

Marquette Law School

Samantha Brown

123 N. Blount St. #503
Madison, WI 53703
(262) 707-1467

TRIBAL SOVEREIGN IMMUNITY AS A DEFENSE AT THE PATENT TRIALS AND APPEAL BOARD? OR A VIOLATION OF US ANTITRUST LAWS?

I. INTRODUCTION

Pharmaceutical companies have been known to make moves that much of the general public may find questionable at best, reprehensible at worst. There was the infamous case of Martin Shkreli, who earned the title of “most-hated man in America,” after he was accused of serious price gouging on a life-saving medication.¹ There is also the companies that produce opioids, which have been accused of worsening the opioid epidemic.² However, despite the bad press these pharmaceutical companies endure and the ire raised in many Americans (including politicians who threaten to reign in the pharmaceutical industry) due to these questionable decisions, it does not seem to deter more poor decision-making from other pharmaceutical companies.

Most recently,³ Allergan was taken to task after it transferred its patent for Restasis (an incredibly profitable drug for the company) to the Saint Regis Mohawk Indian Tribe in an attempt to avoid an *inter partes review* (IPR) by the Patent Trials and Appeals Board (PTAB).⁴ According to Allergan’s press release, the Tribe would receive \$13.75 million upon execution of the agreement and \$15 million each year in royalties.⁵ In return, the Tribe promised to not waive its sovereign immunity in any forthcoming IPR challenges, and Allergan would have an exclusive

¹ Misyrlena Egkolfopoulou, Patricia Hurtado, and Chris Dolmetsch, *Why “Pharma Bro” Martin Skreli is Swagging Into Jail*,” BLOOMBERG (Aug. 4, 2017, 4:01 PM), <https://www.bloomberg.com/news/articles/2017-08-04/-pharma-bro-fall-why-most-hated-ceo-is-swagging-into-jail>.

² Samantha Raphelson, *Alabama Targets OxyContin Maker Purdue Pharma in Opioid Suit*, NPR (Feb. 7, 2018, 4:02 PM), <https://www.npr.org/2018/02/07/584034397/alabama-targets-oxycotin-maker-purdue-pharma-in-opioid-suit>.

³ Most recently at the time this article was written. The author acknowledges that another pharmaceutical company may very well take it upon itself to try to one-up Allergan.

⁴ Press Release, Allergan, Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS® Patents (Sep. 8, 2017) (published on Allergan’s website). The *inter partes* review process is a point of contention for drug companies. Pharmaceutical companies contend that the IPR process allows for unnecessary increases in the amount of litigation they have to defend against. Competing drug companies still have other routes for invalidating the patent in federal court. However, the IPR process is a quicker process with a higher success rate. Over fifty percent of patents challenged before the PTAB are invalidated. Rephrase and cite

⁵ *Id.*

license to continue producing and profiting from Restasis.⁶ By shielding Restasis from any IPR challenges, other drug companies will have one less option for invalidating the patent and opening up the market for generics.⁷

In an opinion from the Eastern District of Texas, the court had to determine whether to join the Saint Regis Mohawk Tribe to a suit between Allergan, the plaintiff, and competitor TEVA, the defendant.⁸ The court questioned the validity of Allergan's arrangement with the tribe on multiple grounds, including questioning whether there was a valid contract between Allergan and Regis, or if the transfer was a sham and the contract was void due to lack of valid consideration.⁹ The court ultimately did not have to decide on this issue, leaving it for the PTAB to decide at a later date.¹⁰ While there may be a valid issue with the patent transfer in this case, for the purposes of this article, I will assume that the contract was valid.

Allergan and the Tribe made this deal following a decision by the PTAB in early 2017 that held that state entities are protected from IPR due to their sovereign immunity.¹¹ Presumably, they assumed that the sovereign immunity rights given to state entities would extend to tribal sovereign immunity. This comment will analyze the basis of sovereign immunity rights of tribes and then discuss whether this arrangement violates United States antitrust laws.

II. TRIBAL SOVEREIGN IMMUNITY

⁶ *Id.*

⁷ Currently, the two main process available are the *inter partes review* process and actions available through the Hatch-Waxman Act. See discussion *infra* Part IV.

⁸ *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *1 (E.D. Tex. Oct. 16, 2017).

⁹ *Id.* at *3.

¹⁰ *Id.* at *4-5.

¹¹ *Covidien LP v. Univ. of Florida Research Found.*, Nos. IPR2016-01274, IPR2016-01275, IPR2016-01276, 2017 WL 4015009 (P.T.A.B. Jan. 25, 2017).

