2018–1638

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

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

APPELLEES' BRIEF

Eric D. Miller
PERKINS COIE LLP
1201 Third Avenue, Suite 4900
Seattle, Washington 98101
Phone: (206) 359–3773
E-mail: EMiller@perkinscoie.com

Shannon M. Bloodworth
Brandon M. White
PERKINS COIE LLP
700 Thirteenth Street, N.W., Suite 600
Washington, D.C. 20005
Phone: (202) 654–6200
E-mail: SBloodworth@perkinscoie.com

Charles G. Curtis, Jr.
Andrew T. Dufresne
PERKINS COIE LLP
One East Main Street, Suite 201
Madison, Wisconsin 43703
Phone: (608) 663–5411
E-mail: CCurtis@perkinscoie.com

Dan L. Bagatell
PERKINS COIE LLP
3 Weatherby Road
Hanover, New Hampshire 03755
Phone: (602) 351–8250
E-mail: DBagatell@perkinscoie.com

Counsel for Appellee Mylan Pharmaceuticals Inc.

[counsel listing continued on next page]

Steven W. Parmelee
Jad A. Mills
WILSON SONSINI GOODRICH & ROSATI
701 Fifth Avenue, Suite 5100
Seattle, Washington 98104
Phone: (206) 883–2542
E-mail: sparmelee@wsgr.com

Richard Torczon
WILSON SONSINI GOODRICH & ROSATI
1700 K Street, N.W.
Washington, D.C. 20006
Phone: (202) 973–8811
E-mail: rtorczon@wsgr.com

Co-Counsel for Appellee Mylan Pharmaceuticals Inc.

J.C. Rozendaal
Michael E. Joffre
Ralph Powers III
William H. Milliken
Pauline Pelletier
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Ave. NW
Washington, D.C. 20005
Phone: (202) 371–2600
E-mail: jcrozendaal@sternekessler.com

Counsel for Appellee Teva Pharmaceuticals USA, Inc.

Michael R. Dzwonczyk
Mark Boland
SUGHRUE MION, PLLC
2100 Pennsylvania Avenue NW, Suite 800
Washington, D.C. 20037
Phone: (202) 293–7060
E-mail: mdzwonczyk@sughrue.com

Counsel for Appellee Akorn, Inc.

May 11, 2018

CERTIFICATES OF INTEREST

Counsel for appellee Mylan Pharmaceuticals Inc. certifies the following:

The full names of every party represented by me are:

Mylan Pharmaceuticals Inc.

The names of the real parties in interest (if the parties named in the caption are not the real party in interest) represented by me are:

none

The parent corporations and publicly held companies that own 10% or more of stock in the party:

Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc., which is indirectly wholly owned by Mylan N.V., a publicly held company.

The names of all law firms and the partners or associates that appeared for the party or amicus curiae now 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:

PERKINS COIE LLP

Crystal R. Canterbury Jennifer A. MacLean Benjamin S. Sharp

WILSON SONSINI GOODRICH & ROSATI

Michael T. Rosato Douglas H. Carsten Wendy L. Devine

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

Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2018-1130 (Fed. Cir.)
Allergan, Inc. v. Deva Holding A.S., No. 2:16-cv-1447 (E.D. Tex.)

Dated: May 11, 2018

/s/Eric D. Miller
Eric D. Miller

Counsel for appellee Teva Pharmaceuticals USA, Inc. certifies the following:

The full names of every party represented by me are:

Teva Pharmaceuticals USA, Inc.

The names of the real parties in interest (if the parties named in the caption are not the real party in interest) represented by me are:

none

The parent corporations and publicly held companies that own 10% or more of stock in the party:

Teva Pharmaceuticals Holdings Coöperatieve U.A.; IVAX LLC; Orvet UK; Teva Pharmaceuticals Europe B.V.; Teva Pharmaceuticals Industries Ltd.

The names of all law firms and the partners or associates that appeared for the party or amicus curiae now 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:

CARLSON, CASPERS, VANDENBURGH, LINDQUIST & SCHUMAN, P.A.

Gary Speier Mark Schuman

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

Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2018-1130 (Fed. Cir.)
Allergan, Inc. v. Deva Holding A.S., No. 2:16-cv-1447 (E.D. Tex.)

Dated: May 11, 2018 /s/J.C. Rozendaal
J.C. Rozendaal

Counsel for appellee Akorn, Inc. certifies the following:

The full names of every party represented by me are:

Akorn, Inc.

The names of the real parties in interest (if the parties named in the caption are not the real party in interest) represented by me are:

none

The parent corporations and publicly held companies that own 10% or more of stock in the party:

none

The names of all law firms and the partners or associates that appeared for the party or amicus curiae now 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:

SUGHRUE MION, PLLC

Azadeh Kokabi Travis Ribar

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

Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2018-1130 (Fed. Cir.)
Allergan, Inc. v. Deva Holding A.S., No. 2:16-cv-1447 (E.D. Tex.)

Dated: May 11, 2018 /s/Michael R. Dzwonczyk
Michael R. Dzwonczyk

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Pages**

Constitutional Provisions, Statutes, Regulations, and Rules **Pages**

Other Authorities **Pages**

TABLE OF ABBREVIATIONS AND CONVENTIONS

AIA	Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011)
Akorn	Akorn Pharmaceuticals, Inc.
Allergan	Allergan, Inc.
appellants	the Saint Regis Mohawk Tribe and Allergan, Inc., collectively
appellees	Mylan Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Akorn, Inc., collectively
Appx__	joint appendix page ___
Board or PTAB	the Patent Trial and Appeal Board
the district court	the district court that presided over Allergan's parallel patent infringement lawsuit, No. 2:15-cv-1455-WCB (E.D. Tex.)
FDA	Food and Drug Administration
FMC	Federal Maritime Commission
IPR	*inter partes* review
Mylan	Mylan Pharmaceuticals Inc.
NDA	New Drug Application
NLRB	National Labor Relations Board
Orange Book	FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations*
OSHA	Occupational Health and Safety Administration
PTO	Patent and Trademark Office
Teva	Teva Pharmaceuticals USA, Inc.

Tribe	the Saint Regis Mohawk Tribe
’191 patent	U.S. Patent 9,248,191
’930 patent	U.S. Patent 8,685,930
’048 patent	U.S. Patent 8,648,048
’556 patent	U.S. Patent 8,642,556
’162 patent	U.S. Patent 8,633,162
’111 patent	U.S. Patent 8,629,111

RELATED CASES

Many of the patent claims at issue in this proceeding were asserted in litigation that was filed in the Eastern District of Texas and is now pending before this Court in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2018-1130. *Allergan, Inc. v. Deva Holding A.S.*, No. 2:16-cv-1447 (E.D. Tex.), is a pending action that also involves patent claims asserted here.

INTRODUCTION

In the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA), Congress established the *inter partes* review (IPR) process to allow the Patent and Trademark Office (PTO) to take "a second look at an earlier administrative grant of a patent." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016). In so doing, Congress sought to "improv[e] patent quality and provid[e] a more efficient system for challenging patents that should not have issued." H.R. Rep. No. 112-98, pt. 1, at 39-40 (2011). Just last month, the Supreme Court upheld the constitutionality of the statute. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1370 (2018).

Although the constitutionality of the IPR process is now settled, not everyone is willing to follow the rules that Congress established. Allergan, Inc. obtained a set of patents on Restasis®, a drug for alleviating the symptoms of "dry eye" that produces more than $1 billion in annual revenue. After Allergan sued Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., and Akorn, Inc. (collectively, appellees) alleging patent infringement, appellees asked the PTO to institute IPRs and declare the claims unpatentable over prior art. The PTO instituted review, and the reviews have not gone well for Allergan. Facing the imminent demise of the patents on its blockbuster drug before the PTO's Patent Trial and Appeal Board (PTAB), which appellants and their counsel have decried as a "kangaroo court,"

"very unfair," and "a thorn in [Allergan's] side," Allergan decided to "create a playbook … both for us and for others" to evade PTO review of issued patents. Appx1917-1918, Appx1910, Appx1915, Appx1956.

After the IPR briefing was complete, and just days before the PTAB was to hold the oral hearing, Allergan purported to assign its patents to the Saint Regis Mohawk Tribe, a federally recognized Indian tribe that had no previous involvement with the patents or Restasis. The Tribe simultaneously licensed the patents back to Allergan in exchange for payments of millions of dollars. Thus, rather than the Tribe paying Allergan to acquire the patents that protect a billion-dollar-per-year drug franchise, Allergan paid the Tribe to take nominal title to those patents.

The only reason for this unusual series of transactions was to enable the Tribe to assert sovereign immunity in an effort to halt the IPR proceedings. In the parallel district-court litigation now on appeal to this Court, the presiding judge (Circuit Judge Bryson, sitting by designation) found it "clear that Allergan's motivation for the assignment was to attempt to avoid the IPR proceedings that are currently pending in the PTO …." *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *2 (E.D. Tex. Oct. 16, 2017). The court characterized the scheme as an "artifice," a "ploy," and a "tactic" that, "if successful, could spell the end of the PTO's IPR program." *Id.*

The law does not permit such evasion. As the PTAB concluded, appellants' scheme fails for three independent reasons. *First*, Indian tribes are not entitled to assert sovereign immunity to bar the PTO, a federal agency, from reconsidering the validity of its own grant of a patent monopoly. *Second*, even if tribal sovereign immunity could block an IPR, Allergan, not the Tribe, is the true owner of these patents because Allergan retains all substantial rights under the license agreement. *Third*, even if the Tribe were entitled to assert sovereign immunity, and even if it holds some substantial rights in the patents, its presence is not required, and Allergan can more than sufficiently represent whatever interests the Tribe has in the remainder of these proceedings. All three conclusions were correct, and this Court should affirm the Board's decision and allow the Board to complete its review.

JURISDICTIONAL STATEMENT

The Board had jurisdiction over the IPRs under 35 U.S.C. § 316(c).

As explained in their stay-motion briefing and below, appellees contend that continuation of the IPRs will not impugn the Tribe's sovereignty. Nevertheless, appellees acknowledge that, in the circumstances of this case, that issue is intertwined with the merits and thus do not dispute that this Court has appellate jurisdiction by way of the collateral-order doctrine. *See Univ. of Utah v. Max-Planck-Gesellschaft zur Forderung der Wissenschaften e.V.*, 734 F.3d 1315, 1319 (Fed. Cir. 2013). Although this Court may not exercise collateral-order jurisdiction under

35 U.S.C. § 141(c), which applies only to the appeal of a "final written decision," it does have such jurisdiction under 28 U.S.C. § 1295(a)(4)(A), *see Arthrex Inc. v. Smith & Nephew, Inc.*, 880 F.3d 1345, 1348-49 (Fed. Cir. 2018). Alternatively, the Court may exercise mandamus jurisdiction. *See* 28 U.S.C. § 1651. Appellees also agree that Allergan's appeal of the PTAB's denial of its motion to withdraw is intertwined with the Tribe's appeal and that this Court should therefore exercise pendent appellate jurisdiction over the issues raised by Allergan.

