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Tribal Sovereign Immunity as a Defense in Overcoming IPR Challenges of Brand Name Pharmaceutical Patent Validity at PTAB—Effects on the Industry

Elana Williams*

INTRODUCTION

Tribal sovereignty has been recognized by the American government since the establishment of the United States and tribal sovereign immunity has been a part of American jurisprudence for over a century.¹ Tribal sovereign immunity continues to play an important role in modern times, especially in the last few years with the rise of *inter partes* review (IPR) proceedings stemming from the America Invents Act of 2011.² IPR proceedings are filed with the United States Patent and Trademark Office (USPTO) and heard by the Patent Trial and Appeal Board (PTAB) as an alternative to or in conjunction with traditional patent litigation in the U.S. Court of Appeals for the Federal Circuit.³ Therefore, patent owners may have to defend their patents both at PTAB and in federal court.⁴

This is especially true as this situation plays out in the pharmaceutical industry. Under the Drug Price Competition and Patent Restoration Act of 1984 (the Hatch-Waxman Act), patent holders face a congressionally mandated validity review process established to balance the protection of innovation while also facilitating the entrance of low-cost drug alternatives into the market.⁵ The Hatch-Waxman Act allows a pharmaceutical manufacturer to file an abbreviated new drug application (ANDA) with the U.S. Food and Drug Administration (FDA) to produce a low-cost generic version of a patented brand name drug.⁶ In order to do this, the generic manufacturer must include a Paragraph IV certification in its application, which

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¹ 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 (2002).

² Caleb A. Bates, Peter Law & Eric Furman, *Sovereign Immunity and Inter Partes Review*, KNOBBE MARTENS (Oct. 17, 2017), <https://www.knobbe.com/news/2017/10/sovereign-immunity-and-inter-partes-review>.

³ *Id.*

⁴ *Id.*

⁵ Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

⁶ *Id.*

declares that the patents covering the drug at issue are unenforceable and invalid.⁷ The generic companies may also file a petition for IPR with PTAB on issues of invalidity.⁸

PTAB has recently granted its first motion to consider the issue of tribal sovereign immunity as it relates to patents covering the branded drug Restasis®.⁹ This case involves two giants of the pharmaceutical industry: Allergan PLC (Allergan), a brand name drug manufacturer who holds the Restasis® patents, and Mylan N.V. (Mylan), a generic pharmaceutical company.¹⁰ Mylan challenged Allergan's patents covering Restasis® in a district court where a federal judge invalidated the patents on obviousness grounds.¹¹ Mylan also filed a petition with PTAB for IPR in relation to these patents.¹² Prior to the district court ruling and after PTAB granted the petition for IPR, Allergan made a controversial licensing deal with the Saint Regis Mohawk Tribe of New York state (the "Tribe").¹³ Under this deal, Allergan transferred its patents for Restasis® to the Tribe and then licensed them back exclusively for a substantial amount of money in order to assert the Tribe's sovereign immunity as a defense against IPR challenges.¹⁴ This transaction has been widely debated with some applauding the move as innovative and others ardently condemning it as a blatant delay tactic. Although the district court judge has already issued an opinion regarding the Restasis® patents, PTAB has recently extended their statutory deadline for issuing its final written decision from December 8, 2017 to April 6, 2018.¹⁵

This Note will discuss the dual IPR and federal court system in place for reviewing the validity of patents and examine the discourse within the industry surrounding the *Mylan v. Allergan* case. This analysis will offer insight into the future of IPR challenges in the pharmaceutical context. Section I will provide relevant background information surrounding the issues affecting challenges of patent validity and implications of tribal sovereign immunity for generic pharmaceutical companies. Section II will examine a case study involving two pharmaceutical giants, *Allergan* and *Mylan*, which demonstrates the issues discussed

⁷ *Id.*

⁸ 35 U.S.C. §§ 311–19 (2016).

⁹ King L. Wong, *Indian Tribal Sovereign Immunity Asserted in an IPR*, LEXOLOGY (Sept. 25, 2017), <https://www.lexology.com/library/detail.aspx?g=8646562b-50af-4668-ae72-2df6e814b69a>.

¹⁰ Bates et al., *supra* note 2.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ 35 U.S.C. § 316(a)(11) (2016) (PTAB must issue a final determination in an IPR no later than one year after the date of a decision to grant the IPR petition. If there is good cause, PTAB may extend the deadline by no more than six months.).

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in Section I. Section III will focus on the industry split regarding these issues and argue that tactics that attempt to gain patent protection for brand name drugs after statutory coverage has expired, like the one employed by Allergan, are detrimental to the balance that Congress endeavors to maintain between innovation and the entrance of low-cost drug alternatives to the pharmaceutical market.

