

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

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

SAINT REGIS MOHAWK TRIBE and ALLERGAN, INC.,

Appellants,

v.

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

Appellees.

On Appeal from the United States Patent and Trademark Office
Patent Trial and Appeal Board, Administrative Patent Judges Sheridan K. Snedden,
Tina E. Hulse, and Christopher G. Paulraj

**BRIEF FOR THE UNITED STATES AS AMICUS CURIAE
IN SUPPORT OF APPELLEES**

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INTRODUCTION AND INTEREST OF THE UNITED STATES

This case presents the question whether principles of sovereign immunity prevent the United States Patent and Trademark Office (USPTO) from completing an inter partes review of a patent allegedly owned by an Indian tribe. Whether federal administrative proceedings implicate the sovereign immunity of Indian tribes is an issue of cross-cutting significance for the federal government. Transactions like the one at issue here between Allergan and the St. Regis Mohawk Tribe also implicate the interests of federal agencies and offices beyond the USPTO, including the Federal Trade Commission and the Antitrust Division of the Department of Justice. The United States therefore respectfully submits this brief as *amicus curiae*.

In the view of the United States, the Patent Trial and Appeal Board (Board) correctly rejected the St. Regis Mohawk Tribe's motion to terminate the inter partes reviews, for two reasons.

First, an Indian tribe enjoys no immunity from proceedings instituted by agencies of the federal government acting under federal law. The inter partes reviews in this case were instituted by the Director of the USPTO to determine whether the USPTO erred in issuing the Restasis patents in the first place. Although Congress afforded significant participatory rights to the private parties, like Mylan, who persuade the USPTO to institute a review of a particular patent, an inter partes review at bottom involves "reconsideration of the Government's decision to grant a public

franchise.” *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1373 (2018). No principle of sovereign immunity entitles an Indian tribe to withhold a public franchise from reconsideration by the superior sovereign that granted it.

Second, in any event, the Board correctly concluded that Allergan remains the operative patentee under the Patent Act because its license agreement with the St. Regis Mohawk Tribe reserves to Allergan all substantial rights to exploit, maintain, and enforce the Restasis patents. That is not surprising, as the evident purpose of the transaction—in effect, the commercial rental of a tribe’s sovereign immunity to a pharmaceutical company—was to allow Allergan to retain and enforce its patents without risk of an adverse decision in the inter partes review. That gambit cannot succeed. If Allergan enjoys the right to place the validity of the Restasis patents at issue by enforcing the patents itself, it can equally defend the patentability of the challenged claims before the Board.

STATEMENT

A. Administrative Review of Issued Patents

“Over the last several decades, Congress has created administrative processes that authorize the PTO to reconsider and cancel patent claims that were wrongly issued.” *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1370 (2018). This Court is by now well familiar with these processes. Although each may be triggered by the request of a private party, none may proceed unless the

USPTO itself affirmatively decides to take “a second look at an earlier administrative grant of a patent.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016).

First, in 1980, Congress created the ex parte reexamination procedure with the goal of restoring public and commercial “confidence in the validity of patents issued by the PTO” by providing a speedy and inexpensive mechanism for eliminating patents that had been wrongly issued. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 601 (Fed. Cir.), *modified on other grounds on reh’g*, 771 F.2d 480 (Fed. Cir. 1985); *see* Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified at 35 U.S.C. ch. 30). Through ex parte reexamination, the Director may, “[o]n his own initiative” and at “any time,” reexamine an already-issued patent if the Director finds that there exists “a substantial new question of patentability” in light of the prior art. 35 U.S.C. §§ 301(a)(1), 303(a). In addition, “[a]ny person at any time” may “file a request” that the Director make that finding and institute such a reexamination. *Id.* § 302. Upon reexamination, USPTO can cancel any claim of the patent determined to be unpatentable. *See id.* § 307.

Second, in 1999, Congress created inter partes reexamination, the predecessor to inter partes review. Inter partes reexamination was closely akin to ex parte reexamination, including in that the proceeding could not commence unless the Director found a substantial new question of patentability. *See Cuozzo*, 136 S. Ct. at 2137–38. The inter partes process, however, allowed “third parties greater

opportunities to participate in the Patent Office’s reexamination proceedings,” and, after 2002, in any subsequent appeal of the USPTO’s decision. *Id.* (citing statutes).

