

No. 18-899

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IN THE  
**Supreme Court of the United States**

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SAINT REGIS MOHAWK TRIBE AND ALLERGAN, INC.,

v.

*Petitioners,*

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

*Respondents.*

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

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**REPLY BRIEF FOR PETITIONER**

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

JONATHAN S. MASSEY  
*Counsel of Record*  
MASSEY & GAIL LLP  
1000 Maine Ave., SW, Suite 450  
Washington, DC 20024  
Tel: (202) 652-4511

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

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 Saint Regis  
Mohawk Tribe*

*Counsel for Allergan, Inc.*

Dated: March 18, 2019

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BATEMAN & SLADE, INC.

STONEHAM, MASSACHUSETTS

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## REPLY BRIEF FOR PETITIONER

1. Respondents' primary argument is that Allergan's assignment of the patents to the Tribe supposedly was a "cash-for-immunity" deal under which Allergan retained all substantial rights. BIO 1, 30-36.

This is not a reason to deny review. The Federal Circuit did not reach this issue, much less adopt Respondents' characterization of the transaction. Pet. App. 13a ("Because we conclude that tribal sovereign immunity cannot be asserted in IPR, we need not reach the parties' other arguments."). The PTAB expressly declined to find the agreements "a 'sham'" or "otherwise improper under the law." *Id.* at 65a n.11. So did Judge Bryson, Supp. App. 11a, as Respondents admit. BIO 6 (district court "did not need to decide the legality of Petitioners' enterprise").

This Court ordinarily does not "decide in the first instance issues not decided below." *Zivotofsky v. Clinton*, 566 U.S. 189, 201 (2012). Instead, this Court routinely grants certiorari to resolve important legal questions that controlled the lower court's decision notwithstanding a respondent's assertion that, on remand, it may prevail for a different reason. *E.g.*, *Omnicare, Inc. v. Laborers Dist. Council Constr. Industry Pension Fund*, 135 S.Ct. 1318, 1338 (2015); *Department of Transp. v. Association of Am. R.R.s*, 135 S.Ct. 1225, 1234 (2015); *T-Mobile South, LLC v. City of Roswell*, 135 S.Ct. 808, 821 (2015).

That is the proper course here. This Court should review the IPR tribal immunity question

decided by the Federal Circuit, which is an important issue of federal law. If the Court reverses the Federal Circuit’s judgment, it may leave the other issues identified by Respondents for remand. When the Court “reverse[s] on a threshold question,” it “typically remand[s] for resolution of any claims the lower courts’ error prevented them from addressing.” *Zivotofsky*, 566 U.S. at 201. *E.g.*, *Bond v. United States*, 564 U.S. 211, 214 (2011). The Court took precisely this approach in its most recent tribal immunity case. *Upper Skagit Indian Tribe v. Lundgren*, 138 S. Ct. 1649, 1654 (2018) (leaving undecided issues to be addressed “in the first instance” by the lower court). The Court “ordinarily await[s] thorough lower court opinions to guide [its] analysis of the merits.” *Lucia v. SEC*, 138 S.Ct. 2044, 2050 n.1 (2018). The Federal Circuit never reached beyond the threshold immunity question.

There are ample responses to Respondents’ “cash-for-immunity” and “substantial rights” arguments, including this Court’s rejection of similar objections to tribal immunity,<sup>1</sup> its acceptance of strategic uses of sovereign immunity,<sup>2</sup> and the record of this case.<sup>3</sup>

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<sup>1</sup> *See Michigan v. Bay Mills Indian Cmty.*, 572 U.S. 782, 795-801 (2014) (rejecting argument that private companies would abuse immunity by partnering with tribes); *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 758 (1998); *Okla. Tax Comm’n v. Citizen Band Potawatomi Indian Tribe*, 498 U.S. 505, 510 (1991).

<sup>2</sup> *E.g.*, *United States v. United States Fidelity & Guaranty Co.*, 309 U.S. 506, 512-13 (1940) (allowing U.S. to plead immunity to counterclaim in action initiated by U.S.).



But this Court need not consider Respondents' arguments at this time.

