UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ALLERGAN, INC.,
Patent Owner.

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)

AMICUS CURIAE BRIEF OF THE OGLALA SIOUX TRIBE IN SUPPORT OF CORRECTED PATENT OWNER'S MOTION TO DISMISS BASED ON TRIBAL SOVEREIGN IMMUNITY

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES:

ADMINSTRATIVE ORDERS:

CONSTITUTON AND STATUTES:

OTHER AUTHORITIES:

Amicus Curiae Oglala Sioux Tribe hereby submits this brief in support of the Corrected Patent Owner, Saint Regis Mohawk Tribe's Motion to Dismiss the above referenced inter partes review proceeding based on the defense of tribal sovereign immunity.

ARGUMENT

I. It Is For Congress Alone To Consider The Policy Arguments Favoring Abrogation Of The Defense Of Tribal Sovereign Immunity In The Area Of Patents.

Policy arguments have been advanced in opposition to the ability of a tribe, such as the Saint Regis Mohawk Tribe, to enter into commercial contracts with corporations to acquire patents and then license those patents back to the corporations to achieve a stream of royalty income for the tribe, in return for the tribe's promise to assert its sovereign immunity to bar administrative petitions for *inter partes* review (IPR) of the patents before the Patent Trial and Appeal Board (PTAB). Only Congress, however, may act on those policy arguments to limit or abrogate tribal sovereign immunity.

Thus, in *Kiowa Tribe of Oklahoma v. Manufacturing Technologies, Inc.*, 523 U.S. 751 (1998), involving a state court action by a private party on a promissory note given by the defendant tribe, in an opinion by Justice Kennedy, the Court recognized that "[t]here are reasons to doubt the wisdom of perpetuating the [tribal

sovereign immunity] doctrine":

> At one time, the doctrine of tribal immunity from suit might have been thought necessary to protect nascent tribal governments from encroachments by States. In our interdependent and mobile society, however, tribal immunity extends beyond what is needed to safeguard tribal self-governance. This is evident when tribes take part in the Nation's commerce. Tribal enterprises now include ski resorts, gambling, and sales of cigarettes to non-Indians. . . . In this economic context, immunity can harm those who are unaware that they are dealing with a tribe, who do not know of tribal immunity, or who have no choice in the matter, as in the case of tort victims.

523 U.S. at 758 (citations omitted).

The Supreme Court nevertheless refused to limit or restrict the assertion of tribal sovereign immunity "to reservations or to noncommercial activities," saying: "We decline to draw this distinction in this case, *as we defer to the role Congress may wish to exercise in this important judgment*." *Id.* (emphasis added). The Court explained this deference to the Legislative Branch as follows:

> . . . Congress is in a position to weigh and accommodate the competing policy concerns and reliance interests. The capacity of the Legislative Branch to address the issue by comprehensive legislation counsels some caution by us in this area. Congress "has occasionally authorized limited classes of suits against Indian tribes" and "has always been at liberty to dispense with such tribal immunity or to limit it." [*Oklahoma Tax Comm'n v. Citizen Band of] Potawatomi [Tribe of Okla.], supra*, [498 U.S. 505] at 510 [(1991)]. *It has not yet done so.*

Id. at 759 (emphasis added).

The Supreme Court subsequently followed *Kiowa* in *Michigan v. Bay Mills*

Indian Community, ___ U.S. ___, 134 S.Ct. 2024 (2014). In that case, the State of Michigan sought to enjoin the defendant tribe from opening a casino outside of reservation or other Indian lands. The tribe asserted its tribal sovereign immunity to bar the action. On appeal, Michigan argued that the Supreme Court should revisit its holding in *Kiowa* and hold that tribes have no immunity with regard to "illegal commercial activity" conducted outside of the tribe's sovereign territory. 134 S.Ct. at 2036. Michigan further argued that "tribes increasingly participate in off-reservation gaming and other commercial activity, and operate in that capacity less as governments than as private businesses," pointing out that since *Kiowa* was decided tribal casino revenues "have more than tripled." *Id.* Michigan also pointed out that "tribes have broader immunity from suits arising from such conduct than other sovereigns — most notably, because Congress enacted legislation limiting foreign nations' immunity for commercial activity in the United States." *Id.*