The foundation of any tribal sovereignty analysis begins with the Constitution, which states that Congress shall have the power “[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”¹² Conflict between the tribes and the United States has been along for longer than the nation has actually been a nation.¹³ Thus, trying to navigate the extent of the relationship between our nation and the tribal nations has been going on for over two hundred years: initially in treaties and later in congressional acts.¹⁴ Congress’ right to regulate the tribes was described in *Lone Wolf v. Hitchcock*.¹⁵ The Court stated, “Plenary authority over the tribal relations of the Indians has been exercised by Congress from the beginning.”¹⁶

The foundational cases establishing a general concept of tribal sovereign immunity were written in the early 1800s, and taken together, they are referred to as “The Marshall Trilogy.”¹⁷ The first of these cases, *Johnson v. M’Intosh*, established that the tribes possessed rights shy of complete sovereignty.¹⁸ Because they were akin to “independent nations” they had the right to occupy their lands and “use it according to their own discretion,” but the official title to the land belonged to the United States government.¹⁹

Then, in *Cherokee Nation v. Georgia*, the state of Georgia sought to seize the lands of the Cherokee nation and enforce certain laws against the tribe.²⁰ The Cherokee people brought suit in the Supreme Court, arguing that the Supreme Court had jurisdiction over controversies arising

¹² U.S. CONST. art. I, § 8, cl. 8.

¹³ Andrea M. Seielstad, *The Recognition and Evolution of Tribal Sovereign Immunity Under Federal Law: Legal, Historical, and Normative Reflections on a Fundamental Aspect of American Indian Sovereignty*, 37 TULSA L. REV. 661, 683-84 (2002).

¹⁴ *Lone Wolf v. Hitchcock*, 187 U.S. 553, 566 (1903).

¹⁵ *Id.* at 565.

¹⁶ *Id.*

¹⁷ Seielstad, *supra* note 13, at 686.

¹⁸ *Johnson v. M’Intosh*, 21 U.S. 543, 574 (1823).

¹⁹ *Id.*

²⁰ *Cherokee Nation v. Georgia*, 30 U.S. 1, 15 (1831).

between states and foreign states.²¹ The Court rejected the Cherokee nation's argument that they were a foreign state.²² Rather, the Court contended that there was a "peculiar" relationship between the United States and the tribe that was unlike anything else in existence.²³ The tribes relied on the U.S. government for protection, trade, and were granted some representation in Congress, when deemed appropriate.²⁴ Because of this unique relationship, the Cherokee nation could not be considered a foreign nation as it was meant by the Constitution.²⁵ Rather, the Tribes were more appropriately designated "domestic dependent nations" because the United States was essentially their guardians while the nations were merely the nation's wards.²⁶

The last case in the trilogy, *Worcester v. Georgia*, came about after Georgia again attempted to enforce its laws against a member of the Cherokee Nation.²⁷ However, the Court found that the Cherokee nation was "a distinct community occupying its own territory, with boundaries accurately described, in which the laws of Georgia can have no force."²⁸ The regulation of the tribe was "committed exclusively to the government of the union."²⁹ Therefore, only the federal government could exercise any power over the tribe, and the state in which the tribe resided, had no regulatory authority.

Based on this initial framework that was laid out in these earlier cases, the court in *Turner v. United States*, declared that "the Creek Nation was free from liability for injuries to persons or property due to mob violence or failure to keep the peace" after tribal members destroyed the fence

²¹ *Id.* at 16.

²² *Id.* at 19-20.

²³ *Id.* at 16-17.

²⁴ *Id.* at 17.

²⁵ *Id.* at 19-20.

²⁶ *Id.* at 17.

²⁷ *Worcester v. Georgia*, 31 U.S. 515, 537-38 (1832).

²⁸ *Id.* at 561.

²⁹ *Id.*

of a neighboring property.³⁰ No liability could exist against the tribe without authorization from Congress, or consent from the tribe, because the Creek Nation was “a distinct political community.”³¹ However, the Court at the time declined to adopt a full sovereign immunity doctrine, stating, “The fundamental obstacle to recovery is not the immunity of a sovereign to suit, but the lack of a substantive right to recover the damages resulting from failure of a government or its officers to keep the peace.”³²

Finally, in 1940, the Supreme Court, for the first time, talked explicitly of the immunity of the tribal nations, resting on the holding in *Turner*.³³ The Court held that the tribes possessed an immunity from any direct suit or cross suit absent Congressional authorization.³⁴ The Court reaffirmed the tribal sovereign immunity doctrine in 1977 stating, “Absent an effective waiver or consent, it is settled that a state court may not exercise jurisdiction over a recognized Indian tribe.”³⁵

Despite this seemingly settled doctrine, the Supreme Court has recently called into question the continuation of this policy.³⁶ The Court in *Kiowa Tribe of Oklahoma v. Manufacturing Technologies, Inc.* expressed that perhaps *Turner* was never intended to be the basis for a doctrine of tribal immunity, but the doctrine only evolved because later Courts kept citing to it with little analysis.³⁷ The Court criticized the continuance of the doctrine, arguing that its relevance in the modern world was questionable.³⁸ Nevertheless, the Court upheld the doctrine.³⁹ The Court

³⁰ *Turner v. United States*, 248 U.S. 354, 357-58 (1919).

