

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA,  
INC., and AKORN INC.,<sup>1</sup>  
Petitioners

v.

ALLERGAN, INC.,  
Patent Owner

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Case IPR2016-01127 (8,685,930 B2)  
Case IPR2016-01128 (8,629,111 B2)  
Case IPR2016-01129 (8,642,556 B2)  
Case IPR2016-01130 (8,633,162 B2)  
Case IPR2016-01131 (8,648,048 B2)  
Case IPR2016-01132 (9,248,191 B2)

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**BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS  
AMICUS CURIAE IN SUPPORT OF PETITIONERS**

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<sup>1</sup> Cases IPR2017-00576 and IPR2017-00594, IPR2017-00578 and IPR2017-00596, IPR2017-00579 and IPR2017-00598, IPR2017-00583 and IPR2017-00599, IPR2017-00585 and IPR2017-00600, and IPR2017-00586 and IPR2017-00601 have respectively been joined with the captioned proceedings.

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## I. INTEREST OF AMICUS CURIAE<sup>1</sup>

The Association for Accessible Medicines (“AAM”) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products and of bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry.

AAM’s core mission is to improve the lives of patients by providing timely access to safe, effective, affordable prescription medicines. To that end, AAM regularly files briefs as amicus curiae, as did its predecessor, the Generic Pharmaceutical Association. *See, e.g., FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). These briefs reflect the position of AAM as an organization, speaking for the industry, not any individual member.

AAM’s members are frequently IPR petitioners, because the efficiency and speed of IPRs fit the industry’s mission of delivering generic alternatives to patients as soon and as cost-effectively as possible. AAM’s members thus have a significant interest in ensuring that brand-name drug manufacturers are not allowed to abuse the U.S. patent system by attempting to invoke rented Native American tribal immunity to frustrate the Board’s authority to review erroneously issued patents.

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<sup>1</sup> No party or party’s counsel authored any portion of this brief or made a financial contribution intended to fund its preparation or submission. No one other than AAM and its counsel made such a financial contribution. *Cf. Sup. Ct. R. 37.6.*

## II. INTRODUCTION

Facing the likely loss of the remaining patents shielding a multi-billion-dollar drug from generic competition, Allergan Inc. adopted an unprecedented strategy on the eve of the oral hearings in these IPRs: it paid millions of dollars in an attempt to rent the sovereign immunity of the Saint Regis Mohawk Tribe (“Tribe”). Now, the Tribe argues that the Board has no choice but to dismiss these IPRs. But the Board is anything but hamstrung from exercising its authority to take a “second look at an earlier administrative grant of a patent” and to “protect the public’s ‘paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.’” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016) (citation omitted).

First, IPRs do not offend the dignity of sovereign tribal entities because they do not allow private parties to subject a sovereign “to the coercive process of judicial tribunals.” *Fed. Mar. Comm’n v. S.C. State Ports Auth.* (“FMC”), 535 U.S. 743, 760 (2002). Rather, a federal agency permissibly “institute[s] its own administrative proceeding” to take a second look at a patent it issued. *Id.* at 768. Second, courts have refused to dismiss analogous *in rem* property actions when, as in this case, a private party attempted to convey property to a tribal entity in an effort to frustrate judicial adjudication of property rights. And third, even if IPR proceedings were indistinguishable from *in personam* judicial proceedings, the Board need not dismiss these IPRs. The Board had authority to institute

proceedings with Allergan as Patent Owner, and it retains discretion to complete its review notwithstanding a transfer expressly calculated to prevent a final decision.

The Board should deny the Tribe's motion and finish the work it started nearly a year ago when it instituted these IPRs and concluded that there was a "reasonable likelihood" that the challenged claims are unpatentable.

### **III. ARGUMENT**

#### **A. Tribal Immunity Does Not Block The Board From Considering The Validity Of An Issued Patent.**

The Tribe's argument rests on incorrectly equating IPR with civil litigation, trying to benefit from the Supreme Court's holding in *FMC* that state sovereign immunity can apply in certain administrative proceedings. But the Supreme Court held only that where Congress cannot subject a *State* to suit in federal court, Congress also cannot force the same State to answer the complaints of private parties in an administrative tribunal that is indistinguishable from a federal court proceeding. An IPR is not a private dispute like a suit for monetary or equitable relief. Rather, an IPR is a means for the agency to reconsider its own administrative decision to issue a patent. The proceeding differs materially from civil litigation and does not require the sort of jurisdiction over the parties that civil litigation entails.