In an opinion by Justice Kagan, the Court in *Bay Mills* declined to disturb its holding in *Kiowa* refusing to confine tribal sovereign immunity to reservations or to noncommercial activities. The *Bay Mills* Court explained that it ruled as it did in *Kiowa* "for a single, simple reason: because *it is fundamentally Congress's job, not ours, to determine whether or how to limit tribal immunity*. The special brand of sovereignty the tribes retain — both its nature and its extent — rests in the

hands of Congress." *Id.* at 2037 (emphasis added and citations omitted). "Congress should make the call whether to curtail a tribe's immunity for off-reservation commercial conduct — and the Court should accept Congress's judgment." *Id.* at 2038. The Court therefore concluded that

> Having held in *Kiowa* that this issue is up to Congress, we cannot reverse ourselves because some may think its conclusion wrong. Congress of course may always change its mind — and we would readily defer to that new decision. *But it is for Congress, now more than ever, to say whether to create an exception to tribal immunity for off-reservation commercial activity.* As in *Kiowa*— except still more so — "we decline to revisit our case law[,] and choose" instead "to defer to Congress." *Id.*, at 760 . . . .

Id. at 2039 (emphasis added).

Similarly, "[i]f tribal sovereign immunity dramatically distorts patent law, there is a remedy available. . . . *Congress* can readily use its plenary power to abrogate tribal sovereign immunity in patent law." Professor Gregory Ablovsky, "Tribal Sovereign Immunity and Patent Law" blog post on Legal Aggregate (Sept. 13, 2017) [hereinafter "Ablovsky"] (emphasis added) (https://law.stanford.edu/2017/09/13/tribal-sovereign-immunity-and-patent-law/). Congress has yet to do so. Unless and until Congress acts, neither the federal courts nor federal administrative tribunals should prevent the tribes from asserting tribal sovereign immunity to bar *inter partes* review of tribally-owned patents.

II. To Promote Tribal Self-Sufficiency, Tribes Should Be Free To Enter Into New And Innovative Types Of Business Development Contracts, Including Those Requiring Assertion Of Tribal Sovereign Immunity.

As Justice Sotomayor recognized in her concurring opinion in *Michigan v. Bay Mills Indian Community*, "[t]ribes face a number of barriers to raising revenue in traditional ways," and, thus, "[i]f Tribes are ever to become more self-sufficient, and fund a more substantial portion of their own governmental functions, *commercial enterprises will likely be a central means of achieving that goal*." 134 S.Ct. at 2041 (Sotomayor, J., concurring) (emphasis added).

As early as 1980, the Supreme Court recognized that Congress had begun to demonstrate "a firm federal policy of promoting tribal self-sufficiency" and "tribal independence." *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 143-44 (1980) (footnote omitted). More recently, Justice Sotomayor has likewise recognized that "[a] key goal of the Federal Government is to render Tribes more self-sufficient, and better positioned to fund their own sovereign functions, rather than relying on federal funding." *Id.* at 2043, citing 25 U.S.C. § 2702(1) (explaining that Congress' purpose in enacting the Indian Gaming Regulatory Act of 1988 (IGRA) was "to provide a statutory basis for the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments"); *see also* 25 U.S.C. § 4301 (stating

that one of the purposes of the Native American Business Development, Trade Promotion, and Tourism Act of 2000 was "[t]o promote economic self-sufficiency and political self-determination for Indian tribes and members of Indian tribes").

This goal of self-sufficiency cannot be achieved by casinos alone. "Popular imagination might envision casino riches, but Indian gaming revenue is spread very unevenly, with only a handful of well-situated tribes bringing in large sums." Ablovsky. Approximately half of the tribes do not operate casinos at all, and "even among the Tribes that do, gaming revenue is far from uniform. As of 2009, fewer than 20% of Indian gaming facilities accounted for roughly 70% of the revenues from such facilities." *Michigan v. Bay Mills Indian Community*, 134 S.Ct. at 2043 (Sotomayor, J., concurring), citing A. Meister, Casino City's Indian Gaming Industry Report 28 (2009-2010 ed.).

