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

United States Court of Appeals for the Federal Circuit

SAINT REGIS MOHAWK TRIBE and ALLERGAN, INC.,
Appellants,

v.

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

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

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

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CERTIFICATE OF INTEREST

Counsel for The Association for Accessible Medicines certifies the following:

1. The full name of every party or amicus represented by me is:

The Association for Accessible Medicines

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All corporations and publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

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

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will 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.)

May 18, 2018
Date

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INTEREST OF AMICUS CURIAE[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing the leading 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, including before the Patent Trial and Appeal Board in this case and in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365 (2018).

AAM's members are frequently IPR petitioners, because the efficiency and speed of IPRs fit the industry's mission of delivering generic alternatives to brand-name pharmaceuticals 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 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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[1] All parties have consented to the filing of this brief. No party's counsel authored the brief in whole or in part, and no person other than amicus, its members, and its counsel contributed money intended to fund the brief's preparation or submission.

SUMMARY OF ARGUMENT

Facing the likely loss of the remaining patents shielding a multi-billion-dollar drug from generic competition, Allergan, Inc. paid millions of dollars to rent the sovereign immunity of the Saint Regis Mohawk Tribe ("Tribe") on the eve of the oral hearings in these IPRs. Allergan and the Tribe claim that tribes and states have engaged in similar commercial enterprises for decades with the Supreme Court's approval, and that the Patent Trial and Appeal Board ("Board") was compelled to dismiss the IPRs based on the Supreme Court's approval of "this economic development model." Appellants' Br. 34. Appellants are wrong on both counts.

The transaction entered into by Allergan and the Tribe is unprecedented. Unlike the tribal economic enterprises of the past—in which tribes have provided goods or services to their members and members of the public by opening gaming venues, operating resorts, or selling retail products—here the Tribe provides nothing except immunity to a pharmaceutical company. The Tribe has provided no goods and no services and made no contribution to developing the invention claimed in the patents, unlike the state research universities to which the Tribe compares itself. Instead, the Tribe simply promises to assert, and never waive, its tribal immunity in patent proceedings—conferring so much economic benefit on its non-sovereign partner corporation that it is willing to pay the Tribe millions of

dollars just to assert immunity.

Allowing *any* non-sovereign company to cloak itself in immunity rented from an Indian tribe, for the admitted purpose of stopping a federal agency from exercising its authority to regulate patents through inter partes review, would be unsupportable under the law. Allowing *this* type of company to do so would harm not only the patent system but the health care system as well. When invalid pharmaceutical patents remain on the books, affordable generic and biosimilar medicines are often kept off the shelves, and drug prices are kept up at monopoly levels. Inter partes review is one key mechanism to ensure that the statutory limits on patentability are enforced—and that invalid patents are cleared away from the path of generic competition.

Despite Appellants' arguments that well-settled authority required the Board to dismiss these IPRs, the Board is anything but hamstrung from exercising its regulatory 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.'" *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) (quoting *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016)).

First, IPRs do not offend the dignity of tribes. All patent owners (including sovereign ones) take patents subject to the qualification that the PTO may

reconsider them through IPR proceedings. Furthermore, IPRs 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). IPRs instead simply permit a federal agency to "institute[s] its own administrative proceeding" to take a second look at a patent it issued, which does not implicate sovereign immunity. *Id.* at 768.

Second, even if sovereign immunity applied in IPRs, the Board need not dismiss instituted IPRs simply because a non-sovereign IPR respondent transfers its patents to a sovereign entity for the express purpose of preventing a final IPR decision.

This Court should affirm the Board's decision and allow the Board to finish the work it started when it found a "reasonable likelihood" that the challenged claims are invalid.

ARGUMENT

I. Allowing Appellants' Unprecedented Transaction To Block IPRs Would Prop Up Drug Prices and Harm the U.S. Health Care System.

Appellants contend that their transaction simply follows the economic partnerships that courts have approved of for decades and likewise should not be greeted with skepticism. Appellants' Br. 31, 34. But the monetization of tribal immunity here would deal an extraordinary blow not only to the U.S. patent system, but to the health care system as well. The considerations of tribal

"economic development" that Appellants advance do not justify that impact; indeed, the arrangement between Allergan and the Tribe does not even resemble past partnerships between sovereigns and private industries.