2. Respondents contend that IPRs do not trigger tribal immunity because they involve the reconsideration of a "public right." BIO 11-18. But that argument provides another reason for granting certiorari. Creating a "public rights" exception to sovereign immunity would eliminate immunity in a wide range of administrative adjudications. This Court should grant plenary review before such a significant step is taken.

Respondents' argument underscores the conflict between the Federal Circuit's decision and *Federal Maritime Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743 (2002) ("*FMC*"), which applied state sovereign immunity to an administrative adjudication involving public rights — docking rights at a public port under the Shipping Act of 1984. The Fourth Circuit expressly rejected the Government's reliance on the "public rights doctrine." *S.C. State Ports Auth. v. Fed. Mar. Comm'n*, 243 F.3d 165, 175 n.\* (4th Cir. 2001), *aff'd*, 535 U.S. 743 (2002).

Before this Court, the Government argued at length that adjudications involving "public rights" do not trigger sovereign immunity. U.S Brief in No. 01-46, 2001 WL 1530159, at \*17-24 (Nov. 29, 2001). The Government expressly raised *patents* as an example of public rights. Its reply brief analogized docking rights to patents, comparing the FMC to the first Patent Board, which "adjudicated the

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<sup>3</sup> Judge Bryson regarded the question of whether the Tribe possessed substantial rights in the patents "as a close one." Supp. App. 9a.

patentability of inventions,” and the Government argued that immunity should be inapplicable in the public rights context, even though “administrative adjudication bears a functional resemblance to judicial action.” U.S. Reply Brief in No. 01-46, 2002 WL 221018, at \*12-13 (Feb. 11, 2002) (internal quotation marks and citation omitted). The FMC’s briefs made extensive public rights arguments as well. *See* FMC Brief in No. 01-46, 2001 WL 1530155, \*34-41 (Nov. 29, 2001), FMC Reply Brief in No. 01-46, 2002 WL 225886, \*13-16 (Feb. 11, 2002).

This Court gave the Government’s “public rights” argument the back of its hand in *FMC*, and Respondents are rehashing an issue this Court has already resolved. *See Covidien LP v. University of Florida Research Foundation, Inc.*, 2017 WL 4015009, \*5-6 (PTAB Jan. 25, 2017) (interpreting *FMC* as rejecting “public rights” argument).

3. Relying heavily on Judge Dyk’s concurrence rather than the majority opinion, Respondents contend that the Federal Circuit’s decision is consistent with this Court’s precedent. BIO 19-28. That contention fails.

**SAS:** The BIO confirms that the Federal Circuit’s decision conflicts with *SAS Inst. Inc. v. Iancu*, 138 S.Ct. 1348 (2018). Respondents concede that the Federal Circuit treated IPRs as “agency proceedings.” BIO 12; *id.* at 16 (“fundamentally agency reconsideration”). In *SAS*, this Court held the opposite — that IPRs are not “agency-led, inquisitorial” proceedings but rather “party-directed, adversarial” proceedings. 138 S. Ct. at 1355. If IPRs truly were “actions of a federal agency” (BIO 18), then *SAS* would have been decided differently, since

an agency in an enforcement action exercises control over the proceeding's scope. Instead, in IPRs, "the petitioner is master of its complaint" and "the petitioner's petition, not the Director's discretion, . . . guide[s] the life of the litigation," notwithstanding the PTAB's discretion whether to institute review. 138 S.Ct. at 1355, 1356.

Respondents argue that the Federal Circuit correctly treated IPRs as similar to *ex parte* and *inter partes* reexamination. BIO 15-16. But in *SAS* this Court held the opposite, explaining that "rather than create (another) agency-led, inquisitorial process for reconsidering patents," which Congress "knew exactly how to do," "Congress opted for a party directed, adversarial process." 138 S.Ct. at 1355.

The BIO, like the Federal Circuit's decision, echoes the Director's arguments in *SAS*, which this Court rejected. Pet. 17. The Court should grant review to establish that *SAS* means what it says.