³¹ *Id.* at 357-59.

³² *Id.* at 358.

³³ *United States v. United States Fidelity & Guaranty Co.*, 309 U.S. 506, 512 (1940).

³⁴ *Id.* 512-13.

³⁵ *Puyallup Tribe, Inc. v. Dept. of Game of State of Washington*, 433 U.S. 165, 172 (1977).

³⁶ *Kiowa Tribe of Oklahoma v. Manufacturing Technologies, Inc.*, 523 U.S. 751, 757 (1998).

³⁷ *Id.*

³⁸ *Id.* at 757-58.

³⁹ *Id.* at 759.

recognized Congress' right to regulate tribal policy and deferred to Congress to make any changes to the currently standing doctrine.⁴⁰ However, acts of Congress since *Kiowa* have done little to disturb the tribal immunity doctrine.⁴¹

This tribal sovereign immunity is different from what is enjoyed by the states, which are granted their immunity under the Eleventh Amendment.⁴² While both types of sovereignties are generally immune from suit by private parties, there are a few important distinctions. There are only two circumstances that allow an *individual* to sue a State.⁴³ "First, Congress may authorize such a suit in the exercise of its power to enforce the Fourteenth Amendment . . . Second, a State may waive its sovereign immunity by consenting to suit."⁴⁴ This is a broader interest than the tribes because tribes can also have their immunity abrogated by Congress, whereas states generally cannot.⁴⁵ However, tribes are immune from suit by states, whereas states are not immune from suit by sister states.⁴⁶

What makes the States' surrender of immunity from suit by sister States plausible is the mutuality of that concession. There is no such mutuality with either foreign sovereigns or Indian tribes . . . as it would be absurd to suggest that the tribes surrendered immunity in a convention to which they were not even parties.⁴⁷

This difference between the two entities can perhaps explain the different outcomes tribes and states have had at the PTAB when trying to use a sovereign immunity argument.

⁴⁰ *Id.* As suggested by one author, the Court at the time knew that Congress was in the process of reconsidering the tribal sovereign immunity doctrine and may have ruled as it did thinking Congress would remedy the situation on its own. Seielstad, *supra* note 13, at 665-66.

⁴¹ See e.g., Indian Tribal Economic Development and Contracts Encouragement Act of 2000 (Public Law 106-179 Mar. 14, 2000). This legislation increased the clarity with which contracts with tribes must be made to avoid issues with sovereign immunity upon a breach of the agreement. *Id.*

⁴² "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. CONST. amend. XI.

⁴³ *College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 670 (1999).

⁴⁴ *Id.*

⁴⁵ See e.g., discussion *infra* Part III.

⁴⁶ *Blatchford v. Native Village of Noatak and Circle Village*, 501 U.S. 775, 782 (1991).

⁴⁷ *Id.* (explaining that the tribes never surrendered their immunity from suit because they were not present at the Constitutional Convention).

III. SOVEREIGN IMMUNITY AND INTELLECTUAL PROPERTY

As previously established, tribal sovereign immunity can only be abrogated by Congress or an express waiver by the tribe.⁴⁸ There are quite a few areas where Congress has used its authority to limit tribal immunity (e.g., murder, kidnapping, arson),⁴⁹ but intellectual property is not one of them.

However, Congress did pass two acts attempting to abrogate *state* sovereign immunity with respect to patents and trademarks: the Trademark Remedy Clarification Act of 1992 (TRCA)⁵⁰ and the Patent and Plant Variety Protection Remedy Clarification Act (PRCA).⁵¹ Prior to the TRCA, individuals did not have a private right of action against a state that misrepresented its product in violation of section 43(a) of the Trademark Act of 1946.⁵² By enacting the TRCA, Congress intended to extend the phrase “[a]ny person” in section 43(a) to include state entities, thus abrogating the immunity of the states with regard to trademark infringement.⁵³ Similarly, the PRCA was enacted to abrogate state immunity with regard to patent infringement.⁵⁴ In two sister cases, the Supreme Court addressed the validity of these acts after a claim that a Florida state entity falsely represented its product in violation of section 43⁵⁵ and infringed on College Savings Bank’s patent.⁵⁶ In both of these instances, the Court held that Congress did not have the power to abrogate

⁴⁸ See discussion *infra* Part II.

⁴⁹ USC § 1153(a) (2012).

⁵⁰ Trademark Remedy Clarification Act, Pub. L. No. 102-542, 106 Stat. 3567 (1992)

⁵¹ Patent and Plant Variety Protection Remedy Clarification Act, Pub. L. No. 102-560, 106 Stat. 4230 (1992).