Finally, in 2011, Congress enacted the Leahy–Smith America Invents Act (AIA), which replaced inter partes reexamination with inter partes review. *See* Pub. L. No. 112-29, § 6, 125 Stat. 284, 299–304 (2011); *see generally* *Cuozzoco*, 136 S. Ct. at 2137. Inter partes review, like inter partes reexamination, allows the USPTO to take “a second look at an earlier administrative grant of a patent,” but provides third parties with “broader participation rights” if the USPTO institutes a proceeding. *Cuozzoco*, 136 S. Ct. at 2137, 2144; *see* 35 U.S.C. § 311 *et seq.*

Under the inter partes review scheme, any individual other than the patent owner may file a petition for review of an issued United States patent on the ground that, at the time the patent was issued, the invention was not novel or was obvious in light of specified forms of prior art. 35 U.S.C. §§ 311, 312. The patent owner must be given a copy of the petition, *id.* § 312(a)(5), and has the option to file a preliminary response, *id.* § 313, but need not respond at all. An inter partes review does not commence unless and until the Director of the USPTO reviews the submissions and affirmatively decides to institute the review after finding a reasonable likelihood that the challenger can establish the unpatentability of “at least 1 of the claims challenged in the petition.” *Id.* § 314(a).¹ The Director’s decision whether to institute an inter

¹ The Director has delegated this authority to the Board. *Cuozzoco*, 136 S. Ct. at 2149 n.2.

partes review is final and nonappealable. *Id.* § 314(d); *see also* *Cuozzok*, 136 S. Ct. at 2141–42.

If the Director elects to institute a review, the Patent Trial and Appeal Board conducts the proceeding. *See* 35 U.S.C. § 316(c). The burden of showing the unpatentability of every challenged claim is on the petitioner. *Id.* § 316(e). The Board may resolve the patentability of the contested patent claims, however, without regard to whether the petitioner continues to dispute any proposition, and “even after the adverse party has settled.” *Cuozzok*, 136 S. Ct. at 2144; *see* 35 U.S.C § 317(a).

At the conclusion of the proceedings, the Board issues a final written decision addressing the patentability of the claims. 35 U.S.C. § 318(a). The USPTO may intervene in any ensuing appeal, *see id.* § 143, and frequently does so when the challenger drops out of the case as a result of a settlement or business indifference. After any appeals are exhausted, the USPTO issues a “certificate” cancelling any claims deemed unpatentable, confirming any claims deemed patentable, and “incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.” *Id.* § 318(b). New and amended claims are enforceable against the public at large in the same manner as claims in reissued patents. *See id.* § 318(c).

B. Prior Proceedings

The Board instituted inter partes review on six patents owned by Allergan that relate to Restasis, an eye-drop medication approved by the Food and Drug Administration (FDA) for treating chronic dry eyes. *See* Appellants’ Br. 6.²

After Allergan and the petitioners filed papers addressing the patentability of the asserted claims, and one week before the scheduled oral hearing, Allergan assigned the patents to the St. Regis Mohawk Tribe (Tribe). *See* Appellants’ Br. 11.

Simultaneously, the parties executed a license agreement that granted back to Allergan an exclusive license to exploit the Restasis patents “for all FDA-approved uses in the United States” that refer or relate to the uses for which Restasis is approved by the FDA. *See* Appx2572–2606 (License). Under the terms of the agreements, the Tribe will receive \$13.5 million, plus an additional \$15 million in annual royalties. The license specifically obligates the Tribe to “assert its sovereign immunity in any Contested PTO Proceeding, including in the [inter partes review] Proceedings” at

² Four of the six patents at issue in these inter partes review proceedings are the subject of infringement litigation in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-CV-1455-WCB (E.D. Tex.). In October 2017, the district court—Circuit Judge Bryson, sitting by designation—found the four patents invalid for obviousness. *See* Findings of Fact & Conclusions of Law, *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 4803941, at *65 (E.D. Tex. Oct. 16, 2017). The district court joined the Tribe as a plaintiff in that litigation, but expressed “serious doubts that the transaction in which Allergan has sought to obtain immunity from inter partes review by the PTO in exchange for payments to the Tribe is the kind of transaction to which the Tribe’s sovereign immunity was meant to extend.” Mem. Op. & Order, *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 4619790, at *3 (E.D. Tex. Oct. 16, 2017).

issue in this case. Appx2584 (License § 5.3). Consistent with this agreement, the Tribe moved to terminate the inter partes reviews on the grounds of tribal sovereign immunity, and Allergan moved to withdraw from the proceedings. *See* Appellants’ Br. 11.

The Board denied both motions. The Board first found that inter partes review proceedings do not implicate tribal sovereign immunity from private suit. Appx1; Appx43. The Board rejected the Tribe’s argument that, under the Supreme Court’s reasoning in *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. 743, 757–58 (2002), inter partes reviews are akin to private civil litigation from which the Tribe would be immune. Appx16–18. Alternatively, the Board concluded that, even if the inter partes reviews implicated tribal sovereign immunity, the proceedings could continue without the Tribe’s participation because the license between the Tribe and Allergan granted to Allergan all substantial rights to the patents. Appx18–35.

