This article was first published in the May 18, 2018, issue of the *New York Law Journal* and is republished here with permission.

Will Sovereign Immunity Shield Patent Owners From IPR Challenges?

By Ronald M. Daignault, Debra Doby and Michael Siem

One of the most interesting issues that's being litigated in patent law these days is the ability to sue a sovereign entity for patent infringement or challenge the validity of a patent owned by a sovereign entity at the U.S. Patent Office. It is well established that the Eleventh Amendment precludes any suit against a sovereign entity, unless it has waived its immunity. Presently, each U.S. state and American tribal nation is considered its own sovereign entity. Patent litigants have attempted to use this doctrine to shield either their patents from challenges at the PTO or themselves from litigation.

Sovereign Immunity

In the United States, sovereign immunity is set forth in the Eleventh Amendment in the U.S. Constitution. The Amendment precludes any suit against a sovereign entity unless it has specifically waived that immunity. In intellectual property, this limits the ability to sue a sovereignty entity for patent infringement or challenge the validity of a patent owned by a sovereign entity in courts and at the U.S. Patent Office.

When, in 2013, Congress overhauled the America Invents Act (AIA), the idea of Sovereign Immunity came back into play for patent holders. The reason for this was the AIA's sweeping reforms to Patent Office's administrative proceedings, allowing private parties to challenge the validity of already-issued patents at the PTO's Patent Trial and Appeal Board (PTAB)—known as inter partes review (IPR). 35 U.S.C §314. Pharmaceutical companies, in an attempt to find creative and unique solutions to protect their patents, attempted to use Sovereign Immunity to shield the validity of their patents—the most notable is Allergan's deal with the Mohawk Tribe.

Native American Tribal Sovereignty

Native American Tribes are "domestic dependent nations" that have "long been recognized as possessing the common-law immunity from suit traditionally enjoyed by sovereign powers … [but its sovereignty is] "subject to the superior and plenary control of Congress." *Kiowa Tribe of Okla. v. Mfg. Techs.*, 523 U.S. 751, 754 (1998). This immunity extends to the individual Native Americans, Native American tribes, Native American institutions, and agencies formed by several tribal governments. *Fed. Power Comm. v. Tuscarora Indian Nation*, 362 U.S. 99 (1960). This immunity can only be waived by the Tribes' unequivocal express waiver of its immunity or where Congress authorized suit. *U.S. v. Testan* 424 U.S. 392 (1976); *Enterprises v. Citizen Band*

Potawatomi Tribe of Okla., 532 U.S. 411 (2001).

In *Michigan v. Bay Mills Indian Cmty.*, 572 U.S. __ (2014), the Supreme Court dismissed Michigan's suit and upheld the Tribe's sovereignty authority, and its inherent immunity from suit, absent express waiver or "[u]ntil Congress acts," relying on *United States v. Wheeler,* 435 U.S. 313 (1978) (*Wheeler*). Sovereign immunity applies whether suit is brought by a State or an individual. *Kiowa*, 523 U.S. at 756. Despite this, the Supreme Court continues to hold that Tribal sovereignty "is not co-extensive with that of the States" (id.) and remains subject to the "sufferance of Congress and is subject to complete defeasance." *Wheeler*, 435 U.S. at 323.

Allergan 'Sells' Its Patents to Mohawk Tribe

In 2017, the drugmaker Allergan announced the transfer of some of its patents, including patents covering its Restasis dry eye treatment, to the Saint Regis Mohawk Tribe in upstate New York, invoking the sovereign immunity doctrine in an attempt to prevent challenges to those patents.

In *Mylan Pharmaceuticals v. St. Regis Mohawk Tribe*, Case No. 2016-01127, Paper No. 14 (PTAB, Feb. 23, 2018) (per curiam), the PTAB denied the Mohawk Tribe's attempt to block patent review by invoking the sovereign immunity doctrine. The PTAB determined the Tribe failed to establish that its sovereign immunity applies to inter partes proceedings. In doing so, the PTAB primarily focused on the "application of non-statutory defenses in inter partes review proceedings," the coincidental timing of Allergans' patent transfer to the Tribe *after* Mylan's challenges resulted in the initiation of inter partes proceedings, and the degree to which Allergan retained ownership control. Id. at 3. The PTAB determined that the Tribe "cannot be compelled to appear as a party in these proceedings," but "the Board does not exercise personal jurisdiction over the patent owner … [but rather] the patent." Id. at 4.

Remarkably, the PTAB determined that the "Tribe [failed to] point to any federal court or Board precedent suggesting that with respect to state sovereign immunity can or should be extended to an assertion of tribal immunity in similar federal administrative proceedings." Id. at 3 (internal citations omitted). The PTAB cited multiple instances where Congress abrogated Tribal sovereignty with respect to various federal agencies, but failed to address the fact that Congress had not specifically abrogated the Tribal sovereignty in this context.

The PTAB paid particular attention to the timing of the relevant events. Following notification of the commencement of inter partes proceedings in December 2016, Allergan approached the Mohawk Tribe in early 2017 and allegedly intended to use the tribal sovereignty to dismiss the federal infringement case. Id. at 5-6. In return, the Mohawk Tribe would receive approximately $15 million annually, with an upfront amount of $13.75 million. Id. Shortly thereafter, the Mohawk Tribe created its own Office of Technology, Research and Patents and entered into a Patent Assignment Agreement with Allergan, effective Sept. 8, 2017. Id. On the *same* day, the Tribe and Allergan entered into an *exclusive* Patent License Agreement giving control back to Allergan. Id. Looking at the nature of the circumstances, the PTAB denied the Mohawk Tribe's attempt to prevent parties from challenging Allergan's patents by asserting tribal sovereignty, but notably only decided that tribal sovereign immunity cannot be utilized in inter partes proceedings.

Allergan's rather blatant attempt to use tribal sovereignty as a shield has incurred the ire of several members of Congress as well. Four U.S. Senators have asked the Senate Judiciary Committee to launch an investigation into this Allergan/Mohawk deal alleging anti-competitive behavior.

Although Congress' attempts to abrogate states' sovereign immunity failed, in *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank,* 527 U.S. 627 (1999) the Supreme Court held that Congress has the legislative ability to alter a Tribes' sovereignty and, therefore, the question remains whether Allergan's recent maneuver will cause Congress to act. The Allergan/Mohawk deal is not the end of this story. The potential remains for additional big pharma companies to seek out similar arrangements with Native American Tribes in the hope of using tribal sovereignty to protect their patents, particularly in less controversial circumstances. It is imperative to question the motive and facts surrounding the patent transfer, determine the amount of control the Tribe has over the patent(s), scrutinize the terms of the deal, and question whether the Tribe is a true owner of the patents or merely a "straw man" serving at the pleasure of big pharma.

It should be noted that Allergan and the Saint Regis Mohawk Tribe have filed a Notice of Appeal to the U.S. Court of Appeals for the Federal Circuit on several issues, including whether tribal sovereign immunity applies to IPR proceedings.

Ronald M. Daignault, Debra Doby and Michael Siem are partners at Goldberg Segalla.