INTHE

Supreme Court of the United States

SAINT REGIS MOHAWK TRIBE AND ALLERGAN, INC.,

Petitioners,

V.

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

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI

MARSHA KOSTURA SCHMIDT ATTORNEY AT LAW 14928 Perrywood Drive Burtonsville, MD 20866 Tel: (301) 949-5176

MICHAEL W. SHORE ALFONSO GARCIA CHAN CHRISTOPHER L. EVANS JOSEPH F. DEPUMPO SHORE CHAN DEPUMPO LLP 901 Main St., Suite 3300 Dallas, TX 75202 Tel: (214) 593-9110

Counsel for Saint Regis Mohawk Tribe

Dated: December 20, 2018

JONATHAN S. MASSEY

Counsel of Record

MASSEY & GAIL LLP
1325 G St., N.W., Suite 500

Washington, DC 20005

Tel: (202) 652-4511

ROBERT A. LONG, JR.
JEFFREY B. ELIKAN
THOMAS R. BRUGATO
ALAINA M. WHITT
COVINGTON & BURLING LLP
850 Tenth Street, N.W.
Washington, DC 20001-4956
Tel: (202) 662-5612

Counsel for Allergan, Inc.

QUESTION PRESENTED

This case involves the legal characterization of the *inter partes* review procedure for patents, created by the Leahy–Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). This Court has described *inter partes* review as a "procedure allow[ing] private parties to challenge previously issued patent claims in an adversarial process before the Patent Office that mimics civil litigation." *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1352 (2018).

In this case, the Federal Circuit held that a federally recognized Indian tribe owning a patent could not assert tribal sovereign immunity in an *inter partes* review proceeding because the proceeding is "more like an agency enforcement action than a civil suit brought by a private party." Pet. App. 9a.

The Question Presented is:

Whether *inter partes* review before the Patent Trial and Appeal Board is the type of proceeding in which tribal sovereign immunity may be asserted.

PARTIES TO THE PROCEEDING

The caption to the case contains the names of all parties.

RULE 29.6 STATEMENT

The Saint Regis Mohawk Tribe is a federally recognized Indian tribe.

Allergan plc is the parent company of Allergan, Inc. and owns more than 10% of its stock.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners the Saint Regis Mohawk Tribe (the "Tribe") and Allergan, Inc. ("Allergan") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the Federal Circuit (Pet. App. 1a-28a) is published at 896 F.3d 1322 (2018). The decisions of the Patent Trial and Appeal Board (Pet. App. 29a-73a, 74a-80a) are published at 2018 WL 1100950 and 2018 WL 1055669.

JURISDICTION

Petitioners' position is that the Patent Trial and Board ("PTAB" or "Board") Appeal jurisdiction below, due to the doctrine of tribal sovereign immunity, but the PTAB rejected that objection. Pet. App. 39a-47a. The Court of Appeals had jurisdiction to review the PTAB's decision pursuant to 35 U.S.C. § 141(c) and 28 U.S.C. § 1295 (a)(4)(A). The Court of Appeals issued its decision on July 20, 2018 (Pet. App. 1a) and denied Petitioners' timely petition for rehearing en banc on October 22, 2018. Pet. App. 84a-86a. This Court has jurisdiction under 28 U.S.C. § 1254 (1).

STATUTORY PROVISIONS INVOLVED

Relevant statutory provisions, including portions of the Leahy–Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA") are reproduced in the Appendix. Pet. App. 92a-104a.

STATEMENT

This case presents the question whether *inter* partes review ("IPR") before the PTAB is the type of proceeding in which a federally recognized Indian tribe – or indeed any sovereign – may assert sovereign immunity. In *Federal Maritime Comm'n* v. S.C. State Ports Auth., 535 U.S. 743 (2002) ("FMC"), this Court held that sovereign immunity applies in administrative adjudications between private parties, even when the proceedings concern "public rights."

In SAS Inst. Inc. v. Iancu, 138 S. Ct. 1348 (2018), this Court unequivocally concluded that an IPR is a "procedure allow[ing] private parties to challenge previously issued patent claims in an adversarial process before the Patent Office that mimics civil litigation." Id. at 1352. In Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365 (2018), this Court confirmed that IPRs use "court-like procedures" before "an adjudicatory body" composed of "judges" and include "some of the features of adversarial litigation." Id. at 1371, 1378.

A straightforward application of the legal rule established by *FMC* to the nature of IPR proceedings as described in *SAS* leads to the conclusion that sovereign immunity applies in IPRs.

In this case, however, the Federal Circuit held that sovereign immunity does not apply in IPRs because they are "more like an agency enforcement action than a civil suit brought by a private party," Pet. App. 9a, despite this Court's contrary understanding of IPRs in SAS. The Court of Appeals described the Director of the U.S. Patent &

Trademark Office ("Director") — who has the authority under the statute to decide whether to institute a privately-filed petition for IPR — as a "politically accountable, federal official" who exercises "political responsibility for each suit prosecuted." *Id.* at 9a-10a (citation and internal quotation marks omitted).

In so holding, the Federal Circuit wrongly decided an important question of federal law in a manner inconsistent with this Court's precedent, and in doing so created conflicts with decisions of other circuits.

Moreover, the Federal Circuit's rationale applies equally to state sovereign immunity and other kinds of sovereign immunity in IPR proceedings. amicus brief below, the United States described the sovereign immunity issue in this case as one of "cross-cutting significance." U.S. Brief Amicus Curiae, at 1 (May 11, 2018). The broad implications of the Federal Circuit's decision stem from the fact that it turns on the nature of IPRs, rather than the identity of the patent owner. Under the Federal Circuit's decision, IPRs filed by private parties regarding patents owned by state universities and other sovereigns (including the United States) will evade any defense of sovereign immunity, putting at risk the sovereign's dignity and treasury. No fewer than nine States or state entities filed amici briefs in support of rehearing en banc, reflecting the importance of this case for principles of state sovereign immunity. This Court should grant review to decide whether IPRs are the type of proceeding in which Indian tribes, state universities, or indeed any sovereign entity may assert sovereign immunity.

A. Statutory Background.

Last Term, this Court twice addressed the nature of IPRs (created as part of the 2011 AIA), in SAS and Oil States. This Court observed that "[t]he new inter partes review regime looks a good deal more like litigation" than previous systems administrative review of patents. SAS, 138 S. Ct. at 1353. It described **IPRs** as "party-directed, adversarial" proceedings before neutral PTAB judges with "many of the usual trappings of litigation" such as discovery, briefing, and oral hearing. *Id.* at 1354-55. The Board's own rules define IPRs as "trials." 37 C.F.R. § 42.100(a).