ARGUMENT

The United States has long been “committed to a policy of supporting tribal self-government and self-determination.” *National Farmers Union Ins. Cos. v. Crow Tribe of Indians*, 471 U.S. 845, 856 (1985). The Supreme Court has explained that a tribe’s immunity from suit is “a necessary corollary to Indian sovereignty and self-governance.” *Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2030 (2014). The

United States has frequently supported and defended that immunity against intrusion by States and private litigants.

A USPTO proceeding to reconsider the agency's own prior grant of a patent, however, does not implicate a tribe's sovereign immunity from suit. An Indian tribe enjoys no prerogative to shield a United States patent from reconsideration by the federal sovereign that granted it. And in any event, as the Board explained, the inter partes reviews in this case may proceed without the Tribe, because Allergan remains the operative patentee under the Patent Act.

I. Inter Partes Reviews Do Not Implicate Tribal Immunity from Suit

A. Tribal immunity does not preclude the USPTO from reconsidering its own decision to grant the Restasis patents.

An Indian tribe's sovereign immunity from suit extends to suits brought by private individuals and to suits brought by States. *Bay Mills*, 134 S. Ct. at 2030–31. But the sovereign immunity of a tribe, like the sovereign immunity of a State, “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); *see, e.g., Washington v. Confederated Tribes of Colville Indian Reservation*, 447 U.S. 134, 154 (1980) (explaining that “tribal sovereignty is dependent upon, and subordinate to, only the Federal Government”). Consequently, neither a State nor an Indian tribe enjoys immunity against proceedings instituted by agencies of the federal government acting under federal law. *See Federal Mar. Comm'n v. South Carolina State Ports Auth.*, 535 U.S.

743, 768 (2002) (explaining that a state agency would not be immune from an administrative proceeding commenced by the Federal Maritime Commission); *Pauma v. NLRB*, --- F.3d ----, 2018 WL 1955043, at *8 (9th Cir. Apr. 26, 2018) (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).

That principle resolves this case. The St. Regis Mohawk Tribe could not claim immunity from a civil action by the United States for a declaratory judgment that the Restasis patents were wrongly granted. *Cf. United States v. American Bell Tel. Co.*, 128 U.S. 315 (1888). That would be true even if a private party brought the patentability issue to the government’s attention and petitioned the United States to commence that proceeding. For the same reasons, the Tribe cannot claim immunity from an inter partes review instituted by the Director of the USPTO to reconsider whether the agency erred in granting the Restasis patents in the first place.

Inter partes review is a discretionary administrative mechanism for the USPTO to correct its own mistakes. Although it is triggered by a petition from a private party, 35 U.S.C. § 311, that petition does not itself commence the inter partes review, but rather asks the Director of the USPTO to exercise his discretion to institute a

proceeding.³ The decision whether to grant the petition and undertake a review is the Director’s alone: Congress provided that his determination whether to institute the proceeding “shall be final and nonappealable.” 35 U.S.C. § 314(d). The Director may deny a petition on the merits, or for any other reason—for example, that the challenged claims have no economic significance, or that the Board’s docket is already too crowded. As the Supreme Court has stressed, the “decision to deny a petition is a matter committed to the Patent Office’s discretion” under the Administrative Procedure Act. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (citing 5 U.S.C. § 701(a)(2)); *see also id.* at 2153 (Alito, J., dissenting) (“I agree that one can infer from the statutory scheme that the Patent Office has discretion to deny inter partes review even if a challenger satisfies the threshold requirements for review.”).

Congress’s decision to vest the institution decision exclusively in the Director’s discretion makes clear that inter partes review is, at bottom, a tool for the USPTO itself to “revisit and revise earlier patent grants.” *Cuozzo*, 136 S. Ct. at 2140. That

³ The Supreme Court held in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018), that the AIA does not authorize the Director to institute review on a claim-by-claim basis; rather, the Director must make a “binary choice” on the petition presented to the agency—“either institute review or don’t.” Nonetheless, as *SAS Institute* makes clear, the choice “*whether* to institute review” is within the Director’s exclusive discretion. *Id.* (citing § 314(a)). And as the Court stressed in its decision issued on the same day in *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365 (2018), although inter partes review is triggered by a private party’s petition, “inter partes review is not initiated by private parties in the way that a common-law cause of action is” because “the decision to institute review is made by the Director and committed to his unreviewable discretion.” *Id.* at 1378 n.5.

understanding accords with the history of the Patent Act. Congress has for decades permitted the Director of the USPTO to institute proceedings to reexamine patents previously granted by the agency. 35 U.S.C. § 301 *et seq.* (ex parte reexamination); 35 U.S.C. § 311 *et seq.* (2006) (inter partes reexamination). As relevant here, inter partes review differs from prior reexamination schemes principally in the degree to which it relies on the knowledge and incentive of interested members of the public to bring examination errors to the agency’s attention, and to establish the existence of those errors to the agency’s satisfaction. But the fundamental purpose of the proceeding is the same: to allow the USPTO to revisit its earlier decision to grant the 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.” *Cuozz*, 136 S. Ct. at 2144.