I. BACKGROUND

A. *Issues Affecting Challenges of Patent Validity*

The United States Patent and Trademark Office (USPTO) was formed on September 16, 2012 as part of the America Invents Act and is the federal agency responsible for granting U.S. patents and registering trademarks.¹⁶ The Patent Trial and Appeal Board (PTAB) works within the USPTO.¹⁷ PTAB is composed of administrative patent judges (APJs), a Director and Deputy Director of the USPTO, the Commissioner for Patents, and the Commissioner for Trademarks.¹⁸ APJs are required to be persons of competent legal knowledge and scientific ability, who must have worked, at some point in their professional career, as a patent examiner at the USPTO.¹⁹ APJs are also generally required to have experience working in private practice, other government agencies, or in-house for a corporation and must be able to handle cases in various fields of technology.²⁰ APJs are responsible for adjudicating two different types of cases.²¹ The first type are appeals from adverse decisions by patent examiners for questions of patentability in patent applications.²² PTAB must decide the correctness of the examiner's decision in these cases.²³ The second type are trials under the America Invents Act to determine the patentability of issued patents.²⁴

1. *Inter Partes Review*

In 2012, Congress passed the America Invents Act which created a streamlined procedure, known as *inter partes* review (IPR), for the adjudication of patent

¹⁶ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

¹⁷ 35 U.S.C. § 6(a) (2016).

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Jennifer R. Bush, *Administrative Patent Judges: Not Your Typical Federal Judge*, FENWICK & WEST LLP (July 10, 2014), <https://www.fenwick.com/publications/pages/administrative-patent-judges-not-your-typical-federal-judge.aspx>.

²¹ 35 U.S.C. § 6(b) (2016).

²² *Id.*

²³ *Id.*

²⁴ *Id.*

challenges by the USPTO.²⁵ PTAB has jurisdiction to hear an IPR under 35 U.S.C. § 314(a), which provides that an IPR may be instituted if there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition.²⁶ IPR provides a less expensive and expedited forum for patent litigation than a U.S. district court proceeding.²⁷ The two systems are often used in conjunction with each other.²⁸ IPR maintains its streamlined approach by holding a hearing before three APJs of PTAB rather than having a jury and by focusing on only specific invalidity issues to patents.²⁹ Therefore, no infringement issues or enforceability issues can be addressed in the IPR system.³⁰

The IPR process also must be completed within one year of PTAB's decision to hear the IPR.³¹ Either party who does not agree with PTAB's final ruling on the validity or invalidity of a patent may appeal to the U.S. Court of Appeals for the Federal Circuit, which is the court that oversees every patent appeal in the country.³² Further, the parties may agree to settle at any time as long as PTAB agrees to end the IPR as well.³³ Anyone other than the patent owner may file an IPR.³⁴ This includes everyone from a third party to a competitor, and there is no requirement to show any dispute between the parties.³⁵ For example, if Company A is ready to launch a new product on the market and Company B is a competitor who holds a patent that may block Company A's new product from launching, Company A can file an IPR in order to invalidate Company B's patent and launch its product or vice versa.

2. Tribal Sovereign Immunity

Understanding the concept of sovereignty is a prerequisite to understanding tribal sovereign immunity. Sovereignty is the supreme independent authority within

²⁵ *Summary of the America Invents Act*, AM. INTELL. PROP. L. ASS'N (2017), <http://www.aipla.org/advocacy/congress/aia/Pages/summary.aspx>.

²⁶ 35 U.S.C. § 314(a) (2016).

²⁷ Josh Landau, *Inter Partes Review: Five Years, Over \$2 Billion Saved*, PATENT PROGRESS (Sept. 14, 2017), <https://www.patentprogress.org/2017/09/14/inter-partes-review-saves-over-2-billion>.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Inter Partes Review*, U.S. PAT. & TRADEMARK OFF. (May 9, 2017), <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review>.

³² 35 U.S.C. § 141 (2016).

³³ 35 U.S.C. § 317(a) (2016) (“[A]n inter partes review instituted under this chapter shall be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the Office has decided the merits of the proceeding before the request for termination is filed.”).

³⁴ *Inter Partes Review*, *supra* note 31.

³⁵ 35 U.S.C. § 42.101 (2016).