Private parties, not the Director or PTAB, file the petition, determine the issues adjudicated (or not adjudicated), and prosecute the case. As this Court explained, a private party "must file 'a petition to institute an *inter partes* review of [a] patent." 138 S. Ct. at 1353 (quoting 35 U.S.C. § 311 (a)). The PTAB and Director are not parties to the proceeding, 37 C.F.R. § 42.2, and lack authority to initiate an IPR without a private party's petition. Indeed, "*inter partes*" means "between parties."

The private-party petitioner has complete and exclusive control over the claims challenged and the grounds of the attacks. "The petition may request to cancel as unpatentable 1 or more claims of [the] patent' on the ground that the claims are obvious or not novel." 138 S. Ct. at 1353 (quoting 35 U.S.C. § 311 (b)). "In doing so, the petition must identify each claim challenged,' the grounds for the challenge, and the evidence supporting the challenge." *Id.* (quoting 35 U.S.C. § 312 (a)(3)). "The patent owner, in turn, may respond with 'a

preliminary response to the petition' explaining 'why no *inter partes* review should be instituted." *Id.* (quoting 35 U.S.C. § 313).

As this Court explained, "[w]ith the parties' submissions before him, the Director then decides 'whether to institute an *inter partes* review...pursuant to [the] petition." 138 S. Ct. at 1353 (quoting 35 U.S.C. § 314 (b)). In practice, the PTAB exercises this authority on behalf of the Director, because he has delegated his power in this respect to the Board. *Id.* (citing 37 C.F.R. § 42.4(a)).

Once an IPR is initiated, neither the statute nor regulations provide any role for the PTAB or any federal officer to act as advocates in the proceedings, to add (or remove) patent claims to an existing IPR, or to add prior art to that cited by the petition. The private-party petitioner provides the evidence, 35 U.S.C. § 312 (a)(3)(B), and shoulders the burden of proof. *Id.* at § 316 (e).

This Court explained that, once instituted, an IPR "proceeds before the Board with many of the usual trappings of litigation. The parties conduct discovery and join issue in briefing and at an oral hearing." *SAS*, 138 S. Ct. at 1353-54 (citing 35 U.S.C. §§ 316 (a)(5), (6), (8), (10), (13)). The parties (*i.e.*, the petitioner and patent owner) can seek discovery, which the PTAB can enforce through sanctions. 37 C.F.R. §§ 42.51-42.65. The PTAB and Director have no power to initiate discovery.

The Federal Rules of Evidence generally apply to IPRs. *Id.* at § 42.62. The parties (but not the Board) may offer rebuttal evidence "which is responsive to the *adversary's* evidence." *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1082 (Fed. Cir. 2015) (emphasis

added). The Board must decide the case based on the "arguments that were advanced by a party." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380-81 (Fed. Cir. 2016). The PTAB has continued to borrow judicial practices for IPR trials, including recently revised procedures for expert testimony, word counts, motion practice, and other matters.¹

At the conclusion of an IPR, the three PTAB "judges" issue a final written decision known as a "judgment." 77 Fed. Reg. at 48,766-67. As this Court held in *SAS*, the PTAB must resolve all the claims presented by the private-party petitioner; it may not choose to limit its review to only some of them. 138 S. Ct. at 1353. The loser of the IPR may be subject to estoppel. 37 C.F.R. § 42.73(d)(3). The Board, which is not a party, is not estopped.

If a patent owner withdraws from an IPR, the Board may issue an "adverse judgment" cancelling the patent owner's claims. 37 C.F.R. § 42.73(b)(4). The judgment is strictly limited to the grounds raised by petitioner. The parties may settle the IPR, but "the Board is not a party to the settlement," id. at § 42.74(a), and the Board lacks authority to settle an IPR if the petitioner wishes to proceed. authority to either "terminate Board's proceeding or issue a final written decision" upon settlement does not empower the Board to take over "prosecution" of the IPR. Oil States, 138 S. Ct. at Even in written decisions issued after settlements, the Board may adjudicate only the

¹ USPTO, Trial Practice Guide Update, at 4, 6, 16 (Aug. 2018), available at https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-trial-practice-guide-august-2018.

arguments made by the parties. See Magnum Oil, 829 F.3d at 1380-81. Typically, settlement ends the proceeding "unless the Board has already decided the merits." 77 Fed. Reg. at 48,768.

B. Procedural History Of This Case.

Factual And Procedural Background.

This case involves patents related to Restasis®, an FDA-approved cyclosporin product for treating a condition known as "dry eye," by increasing a patient's natural tear production. Pet. App. 4a, 51a. 2015,Allergan sued Respondents Pharmaceuticals, Inc. ("Mylan"), Teva Pharmaceuticals USA, Inc. ("Teva"), Akorn, Inc. ("Akorn"), and other parties in the Eastern District of Texas, alleging infringement of Restasis® patents. Id. at 4a-5a. On June 3, 2016, Mylan petitioned for IPR of six Restasis® patents, and subsequently Teva and Akorn filed similar petitions. *Id.* at 5a. The Board instituted IPRs.

Meanwhile, the Eastern District of Texas held a week-long bench trial beginning August 28, 2017 on the infringement action. The trial involved thirteen claims in four of the six Restasis® patents. *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4803941, at *15 (E.D. Tex. Oct. 16, 2017).²

² Allergan agreed that the thirteen litigated claims would be representative of any other originally asserted claims in the four patents and that "any remedy that [the Court] might enter as to the representative claims would apply equally to the unasserted claims." *Allergan*, 2017 WL 4803941, at *15.

In September 2017, during the pendency of the IPRs and the infringement action in the Eastern District of Texas, Allergan and the Tribe entered into an assignment transferring the Restasis® patents from Allergan to the Tribe and granting Allergan an exclusive field-of-use license. Pet. App. 5a. The assignment was recorded with the USPTO on September 8, 2017. *Id.*

The Tribe granted Allergan an exclusive license "for all FDA-approved uses in the United States." Appx2578-2579.³ The Tribe retained all rights under the patents "not expressly granted" to Allergan. Appx2579. These retained rights include the right to practice the patents (subject to certain limitations)⁴ in all other fields of use outside the Allergan license.

For example, if the Tribe were to conduct clinical trials for a cyclosporin product and obtain FDA approval for it without reference to or reliance on the Restasis® New Drug Applications ("NDAs") and with a different indication, the Tribe would be able to practice the patents and retain all rights in that product. The Tribe also retains the right to use and practice the patents for "research, scholarly use, teaching, education, patient care incidental to the foregoing [and] sponsored research" in connection with the FDA-approved use of Restasis®, as well as off-label uses. Appx2579.

³ Citations to "Appx_" are references to the Appendix in the Federal Circuit.

⁴ The Tribe may not develop a product relying on the Restasis® NDAs or qualifying as or competing with a "Licensed Product." Appx2575, Appx2579.