Other features of the statutory scheme underscore that inference. In section 317, for example, Congress provided that the USPTO may continue with an inter partes review and issue a final written decision addressing the patentability of the challenged claims even when every petitioner in the review has settled or dropped out. *See* 35 U.S.C. § 317(a) (“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).*” (emphasis added)). Likewise, as this Court knows well, “the Patent Office may intervene in a later *judicial* proceeding to defend its decision—even if the private challengers drop out.” *Cuozz*, 136 S. Ct. at 2144; *see* 35 U.S.C. § 143; *see also Knowles*

Elecs. LLC v. Iancu, 886 F.3d 1369, 1372 n.2 (Fed. Cir. 2018) (rejecting a challenge to this practice).

These features of the statutory scheme make sense only on the understanding that the inter partes review is the USPTO's own proceeding, instituted by the Director and conducted for a superseding public purpose: to "improve patent quality and restore confidence in the presumption of validity that comes with issued patents." H.R. Rep. No. 112-98, pt. 1, at 48 (2011). Indeed, Allergan and the St. Regis Mohawk Tribe have relied on that presumption of validity, *see* 35 U.S.C. § 282(a), and the clear-and-convincing evidence standard it provides, *see Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011), in asserting infringement of the Restasis patents in district court. Yet as the Supreme Court has noted, the primary rationale for that presumption is "that the [USPTO], in its expertise, has approved the claim." *KSR Int'l Co. v. Teleflex Co.*, 550 U.S. 398, 426 (2007). Congress authorized the USPTO to conduct inter partes reviews to ensure that the existence of a United States patent actually reflects the USPTO's current, informed judgment that the claimed invention satisfies statutory patentability requirements.

Because inter partes review is a proceeding instituted by the federal government for the benefit of the public at large, tribal sovereign immunity poses no obstacle to its conduct. The USPTO granted the claims of the Restasis patents, and the Director of the USPTO is entitled to institute a proceeding to reconsider that decision so that the public may be certain of what properly belongs to it. *Cf. Graham*

v. John Deere Co., 383 U.S. 1, 6 (1966) (statutory conditions of patentability prevent the “issuance of patents whose effects are to remove existent knowledge from the public domain”). As the Board correctly concluded, no principle of Indian sovereign immunity permits a tribe to impede that inquiry.

B. *Oil States* confirms that inter partes reviews involve the federal government’s discretionary reconsideration of its own prior decisions.

The Supreme Court recently confirmed that inter partes review is properly understood as the government’s reconsideration of the government’s own decision to approve a public franchise. *Oil States Energy Servs., LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365 (2018). The Court’s reasoning in *Oil States* leaves no room for the Tribe’s characterization of inter partes review as merely private civil litigation by another name.

The petitioner in *Oil States* contended that inter partes review violates Article III and the Seventh Amendment by allowing the USPTO to adjudicate litigation between private litigants over the validity of private property rights. The Supreme Court rejected that contention and upheld the constitutionality of the statute. The Court explained that inter partes review is consistent with Article III because it simply allows the USPTO to take “a second look at an earlier administrative grant of a patent” and thereby protect “the public’s paramount interest in seeking that patent monopolies are kept within their legitimate scope.” 138 S. Ct. at 1374 (quoting *Cuozzo*, 136 S. Ct. at 2144); *see also MCM Portfolio LLC v. Hewlett-Packard*

Co., 812 F.3d 1284, 1290 (Fed. Cir. 2015) (explaining that Congress created inter partes review “for an important public purpose—to correct the agency’s own errors in issuing patents in the first place”).

As particularly relevant here, the Court rejected the contention that inter partes review is constitutionally equivalent to private infringement litigation merely because inter partes review occurs after the patent has issued. *Oil States*, 138 S. Ct. at 1374. Patents are public franchises, the Court explained, and they are granted subject to the lawful condition that they may be reexamined for compliance with the statutory conditions of patentability. *See id.*; *see also id.* at 1375 (explaining that the property rights conferred by a patent are “qualifie[d]” by “the express provisions of the Patent Act,” “includ[ing] inter partes review”). An Indian tribe that takes assignment of a United States patent takes ownership subject to that same lawful condition.

