Paper No. __
Filed: December 1, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
TEVA PHARMACEUTICALS USA, INC., and AKORN INC.,[1]
Petitioners,

v.

SAINT REGIS MOHAWK TRIBE,
Patent Owner.

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

BRIEF OF THE HIGH TECH INVENTORS ALLIANCE, COMPUTER & COMMUNICATIONS INDUSTRY ASSOCIATION, AND INTERNET ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

[1] 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. The word-for-word identical paper is filed in each proceeding identified in the caption pursuant to the Board's Scheduling Order (Paper 10).

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INTEREST OF *AMICI CURIAE*

The High Tech Inventors Alliance ("HTIA") is dedicated to advancing a patent system that promotes and protects real investments in technologies and American jobs. Collectively, HTIA's members employ nearly 500,000 U.S. employees, spent $63 billion last year alone on research and development, hold more than 115,000 U.S. patents, and have a market capitalization of more than $2 trillion. The Computer & Communications Industry Association ("CCIA") is dedicated to innovation and enhancing society's access to information and communications. CCIA's 29 members engage in research, development, and sale of high-technology products and services, and are both patentees and defendants in patent litigation. The Internet Association represents the interests of leading Internet companies and their customers, seeking to protect Internet freedom, promote innovation and economic growth, and empower customers and users.[2]

INTRODUCTION AND SUMMARY

This case concerns the drugmaker Allergan's arrangement with the St. Regis Mohawk Tribe to shield Allergan's questionable patents on the dry-eye treatment Restasis from inter partes review by the Patent Office. A week before the patents

[2] HTIA is a nonprofit corporation whose members are Adobe Systems, Inc.; Amazon.com, Inc.; Cisco Systems, Inc.; Dell Inc.; Google LLC; Intel Corporation; Oracle Corporation; and salesforce.com, inc. Current lists of CCIA's and the Internet Association's members are available at https://www.ccianet.org/members and https://internetassociation.org/our-members/.

were due to be reviewed, Allergan transferred them to the Tribe so that the Tribe could assert tribal sovereign immunity to frustrate this proceeding. The Panel should not allow Allergan to circumvent the review process in this way.

Tribes are domestic dependent nations whose sovereignty gives them immunity from lawsuits by states or third parties, but not from the United States when it is enforcing laws of general applicability. Tribal immunity therefore does not bar inter partes review – a discretionary procedure through which the Patent Office enforces the generally applicable statutory requirements for any patent to be valid. Although private petitioners participate in inter partes review and help the Patent Office make decisions, they cannot compel the Patent Office to conduct a review and their ongoing participation is unnecessary to complete one. An agency's review of its own actions (here, issuing patents) is fundamentally unlike a judicial case where private parties assert rights and seek remedies. And the Patent Office's review is lawful as a congressionally imposed condition on the grant of a patent. Everyone who applies for a patent knows that the Patent Office may (and sometimes does) later reconsider its decision to grant that privilege.

Inter partes review is fully compatible with tribal immunity also because – to the limited extent that review resembles any judicial proceeding – it is similar to a proceeding *in rem*, such as bankruptcy proceedings or certain maritime cases. Sovereign immunity does not bar *in rem* proceedings because they concern not the

competing rights and obligations of particular adverse parties, but the status of an item or estate (here, a patent) whose owner can assert claims against the entire world. Accordingly, this Panel's statutory authority to review whether the Restasis patents were properly granted as a matter of federal law does not and should not depend on the identity of the patent's owner.

ARGUMENT

I. Tribal Sovereign Immunity Cannot Bar Inter Partes Review.

A. Tribes Are Not Immune from Federal Enforcement Proceedings or Exempt from Generally Applicable Federal Laws.

Indian tribes have been recognized for nearly two centuries as "domestic dependent nations" that are "under the sovereignty and dominion of the United States." *Cherokee Nation v. Georgia*, 30 U.S. (5 Pet.) 1, 17 (1831) (Marshall, C.J.). They retain "many of the attributes of sovereignty," primarily "the rights which belong to self government." *Worcester v. Georgia*, 31 U.S. (6 Pet.) 515, 580 (1832) (Marshall, C.J.). Their powers include "'regulating their internal and social relations'" and making and enforcing "their own substantive law in internal matters." *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 55 (1978) (quoting *United States v. Kagama*, 118 U.S. 375, 381-82 (1886)). Tribes do not, however, retain aspects of sovereignty "inconsistent with the overriding interests of the National Government.'" *Washington v. Confederated Tribes*, 447 U.S. 134, 153 (1980).