The Board's decision was entered on February 23, 2018, Appx1-42, and appellants filed a timely notice of appeal five days later, Appx3186-3192.

STATEMENT OF ISSUES

1. May a sovereign that claims to own a patent prevent the PTO from conducting *inter partes* review of that patent by asserting immunity from the agency's reconsideration of patentability?

2. Even if a State may assert constitutional sovereign immunity to bar an *inter partes* review of a patent it owns, does the federal common-law doctrine of tribal sovereign immunity require the same result?

3. Have appellants abused the federal common-law doctrine of tribal sovereign immunity by, among other things, treating it as a monetizable commodity that can be purchased by private entities to avoid *inter partes* review?

4. Can the Tribe invoke sovereign immunity to block *inter partes* review in these proceedings, when Allergan has retained all substantial rights in the patents and thus remains the sole true patent owner?

5. Did the PTAB reasonably conclude that the Tribe is not a necessary or indispensable party in these IPRs, given Allergan's continuing interest in the patents and its direction and control of the patentability defense throughout the IPRs?

STATEMENT OF THE CASE

Restasis is an ophthalmic emulsion—an eye drop—used to alleviate the symptoms of chronic dry eye by increasing tear production in certain patients. Appx3725-3726. Its active ingredient is cyclosporin A, an immunosuppressant compound that has been used in medicine since the early 1980s. The Food and Drug Administration (FDA) approved Restasis for prescription use in 2002, and Allergan has manufactured and marketed it since then. Appx2120. The drug has been highly lucrative for Allergan, producing annual sales of over $1 billion. Appx1938, Appx2191. Allergan claims that Restasis is covered by at least six patents, the last of which expires in late 2024. Appx1925, Appx1987, Appx3713-3714.

In 2015, Allergan sued appellees in the District Court for the Eastern District of Texas, alleging that appellees had infringed its patents by filing Abbreviated New Drug Applications seeking FDA approval to market generic equivalents to

Restasis. Appx2116; *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB (E.D. Tex. filed August 24, 2015). Appellees responded with counterclaims seeking a declaration that the patents were invalid as obvious in view of prior art.

While the district-court litigation was pending, Mylan filed petitions for *inter partes* review of the Restasis patents. Appx184, Appx254, Appx322, Appx390, Appx457, Appx524. Teva and Akorn later filed similar petitions, which were joined with Mylan's petitions. Appx592, Appx671, Appx746, Appx824, Appx900, Appx975, Appx1050, Appx1129, Appx1205, Appx1286, Appx1365, Appx1442, Appx3138-39. In December 2016, the Board instituted review. Appx3731-3756, Appx3139. Allergan thereafter participated fully in proceedings before the Board.

On September 8, 2017, after briefing was complete and less than a week before the Board was to hold the oral hearing, Allergan purported to assign the patents to the Saint Regis Mohawk Tribe, a federally recognized Indian tribe in upstate New York. Appx2556-2571, Appx3139. The only consideration the Tribe provided in exchange was a promise not to waive its sovereign immunity in the IPR proceedings. Appx2565 § 12(i); *see also* Appx2597 § 10.8.9; *Allergan*, 2017 WL 4619790, at *2 (confirmation by Allergan that the Tribe's sole consideration for the assignment was its promise not to waive immunity). In a concurrent agreement, the Tribe granted back to Allergan an exclusive license covering all commercially significant uses of the patented formulation. Appx2572-2606. In ex-

change for that license, Allergan paid the Tribe $13.75 million up-front and promised to pay ongoing royalties of $3.75 million per quarter. Appx2579-2580 §§ 4.1, 4.2. Under the license, Allergan retained, among other things, the sole right to practice the patents for purposes of marketing Restasis products, the right to make litigation decisions regarding the patents, the right to control sublicenses, and the right to receive proceeds from its litigation and licensing activities. Appx2575-2576, Appx2578-2579, Appx2581-2584, Appx2594, Appx2603 §§ 1.19, 1.31, 1.33, 2.1, 2.3, 3.1, 5.1.1, 5.2.2, 5.2.5, 5.3, 10.4, Schedule 1.31.

Allergan and the Tribe made no secret of the purpose of this unusual transaction: their goal was to block the IPRs and prevent the Board from declaring the claims unpatentable by invoking the Tribe's sovereign immunity. As reflected in the record before the Board, Allergan has touted its strategy as "creat[ing] a playbook … both for us and for others" to avoid IPRs. Appx1956. The Tribe, in turn, has invited other patent owners "to pay [it] for holding [their] patents and protecting them" from exposure to IPRs. Appx1910. The Tribe seeks to use its sovereign immunity as an "arbitrage opportunity" because "there's a huge value difference between patents which can be subject to IPRs and patents that are not." Appx1914, Appx1921.

Shortly after concluding the transaction, Allergan moved in the district court to join the Tribe as a party. In addressing that motion, the court characterized ap-

pellants' arrangement as an "artifice," a "ploy," and a "tactic" to "attempt to avoid the IPR proceedings that are currently pending in the PTO by invoking the Tribe's sovereign immunity as a bar to those proceedings." *Allergan,* 2017 WL 4619790, at *2. It also expressed "serious reservations about whether the contract between Allergan and the Tribe should be recognized as valid, rather than being held void as being contrary to public policy." *Id.* at *3 (citing Restatement (Second) of Contracts §§ 178-179, 186 (1981)). Additionally, the court expressed doubt that the Tribe had any true ownership interest in the patents, noting that although "[s]ome provisions" of the exclusive license appear to "give the Tribe at least nominal rights" in the patents, it is "questionable whether those rights have any practical value." *Id.* at *4. "There is no doubt," the court explained, "that at least with respect to the patent rights that protect Restasis against third-party competitors, Allergan has retained all substantial rights in the patents, and the Tribe enjoys only the right to a revenue stream in the form of royalties." *Id.* The court noted, however, that it did not need to decide the legality of appellants' enterprise because the Tribe was voluntarily joining the litigation as a plaintiff and waiving any claims of sovereign immunity from the pending counterclaims. It was better, the court concluded, to add the Tribe to ensure that it would be fully bound by the court's final resolution of the claims in that litigation. *Id.* at *4-5.

In a separate order issued the same day, the district court declared all asserted claims invalid for obviousness. Appx2227-2228. The Tribe and Allergan have appealed that decision to this Court in No. 2018-1130. That case is fully briefed but has not yet been argued.

Meanwhile, the Tribe moved to dismiss the IPRs on the basis of tribal sovereign immunity, and the Board denied the motion. Appx1-42. The Board first concluded that tribal sovereign immunity does not apply in IPR proceedings. Appx11-18. In reaching that conclusion, the Board noted that the proceedings "do not merely serve as a forum for the parties to resolve private disputes that only affect themselves" but rather advance "the 'important public purpose' of 'correct[ing] the agency's own errors in issuing patents in the first place.'" Appx12 (quoting *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1290 (Fed. Cir. 2015)). The Board also emphasized that "Indian tribes have not enjoyed immunity in other types of federal administrative proceedings used to enforce generally applicable federal statutes." Appx14.

The Board further concluded that even if the Tribe were entitled to assert immunity, the proceedings could nevertheless continue "because Allergan is the true owner of the challenged patents." Appx19. The Board recognized that under this Court's precedent, the "party that has been granted all substantial rights under the patent is considered the owner regardless of how the parties characterize the

transaction that conveyed those rights." *Id.* (quoting *Speedplay, Inc. v. Bebop, Inc.*, 211 F.3d 1245, 1250 (Fed. Cir. 2000)). Based on a close examination of the terms of the license agreement, the Board determined that the license "transferred 'all substantial rights' in the challenged patents back to Allergan." Appx20. Finally, the Board determined that the Tribe was not an indispensable party to the IPR proceedings, so they could continue "without the Tribe's participation." Appx39.

Allergan and the Tribe now appeal.

SUMMARY OF ARGUMENT

An IPR proceeding is not the type of common law "suit" that is subject to sovereign immunity. Instead, it is a federal agency proceeding in which the PTO reexamines its own grant of a patent monopoly. The Supreme Court's recent *Oil States* decision upholding the constitutionality of the AIA emphasized that "patents are 'public franchises' that the Government grants" subject to its reserved "authority to reexamine—and perhaps cancel—a patent claim in an inter partes review," and that an administrative decision to cancel them is therefore not equivalent to an adjudication in court. 138 S. Ct. at 1373-74. Moreover, even if the constitutional doctrine of *state* sovereign immunity applies in IPRs, the common-law doctrine of *tribal* sovereign immunity does not prevent a federal agency from carrying out its congressional mandate. In any event, *no* sovereign or private party should be allowed to abuse sovereign immunity in the way appellants are attempting here: by

selling the Tribe's immunity and using a sham transaction to defeat the Board's ongoing jurisdiction over these proceedings, while simultaneously invoking federal-court jurisdiction over an infringement action based on the same patents.

The Board also correctly concluded that even if the Tribe could invoke sovereign immunity in these IPRs, Allergan has retained all substantial rights in the patents and thus remains their sole "owner" for purposes of these IPRs. In particular, Allergan retains the right to sue for infringement, and it holds the exclusive right to make, use, and sell products under the patents.

Finally, even if the Tribe held anything beyond illusory and contingent rights, the Board correctly determined that it can fairly and equitably complete these IPRs in the Tribe's absence and that Allergan will more than adequately represent the Tribe's interests in defending these patents in the PTAB and on appeal. Indeed, appellants' own agreement specifies that Allergan, rather than the Tribe, has the first right to "defend and control the defense of the validity, enforceability and patentability of the Licensed Patents" in these IPR proceedings. Appx2583-2584 § 5.3.

ARGUMENT

I. The Tribe may not invoke sovereign immunity to block these IPR proceedings

The Tribe's assertion of sovereign immunity fails on at least three levels. First, sovereign immunity cannot bar an IPR proceeding. Second, even if s*tate*

sovereign immunity barred IPRs, *tribal* sovereign immunity does not. Third, even if tribal sovereign immunity could apply in IPRs in some circumstances, it does not apply here because appellants' scheme represents an impermissible abuse of immunity.

