Nos. 18-1638, 18-1639, 18-1640, 18-1641, 18-1642, 18-1643

In the United States Court of Appeals For the Federal Circuit

SAINT REGIS MOHAWK TRIBE, ALLERGAN, INC.,

Appellants,

v.

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

Appellees.

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

PETITION FOR REHEARING EN BANC OF APPELLANTS SAINT REGIS MOHAWK TRIBE AND ALLERGAN, INC.

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CERTIFICATE OF INTEREST

Counsel for Appellants certify the following:

1. Full Name of Party Represented by me	2. Name of Real Party in interest represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Saint Regis Mohawk Tribe	N/A	N/A
Allergan, Inc.	N/A	Allergan plc

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will affect or be directly affected by this Court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a) (5) and 47.5(b).

Federal Circuit: Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.,

No. 2018-1130

Regents of the University of Minnesota v. LSI Corp.,

No. 2018-1559

E.D. Texas: Allergan, Inc. v. Deva Holding A.S., No. 2:16-cv-1447

August 20, 2018 Respectfully submitted,

/s/ Marsha K. Schmidt /s/ Jonathan S. Massey

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Saint Regis Mohawk Tribe Allergan, Inc.

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STATEMENT OF COUNSEL PURSUANT TO RULE 35(b)(2)

Based on my professional judgment, I believe the panel decision is contrary

to the following decision(s) of the Supreme Court of the United States or the

precedent(s) of this court: Federal Maritime Comm'n v. S.C. State Ports Auth., 535

U.S. 743 (2002); SAS Inst. Inc. v. Iancu, 138 S.Ct. 1348 (2018); Alden v. Maine, 527

U.S. 706 (1999); Vas-Cath, Inc. v. Curators of Univ. of Mo., 473 F.3d 1376 (Fed.

Cir. 2007).

Based on my professional judgment, I believe this appeal requires an answer

to one or more precedent-setting questions of exceptional importance: whether

sovereign immunity may be asserted in inter partes reviews before the Patent Trial

and Appeal Board.

/s/ Marsha K. Schmidt

Counsel for Appellant Saint Regis Mohawk Tribe

/s/ Jonathan S. Massey

Counsel for Appellant Allergan, Inc.

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INTRODUCTION

This case presents the question whether a federally recognized Indian tribe – and, in fact, whether any sovereign – may assert sovereign immunity in an *inter partes* review ("IPR") before the Patent Trial and Appeal Board ("Board" or "PTAB"). As the panel acknowledged, "Indian tribes possess 'inherent sovereign immunity,' and suits against them are generally barred 'absent a clear waiver by the tribe or congressional abrogation." Add.5 (citation omitted). The panel also recognized that sovereign immunity applies in administrative adjudications between private parties. Add.6-7; *see Federal Maritime Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743 (2002) ("*FMC*").

But the panel held that sovereign immunity does not apply in IPRs. Add.8. In so holding, the panel failed to follow the Supreme Court's decision in *FMC*, which held that an administrative system of adversarial adjudications between private parties triggers sovereign immunity. 535 U.S. at 747.

The panel's decision is also inconsistent with the Supreme Court's decision in SAS Inst. Inc. v. Iancu, 138 S.Ct. 1348 (2018), 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 (emphases added).

Further, the panel misconstrued *Alden v. Maine*, 527 U.S. 706, 756 (1999), in opining that the Director's discretion whether to institute an IPR is comparable to the Attorney General's control over whether, how, and when to sue a sovereign state and in controlling the prosecution of any such action. Add.8.

The panel's decision also conflicts with this Court's determination in *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376 (Fed. Cir. 2007), that patent interference proceedings before the Board of Patent Appeals and Interferences trigger sovereign immunity. The panel did not cite, much less discuss, *Vas-Cath*.

The case presents an important question of federal law. The panel's reasoning effectively forecloses IPR immunity claims by any sovereign entity. Indeed, the United States described the immunity issue in this case as one of "cross-cutting significance." U.S. Brief *Amicus Curiae*, at 1 (filed May 11, 2018). An appeal involving state university immunity is already before this Court. *See* No. 2018-1559, *Regents of the University of Minnesota v. LSI Corp.* A question this momentous warrants consideration by the full Court.

STATEMENT

IPRs are "party-directed, adversarial" proceedings before neutral judges with "many of the usual trappings of litigation" such as discovery, briefing, and oral hearing. *SAS*, 138 S.Ct. at 1354-55. The Board's own rules define IPRs as "trials."

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37 C.F.R. § 42.100(a). Private parties, not the Board, determine the issues adjudicated. Indeed, "inter partes" means "between parties."