These principles define the contours of tribal immunity and a tribe's duty to follow federal law. Indian tribes are immune from many suits brought by states and by private parties. *See Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024 (2014) (immunity barred state's suit to enjoin casino operation outside reservation); *Kiowa Tribe of Okla. v. Manufacturing Techs., Inc.*, 523 U.S. 751 (1998) (immunity barred private suit on promissory note). A tribe may not, however, "interpose its sovereign immunity against the United States." *United States v. Red Lake Band of Chippewa Indians*, 827 F.2d 380, 382 (8th Cir. 1987); *see also Reich v. Mashantucket Sand & Gravel*, 95 F.3d 174, 182 (2d Cir. 1996) ("Tribal sovereign immunity does not bar suits by the United States.").

Further, tribes and their members must comply with federal statutes of general applicability. *See Federal Power Comm'n v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960) (declaring it "well settled" that "a general statute in terms applying to all persons includes Indians and their property interests"). There are narrow exceptions to this general rule, such as when a statute would encroach on a tribe's internal affairs or implicate matters of traditional sovereign concern (for example, treaty rights). *See, e.g.*, *Donovan v. Coeur d'Alene Tribal Farm*, 751 F.2d 1113, 1116 (9th Cir. 1985) (federal statutes of general applicability apply to tribes unless they touch on "exclusive rights of self-governance in purely intramural matters," abrogate treaty rights, or evince proof that Congress intended

the law not to apply on reservations). Where, however, tribes engage in commercial activity unrelated to internal tribal governance, the federal government may enforce generally applicable federal statutes and reject tribal immunity defenses. *See, e.g.*, *NLRB v. Little River Band of Ottawa Indians Tribal Gov't*, 788 F.3d 537, 555 (6th Cir. 2015) (holding tribe subject to NLRB enforcement of federal labor statute), *cert. denied*, 136 S. Ct. 2508 (2016).[3]

B. Tribes Are Not Immune from the Federal Government's Discretionary Review of Patent Validity.

An inter partes review proceeding is not barred by tribal immunity or sovereignty because inter partes review is a discretionary administrative procedure in which the federal government (through the Patent Office and this Board) is enforcing federal law, rather than adjudicating grievances of private parties; and because the laws being enforced apply generally to all patent owners (including tribes) as conditions of a statutory grant.

[3] *See also San Manuel Indian Bingo & Casino v. NLRB*, 475 F.3d 1306, 1315 (D.C. Cir. 2007) (upholding application of the NLRA to tribally owned casino because it "does not impinge on the Tribe's sovereignty" with respect to "a traditional attribute of self-government"); *Reich*, 95 F.3d at 180 (upholding application of OSHA to tribally owned construction business whose "activities are of a commercial and service character"); *Menominee Tribal Enters. v. Solis*, 601 F.3d 669, 670-71 (7th Cir. 2010) (holding that "[s]tatutes of general applicability that do not mention Indians are nevertheless usually held to apply to them" if they do not "interfere with tribal governance" or infringe treaty rights, and applying OSHA to tribally owned sawmill).

1. Inter Partes Review Is a Proceeding in the Sole Discretion of the Patent Office To Enforce the Novelty and Nonobviousness Requirements of the Patent Act.

Speaking for the Director of the Patent Office, the Solicitor General recently described inter partes review as a procedure the federal government uses to "protect the public interest in the integrity of existing patents" by ensuring their validity. Br. for Federal Resp't at 25, *Oil States Energy Servs., Inc. v. Greene's Energy Grp., LLC*, No. 16-712 (U.S. filed Oct. 23, 2017) ("*Oil States* Br."). The public has a "paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). The limits on patent scope have "constitutional underpinnings," *Oil States* Br. 19, because Congress's Article I power to grant patents is tethered to "promot[ing] the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries," U.S. Const. art. I, § 8, cl. 8. The Patent Office's ongoing review of patents ensures they meet the statutory, constitutionally informed standards of novelty and utility. Inter partes review is thus "less like a judicial proceeding and more like a specialized agency proceeding" in which third parties that petition for review "need not have a concrete stake in the outcome; indeed, they may lack constitutional standing." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2143-44 (2016).