***FMC***: Despite Respondents' denials (BIO 27-28), the adjudications in *FMC* were functionally indistinguishable from IPRs. 535 U.S. at 758-59 (depositions and written discovery, briefs and motions, oral hearing, and impartial position of ALJ, which are all present in IPRs). Respondents do not dispute that, in *FMC*, the Commission exercised discretion over the commencement of proceedings (Pet. 29), akin to the Director's role in instituting an IPR.

This Court in *FMC* found sovereign immunity applicable even though it identified differences between *FMC* adjudications and civil trials. 535 U.S. at 761-67. Identity with federal civil litigation

is not the test for whether an administrative adjudication triggers immunity.

Respondents note that a patent owner is not subject to a monetary judgment in an IPR and that the PTAB may continue an IPR without the petitioner's participation. BIO 13-14, 21, 27. But *FMC* made clear that the type of relief sought is irrelevant: “[S]overeign immunity applies regardless of whether a private plaintiff’s suit is for monetary damages or some other type of relief.” *FMC*, 535 U.S. at 765. The PTAB, with its power to cancel patent claims, is *more* adjudicatory than the FMC, which cannot enforce its own orders. *Id.* at 762-64.

Patent owners failing to appear in IPRs risk entry of adverse judgments by the PTAB. Pet. 6.<sup>4</sup> The PTAB’s ability to continue an IPR without the petitioner (an ability Respondents overstate, Pet. 28 n.10) reflects the absence of a case-or-controversy requirement, which *FMC* described as an even greater risk to a sovereign’s interests. 535 U.S. at 760 n.11. The PTAB’s powers magnify the need for this Court’s review.

Respondents fail to distinguish cases faithfully applying *FMC*: *R.I. Dep’t of Env’tl. Mgmt. v. United States*, 304 F.3d 31 (1st Cir. 2002), and *Conn. Dep’t of Env’tl. Prot. v. OSHA*, 356 F.3d 226 (2d Cir. 2004).

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<sup>4</sup> *E.g.*, *K/S Himpp v. III Holdings 7, LLC*, IPR2017-00929, 2018 WL 357361 (PTAB Jan. 10, 2018); *VDF Futurceuticals, Inc. v. Kazerooni*, IPR2017-00547, 2018 WL 842176 (PTAB Feb. 9, 2018); *Fanuc Corp. v. Diffracto Ltd.*, IPR2016-01047, 2016 WL 9000408 (PTAB July 12, 2016); *Shire Development LLC v. Lucerne Biosciences, LLC*, IPR2014-00739, 2015 WL 4035976 (PTAB June 4, 2015).

Both cases involved statutory, government-created rights (like patents). Contrary to Respondents' assertion, the administrative proceedings in these cases did not necessarily involve "coercive relief against a State." BIO 28. *See* 304 F.3d at 38 ("Unlike a court, the Secretary does not have inherent authority to issue enforceable orders" or "the power of contempt, mandamus, or the like"); 356 F.3d at 229 ("If a petition for review is timely filed, the recommended decision of the ALJ becomes inoperative unless and until the Board issues an order adopting the recommended decision."). Regardless, *FMC* makes clear that immunity does not turn on the type of relief sought and whether it is coercive.

***Alden***: Respondents misstate the relevance of *Alden v. Maine*, 527 U.S. 706 (1999). They nowhere deny that *Alden* requires a lawsuit be "control[led]," "prosecuted," and conducted by a federal official exercising "political responsibility" (not merely initially instituted by a federal official), in order to qualify for the sovereign immunity exception. 527 U.S. at 755-56. IPRs flunk this test. Even if the Director were a politically accountable officer comparable to the Attorney General, the Director lacks the requisite control over the prosecution and conduct of the IPR, which are controlled by private parties.

Respondents do not deny that no other circuit has interpreted *Alden* as allowing an action commenced and prosecuted by a private party against a sovereign entity to evade immunity simply because of the discretionary role of a federal official in deciding whether to permit that action to proceed. Pet. 22-25. Instead, Respondents argue that the

cases cited in the Petition are inapposite because patents involve public rights. BIO 24. But the “public rights” argument is foreclosed by *FMC*, as noted above. Further, Respondents ignore that the cases cited in the Petition at 22-25 involved *qui tam* suits, taxes (quintessential public rights), and other governmentally conferred rights under statutory schemes — confirming that the Federal Circuit flouted *Alden*.

