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.,

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 AMICUS CURIAE U.S. INVENTOR, LLC IN SUPPORT OF PATENT OWNER, THE SAINT REGIS MOHAWK TRIBE

ISSUE OF FIRST IMPRESSION PRESENTED

Whether the Patent Trial and Appeals Board (the "Board") has the authority to decide whether the Saint Regis Mohawk Tribe – which is a federally recognized, sovereign Native American Tribe and which is indisputably a non-consenting sovereign – is subject to the jurisdiction of the Board.

INTERESTS OF AMICUS CURIAE – U.S. INVENTOR, LLC[1]

U.S. Inventor, LLC is a nation-wide inventor advocacy organization which lobbies Capitol Hill, private trade organizations and the public to encourage strong patent protection in order to foster and protect American innovation and American inventors. U.S. Inventor has over 13,000 members including, independent inventors, early-stage businesses, members of the venture capital community, patent holders, research organizations, emerging technology companies, and patent-dependent enterprises. U.S. Inventor has been at the forefront of teaching, promoting and defending the invention processes and business methods used by American inventors and innovators to develop cutting edge products and services which will extend and enhance American global competitiveness in the 21st Century and beyond.

U.S. Inventor has a direct and vital interest in this issue because its members are concerned that the Board may attempt to usurp Congressional authority over Native American tribal sovereign immunity and contravene long-standing, black-letter U.S. Supreme Court precedent by unilaterally and unjustifiably abrogating Congressionally

[1] No counsel for any party to these proceedings participated in or authored this brief in whole or in part. No person or entity other than the *amicus curaie* or their counsels made a monetary contribution to the preparation or submission of this brief. Because this is an issue of first impression, the Board has authorized the filing of briefs in this case by interested *amicus curaie*. *See* e.g. Paper No. 98 in IPR2016-01128.

mandated Native American tribal sovereign immunity. Moreover, the value of intellectual property assets (and the ability of inventors to protect products and services that they have created against unauthorized copying and misappropriation) will be significantly affected by whether such inventors – under the appropriate circumstances – have the ability to partner with groups and organizations that can assert and maintain sovereign immunity in Board proceedings which have been initiated by infringers of intellectual property.

RELEVANT PTAB HISTORY[2]

On June 3, 2016, Mylan Pharmaceuticals Inc. ("Mylan") filed six petitions for *inter partes* review against U.S. Patent Nos. 8,685,930, 8,629,111, 8,642,556, 8,633,162, 8,648,048, and 9,248,191 (collectively, the "Patents-at-Issue") which were then owned by Allergan, Inc. ("Allergan").[3]

On September 8, 2017, Allergan, Inc. assigned the Patents-at-Issue to the Saint Regis Mohawk Tribe (the "Saint Regis Tribe"). Concurrently with this assignment, the Saint Regis Tribe granted back to Allergan an exclusive limited field-of-use license and then notified the Board that it was the new owner of the Patents-In-Issue. On September 22, 2017, the Saint Regis Tribe filed a Motion to Dismiss For Lack of

[2] For purposes of brevity, the history of the District Court proceedings between the parties has been omitted from this brief. Due the Board's familiarity with this case, this Brief also generally omits citations to filings submitted by the parties.

[3] *See* IPR2016-01127; IPR2016-01128; IPR2016-01129; IPR2016-01130; IPR2016-01131; IPR2016-01132. Additional petitions for *inter partes* review of the Patents-In-Issue were then filed by Teva Pharmaceuticals USA, Inc. ("Teva") (IPR2017-00576; IPR2017-00578; IPR2017-00579; IPR2017-00583; IPR2017-00585; IPR2017-00586) and by Akorn Inc. ("Akorn") (IPR2017-00594; IPR2017-00596; IPR2017-00598; IPR2017-00599; IPR2017-00600; IPR2017-00601). Each of the corresponding Mylan, Teva and Akorn petitions for *inter partes* review were subsequently joined *See, e.g.*, Paper Nos. 18 and 19 in IPR2016-01127

Jurisdiction Based on Tribal Sovereign Immunity (the "Motion To Dismiss"). Subsequently, the Board received requests from two organizations (unaffiliated with any of the parties) seeking leave to file briefs as *amicus curiae* on the issues raised by Allergan's assignment of the Patents-In-Issue to the Saint Regis Tribe and by the subsequently filed Motion To Dismiss. On November 3, 2017, the Board granted leave to these organizations as well as to any other interested parties which wanted to file briefs in this case as *amicus curiae*.[4]

ARGUMENTS AND AUTHORITY

A. Only Congress May Limit Tribal Sovereign Immunity.

It is undisputable that as domestic dependent nations, Native American tribes possess and exercise inherent sovereign immunity. It is also undisputable that such power may be abrogated, limited or qualified only by the express and unequivocal action of Congress. In *Kiowa Tribe of Oklahoma v Manufacturing Technologies, Inc.*, the U.S. Supreme Court explicitly affirmed that no court or administrative agency may interfere with that power absent Congressional legislation.[5]