⁵² “Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), enacted in 1946, created a private cause of action against ‘[a]ny person’ who uses false descriptions or makes false representations in commerce.” *College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 670 (1999).

⁵³ *Id.*

⁵⁴ *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 630 (1999).

⁵⁵ *College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 671 (1999).

⁵⁶ *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 630 (1999).

the state's sovereign immunity.⁵⁷ These cases seemed to suggest that where intellectual property rights had been infringed upon, sovereign immunity would prevail.

Even more recently, the PTAB held that state entities were protected from *inter partes review* due to their sovereign immunity.⁵⁸ The PTAB held that the Eleventh Amendment “limit[ed] not only the judicial authority of the federal courts to subject a state to an unconsented suit, but also preclude[d] certain adjudicative administrative proceedings.”⁵⁹ The holding in *Covidien* applied not only to the state of Florida proper but also extended to any state agents or instrumentalities, which included the University of Florida's research foundation.⁶⁰

It seems that Allergan was emboldened by the PTAB's decision in *Covidien* because less than a year after that decision came out, Allergan put out its press release announcing the transfer of its patent to the Regis Mohawk Tribe.⁶¹ This may have been a gamble that was not worth its initial \$13.75 million price tag (not to mention the additional \$15 million per year in royalties)⁶² because the PTAB rejected the tribe's argument that tribal sovereign immunity applied to the *inter partes review* proceedings and declared Allergan was still the owner for purposes of the proceedings.⁶³ In coming to this decision, the PTAB recognized that the tribe was a “domestic

⁵⁷ *Id.* at 647; *College Sav. Bank*, 527 U.S. at 691.

⁵⁸ *Covidien LP v. Univ. of Florida Research Found.*, Nos. IPR2016-01274, IPR2016-01275, IPR2016-01276, 2017 WL 4015009, *17 (P.T.A.B. Jan. 25, 2017). It should, however, be noted that future PTAB decisions are typically not bound by *stare decisis* in the same manner as the judiciary branch of the government. USPTO, *PTAB's Designations for Opinions* (Jan. 12, 2016), <https://www.uspto.gov/sites/default/files/documents/PTAB%20Designations%20for%20Opinions%201-12-2016.pdf>. This lack of consistency when issuing opinions is another source of frustration between industry professionals and the PTAB – without *stare decisis*, practitioners are left guessing about what the outcome will be at the PTAB. See e.g., Kate Gaudry & Thomas Franklin, *Only 1 in 20,631 ex parte appeals designated precedential by PTAB* (Sep. 27, 2015), <http://www.ipwatchdog.com/2015/09/27/only-1-in-20631-ex-parte-appeals-designated-precedential-by-ptab/id=61999/>. The title refers to *ex parte* appeals, but most PTAB decisions are designated as “routine” and therefore non-precedential. *Supra* USPTO.

⁵⁹ *Covidien LP*, WL 4015009 at *4.

⁶⁰ *Id.* at *12.

⁶¹ Allergan Press Release, *supra* note 4.

⁶² *Id.*

⁶³ *Mylan Pharmaceuticals Inc. v. Saint Regis Mohawk Tribe*, Nos. IPR2016-01127, IPR2016-01128, IPR2016-01129, IPR2016-01130, IPR2016-01131, IPR2016-01132, 2018 WL 1100950, *4 (P.T.A.B. Feb. 23, 2018). The PTAB reiterated the doubt expressed in *Kiowa* to help justify its decision to deny the tribal immunity. *Id.* at *10.

dependent nation' that exercise[s] 'inherent sovereign authority'" and that a tribe can only be subjected to suit when explicitly authorized by Congress or when immunity has been waived by the tribe.⁶⁴ However, despite a lack of express abrogation by Congress or waiver by the tribe, the PTAB held that tribal sovereign immunity did not apply in the same manner as state sovereign immunity.⁶⁵

While recognizing the doctrine of tribal immunity, the PTAB considered a line of cases that may indicate that Congress could *impliedly* abrogate immunity when a statute was of general applicability. The Supreme Court held in *Federal Power Commission v. Tuscarora Indian Nation*, that "a general statute in terms applying to all persons includes Indians and their property interests."⁶⁶ The Court further noted that acts of general applicability will apply to tribes unless there is "a clear expression [of Congress] to the contrary."⁶⁷ This case looked at whether licensees of the Federal Power Commission had power to "take lands owned by Indians, as well as those of all other citizens, when needed for a licensed project, upon the payment of just compensation."⁶⁸ While the Supreme Court appeared to only hold with reference to *actual* property rights, the PTAB took this ruling and applied it to *intellectual* property rights⁶⁹ and held that the Patent Act was a general act with which the tribe was required to comply.⁷⁰

⁶⁴ *Id.* at *7.