A. This Sham Transaction, If Permitted to Block IPR Proceedings, Will Undermine the U.S. Patent System and Have Serious Repercussions on the U.S. Health Care System.

Allergan's immunity-renting transaction with the Tribe is the first of its kind, but if the gambit succeeds, it is sure not to be the last. The owners of non-innovative, competition-blocking patents have every reason to seek out—and pay handsomely for—immunity from inter partes review. Appellants contend that those who seek to challenge invalid patents should be satisfied with litigation in federal district court. Appellants' Br. 57-58. That argument ignores that administrative review and patent litigation serve two different but equally vital functions, and Congress decided to make *both* systems available. It also obscures the impact that these transactions will have on district-court proceedings.

1. The PTO's ability to review its own prior patentability decisions after issuance is a vital component of a healthy patent system. Congress has barred the issuance of patents on purported inventions that are not truly novel, or are just obvious variations on existing knowledge. But a patent examination process does not always uncover all the flaws in a patent application, especially when the examiners come under regular pressure to avoid undue delay in patent issuance.

That is why Congress adopted inter partes review and similar mechanisms for post-grant reconsideration of patents' validity.

The incredible volume of patent applications (more than 600,000 in 2015, with the number rising each year[2]) and limited staffing at the PTO leave patent examiners constrained in their ability to accurately and comprehensively assess patentability. And the patent examination process is an interaction between the patent applicant and the PTO with little (if any) opportunity for third parties to provide evidence or arguments relevant to patentability. Indeed, researchers have found that patent examiners spend an average of just nineteen hours on each patent application, which includes the time spent reading the application, searching for prior art that would render the proposed patent invalid, interviewing the applicant's counsel, responding to the applicant's arguments, and rendering a decision.[3]

These issues are only exacerbated by the nature of patent practices and inventions today, particularly in the pharmaceutical context, with companies seeking dozens of patents and claims covering a single brand-name drug and using second-, third-, and even fourth-generation patents to extend a monopoly. *See, e.g.*, Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to*

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[2] *U.S. Patent Statistics Chart Calendar Years 1963-2015*, U.S. Patent & Trademark Office, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

[3] Melissa D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat'l Bureau of Econ. Research (July 2014), http://www.nber.org/papers/w20337.pdf.

Delay Generic Versions, N.Y. Times, July 15, 2016, https://nyti.ms/2kUxW18 (noting that the manufacturer of Humira "amassed more than 70 newer patents, mostly in the last three years, covering formulations of the drug, manufacturing methods and use for specific diseases").

Pharmaceutical patent owners have incredibly powerful incentives to seek and obtain as many patents as possible, even dubious ones: each new patent can extend the life of an existing monopoly, and even a weak patent can be a powerful deterrent to competition. Indeed, that is exactly what Allergan did here. Allergan knew that the previous patents protecting its Restasis monopoly would expire in May 2014, so in late 2013 and early 2014, Allergan obtained six new patents that, if valid, would have provided Allergan with ten more years of patent exclusivity. *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4803941, at *10-11 (E.D. Tex. Oct. 16, 2017), *appeal pending*, No. 18-1130 (Fed. Cir.). These patents attempted to claim essentially the same formulation and methods of treatment Allergan had previously claimed, with a bit more detail about the proportions of ingredients. *Id.* at *10.

Given these circumstances, it is no surprise that patent applicants are frequently able to obtain weak, non-innovative patents that should never have been issued to begin with, and it is precisely why IPR proceedings are properly understood, as the Supreme Court said in *Oil States*, as part of the "regulation" of

patent rights. 138 S. Ct. at 1375.