The U.S. Supreme Court has been steadfast in upholding this principle against any challenges to the breadth and scope of Native American tribal sovereign immunity. In *Bay Mills*, which was decided just three years ago, the Court noted that the holding in *Kiowa Tribe* was unambiguous, had been relied on by Native American tribes and by parties in subsequent cases, and had been considered (and left alone) by Congress, making any departure from it unwarranted.[6] The Court reaffirmed that Native

[4] *See* Paper No. 98 in IPR2016-01128
[5] 523 U.S. 751 (1998)
[6] *Michigan v Bay Mills Indian Community, et al*, 134 S. Ct. 2024, 2026 (2014)

American tribes are domestic dependent nations that exercise sovereignty based on the fact that immunity "is 'a necessary corollary to Indian sovereignty and self-governance.'"[7] and that tribal immunity is qualified only to the extent it has been placed "in Congress's hands."[8] The Court also noted that in *Kiowa Tribe*, it had refused to limit tribes' inherent immunity to commercial activities on Indian land, deferring any such action to Congress.[9] And that after the Court's decision in *Kiowa Tribe*, Congress considered legislation specifically meant to proscribe tribal immunity, but tellingly chose not to pass any such limiting legislation.[10] In re-affirming *Kiowa Tribe*, the Court in *Bay Mills* held that "[i]t is fundamentally Congress's job . . . to determine whether and how to limit tribal immunity." and that absent congressional limitations, tribes exercise *unqualified* immunity.[11] The Court even went so far as to note that "a fundamental commitment of Indian law is judicial respect for Congress's primary role in defining the contours of tribal sovereignty."[12]

In *Bay Mills*, the Court, when presented with an opportunity to abrogate, or at least qualify, tribal sovereign immunity, instead chose to unequivocally underscore that the power to qualify or limit tribal immunity is within the sole purview of Congress and that tribal immunity is clearly not subject to judicial review or administrative agency oversight.

B. The Board Should Not Decide The Issue of Sovereign Immunity.

1. Only Congress has the authority to qualify or limit sovereign immunity.

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[7] *Id.* at 2030 (quoting *Three Affiliated Tribes of Fort Berthold Reservation* v. *World Engineering, P. C.*, 476 U.S. 877, 890 (1986))
[8] *Id.*
[9] *Id.* at 2031
[10] *Id.* at 2038
[11] *Id.* at 2037
[12] *Id.* at 2039

As noted in the preceding section, Congress has the sole and exclusive right and authority to decide whether and in what context Native American tribal sovereign immunity applies. It would be a flagrant encroachment on Congressional authority for the Board to take the position that an administrative agency has the right and authority to supplant the regulatory power of Congress. Particularly, in the context of Native American tribal sovereign immunity where even the U.S. Supreme Court has conceded it is without authority to act because the administration and oversight of federal tribal law is within the exclusive dominion of Congress. Stated another way, it would be inconceivable that an Article I administrative agency has the authority to make binding decisions concerning the applicability of Native American tribal sovereign immunity when the U.S. Supreme Court – which has plenary judicial oversight of that same administrative agency – has declared that absent Congressional legislation, the Court does not have the power to qualify or limit the assertion of Native American sovereign immunity.

2. The Board is not equipped to undertake the relevant analysis.

Even assuming *arguendo* that the Board has the power (which it doesn't) to decide whether sovereign immunity may be used by a patent owner to divest the Board of jurisdiction over an administrative patent challenge, the Board is simply not the appropriate venue to make this determination for at least the following three reasons: First, every assertion of sovereign immunity to defeat the Board's jurisdiction in a particular case will necessarily involve intensive factual discovery and analysis – regardless of whether that discovery is being sought to prove/disprove that the assignment of a challenged patent is a sham transaction (as alleged by Mylan in this case) or whether discovery is being pursued to ascertain if the patent assignee is indeed

a bona-fide claimant to sovereign immunity.[13] The proceedings before the Board – which afford parties only limited discovery coupled with the fact that the Board has no subpoena powers over non-parties – means that the relevant factual determination will likely be incomplete or even fatally flawed. Second, a finding by a panel of the Board that sovereign immunity is proper in a particular case will not be binding on future petitioners as a result of due process prerogatives. This will undoubtedly lead to serial challenges to assertions of sovereign immunity thereby increasing costs to both patent owners and petitioners. Third, although sovereign immunity which precludes the Board's assertion of jurisdiction is necessarily a gateway matter, it is also a collateral issue to the central function of Board proceedings which are to adjudicate the validity of challenged patents. Requiring panels of the Board and litigants to determine whether a particular assignment to an alleged sovereign was a bona-fide transaction or requiring parties to contest/defend whether a particular assignee is entitled to claim sovereign immunity will undoubtedly further tax the time and resources of both the Board and litigants who are already laboring under a compressed trial schedule to determine the core issue of patent validity.