Taxation of reservation businesses is also problematic. "States have the power to tax certain individuals and companies based on Indian reservations, making it difficult for Tribes to raise revenue from those sources." *Michigan v. Bay Mills Indian Community*, 134 S.Ct. at 2043 (Sotomayor, J., concurring), citing *Oklahoma Tax Comm'n v. Citizen Band Pottawatomie Tribe of Okla.*, 498 U.S. 505 (1991) (allowing State to collect taxes on sales to non-Indians on Indian land); *Arizona Dep't of Revenue v. Blaze Constr. Co.*, 526 U.S. 32 (1999) (allowing State

taxation of companies owned by non-Indians on Indian land); and *Thomas v. Gay*, 169 U.S. 264 (1898) (allowing taxation of property owned by non-Indians on Indian land). "[I]f Tribes were to impose their own taxes on these same sources, the resulting double taxation would discourage economic growth." *Id.* at 2043-44 (citations omitted). Thus, tribes are presented with the Hobson's choice "of imposing double taxation on reservation businesses or foregoing their own tax revenue." Ablovsky.

Consequently, the development of new and innovative "tribal business operations are critical to the goals of tribal self-sufficiency because such enterprises in some cases 'may be the only means by which a tribe can raise revenues[.]" *Michigan v. Bay Mills Indian Community*, 134 S.Ct. at 2043 (Sotomayor, J., concurring), quoting Struve, "Tribal Immunity and Tribal Courts," 36 Ariz. St. L.J. 137, 169 (2004). "Tribal leaders are understandably anxious to make deals that will bring much-needed jobs and money to places that have long lacked both." Ablovsky.

In the case of the Saint Regis Mohawk Tribe, a tribal community of 13,000 in a rural area of New York bordering Canada with an annual budget of $50 million, "the [Allergan] deal offers the promise of a new revenue stream [$15 million in annual royalties as long as the patents remain valid] that would bring in

income beyond that of a casino the tribe runs near the reservation." Katie Thomas, "How to Protect a Drug Patent? Give It to a Native American Tribe," *New York Times* (Sept. 8, 2017) (https://www.nytimes.com /2017/09/08/health/allergan-patent-tribe.html). As the Tribe's general counsel puts it, "The tribe has many unmet needs, . . . We want to be self-reliant." (*Id.*) The Tribe, as part of its economic diversification strategy, has also received around forty (40) patents from SRC Labs LLC, a research, and development technology corporation specializing in the areas of defense, environment and intelligence. Carlos Quijada, "Patents and Tribal Sovereign Immunity," BioLawToday.org (Oct. 23, 2017) [hereinafter "Quijada"] (https://www.law.utah. edu/patents-and-tribal-sovereign-immunity/). The Tribe plans to invest the licensing and royalty revenues earned from these patents in health, safety, education and cultural programs. *Id.*

Congress has expressly found that, "consistent with the principles of inherent tribal sovereignty and the special relationship between Indian tribes and the United States, *Indian tribes retain the right to enter into contracts and agreements to trade freely* [.]" 25 U.S.C. § 4301 (emphasis added). This tribal freedom of contract should not be curtailed, but rather should be encouraged as necessary to achieve the goal of tribal self-sufficiency. Tribes should therefore be allowed to enter into a variety of business development arrangements, including

those where, as here, part of the consideration for the agreement involves a promise by the tribe to assert its sovereign immunity as a defense in legal proceedings.

III. Patent-Holding Tribes, Like State Universities, Should Be Allowed To Assert Sovereign Immunity To Bar Patent Challenges.

"Using sovereign immunity to dismiss patent challenges is not without precedent." Quijada. In two cases decided earlier this year, the PTAB ruled that state university-owned patents are not subject to the *inter partes* review process because the state universities enjoy sovereign immunity.