Likewise, the Court in *Oil States* rejected the petitioner’s characterization of inter partes review as merely traditional civil litigation transplanted into an administrative agency. “Although inter partes review includes some of the features of adversarial litigation,” the Court observed, “it does not make any binding determination regarding ‘the liability of [one party] to [another] under the law as defined.’” 138 S. Ct. at 1378 (citation omitted). Rather, the Court explained, inter partes review comports with the Constitution because it involves administrative “reconsideration of the Government’s decision to grant a public franchise.” *Id.* at 1373. Inter partes review therefore involves “matters ‘which arise between the

Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive . . . department[].” *Id.* (quoting *Crowell v. Benson*, 285 U.S. 22, 50 (1932)).

Although the Board in this case did not have the benefit of *Oil States*, the Supreme Court’s reasoning leaves no doubt that the Board correctly rejected the Tribe’s assertion of immunity. As the Board explained, an Indian tribe is not immune from federal administrative proceedings instituted by the federal government itself, *see* Appx14, even if those proceedings are initiated at the instance of, and accommodate participation by, private parties, Appx15. *Oil States* establishes that, notwithstanding the participatory rights enjoyed by petitioners before the Board, inter partes reviews involve reconsideration of a matter arising “between the Government and persons subject to its authority.” 138 S. Ct. at 1373 (internal quotation marks and citation omitted). Because Indian tribes are subject to the authority of the federal government and have no claim of immunity against it, the Board correctly denied the motions to terminate.

C. The Tribe’s reliance on *Federal Maritime Commission* is misplaced.

In urging reversal, Allergan and the Tribe principally rely (Br. 21–24) on *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. 743 (2002) (FMC). But that case is no help to appellants here, because inter partes review differs from the

coercive administrative proceedings at issue in *FMC* in ways critical to the Court’s analysis.

FMC involved a claim by a private company that the South Carolina State Ports Authority, a state agency, had unreasonably discriminated against and refused to negotiate with the company in violation of the Shipping Act, causing the company to suffer damages and lost profits. *See* 535 U.S. at 748. The company filed a complaint with the Federal Maritime Commission (Commission) under 46 U.S.C. app. § 1710(a), which provides that any person “may file with the Commission a sworn complaint alleging a violation of [the Shipping Act] . . . and may seek reparation for any injury caused to the complainant by that violation.” *FMC*, 535 U.S. at 748 n.1. The company’s “sworn complaint” sought, *inter alia*, an order from the Commission directing the state agency “to pay reparations . . . as well as interest and reasonable attorney’s fees,” as well as an order “commanding” the state agency “to cease and desist from violating the Shipping Act” in the future. *Id.* at 749.

The Supreme Court concluded that state sovereign immunity barred the Commission from adjudicating such a complaint against a nonconsenting State. *FMC*, 535 U.S. at 760. In so holding, the Court emphasized the respects in which the Commission’s proceedings mirrored federal litigation, in which the State would enjoy immunity against similar claims. *See id.* at 757 (noting the “remarkably strong resemblance to civil litigation in federal courts”). The administrative proceeding commenced automatically upon the company’s filing of its sworn complaint; the

Commission had no discretion to refuse to adjudicate the claim. *Id.*; *see id.* at 764.

The state agency, in turn, was required to answer the complaint, and the Commission could enter a default judgment against the state agency if the state agency failed to do so. *Id.* The private plaintiff in the Commission proceeding was entitled to discovery “virtually indistinguishable” from that available under civil discovery rules, including wide-ranging depositions, interrogatories, and requests to enter and inspect property. *Id.* at 758. And the administrative law judge presiding over the case had authority analogous to that of an Article III judge, *id.* at 756, 758–59, including the power to direct the payment of reparations and attorney’s fees, *id.* at 759.

FMC thus involved exactly what the Supreme Court in *Oil States* concluded that inter partes review does not: coerce private litigation, commenced by private claimants, over which the federal agency presided only as a disinterested decisionmaker. Inter partes review, by contrast, is instituted by the USPTO itself. The Supreme Court recognized in *FMC* that sovereign immunity would not have posed an obstacle if the Commission had instituted its own proceeding against the state agency: “The FMC . . . remains free to investigate alleged violations of the Shipping Act, either upon its own initiative or upon information supplied by a private party, and to institute its own administrative proceeding against a state-run port.” 535 U.S. at 768 (citations omitted). Appellants contend (Br. 28–29) that inter partes review is different from such an enforcement proceeding. But that is because inter partes review presents an even easier case: it is a proceeding instituted in a federal

agency's discretion, based upon information supplied by a private party, to determine *whether the agency itself previously erred* in issuing a public franchise under federal law. *See Oil States*, 138 S. Ct. at 1373 (describing inter partes review as the “reconsideration of the Government’s decision to grant a public franchise”).