For more than 40 years (even before the creation of the modern generic drug approval process in the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetics Act, *see infra* pp. 10-11), the PTO has had some ability to reconsider and cancel patents that never should have issued, but the initial administrative-review processes created by Congress suffered from structural deficiencies that hampered the PTO's ability to weed out bad patents. Thus, Congress reformed the system for re-examining issued patents as part of the Leahy-Smith America Invents Act (AIA) enacted in 2011.[4] The AIA created new procedures, including inter partes review and other forms of post-grant review, "to ensure that the poor-quality patents can be weeded out through administrative review rather than costly litigation" to "improve patent quality and limit unnecessary and counterproductive litigation costs."[5] These new procedures gave third parties a greater opportunity to interact with and present evidence to the Board (which is now the first-line adjudicator), as well as limited discovery, and it simultaneously gave patent owners an opportunity to amend their patents during IPR proceedings. *Oil States*, 138 S. Ct. at 1371.

To ensure the efficiency of IPRs and other post-grant reviews, the AIA

[4] H.R. Rep. No. 112-98, at 39 (2011).
[5] 157 Cong. Rec. S5409 (daily ed. Sept. 8, 2011) (Sen. Schumer); 157 Cong. Rec. S1348 (daily ed. Mar. 8, 2011) (Sen. Leahy).

placed strict time limitations on Board decisions—no more one year to resolve an instituted IPR absent good cause to extend that deadline by no more than six additional months.[6] These time limits ensure that decisions are reached quickly and relatively cheaply, compared with the years of effort and millions of dollars it often takes to resolve patent litigation in federal court. The AIA also established a sufficiently high threshold for instituting an IPR to "weed out marginal challenges" and to "prevent abuse of these proceedings for purposes of harassment or delay."[7]

Sham transactions like Allergan's threaten to undo Congress's valuable reform of the patent system. Inter partes review is not simply an alternative venue for patent litigation; it serves a distinct and crucial role in a healthy patent system. If brand-name drug manufacturers can make themselves invulnerable to IPRs simply by paying a tribe a small fraction of the amount they receive in revenues each year, the cost of eliminating flawed patents from our patent system will skyrocket once again. And if flawed patents are harder to eliminate, companies will have greater incentives to pursue non-innovative patents as a means of improperly extending pharmaceutical monopolies. Low-quality patents will once again be roadblocks to innovation and competition, and those who will suffer most are patients who rely on innovation and competition to deliver more affordable

[6] 35 U.S.C. § 316(a)(11).
[7] 157 Cong. Reg. S1041 (daily ed. Mar. 1, 2011) (Sen. Kyl); 157 Cong. Rec. S1374 (daily ed. Mar. 8, 2011) (Sen. Kyl).

medicines.

2. Appellants contend that this Court should be unconcerned about the kneecapping of PTO review through this type of sham transaction, because federal district court litigation will remain available as an alternative. Appellants' Br. 31, 57-57. Those soothing assurances are mistaken. Tribal immunity could have a profound impact on district court proceedings as well, particularly in pharmaceutical patent litigation.

Under Hatch-Waxman, Congress created a pathway for faster approval of generic drugs that promotes prompt litigation between brand-name and generic drug manufacturers. If a generic manufacturer applies to market a drug covered by patents listed in the "Orange Book" and the brand-name manufacturer does not sue within 45 days, the generic manufacturer can obtain "patent certainty" by bringing a civil action for a declaratory judgment that the brand company's patents are invalid or not infringed. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5). Generic drug applicants that are sued on some patents but not others can also file a counterclaim to litigate the validity of the additional patents.

If brand-name manufacturers can shield themselves from generic applicants' declaratory-judgment actions by renting tribal immunity, they can effectively delay generic drug launch by holding some of their patents in reserve and waiting until after FDA approval of a generic to file or threaten suit. Generic drug applicants

are typically reluctant to launch their products "at risk"—that is, without "patent certainty" that the brand-name manufacturer's patents are not infringed or are invalid—because the damages sought for infringement following an "at risk launch" are potentially quite significant, and often greater than the profits that the generic applicant could hope to earn. Thus, even the threat of a lawsuit can have a chilling effect on generic drug manufacturers, which is exactly why Hatch-Waxman allows a potential infringer to file for declaratory relief—and why, without that option available due to sovereign immunity, the possibility of agency reconsideration through IPRs is all the more vital. For a blockbuster drug like Restasis, which brought in an average of $4 million *per day* in 2016, the prospect of delaying (if not preventing) launch is worth the relatively marginal cost of renting tribal immunity.