A. Neither state nor tribal sovereigns are immune from the PTO's review of its own patentability decisions

Sovereign immunity rests on the principle that "[i]t is inherent in the nature of sovereignty not to be amenable to the suit of an individual without [the sovereign's] consent." *Alden v. Maine*, 527 U.S. 706, 716 (1999) (emphasis omitted) (quoting *The Federalist* No. 81, at 487 (Hamilton) (C. Rossiter ed. 1961)). As the Board recognized, however, an IPR proceeding is not a "suit" against a patent holder. In such a proceeding, the Board is "not adjudicating any claims," and it can "neither restrain the [patent holder] from acting nor compel it to act in any manner." Appx16. Instead, the Board's role "is limited to assessing the patentability of the challenged claims." *Id.* For that reason, sovereign immunity cannot bar an IPR.

1. The Supreme Court recently confirmed the Board's understanding of the IPR process in *Oil States*. The Court reaffirmed that a patent is "the grant of a public franchise," a right that "'did not exist at common law'" and "is a 'creature of statute law.'" 138 S. Ct. at 1373-74. (citations omitted). An IPR is simply a "reconsideration of the Government's decision to grant [that] public franchise." *Id.* at

1373; *accord Cuozzo*, 136 S. Ct. at 2144 (IPR is "a second look at an earlier administrative grant of a patent").

That understanding of the IPR process was critical to the Court's resolution of *Oil States*. The Court acknowledged that, as a general rule, "Congress may not 'withdraw from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty.'" 138 S. Ct. at 1376 (quoting *Stern v. Marshall*, 564 U.S. 462, 484 (2011)). But the Court explained that patent validity is not "a matter that ... must be decided by a court." *Id.* Instead, just as the decision to grant a patent is a matter involving public rights that "need not be adjudicated in Article III court," *id.* at 1374, so too is the decision to revoke a patent through the IPR process, *id.* at 1374-75. An IPR is thus not analogous to a suit in court but rather is more akin to the historical practice of "cancellation" of patents "in [an] executive proceeding." *Id.* at 1377.

2. Appellants rely heavily (at 21-24) on *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. 743 (2002) (*FMC*), but that case does not support their position. *FMC* dealt with an "adjudicative proceeding" conducted in response to a private party's complaint that a state entity had violated a federal statute. *Id.* at 747. The private claimant sought an award of monetary "reparations" from the state entity as well as injunctive relief targeted directly at the state entity. *Id.* at 748-49. The Federal Maritime Commission lacked "discretion to

refuse to adjudicate complaints brought by private parties" and "had no choice but to adjudicate this dispute." *Id.* at 764 (citation omitted). In doing so, it applied rules "quite similar to those found in the Federal Rules of Civil Procedure," including allowing discovery that "largely mirror[ed] discovery in federal civil litigation." *Id.* at 757-58. Based on those characteristics of the adjudicatory scheme, the Court concluded that "FMC administrative proceedings bear a remarkably strong resemblance to civil litigation in federal courts," and that the "similarities" between the two are "overwhelming." *Id.* at 757, 759; *see id.* at 757 (concluding that an FMC adjudicative proceeding "walks, talks, and squawks very much like a lawsuit" (citation omitted)). For that reason, the Court held, the State's sovereign immunity barred the proceeding.

An IPR is very different. As the Supreme Court has explained, it is "less like a judicial proceeding and more like a specialized agency proceeding" in which the PTO takes "a second look at [its] earlier administrative grant of a patent." *Cuozzo*, 136 S. Ct. at 2143-44. Unlike the agency adjudication in *FMC*, which was instituted by a private party, "[t]he decision whether to institute inter partes review is committed to the [PTO] Director's discretion." *Oil States*, 138 S. Ct. at 1371; *see Cuozzo*, 136 S. Ct. at 2141 ("Congress has told the *Patent Office* to determine whether inter partes review should proceed, and it has made the agency's decision 'final' and 'nonappealable.'" (citing 35 U.S.C. § 314(d))). Indeed, the PTO may

institute an IPR only if *it* determines "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Appellants thus are wrong in repeatedly claiming (at 13, 22, 25, 27-28) that IPRs are "initiated" and "instituted" by "private litigant[s]." IPRs are instituted only by the PTO, and only upon a likelihood-of-success determination by the PTO. They do not impose the "affront to a [sovereign's] dignity" that comes from being "required to answer the complaints of private parties." *FMC*, 535 U.S. at 760.

IPRs also differ from court adjudications in that they do not require the presence of adverse parties. As an initial mater, *anyone* other than the patent owner may ask the PTO to initiate an IPR. 35 U.S.C. § 311(a). Unlike the plaintiff in a lawsuit, such persons "need not have a concrete stake in the outcome; indeed, they may lack constitutional standing." *Cuozzo*, 136 S. Ct. at 2143-44. Once the PTO initiates the proceeding, "challengers need not remain in the proceeding; rather, the Patent Office may continue to conduct an inter partes review even after the adverse party has settled" and "may intervene in a later judicial proceeding to defend its decision—even if the private challengers drop out." *Id.* at 2144 (citing 35 U.S.C. § 317(a)) (emphasis omitted).

Nor is the patent owner required to participate. The Board may "institute trial and proceed to a final written decision even in the absence of any preliminary

response or response by the patent owner," and an "owner of a part interest" in a patent may "act to the exclusion" of another owner that cannot or will not participate or if it is "in the interests of justice to permit the owner of a part interest to act in the trial." *Reactive Surfaces Ltd. v. Toyota Motor Corp.*, IPR2017-00572, Paper 32 at 11-12 (PTAB Jul. 13, 2017) (citing 37 C.F.R. §§ 42.108(c), 42.120(a), 42.9(b)); *see also* Appx17 (citing instances in which "*inter partes* reviews have proceeded to a final written decision … even where the patent owner has chosen not to participate").

In addition, a final written decision by the Board imposes no liability or obligation on the owner itself. The Board emphasized below that "we are not adjudicating any claims in which Petitioners may seek relief from the Tribe, and we can neither restrain the Tribe from acting nor compel it to act in any manner based on our final decisions." Appx16. Unlike in *FMC,* "there is no possibility of monetary damages or an injunction as a 'remedy'" against the patent owner. *Id.* The Board's scope of authority "is limited to assessing the patentability of the challenged claims." *Id.* The proceeding therefore does not "threaten the financial integrity" of a sovereign. *Alden*, 527 U.S. at 750; *see FMC*, 535 U.S. at 765 ("[S]overeign immunity serves the important function of shielding state treasuries.").

3. To be sure, IPRs use some "court-like procedures" and "trappings of litigation," *Oil States*, 138 S. Ct. at 1378; *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348,

1353-54 (2018), but that does not transform them into "adjudications" of the sort that trigger sovereign immunity. To begin, the similarities in procedures between IPRs and lawsuits should not be overstated. Discovery in IPRs, for example, is significantly more limited than discovery under the Federal Rules of Civil Procedure, *see* 35 U.S.C. § 316(a)(5); 37 C.F.R. § 42.51(b), and the "trial" occurs largely on a paper record without live testimony. More importantly, federal administrative proceedings do not become private "suits" simply because private parties are allowed to file complaints and participate. *See San Manuel Indian Bingo & Casino v. NLRB*, 475 F.3d 1306, 1312-13 (D.C. Cir. 2007) (holding that NLRB could issue an unfair labor practice order against a tribe in response to non-Indian charges in proceedings in which non-Indians participated). "Although inter partes review includes some of the features of adversarial litigation," the crucial distinction is that "it does not make any binding determination regarding the liability of" the parties but remains "a matter involving public rights, one between the government and others." *Oil States*, 138 S. Ct. at 1378 (internal quotation marks and citations omitted). It therefore does not implicate sovereign immunity for States, much less tribes.

B. Even if States' constitutional sovereign immunity applies in IPRs, common-law tribal sovereign immunity does not

Even if States and state entities may invoke Eleventh Amendment sovereign immunity in IPRs, the Board correctly determined that the federal common law of

tribal sovereign immunity does not apply in an IPR, which "is not the type of 'suit' to which an Indian tribe would traditionally enjoy immunity under the common law." Appx16.

1. The Supreme Court has repeatedly held that "the immunity possessed by Indian Tribes is not coextensive with that of the States." *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 756 (1998); *see also Bodi v. Shingle Springs Band of Miwok Indians*, 832 F.3d 1011, 1020 (9th Cir. 2016) ("Tribal immunity is not synonymous with a State's Eleventh Amendment immunity, and parallels between the two are of limited utility."). Rules of state sovereignty "provide a helpful point of reference" in tribal sovereignty cases, but they "do not dictate a result." *City of Sherrill v. Oneida Indian Nation of N.Y.*, 544 U.S. 197, 218 (2005). Indeed, the Supreme Court has emphasized that tribal sovereign immunity is "[o]f course" narrower than, "not congruent with," state sovereign immunity. *Three Affiliated Tribes of the Fort Berthold Reservation v. Wold Eng'g*, 476 U.S. 877, 890-91 (1986).

State sovereign immunity is anchored in the Eleventh Amendment, "a specific [constitutional] text with a history that focuses upon the State's sovereignty vis-à-vis the Federal Government." *Lapides v. Bd. of Regents*, 535 U.S. 613, 623 (2002). State sovereign immunity is thus part of "[t]he constitutionally mandated balance of power between the States and the Federal Government." *FMC*, 535 U.S.

at 769 (alterations and citation omitted). But whereas "[t]he Constitution specifically recognizes the States as sovereign entities," tribes were not parties to the Constitutional Convention, and the Constitution does not guarantee their reserved sovereignty. *Seminole Tribe of Fla. v. Florida*, 517 U.S. 44, 71 n.15 (1996). To the contrary, the "incorporation [of tribes] within the territory of the United States, and their acceptance of its protection, necessarily divested them of some aspects of the sovereignty which they had previously exercised." *United States v. Wheeler*, 435 U.S. 313, 323 (1978).

Tribal sovereign immunity is therefore significantly different from state sovereign immunity. It is a common-law doctrine that developed "almost by accident," and it is subject to complete defeasance by the federal government. *Kiowa*, 523 U.S. at 756; *see Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2030 (2014) ("[T]ribes are subject to plenary control by Congress.").