In addition, the Tribe retained the first right to enforce the patents against third parties with respect to any infringement outside of Allergan's field-of-use. Appx2582-2583. Although the license grants Allergan the right to enforce the patents against generic equivalents of Restasis®, the Tribe has the right to sue third parties in this field-of-use if Allergan declines to do so. Appx2582. Moreover, the Tribe must approve any settlements relating to patents. even in Allergan's field-of-use. Appx2583. In the license, Allergan agreed to pay the Tribe a lump sum of \$13,750,000 and quarterly royalties of \$3,750,000. Appx2580, Appx2593.

On October 13, 2017, the Eastern District of Texas issued findings of fact and conclusions of law holding thirteen representative claims for four of the Restasis® patents invalid for obviousness. Allergan, 2017 WL 4803941, at *51. The court found that Mylan, Teva, and Akorn infringed all the asserted claims, that the Restasis® patents were not invalid for anticipation, and that the patents were not invalid for lack of enablement or improper inventorship. *Id.* at *52-*63. Indeed, the district court acknowledged that "[t]here is no doubt that Allergan has invented a useful and successful pharmaceutical product." Id. at *63. The court indicated it was "not required to decide whether the assignment . . . was valid," but in dicta it criticized the business arrangement between the Tribe and Allergan, Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *4 (E.D. Tex. Oct. 16, 2017).

The judgment of the Eastern District of Texas was appealed separately to the Federal Circuit and is not part of the instant petition for certiorari. On November 13, 2018, the Federal Circuit affirmed the district court's judgment. Pet. App. 89a-91a. A petition for rehearing is due December 21, 2018.

2. The Board's Decision Rejecting Tribal Immunity In IPRs.

Before the PTAB, the Tribe made a special appearance and moved to terminate the IPRs on the ground that the Board had no jurisdiction over the Tribe because of tribal sovereign immunity. Pet. App. 5a. Allergan moved to withdraw from the IPRs on the ground that it was no longer the patent owner. *Id.* The Board invited *amici curiae* briefs on the issues raised by the Tribe. *Id.* at 31a. A PTAB Judge noted it was the "very first time that the board has authorized the filing of amicus briefs in any of [its] cases." Appx2617.

On February 23, 2018, the Board denied the Tribe's motion to terminate and Allergan's motion to withdraw. Pet. App. 29a-73a, 74a-80a. Even though the PTAB had repeatedly recognized IPR sovereign immunity defenses by state universities that own and license patents,⁵ in this case the Board held that

⁵ In proceedings involving state universities, the PTAB concluded that "the analysis in *FMC* applies to" IPRs, *Covidien LP v. Univ. of Fla. Research Found. Inc.*, 2017 WL 4015009, at *8 (PTAB Jan. 25, 2017); that sovereign immunity applies even in IPRs involving licensing arrangements, *NeoChord, Inc. v. Univ. of Md., Balt.*, No. IPR2016-00208, Paper 28, at 7 (PTAB May 23, 2017); and, that "under *FMC*... inter partes reviews are similar to lawsuits" and therefore trigger sovereign immunity. *Reactive Surfaces, Ltd. v. Toyota Motor Corp.*, No. IPR2017-00572, 2017 WL 2992435, at *2 (PTAB July 13, 2017).

an IPR "is not the type of 'suit" to which tribal immunity applies. *Id.* at 45a. In the alternative, the Board held that the IPR could proceed without the Tribe's participation because the Board found that Allergan is the "effective patent owner" (*id.* at 65a), a term that does not appear in the Patent Act or relevant regulations. The Board further held the Tribe was not an indispensable party because Allergan purportedly could represent its interest (*id.* at 68a-70a), even though the Tribe is a sovereign and Allergan is a publicly traded company. The Board declined to find that the Allergan-Tribe agreement was a "sham" or "otherwise improper under the law." *Id.* at 65a n.11.

The Board denied a motion by the Tribe and Allergan for stay pending interlocutory appeal to the Federal Circuit. By Order of March 28, 2018, the Federal Circuit stayed the PTAB proceedings pending interlocutory appeal. *Id.* at 81-83a.

C. The Decision Under Review.

The Federal Circuit affirmed. The Court of Appeals began by acknowledging that "[a]s '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." Pet. App. 5a (quoting Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Okla., 498 U.S. 505, 509 (1991)).

Nevertheless, the Federal Circuit explained, "[g]enerally, immunity does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action." *Id.* at 6a. The Court of

Appeals described IPRs as a "hybrid proceeding" with "adjudicatory characteristics" similar to court proceedings, but noted that in other respects it "is less like a judicial proceeding and more like a specialized agency proceeding." *Id.* at 8a (quoting *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2143-44 (2016)). The Court of Appeals explained that "[t]his tension was laid bare in two recent Supreme Court decisions decided on the same day": *Oil States* and *SAS Institute. Id.*

Ultimately, the Federal Circuit cited "several factors" to support its conclusion that an "IPR is more like an agency enforcement action than a civil suit brought by a private party." *Id.* at 9a. First, the Court observed that the Director of the USPTO has discretion in deciding whether to institute an IPR, and cited *Alden v. Maine*, 527 U.S. 706 (1999), in comparing that discretion to the United States' decision whether, how, and when to commence an action against a sovereign State. Pet. App. 10a.

Next, the Federal Circuit noted that the PTAB may "continue review even if the petitioner chooses not to participate" in an IPR, id. at 11a, and may intervene in subsequent appeals. Id. It added that "procedures in IPR do not mirror the Federal Rules of Civil Procedure." Id.Finally, the Court of Appeals opined that "[t]he 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." Id. at 12a. Judge Dyk wrote separately to set forth his view that "the history of *inter partes* review . . . confirms that those proceedings are not adjudications between private parties." *Id.* at 15a-16a.

The Federal Circuit denied rehearing *en banc* and denied Petitioners' motion to stay the mandate. Pet. App. 84a-86a, 87a-88a. On November 30, 2018, the Board issued an order setting oral argument in the IPR trial for January 11, 2019 and directing briefing on the impact of the Federal Circuit's affirmance of the Eastern District of Texas' judgment.

REASONS FOR GRANTING THE WRIT

In holding sovereign immunity inapplicable in IPRs because they are "more like an agency enforcement action than a civil suit brought by a private party," Pet. App. 9a, the Federal Circuit has decided an important question of federal law that warrants this Court's review. Further, the Federal Circuit's decision disregards or misconstrues this Court's precedent in three ways.

First, the Court of Appeals failed to follow this Court's decision in *SAS* that IPRs are *not* "agencyled, inquisitorial" proceedings but instead are "partydirected, adversarial" proceedings. 138 S. Ct. at 1355. At the urging of the United States, the Federal Circuit adopted the same expansive view of the USPTO Director's role in the IPR process that this Court expressly *rejected* in *SAS*.

