

**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

**BRIEF FOR *AMICUS CURIAE*
STC.UNM AND WILLIAM ESKRIDGE, JR. FOR
APPELLANTS SAINT REGIS MOHAWK TRIBE AND ALLERGAN, INC.**

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CERTIFICATE OF INTEREST

Counsel for amici curiae certify the following:

1. The full name of every amicus I represent is:

STC.UNM and William Eskridge, Jr.

2. The name of the real party-in-interest I represent is:

STC.UNM and William Eskridge, Jr.

3. The parent corporation and publicly held companies that own 10 percent or more of stock of the party I represent is:

STC.UNM is a nonprofit research park formed under the laws of the State of New Mexico. Its sole member is the Regents of the University of New Mexico (“The University”). STC.UNM is governed by an independent board of directors appointed by The University.

William Eskridge, Jr. is a professor and scholar of civil procedure, statutory interpretation, and constitutional law.

4. The names of all law firms and the partner or associates that appeared for this party represented by me in the trial court or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

William Eskridge, Jr.

5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be affected by this Court's decision in this appeal:

Regents of the University of Minnesota v. LSI Corporation et al, Nos. 2018-1559 (Lead), -1560, 1561, 1562, 1563, 1564, 1565.

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STATEMENT BY *AMICUS CURIAE*

STC.UNM is a New Mexico nonprofit research park corporation created and controlled by the Regents of the University of New Mexico. The STC.UNM mission is to “foster a Rainforest in the Desert” and play a vital role in The State of New Mexico’s economic development strategy by nurturing innovation and commercializing technological advances created or developed by The University. To achieve its goals, STC.UNM seeks patent protection for the technologies developed at The University. A key driver of the innovation cycle is STC.UNM’s ability to license its patented technology both to generate income necessary to support additional research and to incent licensees as economic stakeholders to develop the technologies and foster their adoption in the marketplace. Thus, STC.UNM possesses a strong interest in ensuring that it retains its right to participate in the patent system as a sovereign.

William Eskridge, Jr. is a professor and scholar of civil procedure, statutory interpretation, and constitutional law and has a professional and academic interest in seeing that the law develops in accordance with the dictates of the Constitution and sound public policy. Professor Eskridge’s expertise in civil procedure, statutory interpretation, and constitutional law may assist the Court in setting proper precedent.

This brief was not authored by counsel for any party to this case. No party in this case or counsel for a party in this case contributed money that was intended to fund preparing or submitting this brief. No person other than Amici contributed money that was intended to fund preparing or submitting the brief.

Appellants and Teva have consented to the filing of this brief. Mylan “takes no position and does not intend to file a response.” Akorn never responded so its position is unknown.

SUMMARY OF THE ARGUMENT

This brief amicus curiae is submitted in support of the petition for rehearing en banc filed by the St. Regis Mohawk Tribe, the Patent Owner. The panel’s decision of July 20, 2018 mistakenly applied the Supreme Court’s decision in *Alden v. Maine*, 527 U.S. 706, 756 (1999) to analogize *inter partes* review (IPR) proceedings to lawsuits by the United States against the states and ignored the overwhelming evidence that IPRs are classic agency adjudications, as to which sovereign immunity applies.

ARGUMENT

The panel’s decision rested upon its determination that an *inter partes* (“between the parties”) review is analogous to a lawsuit or administrative action by the United States, as the plenary sovereign, against the Tribe and, conversely, is not analogous to an agency adjudication of rights “between the parties” that must respect tribal and state immunity. E.g., *Federal Maritime Comm’n v. South Carolina State*

Ports Auth., 535 U.S. 743, 754-56 (2002) (*FMC*). The panel critically relied on *Alden*, 527 U.S. at 756, where the Supreme Court contrasted an adjudication against a state in its own courts, as to which sovereign immunity is the rule, and a lawsuit brought by the United States itself, where the state enjoys no immunity. Add. 8, 11.