⁶⁵ *Id.* at *4-6.

⁶⁶ *Federal Power Commission v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960).

⁶⁷ *Id.* at 120.

⁶⁸ *Id.* at 123.

⁶⁹ Actual property rights and intellectual property rights are not exactly analogous bodies of law. *See e.g.*, Andrew Lee, *Intellectual Property, Moral Rights, and Social Utility: A Classically Liberal Exploration of the Normative and Practical Implications of Intellectual Property Rights*, 7 N.Y.U. J.L. & LIBERTY 431, 432-33 (2013) ("The protection of intellectual property creates interesting problems for scholars and lawmakers who, despite their devotion to the preservation of physical property rights, nonetheless feel that intellectual property rights represent a set of concerns and principles that can be quite distinct from those evoked by ownership of a plot of land or a bag of gold.").

⁷⁰ *Mylan Pharmaceuticals*, WL 1100950 at *4-6.

A prominent case extending the holding of *Federal Power Commission* beyond property rights is *Donovan v. Coeur d'Alene Tribal Farm*.⁷¹ In this case, an Occupational Safety and Health Administrator (OSHA) compliance officer found twenty-one health and safety violations at the Coeur d'Alene Tribal Farm, which was wholly owned and operated by the Coeur d'Alene Indian Tribe.⁷² The Tribe did not argue the validity of the violations but instead argued that they had tribal immunity from any liability under the Occupational Safety and Health Act.⁷³ The Ninth Circuit Court of Appeals held that Congress limited the Tribe's immunity when it created this Act because it was of general applicability to all "employers."⁷⁴ The court noted three exceptions to this rule that general acts should apply to Tribes equally as to any other body:

(1) the law touches 'exclusive rights of self-governance in purely intramural matters'; (2) the application of the law to the tribe would 'abrogate rights guaranteed by Indian treaties'; or (3) there is proof 'by legislative history or some other means that Congress intended [the law] not to apply to Indians on their reservations.'⁷⁵

This reasoning has been applied with mixed results in different circuits.⁷⁶

The PTAB's decision that patent laws are generally applicable and thus abrogate the tribe's sovereign immunity is not entirely novel. However, this argument has not been addressed in a patent law context by the Supreme Court, and the lower courts that have heard such claims have typically found the argument lacking. For example, in *Microlog Corp. v. Continental Airlines, Inc.*, the court held that "[t]he Patent Act, though authorizing civil actions for infringement, does

⁷¹ *Donovan v. Coeur d'Alene Tribal Farm*, 751 F.2d 1113 (1985).

⁷² *Id.* at 1114.

⁷³ *Id.* at 1115.

⁷⁴ *Id.*

⁷⁵ *Id.* at 1116 (quoting *United States v. Farris*, 624 F.2d 890, 893-94 (9th Cir. 1980).

⁷⁶ See e.g., *Donovan v. Navajo Forest Prods, Indus.*, 692 F.2d 709, 711-12 (10th Cir. 1982) (holding that OSHA did not apply to the Navajo Tribe because it violated treaty rights to exclude non-Indians from tribal property, interfered with tribal sovereignty and self-government, and the general applicability language was not strong enough to abrogate rights granted by treaties); *EEOC v. Cherokee Nation*, 871 F.2d 937 (10th Cir. 1989) (holding that the EEOC did not have authority over the Cherokee Nation because the tribe had a "treaty-protected right of self-government," and the statute did not expressly abrogate the treaty rights).

not unequivocally abrogate an Indian Tribe's immunity from suit for patent infringement."⁷⁷ The court in *Specialty House of Creation, Inc. v. Quapaw Tribe of Oklahoma* took the analysis one step further and argued that the fact that Congress did not include tribes as possible infringing parties in the PRCA "[d]espite providing specifically for waiver of state sovereign immunity" demonstrated that Congress had not unequivocally waived any tribal sovereign immunity.⁷⁸

IV. EVEN IF ALLERGAN WERE TO SUCCESSFULLY APPEAL THE PTAB'S RECENT DECISION, IT SHOULD STILL FACE CONSEQUENCES UNDER UNITED STATES ANTITRUST LAW

A patent-owner essentially has a government-sanctioned monopoly over its product for the life of the patent.⁷⁹ The importance of stimulating discovery and invention was recognized by the Constitution, which granted Congress the power "[t]o promote 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."⁸⁰ This is exemplified under Section 154 of the Patent Act, which states that a patent-holder has "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a period of twenty years from the date of filing the application.⁸¹ As part of the system that grants these monopolies, the government has set up certain systems to regulate, including the *inter parte review* system through the PTAB.

⁷⁷ *Microlog Corp. v. Cont'l Airlines, Inc.*, No. 6:10-CV-260, 2011 WL 13141413, at *2 (E.D. Tex. Jul. 22, 2011).