##### **1. IPRs Are Administrative Proceedings Instituted By A Federal Agency, Not Judicial Disputes Between Private Parties.**

Tribal sovereignty "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). Tribes suffer no harm to their sovereign dignity when the federal government corrects its own error by cancelling a patent that never should have issued.

First, the Board plays a different role than the agency adjudicator in *FMC*. In the challenged Federal Maritime Commission proceeding, the agency played no role except refereeing a private dispute in which one party claimed that the other had violated federal law and demanded a remedy. *FMC*, 535 U.S. at 764. The Court emphasized that the agency “d[id] not even have the discretion to refuse to adjudicate complaints brought by private parties.” *Id.* The Court therefore concluded that the agency was in substance no different from a court, where sovereign immunity would apply. But, the Court made clear, the agency was free to “institute its own administrative proceeding” against a sovereign entity, “either upon its own initiative *or upon information supplied by a private party.*” *Id.* at 768 (emphasis added).

That distinction is crucial here, because the Board does *not* simply act as an adjudicator of a private dispute. The Board is limited to taking a “second look” at the agency’s own actions in issuing a patent, not the conduct of the patent owner in obtaining it. *Cuozzo*, 136 S. Ct. at 2144. That is not a private dispute, which is why any interested member of the public may file a petition. *Cf. Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1262 (Fed. Cir. 2014). Unlike the

Federal Maritime Commission, the Board has “discretion to refuse” to institute an IPR. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016). And once the Board has decided to institute an IPR, it may keep reviewing the patent even if the patent owner and petitioner reach a settlement: the agency “may continue to conduct an [IPR]” and “may intervene in a later *judicial* proceeding to defend its decision—even if the private challengers drop out.” *Cuozzo*, 136 S. Ct. at 2144 (emphasis in original). These characteristics, which civil litigation does not share, make clear that IPRs are just the type of administrative proceedings that the government “remains free” to continue irrespective of sovereign immunity, even where the IPRs were instituted based “upon information supplied by a private party.” *FMC*, 535 U.S. at 768.

Second, there are fundamental differences between adversarial civil lawsuits and IPRs, as the Supreme Court detailed just a year ago when it rejected the argument that *inter partes* review is “a ‘surrogate’ for court proceedings” and stated instead that in many ways “inter partes review is less like a judicial proceeding and more like a specialized agency proceeding.” *Cuozzo*, 136 S. Ct. at 2143. Perhaps most important, the “basic purpose[]” of an IPR is different from the purpose of district court litigation. *Id.* at 2144. Indeed, IPR proceedings even allow a patent owner to move to amend his claims—“just [as] he would do in the examination process,” and which he could not do in federal court. *Id.* at 2145.

Third, these points are especially salient here, because the putative sovereign entered the case at the last possible moment. To the extent that IPRs bear any resemblance to civil litigation, the similarities (such as deposition discovery) were conducted with a non-sovereign Patent Owner in the case, and were already over by the time the Tribe appeared. All that remained was the final IPR hearing, which Patent Owner *Allergan* had requested. Paper 47. There is no precedent for finding a *present* affront to sovereignty based on *past* proceedings.

The Board's previous treatment of how its role in IPR proceedings bears on sovereign immunity boils down to one key sentence of analysis. After reciting various procedural features of IPR, the Board opined that "the Board's role in the *inter partes* review is not unlike that of the Commission in *FMC*, which is to assess the merits of the arguments presented by the parties in an impartial manner." *Covidien LP v. Univ. of Fla. Research Found. Inc.*, IPR2016-01274, Paper 21, 16-17 (P.T.A.B. Jan. 25, 2017). The Tribe here relies heavily on *Covidien*. But the Board did not address key features of IPR—in particular, the fact that an IPR (unlike the proceeding in *FMC*) requires the exercise of the Board's discretion, but does not require adversity between parties. It should do so here.

**2. Instituted IPRs Are *In Rem* Proceedings, And The Transfer Of The Subject Patents To A Tribe Does Not Defeat *In Rem* Jurisdiction.**

Though Allergan's sham transaction is the first to involve a patent, the company is far from the first to pursue sovereign-immunity protection. Courts have

repeatedly refused to dismiss real-property actions when faced with virtually identical circumstances—private parties attempting to convey real property to a tribal entity and thereby to frustrate judicial adjudication of property rights.