Prior to this case, the PTAB had repeatedly followed *FMC* and *Vas-Cath* to conclude that IPRs are adjudications triggering sovereign immunity. The PTAB concluded that "the analysis in *FMC* applies to" IPRs,¹ "the same factors that led the *Vas-Cath* court to analogize interference proceedings to district court proceedings also exist" regarding IPRs,² and, "under *FMC* and *Vas-Cath*, *inter partes* reviews are similar to lawsuits."³

The PTAB had sound reasons for these conclusions:

- IPRs "begin with the filing of a petition [by a private party] that identifies all of the claims challenged and the grounds and supporting evidence on a claim-by-claim basis." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,757 (Aug. 14, 2012). The private-party petitioner controls the claims challenged and the grounds of the attacks.
- The proceeding cannot start until the private-party petitioner serves the patent owner with the petition. 35 U.S.C. § 312(a)(5).

¹ Covidien LP v. Univ. of Fla. Research Found. Inc., 2017 WL 4015009, at *8 (PTAB Jan. 25, 2017).

² NeoChord, Inc. v. Univ. of Md., Balt., No. IPR2016-00208, Paper 28, at 7 (PTAB May 23, 2017)

³ Reactive Surfaces, Ltd. v. Toyota Motor Corp., 2017 WL 2992435, at *2 (PTAB July 13, 2017).

• The patent owner may respond to the petition with a motion or a preliminary response. 37 C.F.R. §§ 42.20-42.25.

- The PTAB and Director are not parties to the proceeding. 37 C.F.R.
 § 42.2. They lack authority to initiate a proceeding without a private party's petition or to engage in investigations that would lead to the filing of a claim.
- 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.
- 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).
- 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).

• 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 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.
- The parties have the right to an oral hearing. 35 U.S.C. § 316(a)(10).
- The three PTAB "judges" issue a final written decision known as a "judgment." 77 Fed. Reg. at 48,766-67.
- 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 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.

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 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.⁴

The panel nevertheless rejected the Tribe's assertion of immunity. It cited "several factors" suggesting that an "IPR is more like an agency enforcement action than a civil suit brought by a private party" (Add.8): (1) the Director has discretion in deciding whether to institute an IPR (*id.*); (2) the Board may "continue review even if the petitioner chooses not to participate" and intervene in appeals (*id.* at 9); (3) "procedures in IPR do not mirror the Federal Rules of Civil Procedure" (*id.*); and (4) "[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 11.

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 13.

⁴ *See* 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.

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ARGUMENT

I. This Case Presents Issues Of Exceptional Importance Warranting En Banc Review.

The panel's decision effectively abrogated all sovereign immunity in IPRs. Although the panel stated that its decision was limited to the assertion of tribal immunity (Add.12), the panel's holding turns entirely on the inherent attributes of the IPR proceeding itself. Those attributes are the same for all IPRs, and thus the panel's decision effectively bars States and even federal agencies, such as NASA, HHS, the U.S. Army, and the U.S. Navy, which are some of nation's most prolific patent filers, from asserting sovereign immunity in IPRs brought against them as patent owners.

An appeal raising state immunity is already before this Court. *See* No. 2018-1559, *Regents of the University of Minnesota v. LSI Corp.* The pendency of cases presenting closely related sovereign immunity questions warrants *en banc* review.

- II. The Panel Decision Is Contrary To Precedent Of The Supreme Court And This Court.
 - A. The Panel Failed To Follow FMC, SAS, Alden, And Vas-Cath.

Although the panel articulated four factors to justify its departure from the Supreme Court's decision in *FMC*, none withstands scrutiny. The panel did not cite,

⁵ "Top 300 Organizations Granted U.S. Patents in 2017," http://www.ipo.org/wp-content/uploads/2018/06/2017_Top-300-Patent-Owners.pdf.

let alone attempt to distinguish, this Court's determination in *Vas-Cath* that patent interference proceedings between private parties trigger sovereign immunity. The panel's reasoning conflicts not only with *FMC* and *Vas-Cath*, but also with the Supreme Court's decisions in *SAS* and *Alden*.

1. The Director's Role In Deciding Whether To Institute An IPR Does Not Eliminate Sovereign Immunity.

The panel found that the Director's role in deciding whether to institute an IPR means that "a politically accountable, federal official has authorized the institution of that proceeding." Add.8 (citing *Alden v. Maine*, 527 U.S. 706, 756 (1999)).

But the Supreme Court in *SAS* rejected a similar argument about the significance of the Director's role in instituting an IPR. The Court ruled the Director's role does not transform an IPR into an "agency-led, inquisitorial process"; instead, it remains a "party-directed adversarial process" that "mimics civil litigation." 138 S.Ct. at 1352, 1355. The Court observed that the Director may not "start proceedings on his own initiative" or "initiate whatever kind of *inter partes* review he might choose." *Id.* at 1355. That distinction is critical and distinguishes IPRs from typical agency proceedings, where the agency (as prosecutor) has discretion over the scope and nature of the proceedings. With respect to IPRs, "the petitioner's petition, not the Director's discretion, is supposed to guide the life of the litigation," and in multiple ways, "the statute tells us that the petitioner's contentions,

not the Director's discretion, define the scope of the litigation all the way from institution through to conclusion." 138 S.Ct. at 1356-57. This reasoning in *SAS* was not dicta; the significance of the Director's role in instituting an IPR was integral to the question whether the PTAB was required to address, in its final written decision, every claim challenged in an IPR.