Respondents deny that patent owners are compelled as a practical matter to respond to IPR petitions, citing three examples in the past seven years where IPRs were not instituted even though patent owners declined to file preliminary responses. BIO 24 n.3. Given that over 9,000 IPRs have been filed since Sept. 16, 2012, with over 5,800 instituted,<sup>5</sup> three counterexamples are not probative or reassuring to patent owners.

*Oil States* and *Cuozzo*: Respondents read *Oil States Energy Services v. Greene’s Energy Group, LLC*, 138 S.Ct. 1365 (2018), and *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131 (2016), as negating *SAS*s holding as to the adjudicatory nature of IPRs. But *Oil States* and *Cuozzo* both reaffirmed that IPRs possess adjudicatory attributes; they merely opined that IPRs are not identical to district court proceedings. *See Oil States*, 138 S.Ct. at 1371, 1378 (IPRs use “court-like procedures” before “an adjudicatory body” composed of “judges” and include “some of the features of adversarial litigation”); *Cuozzo*, 136 S.Ct. at 2143 (IPRs have “adjudicatory

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<sup>5</sup> [https://www.uspto.gov/sites/default/files/documents/trial\\_statistics\\_jan2019.pdf](https://www.uspto.gov/sites/default/files/documents/trial_statistics_jan2019.pdf).

characteristics” and are “similar to court proceedings,” but not a “surrogate”). *FMC* makes clear that an administrative adjudication need not be identical to court proceedings in order to trigger immunity.

4. Respondents acknowledge that, under the Federal Circuit’s decision, IPRs could be instituted against federally owned patents under certain circumstances. BIO 30. That significant admission demonstrates the breadth of the decision below.

Respondents insist the Federal Circuit did not decide questions of state immunity (BIO 29), but they offer no response to the Petition’s showing that the Federal Circuit’s rationale (which turns on the nature of IPRs, rather than the identity of the patent owner) applies equally to state and federal immunity in IPRs. That is why nine States or state entities filed *amici* briefs in support of rehearing *en banc*, stressing the importance of this case for principles of state immunity.

In the pending case of *Regents of Univ. of Minn. v. LSI Corp.*, No. 18-1559 (Fed. Cir.), which presents the question of state immunity in IPRs, the United States explained that “the Court’s reasoning [in *Saint Regis Mohawk*] leaves no room for doubt that the same analysis applies to state sovereign immunity.” U.S. Br. in No. 18-1559, at 7 (Fed. Cir.). At argument, the Government reiterated that “*Saint Regis* controls this case.”<sup>6</sup> A Federal Circuit judge told the State, “your problem is that we went

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<sup>6</sup> Available at <http://oralarguments.ca9.uscourts.gov/default.aspx?fl=2018-1559.mp3>.

through all of this in *Saint Regis* . . . . I’m having difficulty in seeing why the reasoning of that, while limited in context to tribal sovereign immunity, doesn’t apply equally to state sovereign immunity.”<sup>7</sup>

Respondents’ argument that tribes lack immunity regarding the federal government’s superior sovereign powers (BIO 18) only serves to underscore the sweeping nature of the Federal Circuit’s ruling. States lack such immunity as well, *Alden*, 527 U.S. at 755, reinforcing the conclusion that the decision below governs state immunity.