In one case, a plaintiff filed suit to quiet title to a parcel of real property, and it recorded a *lis pendens* to provide record notice of the action. *Anderson & Middleton Lumber Co. v. Quinault Indian Nation*, 929 P.2d 379, 381 (Wash. 1996). More than a month later, ten individuals who were named as defendants in the quiet-title action conveyed their interest in the land to the Quinault Indian Nation. *Id.* The defendants then moved to substitute the Nation as a defendant in the lawsuit, and the Nation moved to dismiss the action based on tribal sovereign immunity. *Id.* The trial court nonetheless continued to exercise jurisdiction over the quiet-title action, and the Supreme Court of Washington affirmed. Because the trial court had proper *in rem* jurisdiction over the *res* in dispute at the time the property transfer took place, any lack of *in personam* jurisdiction over an entity that obtained interest in the property in a “subsequent sale” did not divest the trial court of its *in rem* jurisdiction to divide the property among its legal owners. *Id.* at 385.

In another case, a couple sought to quiet title to property they claimed to have acquired through adverse possession. *Smale v. Noretap*, 208 P.3d 1180, 1180 (Wash. Ct. App. 2009). Thereafter, the defendant deeded the property to the Stillaguamish Tribe of Indians, and the Tribe sought to dismiss the action based on

tribal immunity. *Id.* Affirming the trial court’s denial of the Tribe’s motion to dismiss, the court of appeals held that the trial court’s “continuing jurisdiction over the land claimed by the Smales for the purposes of determining ownership does not offend the Tribe’s sovereignty,” because the Tribe was not being sued for monetary relief and instead the plaintiffs were seeking a court’s disposition of a property res over which the court had properly assumed jurisdiction. *Id.* at 1180, 1183.

Another state supreme court reached a similar result in a condemnation action. An individual conveyed his property rights to the Turtle Mountain Band of Chippewa Indians, trying to prevent the county from using eminent domain to acquire his land to build a dam. *Cass Cnty. Joint Water Res. Dist. v. 1.43 Acres of Land*, 643 N.W.2d 685, 688 (N.D. 2002). The court held that the condemnation action was not barred by tribal immunity because the trial court’s jurisdiction was *in rem*: the court’s judgment would not “impose responsibility or liability on a person directly, but operate[] directly against the property in question . . . irrespective of whether the owner is subject to the jurisdiction of the court in personam.” *Id.* at 689 (citation omitted). The court noted that a contrary rule would have “far-reaching effects on the eminent domain authority of states and all other political subdivisions”: “Indian tribes would effectively acquire veto power over any public works project attempted by any state or local government merely by purchasing a small tract of land within the project.” *Id.* at 694.

Relying on the Supreme Court’s recognition that *in rem* actions do not offend tribal sovereignty in the way that *in personam* actions do, these courts concluded that while tribal sovereign immunity bars actions against the tribe itself, it does not bar *in rem* actions in which a court need not obtain *in personam* jurisdiction over the property holder, much less over a transferee to whom the property is conveyed in order to evade the court’s resolution of property disputes. *See, e.g., Cass Cnty.*, 643 N.W.2d at 691 (discussing *County of Yakima v. Confederated Tribes & Bands of the Yakima Indian Nation*, 502 U.S. 251, 264-265 (1992)). Indeed, even where a tribe has acquired land from a private party *before* the court action, many courts have held that tribal immunity poses no bar to *in rem* actions involving the disposition of that property. *See, e.g., Lundgren v. Upper Skagit Indian Tribe*, 389 P.3d 569, 572-573 (Wash. 2017), *as amended* (June 8, 2017) (adverse-possession claim against tribe), *petition for cert. filed*, No. 17-387 (Sept. 11, 2017) (discussing split of authority on this issue); *Miccosukee Tribe of Indians of Fla. v. Dep’t of Env’tl. Prot. ex rel. Bd. of Trs. of Internal Improv. Tr. Fund*, 78 So. 3d 31, 32 (Fla. Dist. Ct. App. 2011) (eminent domain action against land held in fee by Tribe).