Notably, the Government made the same arguments in *SAS* as the panel decision here, and the Supreme Court flatly rejected them. *See* No. 16-989, Brief of Federal Respondent, at 12 (arguing that Director's "broad discretion in determining whether to institute" an 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 review "differs from district-court litigation" and is "a mechanism for the agency to revisit its own prior determination").

The panel's decision also conflicts with *Alden v. Maine* (cited by the panel at Add.8), where the Supreme Court explained that "[s]uits brought by the United States itself require the exercise of political responsibility for each suit prosecuted against a State, a control which is absent from a broad delegation to private persons to sue nonconsenting States." 527 U.S. at 756. The Supreme Court stressed that a suit brought in the name of the United States "is commenced and prosecuted . . . by

those who are entrusted with the constitutional duty to 'take Care that the Laws be faithfully executed.'" *Id.* at 755.

IPRs do not involve the kind of political accountability discussed in *Alden*. The Attorney General decides *whether*, *how*, *when*, and *where* to sue a sovereign State and also *determines* the claims that are brought (or not brought) and *controls* the subsequent litigation. In contrast, IPRs are brought in the name (and for the benefit) of a private-party petitioner, not the government. Private parties draft IPR petitions and litigate the proceedings; the Director has no role in how IPRs are prosecuted. Moreover, the Director has delegated to the 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. In short, the Director's attenuated role in IPRs is far removed from the Attorney General's responsibility in *Alden*.

The panel's reasoning is also inconsistent with *FMC*, where the FMC controlled the conduct of proceedings before administrative adjudication actually occurred. 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). Despite the control vested in the FMC, the Supreme Court held that sovereign immunity applied.

Moreover, in *FMC* the Court rejected the Government's argument that sovereign immunity should not apply because the politically accountable Attorney General would ultimately be responsible for enforcement of any Commission decision, as the FMC lacks the authority to enforce its own orders. 535 U.S. at 761-62. Instead, the Court held that a subsequent enforcement action by the Attorney General does not "retroactively convert an [administrative] adjudication initiated and pursued by a private party into one initiated and pursued by the Federal Government." *Id.* at 764. By the same token, IPRs are initiated and pursued by private parties, and therefore remain adversarial adjudications between private parties, regardless of the PTAB's role in instituting them.

The panel's reasoning also provides no basis for distinguishing *Vas-Cath*, which involves interference proceedings. As with IPRs, "the Director has discretion whether or not to declare an interference." *Eli Lilly and Co. v. Board of Regents of the University of Washington*, 334 F.3d 1264, 1272 (Fed. Cir. 2003) (Lourie, J., dissenting) (citing 35 U.S.C. § 135 (containing the provisos "in the opinion of the Director" and "an interference *may* be declared")) (emphasis added). An examiner may reject a suggestion of interference if the criteria specified in 37 C.F.R. § 41.202(a)(1)-(6) are not met. Manual of Patent Examination Procedure Rule 2304.02(c) explains that an examiner may reject a claim suggested for an

interference under 35 U.S.C. §§ 102(a), 102(e), or 135(b). The panel thus failed to distinguish either *FMC* or *Vas-Cath*.

In fact, the panel's reasoning is backwards. Contrary to Judge Dyk's concurrence, the history of IPRs shows that Congress gave the Director discretion to institute privately-filed IPRs precisely *because* they mimic private litigation. The Committee Report accompanying the American Invents Act explained that the legislation was intended to "convert[] inter partes reexamination from an examinational to an *adjudicative* proceeding." H.R. Rep. No. 112-98, at 46 (2011) (emphasis added). The report recognized the dangers posed by IPRs "as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent." *Id.* at 48. Accordingly, the Report instructed the Director to use his authority "to address potential abuses." *Id.* The statutory safeguard of the Director's discretion *not* to institute IPRs reflects a congressional understanding that they are *not* agency actions.

The panel's decision is also inconsistent with the Board's own rules, which provide that the Board may adjudicate the "preliminary proceeding" of an IPR, which "begins with the filing of a petition," even *prior to* any decision to institute review. 37 C.F.R. § 42.2. For example, even before institution, the Board can order discovery, sanction parties, conduct oral hearings, and authorize and decide motions. *E.g.*, *RPX Corp. v. Applications in Internet Time, LLC*, IPR2015-01750, Paper 11

(PTAB Oct. 20, 2015) (granting a deposition before institution); *id.*, Paper 23 (PTAB Dec. 4, 2015) (authorizing a protective order before institution); *id.*, Paper 58 (PTAB May 6, 2016) (ordering sanctions before institution).

2. The PTAB's Ability To Issue A Decision Absent The Petitioner And To Intervene On Appeal Does Not Eliminate Sovereign Immunity.

As a further reason for departing from *FMC*, the panel pointed to the PTAB's ability to issue a decision under 35 U.S.C. § 317(a) if the petitioner withdraws. Add.9. But that feature of IPRs cuts in favor of applying sovereign immunity under *FMC*, not against it. The feature reflects the absence of a case-or-controversy requirement in administrative tribunals, which *FMC* described as an even "greater insult" to a sovereign's interests. 535 U.S. at 760 n.11.