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a territory.³⁶ The sovereign must have authority or the right to command and be obeyed derived from a mutually acknowledged source of legitimacy from within the community.³⁷ The authority of the sovereign is superior to all other authorities in its domain.³⁸ The sovereign must also occupy territory and the individuals residing in that geographical location must be subject to its authority.³⁹

Tribal sovereignty was recognized as early as the time of European expansion, into what is now the United States of America, through treaties and a legal framework which continued throughout the American Revolution and the establishment of the U.S.⁴⁰ The U.S. is considered a federated state, meaning each state within the U.S. territory has transferred portions of their sovereign powers to the federal government.⁴¹ Federally-recognized tribes are also subject to the authority of the federal government.⁴² That being said, the U.S. government recognizes tribes as domestic sovereign, self-governing nations.⁴³ These tribes maintain a nation-to-nation relationship with the United States and state governments have limited power over tribes.⁴⁴

It is a well-established rule that a federally-recognized Native American tribe is immune from lawsuits by anyone other than the United States, absent the tribe's consent or congressional abrogation.⁴⁵ This common law rule was established through a series of late 19th and early 20th Supreme Court decisions.⁴⁶ In *Turner v. United States*, the Court held that a tribe was barred from personal liability because "like other governments, municipal as well as state, the Creek Nation was free from liability for injuries to persons or property."⁴⁷ Further, the Court stated that "without authorization from Congress, the Nation could not then have been sued in any court; at least without its consent."⁴⁸ However, tribal sovereign immunity is a common-law privilege that is subject to regulation by Congress and not covered under the Eleventh

³⁶ *What is Sovereignty?*, LAW DICTIONARY, <https://thelawdictionary.org/sovereignty> (last visited Mar. 3, 2018).

³⁷ *Id.*

³⁸ *Id.*

³⁹ *What is Territorial Sovereignty?*, *supra* note 36.

⁴⁰ Seielstad, *supra* note 1, at 683.

⁴¹ *Id.* at 669.

⁴² *Id.*

⁴³ *Id.* at 690.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *See Turner v. United States*, 248 U.S. 354 (1919).

⁴⁷ *Id.* at 357–58.

⁴⁸ *Id.* at 358.

Amendment of the U.S. Constitution.⁴⁹ The immunity applies in federal or state court without regard to the relief sought or the nature of the controversy.⁵⁰ This immunity also may be waived by the tribe involved or by undisputed congressional abrogation.⁵¹ Further, the immunity does not extend to actions taken by tribe members acting in their individual capacities, such as tribal officers or employees when they are alleged to have violated federal law.⁵²

B. Implications of Tribal Sovereign Immunity to Generic Pharmaceutical Companies

Understanding of the Hatch-Waxman Act and the ANDA process is required to demonstrate the balance Congress has put in place for brand name manufacturers and generic companies working in the pharmaceutical industry. In order to bring a new drug to market, a brand name drug manufacturer must submit a new drug application (“NDA”) to the Food and Drug Administration (FDA) for approval, which is a long and costly process.⁵³ The NDA must describe aspects like a statement of the drug’s components, scientific data showing that the drug is safe and effective, and proposed labeling describing the uses for which the drug may be marketed.⁵⁴

After the FDA has approved a brand name manufacturer’s drug, the Hatch-Waxman Act provides a pathway for another company to seek permission to market a generic version of the same drug.⁵⁵ The Hatch-Waxman Act allows a generic competitor to file an abbreviated new drug application (“ANDA”) which utilizes the information from a brand name manufacturer’s already approved NDA.⁵⁶ Thus, instead of providing independent evidence of safety and efficacy, an ANDA need only show that the generic drug has the same active ingredients and is biologically equivalent to the brand name drug.⁵⁷ The Act, by allowing the generic drug manufacturer to use the brand name’s approval efforts, speeds up the introduction of low-cost generic drugs to market. Thus, the ANDA process promotes drug competition and provides for inexpensive alternative medications to consumers.

The FDA is not allowed to approve a generic drug that would infringe on a brand name drug manufacturer’s patent, so the timing of an ANDA’s approval

⁴⁹ Clay Smith, *Tribal Sovereign Immunity: A Primer*, 50 *ADVOC.* 19, 20 (2007).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*; see also *Lewis v. Clarke*, 137 S. Ct. 1285 (2017) (where the Supreme Court declined to extend tribal sovereign immunity to a tribal employee sued for damages in his individual capacity).

⁵³ 21 U.S.C. § 355(b)(1) (2016).

⁵⁴ *Id.* §§ 355(b)(1), (d).

⁵⁵ *Id.*

⁵⁶ *Id.* §§ 355(j)(2)(A)(ii), (iv).

