United States Court of Appeals for the Federal Circuit

SAINT REGIS MOHAWK TRIBE, ALLERGAN, INC.,
Appellants

v.

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

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

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, IPR2017-00599, 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*.

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

BACKGROUND

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

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

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

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

ANALYSIS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

AFFIRMED

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DYK, *Circuit Judge*, concurring.

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

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

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

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

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[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 post-grant review of tribe-owned patents by simply converting the inter partes reviews to ex parte reexaminations. Oral Arg. 6:30–7:08, 54:48–55:15. But inter partes review is not fundamentally different from other reexamination procedures. Rather, inter partes review is a direct successor to ex parte and inter partes reexamination. It shares many of the same procedural features and is designed to address the same problems. And like the reexaminations from which it descends, it is fundamentally agency reconsideration, assisted by third parties, rather than agency adjudication of a private dispute.

Post-grant administrative review of issued patents is a relatively new feature of the patent system. It was first enacted in 1980 to address longstanding concerns about the reliability of the original examination process. *Patlex Corp. v. Mossinghoff,* 758 F.2d 594, 603 (Fed. Cir. 1985). Before reexamination procedures, once a patent was issued, "there was no way the PTO or private persons could have forced . . . patents back into the examination phase against [the patent owner's] will." *Id.* at 601.[2] This

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

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

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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).[3] In

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

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

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

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

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

covered business method review, and post-grant review, while retaining ex parte reexamination. *See* Pub. L. No. 112-29, § 6, 125 Stat. 284, 299–304 (2011). Inter partes review in particular was designed to improve upon the inter partes reexamination process. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016).[5] Similar to reexamination, the purpose behind creating inter partes review was to "improve patent quality and restore confidence in the presumption of validity." H.R. Rep. 112-98, pt. I, at 48 (2011).

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

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

§ 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).

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.