Moreover, the statute makes clear that the PTAB's authority to issue a decision 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." 35 U.S.C. § 317(a). 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 actually to prosecute a claim in the petitioner's absence.

Nor does the Director's statutory right to participate in appeals (Add.9) support the panel. 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 Fourth Circuit and the Supreme Court. Yet the courts still applied sovereign immunity. Moreover, this Court has held that the Director's ability to intervene on appeal is derivative of the patent owner's injury. *Knowles Electronics LLC v. Iancu*, 886 F.3d 1369, 1372 n.2 (Fed. Cir. 2018). IPRs are party-based, not agency-led, and the panel's reasoning does not justify its departure from *FMC*, *SAS*, and *Vas-Cath*.

3. The Lack Of Complete Identity Between IPRs And Federal Civil Litigation Does Not Eliminate Sovereign Immunity.

The panel acknowledged that IPRs possess "adjudicatory characteristics' similar to court proceedings" but opined that IPR procedures do not "mirror" the Rules of Civil Procedure governing federal district courts. Add.7, 9. But *FMC* and *Vas-Cath* did not require that the procedures be identical, and there is no reason for such a requirement.

In *Vas-Cath*, the Court concluded that interference proceedings "bear 'strong similarities' to civil litigation" (473 F.3d at 1382 (citation omitted)): "PTO interferences involve adverse parties, examination and cross-examination by deposition of witnesses, production of documentary evidence, findings by an impartial federal adjudicator, and power to implement the decision." *Id.* All these

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features are present in IPRs, making the panel's decision irreconcilable with *Vas-Cath*.

The panel's decision also conflicts with *FMC*, which 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. In fact, the PTAB, which has the power to cancel patent claims, is considerably *more* adjudicatory than the FMC, which cannot enforce its own orders and must rely on a district court. *Id.* at 762-64.

The panel noted certain differences between IPRs and federal civil litigation, such as the amendment of pleadings, length of typical hearings, and frequency of live testimony. (Add.10.)⁶ But neither *Vas-Cath* nor *FMC* mentioned, let alone turned on, these factors. Indeed, *FMC* warned that the differences between an administrative tribunal and an Article III court actually presented a greater danger to sovereign interests. 535 U.S. at 760 n.11.

Previously, the PTAB correctly construed *FMC* and *Vas-Cath*. The PTAB explained that IPRs "are not identical to lawsuits," "[b]ut the test for Eleventh

⁶ In fact, the PTAB has made clear that it "will permit live testimony at the oral hearing." Trial Practice Guide Update at 22. The panel also understated the availability of discovery in IPRs (Add.10), which includes documents cited in filings, depositions of affiants, and information inconsistent with a position being advanced by a party. Additional discovery is available "in interests of justice." 37 C.F.R. § 42.51(b)(2)(i).

Amendment applicability does not require identity with civil litigation in all respects." *Reactive Surfaces*, 2017 WL 2992435, *2 (quoting *FMC*); *see also LSI Corp. v. Regents of the University of Minnesota*, 2017 WL 6517562, *2 & n.2 (PTAB Dec. 19, 2017) (applying *FMC* and *Vas-Cath* despite "the differences between court and agency proceedings"). By asking whether IPRs "mirror" civil litigation (Add.9), the panel failed to follow *FMC* and *Vas-Cath*.

4. The Contrast Between IPRs And Ex Parte Re-Examinations Supports The Availability Of Sovereign Immunity.

The panel found irrelevant the contrast between adversarial IPRs and inquisitorial *ex parte* reexaminations. (Add.11). But *SAS* found the opposite. It compared IPRs with the *ex parte* reexamination scheme, where the Director is authorized "to investigate a question of patentability '[o]n his own initiative, and at any time." 138 S.Ct. at 1355. The PTAB has similarly recognized that, unlike IPRs, "[a]n ex parte reexamination proceeding is not a trial proceeding." *SAS* concluded 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" – "a choice [that] neither [the Court] nor the agency may disregard." *Id.* The panel's decision is inconsistent with *SAS* in this additional respect.

⁷ Trial Practice Guide Update at 13.

B. Oil States and Cuozzo Do Not Support the Panel's Decision.

The panel cited Oil States Energy Services v. Greene's Energy Group, LLC, 138 S.Ct. 1365 (2018), but it confirms 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. Moreover, Oil States did not address the question here. Instead, Oil States concerned whether IPRs entail the exercise of the Article III "judicial power." The Court described its "narrow[]" holding, id. at 1379, as limited to the Article III question: "[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. But the Article III "public rights" analysis is separate from whether an adjudication triggers sovereign immunity. After all, both FMC and Vas-Cath concerned "public rights," but those decisions 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).