⁵⁷ *Id.*

depends on the scope and duration of the patents covering the brand name drug.⁵⁸ To approve generic drugs as soon as a brand name manufacturer's patents allow, a brand name drug manufacturer must file information about its patents with the FDA.⁵⁹ A brand name drug manufacturer must submit its NDA with the patent number and the expiration date of any patent which claims the drug for which the brand submitted the NDA.⁶⁰ Once an NDA is approved, the FDA publishes the information in the "Orange Book."⁶¹

After consulting the Orange Book for relevant patents, a generic drug company wishing to file an ANDA must assure the FDA that its proposed generic drug will not infringe any of the listed patents.⁶² When no patents are listed in the Orange Book or all listed patents have expired or will expire before the ANDA's approval, the generic manufacturer must supply assurance of this to the FDA.⁶³ What is referred to as a "Section VIII" statement gives the generic manufacturer an option to market the drug for methods of use not covered by the brand name's patents.⁶⁴ This option is mainly used when the brand name's patent on the drug compound expired, but the brand name still holds the patents on some approved methods of using the drug.⁶⁵ A Section VIII statement may allow the generic manufacturer to market the drug using labeling that does not infringe on the methods of use still patented by the brand name.⁶⁶ This is an exception to the rule that the generic drug must bear the same label as its brand name counterpart.⁶⁷ This allows the generic manufacturer to get its drug to market, assuming it has met the other ANDA requirements, but only for the approved methods of use not covered by the brand name's patents. In other words, the Hatch-Waxman Act allows a generic manufacturer to market a generic drug for unpatented uses even if other patented uses are not allowed.⁶⁸

There are several ways in which a generic manufacturer can provide assurance that its drug will not infringe the brand name's patents.⁶⁹ It can (1) certify that the

⁵⁸ Caraco Pharmaceutical Labs v. Novo Nordisk, 132 S. Ct. 1670, 1676 (2012).

⁵⁹ *Id.*

⁶⁰ 21 U.S.C. § 355(b)(1).

⁶¹ The Orange Book is officially called Approved Drug Products with Therapeutic Equivalence Evaluations. The Orange Book identifies all drug products approved by the FDA. The FDA must also list all patents that purport to protect each drug in the Orange Book.

⁶² 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)–(III).

⁶³ *Id.*

⁶⁴ *Id.* § 355(j)(2)(A)(viii).

⁶⁵ *Id.*

⁶⁶ 21 C.F.R. § 314.94(a)(8)(iv) (2017).

⁶⁷ 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G).

⁶⁸ *Id.* § 355(j)(2)(A)(viii).

⁶⁹ *Id.* § 355(j)(2)(A)(vii).

brand name manufacturer has not listed any relevant patents; (2) certify that any relevant patents have expired; (3) request approval to market beginning when any still in force patents expire; or (4) certify that any listed, relevant patent is invalid or will not be infringed by the manufacture, use, or sale of the drug described in the ANDA.⁷⁰ If a generic manufacturer employs the last method (the “Paragraph IV” method), it is a technical infringement of the brand name drug manufacturer’s patents and, in most instances, leads to litigation.⁷¹ The brand name manufacturer then must bring an infringement suit within 45 days causing the FDA to withhold final approval of the generic for 30 months while the matter is litigated.⁷² If the court decides the matter within that period of time, the FDA will follow that determination; if the courts do not decide the matter within that time period, the FDA is free to give approval to market the generic drug.⁷³

Using the Paragraph IV method in order to be the first to file an ANDA with the FDA is incentivized in the Act. The applicant who files the ANDA first will receive 180 days of exclusivity in the market if it prevails in its litigation.⁷⁴ During this period of exclusivity, no other generic can come to market even if the patent(s) in question is found to be invalid.⁷⁵ The generic manufacturer that is first to file the ANDA is the only company that can enjoy the exclusivity period.⁷⁶ If the generic manufacturer that is first to file the ANDA forfeits its rights to exclusivity, no other generic manufacturer can obtain it.⁷⁷

II. CASE STUDY: *MYLAN V. ALLERGAN*

Allergan PLC (Allergan) is a global pharmaceutical company focused on developing, manufacturing, and commercializing branded pharmaceuticals, devices, and biologic products and headquartered in Dublin, Ireland.⁷⁸ Mylan N.V. (Mylan) is an American global generic and specialty pharmaceuticals company headquartered in Canonsburg, Pennsylvania.⁷⁹ Allergan is the company that manufactures the

⁷⁰ *Id.* § 355(j)(2)(A)(vii)(IV).

⁷¹ 35 U.S.C. § 271(e)(2)(A) (2016).

⁷² 21 U.S.C. § 355(j)(5)(B)(iii) (2017).

⁷³ *Id.*

⁷⁴ § 355(j)(5)(B)(iv).

⁷⁵ *Id.*

⁷⁶ § 355(j)(5)(D).

⁷⁷ *Id.*

⁷⁸ *Company Profile*, ALLERGAN, <https://www.allergan.com/About/Company-Profile> (last updated 2018).

⁷⁹ *About Us*, MYLAN (2017), <http://www.mylan.com/en/company/about-us>.