If transactions like Allergan's are upheld, tribal immunity could also preclude generic drug companies from asserting invalidity counterclaims to challenge patents covering brand-name drugs even when tribes *sue them* for infringement.[8] And while generic drug defendants could defend their own alleged infringement by arguing that any asserted claims are invalid, brand-name manufacturers have historically attempted to keep multiple and late-listed patents

[8] *See Okla. Tax Comm'n v. Citizen Band Potawatomi Indian Tribe*, 498 U.S. 505, 509 (1991) ("[A] tribe does not waive its sovereign immunity from actions that could not otherwise be brought against it merely because those actions were pleaded in a counterclaim to an action filed by the tribe.").

in reserve, unasserted until the last minute, to discourage generics from launching. With tribal immunity potentially blocking counterclaims challenging unasserted patent claims, and generic manufacturers' reticence to launch products at risk, brand-name drug companies can again delay generic drug launch for the cost of renting tribal immunity—minimal compared to the profits at stake.

3. If Allergan's patent gamesmanship is permitted, the impact on the U.S. health care industry would be profound. IPRs and Hatch-Waxman litigation have played a crucial role in challenging weak patents and ensuring that generic pharmaceuticals get to the market more quickly. With patients taking brand-name drugs at brand-name drug prices paying upwards of five times the cost of a generic alternative, the impact cannot be overstated. *See Generic Drug Facts*, U.S. Food & Drug Admin., https://bit.ly/2tNB8ni (last updated Oct. 6, 2017) ("[G]eneric drugs saved the U.S. health care system $1.67 trillion from 2007 to 2016."). Tribal entities certainty have the power to engage in economic development activities to ensure the well-being of their members. But they do not, and should not, have the power to disrupt the U.S. patent system and pharmaceutical market by renting their immunity to non-sovereign patent holders attempting to shield their weak patents from review.

B. The Tribe's "Economic Development Model" Is Unprecedented.

Appellants contend that the Tribe is simply engaging in economic activities

to improve the economic condition of its members, as states and tribes have done for years, and that the Supreme Court has approved of "this economic development model" by recognizing that tribal immunity applies to commercial enterprises. Appellants' Br. 16, 34. But that is not what this case is about. While existing Supreme Court precedent allows the Tribe to invoke its immunity to protect its *own* commercial activities, that does not mean that the Tribe may *rent out* its immunity to protect *someone else's* business—and certainly not to protect its partner's business from the federal government's enforcement of federal law.

Moreover, the agreement between Allergan and the Tribe is not at all similar to the commercial activities discussed in Appellants' brief (involving on-reservation or off-reservation, tribe-owned and tribe-run business establishments, *see, e.g.*, *California v. Cabazon Band of Mission Indians*, 480 U.S. 202 (1987) (holding that *states* cannot force on-reservation gaming clubs to comply with gaming ordinances)), or the types of "economic development model[s]" the Supreme Court has approved. When a tribe opens a gaming establishment, sells cigarettes, or operates hotels and resorts, itself or in partnership with non-tribal entities, it is providing goods, services, or entertainment venues for its members or the public at large. *See Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2037 (2014) (describing tribal business ventures); *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 758 (1998) ("Tribal enterprises now include ski resorts,

gambling, and sales of cigarettes to non-Indians.").[9]

Here, however, the Tribe's "economic enterprise" is a fiction—the Tribe engages in no technological innovation, and it provides no goods or services to its members or the public. Indeed, though Appellants characterize this scheme (at 5) as merely "investing in innovative businesses and various enterprises," the Tribe has made no investment whatsoever in the blockbuster prescription drug whose manufacturer it is shielding. Instead, the investment all goes the other way—from a corporation holding patents on a multi-billion drug *to* the Tribe. The Tribe simply accepts money in exchange for trying to block the PTO from exercising the review authority it reserved when it granted the patents. Thus, this "enterprise" bears no similarity to the "economic development model" that the Supreme Court has approved or that tribes have long engaged in. And there is no inconsistency between Supreme Court precedent condoning immunity from liability for economic enterprises and a decision in this case prohibiting tribes from monetizing immunity to harm public rights and undermine the patent system.