Nor does *Cuozzo Speed Techs.*, *LLC v. Lee*, 136 S.Ct. 2131 (2016), support the panel. *Cuozzo* explained that IPRs "help[] resolve concrete patent-related disputes *among parties*." *Id.* at 2144 (emphasis added). *Cuozzo* acknowledged the "adjudicatory characteristics" of IPRs, "which make these agency proceedings

similar to court proceedings." *Id.* at 2143. *Cuozzo* described IPRs as enabling a "second look" at patent validity, *id.* at 2144, but under *FMC* and *Vas-Cath* a "second look" triggers sovereign immunity if it is achieved via adversarial adjudications between private parties.

CONCLUSION

This Court should grant the Petition for rehearing *en banc*, vacate the panel decision, reverse the Board's decision, and direct the dismissal of the IPRs.

Dated: August 20, 2018 Respectfully submitted.

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ADDENDUM

Casse: 18-1638 Document: 136-1 Page: 29 Filed: 07/20/2018

United States Court of Appeals for the Federal Circuit

SAINT REGIS MOHAWK TRIBE, ALLERGAN, INC., Appellants

 \mathbf{v} .

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

Appellees

 $2018\text{-}1638, 2018\text{-}1639, 2018\text{-}1640, 2018\text{-}1641, 2018\text{-}1642, \\ 2018\text{-}1643$

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

Decided: July 20, 2018

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Before Dyk, Moore, and Reyna, Circuit Judges.

Opinion for the court filed by Circuit Judge MOORE.

Concurring opinion filed by Circuit Judge DYK.

MOORE, Circuit Judge.

Casse: 18-1638 Document: 137-1 Page: 32 Filed: 07/20/2018

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

BACKGROUND

This appeal stems from a multifront dispute between Allergan and various generic drug manufacturers regarding patents related to Allergan's Restasis product (the "Restasis Patents"), a treatment for alleviating the symptoms of chronic dry eye. In 2015, Allergan sued Appellees in the Eastern District of Texas, alleging infringement of the Restasis Patents based on their filings of Abbreviated New Drug Applications. On June 3, 2016, Mylan petitioned for IPR of the Restasis Patents. Subsequently, Teva and Akorn filed similar petitions. The Board instituted IPR and scheduled a consolidated oral hearing for September 15, 2017.

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

Allergan and the Tribe appeal. We have jurisdiction pursuant 28 U.S.C. § 1295(a)(4)(A). Board decisions must be set aside if they are "arbitrary, capricious, an abuse of

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discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

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Analysis

As "domestic dependent nations," Indian tribes possess "inherent sovereign immunity," and suits against them are generally barred "absent a clear waiver by the tribe or congressional abrogation." Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Okla., 498 U.S. 505, 509 (1991). This immunity derives from the common law, Santa Clara Pueblo v. Martinez, 436 U.S. 49, 58 (1978), and it does not extend to actions brought by the federal government, see, e.g., E.E.O.C. v. Karuk Tribe Hous. Auth., 260 F.3d 1071, 1075 (9th Cir. 2001); United States v. Red Lake Band of Chippewa Indians, 827 F.2d 380, 383 (8th Cir. 1987). Generally, immunity does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action. See, e.g., Pauma v. NLRB, 888 F.3d 1066 (9th Cir. 2018) (holding the NLRB could adjudicate unfair labor charges brought by the Board against a tribally-owned business operating on tribal land); Karuk Tribe Hous. Auth., 260 F.3d at 1074 (holding tribe not immune in EEOC enforcement action); cf. Fed. Power Comm'n v. Tuscarora Indian Nation, 362 U.S. 99, 122 (1960) (holding that tribal lands were subject to takings by the Federal Power Commission). There is not, however, a blanket rule that immunity does not apply in federal agency proceedings. Fed. Maritime Comm'n v. S.C. State Ports Auth., 535 U.S. 743, 754–56 (2002) ("FMC").

In *FMC*, the Supreme Court considered whether state sovereign immunity precluded the Federal Maritime Commission from "adjudicating a private party's complaint that a state-run port ha[d] violated the Shipping Act of 1984." *Id.* at 747. In answering this question, the Court asked whether Commission adjudications "are the

type of proceedings from which the Framers would have thought the States possessed immunity when they agreed to enter the Union." Id. at 756. It decided they were, given the FMC proceedings' "overwhelming" similarities with civil litigation in federal courts. *Id.* at 759. example, the Court noted the procedural rules in the Commission's proceedings "bear a remarkably strong resemblance" to the rules applied in civil litigation, and the discovery procedures were "virtually indistinguishable" from the procedures used in civil litigation. Id. at 757-58. The Court also distinguished the proceedings at issue from other proceedings in which the Commission had the authority to decide whether to proceed with an investigation or enforcement action. Id. at 768. In doing so, the Court recognized a distinction between adjudicative proceedings brought against a state by a private party and agency-initiated enforcement proceedings.