⁷⁸ *Specialty House of Creation, Inc. v. Quapaw Tribe of Oklahoma*, No. 10-CV-371-GKF-TLW, 2011 WL 308903, at *1 (Jan. 27, 2011). The Second Circuit also conducted a similar analysis when analyzing a copyright infringement case against the Mashantucket Pequot Tribe. The court held that the Tribe enjoyed immunity from copyright infringement claims because the Copyright Act does not expressly abrogate tribal immunity. Further stating, "the fact that a statute applies to Indian tribes does not mean that Congress abrogated tribal immunity in adopting it." *Bassett v. Mashantucket Pequot Tribe*, 204 F.3d 343, 357 (2d Cir. 2000).

⁷⁹ See *FTC v. Actavis, Inc.*, 570 U.S. 136, 148 (2013).

⁸⁰ U.S. Const. art. I, § 8, cl. 8.

⁸¹ 35 USC § 154.

The *inter partes review* process was created as part of an effort by Congress create a “quicker resolution to patent disputes than litigation.”⁸² This process allows a party to challenge the validity of an existing patent and, if the PTO finds “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims,” an adjudicatory hearing will take place before the PTAB.⁸³ By statute, the PTAB must make a final decision within twelve to eighteen months (a relatively quick resolution).⁸⁴ This has been a popular process for patent challengers because the system is set up in their favor, with a lower burden of proof, easier standard of review, and greater deference to the PTAB decision, than previous invalidation processes.⁸⁵ It has been unpopular with patent-holders for that same reason. From the time of enactment in 2011 through June 30, 2016, there were 1046 completed trials: 85.66% invalidated at least one patent claim, and 70.36% invalidated all patent claims.⁸⁶

Further, the *inter partes review* system is widely criticized within the pharmaceutical industry as being largely duplicative of the Hatch-Waxman Act. The Hatch-Waxman Act made it easier for companies that produce generic drugs to enter the market before the branded drug’s patent has expired because it provides another route for the generic companies to challenge the validity of the brand-named drug.⁸⁷ By enacting this, Congress hoped “to make available more low cost generic drugs.”⁸⁸ The frustration of pharmaceutical companies in having to defend their patents on both of these fronts (as success or failure in federal district court under the Hatch-

⁸² Joanna Shepherd, *Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Partes Review*, 6 N.Y.U. J. OF INTELL. PROP. & ENT. LAW 14, 31 (2016).

⁸³ *Id.* at 32-33.

⁸⁴ *Id.* at 33.

⁸⁵ *Id.* at 33-36.

⁸⁶ *Id.* at 33.

⁸⁷ Jennifer E. Sturiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 Ala. L. Rev. 59, 62-63 (2017).

⁸⁸ House Report No. 98-857(1).

Waxman Act does not preclude the same litigation from being repeated in front of the PTAB⁸⁹) has led to contention and can perhaps partially explain why Allergan took such a drastic measure to avoid the *inter partes review* process.⁹⁰

Despite the fact that the granting of a patent establishes what is essentially a monopoly, patent-holders still must strike a balance between their patent-monopoly and any applicable antitrust laws.⁹¹ The most applicable law to the discussion of the actions at question here is the Sherman Act. Section 1 of the Sherman Act states, “Every contract . . . or conspiracy, in restraint of trade or commerce among the several States . . . is hereby declared to be illegal.”⁹² Section 2 of the Sherman Act states, “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony.”⁹³

There are two types of analysis that courts use to assess if a party has operated in violation of the Sherman Act. The evaluating body will either use a *per se* analysis or a rule of reason analysis.⁹⁴ A *per se* analysis is used where a restraint on trade is “so plainly anticompetitive” that there is no need for “an elaborate inquiry into the restraint’s likely competitive effect.”⁹⁵ This is typically reserved for situations such as “naked price-fixing, output restraints, and market division among horizontal competitors, as well as certain group boycotts.”⁹⁶ Most challenges in intellectual

⁸⁹ See Sturiale, *supra* note 87, at 86.

⁹⁰ See Sy Mukherjee, *Botox Maker Allergan’s CEO Defends Selling Drug Patents to Native American Tribe to Thwart Rivals*, FORTUNE.COM, www.fortune.com/2017/09/09/allergan-drug-patents-native-american/ (Sep. 9, 2017) (where Allergan’s CEO and chief legal officer argued that parties in patent disputes have to overcome a “double jeopardy” in defending their patents).

⁹¹ Glen P. Belvis, *Intellectual Property in Business Transactions* § 6.07 The Interaction of Patent and Antitrust Law (Law Journal Press 2018).

⁹² 15 U.S.C. § 1 (2012).

⁹³ 15 U.S.C. § 2 (2012).