Appellants are similarly incorrect that the Tribe's purported "economic development model" here is similar to the technology initiatives of state universities, as the Tribe has repeatedly suggested. Appellants' Br. 5; *Tribe*

[9] Notably, the tribe is not immune from regulation when it engages in off-reservation business ventures. *Kiowa*, 523 U.S. at 755. And that is precisely how the Supreme Court described IPRs in *Oil States*—as a form of federal "regulation." 138 S. Ct. at 1375.

Provides Clarification on Allergan Agreement, Saint Regis Mohawk Tribe, Sept. 14, 2017, https://bit.ly/2IcAlyR (stating that the Tribe used the same business model and legal arguments employed by public universities, which engage in technological innovation and license intellectual property to corporations and start-ups). But Appellants have not pointed to a single state university that has accepted a sham transfer of property from a private business patent owner to avoid inter partes review, much less one that did so to *shut down* inter partes review on the eve of the final hearing. Unlike the Tribe, universities actually engage in research and innovation, for which they seek and obtain their own patents. And if there were any question about whether the Tribe's transaction is typical, one need only look at the flow of money—from the assignor (Allergan) to the assignee (the Tribe, which received the patent portfolio covering a multi-billion-dollar product without having to pay a dime or do anything except refrain from waiving immunity).

In short, no economic-development precedent justifies this wholly *unprecedented* arrangement. Invalid patents are subject to cancellation, and that is no less true if the pharmaceutical patent owner agrees to share a sliver of the profits with an Indian Tribe in exchange for the rental of sovereign immunity.

II. Tribal Immunity Provides No Bar to Inter Partes Review.

The "primary function" of immunizing sovereigns from being required to answer private complaints in judicial proceedings is to afford them "the dignity

and respect due sovereign entities." *FMC*, 535 U.S. at 769; *cf. Republic of Philippines v. Pimentel*, 553 U.S. 851, 866 (2008) (foreign sovereign immunity derives from "respect for the power and dignity of the foreign sovereign" (quotation marks omitted)). At the same time, 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).

The issuance of a patent is itself an exercise of the United States' exclusive sovereign power. And in the pharmaceutical context at issue here, the Hatch-Waxman Amendments pair that power with the sovereign power to regulate interstate commerce, in allowing Orange Book-listed patents to be the basis for keeping generic pharmaceuticals off the market. But Congress has placed limitations on the Executive Branch's exercise of that power: relevant here, a patent "may not be obtained" if the claims are obvious. 35 U.S.C. § 103. An IPR simply conforms the exercise of sovereign power to the statutory limits written by Congress.

Appellants insist that the Board simply "failed to follow" the well-settled principle that tribes cannot be "subject to suit" absent congressional authorization or waiver. Appellants' Br. 15. That wrongly assumes the conclusion—that an IPR is a private "suit." Under the Supreme Court's decisions, however, an IPR is *not* a

private suit in an administrative tribunal as was the case in *FMC*. Instead, IPRs are properly understood as the federal government's exercise of its administrative power to review the propriety of patent grants, which does not offend the dignity and respect owed to tribes.

A. All Patent Owners, Regardless of Immunity, Take Patents Subject to the Qualification That the PTO May Reconsider Them.

The Supreme Court recently held in *Oil States* that the grant of a patent does not confer an absolute property right upon a patentee. Instead, all "[p]atent claims are granted subject to the qualification that the PTO has the authority to reexamine—and perhaps cancel—a patent claim in an inter partes review." 138 S. Ct. at 1374 (quotation marks omitted). Thus, when a tribe takes a patent (either as the original patent owner or as an assignee), it does so subject to the expectation that the federal government has "reserved the PTO's authority" to reconsider its early grant of the patent, which is exactly what the Board did here by making the discretionary, unreviewable decision to institute IPR proceedings. *Id.* at 1373.

A sovereign's dignity cannot be offended by the inability to keep that which it never had—an unqualified and irrevocable public patent franchise. Because tribes who take a patent do not receive an unqualified private right to a monopoly, the PTO's decision to institute a proceeding to correct its own error pursuant to its reserved right to do so does not implicate sovereign immunity.