To the extent IPR proceedings resemble judicial proceedings rather than specialized administrative ones, they bear the hallmarks of *in rem* real-property actions, which can be resolved irrespective of tribal sovereign immunity. *In rem* proceedings are actions “[i]nvolving or determining the status of a thing, and

therefore the rights of persons generally with respect to that thing,” *Black’s Law Dictionary* 864 (9th ed. 2009), whereas *in personam* cases seek personal judgments regarding “personal rights and obligations” that bind only the parties. *Black’s Law Dictionary* 807 (8th ed. 2004). IPR petitioners do not seek to hold a patent holder liable or to obtain a personal judgment against him. Rather, they ask the Board to determine the scope of a government-granted monopoly and whether that grant comports with the governing statutes. Given the *in rem* nature of IPRs, sovereign immunity poses no bar to the Board’s taking a “second look” at patents that were previously administratively granted, *Cuozzo*, 136 S. Ct. at 2144, and, as in *Smale*, it does not bar the Board from “continuing” to resolve IPRs over which it unquestionably had jurisdiction at institution. 208 P.3d at 1180.

Previous decisions concluding that IPR proceedings are unlike *in rem* actions do not bind this Board. See *Neochord, Inc. v. Univ. of Md.*, IPR2016-00208, Paper 28, 12-13 (P.T.A.B. May 23, 2017); *Covidien*, Paper 21, 12-15; *Reactive Surfaces Ltd. v. Toyota Motor Corp.*, IPR2016-01914, Paper 36, 7 (P.T.A.B. July 13, 2017). The Board in *Reactive Surfaces* rejected an analogy to *in rem* actions without any discussion or supporting authority, and only “on the present record and arguments.” Paper 36, 7. The *Neochord* and *Covidien* petitioners compared IPRs to *in rem bankruptcy* jurisdiction, and the Board concluded that the “analogy to bankruptcy law is without merit.” *Neochord*, Paper 28, 13; *Covidien*, Paper 21, 15 (“Petitioner’s

reliance on bankruptcy actions . . . is misplaced.”). The Board has never considered similarities between IPR proceedings regarding the boundaries of patent property and real-property actions. Those cases, in which courts continued to exercise *in rem* jurisdiction when an individual transferred real property to a tribe to evade judicial adjudication of property rights, furnish the closest analogy to this one.

**B. Tribal Immunity Does Not Block The Board From Completing Instituted IPRs When A Patent Owner Transfers Its Patents To Avoid An Adverse Decision.**

The Board can and should complete its review of patent claims that it has found reasonably likely to be invalidated, even if tribal immunity applies in an IPR and even if the patent owner transfers its patents to a sovereign entity for the express purpose of preventing a final IPR decision (which is exactly what Allergan and the Tribe have admitted doing, *see* EX. 1145; EX. 1157). The Tribe contends (at 16) that “[t]his case cannot proceed” without its consent. But nothing in the governing statutes or regulations precludes the Board from completing its resolution of an instituted IPR in this situation. Indeed, IPRs may continue even with *no* parties participating. *See* 37 C.F.R. § 42.74(a); *see also* 35 U.S.C. § 317(a) (“If no petitioner remains in the inter partes review, the Office may terminate the review or proceed to a final written decision . . . .”); *accord* *Cuozzo*, 136 S. Ct. at 2144. If an IPR can proceed even when a petitioner and patent owner *jointly decide* to settle, it plainly is not true that an IPR “cannot” proceed simply because a patent owner

unilaterally tries to pay its way out of an IPR by renting tribal immunity.

Furthermore, when determining whether to continue IPRs in light of an absent sovereign patent owner, the Board has sometimes looked for guidance from Federal Rule of Civil Procedure 19(b), which addresses when an action should be dismissed if a person considered necessary to the dispute is unable to be joined.<sup>2</sup> The Rule is expressly premised on “equity and good conscience,” Fed. R. Civ. P. 19(b), and allows courts to consider any “considerations which may be applicable in particular situations,” Fed. R. Civ. P. 19 advisory committee note (1966); *see also Cloverleaf Standardbred Owners Ass’n, Inc. v. Nat’l Bank of Wash.*, 699 F.2d 1274, 1279 n.11 (D.C. Cir. 1983) (“The four enumerated factors [in Rule 19(b)] do not have independent significance; they serve as guides to the overarching ‘equity and good conscience’ determination.”). The Rule focuses on “pragmatic considerations,” and not on “the technical or abstract character of the rights or obligations of the persons whose joinder [is] in question.” *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 635 (1st Cir. 1989) (alteration in original) (citation omitted). It is intended to balance the interests of the parties properly before the court, the absent party that cannot be joined, the courts, *and* the public. *See*

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<sup>2</sup> As is true of IPR proceedings, a court’s inability to include a relevant party in litigation does not “negate the court’s power to adjudicate as between the parties who have been joined.” *See* Fed. R. Civ. P. 19 advisory committee note (1966).