⁹⁴ U.S. DOJ and FTC, Antitrust Guidelines for the Licensing of Intellectual Property, 16-17 (Jan. 12, 2017).

⁹⁵ *Id.* at 17.

⁹⁶ *Id.*

property will require a rule of reason analysis.⁹⁷ This will require an assessment of “whether the restraint is likely to have anticompetitive effect and, if so, whether the restraint is reasonably necessary to achieve procompetitive benefits that outweigh those anticompetitive effects.”⁹⁸

However, patents present a unique challenge to antitrust analysis because “[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition.”⁹⁹ This analysis issue has arisen in another pharmaceutical arrangement that has drawn criticism as being against the Sherman Act: “reverse payment” settlements aka “pay-to-delay” schemes.¹⁰⁰ The issues with this type of arrangement was well-described by the Supreme Court in *FTC v. Actavis, Inc.*¹⁰¹ The Court explained:

Company A sues Company B for patent infringement. The two companies settled under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent’s term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement is often called a “reverse payment” settlement agreement.¹⁰²

In *FTC*, the Court noted that this arrangement occurs mostly “in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer . . . to challenge the validity of a patent owned by an already-approved brand-name drug owner.”¹⁰³

⁹⁷ *Id.* at 16.

⁹⁸ *Id.* at 17.

⁹⁹ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065-66 (11th Cir. 2005).

¹⁰⁰ See e.g., *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298, 1301 (11th Cir. 2012) (explaining that in “pay for delay” or “reverse payment” arrangements, “a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor”).

¹⁰¹ *FTC v. Actavis, Inc.*, 570 U.S. 136 (minority held that “[a] patent carves out an exception to the applicability of antitrust laws.”)

¹⁰² *Id.* at 140.

¹⁰³ *Id.*

The Eleventh Circuit Court of Appeals that heard *FTC v. Actavis* prior to the Supreme Court held that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”¹⁰⁴ This holding essentially protected reverse payments from antitrust challenges. However, on appeal, the Supreme Court rejected that idea because the Sherman Act “imposes strict limitations on the concerted activities in which patent owners may lawfully emerge,”¹⁰⁵ and these arrangements have the “potential for genuine adverse effects on competition.”¹⁰⁶

The Court concluded that the rule of reason analysis that applies to any other type of antitrust litigation, must also apply when assessing an arrangement where one party is a patent-holder.¹⁰⁷ It also noted that the Hatch-Waxman Act itself, which was clearly procompetitive, ran contrary to the Court of Appeals’ conclusion that reverse payment schemes should be immune from antitrust attack.¹⁰⁸ The Court remanded for further proceedings but suggested some areas where the lower court might find anticompetitive effects as part of its analysis.¹⁰⁹ The Court noted that only *valid* patents had a right to exclude others from use; “an *invalidated* patent carries with it no such right.”¹¹⁰ However, if the reverse payment scheme is allowed to stand without further analysis, it is possible that the patent-monopoly will be allowed to continue, at the expense of the consumer, even though the patent may in fact be invalid.¹¹¹ Also, the Court questioned whether a large

¹⁰⁴ *FTC v. Watson*, 677 F.3d at 1312.

¹⁰⁵ *FTC v. Actavis*, 570 U.S. at 149 (quoting *United States v. Slinger Mfg.*, 374 U.S. 174, 197 (1963)).

¹⁰⁶ *Id.* at 154 (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460-61 (1986)).

¹⁰⁷ *Id.* at 156.

¹⁰⁸ *Id.* at 152.

¹⁰⁹ *Id.* at 154-57.

¹¹⁰ *Id.* at 147 (emphasis in original).

¹¹¹ *Id.* at 153-54.

reverse payment might demonstrate that the patentee was charging prices that were “higher than the competitive level,” referring to the FTC’s claim that “reverse payment agreements are associated with the presence of higher-than-competitive profits.”¹¹² The Court acknowledged that the patentee may be able to justify the large reverse payment, making it a permissible settlement agreement, but there was no immunity preempting the parties from having to demonstrate this kind of analysis.¹¹³

While looking at settlement arrangements between brand-named patent holders and generic-brand would-be competitors is not an exact equivalent to the arrangement between Allergan and the Regis Mohawk Tribe, the Court’s logic still seems very applicable. Despite the fact that Allergan had a patent that it would normally be free to assign or use in any other manner it found suitable, the patent should not provide complete immunity because the Sherman Act “imposes strict limitations on the concerted activities in which patent owners may lawfully engage.”¹¹⁴ Thus, it must be determined if the arrangement between Allergan and the Tribe, “is likely to have anticompetitive effect and, if so, whether the restraint is reasonably necessary to achieve procompetitive benefits that outweigh those anticompetitive effects” using a rule of reason analysis.¹¹⁵

The anticompetitive effects seem obvious and significant. Allergan has not tried to cover up the fact that the sole reason for the arrangement with the Tribe was to avoid having its patent invalidated, which would result in the market opening up for generic drug-makers to enter. These actions were intended to prolong the patent-monopoly beyond what might have been otherwise allowable – this is the epitome of an anticompetitive arrangement.