2. The limited immunity that tribes enjoy "does not extend to preventing the federal government from exercising its superior sovereign powers." *United States v. Yakima Tribal Ct.*, 806 F.2d 853, 861 (9th Cir. 1986) (citation omitted); *see also United States v. Red Lake Band of Chippewa Indians*, 827 F.2d 380, 382 (8th Cir. 1987) ("[I]t is an inherent implication of the superior power exercised by the United States over the Indian tribes that a tribe may not interpose its sovereign immunity against the United States."). Thus, federal agencies may apply and enforce gen-

erally applicable federal statutes to tribes and tribal entities, including through licensing and enforcement proceedings, even in the absence of any express mention of tribes in the applicable laws. *Pauma v. NLRB*, ___ F.3d ___, Nos. 16-70397 & 16-70756, 2018 WL 1955043, at *6-8 (9th Cir. Apr. 26, 2018) (enforcement of federal labor laws); *NLRB v. Little River Band of Ottawa Indians Tribal Gov't*, 788 F.3d 537, 555 (6th Cir. 2015) (same); *Menominee Tribal Enters. v. Solis*, 601 F.3d 669, 670-71 (7th Cir. 2010) (enforcement of OSHA); *see generally Fed. Power Comm'n v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960) ("a general statute in terms applying to all persons includes Indians and their property interests").

Appellants note (at 28-30) that an IPR is not the same as a typical agency enforcement proceeding because it is not brought by a government prosecutor and instead is initiated by the agency at the suggestion of a private party. As the Board explained, however, some agency enforcement proceedings "may be initiated based on third-party complaints," and "the third party may be permitted to intervene in such proceedings and participate beyond just the initial role of filing the complaint." Appx15. The involvement of a private entity in an IPR thus does not alter the status of that proceeding as one in which the PTO reconsiders its own administrative action in granting a patent. *See Oil States*, 138 S. Ct. at 1373-75. And it does not alter the black-letter rule that an agency may apply generally applicable federal law to Indian tribes through enforcement proceedings authorized by

statute. *See San Manuel*, 475 F.3d at 1312-13 (permitting NLRB proceeding against tribal casino based on complaint filed by labor union, which participated in case as intervenor). Because IPRs are actions of a federal agency carrying out federal law, they are not barred by tribal sovereign immunity.

3. In addition, the Supreme Court has cautioned that "special justifications" may warrant the recognition of additional exceptions to the federal common-law doctrine of tribal sovereign immunity, and one such justification is the lack of an adequate alternative remedy. *Bay Mills*, 134 S. Ct. at 2036 n.8. The Court has permitted tribes to assert immunity only where there appeared to be "many alternative remedies" available to non-Indians and a "panoply of tools" to ensure tribal compliance with governing federal and state law. *Id.* at 2035, 2036 n.8; *see also Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe of Okla.*, 498 U.S. 505, 514 (1991). Those enforcement mechanisms include *Ex parte Young* proceedings against tribal officials and agents to obtain declaratory and injunctive relief against violations of federal and state rights, damage suits against individual tribal officials responsible for the violations, and off-reservation *in rem* remedies such as seizure of tribally owned contraband. *Bay Mills*, 134 S. Ct. at 2034-35; *see also Washington v. Confederated Tribes of Colville Indian Reservation*, 447 U.S. 134, 161-62 (1980) (approving of alternative enforcement mechanisms as a way to "police[ ] against wholesale evasion" of substantive law "without unnecessarily intruding on

core tribal interests"). Here, there are no alternative ways to enforce tribal compliance with and participation in the IPR system mandated by Congress. The question is not which among a "panoply of tools" may be used to enforce the AIA against tribes, *Bay Mills,* 134 S. Ct. at 2035, but whether tribes will be exempt from the statutory requirements altogether. Tribal sovereign immunity has never been applied to create such a complete exemption.

It is no answer to say that private defendants can challenge the validity of a tribally owned patent in district court *if* the tribe waives sovereign immunity by filing district-court litigation. A tribe may simply choose to threaten suit; in the absence of an actual tribal suit, the patent would remain as a cloud on others' activities with no alternative means of challenging the patent's validity. Moreover, the evidentiary standard in patent litigation is more stringent than in IPRs, and thus less favorable to parties seeking to challenge patent validity. *See* § III.B *infra.* Private defendants are not the federal government, and the AIA recognizes that PTO review of the agency's own patentability determinations has unique advantages, including reliance on the agency's expertise.

The supreme federal authority of a generally applicable regulatory system is thus a "special justification" that must prevail over common-law tribal sovereign immunity, at least for purposes of enabling the Board to exercise its jurisdiction and carry out its responsibilities in reconsidering the validity of the patents it is-

sues. *Bay Mills*, 134 S. Ct. at 2036 n.8. Patent owners do not have the option to opt out of IPR review simply by finding a compliant tribe willing to take a paper "assignment" to destroy the Board's jurisdiction in exchange for cash.

C. Even if a tribe could otherwise assert sovereign immunity in an IPR, appellants' scheme here is an impermissible abuse of tribal sovereign immunity

Even if tribal sovereign immunity could apply in IPRs in other circumstances, it does not apply here because appellants have abused any such immunity. Under fundamental "[p]rinciples of fairness and consistency," sovereign immunity may not be wielded for "tactical advantage" to enable a sovereign to retain the "fruits" of the patent system while escaping its burdens. *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376, 1383-85 (Fed. Cir. 2007).

The Board elected not to address these objections, Appx35 n.11, deciding instead that tribal sovereign immunity does not apply in IPRs under any circumstances. But this Court may nevertheless affirm the Board's decision on abuse-of-immunity grounds, which present questions of law, rest on undisputed facts, and do not involve the exercise of any agency expertise. *See In re Comiskey*, 554 F.3d 967, 974 (Fed. Cir. 2009); *see also In re Aoyama*, 656 F.3d 1293, 1298-99 (Fed. Cir. 2011).

1. Tribal sovereign immunity is not a commodity that can be bought and sold

The only value the Tribe has contributed to what appellants call (at 10) their "business arrangement" is its promise not to waive sovereign immunity in proceedings before the PTO. Appx2565 § 12(i), Appx2597 § 10.8.9. The transaction is an unadulterated exchange of money for immunity. Such an arrangement flouts bedrock principles of federal Indian law.

As Judge Bryson explained in the parallel district-court litigation, tribal sovereign immunity is not "a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities," nor is it "an inexhaustible asset that can be sold to any party that might find it convenient to purchase immunity from suit." *Allergan,* 2017 WL 4619790, at *3. Tribes may not "market an exemption" from the law, thereby gaining an unfair "artificial competitive advantage over all other businesses." *Colville*, 447 U.S. at 155. Simply put, "a tribe has no legitimate interest in selling an opportunity to evade [the] law" to non-Indians. *Otoe-Missouria Tribe v. N.Y. Dept. Fin. Servs.*, 769 F.3d 105, 114 (2d Cir. 2014). Although selling immunity undoubtedly would provide revenue, the tribal interest in making money from helping non-Indians circumvent the law is not one that the Supreme Court has been willing to recognize. *See Dep't of Taxation & Fin. of N.Y. v. Milhelm Attea & Bros., Inc*., 512 U.S. 61, 75-76 (1994).

Likewise, non-Indian companies like Allergan have no legitimate interest in using tribal sovereign immunity to "circumvent" the law and "reap a windfall at the public's expense." *Barona Band of Mission Indians v. Yee*, 528 F.3d 1184, 1187, 1190 (9th Cir. 2008). Non-Indians may not simply purchase a "legal loophole in the cloak of tribal sovereignty." *Otoe-Missouria Tribe*, 769 F.3d at 114. And they "may not alter the economic reality of a transaction" to take advantage of an immunity "rooted in due respect for Indian autonomy" as a way to make more money by evading otherwise-applicable law. *Barona Band*, 528 F.3d at 1190.

The Tribe suggests (at 10) that it has done "nothing more than follow the model created by state universities." That is not so. State universities' patent portfolios are often derived from research funded by the State, while the Tribe funded none of the research and development involving these patents. Neither the Tribe nor any tribal entity nor any tribal members had anything to do with the conception, discovery, development, licensing, or marketing of Restasis. The Tribe was a complete stranger to Restasis (and to pharmaceutical patents in general) until Allergan paid it to enter into a transaction after the close of evidence in these IPRs. Indeed, the Tribe has boasted that it "is not investing any money" in the venture, is not covering any PTAB or litigation expenses, and faces no downside risk. Appx1910-1911.

The Tribe also claims (at 33-34) it is simply following the same "economic development model" that "[t]he Supreme Court approved" in *California v. Cabazon Band of Mission Indians*, 480 U.S. 202 (1987). Here again, the Tribe is mistaken. Indeed, the reasoning of *Cabazon* condemns rather than "approve[s]" the Tribe's "model." *Cabazon* involved on-reservation gambling; the tribes themselves were "generating value on the reservations through activities in which they have a substantial interest," such as by "buil[ding] modern facilities which provide recreational opportunities and ancillary services to their patrons," who "spend extended periods of time there enjoying the services the Tribes provide." *Id.* at 219-20. The Court in *Cabazon* drew a sharp distinction between these value-generating tribal efforts and other tribal activities that "merely market[ ] an exemption" from the law to non-Indians. *Id.* at 219. The Court pointed (*id.*) to its previous decision in *Colville*, which upheld state regulation and taxation of on-reservation cigarette sales to non-Indians on the grounds that tribes may not "market an exemption" from the law "to persons who would normally do their business elsewhere," 447 U.S. at 155. "It [was] painfully apparent" in *Colville* "that the value marketed by the smokeshops to persons coming from outside is not generated on the reservations by activities in which the Tribes have a significant interest." *Id.*

The same is true here. Indeed, appellants' scheme is an even more blatant attempt to "market an exception" to the law than in *Colville*, where the tribes at least

were actively involved in the wholesale and retail distribution and sale of the untaxed cigarettes. Here the Tribe does nothing beyond collecting its quarterly royalty payments. Tribal immunity is not available where "the tribal contribution to an enterprise is *de minimis*." *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324, 341 (1983).

2. The assignment was a sham designed to defeat the PTAB's jurisdiction

A party may not divest a federal court or agency of its jurisdiction "by making a transfer which is an assignment in name only." *Attorneys Trust v. Videotape Computer Prods., Inc*., 93 F.3d 593, 595 (9th Cir. 1996); *accord Kramer v. Caribbean Mills, Inc*., 394 U.S. 823, 827 (1969) (party may not use assignment that is "a mere contrivance, a pretense, the result of a collusive arrangement" to manipulate federal jurisdiction) (citation omitted); *Grassi v. Ciba-Geigy, Ltd*., 894 F.2d 181, 184-85 (5th Cir. 1990) (purported assignment did not alter jurisdiction where assignor retained 98% interest and control of the litigation). Litigants may not "manipulat[e]" jurisdiction through assignments that "lack reality and amount to no change in the identity of the party with the real interest in the outcome of the case." *Attorneys Trust*, 93 F.3d at 597.