B. Tribal Immunity Does Not Allow Patent Owners To Resist the Government's Exercise of Sovereign Power To Reconsider Invalid Patents.

Tribal sovereignty "does not extend to preventing the federal government from exercising its superior sovereign powers." *Yakima*, 806 F.2d at 861 (citation omitted).[10] As the Supreme Court has explained, IPRs are one of the ways the federal exercises its superior sovereign power to grant and "regulat[e]" patents. *Oil States*, 138 S. Ct. at 1375. Tribes suffer no harm to their sovereign dignity when the government corrects its own error by cancelling a patent that, by law, never should have issued.

Appellants are correct that *FMC* sets forth the governing framework for determining whether an administrative proceeding involves an agency's resolution of a dispute between private parties, in which case sovereign immunity applies, or whether it involves the federal government's exercise of its own sovereign authority, in which case immunity does not apply. But Appellants misinterpret *FMC* and, in the process, ignore the Supreme Court's detailed analysis of the nature of IPR proceedings—not only in the recent *Oil States* decision, but also in *Cuozzo*, which Appellants fail to cite even once. Properly understood, *FMC*

[10] *See, e.g., e.g., Pauma v. NLRB*, __ F.3d __, 2018 WL 1955043, at *8 (9th Cir. Apr. 26, 2018) (federal government can enforce NLRA against tribe); *Reich v. Mashantucket Sand & Gravel*, 95 F.3d 174, 182 (2d Cir. 1996) (federal government can enforce OSHA against tribe).

underscores why sovereign immunity does not allow the Tribe to block the PTO's exercise of its reserved authority to reconsider its earlier grant of a patent.

The agency here plays a different decisionmaking role than the adjudicator did in *FMC*. The agency's sole function in that case was to referee a private dispute in which one party claimed that the other had violated federal law and demanded a private remedy (damages and injunctive relief). 535 U.S. at 764. The Supreme Court emphasized that the agency "d[id] not even have the discretion to refuse to adjudicate complaints brought by private parties." *Id.* Instead, the agency simply provided an alternative forum for one private party to seek to hold another party liable for violating federal law, with effectively the same procedures as are used in federal court (where sovereign immunity would apply). *Id.* at 760-761. The Court therefore concluded that the agency was in substance no different from a court, and immunity no less applicable there. But, the Court made clear, the agency was free to "institute" its own proceeding against a sovereign entity, even if that action was based on "information supplied by a private party." *Id.* at 768.

That distinction is crucial here, because the Board does *not* simply act as an adjudicator of a private dispute. In IPRs, 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. Indeed, the Court said in *Oil States* that inter partes review involves the same exercise of power as the initial

granting of a patent; the "primary distinction" is simply one of timing—"inter partes review occurs *after* the patent has issued." 138 S. Ct. at 1374. Inter partes review is not a private dispute, which is why anyone may file a petition. *Id.* at 1371 (citing 35 U.S.C. § 311(a)). There is no determination of liability, there are no remedies available against a patent owner that obtained an invalid patent, and the judgment does not dictate what a patent owner can or cannot do—it simply cancels any claims determined to be unpatentable and confirms claims determined to be patentable. *Id.* at 1372.

Furthermore, while appellants repeatedly suggest (at 22, 25, 26) that a private party has the power to institute IPRs, which the Court found important in *FMC*, precisely the opposite is true. While "any third party can *ask* the agency to initiate inter partes review of a patent claim," *Cuozzo*, 136 S. Ct. at 2137 (emphasis added), the agency has discretion to say no, *id.* at 2140. Indeed, the Court described the initiation decision in *Cuozzo* as unreviewable because it is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2), *cited in Cuozzo*, 136 S. Ct. at 2140. The petitioners' role in requesting that the agency institute an IPR does not change the nature of the IPR itself; as the Court said in *FMC*, an agency may sometimes "institute its own administrative proceeding . . . *upon information supplied by a private party*." 535 U.S. at 768 (emphasis added).