The Patent Office's ongoing review of its own decisions is not new. To the contrary, before inter partes review, the agency used other procedures for the same purpose. Since 1980, ex parte reexamination has provided one such procedure. *See* 35 U.S.C. §§ 301, 303. The Patent Office can undertake ex parte reexamination based either on a request for reexamination filed by a third party, or on its own initiative. *Id.* In recent decades, Congress added inter partes reexamination, which gave "third parties greater opportunities to participate in the Patent Office's reexamination proceedings." *Cuozzo*, 136 S. Ct. at 2137. The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011), renamed inter partes reexamination "inter partes review." 35 U.S.C. § 311.

The participation of third parties in inter partes review amounts to a "mechanism by which the [Patent Office] can leverage knowledge possessed by persons outside the government to assist it in making a decision within its bailiwick." *Oil States* Br. 11. Whatever information a petitioner may provide or arguments it may make, the Patent Office exercises unreviewable discretion to decide whether to commence inter partes review. 35 U.S.C. § 314(a), (d); *Cuozzo*, 136 S. Ct. at 2139-40. Further, no party has a right to compel review, and the Patent Office has full authority to go forward with or without the ongoing participation of third parties. 35 U.S.C. § 317(a); *Cuozzo*, 136 S. Ct. at 2140

(government retains "the ability to continue proceedings even after the original petitioner settles and drops out").

The characteristics of inter partes review make it fundamentally unlike a judicial proceeding (such as a patent infringement action) in which a state or a private party might sue a tribe without its consent. Thus, the authorities cited by the Tribe (at 8-12) supporting its immunity from lawsuits by states and private parties are inapposite. Indeed, those authorities confirm that tribes lack immunity against the United States and that no "abrogation" of immunity is required for the federal government to enforce statutory requirements. *See*, *e.g.*, *Florida Paraplegic Ass'n, Inc. v. Miccosukee Tribe of Indians of Fla.*, 166 F.3d 1126 (11th Cir. 1999) (cited by Tribe at 10) (holding that Title III of the Americans with Disabilities Act applies to tribes and the U.S. Attorney General may sue to enforce compliance, but tribes' immunity bars *private parties* from bringing ADA actions).

Inter partes review, therefore, is properly understood as a discretionary enforcement proceeding. As such, *Federal Maritime Commission v. South Carolina State Ports Authority*, 535 U.S. 743 (2002) ("*FMC*"), on which the Tribe relies (at 14-15), supports the Patent Office's authority to review a patent held by a tribe. *FMC* held that an adversarial administrative adjudication of a private party's complaint against a state's ports authority for violation of the federal Shipping Act, 46 U.S.C. app. § 1701 *et seq.*, was barred by state sovereign immunity. But *FMC*

made clear also that federal enforcement of the Shipping Act against the state would not have been barred. The key to *FMC*'s holding was that the federal agency had no "discretion to refuse to adjudicate complaints brought by private parties." 535 U.S. at 764. As a result, it was not the United States that controlled prosecution of a complaint before the Commission but rather the private party. *Id.*

FMC expressly recognized that sovereign immunity did *not* preclude the government from prosecuting "alleged violations of the Shipping Act, either upon its own initiative *or upon information supplied by a private party*, and . . . institut[ing] its own administrative proceeding against a state-run port." *Id.* at 768 (emphasis added; citation omitted). Based on that analysis, inter partes review is precisely the type of proceeding that does not trigger sovereign immunity. *Id.* at 768 n.19 (so long as "the Federal Government [remains] free to take subsequent legal action," private parties are "perfectly free to complain to the Federal Government about unlawful state activity").[4]

[4] In decisions not binding on this Panel, other PTAB panels have determined that *state* sovereign immunity may bar inter partes review. *See Covidien LP v. University of Fla. Research Found. Inc.*, Case IPR 2016-01274, Paper 21 (Jan. 25, 2017); *Neochord, Inc. v. University of Md., et al.*, Case IPR2016-00208, Paper 28 (May 23, 2017); *see also Reactive Surfaces Ltd. v. Toyota Motor Corp.*, Case IPR2016-01914, Paper 36 (July 13, 2017) (finding state owner immune but permitting case to continue). Those decisions did not involve common-law tribal immunity; nor, as Mylan points out (at 16), did they involve attempts to "manipulate [PTAB] jurisdiction through a post-institution assignment." In any case, those decisions were incorrect. They ignored the fact that inter partes review is not concerned with "determining the respective rights of adverse litigants" but