The panel’s determination that the IPR is a proceeding “in which an agency chooses to institute a proceeding on information supplied by a private party,” and not an adjudication “between the parties,” is 180 degrees opposite to the determination made by Congress when it created the IPR process in the America Invents Act of 2011, P.L. 112-29, § 6. Moreover, the panel understated the close parallels between the IPR process and ordinary civil adjudication. Finally, the actual analysis in *Alden v. Maine* confirms and amplifies the foregoing analysis.

I. The 2011 Act creating the IPR established an agency adjudication between adverse parties, not another bureaucratic reexamination.

The Patent Act has long afforded private parties opportunities to challenge the validity of a patent in civil litigation—either as a defense in an infringement action, 35 U.S.C. § 271, or in a declaratory judgment action. Although patents enjoy a presumption of validity in court, the Patent Office often missed relevant prior art. In P.L. 96-57 (1980), Congress created a process of ex parte reexamination, but few patent challengers took advantage of it. Concluding that patent challengers would be more willing to forego lawsuits if they had “an opportunity to argue their case for patent invalidity in the USPTO,” H.R. Rep. No. 106-464, at 133 (1999), Congress

created a process of inter partes reexamination, as a hybrid of the inquisitorial agency examination process and an adversarial adjudication process. P.L. 106-113 (1999), adding new 35 U.S.C. § 31.

In 2011, Congress found that the existing processes were not working efficiently. H.R. Rep. 112-98, at 39 (2011). The 2011 Act rewrote chapter 31 to create the new IPR process. Judge Dyk’s lengthy concurring opinion observed that Congress was trying to improve the process for correcting patent errors, Add. 21-22, but missed the fact that Congress understood the new process as a different kind of procedure than the various reexamination procedures. The House Report summed up the plan: “The Act converts inter partes reexamination *from an examinational to an adjudicative proceeding*, and renames the proceeding ‘inter partes review.’” H.R. Rep. No. 112-98, at 46-47 (2011) (emphasis added) (describing new chapter 31). The Supreme Court held in *SAS Inst., Inc. v. Iancu*, 138 S.Ct. 1348 (2018), that IPR is a “procedure allow[ing] private parties to challenge previously issued patent claims in an *adversarial process that mimics civil litigation*,” not an inquisitorial process that mimics the original agency decision. *Id.* at 1352 (emphasis added).

Putting the same point another way, Congress intended that the IPR be an attractive alternative to a federal court adjudication and not merely another internal agency review. Unlike the reexamination processes created in earlier statutes, the IPR cannot proceed if the petitioner has filed a civil action challenging the validity

of the patent. 35 U.S.C. § 315(a)(1). Likewise, if the IPR judgment is that the patent is valid, the petitioner is estopped from making its claims of invalidity in another IPR or in a civil lawsuit. 35 U.S.C. § 315(e). “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.” Add. 10.

II. The IPR process is a party-directed administrative adjudication that mimics federal court adjudication.

IPRs are “party-directed, adversarial” proceedings before neutral judges, with most of the “usual trappings of litigation,” *SAS*, 138 S.Ct. at 1354-55, including the many features identified in the Petition for Rehearing En Banc 3-6. Thus, the panel erroneously concluded that “procedures in IPR do not mirror the Federal Rules of Civil Procedure [FRCP].” Add. 9. Indeed, the PTAB procedures followed in an IPR mirror the FRCP much like the agency procedures the Supreme Court evaluated in *FMC*, 535 U.S. at 756-59, including discovery rules, where administrative adjudications are almost always more informal. *Id.* at 758-59. The Patent Office Trial Practice Guide, 77 Fed. Reg. 48756, 48761-62 (Aug. 14, 2012), offers a broad array of discovery rights monitored by the administrative patent judges, including rules for protective orders, *id.* at 48769-71 (app. B), and for e-discovery, *id.* at 48771-72 (app. C), that are more detailed than those in the FRCP. Cf. FRCP 26(b)(1)-(2), (c) (protective orders); FRCP 26(b)(2)(B) and 34(a)(1), (b)(1)(C), (b)(2)(B) & (D)-(E) (electronic discovery).