Thus, in *Covidien LP v. Univ. of Fla. Research Found. Inc.*, Case IPR2016-1274, Patent No. 7,062,251 B2 (PTAB Jan. 25, 2017), the petitioner argued that allowing the University of Florida Research Foundation (UFRF) to assert sovereign immunity to bar *inter partes* review before the PTAB of the patents the state university foundation holds "would have harmful and far-reaching consequences":

> One, invalid patents would stand simply because they are assigned to a state entity. Two, a patent owned by a monetization foundation affiliated with a state university would be insulated from the *inter partes* review process.

Id. at 25.[1] Rejecting this argument, the PTAB stated as follows:

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1 It was undisputed that "UFRF's entire business is that of a technology

> [W]e are cognizant of the fact that applying an Eleventh Amendment immunity to *inter partes* review, absent waiver by the state entity, precludes the institution of *inter partes* review against a state entity entitled to Eleventh Amendment immunity. This, indeed, is precisely the point of the Eleventh Amendment, which is the preservation of the dignity afforded to sovereign states. . . . When sovereign immunity conflicts with legislation, Congress may abrogate sovereign immunity if it has unequivocally expressed its intent to abrogate the immunity and has acted pursuant to a valid exercise of power. *Seminole Tribe [of Fla. v. Florida]*, 517 U.S. [44] at 55 [(1996)]. Petitioner does not point to, and we do not find there is, an unequivocal, express intent by Congress in the AIA[[2]] to abrogate immunity for the purposes of *inter partes* review.

Id. at 26.

The PTAB further concluded that "there is no evidence that the harm to the patent system, described by the Petitioner, will come to pass, let alone exists as a basis to divest States of sovereign immunity." *Id.* at 27.

Thus, after concluding that the university foundation was an arm of the State of Florida, *id.* at 27-39, the PTAB in *Covidien* concluded that "Eleventh Amendment immunity applies to *inter partes* review proceedings, and that UFRF, having shown it is an arm of the State of Florida, is entitled to assert its sovereign immunity as a defense to the institution of an *inter partes* review," requiring dismissal of the petitions for the review of the UFRF's patents. *Id.* at 39.

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licensor designed to monetize University of Florida patents." *Id.* at 29.

2 Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284, 331 (2011).

Subsequently, the PTAB granted a similar motion to dismiss on the basis of sovereign immunity under the Eleventh Amendment filed by the University of Maryland, Baltimore (UMDB). *See NeoChord, Inc. v. Univ. of Md., Baltimore*, Case IPR2016-208, Patent No. 7,635,386 B1 (PTAB May 23, 2017). The PTAB found that the fact that UMDB had transferred less than "substantially all" rights to the licensee made UMDB a necessary and indispensable party to the proceedings, and granted the motion to dismiss based on UMDB's sovereign immunity (*Id*. at 19-20). In doing so, the PTAB "recognized that the University's assertion of sovereign immunity creates special treatment for a State entity" but pointed out that "any asymmetry is the result of the Eleventh Amendment itself":

> In contrast, a suit by an individual against an unconsenting State is the very evil at which the Eleventh Amendment is directed— and it exists whether or not the State is acting for profit, in a traditionally "private" enterprise, and as a "market participant." In the sovereign-immunity context, moreover, "[e]venhandness" between individuals and States is not to be expected: "[T]he constitutional role of the States sets them apart from other employers and defendants."

Id. at 18 (quoting *College Savings [Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.]*, 527 U.S. [666] at 685–86 [(1999)](citations and footnote omitted).

See also, *Reactive Surfaces Ltd., LLP v. Toyota Motor Corp.*, Case IPR2016-1914 Patent No. 8,394,618 B2 (July 13, 2017), wherein the PTAB dismissed the Regents of the University of Minnesota from the IPR proceeding because they had

sovereign immunity, but declined to dismiss Toyota, which was co-owner of the patent. *Id.* at 17.