"[C]lassic elements of an assignment which does not affect jurisdiction" are a purported assignee with "no prior interest" in the matter, an assignee that paid little if any consideration, an assignment "timed to coincide with the commence-

ment of litigation," a purported assignor that has retained significant control and most of the profits, and evidence that the "real motive" was to destroy jurisdiction. *Id*. at 598-99. Each element of such a sham assignment is present here.

First, the Tribe had no connection to Allergan or the challenged patents before the purported assignment in September 2017.

Second, the Tribe paid nothing for the patents even though they currently generate over $1 billion in annual revenues. Instead, the Tribe *charged* Allergan an up-front fee of $13,750,000 and future royalties of $3,750,000 quarterly in exchange for the Tribe's acceptance of title and promise to assert immunity. Appx2579-2580 §§ 4.1, 4.2; Appx2597 § 10.8.9; *Allergan*, 2017 WL 4619790, at *2 (Allergan's confirmation that the Tribe's sole consideration for the assignment was its promise not to waive immunity). The transaction makes no economic sense except as a cash-for-immunity arrangement.

Third, the assignment occurred only after the IPRs were nearly complete, in a transparent effort to pull the plug on proceedings that had not gone well for Allergan. Allergan's tactical delay allowed it to participate fully in the IPRs and assess its prospects before attempting to prevent an adverse final written decision by the Board.

Fourth, as the Board demonstrated in painstaking detail, Allergan structured the transaction so that the Tribe would obtain only nominal title while Allergan

would retain all practical control and receive the vast bulk (99%) of the revenue from sales of Restasis. Appx18-35; *see* § II.B *infra*.

Fifth, appellants have been remarkably candid about their motives, admitting—even boasting—that their transaction was crafted to "remove[ ] the risk of IPR," a "process [that] has been a thorn in [Allergan's] side." Appx1915-1916. Appellants have confessed to this Court (at 6) that through their arrangement, "Allergan sought to strengthen the defense of its intellectual property in IPR proceedings." *See also Allergan*, 2017 WL 4619790, at *2 ("[I]t is clear that Allergan's motivation for the assignment was to attempt to avoid the IPR proceedings that are currently pending in the PTO by invoking the Tribe's sovereign immunity as a bar to those proceedings.").

Appellants say (at 31, 33 n.8) that the Tribe is simply trading on its sovereign immunity "like all sovereigns" do, and that private companies "frequently engage in legal arrangements" like this. That is false, and appellants have not provided a single relevant example. Instead, they cite (at 32-33) only cases in which state legislatures transferred the assets of state-created affiliate entities to the States themselves, thereby triggering Eleventh Amendment immunity. Those cases are not analogous to the situation here, in which Allergan—a private corporation with no prior affiliation with the Tribe—has paid the Tribe money to accept a patent "assignment" that leaves Allergan in practical control of the patents and receiving

99% of the revenue they generate. Notably, in one of the cases appellants cite, the First Circuit addressed a situation in which an Indian tribe had chosen to acquire property subject to a pending legal dispute—and suggested that such an acquisition *would* amount to a waiver of the tribe's immunity. *Maysonet-Robles v. Cabrero*, 323 F.3d 43, 49-50 n.4 (1st Cir. 2003). Here too the Tribe knew the patents were under active—and nearly completed—Board review at the time of the purported assignment; indeed, the deal obligated the Tribe to challenge the Board's jurisdiction promptly upon execution. Appx2583-2584 § 5.3; Appx2590 § 7.2.12; Appx2565 § 12(i). This is precisely the scenario that the First Circuit recognized would bar an assertion of immunity.

3. The Tribe has waived any sovereign immunity by suing on the patents

Even when considering the constitutional sovereign immunity of States, the Supreme Court "has made clear in general that 'where a State *voluntarily* becomes a party to a cause and submits its rights for judicial determination, it will be bound thereby and cannot escape the result of its own voluntary act by invoking the prohibitions of the Eleventh Amendment.'" *Lapides*, 535 U.S. at 619 (quoting *Gunter v. Atl. Coast Line R.R. Co.*, 200 U.S. 273, 284 (1906)). That principle bars the Tribe's assertion of immunity here.

The Tribe affirmatively invoked federal jurisdiction in the parallel district-court action involving many of the same patents and patentability issues by joining

in Allergan's infringement action against appellees. *Allergan,* 2017 WL 4619790, at *2, 5. Now, on appeal in that case, the Tribe is asking this Court to allow it to enforce the patents against appellees while simultaneously insisting in this case that sovereign immunity shields the patents from *inter partes* review.

This represents an abuse and waiver of sovereign immunity because immunity may not be wielded for "tactical advantage" in an effort to game the patent system so as to retain the benefits of that system while escaping its burdens. *Vas-Cath,* 473 F.3d at 1383, 1385. In *Vas-Cath*, this Court held that a state university could not initiate an interference proceeding "for adjudication of its claim of prior inventorship and thus of patent ownership" and then invoke Eleventh Amendment immunity to bar an appeal of the agency's decision. *Id.* at 1383-84. The interference proceeding and judicial review of the results of that proceeding were part of the same "statutory system" for resolving patent disputes. *Id.* at 1383. "Principles of fairness and consistency," the Court reasoned, "prohibit selective assertion of immunity to avoid appeal by the loser after the University won the first round." *Id.* at 1384.

That reasoning is equally applicable here. The Tribe is seeking to enforce its alleged federal patent rights through infringement litigation in federal court, and *inter partes* review is part of the same "statutory system" of patent dispute resolution. *Id.* at 1383. Congress has given defendants in patent infringement litigation

the right to seek IPR of patents involved in that litigation, *see* 35 U.S.C. § 315(b), and appellants are seeking to destroy that right. Even if sovereign immunity is otherwise available in IPR proceedings, a tribe and its non-Indian commercial partners should not be permitted to game the federal patent system through "selective assertion of immunity" to steer patent disputes to their preferred forum. *Vas-Cath,* 473 F.3d at 1384.

II. Allergan retained all substantial rights in the challenged patents and thus remains the sole patent owner for purposes of these IPRs

As an independent basis for its decision, the Board examined the transaction between Allergan and the Tribe and determined that Allergan remains the true patent owner. The Board accordingly concluded that "these proceedings may continue with Allergan as the 'patent owner.'" Appx19.

The Board applied the correct analysis and reached the correct result. Appellants attack the Board's terminology, suggest that Congress introduced a specialized concept of patent ownership for IPRs, and contend that the Board misapplied existing precedent. All three contentions are mistaken. Because the Board correctly determined that Allergan retained patent ownership, any sovereign immunity the Tribe might enjoy does not bar these IPRs.

A. Appellants identify no meaningful distinction between patent ownership in general and patent ownership in an IPR

Appellants criticize the Board (at 35) for using the term "effective patent owner" at three places in its decision. *See* Appx35, Appx37, Appx44. Specifically, appellants argue that the IPR statutes use the term "patent owner," so the Board's references to "effective" patent ownership must mean that it was applying some other, incorrect legal standard. That argument lacks merit.

The record confirms that the Board found Allergan to be the "patent owner" for purposes of these IPRs. It concluded, for example, that "these proceedings may continue with Allergan as the *patent owner*," and it referred to Allergan's patent *ownership* repeatedly throughout its decision. Appx40 (emphasis added); *see also* Appx4, Appx6 n.3, Appx19.

In any event, appellants do not identify any substantive difference between the terms "patent owner" and "effective patent owner." And there is no basis to conclude that the AIA introduced a new concept of patent ownership that departs from established standards. Appellants emphasize (at 35-36) that several IPR statutes refer to a "patent owner" rather than "patentee," a term that appears in other provisions of the Patent Act. But Congress and the courts have long used the terms "patent owner" and "patentee" interchangeably, and the question of whether and how a nominal patent license affects patent ownership does not turn on which of those terms appears in a given statute. Under 35 U.S.C. § 100(d), "patentee" in-

cludes the original party to whom the patent was issued as well as successors in title—that is, whoever "*owns* the patent." *Speedplay*, 211 F.3d at 1249-50 (emphasis added). The current "patentee" is thus the current "patent owner." Even within 35 U.S.C. § 271, on which appellants rely, Congress used both "patent owner" and "patentee" without distinction. *Compare id.* § 271(d) ("No *patent owner* otherwise entitled to relief for infringement ….") (emphasis added), *with id.* § 271(i) ("a person other than the *patentee*") (emphasis added).

Appellants' argument (at 36-37) that the identity of the "patent owner" turns on nominal title rather than substantive reality is contrary to longstanding precedent. This Court has consistently looked to substantive reality in assessing whether a licensee qualifies as a "patentee" with standing to pursue infringement claims. The Court has recognized that even when a license nominally separates patent rights across multiple parties, if "a sufficiently large portion of this bundle of rights is held by one individual, we refer to that individual as *the owner of the patent*." *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1360 (Fed. Cir. 2010) (emphasis added).

If appellants were right, the Board could look no further than the face of an agreement to see whether it is denominated a "license" or an "assignment" when identifying a "patent owner" for IPR purposes. That approach would reduce patent ownership to a matter of pure formalism and invite manipulation by contracting

parties and their lawyers. The Board correctly rejected that view and instead applied this Court's precedents to conclude that a party that holds "all substantial rights under the patent is considered the owner regardless of how the parties characterize the transaction that conveyed those rights." Appx19 (quoting *Speedplay*, 211 F.3d at 1250).

B. Allergan has retained all substantial rights in these patents

To evaluate whether an exclusive license is tantamount to ownership, this Court has examined various rights that may be allocated under such an agreement, including (1) the nature and scope of the right to bring suit; (2) the exclusive right to make, use, and sell products under the patent; (3) the scope of the licensee's right to sublicense; (4) the duration of license rights and reversionary rights of the licensor; (5) the right of the licensor to receive a portion of the recovery in infringement suits brought by the licensee; (6) the obligation of the licensor to continue paying patent maintenance fees; and (7) the nature of any limits on the licensee's right to assign its interests in the patent. *Mann Foundation*, 604 F.3d at 1360-61.

In this case, each of those factors points to the same conclusion: under the license agreement between Allergan and the Tribe, Allergan continues to hold all substantial rights in the challenged patents.

1. Allergan owns the only realistic right to sue for infringement

Of the factors identified in *Mann Foundation*, the nature and scope of the parties' respective rights to sue for infringement is "the most important consideration." 604 F.3d at 1361. The Board examined the license agreement in detail and correctly found the Tribe received no more than "an illusory or superficial right to sue for infringement of the challenged patents." Appx22; *see* Appx20-26.

