

Before PROST, C*HIEF JUDGE*, NEWMAN, LOURIE, DYK, MOORE, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL*, CIRCUIT JUDGES**.

PER CURIAM.

O R D E R

Appellants Allergan, Inc. and Saint Regis Mohawk Tribe filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by Appellees Akorn, Inc., Mylan Pharmaceuticals Inc. and Teva Pharmaceuticals USA, Inc. The petition was first referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied

The mandate of the court will issue on October 29, 2018.

FOR THE COURT

October 22, 2018
Date

/s/Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

*Circuit Judge O'Malley did not participate.

APPENDIX F

NOTE: This order is nonprecedential.

United States Court of Appeals
for the Federal Circuit

SAINT REGIS MOHAWK TRIBE,
ALLERGAN, INC.,
Appellants

v.

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

2018-1638, 2018-1639, 2018-1640, 2018-1641, 2018-1642, 2018-1643

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00576, IPR2017-00578, IPR2017-00579, IPR2017-00583, IPR2017-00585, IPR2017-00586, IPR2017-00594, IPR2017-00596, IPR2017-00598, IPR2017-00599, IPR2017-00600, IPR2017-00601.

ON MOTION

PER CURIAM.

O R D E R

Appellants Saint Regis Mohawk Tribe and Allergan, Inc. move to stay issuance of the Court's mandate pending the filing and disposition of a petition for a writ of certiorari in the United States Supreme Court. Appellees Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., and Akorn, Inc. oppose the motion.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.

FOR THE COURT

November 13, 2018
Date

/s/Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX G

NOTE: This disposition is nonprecedential.

United States Court of Appeals
for the Federal Circuit

ALLERGAN, INC.,
SAINT REGIS MOHAWK TRIBE,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
AKORN, INC., MYLAN PHARMACEUTICALS
INC., MYLAN, INC.,
Defendants-Appellees

2018-1130

Appeal from the United States District Court for the Eastern District of Texas in No. 2:15-cv-01455-WCB, Circuit Judge William C. Bryson.

JUDGMENT

JONATHAN ELLIOT SINGER, Fish & Richardson, PC, San Diego, CA, argued for all plaintiffs-appellants. Allergan, Inc. also represented by JUANITA ROSE BROOKS; JOSEPH HERRIGES, JR., DEANNA JEAN REICHEL, Minneapolis, MN; SUSAN E. MORRISON, ROBERT M. OAKES, Wilmington, DE.

MICHAEL W. SHORE, Shore Chan DePumpo LLP, Dallas, TX, for plaintiff-appellant Saint Regis Mohawk Tribe. Also represented by RUSSELL J. DEPALMA, CHRISTOPHER LIIMATAINEN EVANS.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, argued for all defendants-appellees. Teva Pharmaceuticals USA, Inc. also represented by MICHAEL E. JOFFRE, WILLIAM H. MILLIKEN, PAULINE PELLETIER, RALPH WILSON POWERS, III.

MICHAEL R. DZWONCZYK, Sughrue Mion PLLC, Washington, DC, for defendant-appellee Akorn, Inc. Also represented by MARK BOLAND, BENJAMIN CAPPEL.

DOUGLAS H. CARSTEN, Wilson, Sonsini, Goodrich & Rosati, PC, San Diego, CA, for defendants-appellees Mylan Pharmaceuticals Inc., Mylan, Inc. Also represented by CHRISTINA ELIZABETH DASHE; WENDY L. DEVINE, San Francisco, CA.

AARON STIEFEL, Arnold & Porter Kaye Scholer LLP, New York, NY, for amicus curiae Pharmaceutical Research and Manufacturers of America. Also represented by DAVID EVAN KORN, Pharmaceutical Research and Manufacturers Association of America, Washington, DC.

THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (PROST, *Chief Judge*, REYNA and HUGHES, *Circuit Judges*).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

November 13, 2018
Date

/s/Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX H

35 U.S.C. § 135(a) (2010)

Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared and the Director shall give notice of such declaration to the applicants, or applicant and patentee, as the case may be. The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability. Any final decision, if adverse to the claim of an applicant, shall constitute the final refusal by the Patent and Trademark Office of the claims involved, and the Director may issue a patent to the applicant who is adjudged the prior inventor. A final judgment adverse to a patentee from which no appeal or other review has been or can be taken or had shall constitute cancellation of the claims involved in the patent, and notice of such cancellation shall be endorsed on copies of the patent distributed after such cancellation by the Patent and Trademark Office.

35 U.S.C. § 311

(a) In General.—

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

determines to be reasonable, considering the aggregate costs of the review.

(b) Scope.—

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

(c) Filing Deadline.—

A petition for inter partes review shall be filed after the later of either—

(1) the date that is 9 months after the grant of a patent; or

(2) if a post-grant review is instituted under chapter 32, the date of the termination of such post-grant review.

35 U.S.C. § 312

(a) Requirements of Petition.—A petition filed under section 311 may be considered only if—

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

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

(3) the petition identifies, in writing and with particularity, each claim challenged, the grounds

on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim, including—

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

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

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

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

(b) Public Availability.—

As soon as practicable after the receipt of a petition under section 311, the Director shall make the petition available to the public.

35 U.S.C. § 313

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

35 U.S.C. § 314

(a) Threshold.—

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

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

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

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

(c) Notice.—

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

(d) No Appeal.—

The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.

35 U.S.C. § 315

(a) Infringer's Civil Action.—

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

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

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

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

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

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

(b) Patent Owner's Action.—

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

(c) Joinder.—

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

(d) Multiple Proceedings.—

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

(e) Estoppel.—

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

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

35 U.S.C. § 316

(a) Regulations.—

The Director shall prescribe regulations—

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

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

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

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

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

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

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

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

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

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

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

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

(11) requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause

shown, extend the 1-year period by not more than 6 months, and may adjust the time periods in this paragraph in the case of joinder under section 315(c);

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

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

(b) Considerations.—

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

(c) Patent Trial and Appeal Board.—

The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter.

(d) Amendment of the Patent.—

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

(A) Cancel any challenged patent claim.

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

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

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

(e) Evidentiary Standards.—

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

35 U.S.C. § 317

(a) In General.—

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

no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision under section 318(a).

(b) Agreements in Writing.—

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

35 U.S.C. § 318

(a) Final Written Decision.—

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

(b) Certificate.—

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

(c) Intervening Rights.—

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

(d) Data on Length of Review.—

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