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branded drug, Restasis®, which is used to treat chronic dry eye.⁸⁰ Restasis® is one of Allergan's blockbusters, accounting for about 15% of the company's profits and making \$1.5 billion in sales in 2016 alone.⁸¹ Restasis® was approved in 2003, with patent protection until 2014, which led generic manufacturers to prepare to enter the market.⁸² In order to block these generic companies from entering the market, Allergan obtained new patents claiming minor variations of the drug which have patent protection until 2024.⁸³ After which time, and assuming no further exclusivities are granted, generic versions of the drug could enter the market leading to profit loss for the brand name drug manufacturer.⁸⁴

In August of 2015, Mylan was sued by Allergan in a Hatch-Waxman Act case surrounding the Restasis® patents.⁸⁵ The suit arose when Mylan filed an ANDA with the FDA in order to manufacture and sell low-cost bioequivalent drugs having the same components as Restasis® and challenged the Restasis® patents as invalid.⁸⁶ On June 3, 2016, Mylan filed six IPR challenges with PTAB in regards to the Restasis® patents.⁸⁷ On December 8, 2016, PTAB granted Mylan's petitions for IPR finding it reasonably likely that Allergan's evergreened patents were invalid.⁸⁸ Beginning on December 8, 2016, PTAB had a statutory deadline of exactly one year to complete the IPR.⁸⁹ The district court litigation has been decided, however, PTAB has extended its statutory deadline for IPR completion from December 8, 2017 to April 6, 2018.⁹⁰

On September 8, 2017, exactly one-week prior to the scheduled oral hearing at PTAB, Allergan announced the controversial deal with New York state's Saint Regis

⁸⁰ Eric Sagonowsky, *Mylan blasts Allergan's 'desperate' tribal licensing deal on Restasis*, FIERCE PHARMA (Sept. 13, 2017, 10:50 AM), <https://www.fiercepharma.com/legal/mylan-blasts-allergan-s-desperate-tribal-licensing-deal-restasis>.

⁸¹ Lydia Ramsey, *One of Allergan's blockbuster drugs was dealt a major legal blow*, BUS. INSIDER (Oct. 16, 2017), <http://www.businessinsider.com/allergan-restasis-patents-invalid-in-texas-district-court-2017-10>.

⁸² *Id.*

⁸³ Joshua Landau, *Tribal Immunity May Not Be Wonder Drug For Allergan*, LAW 360 (Oct. 17, 2017, 3:10 PM), <https://www.law360.com/articles/974876/tribal-immunity-may-not-be-wonder-drug-for-allergan>.

⁸⁴ Jon Hess & Shannon Litalien, *Battle for the market: Branded drug companies' secret weapons generic drug makers must know*, 3 J. OF GENERIC MED. 20, 21 (2005).

⁸⁵ Allergan, Inc., v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *2 (E.D. Tex. 2017).

⁸⁶ *Id.*

⁸⁷ Mylan Pharm., Inc. v. Allergan, Inc., No. IPR2016-01130 (P.T.A.B. June 3, 2016).

⁸⁸ Landau, *supra* note 83.

⁸⁹ 35 U.S.C. § 316(a)(11) (2016).

⁹⁰ *Id.*

Mohawk Tribe (the Tribe) to transfer ownership of six of its patents (the Patents)—U.S. Patent Nos. 8,629,111; 8,633,162; 8,648,048; 8,685,930; and 9,248,191—for the branded eye drug, Restasis®, to the Tribe.⁹¹ The transaction included the full transfer of ownership of the Patents to the Tribe in exchange for Allergan’s \$13.75 million payment to the Tribe with eligibility for \$15 million in annual royalties and Allergan’s retention of an exclusive license to the Patents.⁹² This was done in order to claim the Tribe’s status as a sovereign nation and shield the Patents from review by the USPTO and ultimately, from competitors.⁹³ The license agreement expressly stated that the Tribe “will and shall assert its sovereign immunity in any Contested PTO Proceeding, including in the IPR Proceedings.”⁹⁴ Allergan previously had to defend these Patents in federal district court against various generic pharmaceutical companies including Mylan.⁹⁵ Mylan, who stated that it would “vigorously oppose this transparent delay tactic before the Patent Trial and Appeal Board,” filed an IPR petition against the Patents as well.⁹⁶ The Tribe, after the ownership change, filed a motion to terminate the pending IPR proceedings using the defense of sovereign immunity.⁹⁷

In the district court litigation decided in October of 2017, Judge William Bryson issued a ruling regarding this dispute between Allergan and Mylan over the Restasis® patents.⁹⁸ Before reaping the benefits of the deal, the judge invalidated four of the six Allergan Patents at issue because they described methods of treatment that were obvious in light of earlier patents granted to the company.⁹⁹ More interestingly, however, the court condemned Allergan’s transaction with the Tribe stating that, “[w]hat Allergan seeks is the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits.”¹⁰⁰ The court went on to seriously question the legitimacy of this kind of deal stating that the Tribe’s sovereign immunity should not be treated

⁹¹ *Allergan and Saint Regis Mohawk Tribe Announce Agreements Regarding RESTASIS Patents*, ALLERGAN (Sept. 8, 2017), <https://www.allergan.com/news/news/thomson-reuters/allergan-and-saint-regis-mohawk-tribe-announce-agr> [hereinafter *Allergan Press Release*].