Second, the Federal Circuit misconstrued this Court's decision in *Alden* in comparing the Director's binary (and one-time) choice whether to institute an IPR to the federal government's ongoing series of decisions in investigating, commencing, and prosecuting an agency enforcement action against a sovereign State. The two situations are quite

different, and the Federal Circuit's interpretation of *Alden* is untenable.

Third, the Federal Circuit misconstrued this Court's decision in FMCin comparing procedures used in IPRs with the Federal Rules of Civil Procedure. FMC held that a State could invoke immunity sovereign in an administrative adjudication where it was "required to defend itself in an adversarial proceeding against a private party before an impartial federal officer." 535 U.S. at 760-61. This holding is squarely applicable to IPRs. In departing from *FMC*, the Federal Circuit focused on the extent to which IPR procedures authorize "interrogatories [and] depositions" or permit "live testimony." Pet. App. 11a-12a. FMC makes clear that the Federal Circuit asked the wrong questions and reached the wrong conclusion.

The Federal Circuit acknowledged that resolving the question presented depends on the proper interpretation of this Court's precedent. But the Court of Appeals misconstrued that precedent. The Federal Circuit erroneously opined that this Court's decisions in *Oil States* and *SAS* "laid bare" "tension" regarding the supposedly "hybrid" nature of IPRs. Pet. App. 8a. But there is no such "tension" and no conflict in this Court's decisions. Neither *SAS* nor *Oil States* referred to IPRs as a "hybrid proceeding." The only conflict is between the Federal Circuit's holding and this Court's precedent (and with the decisions of other lower courts that have faithfully followed this Court).

A. The Federal Circuit's Judgment Is Inconsistent With This Court's Decision In SAS.

The Federal Circuit's judgment rests on an exaggerated view of the Director's role in IPRs that this Court squarely rejected in *SAS*. At the urging of the United States, which filed an *amicus* brief in the Court of Appeals advancing the same arguments it pressed unsuccessfully on behalf of the Director in *SAS*, the Federal Circuit relied on the Director's role in instituting privately-filed petitions to analogize IPRs to agency enforcement actions.

In SAS, this Court adopted the opposite view. This Court opined that an IPR is "a party-directed, adversarial process" and rejected the argument that the Director's one-time choice whether to institute a privately-filed petition converts the entire IPR into an "agency-led, inquisitorial" procedure. 138 S. Ct. at 1355 (emphasis added). This Court explained that the Director "is given only the choice 'whether' to institute an *inter partes* review. That language indicates a binary choice — either institute review or don't. And by using the term 'pursuant to,' Congress told the Director what he must say yes or no to: an inter partes review that proceeds '[i]n accordance with or 'in conformance to' the petition." Id. at 1355-56. The petition is formulated, drafted, and filed by a private party, not the PTAB. Thus. SAS establishes that, in the context of IPRs, the Director does not function as an enforcement arm of the United States.

SAS made clear that the Director's role in instituting IPRs does not transform them into agency proceedings commenced and prosecuted by

the United States. Rather, this Court opined that IPRs allow "private parties to challenge previously issued patent claims in an adversarial process before the Patent Office that mimics civil litigation." Id. at 1352 (emphasis added).

This Court explained that the statute "doesn't authorize the Director to start proceedings on his own initiative," or to "initiate whatever kind of *inter partes* review he might choose." *Id.* at 1355. "Nothing suggests the Director enjoys a license to depart from the petition and institute a *different* inter partes review of his own design." *Id.* at 1356. "Much as in the civil litigation system it *mimics*, in [IPRs] the petitioner is master of its complaint and normally entitled to judgment on all of the claims it raises, not just those the decisionmaker might wish to address." *Id.* at 1355 (emphasis added).

SAS establishes that IPRs are fundamentally different from agency enforcement proceedings, where the agency (as prosecutor and not a neutral judge) has discretion over the scope and nature of the proceedings. This Court explained that, although the Board has "discretion on the question whether to institute review, . . . the petitioner's petition, not the Director's discretion, . . . guide[s] the life of the litigation." Id. at 1356. In holding that the statutory language did not justify the Director's claim to broad discretion in handling IPRs, this Court's reasoning in SAS was not dicta; the significance of the Director's role was integral to the question whether the PTAB is required to address, in its final written decision, every claim challenged in an IPR.

SAS contrasted IPRs to ex parte reexamination, a different process operated by the USPTO where the Director is authorized "to investigate a question of patentability '[o]n his own initiative, and at any time." Id. at 1355. SAS found that "rather than create (another) agency-led, inquisitorial process for reconsidering patents," which Congress "knew exactly how to do," "Congress opted for a partydirected, adversarial process" - "a choice [that] neither [the Court] nor the agency may disregard." Id. The Federal Circuit ignored this Court's reasoning and improperly drew precisely the opposite inference from the contrast between IPRs and ex parte reexamination scheme. Pet. App. 12a-13a.

Tellingly, the arguments this Court rejected in SAS are the very arguments that the Federal Circuit embraced in this case. The Federal Circuit cited the same slim reed on which the Director relied in SAS — the authority to decide whether to institute an IPR. Pet. App. 9a-10a. And the Federal Circuit's reasoning in this case parallels the arguments in the SAS. Director's brief in which this resoundingly rejected. See No. 16-989, Brief of Federal Respondent, at 12 (arguing that Director's "broad discretion in determining whether institute" IPR supported Government's position); id. at 14 (Director's "broad discretion" demonstrates "the USPTO may institute review as to fewer than all of the claims of which review is sought"); id. at 38 (arguing that IPR "differs from district-court litigation" and is "a mechanism for the agency to revisit its own prior determination").

The Director "has [not] proven bashful about asserting . . . statutory powers to secure the 'policy

judgments' he seeks." *Oil States*, 138 S. Ct. at 1380-81 (Gorsuch, J., dissenting) (citation omitted). In this case, the Federal Circuit improperly deferred to the Director's second attempt at claiming broad authority in the IPR process – a claim this Court rejected in *SAS*.

B. The Federal Circuit's Judgment Is Inconsistent With This Court's Decision In Alden.

The Federal Circuit also misconstrued this Court's decision in *Alden* and improperly equated (i) the Director's binary choice whether to institute a privately-filed IPR with (ii) the broad power exercised by the Attorney General and federal agencies in controlling and prosecuting federal litigation on behalf of the United States. Pet. App. The Director has delegated to the 9a-10a, 13a. PTAB responsibility to make institution decisions, SAS, 138 S.Ct. at 1353, and thus plays no role (and exercises no political accountability) in deciding which cases to institute. Nevertheless, the Court of Appeals found that, under *Alden*, the Director's role in instituting IPRs means that "a politically accountable, federal official has authorized the institution of that proceeding." Pet. App. 10a.