Three points of contrast with *FMC* are especially instructive. First, the Supreme Court in *FMC* stressed that “[t]he prosecution of a complaint filed by a private party with the FMC is plainly not controlled by the United States, but rather is controlled by that private party Indeed, the FMC does not even have the discretion to refuse to adjudicate complaints brought by private parties.” *FMC*, 535 U.S. at 764. The Director of the USPTO, by contrast, enjoys exactly that authority: “The decision whether to institute inter partes review is committed to the Director’s discretion.” *Oil States*, 138 S. Ct. 1365, at 1371; *see also id.* at 1378 n.5 (explaining that inter partes review is “not initiated by private parties in the way that a common-law cause of action is”). On that basis alone, the Tribe’s reliance on *FMC* fails: because the power to institute an inter partes review is vested in the Director alone, political accountability for the institution of an inter partes review rests squarely with the federal government, against which an Indian tribe has no claim to immunity. *Cf. FMC*, 535 U.S. at 764 (emphasizing that the United States did not have political accountability for Shipping Act claims against States, but had instead impermissibly delegated that choice to private individuals).

Second, unlike in *FMC*, there should be no possibility of a “default judgment” in an inter partes review against a patent owner who fails to respond to a petition. The patent owner’s response to a petition is optional, *see* 35 U.S.C. § 313, and the burden of establishing unpatentability of the claims challenged in the petition at all times remains on the petitioner, 35 U.S.C. § 316(e).⁴ As already discussed, moreover, “challengers [in inter partes review] need not remain in the proceeding” for the USPTO to continue to conduct its review. *Cuozz*, 136 S. Ct. at 2144. Congress’s focus on the USPTO’s own continued ability to review the patent, rather than the existence of a continuing dispute between adverse parties, demonstrates that inter partes review is the “reconsideration of the Government’s decision to grant a public franchise”—not, as in *FMC*, a forum for the adjudication of disputes between adverse litigants. *Oil States*, 138 S. Ct. at 1373.

⁴ Appellants misunderstand (Br. 27) the Board’s ability to enter adverse judgment against a patent owner who “abandons” the proceedings. The regulation cited by appellants sensibly allows the Board to construe certain actions by the patent owner as a “request for adverse judgment,” including the patent owner’s “concession of unpatentability,” “disclaimer of the involved application or patent,” or “abandonment of the contest.” 37 C.F.R. § 42.73. In this context, “abandonment of the contest” refers to a patent owner’s abandonment of the proceedings after the patent owner has appeared and participated in the proceedings, similar to a “[c]oncession of unpatentability” or “[d]isclaimer” of the patent. *See id.* Appellants acknowledge (Br. 27) that a patent owner is not required to respond to a petition for inter partes review or to file a response after institution. *See* 37 C.F.R. §§ 42.107; 42.120.

Third, and most significant, the administrative law judge in *FMC* could both impose legal liability on the State and direct it to pay monetary reparations and attorneys' fees to the complainant. By contrast, USPTO "does not make any binding determination regarding 'the liability of [one party] to [another] under the law as defined.'" *Oil States*, 138 S. Ct. at 1378. Nor can the USPTO award monetary relief—or, indeed, *any* relief specific to the petitioner. As the Board put it: "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." Appx16.

Rather, at the end of an inter partes review, the USPTO may only "issue and publish a certificate" that cancels or confirms the challenged patent claims and incorporates into the patent any amendments made during the proceeding. 35 U.S.C. § 318. That certificate is a public regulatory act of the federal government in its own right, effective against the world: it amends an issued United States patent for the benefit of the public. *Cf. id.* § 318(c) (specifying the intervening rights of the public under new and amended patent claims incorporated into a patent during an inter partes review). An Indian tribe enjoys no sovereign prerogative to prevent the federal government from taking such an action in the public interest.

In sum, an inter partes review allows the USPTO to do only what the agency could have done "in the first instance" in deciding whether "to grant a patent." *Oil States*, 138 S. Ct. at 1374. While the proceeding is instituted based on information

supplied by a private petitioner, the petitioner takes nothing from the proceeding that it would not equally have gained if the USPTO had simply denied the patent application in the first place. Nothing in *FMC* suggests that an Indian tribe's immunity extends to a federal agency's discretionary reconsideration of its own administrative decision in this manner.