Indeed, once the agency has decided to institute an IPR, it may "continue to

conduct an inter partes review" and reach a final decision even if the patent owner and petitioners reach a settlement. *Cuozzo*, 136 S. Ct. at 2144. The Director can also intervene in a later *judicial* proceeding to defend the agency's decision—even if the private challengers drop out. *See id.*. 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 conduct irrespective of sovereign immunity. *FMC*, 535 U.S. at 768.

Appellants attempt to zoom out to the broadest possible level of generality and insist that IPRs are "adjudicatory." Appellants' Br. 1, 9, 13, 19, 20, 22, 24. That is not the test. Federal agencies that enforce sovereign federal power against tribes (*see* note 10, *supra*) routinely do so through agency adjudication. *See*, *e.g.*, *Martin v. OSHRC*, 499 U.S. 144, 147-148, 151 (1991). The difference is that these proceedings do not adjudicate *private disputes*.

The Supreme Court has already rejected the argument that IPRs are "a 'surrogate' for court proceedings," holding that the "basic purpose[]" of an IPR—"to reexamine an earlier agency decision"—is different from the purpose of district court litigation. *Cuozzo*, 136 S. Ct. at 2143-2144. Indeed, IPR proceedings even allow a patent owner to move to narrow or amend his claims—"just [as] he would do in the examination process," and which he could not do in federal court. *Id.* at 2145.

Appellants emphasize that IPRs have certain procedural similarities to civil litigation, such as discovery, but the *procedures* are not what makes sovereign immunity attach.[11] After all, Appellants do not dispute that tribes can be compelled to produce documents, provide witnesses, and engage in motion practice in government enforcement actions, including before agencies, to which sovereign immunity serves as no barrier. And despite some "adjudicatory characteristics," IPRs are "less like a judicial proceeding and more like a specialized agency proceeding." *Cuozzo*, 136 S. Ct. at 2143.

In sum, unlike the "court-like administrative tribunals" in *FMC*, the America Invents Act did not, in creating IPRs, effect "a broad delegation to private persons to sue nonconsenting [sovereigns]," 535 U.S. at 764 (quotation marks omitted), and the Board is not simply an agency forum for a private dispute. The mechanism Congress created for the PTO to reconsider its own prior decisions poses no affront to sovereignty.

III. Tribal Immunity Does Not Block the Board from Completing Instituted IPRs When a Patent Owner Transfers Its Patents to Avoid an Adverse Decision.

Even if tribal immunity could block an IPR proceeding, the Board can and should still be permitted to complete its review of patent claims when a patent

[11] Moreover, the Tribe never experienced any such procedural attribute of IPRs: discovery was conducted entirely by the non-sovereign patent owner, Allergan, and were already over by the time the Tribe appeared. The Tribe identifies no precedent for finding a *present* affront to sovereignty based on *past* proceedings.

owner transfers its patents to a sovereign entity *during* IPR proceedings for the express purpose of preventing a final IPR decision.

Nothing in the America Invents Act or the PTO's rules or regulations precludes the Board from resolving instituted IPRs in this situation, just as the inability to include a relevant party in litigation does not negate a federal court's authority to adjudicate disputes between the parties who have been joined.[12] Indeed, if an IPR can proceed even when a petitioner and patent owner *jointly decide* to settle, *see* 37 C.F.R. § 42.74(a), it plainly is not the case that an IPR cannot proceed simply because a patent owner unilaterally tries to pay its way out of an IPR by renting tribal immunity.

Appellants rely on Federal Rule of Civil Procedure 19(b), which the Board has sometimes consulted for guidance. *See, e.g.*, *Reactive Surfaces Ltd., LLP v. Toyota Motor Corp.*, No. IPR2016-01914, 2017 WL 2992429, at *6 (PTAB July 13, 2017) (holding that IPR could continue despite a sovereign patent owner). But Rule 19(b) *supports* the Board's decision, not undermines it.