The Federal Circuit's misapplication of *Alden* creates a dangerous blueprint for the evasion of sovereign immunity. As the University of Minnesota warned in an *amicus* brief in this case, the Federal Circuit's decision "could subject States to any private-party-initiated agency proceeding – where States have long had the protection of sovereign immunity – so long as a federal official has the

option to dismiss the proceeding." For example, this Court has expressed "serious doubt" that sovereign immunity permits *qui tam* suits against States, *Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 766 (2000), even though a federal official has the discretionary authority to dismiss the suit, or to permit it to continue, 31 U.S.C. § 3730(b)(1), (c)(2)(A), and even though qui tam suits (unlike IPRs) are brought "for" and "in the name of" the United States. Under the Federal Circuit's reasoning, there would be no immunity in *qui tam* actions.

In Alden, this Court held that Congress could not subject a nonconsenting State to suit by a private party in state court, but distinguished a suit "commenced and prosecuted against a State in the name of the United States by those who are entrusted with the constitutional duty to 'take Care that the Laws be faithfully executed." 527 U.S. at 755 (citation omitted). This Court explained that "[s]uits brought by the United States itself require the exercise of political responsibility for each suit prosecuted against a State." Id. at 756. When the Federal Government sues directly, "the National Government must itself deem the case of sufficient importance to take action against the State." Id. at 759-60.

The Federal Circuit fundamentally misinterpreted *Alden* in opining that the Director's decision whether to institute an IPR was comparable to the Attorney General's role in commencing and prosecuting litigation on behalf of the United States.

⁶ Br. of University of Minnesota as *Amicus Curiae* at 3 (Fed. Cir. Dkt. 153) (filed Sept. 4, 2018).

First, the *Alden* sovereign-immunity exception requires the Government to both "commenc[e]" and "prosecut[e]" a suit (527 U.S. at 756) and there is no colorable argument that the Director "prosecutes" an IPR. An IPR is brought in the name of a private party, not the United States. Private parties draft and file IPR petitions, decide what grounds will be asserted, develop and submit supporting evidence, hire experts, and bear all the costs of the proceeding. The Director has no role in how IPRs are litigated and is not a party to the proceeding. 37 C.F.R. § 42.2. Once an IPR is initiated, neither the statute nor regulations provide any role for the PTAB or any federal officer to act as advocates in the proceedings, to add patent claims to an existing IPR, or to add prior art to that cited by the petition. considering the Director's role in instituting an IPR, "it's the petitioner, not the Director, who gets to define the contours of the proceeding." S.Ct. at 1355.

The Director's authority is limited to the binary choice whether to institute an IPR at the outset of the litigation. He lacks any role in "prosecuting" an IPR and therefore lacks the power the Attorney General possesses in the context addressed by *Alden*: the ability to decide not merely *whether* but also how, when, and where to sue a sovereign, to determine the claims brought (or not brought), and to control the subsequent litigation (including whether and how to settle or to drop the claims brought). The Director's role in instituting an IPR does not transform the private petitioner into a deputy of the government. To the contrary, an IPR involves the kind of "broad delegation to private persons to sue nonconsenting" sovereigns that *Alden*

indicated would be barred by immunity. 527 U.S. at 756; see also Blatchford v. Native Village of Noatak, 501 U.S. 775, 785 (1991) ("We doubt . . . that [the] sovereign exemption can be delegated . . . The consent 'inherent in the convention,' to suit by the United States — at the instance and under the control of responsible federal officers — is not consent to suit by anyone whom the United States might select.") (emphasis in original).

Next, the Director's discretion in instituting an IPR is not comparable to the Attorney General's authority because it is constrained by a clear legal standard. As this Court has opined, "[b]efore instituting review, the Director must determine, based on the parties' papers, 'that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." SAS, 138 S. Ct. at 1353 *Id.* (quoting 35 U.S.C. § 314 (a)). The Director's discretion is "complete" only in the sense that his or her "decision is 'final and nonappealable." Oil States, 138 S. Ct. at 1371 (quoting 35 U.S.C. § 314) (d)). Even with respect to appeals, this Court has indicated that the Director's discretion is not unfettered. Cuozzo, 136 S. Ct. at 2141.

Finally, the Director's discretion whether to institute an IPR occurs *after* the PTAB has exercised initial jurisdiction. The PTAB has asserted jurisdiction prior to institution to order discovery, sanction parties, and decide motions with respect to the identity of the "real party in interest." In

⁷ E.g., RPX Corp. v. Applications in Internet Time, LLC, No. IPR2015-01750, 2015 WL 6157114 (PTAB Oct. 20, 2015) (granting discovery before institution under 37 C.F.R.

addition, as a practical matter, patent owners are compelled to file a preliminary response to an IPR petition under 35 U.S.C. § 313, since (as a recent study found) the PTAB institutes IPR on 100% of the petitions where no preliminary response is filed.⁸ Thus, there is no opportunity prior to the institution decision for the Director to exercise "political accountability" in deciding whether to subject a sovereign to an IPR.

The Federal Circuit's Decision Conflicts With The Decisions Of Other Circuits That Have Followed Alden v. Maine.

The Federal Circuit's decision also conflicts with the way in which other lower courts have applied *Alden v. Maine* and principles of sovereign immunity. In no other case has a federal Court of Appeals held that an action commenced and prosecuted by a private party against a sovereign entity evades immunity simply because of the discretionary role of a federal official in deciding whether to permit that action to proceed.

In *U.S. ex rel. Foulds v. Tex. Tech Univ.*, 171 F.3d 279 (5th Cir. 1999), for example, the Fifth Circuit held that a *qui tam* action brought in the name of the United States was nevertheless barred by

^{§ 42.51(}b)(2)); *id.*, 2015 WL 7889318 (PTAB Dec. 4, 2015) (authorizing a protective order before institution under 37 C.F.R. § 42.54(a)); *id.*, 2016 WL 3577873 (PTAB July 1, 2016) (ordering sanctions before institution under 37 C.F.R. § 42.12(a)).

⁸ Rubén Muñoz et al., How New Testimonial Evidence Affects IPR Institution, Law360 (Jun. 5, 2018), https://www.law360.com/articles/1049967.

sovereign immunity. The Court of Appeals noted that "[t]he government retains some control over the *qui tam* suit commenced by the plaintiff" and may (for example) "intervene upon showing of good cause." *Id.* at 290. But the Court found that the government "does not exercise authoritative control over the case," that the "relator has the right to remain a party to the suit even if the government intervenes," and that the relator controlled "whether to sue," "what manner to make demands, and "whether to settle." *Id.* at 290, 293. The role of private parties in IPRs is even more extensive.