This Court's opinion in *Vas-Cath, Inc. v. Curators of the University of Missouri*, 473 F.3d 1376, 1382 (Fed. Cir. 2007), is not to the contrary. The Court in *Vas-Cath* held that a State's initiation of interference proceedings in the USPTO waived the State's sovereign immunity to subsequent judicial review of those proceedings. *Id.* at 1382–33. The Court analogized interference proceedings to a “lawsuit,” but only in the course of applying the litigation-waiver doctrine, pursuant to which a State's initiation of a lawsuit constitutes a waiver of the State's sovereign immunity for that lawsuit. *See id.* The Court in *Vas-Cath* did not address whether sovereign immunity applied in interference proceedings themselves. And in any event, as the Board recognized, interferences—which involve competing claims between private inventors for priority in a particular invention—are materially different from inter partes reviews. *See* Appx11 n.5 (distinguishing inter partes review proceedings, which assess “the patentable scope of previously granted patent claims,” from interference proceedings, “which necessarily involve determining the respective rights of adverse parties concerning priority of inventorship”).

II. In Any Event, Allergan Remains the “Owner” of the Restasis Patents Under the Patent Act

For the reasons discussed above, this Court should affirm the Board on the straightforward ground that inter partes review does not implicate tribal sovereign immunity. That resolution of the question presented will provide the greatest clarity to the parties and the patent community by establishing that patents held by domestic sovereigns are not impervious to reconsideration by the USPTO, regardless of how they may be acquired, reassigned, or licensed.

If the Court reaches the question, however, it should affirm the Board’s conclusion that the inter partes reviews in this case may proceed without regard to the Tribe because Allergan remains the operative “patent owner” under the Patent Act. *See* Appx18–19. The evident purpose of Allergan’s transaction with the Tribe was to retain the ability to enforce and defend the Restasis patents in court, while eliminating the risk that the USPTO would conclude that it had issued the patents in error. Under the Patent Act, however, Allergan either stands in the shoes of the patentee, or it does not: it cannot claim the mantle of “the patentee” for purposes of exploitation and enforcement, yet disclaim the capacity to act as the “patent owner” in an inter partes review.

In general, only the owner of the patent—that is, the “patentee”—has a cause of action to sue for infringement. *See* 35 U.S.C. § 281 (“A patentee shall have remedy by civil action for infringement of his patent.”). Thus, it is well settled that an

ordinary licensee under a patent may not file an infringement suit to enjoin competitors from practicing the patent without the patent owner's participation in the lawsuit. *Waterman v. Mackenzie*, 138 U.S. 252, 255 (1891). An ordinary licensee is also unable to defend the validity of a patent in his own name. *See, e.g., Delano Farms Co. v. California Table Grape Comm'n*, 655 F.3d 1337, 1342 (Fed. Cir. 2011). In short, “a patentee is a necessary party to an action on the patent.” *Id.*

At the same time, the Patent Act also authorizes a patent owner to confer “an exclusive right” in the patent to others. 35 U.S.C. § 261. In such circumstances, it makes little sense to insist that the original patentee commence and defend infringement litigation, because the original patentee may no longer have any substantial interest in the question. This Court's decisions accordingly recognize that, when a patent owner grants “all substantial rights” in the patent to an exclusive licensee, the exclusive licensee may be deemed the effective “owner of the patent” or “patentee”—that is, the person entitled under the Patent Act to enforce and defend the patent in its own name. *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1360 (Fed. Cir. 2010) (*Mann Foundation*); *Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1340–41 (Fed. Cir. 2006); *see Delano Farms Co.*, 655 F.3d at 1342 (when a patentee transfers all substantial rights in the patent to an exclusive licensee, the patentee is “no longer regarded as the owner of the patent,” and “need not be joined in any action brought on the patent”). Put another way, the “patentee” or “patent owner” under the Patent Act is the person empowered to exploit and assert

the exclusive rights the patent confers, regardless of who has legal title to the instrument. *Aspex Eyewear*, 434 F.3d at 1340–41; *Delano Farms Co.*, 655 F.3d at 1342.

The Board correctly applied this framework in concluding that Allergan remains the effective patent owner under the Patent Act, notwithstanding its assignment to the Tribe of legal title in the Restasis patents, and that Allergan may therefore act as the patentee in the inter partes reviews. *See* Appx18–19. Appellants resist this logic, asserting (Br. 35) that the “effective patentee” inquiry is limited to determining standing in infringement litigation. But appellants offer no principled reason for why this is so. A central point of this Court’s cases allowing an exclusive licensee who enjoys “all substantial rights” in a patent to bring suit for infringement as the “patentee” is that it is the exclusive licensee, not the patentee, whose interests are principally at stake in the litigation. But that reasoning runs both ways: if Allergan controls the right to sue for infringement under the Restasis patents, then it has the power to place the validity of those patents at issue in court, with the concomitant risk of invalidation. And if Allergan is the “patentee” for that purpose, then by the same logic, it is also the “patent owner” before the Patent Trial and Appeal Board.