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

Although the precise contours of tribal sovereign immunity differ from those of state sovereign immunity, the

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

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

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

In contrast, in SAS Institute Inc. v. Iancu, 138 S. Ct. 1348 (2018), the Court emphasized the adjudicatory aspects of IPR and the way in which it "mimics civil litigation." Id. at 1352; see also id. at 1353, 1355. It explained that Congress structured IPR so that the petitioner, not the USPTO Director, "define[s] the contours of the proceeding." Id. at 1355. The Court contrasted the "party-directed, adversarial" IPR process, in which the Director is only given the choice of whether to institute IPR, with the "inquisitorial approach" established by the ex parte reexamination statute, under which the Director

was given the authority to investigate patentability on his own initiative. *Id*.

Ultimately, several factors convince us that IPR is more like an agency enforcement action than a civil suit brought by a private party, and we conclude that tribal immunity is not implicated. First, although the Director's discretion in how he conducts IPR is significantly constrained, he possesses broad discretion in deciding whether to institute review. Oil States, 138 S. Ct. at 1371. Although this is only one decision, it embraces the entirety of the proceeding. If the Director decides to institute, review occurs. If the Director decides not to institute, for whatever reason, there is no review. In making this decision, the Director has complete discretion to decide not to institute review. Oil States, 138 S. Ct. at 1371 ("The decision whether to institute inter partes review is committed to the Director's discretion."). The Director bears the political responsibility of determining which cases should proceed. While he has the authority not to institute review on the merits of the petition, he could deny review for other reasons such as administrative efficiency or based on a party's status as a sovereign. See Wi-Fi One, LLC v. Broadcom Corp., 878 F.3d 1364, 1372 (Fed. Cir. 2018) (en banc). Therefore, if IPR proceeds on patents owned by a tribe, it is because a politically accountable, federal official has authorized the institution of that proceeding. See Alden v. Maine, 527 U.S. 706, 756 (1999) (contrasting suits in which the United States "exercise[s] . . . political responsibility for each suit prosecuted" in order to fulfill its obligation under the Take Care Clause with "a broad delegation to private persons to sue nonconsenting States"). In this way, IPR is more like cases in which an agency chooses whether to institute a proceeding on information supplied by a private party. In FMC, the Court recognized that immunity would not apply in such a proceeding. FMC, 535 U.S. at 768.

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

in the IPR context. It is the Director, the politically appointed executive branch official, not the private party, who ultimately decides whether to proceed against the

sovereign.

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

Third, unlike *FMC*, the USPTO procedures in IPR do not mirror the Federal Rules of Civil Procedure. *See*

FMC, 535 U.S. at 757–58. Although there are certain similarities, the differences are substantial. Federal Rules of Civil Procedure provide opportunities for a plaintiff to make significant amendments to its complaint, see Fed. R. Civ. P. 15, the Board has determined that in IPR a petitioner may only make clerical or typographical corrections to its petition, see Nat'l Envtl. Prods. Ltd. v. Dri-Steem Corp., IPR2014-01503, Paper 11 (PTAB Nov. 4, 2014) (citing 37 C.F.R. § 42.104(c)). At the same time, a patent owner in IPR may seek to amend its patent claims during the proceedings, an option not available in civil litigation. 35 U.S.C. § 316(d). IPR also lacks many of the preliminary proceedings that exist in civil litigation. See, e.g., Farmwald v. Parkervision, Inc., IPR2014-00946, Paper 13 (PTAB Jan. 26, 2015) (declining to conduct a *Markman* hearing). Moreover, in civil litigation and the proceedings at issue in FMC, parties have a host of discovery options, including the use of interrogatories, depositions, production demands, and requests for admission. FMC, 535 U.S. at 758. In IPR, discovery is limited to "(A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice." 35 U.S.C. § 316(a)(5); see also 37 C.F.R. § 42.51. In *FMC*, the Court rejected the idea that sovereign immunity could be circumvented by merely moving a proceeding from an Article III court to an equivalent agency tribunal. FMC, 535 U.S. at 760. An IPR hearing is nothing like a district court patent trial. The hearings are short, and live testimony is rarely allowed. Ultratec, Inc. v. CaptionCall, LLC, 872 F.3d 1267, 1270 n.2 (Fed. Cir. 2017) ("Very seldom do IPR proceedings have the hallmarks of what is typically thought of as a trial."). In IPR, the agency proceedings are both functionally and procedurally different from district court litigation. In short, the agency procedures in FMC much more closely approximated a civil litigation than those in IPR.

Finally, while the USPTO has the authority to conduct reexamination proceedings that are more inquisitorial and less adjudicatory than IPR, this does not mean that IPR is thus necessarily a proceeding in which Congress contemplated tribal immunity to apply. The Tribe acknowledged that sovereign immunity would not apply in ex parte or inter partes reexamination proceedings because of their inquisitorial nature. Oral Arg. at 6:30-8:10. The mere existence of more inquisitorial proceedings in which immunity does not apply does not mean that immunity applies in a different type of proceeding before the same agency. Notably, the Supreme Court in Cuozzo recognized inter partes reexamination and IPR have the same "basic purposes, namely to reexamine an agency decision." 136 S. Ct. at 2144. While IPR presents a closer case for the application of tribal immunity than reexamination, we nonetheless conclude that tribal immunity does not extend to these administrative agency reconsideration decisions.