Respondents propose differences between state and tribal immunity (BIO 17-18), but the Federal Circuit did not rely on them. Instead, it focused on the nature of IPRs. Respondents’ argument is irrelevant as well as inaccurate.<sup>8</sup>

5. The fact that an IPR’s purpose is to ensure compliance with federal law (BIO 18) does not render immunity inapplicable. The purpose of the *FMC* administrative procedure was similarly to enforce federal law. What matters for immunity are the *means* chosen by Congress. If Congress provides for enforcement of federal law through agency

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<sup>7</sup> *Id.*

<sup>8</sup> Respondents’ attempt to diminish tribal immunity is incorrect. In *Three Affiliated Tribes of Fort Berthold Reservation v. Wold Engineering*, 476 U.S. 877, 890 (1986), this Court observed that tribal immunity was different from, not “narrower than” (BIO 17), state immunity, precisely because “tribes were not parties to the Constitutional Convention” (BIO 17) and thus did not surrender immunity from suit by sister States. *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 756 (1998).



action, there is no tribal immunity bar. But if Congress provides for enforcement via administrative adjudication prosecuted by private parties, tribal immunity applies, absent a clear congressional statement of abrogation, which the Federal Circuit did not find and which Respondents do not claim is present. The cases cited by Respondents (BIO 18) recognize the distinction between agency actions and private-party suits. *See Pauma v. NLRB*, 888 F.3d 1066, 1078 (9th Cir. 2018) (NLRB acts “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) (“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”).

Congress’ “plenary control” over tribal immunity (BIO 17, quoting *Bay Mills*, 572 U.S. at 788-89) is just the point: Congress could have abrogated tribal immunity in IPRs (indeed, bills have been introduced to do exactly that<sup>9</sup>), but Congress has not done so. Instead, when Congress created IPRs in 2011, it chose an adversarial, party-based adjudication procedure and departed from the inquisitorial agency-led model of reexaminations — adopting the very approach this Court made clear in *FMC* would trigger sovereign immunity.

6. Respondents note the absence of an inter-circuit conflict (BIO 1), but that is a red herring.

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<sup>9</sup> <https://www.congress.gov/bill/115th-congress/senate-bill/1948/text>; <https://www.congress.gov/bill/115th-congress/senate-bill/2514/text>.

Given the Federal Circuit’s exclusive jurisdiction over PTAB appeals, there is no plausible scenario for a circuit split. That is why “the Supreme Court’s certiorari concerns with the patent decisions of the Federal Circuit turn largely on the importance of the questions presented.” Stephen M. Shapiro, *et al.*, SUPREME COURT PRACTICE § 4.21, at 289 (10th ed. 2017). Nor is the absence of a dissenting opinion (BIO 10) particularly significant. Since the 2013 Term, this Court has granted certiorari in 21 Federal Circuit intellectual property cases, and in nine there were no recorded dissents at the panel or *en banc* stage.<sup>10</sup>

7. Respondents agree that “[t]his case is not moot,” BIO 10, despite the Federal Circuit’s affirmance of the judgment of the Eastern District of Texas in a separate infringement trial. Pet. App. 89a-91a. As the Petition noted, the Texas judgment held thirteen representative claims of *four* of the Restasis® patents invalid for obviousness, while the IPRs involve all claims of *all six* Restasis® patents. Pet. 35. The two proceedings are not coextensive.

Moreover, the Tribe has not disclaimed any of the patent claims, and it suffers irreparable harm from

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<sup>10</sup> See *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 139 S.Ct. 628 (2019); *Oil States*, 138 S.Ct. 1365 (2018) (summary affirmance in Federal Circuit); *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S.Ct. 1514 (2017); *Samsung Elecs. Co., Ltd. v. Apple Inc.*, 137 S.Ct. 429 (2016); *Halo Elecs., Inc. v. Pulse Electronics, Inc.*, 136 S.Ct. 1923 (2016); *Stryker Corp. v. Zimmer*, 136 S.Ct. 1923 (2016); *Teva Pharm. USA v. Sandoz, Inc.*, 135 S.Ct. 831 (2015); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 US 898 (2014); *Octane Fitness LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545 (2014).

being subject to the PTAB's jurisdiction, even if the PTAB is simply deciding whether to follow the judgment of the Eastern District of Texas.

### 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	JONATHAN S. MASSEY <i>Counsel of Record</i> MASSEY & GAIL LLP 1000 Maine Ave., SW, Suite 450 Washington, DC 20024 Tel: (202) 652-4511
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	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
<i>Counsel for Saint Regis Mohawk Tribe</i>	<i>Counsel for Allergan, Inc.</i>

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