The Board correctly concluded that Allergan retains “all substantial rights” under the Restasis patents. *See* Appx20–35. Allergan and the Tribe labor to demonstrate that the Tribe’s rights under the parties’ license agreement are not purely for show. Mylan’s brief demonstrates in detail why those assertions miss the mark

under the factors discussed by this Court in *Mann Foundation*, 604 F.3d at 1360–61, and similar cases.

The essential details of the arrangement, however, leave little doubt about the nature of the transaction. Restasis is a billion-dollar drug. Allergan has not suggested it gave up its right to exclude generic drug companies, such as Mylan, from seeking FDA approval to introduce competing products. And the license agreement makes clear that Allergan did not: after taking assignment of the patents for which the Tribe paid nothing, the Tribe immediately transferred back to Allergan the first right to control and prosecute infringement actions that relate to any “Generic Equivalent” to Restasis. *See* Appx2576; Appx2582 (License §§ 1.23, 5.2.2). The Tribe may bring infringement claims relating a Generic Equivalent only in the unlikely event that Allergan chooses not to do so—and even then, only if Allergan gives the Tribe “written consent” to prosecute such infringement. Appx2582 (License § 5.2.2).

Likewise, the license reserves to Allergan “an irrevocable, perpetual, transferable and exclusive license” to exploit the patents for “all FDA-approved uses in the United States” that refer or relate to Restasis and its approved indication for treating dry eye. *See* Appx2575–2576; Appx2578–2579 (License §§ 1.19, 1.33, 2.1, 3.1). That grant encompasses the entire practical scope of the patents, which are directed to the pharmaceutical composition and methods for treating dry eye. As the Board observed, Allergan’s “right to exploit the patents for ‘all FDA-approved uses’ [for treating dry eye] is effectively co-extensive with the scope of the claimed

inventions.” Appx27. Allergan cannot walk away from an inter partes review on the ground that it no longer owns the Restasis patents, yet retain both the exclusive right to enforce and to exploit the patents for all practical commercial purposes.

It is also telling that Allergan retained the right to act as the patent owner for all *other* purposes before the USPTO. The license agreement preserves for Allergan—not the Tribe, the putative patentee—the primary responsibility to maintain and develop the Restasis patent portfolio. *See* Appx2581 (License § 5.1.1). It is Allergan’s prerogative to prepare, file, and prosecute all related patent applications; it is Allergan’s job to apply for patent term extensions and adjustments; and it is Allergan’s responsibility to pay USPTO maintenance fees on the patents. Appx2581–2582 (License §§ 5.1.1, 5.1.5, 5.1.6). In no real-world sense do these patents belong to the St. Regis Mohawk Tribe.

Indeed, the Tribe has publicly acknowledged as much. The Board cited evidence in the record from the Tribe’s own website, which assured tribal members that the Tribe was “not investing any money in this [patent] business” and that its “only role” was “to hold the patents, get assignments, and make sure that the patent status with the [USPTO] is kept up to date.” Appx28 (citing IPR2016-01127, Ex. 1145). Given this evidence, the Board reasonably refused to give any significance to the minimal, peripheral, and technical rights of exploitation supposedly granted to the Tribe under the parties’ agreement. *See Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1344 (Fed. Cir. 2014), *vacated on other grounds and remanded by* 135 S. Ct. 1384

(2015) (explaining that a hypothetical retained right of exploitation “ha[d] little force” because the licensor did “not make or sell any products” and there was nothing in the record to suggest it would make products “in the future”).

In short, in every respect other than naked legal title, Allergan remains the owner of the Restasis patents. That should not be surprising: it strains credulity to imagine that Allergan would jeopardize its right to enforce the patents protecting Restasis. And as the Board recognized, if Allergan can enforce those patents (and thus place the validity of the patents in question), it can likewise act as the patent owner in the inter partes reviews.

CONCLUSION

For the foregoing reasons, the Court should affirm the Board's decision to proceed with the inter partes reviews.

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CERTIFICATE OF SERVICE

I hereby certify that on May 11, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Courtney L. Dixon

Courtney L. Dixon

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rules of Appellate Procedure 29(a) and 32(a) because it contains 6,973 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2013 in Garamond 14-point font, a proportionally spaced typeface.

s/ Courtney L. Dixon

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