Similarly, numerous circuits have recognized that sovereign immunity applies in declaratory judgment actions, 9 even though judges in such actions (like the Director) retain discretion whether to permit a privately-filed suit to proceed. See Wilton v. Seven Falls Co., 515 U.S. 277, 286 (1995) (Declaratory Judgment Act vests federal courts with "unique and substantial discretion in deciding whether to declare the rights of litigants").

In contrast to the Federal Circuit, other courts of appeals have recognized exceptions to sovereign immunity under *Alden v. Maine* only where federal officials have exercised extensive control over the formulation, commencement, and prosecution of actions. In *Chao v. Virginia Dept. of Transportation*, 291 F.3d 276, 281 (4th Cir. 2002), for example, the Court of Appeals held that sovereign immunity did not bar a suit by the U.S. Secretary of Labor against

⁹ See Progressive Consumers Fed. Credit Union v. United States, 79 F.3d 1228, 1230 (1st Cir. 1996); Goldstein v. Moatz, 364 F.3d 205, 219 (4th Cir. 2004); Seminole Tribe of Florida v. Florida Dept. of Revenue, 750 F.3d 1238, 1243 (11th Cir. 2014).

the Virginia Department of Transportation. The Fourth Circuit explained that the test of *Alden v. Maine* was met because "[t]he case is being litigated by lawyers within, and is under the full control of, the Executive Branch." *Id.* at 281. The contrast with IPRs is plain; the Director's role in an IPR is limited to the one-time institution decision regarding a privately-filed suit (not an action in the name of the United States or a federal agency), and he lacks any day-to-day control of the litigation.

In U.S. v. Alabama Dept. of Mental Health and Mental Retardation, 673 F.3d 1320, 1327 (11th Cir. 2012), the Eleventh Circuit found no sovereign immunity bar where the Department of Justice filed an action in the name of the United States to enforce a violation of a federal statute and secure redress for a single individual. The Court of Appeals held that the lawsuit was not "a private suit, which is subject to sovereign immunity," because "the United States —and not [the private individual] — has control over the prosecution of the case." Id. at 1326-27. The court noted that "the suit is firmly under the control of the executive branch": the private individual "had little control, if any, after the Attorney General accepted his suit. . . . DOJ did not seek permission to file the lawsuit and [the individual] signed an agreement stating that the DOJ did not represent him. Moreover, the DOJ, and not [the private individual, had the right to decide whether to settle the case." Id. at 1327. Moreover, the government paid the expenses of the case. *Id.* "Clearly, the U.S. government, and not [the individual], was in control of this case." Id.

The Director's narrowly circumscribed role in IPRs is far removed from the kind of ongoing

responsibility the Attorney General exercises in the situation posited in *Alden* or that federal agencies exercise under their authorizing statutes. Agencies such as the NLRB, EEOC, and OSHA are expressly granted federal enforcement powers by statute to bring federal suits (not private actions), and their lawsuits are formulated, commenced, and prosecuted by government attorneys. Hence, the Ninth Circuit concluded that a suit by the EEOC qualified as a suit by "the United States itself for the purpose of sovereign immunity analysis." *EEOC v. Karuk Tribe Housing Authority*, 260 F.3d 1071, 1075 (9th Cir. 2001) (citation omitted).

Moreover, IPRs are initiated, prosecuted, and controlled by private-party petitioners. agency enforcement actions. See Pauma v. NLRB, 888 F.3d 1066, 1078 (9th Cir. 2018) ("The NLRB General Counsel 'seeks enforcement [of the NLRA] as a public agent,' not on behalf of any private party.") (citation omitted); NLRB v. Little River Band of Ottawa Indians Tribal Gov't, 788 F.3d 537, 555 (6th Cir. 2015) (stressing that action was filed by NLRB (even though private party filed charge) and acknowledging "Congress may choose to impose an obligation on Indian tribes without subjecting them to the enforcement of that obligation through a private right of action"); San Manuel Indian Bingo & Casino v. NLRB, 475 F.3d 1306, 1309 (D.C. Cir. 2007) (private parties submitted unfair labor practice charges, but complaint was issued. prosecuted, and tried by NLRB).

In short, IPRs are far different from agency enforcement actions, and the Federal Circuit fundamentally misconstrued *Alden*.

C. The Federal Circuit's Decision Is Inconsistent With *FMC*.

Review is warranted for the additional reason that the Federal Circuit failed to follow this Court's decision in *FMC*. Instead, the Federal Circuit looked to whether procedural rules in IPRs allow "significant amendments" and the extent to which they authorize "interrogatories [and] depositions" or permit "live testimony," and concluded that the "procedures in IPR do not mirror the Federal Rules of Civil Procedure." Pet. App. 11a-12a. These aspects of the Court of Appeals' decision are irreconcilable with *FMC*.

1. The Federal Circuit Misconstrued FMC.

The Federal Circuit applied the wrong legal test and arrived at the wrong conclusion. Unlike the Federal Circuit's decision, *FMC* compared agency proceedings with federal civil litigation not as a necessary element of sovereign immunity, but only as shorthand for "the type of proceedings from which the Framers would have thought the States possessed immunity when they agreed to enter the Union." 535 U.S. at 756. The *FMC* test is whether a sovereign "is required to defend itself in an adversarial proceeding against a private party before an impartial federal officer." *Id.* at 760-61 (emphasis added). That test is clearly met in the IPR context.

The Federal Circuit relied on procedural differences between IPRs and civil trials. But *FMC* relied on the similarities concerning discovery and pleadings merely to "confirm" the proceeding was adjudicatory and between adverse parties. 535 U.S. at 757, 760. This Court acknowledged differences

but found them irrelevant to the analysis. *Id.* at 761-67. *FMC* considered the availability of depositions and written discovery, the filing of briefs and motions, an oral hearing, and the impartial position of the ALJ. 535 U.S. at 758-59. All these features are present in IPRs. *FMC* did not suggest that a principle as fundamental as sovereign immunity turns on whether procedural rules allow "significant amendments," authorize "interrogatories [and] depositions" or permit "live testimony." Pet. App. 11a-12a.

If anything, the Federal Circuit's identification of differences between IPRs and federal civil litigation exacerbates the conflict between FMC and the Court of Appeals' decision. FMC instructed that sovereign immunity bars suits that were "anomalous and unheard of" at the founding. 535 U.S. at 755 (internal quotation marks omitted). FMC gave "great significance" to the fact that private agency proceedings against States did not exist at the founding. Id. It warned that "[t]he affront" to a sovereign's "dignity does not lessen when an adjudication takes place in an administrative tribunal as opposed to an Article III court," and indeed one "could argue that allowing a private party to haul a State in front of such an administrative tribunal constitutes a greater insult to a State's dignity." 535 U.S. at 760 & n.11.