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Mylan Pharm., Inc. v. Allergan, Inc.*, No. IPR2016-01130 (P.T.A.B. June 3, 2016).

⁹⁶ Sagonowsky, *supra* note 80.

⁹⁷ *Allergan Press Release*, *supra* note 91.

⁹⁸ Jan Wolfe & Michael Erman, *U.S. judge in Texas invalidates Allergan patents on Restasis*, REUTERS (Oct. 16, 2017, 1:28 PM), <https://www.reuters.com/article/us-allergan-patents/u-s-judge-in-texas-invalidates-allergan-patents-on-restasis-idUSKBN1CL2KE>.

⁹⁹ Landau, *supra* note 83.

¹⁰⁰ *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *4 (E.D. Tex. Oct. 16, 2017).

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as a “monetizable commodity.”¹⁰¹ Despite these contentions, Allergan has maintained that the reasoning behind this transaction was to protect against “double jeopardy” in patent disputes when brand name companies must defend their patents in both federal court and at PTAB.¹⁰²

More recently, on February 23, 2018, PTAB issued a decision denying the Tribe’s motion to terminate Mylan’s patent challenge regarding the Restasis® patents.¹⁰³ PTAB determined that the Tribe did not establish that the doctrine of tribal sovereign immunity applied to IPR proceedings.¹⁰⁴ Further, PTAB found that even if tribal sovereign immunity did apply, the IPR proceeding could continue with or without the Tribe’s participation because Allergan retained ownership interest in the challenged patents.¹⁰⁵ The oral hearing for this case is now scheduled for April 3, 2018 and PTAB has pushed its final written opinion deadline again from April 6, 2018 to June 6, 2018.¹⁰⁶

This case is the first time tribal sovereign immunity will be considered by PTAB.¹⁰⁷ Here, what may be the most interesting is the timing of the transaction. On June 3, 2016, Mylan filed six petitions for IPR review for the Restasis® patents which were owned at that time by Allergan.¹⁰⁸ On September 8, 2017, one week prior to the date scheduled for oral hearing in the IPR, the transaction took place.¹⁰⁹ The Tribe then notified PTAB about the new ownership of the patents, obtained leave, and filed a motion to terminate the IPR proceedings for the Restasis® patents for lack of jurisdiction on the basis of tribal sovereign immunity.¹¹⁰ The three cases prior to this where PTAB had considered issues of state sovereign immunity differed from the present case, because, in those cases, the sovereign patent owner had ownership

¹⁰¹ *Id.*

¹⁰² Steve Brachmann, *Double jeopardy at the PTAB forces Allergan and others to seek sovereign immunity defenses*, IPWATCHDOG (Nov. 2, 2017), <http://www.ipwatchdog.com/2017/11/02/double-jeopardy-ptab-forces-allergan-seek-sovereign-immunity-defenses/id=89847>.

¹⁰³ Mylan Pharm., Inc. v. Saint Regis Mohawk Tribe, No. IPR2017-01127 (P.T.A.B. Feb. 23, 2018).

¹⁰⁴ *Id.* at 4.

¹⁰⁵ *Id.*

¹⁰⁶ Emma Court, *Allergan denied dismissal of patent challenges for dry eye medication Restasis by U.S. patent board*, MARKET WATCH (Feb. 26, 2018, 8:36 AM), <https://www.marketwatch.com/story/allergan-denied-dismissal-of-patent-challenges-for-dry-eye-medication-restasis-by-us-patent-board-2018-02-26-891362>.

¹⁰⁷ Landau, *supra* note 83.

¹⁰⁸ Allergan, Inc., v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *2 (E.D. Tex. Oct. 16, 2017).

¹⁰⁹ Margaux A. Savee, *PTAB Allows Amicus Brief in Allergan IPRs*, POLSINELLI ON POST-GRANT (Nov. 13, 2017), <https://www.polsinellionpostgrant.com/blog/2017/11/10/ptab-allows-amicus-brief-in-allergan-iprs>.