2. The Patent Act and the America Invents Act Are Laws of General Applicability That Apply to Tribes.

Inter partes review is also consistent with tribal sovereignty because laws governing the granting and revocation of patents, including the America Invents Act, are laws of general applicability. Under *Tuscarora*, those laws presumptively apply to tribes that become patent owners. 362 U.S. at 115-17 ("[A] general statute in terms applying to all persons includes Indians and their property interests."). The patent statutes do not intrude on matters of internal tribal self-governance or on tribal treaty rights. *Cf., e.g., EEOC v. Karuk Tribe Hous. Auth.*, 260 F.3d 1071 (9th Cir. 2001) (although tribe did not enjoy immunity from federal agency inquiry, the Age Discrimination in Employment Act did not apply to a tribal authority's "intramural" dispute with a tribe member); *see generally Coeur d'Alene*, 751 F.2d at 1116 (exceptions include statutes that touch on "exclusive rights of self-governance in purely intramural matters," abrogate treaty rights, or evince proof that Congress intended the law not to apply on reservations).

Because patent law is governed by statutes of general applicability and because inter partes review – like its predecessors, ex parte and inter partes reexamination – does not intrude on matters traditionally entrusted to tribal

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with whether the Patent Office correctly granted "a patent monopoly as against the world." *Oil States* Br. 36. This Panel should not follow these erroneous decisions and certainly should not extend them to the tribal-immunity context.

sovereignty, the default rule for general statutes applies: tribes must comply with the statutes governing ownership of patents. Those statutes give the Patent Office the prerogative to reexamine a patent on its own initiative or to initiate inter partes review in response to information it receives. When it does so, the Patent Office is a government body enforcing a federal statute of general applicability. Tribal immunity is no defense.

Further, the privileges of patent owners are public grants under federal constitutional and statutory mandates, subject to conditions that have long included the possibility of governmental reexamination and revocation. *See Magoun v. Illinois Trust & Sav. Bank*, 170 U.S. 283, 288 (1898) (explaining that "the authority which confers [a privilege] may impose conditions upon it"); *see generally Oil States* Br. 16, 36-38 (describing patents as "privileges that the government may revoke without judicial involvement"; cataloguing their history as "sovereign grants" that were "issued, enforced, and revoked" first by the Crown, and later by the Crown's Privy Council) (citing *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 847 (2015) (Thomas, J., dissenting)).[5]

[5] Patents "did not exist at common law," *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 494 (1850), nor did they reflect ideas about a "natural right" of inventors, *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966). Instead, patents are "created by the act of Congress; and no rights can be acquired in [them] unless authorized by statute, and in the manner the statute prescribes." *Gayler*, 51 U.S. (10 How.) at 494; *see also* Edward C. Walterscheid, *The Early Evolution of the*

The Tribe cannot reasonably complain that this situation offends its dignity. By stepping into Allergan's shoes and taking ownership of the patent, the Tribe accepted a federal monopoly allowing it to abridge the economic liberty of the general public. *See generally* Richard A. Epstein, *No New Property*, 56 Brook. L. Rev. 747, 754 (1990) (recognizing that the "creation of . . . patents is in derogation of common law rights of property and labor"). But, in doing so, the Tribe knew that the patent grant was subject to Congress's "authority . . . [to] impose conditions." *Magoun*, 170 U.S. at 288. For example, tribes that own patents must, like all other patentees, pay the fees to maintain the patent, or else the patent will expire. *See* 35 U.S.C. § 41(b). The condition that the Patent Office may reexamine or review the patent is no different.

II. Inter Partes Review Is Akin to an *In Rem* Proceeding in Which Sovereign Immunity Does Not Apply.

For the reasons given in Part I, inter partes review is best understood as a discretionary enforcement proceeding that does not implicate tribal immunity because it is unlike any judicial proceeding. That is enough to reject the Tribe's assertion of immunity. But there is another reason as well: if inter partes review is compared to a lawsuit, it is still unlike an *in personam* proceeding, where one person seeks relief against another. Instead, inter parties review is most like an *in*

United States Patent Law: Antecedents (Part 2), 76 J. Pat. & Trademark Off. Soc'y 849, 859 (1994) (describing the history of patent revocation).

rem proceeding, where a court determines the status of a thing. And *in rem* proceedings are not barred by state or tribal sovereign immunity.