Under the agreement, Allergan holds the first right to bring and control any suit for past, present, or future infringement that "relates to" a Generic Equivalent. Appx2582 § 5.2.2. The license defines a "Generic Equivalent" as any product approved for sale by the FDA, or any product for which approval is being sought, that relies in whole or in part on the prior approval of any "Licensed Product" that is approved under, refers to, or even merely relates to, Allergan's New Drug Applications (NDAs) for Restasis. Appx2576 §§ 1.23, 1.33. As the Board recognized, the challenged patents are all listed in FDA's Orange Book; their claims all recite methods or compositions for treating humans, such that any infringing product would in practice require FDA approval; and all infringement actions to date have involved Generic Equivalents. Appx21-22; *see* Appx3713-3714 (Restasis Orange Book listing); Appx3708-3709 ('191 patent claiming methods of treatment that require administering a specified drug product "to a human eye"); Appx138-139 ('930 patent claiming compositions for treating "an eye of a human"); Appx181

('048 patent); Appx3692-3693 ('556 patent); Appx170 ('162 patent); Appx150 ('111 patent).

Only if Allergan declines to pursue such an infringement claim may the Tribe do so, and even then it may do so only with Allergan's express written consent. Appx2582 § 5.2.2. Similarly, Allergan has the first right to "defend and control" against challenges to the validity or enforceability of the patents, including in these IPR proceedings. Appx2583-2584 § 5.3. Allergan "retain[s] control of the defense in such claim, suit or proceeding," and the Tribe must cooperate in Allergan's defense. *Id.*

In contrast to Allergan's broad rights to enforce and defend the patents, the license affords the Tribe only subordinate, contingent, and ultimately illusory rights. It provides the Tribe with the first right to pursue claims for infringement that "does not relate to a Generic Equivalent." Appx2582-2583 § 5.2.3. But unlike Allergan's first right to pursue infringement relating to Generic Equivalents, the Tribe's "first right" to control other enforcement is qualified: the Tribe must take "commercially reasonable" steps toward enforcement to avoid triggering an opportunity for Allergan to step in. *Id.*

More important, given the nature of the patents' claims and their listing in the Orange Book, there is little practical possibility of any opportunity for enforcement that "does not relate to a Generic Equivalent." In arguing to the contra-

ry, appellants rely (at 42, citing Appx2535-2536) on a single example of a purportedly "non-FDA approved product" for treating dry eye announced by Imprimis Pharmaceuticals, Inc. for which "the Tribe would have the first right to bring and control any lawsuit." To bolster those claims, appellants surmise that Imprimis "has no intention of seeking FDA approval." *Id.* But Allergan has already sued Imprimis for unfair competition, alleging that the proposed Imprimis product requires FDA approval. Appx23 (citing *Allergan USA, Inc. v. Imprimis Pharm., Inc.*, No. 8:17-cv-01551-DOC-JDE, ECF No. 31 (C.D. Cal. Nov. 14, 2017)). Under Allergan's own publicly expressed views, even the proposed Imprimis product would require FDA approval and thus would fall outside of the Tribe's enforcement rights as a "Generic Equivalent" under Sections 1.23 and 5.2.3 of the license. Moreover, as the Board also recognized, neither Allergan nor the Tribe would have any basis to assert infringement unless the proposed Imprimis product contains the specific compositions recited in the claims of the challenged patents. *See* Appx22-23. Appellants do not contend that Imprimis has infringed or will infringe any of the challenged patents (at 42-43), nor have appellants offered any basis to support such an assertion.

The license also renders any enforcement rights allocated to the Tribe nugatory: as the Board found, Allergan is entitled to license any infringement of the patents with no pass-through royalty obligation, thereby terminating any suit

brought by the Tribe. Appx29-30. Under the license, Allergan received "*all licenses and other rights* (including sublicense rights relating to any Generic Equivalent) under the Licensed Patents related, necessary, or useful for Allergan to settle *any Infringement Actions under Section 5.2*." Appx2579 § 2.1 (emphases added). Section 5.2 encompasses *all* enforcement of the patents. In addition, Section 2.3 gives Allergan the right to grant sublicenses "for the purpose of settling *any dispute or proceeding pertaining to the Licensed Patents*, or to comply with Prior Settlement Agreements." Appx2579 § 2.3 (emphasis added). Appellants' contention (at 43) that Allergan may grant licenses "only in its field-of-use" is therefore incorrect. Allergan has a comprehensive right to "indulge" infringements, "which normally accompanies a complete conveyance of the right to sue." *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1132 (Fed. Cir. 1995).

The Tribe's nominal enforcement rights under the license are illusory.

2. Allergan holds all significant rights to make, use, and sell

Appellants further argue (at 38-40) that Allergan received only a limited field-of-use license to make, use, and sell patented products, and that the Tribe reserved substantial rights to practice the patents. The Board correctly rejected that argument as well. Appx26-29.

Under the license, Allergan received an irrevocable exclusive license to make, have made, use, offer to sell, sell, import, or otherwise exploit "Licensed

Products for all FDA-approved uses in the United States." Appx2578-2579 § 2.1. The license defines "Licensed Products" as "any product … approved by the FDA for sale in the United States under, or otherwise relating or referring to, NDA No. 050790 and/or No. 021023, including any supplements, amendments or replacement applications relating to any of the foregoing." Appx2576 § 1.33. Allergan also has "the sole and exclusive right" to obtain and maintain regulatory approvals. Appx2579 § 3.1.

The Tribe retained rights "not expressly granted" under the license, including the "right to use and practice the Licensed Patents for research, scholarly use, teaching, education, patient care incidental to the foregoing, sponsored research for itself and in collaborations with Non-Commercial Organizations ('Non-Commercial Users')." Appx2579 § 2.4. But the license expressly prohibits the Tribe from directly or indirectly developing, marketing, or licensing any "Competing Product" or engaging in or licensing any activities that would result in such a product. *Id*.

As the Board found, Allergan's right to exploit "Licensed Products for all FDA-approved uses" under Section 2.1 is "effectively co-extensive with the scope of the claimed inventions." Appx27. As previously noted, all claims of the licensed patents recite methods or compositions for medical use in humans, so any substantial effort to practice those claims in the United States would require FDA approval. By prohibiting "Competing Products," the license precludes the Tribe from

commercializing any treatment for dry eye or other indications that include dry eye. Appx2575, Appx2579 §§ 1.10, 2.4. In addition, the specific 0.05% cyclosporin formulations recited in the claims of the challenged patents mirror the formulations approved under Allergan's Restasis NDAs. Appx3720 (describing approved Restasis formulation); Appx3728 (same). Even if the Tribe attempted to market the claimed formulation for a different use, that would still at least *relate* to Allergan's NDAs for the same formulation and thus constitute a "Licensed Product" reserved exclusively for Allergan under the license. *See* Appx2576, Appx2578-2579 §§ 1.33, 2.1, 3.1.

Appellants claim (at 40) there is "a significant potential market for cyclosporin products for uses other than dry eye" that the Tribe is entitled "to explore and develop" under the license. But appellants never raised the existence of a "potential market" for uses other than dry eye, and they never addressed the articles now cited on appeal (Appx2957-2963 and Appx2964-2981) in any of their arguments before the Board. They have therefore forfeited any argument about a supposed "substantial potential market" not covered by Allergan's exclusive license. *See*, *e.g.*, *In re Watts*, 354 F.3d 1362, 1367-68 (Fed. Cir. 2004).

In any event, even if such a "potential market for cyclosporin products" did exist, the Tribe's argument would still fail because the patents do not claim "cyclosporin products"—they claim specific methods and compositions based on a par-

ticular formulation containing 0.05% cyclosporin and precise amounts of other substances. As shown above, the formulations recited in the claims correspond to the formulations set forth in the Restasis NDAs, and a later-approved use would at least *relate* to prior approvals of the same formulations and therefore fall within Allergan's exclusive rights. Appx2576, Appx2578-2579 §§ 1.33, 2.1.

Even if the Tribe has a nominal right to pursue uses beyond Allergan's existing NDAs, those rights would not be substantial. First, cyclosporin is an old drug, so *anyone*, not just the Tribe, may "explore and develop" cyclosporin-based treatments for new indications. 35 U.S.C. § 271(e)(1). Second, the license prohibits the Tribe from targeting not only dry eye but also any indication that *includes* dry eye. *See* Appx2575 § 1.10 (defining prohibited "Competing Product" as any product developed "for any indication that *includes or is the same as* any indication for which any Licensed Product is approved by the FDA") (emphasis added). Third—and perhaps most tellingly—the license prohibits the Tribe from developing any drug for approval "under … or referring to" Allergan's NDAs. Appx2576, Appx2578-2579 §§ 1.33, 2.1. Exercising any meaningful rights under the patents would thus require the Tribe to develop a product from square one: to research, identify, and establish a safe and effective treatment and carry that treatment through development, clinical trials, and the entire new-drug-approval process, all before the challenged patents expire in 2024. In practical terms, that is all but im-

possible—as appellants were surely aware in crafting their deal. Not surprisingly, there is no suggestion in the record that the Tribe has pursued such endeavors or intends to do so in the future. *See* Appx1910-1911 (explaining that "the Tribe is not investing any money in this business"); *cf. Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1344 (Fed. Cir. 2014) (licensor's purported right to practice had "little force" where licensor did not "make or sell any products … and the evidence on record suggests that [the licensor] will not make or sell any products in the future"), *vacated on other grounds*, 135 S. Ct. 1846 (2015).

The Board did not err in finding that the license agreement left the Tribe with no substantial rights to make, use, or sell products under the patents.

3. Allergan controls sublicensing

As discussed above, Allergan obtained an unfettered right to license third parties under the patents at issue, with no obligation to pay royalties to the Tribe. Appx29-30; Appx2578-2579 §§ 2.1, 2.3. Unlike in *Mann Foundation*, where any sublicense granted by the licensee required pass-through royalties, 604 F.3d at 1362, this factor points toward concluding that Allergan retained all substantial rights. *See Speedplay*, 211 F.3d at 1251.

4. The Tribe has no reversionary rights because Allergan's rights are perpetual and irrevocable

The Board correctly concluded that "the Tribe does not have *any* reversionary rights in the challenged patents." Appx31. Allergan's exclusive rights under the

license are "perpetual" and "irrevocable." Appx2578 § 2.1. Those rights will thus remain in force until the last licensed patent expires or is rendered invalid in a non-appealable final judgment. Appx2593 § 9.1.1. The Tribe cannot extinguish Allergan's rights.