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

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

CONCLUSION

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

AFFIRMED

United States Court of Appeals for the Federal Circuit

SAINT REGIS MOHAWK TRIBE, ALLERGAN, INC., Appellants

 \mathbf{v} .

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

Appellees

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

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

DYK, Circuit Judge, concurring.

I fully join the panel opinion

I fully join the panel opinion but write separately to describe in greater detail the history of inter partes review proceedings, history that confirms that those proceedings are not adjudications between private parties. While private parties play a role, inter partes reviews are fundamentally agency reconsiderations of the

original patent grant, proceedings as to which sovereign immunity does not apply.

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

The Supreme Court held that state sovereign immunity barred the FMC from adjudicating the complaint, but noted that it would not bar the FMC from "institut[ing] its own administrative proceeding against a state-run port," even if that proceeding were prompted by "information supplied by a private party." *Id.* at 768. Private parties, the Court explained, "remain perfectly free to complain to the Federal Government about unlawful state activity and the Federal Government [remains] free to take subsequent legal action." *Id.* at 768 n.19.

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

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

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

Post-grant administrative review of issued patents is a relatively new feature of the patent system. It was first enacted in 1980 to address longstanding concerns about the reliability of the original examination process. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 603 (Fed. Cir. 1985). Before reexamination procedures, once a patent was issued, "there was no way the PTO or private persons could have forced . . . patents back into the examination phase against [the patent owner's] will." *Id.* at 601.² This

The USPTO did have the authority to reissue patents to cure errors in the original. *See Grant v. Raymond*, 31 U.S. 218, 244 (1832); *see also* 35 U.S.C. § 251. Howev-

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was problematic because the USPTO—then and now—is an agency with finite resources that sometimes issues patents in error. Currently, for instance, the USPTO receives over 600,000 applications a year. U.S. Patent & Trademark Office, Performance & Accountability Report 169 tbl.2 (2017). Patent examiners receive roughly 22 hours to review each application, an amount of time that 70% of examiners report as insufficient. See U.S. Gov't Accountability Office, GAO-16-490, Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity 10, 25–26 (2016). And the USPTO struggles to attract and retain examiners with the technical competence required to understand the inventions being reviewed and to perform sufficiently thorough prior art searches. See U.S. Gov't Accountability Office, GAO-16-479, Patent Office Should Strengthen Search Capabilities and Better Monitor Examiners' Work 28-29 & n.50 (2016).

In considering the enactment of reexamination, Congress was well aware of constraints on the accuracy of initial examination and the adverse effects of the issuance of bad patents. The Senate report on patent reexamination emphasized that the USPTO faced "a situation where a limited staff is trying to cope with a constantly increasing workload and is under pressure to make speedy determinations on whether or not to grant patents." S. Rep. No. 96-617, at 8 (1980); see also Patent Reexamination: Hearing on S. 1679 Before the Comm. on the Judiciary, 96th Cong. 3 (1980) (statement of Sen. Bayh) (characterizing the USPTO as "an understaffed and overworked office trying to handle an ever increasing

er, reissue proceedings could only be initiated at the request of the patentee, so they were of limited use in ensuring patent quality. See Russell E. Levine et. al., Ex Parte Patent Practice and the Rights of Third Parties, 45 Am. U. L. Rev. 1987, 2008 (1996).

workload."). The USPTO Commissioner testified that these resource constraints led to uncertainty in the patent system "because pertinent prior patents and printed publications... often are discovered only after a patent has issued and become commercially important." S. Rep. No. 96-617, at 9 (1980). The Commissioner also explained that

The main reason reexamination is needed is because members of the public interested in the validity of a patent are sometimes able to find pertinent prior patents and printed publications not known or available to the PTO. . . .

The patent owner's competitors will devote great effort and expense to invalidating a patent that affects their business. They can afford to look for documentary evidence of unpatentability in library collections, technical journals and other sources not within the PTO's search file. Because of budgetary and time constraints, the examiner's search seldom extends beyond the PTO's 22 million document collection.

Industrial Innovation and Patent and Copyright Law Amendments: Hearing on H.R. 6033, H.R. 6934, H.R. 3806, and H.R. 2414 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the H. Comm. on the Judiciary, 96th Cong. 576 (1981) (statement of Sidney A Diamond, Commissioner of Patents and Trademarks). In

³ See also Thomas E. Popovich, Patent Quality: An Analysis of Proposed Court, Legislative, and PTO—Administrative Reform—Reexamination Resurrected (Part I), 61 J. Pat. Off. Soc'y 248, 269 (1979) (concluding that the issuance of low quality patents was attributable to the USPTO's failure to discover and adequately to consider

short, given the high volume of applications and the USPTO's manpower limitations, pre-grant patent examination was—and still is—an imperfect way to separate the good patents from the bad. Resource constraints in the initial examination period inevitably result in erroneously granted patents.⁴

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

the most relevant prior art and that patent reform should be directed at these failures).