For example, a bankruptcy court's exercise of *in rem* jurisdiction to discharge loans does not abridge state sovereign immunity, because bankruptcy courts "have exclusive jurisdiction over a debtor's property, wherever located, and over the estate." *Tennessee Student Assistance Corp. v. Hood*, 541 U.S. 440, 447 (2004). A bankruptcy court's jurisdiction is not premised on the status or nature of creditors, but rather on the estate itself; the proceeding is not adversarial but "'one against the world.'" *Id.* at 448 (quoting 16 James W. Moore et al., *Moore's Federal Practice* § 108.70[1] (3d ed. 2004)); *accord Central Va. Cmty. Coll. v. Katz*, 546 U.S. 356 (2006) (sovereign immunity cannot bar a bankruptcy trustee's proceeding to set aside some preferential transfers).

Similarly, sovereign immunity does not bar federal jurisdiction over an *in rem* admiralty action where the sovereign entity does not possess the property. *California v. Deep Sea Research, Inc.*, 523 U.S. 491, 495 (1998). Although sovereign immunity becomes an issue when a state possesses a ship because of the "special concern in admiralty that maritime property of the sovereign is not to be seized," *Florida Dep't of State v. Treasure Salvors, Inc.*, 458 U.S. 670, 709-10 (1982), no similar concern is present here. A patent is an intangible privilege that cannot be physically seized. *See Ager v. Murray*, 105 U.S. 126, 130 (1881)

("There is nothing in any act of Congress, or in the nature of [patent] rights themselves, to give them locality anywhere, so as to subject them to the process of courts having jurisdiction limited by the lines of States and districts."). Nor does inter partes review resemble a seizure or transfer. The patent owner continues to own the patent and can assert it unless and until a panel determines that it does not meet statutory requirements – at which point the patent is canceled, not transferred.

The principle that sovereign immunity does not defeat *in rem* jurisdiction has been applied to limit the applicability of common-law tribal immunity. Jurisdiction, for tax purposes, over certain fee-patented lands located on a reservation is permissible if it is *in rem*, as opposed to *in personam*. *County of Yakima v. Confederated Tribes & Bands of Yakima Indian Nation*, 502 U.S. 251, 265 (1992) ("While the *in personam* jurisdiction over reservation Indians . . . would have been significantly disruptive of tribal self-government, the mere power to assess and collect a tax on certain real estate is not.").

Inter partes review is like an *in rem* proceeding because it is an inquiry about the patent – over which the Patent Office unquestionably has authority – rather than about the patentee. *See* 35 U.S.C. § 311(a) ("[A] person who is not the owner of a patent may file with the Office a petition to institute an inter partes review *of the patent*.") (emphasis added). The Patent Office has used the same language to describe patent examination as the Supreme Court used in *Hood* with respect to

bankruptcy: "in determining whether a patent should issue, a patent examiner decides whether the applicant will have certain rights *as against the world*." *Compare Oil States* Br. 18 *with Hood*, 541 U.S. at 448. Thus, inter partes review advances the same public purposes as the original patent examination process, *Oil States* Br. 18; through review, the government fulfills its "'obligation to protect the public' from improperly issued patents," *id.* at 20 (quoting *United States v. American Bell Tel. Co.*, 128 U.S. 315, 357, 367 (1888)).

The Supreme Court has cautioned that sovereign immunity is not implicated merely because an "'adversary proceeding'" involving the state "has some similarities to a traditional civil trial." *Hood*, 541 U.S. at 452-53 (distinguishing *FMC*, 535 U.S. at 755: "irrelevant" whether an *in rem* bankruptcy proceeding "is similar to civil litigation"). Even where it is "arguable that the particular procedure . . . could have been characterized as a suit against the State rather than a purely *in rem* proceeding," sovereign immunity is not an obstacle so long as the "proceeding . . . [is] merely ancillary to" *in rem* jurisdiction. *Katz*, 546 U.S. at 371. Here, this Panel will decide the validity of the patent itself, regardless of its owner. Any effect on the Tribe's interests arising from its arrangement with Allergan is an ancillary matter that does not implicate tribal immunity.

CONCLUSION

The Court should deny the Tribe's motion to dismiss.

December 1, 2017

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I hereby certify that, on December 1, 2017, a true and correct copy of the foregoing document was served on the following counsel of record by electronic mail.

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CERTIFICATION OF COMPLIANCE

I hereby certify that the foregoing brief complies with the page limit set forth in the Board's November 3, 2017 Order (Paper No. 96) granting *amici curiae* leave to file a brief of no more than 15 pages.

I also certify that this brief has been prepared in a proportionally spaced type (Times New Roman, 14-point) using Microsoft Word 2013.

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