By direct analogy to the PTAB's decisions in *Covidien* and *NeoChord*, the St. Regis Mohawk Tribe may assert its tribal sovereign immunity to require the dismissal of the petitions challenging the Restasis patents that the tribe now owns. Absent a waiver by the tribe, tribal sovereign immunity precludes the institution of *inter partes* review proceedings against the tribe, and there is no unequivocal, express intent by Congress in the America Invents Act to abrogate tribal sovereign immunity for the purposes of *inter partes* review. No evidence, moreover, has been presented that the alleged harm to the patent system described by the Petitioners, will come to pass.

In particular, there is no real difference in the role of the university foundation in *Covidien* and that of the Saint Regis Mohawk Tribe in this case. Both merely took an assignment of the patent or patents in question for purposes of monetizing the patents through licensing and generating royalty revenue. To deny the Tribe the right to assert its tribal sovereign immunity to defeat *inter partes* review of the Restasis patents would constitute improper unequal treatment and discrimination against the Tribe.

Indeed, one patent attorney/commentator has observed, in criticizing as

"discriminatory" the bill recently introduced by Senator Claire McCaskill (D-Mo) to abrogate tribal sovereign immunity as a defense in *inter partes* review:

> An important question needs to be asked: Why is everyone so upset that Native American Indians are asserting sovereign immunity? No one was upset when it was the University of Florida Research Foundation. Would Senator McCaskill or other[s] call it clearly illegal if Allergan or other companies were to do the same deal with a state university instead of a Native American Indian Tribe?

Gene Quinn, "Senator McCaskill Introduces Bill to Abrogate Native American Sovereign Immunity," IPWatchdog Blog (Oct. 5, 2017) (http://www.ipwatchdog .com/2017/10/05/senator-mccaskill-legislation-abrogate-native-american-sovereign-immunity/id=88975/).

In short, given the PTAB's recent decisions permitting universities, and even a university monetization foundation, to raise Eleventh Amendment immunity to defeat IPR review, the Tribe should likewise be allowed to assert its tribal sovereign immunity as a defense to *inter partes* review of the Restasis patents.

IV. The Allergan-Saint Regis Mohawk Patent Assignment Is Not A Sham Assignment.

After taking the assignment of the Restasis patents from Allergan, the St. Regis Mohawk tribe granted Allergan an exclusive license. That license, however, placed "limitations on Allergan's rights to a[] particular field of use—specifically, to practice the patents in the United States for all FDA-approved uses," thus

"giv[ing] the Tribe at least nominal rights with regard to the Restasis patents." *See Allergan, Inc. v. Teva Pharmaceuticals USA Inc.*, No. 2:15-cv-1455-WCB, Mem. Opinion & Order, p. 7 (E.D.Tex. Oct. 16, 2017) (Bryson, J.) [Doc. 522]. In addition, the Tribe retained other substantial rights, "including the right to practice the patents for research, education, and other non-commercial uses, and the first right to sue third parties not related to Restasis bioequivalents." *Id.* Even Judge Bryson considered it at least a "close question" whether the Tribe retained substantial rights in the Restasis patents, thereby validating the assignment of the patents to the Tribe. *Id.*

That the assignment is not a sham can also be seen from the fact that the St. Regis Mohawk Tribe has opened an Office of Technology, Research and Patents to manage the Tribe's patent business. There would be no need for such an office if all the Tribe was reduced to by the exclusive license granted to Allergan was to receive and cash royalty checks.

CONCLUSION

In view of the arguments made and authorities cited above, amicus curiae, Oglala Sioux Tribe, urges the PTAB to grant the motion to dismiss the instant IRP proceeding filed by the Corrected Patent Holder, Saint Regis Mohawk Tribe, as barred by the doctrine of tribal sovereign immunity.

Date: November 29, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR 42.6(3)(4) and 42.205(b), the undersigned certifies that on November 29, 2017, a complete entire copy of the Amicus Curiae Brief of the Oglala Sioux Tribe In Support Of Corrected Patent Owner's Motion To Dismiss Based on Tribal Sovereign Immunity was provided, via electronic service, to the persons named below at their address of record, viz:

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