Also important to the panel’s analogy of the IPR to a lawsuit brought by the United States was its view that the Director “has broad discretion in deciding whether to institute review,” meaning that “a politically accountable, federal official has authorized the institution of the proceeding.” Add. 8. This analysis is completely wrong. Section 314(a) says that the “Director may not authorize an inter partes review to be instituted, unless the Director determines that the information presented in the petition * * * shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” The Director has delegated this screening decision to the PTAB. *SAS*, 138 S.Ct. at 1353. This is apt, because screening out unmeritorious claims is a core feature of adjudication. As FRCP 8 and 12(b)(6) have been interpreted by the Supreme Court, federal judges should not allow civil lawsuits to continue unless they find that a complaint “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 667 (2009).

The main difference between the screening authority of administrative patent judges under § 314(a) and the authority of Article III judges under the FRCP is that the decision of the patent judges not to proceed is unreviewable. 35 U.S.C. § 314(d). That feature vests the patent judges with more discretionary control over their docket than federal judges have, but the discretion of a tribunal to control its docket does not affect the proper characterization of the IPR as an adjudication. *Iqbal*, 556 U.S.

at 678-79, 684-85. In the House Report, the discussion of the standard for instituting IPRs immediately followed the statement that the 2011 Act changed chapter 31 from “an examinational to an adjudicative proceeding.” H.R. Rep. No. 112-98, at 47.

Additionally, the tribunal’s discretion is one-way: it has broad discretion not to allow an IPR to go forward, but § 314(a) imposes a legal standard on the tribunal before the IPR can proceed. The “reasonable likelihood of prevailing” standard is the standard applied by federal courts deciding whether to issue a preliminary injunction under FRCP 65. “Satisfaction of the [IPR] threshold will be assessed based on the information presented both in the petition for the proceeding and in the patent owner’s response to the petition.” H.R. Rep. No. 112-98, at 47 (2011). See also *Republic of Philippines v. Pimentel*, 553 U.S. 851, 864-67 (2008) (once a tribunal recognizes that an assertion of sovereign immunity is “not frivolous,” it is “error” for the tribunal to address the merits).

Finally, the panel claimed that, once an IPR has been initiated, the Board has the discretion to continue the review process even if the petitioner or the patent owner is not participating. Add. 9. The statutory text tells a much more constrained story. Section 317(a) provides that “[a]n inter partes review instituted under this chapter *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. * * * If no petitioner remains

in the inter partes review, the Office may terminate the review or proceed to a final written decision” (emphasis added). Accord, Trial Practice Guide, 77 Fed. Reg. at 48768 (PTAB is supposed to facilitate settlement but may issue a decision nonetheless if it had already decided the merits by the time the parties settle).

The PTAB has relied on this rule to issue a decision after the parties’ settlement late in the process. *See e.g., Apple, Inc. v. OpenTV, Inc.*, Case No. IPR2015-00969 (Sept, 9, 2016); Buchanan Ingersoll & Rooney, *Terminating a Post-Grant Proceedings By Settlement Before the Patent Trial Appeals Board Has “Decided the Merits”* (Dec. 12, 2016). “Using its discretion in this manner is fairly consistent with how courts generally issue decisions ‘on the merits.’” *Id.* at 4. For example, in *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983), the Supreme Court decided a big tax policy question, notwithstanding the fact that the taxpayer and the government had reached agreement, after review had been granted, that the lower court was incorrect. (The Supreme Court affirmed.)

III. The PTAB is not exercising the politically accountable prosecutorial role that *Alden v. Maine* contrasted with adjudication.