*Provident Tradesmens Bank & Tr. Co. v. Patterson*, 390 U.S. 102, 109-111 (1968).

Considering the interests of the public, the Board, and the parties that must be balanced, and the “pragmatic” consequences of the standard the Tribe advocates, dismissing these IPRs would not in any way advance “equity and good conscience.” To the contrary, allowing a drug company patent owner to force an IPR to halt on the eve of an IPR hearing, by paying tens of millions of dollars to rent tribal immunity, would reward bad-faith behavior. It would also provide other holders of weak but extremely profitable patents with a roadmap for shielding their patents from review while wasting the valuable resources of their competitors and the Board. A rule that has as guideposts “equity” and “good conscience” would not create such incentives or countenance such a result.

The compelling public interest in preventing the abuse of the patent system warrants the Board’s continued jurisdiction over this case. As the National Academy of Sciences, Engineering, and Medicine recognized just this week, “[a]ctions to continually foster greater access to off-patent generic drugs, which are usually much less expensive than branded products, should be taken. One way this could be accomplished would be to prevent the common industry practices that delay entry of generics into the market and extend market exclusivity of branded products.” Nat’l Acad. of Scis., Eng’g, and Med., *Making Medicines Affordable: A National Imperative* 3 (2017), available at <http://bit.ly/2AAxzDn>. Allergan’s

scheme is precisely the type of patent “evergreening” that NAS has stated must be prevented to address the high and rising costs of prescription drugs. *Id.* at 3, 44.

Prior Board decisions involving sovereign state entities are of limited relevance here because none of those cases involved last-minute bad-faith transfers specifically intended to divest the Board of its authority to take a second look at an issued patent—actions that cannot be squared with equity or good conscience. Nevertheless, it is notable that the Board has permitted IPRs to continue in the absence of a sovereign state entity (the Regents of the University of Minnesota) where a remaining party (Toyota) could adequately represent the sovereign’s interest. *See Reactive Surfaces Ltd., LLP v. Toyota Motor Corp.*, No. IPR2016-01914, Paper 36, 11-17 (P.T.A.B. July 13, 2017) (rejecting a bright-line rule that IPRs must be dismissed when one party successfully asserts sovereign immunity). The same is certainly true here. Allergan not only has an enormous financial stake in its product—Restasis<sup>®</sup> is Allergan’s second-largest revenue producer, bringing in nearly \$1.5 billion in 2016 alone, *see* EX.1146; EX. 1155—but it has litigated the validity of its patents since their issuance, including in the Eastern District of Texas litigation, which the Tribe did *not* initially join after the transaction with Allergan.

In sum, there is no statute, rule, or precedent that requires the Board to dismiss instituted IPRs if a patent holder assigns its patents to a sovereign entity to avoid a final IPR decision. To maintain the integrity of the patent system and

discourage the large-scale use of sham patent transfers, the Board can and should continue to exercise its lawful authority to reexamine the challenged claims.

#### **IV. CONCLUSION**

As Judge Bryson concluded in the related Hatch-Waxman case, “sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities.”

*Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at \*3 (E.D. Tex. Oct. 16, 2017). That applies with particular force here, before the Board. Given the volume of patent applications (more than 600,000 in 2015, with the number rising each year, U.S. Patent & Trademark Office, U.S. Patent Statistics Chart Calendar Years 1963-2015, <http://bit.ly/2jCjZ5V>), and the limited number of patent examiners, IPRs and similar post-grant reviews play a vital role in allowing the PTO to ensure accuracy and reliability by taking a second look at patents it issued. The Board can carry out that function notwithstanding the assertion of sovereign immunity by a patent owner, or its eleventh-hour transferee.

The Board should deny the Tribe’s motion to dismiss.

Dated: December 1, 2017

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## CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 1, 2017, a complete and entire copy of this “BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS AMICUS CURIAE IN SUPPORT OF PETITIONERS” was provided, via electronic mail, to Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., Akorn Inc., Allergan, Inc., and the Saint Regis Mohawk Tribe by serving the correspondence e-mail addresses of record as follows:

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