⁴ See U.S. Gov't Accountability Office, GAO-16-490, Patent Office Should Define Quality, Reassess Incentives, and Improve Clarity 25 (2016) (reporting that "examiners' time pressures are one of the central challenges for patent quality"); see also Michael D. Frakes & Melissa F. Wasserman, Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment, 67 Stan. L. Rev. 613, 652–53 (2015) (finding increased patent grant rates correlated with increased resource strain on the USPTO); Shawn P. Miller, Where's the Innovation: An Analysis of the Quantity and Qualities of Anticipated and Obvious Patents, 18 Va. J.L. & Tech. 1, 45 (2013) (estimating that 28% of issued patents would be invalidated as anticipated or obvious).

the presumption of patent validity, as "many courts treated the presumption of validity as coextensive with the presumption of administrative correctness." *Id.* at 12.

Some kind of reexamination procedure was therefore desirable, particularly as to issues of anticipation and obviousness where prior art has always played a central role. "After reexamination," the Commissioner testified, "the presumptive validity of the patent as it leaves the reexamination process will be enhanced. The court will have greater confidence that the patent claims are of exactly the right scope and that any unpatentable original claims have been canceled." Industrial Innovation and Patent and Copyright Law Amendments: Hearing on H.R. 6033, H.R. 6934, H.R. 3806, and H.R. 2414 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the H. Comm. on the Judiciary, 96th Cong. 580– 81 (1981) (statement of Sidney A Diamond, Commissioner of Patents and Trademarks). Reexamination would allow the USPTO to cure its own errors, thereby improving patent quality, bolstering the presumption of patent validity, and restoring the public's and the judiciary's confidence in the USPTO.

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

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

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

In light of these deficiencies, Congress sought to introduce a new system that would make reexamination more effective and broaden its use. H.R. Rep 106-464 at 133 (1999). In 1999, it enacted a new procedure, known as inter partes reexamination, adding to the 1980 Reexamination Act's ex parte option. Act of Nov. 29, 1999, Pub. L. No. 106-113, 113 Stat. 1501 (1999). Inter partes reexamination allowed a third party to file a request for reexamination based on prior art, and if a substantial new

question of patentability was raised, the USPTO would grant the request and proceed with reexamination. 35 U.S.C. § 312 (2002). Unlike exparte reexamination, however, inter partes reexamination allowed third party requesters to participate in the process by providing that "[e]ach time that the patent owner files a response to an action on the merits from the Patent and Trademark Office, the third-party requester shall have one opportunity to file written comments addressing issues raised by the action of the Office or the patent owner's response thereto." Id. at § 314. It also permitted a requester to appeal an examiner's determination that the reexamined patent is valid to the Board of Patent Appeals and Interferences. "The participation by third parties [was] considered vital" to the goal of "improving patent quality and validity" because "in many circumstances they [would] have the most relevant prior art available and incentive to seek to invalidate an allegedly defective patent." H.R. Rep. 107-120, at 4 (2001).

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

It was against this background that, in 2011, Congress enacted the Leahy–Smith America Invents Act, which replaced inter partes reexamination with new postgrant review procedures, such as inter partes review,

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covered business method review, and post-grant review, while retaining ex parte reexamination. See Pub. L. No. 112-29, § 6, 125 Stat. 284, 299–304 (2011). Inter partes review in particular was designed to improve upon the inter partes reexamination process. Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2137 (2016). Similar to reexamination, the purpose behind creating inter partes review was to "improve patent quality and restore confidence in the presumption of validity." H.R. Rep. 112-98. pt. I, at 48 (2011).

Inter partes review, like inter partes reexamination, begins with a third party's filing a petition challenging the validity of one or more claims in a patent on the basis of prior art. The USPTO may institute review if the petitioner demonstrates a "reasonable likelihood that [it] would prevail" in the dispute, rather than instituting if it demonstrates a "substantial new question of patentability," as was the case in reexamination. See 35 U.S.C.

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

§ 314(a). Like inter partes reexamination, the third party remains involved throughout the proceeding, but inter partes review can include discovery and an oral hearing in addition to written comments. It is conducted before the Patent Trial and Appeal Board rather than an examiner. § 316(c).

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

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

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

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

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

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

Student Assistance Corp. v. Hood, 541 U.S. 440, 448 (2004) (bankruptcy).

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

CERTIFICATE OF COMPLIANCE

1. This petition complies with the type-volume limitations of Federal Rule

of Appellate Procedure 35(b)(2(A) because this brief contains 3,896 words,

excluding the exempted parts of the brief.

2. This petition complies with the typeface requirements of Federal Rule

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Dated: August 20, 2018

/s/ Jonathan S. Massey

Jonathan S. Massey

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 20th day of August 2018,

a copy of the foregoing was filed electronically through the Court's CM/ECF

system. Pursuant to Federal Circuit Rule 25, the Notice of Docketing Activity

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Dated: August 20, 2018 /s/ Jonathan S. Massey

Jonathan S. Massey