C. The Proper Forum For Parties To Challenge Tribal Sovereign Immunity Is Federal District Court

If a party that is contesting an assertion of sovereign tribal immunity does believe that it should be allowed to challenge that claim (notwithstanding the fact that the U.S. Supreme Court has unequivocally held that Congress has the sole authority to review or qualify the scope of tribal sovereign immunity), the proper forum to raise a challenge to tribal sovereign immunity is not the Board. Instead, and based on

[13] *See* the "arm of the tribe" discussion *infra*.

analogous proceedings involving Indian tribes, the correct forum for such challenges is clearly in federal district court.

For example, when a party challenges whether the relationship between the tribe and the entity asserting immunity is sufficiently close to properly permit that entity to share in the tribe's immunity, federal district courts do undertake an analysis of the bona-fides of an assertion of sovereign tribal immunity.[14] This analysis is commonly referred to as the "arm of the tribe" test. To that end, all of the federal courts of appeals have developed standards for determining which tribally affiliated entities are allowed immunity from regulation and legal suit. Rather than depending on the nature of the business a tribe is conducting through a particular entity, the question of whether tribal immunity is to be extended to the entity depends on whether, the entity is an "arm of the tribe" such that the activities of the challenged entity are properly deemed to be those of the tribe.[15]

As part of that analysis, each of the federal courts of appeals applies a unique arm of the tribe test, taking numerous and varied factors into consideration when determining which entities are entitled to tribal sovereign immunity. In general, the federal courts of appeals implement tests that typically evaluate the following: (1) the creation, funding and control of the entity; (2) the benefits accorded to the tribe by the entity; (3) the amount of control the tribe exerts over the entity; and (4) whether the

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[14] *See Ninigret Dev. Corp. v. Narragansett Indian Wetuomuch Housing Authority*, 207 F.3d at 29 (stating that tribal housing authority "as an arm of the Tribe, enjoys the full extent of the Tribe's sovereign immunity"); *Marceau v. Blackfeet Housing Authority*, 455 F.3d 974, 978 (9th Cir.2002) (recognizing that tribal sovereign immunity "extends to agencies and subdivisions of the tribe").

[15] *Allen v. Gold Country Casino*, 464 F.3d at 1046; see also *Hagen v. Sisseton-Wahpeton Community College*, 205 F.3d at 1043; *Ninigret Dev. Corp. v. Narragansett Indian Wetuomuch Housing Authority,* 207 F.3d at 29.

policies of tribal sovereign immunity would be served by holding the entity as an arm of the tribe.[16]

Having parties raise and prosecute or defend in federal district court challenges to assertions of sovereign tribal immunity would also not impose any undue hardship or unfair burden upon litigants. Based on a five-year study (from 2012 through the end of the second quarter of 2017), nearly 80% of patents being challenged in Board proceedings are also subject to concurrent district court litigation.[17] For the great majority of parties, asking the district court to resolve the issue of whether sovereign immunity applies in a particular case would be a relatively simple matter of filing motions in an already pending district court litigation. Moreover, federal district courts with their broad jurisdictional discovery powers and ability to issue subpoenas to third-party witnesses are uniquely situated to allow the parties a full and fair opportunity to develop a comprehensive factual record to challenge or defend assertions of sovereign immunity. In addition, given that more than 70% of district court proceedings get stayed once a petition for *inter partes* review has been granted,[18] a motion to challenge an assertion of sovereign immunity will almost certainly get decided in short order given the lack of other activity in the district court in that particular case. Finally, having parties adjudicate tribal sovereign immunity challenges in federal district court will remove that burden from panels of the Board

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[16] *See Ninigret Dev. Corp. v. Narragansett Indian Wetuomuch Hous. Auth*., 207 F.3d 21 (1st Cir.2000); *Hagen v. Sisseton-Wahpeton Cmty. Coll.*, 205 F.3d 1040 (8th Cir. 2000); *Allen v. Gold Country Casino*, 464 F.3d 1047 (9th Cir.2006); *Breakthrough Management Group, Inc. v. Chukchansi Gold Casino and Resort*, 629 F.3d 1173, 1181 (10th Cir.2010)

[17] See https://www.patexia.com/feed/patexia-chart-44-80-percent-of-ipr-filings-are-for-defensive-purposes-20171107 (last accessed on November 28, 2017)

[18] https://www.morganlewis.com/-/media/files/publication/report/ptab-post-grant-proceedings_fin_screen.ashx (last accessed on 11-28-17)

which are already under intense pressure to adjudicate the issue of patent validity within a statutorily proscribed time-frame.

CONCLUSION

Because the Board lacks the adjudicatory authority to decide the applicability of tribal sovereign immunity, the Motion to Dismiss For Lack of Jurisdiction Based on Tribal Sovereign Immunity filed by patent owner Saint Regis Mohawk Tribe should be granted.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2017, I caused the foregoing Brief of Amicus Curiae U.S. Inventor, LLC in Support of Patent Owner Saint Regis Mohawk Tribe to be served by email on the following counsel of record:

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