Thus, the Federal Circuit aggravated the conflict with *FMC* by pointing to the PTAB's ability to proceed to final decision without the parties. Pet. App. 10a-11a. That scenario simply reflects the absence of a case-or-controversy requirement in Article I courts, and increases the risk to sovereigns

subjected to administrative adjudications initiated and pursued by private parties.¹⁰

The Federal Circuit also cited the Director's statutory right to intervene in appeals. *Id.* at 11a. But every agency has a right to intervene under 28 U.S.C. § 2348, and in fact both the United States and the FMC filed separate briefs as parties in the Yet this Fourth Circuit and this Court in *FMC*. Court still found sovereign immunity. IPRs remain private actions initiated by private regardless of the PTAB's ability to intervene on appeal. Without a private petitioner, there is no IPR to begin with. IPRs are party-based, not agency-led, and the Federal Circuit's reasoning does not justify its departure from *FMC*.

Moreover, the Federal Circuit's reliance on the Director's role in instituting an IPR is another respect in which the Federal Circuit departed from

¹⁰ The PTAB's authority to issue a decision in the event of petitioner's withdrawal is limited to exceptional circumstances: an IPR "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." U.S.C. § 317 (a). Compare Apple, Inc. v. OpenTV, Inc., Nos. IPR2015-00969, IPR2015-00980, IPR2015-01031, Paper 29, at 4 (PTAB Sept. 10, 2016) (requests for termination denied when briefing was complete and oral hearings already held), with Clio USA, Inc. v. The Proctor and Gamble Co., No. IPR2013-00438, Paper No. 57 (PTAB October 31, 2014) (terminating IPR where Board had not yet decided merits of proceeding). Thus, only where the PTAB has already reached a decision (based on the petitioner's arguments using only the evidence submitted by the parties) may it issue a ruling when the petitioner withdraws. The Board lacks the power to prosecute an IPR in the petitioner's absence.

FMC. In *FMC*, this Court held that sovereign immunity applied even though the agency exercised discretion over the conduct of proceedings; after a complaint was filed, the FMC had the power to specify a "reasonable time" for its satisfaction, to decide whether it had been satisfied, and to decide the "appropriate manner" to investigate it. 46 U.S.C. App. § 1710 (b) (2001). *FMC* reasoned that the agency's obligation to explain the use of discretion made the adjudication more like civil litigation. 535 U.S. at 757. Thus, FMC instructs that, where a private party controls the decision to bring and prosecute a suit, courts cannot sidestep sovereign immunity simply because a federal official exercises some discretion in determining whether or how a case proceeds. FMC makes clear that where a private party's "prosecution of a complaint" is "not controlled by the United States" but rather "by the private party," sovereign immunity applies. Id. at 765. And even though the politically accountable Attorney General played a key role in the statutory scheme in FMC - the Attorney General was ultimately responsible for enforcement of any Commission decision, because the FMC lacked the authority to enforce its own orders - this Court rejected the argument that the Attorney General's role meant that sovereign immunity should not apply. *Id.* at 761-64.

2. The Court Of Appeals Created A Conflict With Other Circuits That Have Followed *FMC*.

The Federal Circuit's decision is not consistent with other circuits' interpretation of *FMC*. In *R.I. Dep't of Envtl. Mgmt. v. United States*, 304 F.3d 31

(1st Cir. 2002), for example, the First Circuit held immunity barred that sovereign federal administrative proceedings in which Department of Labor ("DOL") employees sought monetary and injunctive relief for alleged violations of the Solid Waste Disposal Act's whistleblower provision. of Appeals explained that $_{
m the}$ DOLproceedings were "adjudicated before an ALJ, whose role is similar to that of a trial judge"; "conducted in a manner that roughly conforms to the rules of procedure that govern the course of a traditional civil lawsuit"; and culminated "in a final decision that includes the types of relief typically available in civil litigation." Id. at 46. Precisely the same is true with respect to IPRs. Under the First Circuit's interpretation of FMC, the Federal Circuit would have reached the opposite conclusion in this case.

In Conn. Dep't of Envtl. Prot. v. OSHA, 356 F.3d 226 (2d Cir. 2004), OSHA conceded that FMC barred administrative adjudication of a private party's complaint against a state agency. Id. at 232. The OSHA scheme entailed *more extensive* agency involvement than a privately-filed IPR: after a determination of a violation by the Assistant Secretary of OSHA (rather than a privately-filed IPR petition), OSHA held a hearing before administrative law judge. *Id.* at 229. "During the hearing, formal evidentiary rules do not apply, but the parties have the right to be represented by counsel, to file briefs, and to present oral argument." *Id.* "The Assistant Secretary may participate in the hearing as a party or as 'amicus curiae." *Id.* (By comparison, the Director does not participate in IPRs.) "If the ALJ determines that a violation has occurred, he or she must issue an order requiring that the respondent take appropriate action to abate the violation." *Id.*

Notably, OSHA was unwilling to defend this scheme in court as consistent with *FMC*. By comparison, IPRs present a much stronger case for the application of sovereign immunity, and the Federal Circuit's decision otherwise cannot be reconciled with other courts' interpretation of *FMC*.

D. This Court's Decisions In *Oil States* And *Cuozzo* Do Not Support The Federal Circuit's Judgment.

The Federal Circuit pointed to *Oil States* to support its decision. Pet. App. 8a. But *Oil States* confirms that IPRs use "court-like procedures" before "an adjudicatory body" composed of "judges" and include "some of the features of adversarial litigation." 138 S. Ct. at 1371, 1378. *Oil States* held "[t]he fact that an agency uses court-like procedures does not necessarily mean it is exercising the judicial power" in violation of Article III. *Id.* at 1378. That holding, which the Court itself characterized as "narrow[]," *id.* at 1379, hardly prevents IPRs from qualifying as administrative adjudications triggering sovereign immunity.

The Federal Circuit miscited *Oil States* as holding that "*IPR* is a matter which arises between the Government and [patent owners]." Pet. App. 8a (emphasis added). In fact, *Oil States* held that *patents* are public rights that "arise between the Government and [the patent owner]." 138 S.Ct. at 1373.

A reconsideration of "public rights" via an adjudication initiated by a private party can trigger

sovereign immunity. *FMC* involved "public rights" (docking rights at a public port) and nonetheless applied sovereign immunity. "Invoking the public rights doctrine . . . does not change the fact that a private party simply cannot commence an adversarial proceeding against an unconsenting state." *S.C. Ports Auth. v. Fed. Mar. Comm'n*, 243 F.3d 165, 175 n.8 (4th Cir. 2001), *aff'd*, 535 U.S. 743 (2002).