Citing *Alden*, 527 U.S. at 756, the panel analogized a lawsuit by the United States against a sovereign with the IPR, because the latter proceeds only “because a politically accountable, federal official has authorized the institution of that proceeding.” Add. 8; also 11. As demonstrated above, the tribunal of administrative

patent judges makes the decision to allow an IPR to proceed, and it does so under standard legal criteria of the sort that federal judges apply in civil litigation. Unlike a lawsuit by the United States—which would be captioned something like *United States v. St. Regis Mohawk Tribe*—the adjudication in *St. Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc.* was initiated by a private requester, the issues have been limited to those raised by the private parties, discovery exchanges have been between the private parties, and the briefing and litigation strategy have been driven by the private parties. When the “United States” (represented by the Department of Justice) participated in this court, it did so as an amicus curiae, not as a party with political responsibility for the prosecution of this litigation. The panel’s extension of *Alden*’s dictum to this proceeding borders on the bizarre.

Indeed, the panel’s ambitious reading of the *Alden* dictum would swallow up the Supreme Court’s holding in *FMC*. Although the FMC had discretion to determine the “appropriate manner” to investigate the complaining party’s grievance, 46 U.S.C. App. § 1710(b), the Supreme Court found the agency proceedings to be adjudications as to which sovereign immunity applied. *FMC*, 535 U.S. 743. Indeed, the FMC’s order could not be directly enforced and required the Attorney General to file a lawsuit, which would bring *FMC* within the panel’s reasoning.

Moreover, the panel's conclusion is inconsistent with *Alden*'s core reasoning. *Alden* rested upon the foundational "importance of sovereign immunity to the founding generation," 527 U.S. at 726-27, partly to protect the sovereign's ability to govern according to the will of its citizens and to raise money and allocate scarce resources. *Id.* at 751. The founders considered lawsuits against sovereign entities inconsistent with Article III's grant of adjudication authority. *Id.* at 719-26. Exceptions to this baseline were "[s]uits brought by the United States itself," which "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." *Id.* at 756; *see id.* at 759-60.

The IPR process "between the parties" is a far cry from a major lawsuit brought by the United States itself. For example, *Alden* suggests that it is important that the United States exercise political control of the litigation. 527 U.S. at 756. That means a case must be "litigated by lawyers within, and * * * under the full control of the Executive Branch." *Chao v. Virginia Dept. of Transportation*, 291 F.3d 276, 281 (4th Cir. 2002); *accord, U.S. v. Alabama Dept. of Mental Health and Mental Retardation*, 673 F.3d 1320, 1327 (11th Cir. 2012). That is not the case here. "Congress chose to structure a process in which it's the petitioner, not the Director, who gets to define the contours of the proceeding." *SAS*, 138 S.Ct at 1355.

Finally, the PTAB's assertion of authority over a sovereign tribe is inconsistent with cautionary principles of statutory construction. The Supreme Court has admonished agencies (like the Patent Office) not to make bold policy moves beyond their narrow competence. *See e.g., King v. Burwell*, 135 S. Ct. 2480, 2489 (2015); *Hampton v. Mow Sun Wong*, 426 U.S. 88, 114-16 (1976). Further, to the extent the panel suggested that the Director is exercising political responsibility under the Take Care Clause (noted in *Alden*, 527 U.S. at 756), there is nothing in the statutory text or legislative history to allow the panel conclude that the Director is to play any such role or has the authority to decide whether a sovereign may be subject to suit.

CONCLUSION

The Patent Owner's Motion for Rehearing En Banc should be granted.

Dated: September 6, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This petition complies with the type-volume limitations of Federal Rule of Appellate Procedure 32 because this brief contains 2599 words, excluding the exempted parts of the brief.

2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2018 in Times New Roman 14-point font.

Dated: September 6, 2018

/s/ Rajkumar Vinnakota

Rajkumar Vinnakota

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 4th day of September 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 generated by that filing constitutes service on opposing counsel.

Dated: September 6, 2018

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