¹¹² *Id.* at 157.

¹¹³ *Id.* at 158.

¹¹⁴ *Id.* at 149 (quoting *United States v. Slinger Mfg.*, 374 U.S. 174, 197 (1963)).

¹¹⁵ See U.S. DOJ and FTC, Antitrust Guidelines for the Licensing of Intellectual Property, 17 (Jan. 12, 2017).

Also, as suggested by the Court in *FTC*, an invalid patent has no right to any patent protection. By circumventing the system that seeks to determine the validity of the patent, a patent-monopoly may be extended to a product that is not actually deserving of such protection. The possibility that an invalid patent for the brand-name drug is allowed to stand and continue to exclude generics from entering into the market is plainly anticompetitive.

Finally, the Court in *FTC* questioned whether the presence of a large reverse payment demonstrated that the patentee was charging prices that were “higher-than-competitive.” A similar question could be asked of Allergan’s drug pricing given that it was willing and able to pay the Regis Mohawk Tribe a substantial sum of money to take over its patent. If no legitimate explanation can be offered by Allergan, it is possible that this “sale” might be demonstrative of a severe anticompetitive effect.

The procompetitive benefits are less obvious, but they do exist. Typically, licensing agreements are favored because they tend to allow more people access to the patent.¹¹⁶ Furthermore, the Native American population is a group that has historically discriminated against and disenfranchised.¹¹⁷ The Tribe has retained rights in this agreement to “practice the patents for research, education, and other non-commercial uses.”¹¹⁸ Theoretically, if the Tribe took advantage of these rights, the Tribe could have an opportunity to gain valuable experience and become a competitive player in the market. These potential

¹¹⁶ *Id.* at 5-7.

¹¹⁷ See e.g., Jeremiah A. Bryar, *What Goes Around, Comes Around: How Indian Tribes Can Profit in the Aftermath of Seminole Tribe and Florida Prepaid*, 13 MARQ. INTELL. PROP. L. REV. 229, 230 (2009). This article suggests that the creation of “sovereign chartered research groups [would] drive additional funding into the tribes, create jobs for tribal members, and bring hope into the lives of a people who desperately need it.” *Id.* at 248.

¹¹⁸ *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *15 (E.D. Tex. Oct. 16, 2017).

benefits could be a serious benefit to the Tribe, but there is nothing that indicates the Tribe has any intention to take advantage of them.

The anticompetitive effects are clearly unreasonable, even considering any possible procompetitive benefits. They run counter to the purpose of two large acts of Congress that attempted to curb such effects. The Hatch-Waxman Act was clearly intended to allow generics to enter the market sooner, and the *inter partes review* proceedings functions to invalidate patents in an expedient manner. The arrangement between Allergan and the Tribe was an attempt to dodge these restraints that Congress enacted upon the patent-monopoly.

Despite the analysis weighing towards a violation of the Sherman Act, there is of course still a question of whether the Tribe would attempt to shield itself behind its tribal sovereign immunity. Given the perceived egregiousness of this arrangement, it seems very possible that (if this were to reach the Supreme Court), the Court would use this occasion to act on the doubts it expressed in *Kiowa* about the continued benefit of tribal immunity in a modern world. Even if the Tribe were found to be protected, Allergan would have no such protection and could still be held responsible for its actions. The punishment of the one party would still be enough to deter any similar arrangements in the future.

V. CONCLUSION

Congress could address these issues to prevent any such instances in the future. The case law is clear: Congress can abrogate the tribal immunity with respect to patent (and other intellectual property law) – it just has to do so in a manner that is unequivocal. Perhaps taking such actions would prevent similar unscrupulous business decisions in the future. If Congress has purposefully not abrogated tribal immunity with respect to intellectual property law for whatever

reason,¹¹⁹ it could also stipulate that tribal immunity applies where the Tribe was the inventor or rightfully obtained rights to a patent (i.e., through purchasing the rights; not for being paid to hold onto the rights). But “sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities.”¹²⁰ In the absence of such Congressional action, this arrangement should be recognized for what it is – an attempt to bypass current patent laws at the expense of the public that depends on critical drugs and a violation of U.S. antitrust law.

¹¹⁹ And there are legitimate reasons. American tribal relations are notably tainted by a sordid past, and there are situations where sovereign immunity is an important right. However, one could hardly argue that the intention behind creating a tribal immunity policy was to grant tribes the right to collude with powerful industry players to circumvent antitrust laws.

¹²⁰ *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *12 (E.D. Tex. Oct. 16, 2017).