¹¹⁰ *Id.*

of the patents prior to the beginning of the IPR proceedings and were protected under the Eleventh Amendment.¹¹¹ However, in this case, the patents involved in the transaction were already subject to IPR at the time the Tribe took ownership of them and there is no Eleventh Amendment defense.¹¹²

III. THE INDUSTRY SPLIT: INNOVATION OR UNJUST DELAY TACTIC?

The Allergan transaction at issue has stirred controversy in the industry, with everyone from reporters to practitioners to judges weighing in on the debate. Evidence of this controversy lies in the PTAB’s decision to allow submission of amicus briefs in the Allergan IPR proceedings for the first time in a post-grant challenge.¹¹³ Allergan leads one side of the discussion, hailing the transaction as an innovative way to ward off intellectual property challenges.¹¹⁴ Allergan’s CEO, Brent Saunders, and CLO, Bob Bailey, have said that the principal motivation behind this deal was to protect itself against “double jeopardy” in patent disputes from having to defend its patents in both federal court and from IPR challenges at PTAB.¹¹⁵ Secondly, Allergan has stated that another goal is to help the Tribe become self-reliant and diversify its economy.¹¹⁶ In an Allergan press release about this transaction, Bob Bailey stated that, “the Tribe’s thoughtful and enterprising approach . . . will allow them to achieve their goals of self-reliance and help them address the most urgent needs in their community.”¹¹⁷ Both Allergan and the Tribe also stated that, “[t]his is a viable and sound opportunity for the Saint Regis Mohawk Tribe to enter into the patent, technology and research sector as part of [the Tribe’s] overall economic diversification strategy.”¹¹⁸ Allergan also sought to create a precedent for future companies to initiate similar deals in order to shield their patents from IPR.¹¹⁹ Bailey said, “I would expect it [the transaction] creates a playbook for other cases down the road for us and for others.”¹²⁰

¹¹¹ Covidien LP v. Univ. of Fla. Research Found. Inc., No. IPR2016-1274 (P.T.A.B. Jan. 25, 2017); Neochord, Inc. v. Univ. of Md., Balt., No. IPR20162016-208 (May 23, 2017); Reactive Surfaces Ltd. v. Toyota Motor Corp., No. IPR2016-1914 (P.T.A.B. July 13, 2017).

¹¹² *Id.*

¹¹³ Savee, *supra* note 109.

¹¹⁴ *Allergan Press Release, supra* note 91.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ Cynthia Koons & Susan Decker, *A Native American Tribe, a Drugmaker and an Unusual Patent Plan*, BLOOMBERG TECH. (Sept. 8, 2017, 3:22 PM), <https://www.bloomberg.com/news/articles/2017-09-08/allergan-makes-deal-with-native-american-tribe-over-drug-patents>.

¹²⁰ *Id.*

Mylan leads the other side of the debate that this “protection scheme” is an unjust and illegal tactic used in attempts to shield vulnerable patents from competition for as long as possible.¹²¹ In regards to the Tribe’s assertion of tribal sovereign immunity at PTAB, Mylan adamantly has maintained the position that this tactic could not be upheld for various reasons on the merits such as the public policy argument against monetizing sovereign immunity as a commodity, but also because the Tribe waived its immunity.¹²² In a telephonic hearing before PTAB on September 11, 2017, just three days after the transaction was made public, Mylan said:

[T]his transaction is a sham. There’s no reason to believe that it will lead to any success. But in any case, there’s an unequivocal waiver here. Mylan expects to have a lot of arguments on the merit, but you should have confidence that this motion can’t succeed because they have clearly sought out this forum. Mylan did not drag them into this forum. [. . .] Rather, by their own admissions to the press—the press releases, they have—the tribe has said that they have sought this out as an opportunity that they are marketing to patentees, that this is basically a protection scheme that they have put forth. [. . .] They are going to patentees who they think have weak patents and are at risk of cancellation, and they are offering this protective service. They are explicitly selling immunity.¹²³

Many join Mylan in this line of reasoning including PTAB in its recent denial of the Tribe’s motion to terminate the IPR and Judge Bryson, the appellate court judge sitting by designation and presiding over the ANDA case who recently held Allergan’s patents invalid as obvious.¹²⁴ In Judge Bryson’s opinion granting joinder of the Tribe to the case, he elaborates on the Court’s “serious concerns about the legitimacy of the tactic that Allergan and the Tribe have employed.”¹²⁵ The opinion reads in relevant part:

Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent the Tribe’s sovereign immunity in order to defeat the pending IPR proceedings in the PTO. [. . .] What Allergan seeks is the right to continue to enjoy the considerable benefits of the

¹²¹ Transcript of Hearing at 16, *Mylan Pharm., Inc. v. Allergan, Inc.* No. IPR2016-01127 (P.T.A.B. Sept. 11, 2017).

¹²² *Id.*

¹²³ *Id.*

¹²⁴ Wolfe & Erman, *supra* note 98.

¹²⁵ *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *4 (E.D. Tex. Oct. 16, 2017).