5. Allergan owns the proceeds from its enforcement activities

The Board correctly found that the Tribe receives no proceeds from any of Allergan's litigation and licensing activities. Appx31. Allergan owns all monetary recovery from all commercially relevant litigation against any generic competitor. Appx2582-2583 §§ 5.2.2, 5.2.5. The Tribe is entitled only to reimbursement for costs incurred to appear and cooperate with Allergan. *Id.* The Tribe received a $13.75 million up-front payment plus quarterly payments of $3,750,000. Appx2579-2580 §§ 4.1, 4.2. But those payments are independent of enforcement litigation and amount to only about 1% of Allergan's annual Restasis sales. Appx1947-1948.

6. Allergan is responsible for patent prosecution and maintenance

The license assigns to Allergan the "first right, but not the obligation" to prepare, file, prosecute, and maintain the licensed patents and be responsible for any administrative proceedings concerning the patents. Appx2581 § 5.1.1. Allergan also holds the exclusive rights to apply for patent term extensions and make all

regulatory filings with respect to the licensed patents. Appx2581-2582 §§ 5.1.5, 5.1.6. Despite being the nominal patent owner, the Tribe has no obligation to pay any maintenance fees, and it may elect to pay maintenance fees only if Allergan chooses not to do so. Appx32.

7. Allergan may assign its interests, while the Tribe may not

Allergan's rights under the license are transferable. Appx2578 § 2.1. Allergan may freely transfer or assign its rights "to any of its Affiliates or to a successor" without the Tribe's consent and to other third parties with the consent of the Tribe. Appx2594 § 10.3. The Tribe, by contrast, concedes (at 48) that it "relinquished its right to assign its ownership of the patents to third parties."

Appellants suggest (at 49) that *any* restriction on Allergan's right to assign precludes a finding that Allergan retains substantial rights. But the cases on which they rely, *Sicom Systems Ltd. v. Agilent Technologies., Inc.*, 427 F.3d 971, 979 (Fed. Cir. 2005), and *Intellectual Property Development, Inc. v. TCI Cablevision of California*, 248 F.3d 1333, 1345 (Fed. Cir. 2001), do not say that. In those cases, the licensor's approval was required for any assignment of the licensee's rights, and this Court emphasized that the licensee could not bring suit or sublicense without the licensor's consent. *Sicom*, 427 F.3d at 973, 979; *Intellectual Property Development*, 248 F.3d at 1344-45. Here, Allergan may unilaterally assign its rights to affiliates or successors, and it holds the right to sue for all substantial infringe-

ment and an unfettered right to sublicense. The partial limits on Allergan's ability to assign its rights are not inconsistent with a determination that Allergan holds all substantial rights in the patents. *See Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1346, 1350 (Fed. Cir. 2016) (licensee held all substantial rights even though licensor consent was necessary for assignment, where consent to assign was not to be withheld unreasonably); *Aspex Eyewear, Inc. v. Miracle Optics, Inc*., 434 F.3d 1336, 1342 (Fed. Cir. 2006) ("[G]iven its virtually unfettered right to sublicense, [the licensee's] limited ability to assign its rights to unaffiliated third parties is not controlling.").

8. Appellants' additional arguments do not undermine the Board's determination that Allergan is the true owner

Appellants suggest (at 46) that the Tribe retained a "key right" in the form of "sole and exclusive control over the means and manner in which its sovereign immunity is asserted or waived." Sovereign immunity, however, is not a *patent* right and is therefore irrelevant to whether the license transferred "'all substantial rights' *in the patents*." *Mann Foundation*, 604 F.3d at 1359 (emphasis added). Moreover, far from retaining "sole and exclusive control" over its sovereign immunity, the Tribe agreed to numerous limitations on when and how it must assert its immunity. *E.g.*, Appx2582 § 5.2.2 (the Tribe "shall not assert its sovereign immunity … in the E.D. Texas Litigations"); Appx2584 § 5.3 (the Tribe "will and

shall assert its sovereign immunity in any Contested PTO proceeding, including in the IPR Proceedings").

Appellants also cite three decisions in which, they say (at 49-51), this Court or the PTAB deemed similar agreements to convey fewer than all substantial rights in a patent. Those analogies do not withstand scrutiny. Appellants argue that the licensor in *Abbott* held more limited rights to practice the patents and sue for infringement. In *Abbott*, however, the licensee's rights to make, use, and sell patented products were exclusive *except as to the licensor*—the licensor also continued to make, use, and sell such products. 47 F.3d at 1129, 1132. In addition, the licensee in *Abbott* could not indulge infringements, "which normally accompanies a complete conveyance of the right to sue." *Id.* at 1132. In contrast, Allergan's rights to produce commercially relevant Licensed Products are exclusive even as to the Tribe, Appx2578-2579 § 2.1, and Allergan can grant licenses to settle *any* litigation involving the licensed patents, including litigation initiated by the Tribe, Appx2579 §§ 2.1, 2.3. As a result, Allergan has an unfettered right to indulge infringements.

Appellants also rely on *AsymmetRx, Inc. v. Biocare Medical, LLC*, 582 F.3d 1314 (Fed. Cir. 2009), but the license there differed from the license here in several important respects: (1) the licensor in *AsymmetRx* retained substantial control over the licensee's activities within the licensed field; (2) the licensee could not grant

licenses to terminate suits brought under the licensor's secondary right to sue; (3) the licensee required licensor approval to settle any suit; and (4) the licensor was entitled to join and control any suit brought by the licensee. *Id.* at 1320-21. Each of those provisions severely constrained the licensee's authority to practice and enforce the patents, and none of them is present here.

Appellants' passing reference to *NeoChord, Inc. v. University of Maryland, Baltimore*, IPR2016-00208, Paper 28 (PTAB May 23, 2017), is equally misplaced. Appellants argue (at 51) that the University's retained secondary right to bring suit in that case aligns with the Tribe's secondary right to sue "and should compel the same result here." But the *NeoChord* license required pass-through royalties on any sublicense granted by the licensee, specified that the licensor shared in any litigation recovery by the licensee, required licensor approval for any settlement, and allowed the licensor to intervene in any action regarding the licensed patent. Appx1698. The Tribe's rights here are far more limited; the Tribe receives no proceeds from Allergan's licensing and litigation activities, and it has minimal to no control over litigation concerning the licensed patents.

In sum, the factors this Court has used to distinguish between an exclusive license and an assignment point overwhelmingly to the conclusion that the Tribe reassigned ownership to Allergan. Any rights allocated to the Tribe in this case are at most a "minor derogation" and did not "substantially interfere" with Allergan's

receipt of all substantial rights under the license. *Vaupel Textilmaschinen KG v. Meccanica Euro Italia, S.p.A.*, 944 F.2d 870, 875 (Fed. Cir. 1991). The Board correctly concluded that the license agreement leaves Allergan holding all substantial rights in the patents, making Allergan the true patent owner.

III. The Tribe is not a necessary or indispensable party in the IPRs, so the IPRs may properly proceed without it

Even if the Tribe were entitled to assert immunity in these IPRs, and even if the Tribe retained any substantial rights in the patents, these IPRs should still be allowed to proceed in the Tribe's absence because the Tribe is not a necessary and indispensable party. The Board concluded that although the Federal Rules of Civil Procedure do not apply in IPRs, the factors set out in Rule 19(b) are "instructive" in evaluating the identity of interests between present and absent parties. Appx36 (citation omitted). The Board did not abuse its discretion in applying those factors and determining that the Tribe is not a necessary and indispensable party.

A. *Republic of Philippines v. Pimentel* does not require dismissal

Appellants argue (at 52) that *Republic of Philippines v. Pimentel,* 553 U.S. 851 (2008), requires dismissal of the IPRs without regard to Rule 19 because that decision established categorical rules that "[a] case may not proceed when a required-entity sovereign is not amenable to suit" and that "dismissal of the action must be ordered where there is a potential for injury to the interests of the absent sovereign." (quoting *Pimentel*, 553 U.S. at 867). But appellants' argument begs the

question by assuming the Tribe is a required party that has sovereign "interests" that are relevant to these proceedings. If, as the Board determined, the Tribe's limited interests in these proceedings are minimal compared to those of Allergan, *see* Appx37-38, then neither predicate to appellants' argument is valid.

In addition, as the Board explained, this case differs significantly from *Pimentel*, which involved a claim of *foreign* sovereign immunity in litigation arising from disputed claims to money that had been stolen from the Republic of the Philippines by its former leader and that was the subject of pending proceedings in that country. Appx36-37; *see* 553 U.S. at 854-55, 857-58. The Court gave great weight to the strong "comity interest" under international law "in allowing a foreign state to use its own courts for a dispute if it has a right to do so." 553 U.S. at 866. It also emphasized that the litigation arose from "events of historical and political significance for the Republic and its people," and that the Republic had a "unique interest in resolving the ownership of or claims to the [disputed] assets and in determining if, and how, the assets should be used to compensate those persons who suffered grievous injury under Marcos." *Id.*

The Tribe's claim of sovereign immunity, by contrast, does not raise "comity concerns" between co-equal sovereigns. *Id.* at 869. Instead, it is an attempt by an Indian tribe and a pharmaceutical company to prevent the dominant sovereign from reconsidering a "public franchise," *Oil States*, 138 S. Ct. at 1373-75, granted and

regulated by that dominant sovereign. Moreover, the patent claims under consideration by the PTAB have no historical connection to the Tribe, which was a stranger to these proceedings until September 2017, when it purported to acquire the patents for nothing other than its promise not to waive sovereign immunity in PTO proceedings to review patentability.

Appellants claim (at 54) that "[n]early every court that has considered the impact of tribal immunity in a Rule 19 analysis has concluded dismissal is warranted because of the weight given to a tribe's sovereign interest in its government authority, its property, or in a contract." On the contrary, many courts have found in a variety of circumstances that tribes were not indispensable parties and that legal proceedings could continue in their absence. *See*, *e.g.*, *Thlopthlocco Tribal Town v. Stidham*, 762 F.3d 1226, 1235-36 (10th Cir. 2014); *Vann v. U.S. Dep't of Interior*, 701 F.3d 927, 929-30 (D.C. Cir. 2012); *Salt River Project Agric. Improvement & Power Dist. v. Lee*, 672 F.3d 1176, 1179-82 (9th Cir. 2012); *Sac & Fox Nation of Mo. v. Norton*, 240 F.3d 1250, 1258-60 (10th Cir. 2001); *Bassett v. Mashantucket Pequot Tribe*, 204 F.3d 343, 358 (2d Cir. 2000).