Appellants suggest (at 53-54) that when a tribe is immune from suit but would otherwise need to be joined, then dismissal is effectively automatic because of the "tribe's sovereign interest in its government authority, its property, or in a contract." Appellants call this the "weighted sovereignty test," Appellants' Br. 54,

[12] *See* Fed. R. Civ. P. 19 advisory committee note (1966).

a term that Appellants appear to have coined themselves. This assertion is misguided for several reasons. First, as *Oil States* made clear, patent holders do not have an absolute interest in patents they obtain from the PTO; rather, they take a patent *subject to the express qualification* that the PTO may reconsider it. 138 S. Ct. at 1374. Allergan could not have conferred upon the Tribe anything more than Allergan itself received—the grant of a patent that was subject to reconsideration by the PTO. Thus, the Tribe has no right to an unqualified sovereign property interest that must be protected by Rule 19.

Second, the Supreme Court has rejected arguments that sovereign status (or any other single factor) has dispositive effect, recognizing that a Rule 19 analysis requires a flexible approach and that "whether to proceed will turn upon factors that are case specific, which is consistent with a Rule based on equitable considerations." *Pimentel*, 553 U.S. at 863. Indeed, in *Pimentel*—a decision with which Appellants argue (at 52) the Board's decision "conflicts"—although the Court held that a sovereign foreign nation was an indispensable party, it undertook a full Rule 19(b) analysis and acknowledged that "the balance of equities may change in due course" even as to that nation. 553 U.S. at 873. Likewise, in *A123 Systems, Inc. v. Hydro-Quebec*, 626 F.3d 1213 (Fed. Cir. 2010), which Appellants argue (at 55) the Board "failed to follow," this Court made clear that sovereign status is not a silver bullet to dismissal. Instead, it acknowledged that it must give

"sufficient weight" to the prejudice of proceeding without a necessary sovereign party, just as it must give weight to the prejudice of any necessary but unjoinable party. *Id.* at 1221. But that was simply one aspect of the Court's multi-factor analysis, and at no time did this Court suggest that sovereign status demands dismissal. *Id.*

Furthermore, while Appellants point to *some* cases in which courts dismissed actions in light of a necessary sovereign party that could not be joined, *see* Appellants' Br. 54; *but see* Appellees' Br. 51-53 (rebutting those cases), those decisions 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.

Third, 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, absent parties that cannot be joined, the courts, *and* the public. *See Provident Tradesmens Bank & Tr. Co. v. Patterson*, 390 U.S. 102, 109-111 (1968). This is because whether to proceed with an action in which some parties cannot be joined "has consequences for the persons and entities affected by the judgment; for the judicial system and its interest in the integrity of its processes and the respect accorded to its decrees; and for society and its concern for the fair and prompt resolution of disputes." *Pimentel*, 553 U.S. at 863.

Considering the interests of the public, the Board, and the parties that must be balanced, requiring dismissal of these IPRs would advance "equity and good conscience." To the contrary, allowing a pharmaceutical patent owner to halt an IPR on the eve of a hearing, simply by opening its deep pockets to rent the immunity of a tribe, 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 Board's valuable resources. A rule that has as guideposts in "equity" and "good conscience" would not create such incentives or countenance such a result, and allowing a sham transfer to frustrate review at the last minute would implicate exactly the types of consequences "for the judicial system and its interest in the integrity of its processes" the Court recognized in

Pimentel.

The compelling public interest in preventing the abuse of the patent system warrants the Board's completion of its review. As the National Academy of Sciences recognized recently, "[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 must be prevented to address the high and rising costs of prescription drugs. *Id.* at 3, 44.

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 to forestall the large-scale use of sham patent transfers that would delay patient access to more affordable medicines, the Board can and should be permitted to continue to exercise its lawful authority to reexamine the challenged claims.

CONCLUSION

The Court should affirm the Board's decision that tribal sovereign immunity poses no bar to inter partes review, and should promptly permit the Board to resume its consideration of Allergan's patents.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the length limitation set forth in Fed. R. App. P. 29(a)(5) because this brief contains **6,499** words, excluding those parts of the brief exempted by Fed. R. App. P. 32(a)(7)(f) and Fed. Cir. R. 32(b). I further certify that the brief complies with the typeface requirements of Fed. R. App. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface, 14-point Times New Roman, using Microsoft Word.

Dated: May 18, 2018

/s/ William M. Jay
William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2018, I electronically filed the foregoing document using the Court's CM/ECF system, which will send notice of such filing to counsel for all parties.

/s/ William M. Jay
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