The Federal Circuit also misconstrued *Cuozzo* as supporting its decision. Pet. App. 8a, 12a-13a. *Cuozzo* explained that IPRs "help[] resolve concrete patent-related disputes *among parties*" (136 S. Ct. at 2144 (emphasis added)) — confirming that IPRs represent private-party adjudications rather than agency enforcement actions. *Cuozzo* acknowledged the "adjudicatory characteristics" of IPRs, "which make these agency proceedings similar to court proceedings." *Id.* at 2143. Such reasoning supports the application of sovereign immunity in IPRs.

Accordingly, the Federal Circuit's decision conflicts with this Court's decisions in *SAS*, *Alden*, and *FMC* and draws no support from *Oil States* or *Cuozzo*. This Court's review is amply warranted.

E. This Case Presents An Important Question Of Federal Law That Should Be Resolved By This Court.

The question whether IPRs are the type of proceedings in which Indian tribes may assert sovereign immunity is a substantial issue warranting review. This Court has instructed that "[d]etermining the limits on the sovereign immunity held by Indian tribes is a grave question." *Upper*

Skagit Indian Tribe v. Lundgren, 138 S. Ct. 1649, 1654 (2018). "The baseline position, [this Court has] often held, is tribal immunity." Michigan v. Bay Mills Indian Community, 134 S. Ct. 2024, 2031 (2014) (citation omitted). For tribes as well as States, "common-law immunity from suit" is a "core aspect[] of sovereignty." Id. at 2030.

Further, the implications of the Federal Circuit's decision extend well beyond Indian tribes. Although the Court of Appeals stated that its opinion was limited to tribal immunity (Pet. App. 13a), its holding turns entirely on the inherent attributes of the IPR proceeding itself, which are the same for all IPRs. The identity of the patent owner is not relevant under the Federal Circuit's decision. Accordingly, there is no principled basis for differentiating (for purposes of sovereign immunity in IPRs) among patents owned by state entities, Indian tribes, federal agencies, or private persons.

That is why *amici* briefs were filed in the Federal Circuit on behalf of nine States or state entities supporting *en banc* rehearing and warning of the implications of the Federal Circuit's decision for States and state universities. For example, the States of Indiana, Hawaii, Illinois, Massachusetts, Texas, Utah, and Virginia informed the Federal Circuit that "[b]etween 1969 and 2012, 75,353 patents were issued to U.S. institutions of higher education; many of these were public colleges and universities." "The number of patents issued has surged even more in recent years. In 2016, fourteen universities each received over one hundred utility

 $^{^{11}\,}$ Br. of Indiana, et al., as Amici~Curiae at 5 (Fed. Cir. Dkt. 144) (Sept. 4, 2018).

patents."¹² Moreover, universities are frequent patent licensors; approximately 5,000 active university-industry licenses are in effect.¹³ The States warned that stripping sovereign immunity from States and public universities in IPRs would trigger significant institutional harm and economic disruption:

States and their public universities hold many patents, and if States could not claim sovereign immunity in IPR, they would regularly be forced to appear before the PTAB. Beyond this dignitary harm, public universities' patents generate substantial revenues that are reinvested in cutting-edge research and development; subjecting States to IPR would make it more costly and difficult to protect this hard-earned revenue. 14

In addition, the Federal Circuit's decision potentially prevents even federal agencies, such as NASA, the Jet Propulsion Laboratory, HHS, the U.S. Army, and the U.S. Navy, which are some of nation's most prolific patent filers, ¹⁵ from asserting sovereign immunity in IPRs brought against them as patent

¹² *Id.*

¹³ Pam Baker, *The Positive Impact of Academic Innovations on Quality of Life*, THE BETTER WORLD REPORT, http://www.betterworldproject.org/BetterWorldProject/media/Better-World-Reports/Documents/AUTM_BWR_2010_Positive_Impact_Academic_Innovations.pdf (2010).

 $^{^{14}\,}$ Br. of Indiana, et al., as Amici~Curiae at 3 (Fed. Cir. Dkt. 144) (Sept. 4, 2018).

 $^{^{15}}$ "Top 300 Organizations Granted U.S. Patents in 2017," <code>http://www.ipo.org/wp-content/uploads/2018/06/2017_Top-300-Patent-Owners.pdf</code>

owners. The significant ramifications of the Federal Circuit's decision is an additional reason warranting this Court's review.

F. This Case Is A Suitable Vehicle To Review The Question Presented.

This case cleanly presents the question of sovereign immunity in IPRs. The Federal Circuit's judgment is predicated on a purely legal determination regarding the nature of IPRs and whether they are the type of proceeding in which sovereign immunity may be asserted. The Court of Appeals did not rest its decision on the validity of the patent assignment from Allergan to the Tribe, Allergan's rights under the license, or any other issue.

Next, the Federal Circuit's affirmance of the judgment of the Eastern District of Texas (Pet. App. 89a-91a) does not make this case an inappropriate vehicle. The infringement trial adjudicated 13 claims representative of the four asserted Restasis® patents, while the IPR involved all claims of all six patents. As the PTAB has recognized, the Eastern District of Texas' judgment "invalidat[ed] a subset of the claims challenged in" the IPRs. Order, *Mylan Pharmaceuticals Inc. v. Saint Regis Mohawk Tribe*, No. IPR2016-01128, at 3 (PTAB Nov. 30, 2018).

Moreover, the harm to the Tribe's sovereignty is separate from the scope or outcome of the IPR proceeding. The Tribe suffers irreparable harm from being subject to the PTAB's jurisdiction, whatever its decision. As this Court has recognized, the purpose of sovereign immunity is to safeguard "the dignity" of "sovereign entities," which is lost regardless of the

outcome of administrative adjudications brought by private parties. *FMC*, 535 U.S. at 760.

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted.

MARSHA KOSTURA SCHMIDT ATTORNEY AT LAW 14928 Perrywood Drive Burtonsville, MD 20866 Tel: (301) 949-5176

MICHAEL W. SHORE ALFONSO GARCIA CHAN CHRISTOPHER L. EVANS JOSEPH F. DEPUMPO SHORE CHAN DEPUMPO LLP 901 Main St., Suite 3300 Dallas, TX 75202 Tel: (214) 593-9110

Counsel for Saint Regis Mohawk Tribe JONATHAN S. MASSEY Counsel of Record MASSEY & GAIL LLP 1325 G St., N.W., Suite 500 Washington, DC 20005 Tel: (202) 652-4511

ROBERT A. LONG, JR.
JEFFREY B. ELIKAN
THOMAS R. BRUGATO
ALAINA M. WHITT
COVINGTON & BURLING LLP
850 Tenth Street, N.W.
Washington, DC 20001-4956
Tel: (202) 662-5612

Counsel for Allergan, Inc.

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