In support of appellants' contention that the Tribe is indispensable to these proceedings, Section III of appellants' brief cites a total of 18 decisions involving absent tribes. None of the decisions supports appellants' position. One stands for the opposite proposition, *Mesa Grande Band of Mission Indians v. United States*,

121 Fed. Cl. 183, 194-96 (2015) (absent tribe's "interest" was "indirect or contingent"), and one was reversed on appeal, *Vann v. Salazar*, 883 F. Supp. 2d 44, 49-51 (D.D.C. 2011), *rev'd & remanded sub nom. Vann v. U.S. Dept. of Interior,* 701 F.3d 927 (D.C. Cir. 2012) (reversing cited district-court decision and holding that the Cherokee Nation was *not* necessary or indispensable). Moreover, *every one* of the 18 decisions involved disputes that were closely tied to the tribe itself, its reservation lands and resources, or tribal members—in other words, disputes that implicated the interests of the tribe as a sovereign. These IPR proceedings, on the other hand, involve patents with which the Tribe had no connection until it was paid to accept an assignment in exchange for a pledge not to waive sovereign immunity.

In addition, many of appellants' cited decisions turned on the absence in those cases of any disputed "public rights" and thus did not qualify for the "public rights exception" to rules of party joinder. *See*, *e.g.*, *N. Arapaho Tribe v. Harnsberger,* 697 F.3d 1272, 1280-81 (10th Cir. 2012); *Am. Greyhound Racing, Inc. v. Hull*, 305 F.3d 1015, 1025-27 (9th Cir. 2002). But as the Supreme Court recently reiterated, "[i]nter partes review falls squarely within the public-rights doctrine." *Oil States*, 138 S. Ct. at 1373. The Board correctly noted that courts have distinguished *Pimentel* and relaxed the rules requiring sovereign joinder where, as here, "public rights" are in dispute. Appx39-40 n.14.

Finally, appellants overlook the Court's observation in *Pimentel* that the decision whether to proceed in an action absent a sovereign party must be "based on equitable considerations," requires evaluation of a "nonexclusive" list of "case-specific" factors, and ultimately turns on "[t]he balance of equities." 553 U.S. at 862-63, 873. Applying that principle, this Court has concluded that there is no "per se rule that patent owners are automatically indispensable parties," even when they are sovereign actors; that the indispensability determination is guided by "equity and good conscience"; and that an absent sovereign entity is *not* indispensable if it has assigned "sole and exclusive control of [its] suit over to" another party to the proceedings (as the Tribe has done in these proceedings). *University of Utah*, 734 F.3d at 1326, 1327-28; *accord A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1221-22 (Fed. Cir. 2010) (rejecting argument that absence of sovereign "weighs conclusively in favor of dismissal" and instead conducting full Rule 19(b) equitable balancing analysis and ultimately upholding district court's determination that sovereign was indispensable).

B. The balance of equities strongly favors allowing the Board to complete these long-pending IPR proceedings

The balance of equities strongly favors affirming and remanding so that the Board can proceed to issue final written decisions in these proceedings.

As for the first two Rule 19(b) factors—the potential prejudice to the absent party and the extent to which any such prejudice can be lessened or avoided, Fed.

R. Civ. P. 19(b)(1)-(2)—courts often proceed in the absence of a sovereign where its interests are "adequately represented" by a participating party. *See*, *e.g., University of Utah*, 734 F.3d at 1327-28; *Vann*, 701 F.3d at 929-30; *Salt River Project*, 672 F.3d at 1180-81. Allergan will vigorously represent whatever interests the Tribe has in the patents because Allergan has aligned—and much greater—interests in defending the patentability of the claims at issue. *See* Appx37-38 & n.13. Allergan's counsel are uniquely capable of doing so because they were the ones who developed all of the patentability defenses asserted in the IPRs. Because briefing is complete and all evidence has been submitted, the Tribe could not raise new arguments now even if it had identified any (which it has not). 37 C.F.R. § 42.70(a).

Appellants claim (at 56) that "Allergan has no duty to the Tribe" and therefore cannot be trusted to represent the Tribe adequately in the IPRs. That argument, however, ignores Allergan's substantial financial interest in defending the validity of the Restasis patents; all of Allergan's efforts to do so can only redound to the benefit of the Tribe. The argument also ignores the license agreement, which assigns detailed duties and responsibilities to Allergan with respect to the Tribe's interests. These include duties of notice, reasonable consideration of tribal input and suggestions, and reimbursement and indemnification; various "representations, warranties and covenants"; and mechanisms to enforce Allergan's duties.

Appx2581-2584, Appx2587-2588, Appx2591-2592, Appx2595 §§ 5.1-5.3, 7.1, 8.1.1, 10.7. The Tribe has contractually agreed that Allergan will represent its interests in IPRs and subsequent appeals. Appx2583-2584 § 5.3. Under New York law—which governs the agreement, *see* Appx2594 § 10.6.1—"a covenant of good faith and fair dealing is implied in all contracts," which "embraces a pledge that neither party shall do anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract." *Fishoff v. Coty Inc.*, 634 F.3d 647, 653 (2d Cir. 2011) (citation omitted).

Appellants further argue (at 56) that "a publicly traded company" like Allergan can never adequately represent an absent sovereign's interests. There is no such rule. Many federal courts have found that private entities can be adequate representatives of absent sovereigns in appropriate circumstances, including when a private party and a sovereign have a contractual relationship governing litigation representation. This Court's decision in *University of Utah* is again on point. In that case, the University of Massachusetts "handed sole and exclusive control of" litigation involving patents to a pharmaceutical company, which was subsequently sued to correct inventorship of the patents. 734 F.3d at 1327-28. The company moved to dismiss on the ground that the University of Massachusetts was a necessary and indispensable party. The district court denied the motion, and this Court affirmed: the absent state entity's delegation of "sole and exclusive control of this

suit" to a private entity "strongly supported" the conclusion that the state entity would be more than adequately represented by the private entity. *Id.*; *see also Reactive Surfaces*, IPR2017-00572, Paper 32 at 15 & nn.2-3 (determining that the University of Minnesota's interests could be adequately represented by its co-owner Toyota because they "both hold identical interests" in defending the validity of their patent; "there is no difference here between the nature of the claim" against Toyota and the University). The single district-court decision cited by appellants in support of their assertion (at 56) that "a publicly traded company" cannot represent a sovereign is not even about a corporation's ability to represent an absent sovereign's interests; it unremarkably concluded that county government officials could not adequately protect an absent tribe's treaty rights. *See Union Pac. R.R. Co. v. Runyon,* 320 F.R.D. 245, 252 (D. Or. 2017).

In any event, the Board emphasized that "the briefing and evidence on the substantive patentability issues were completed even before the Tribe's involvement in these proceedings," and that, "[o]ther than oral argument, the record in these proceedings is closed." Appx38. The Tribe can offer nothing new, and the Board correctly concluded that its final written decision will "be the same regardless of whether Allergan or the Tribe continues to participate." Appx38-39.

The third Rule 19(b) factor also strongly favors continuing the IPRs, because "a judgment rendered in the [Tribe's] absence would be adequate." Fed. R. Civ. P.

19(b)(3). Clearly so—the patents in issue are "public franchises," *Oil States*, 138 S. Ct. at 1373-74, and the PTO can modify or cancel them without any action by the Tribe.

The fourth Rule 19(b) factor—"whether [appellees] would have an adequate remedy if the [IPRs] were dismissed for nonjoinder," Fed. R. Civ. P. 19(b)(4)—also strongly favors continuing with the IPR proceedings and bringing them to conclusion with dispatch. No adequate alternative remedy is available here. Appellants insist that appellees have an adequate remedy in the parallel district-court litigation if these proceedings are dismissed. But appellants ignore that only a subset of the claims in these proceedings are still at issue in the Texas litigation. They also overlook that IPRs evaluate patentability under a preponderance-of-the-evidence standard, 35 U.S.C. § 316(e), whereas district courts evaluate validity under a clear-and-convincing-evidence standard, *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). Congress's purposes in creating IPR included "improving patent quality and providing a more efficient system for challenging patents that should not have issued." H.R. Rep. No. 112-98, pt. 1, at 39-40 (2011); *see also Cuozzo*, 136 S. Ct. at 2139-40 (the Board's "power to revisit and revise earlier patent grants" was "one important congressional objective"). Allergan and the Tribe may view district-court litigation as an adequate substitute for IPRs, but Congress plainly concluded otherwise in adopting the AIA.

And that is the ultimate point. Appellants' scheme is an assault on the public policies at the heart of the IPR system. Validating their ploy would invite others to repeat the same tactics in the future. IPRs would be rendered toothless if patent owners could unilaterally derail PTAB proceedings through manipulative assignments whenever a patent seemed at risk. In the parallel district-court litigation, Judge Bryson underscored the grave risks appellants' tactics pose:

> Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent—the Tribe's sovereign immunity in order to defeat the pending IPR proceedings in the PTO. ... What Allergan seeks is the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits through the administrative mechanism for canceling invalid patents.
>
> If that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice. In short, Allergan's tactic, if successful, could spell the end of the PTO's IPR program, which was a central component of the America Invents Act of 2011.

Allergan, 2017 WL 4619790, at *2. It would not advance "equity and good conscience" to allow appellants to undermine the integrity of IPRs and the AIA through manipulative tactics and misappropriation of tribal sovereign immunity.

CONCLUSION

The Board's orders should be affirmed, the temporary stay pending appeal should be lifted, and the proceedings should be remanded so that the Board can conclude these long-delayed IPRs and issue final written decisions.

Respectfully submitted,

PERKINS COIE LLP

by /s/Eric D. Miller

Eric D. Miller

Counsel for Appellee Mylan Pharmaceuticals Inc.

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

by /s/J.C. Rozendaal

J.C. Rozendaal

Counsel for Appellee Teva Pharmaceuticals USA, Inc.

SUGHRUE MION, PLLC

by /s/Michael R. Dzwonczyk

Michael R. Dzwonczyk

Counsel for Appellee Akorn, Inc.

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume information of Federal Circuit Rule 32(a). The brief contains 13,829 words, excluding the portions exempted by Federal Circuit Rule 32(b).

2. This brief 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). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 and 14-point Times New Roman type.

Dated: May 11, 2018

/s/Dan L. Bagatell
Dan L. Bagatell

CERTIFICATE OF AUTHORITY AND PROOF OF SERVICE

I certify that I have the authority of Eric D. Miller, J.C. Rozendaal, and Michael R. Dzwonczyk to file this document with their electronic signatures.

I further certify that on May 11, 2018, I electronically filed the foregoing document using the Court's CM/ECF system, which will automatically serve all counsel of record for all parties that are registered CM/ECF users.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: May 11, 2018

/s/Dan L. Bagatell
Dan L. Bagatell