U.S. patent system without accepting the limits that Congress has placed on those benefits through the administrative mechanism for cancelling invalid patents. If that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice. In short, Allergan's tactic, if successful, could spell out the end of the PTO's IPR program, which was the central component of the America Invents Act of 2011.¹²⁶

The judge shares Mylan's concerns that this patent expiration delay tactic is a massive abuse of the system put in place by the legislature which could render it meaningless if allowed.¹²⁷ Further, Judge Bryson also agrees that this commodification of the Tribe's sovereign immunity cannot be tolerated.¹²⁸

Others in the industry have also harshly criticized the arrangement, including various senators.¹²⁹ Among these Congressmen, Senator Claire McCaskill has been outspoken about her contempt for this deal.¹³⁰ In a letter she wrote to the pharmaceutical lobbying group, PhRMA, she said, "[t]his is one of the most brazen and absurd loopholes I've ever seen, and it should be illegal. Given its recent comments regarding corporate responsibility, PhRMA can and should play a role in telling its members that the action isn't appropriate, and I hope they do that."¹³¹ Following a bipartisan U.S. House of Representatives committee decision to investigate the transaction early in October of 2017, the senator introduced legislation seeking to abrogate tribal sovereign immunity as a defense in IPR.¹³² She went on to say, "Congress never imagined tribes would allow themselves to be used by pharmaceutical companies to avoid challenges to patents, and this bill will shut the practice down before others follow suit."¹³³ In putting forth this bill, Senator McCaskill sought to address the fear that Judge Bryson put forth in his opinion: to save the IPR procedure by disallowing the practice of selling tribal sovereign

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ Meg Tirrel, *Judge asks if Allergan's patent deal with Mohawk tribe is a 'sham'*, CNBC (Oct. 6, 2017, 5:45 PM), <https://www.cnn.com/2017/10/06/judge-asks-if-allergans-patent-deal-with-mohawk-tribe-is-a-sham.html>.

¹³⁰ *Id.*; see also Bates et al., *supra* note 2 (the authors state, while discussing Senator McCaskill's bill, "[t]he question also remains as to whether a patent transfer solely to assert sovereign immunity is vulnerable in a manner similar to piercing the corporate veil. While this question remains open at the PTAB, the court of public opinion has already tried this issue.").

¹³¹ Tirrel, *supra* note 129; see also Bates et al., *supra* note 2.

¹³² Michael Erman, *Senator McCaskill drafts bill in response to Allergan patent maneuver*, REUTERS (Oct. 5, 2017, 2:16 PM), <https://www.reuters.com/article/us-allergan-patents-congress/senator-mccaskill-drafts-bill-in-response-to-allergan-patent-maneuver-idUSKBN1CA2D0>.

¹³³ *Id.*

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immunity for the purpose of evading PTAB. While the bill has garnered some support, its critics have called it discriminatory and unlikely to get at the root of the problem.¹³⁴

As previously mentioned, PTAB has also decided to allow amicus briefs for the first time in a post-grant challenge which were to be filed by December 1, 2017.¹³⁵ Jumping at the opportunity to weigh in on this issue of first impression for PTAB, various industry players effected by the outcome filed amicus briefs for both Mylan and Allergan.¹³⁶ For example, U.S. Inventor, LLC, a nation-wide inventor advocacy organization with over 13,000 members, submitted a brief in support of the Saint Regis Mohawk Tribe.¹³⁷ Its main argument is that PTAB lacks the jurisdiction and expertise to make the determination in this case.¹³⁸ In the brief, U.S. Inventor LLC claims that Congress possess exclusive authority over the application of sovereign immunity, and it would be a “flagrant encroachment” on that authority to allow PTAB to decide whether sovereign immunity may be used to divest the Board of Jurisdiction.¹³⁹ The brief goes on to argue that the proper forum for the parties to challenge tribal sovereign immunity is in federal district court and concludes by claiming that the motion to dismiss for lack of jurisdiction based on tribal sovereign immunity filed by the Saint Regis Mohawk Tribe should be granted.¹⁴⁰

Conversely, Askeladden LLC, founder of the Patent Quality Initiative, an education, information, and advocacy effort to improve the understanding, use, and reliability of patents, filed an amicus brief in opposition to the Saint Regis Mohawk Tribe’s motion to dismiss.¹⁴¹ Askeladden LLC based its brief on four arguments: that (1) the Tribe’s motion is based on the misplaced theory that Tribal Sovereign Immunity is applicable to administrative proceedings before PTAB, (2) even if the Tribe cannot be compelled to participate in the proceeding, there is no requirement under the AIA that a patent owner participate in order for it to proceed, (3) the

¹³⁴ Gene Quinn, *Saint Regis Mohawk Tribe Outraged at Senator McCaskill over Sovereign Immunity Bill*, IPWATCHDOG (Oct. 6, 2017), <http://www.ipwatchdog.com/2017/10/06/saint-regis-mohawk-tribe-outraged-senator-mccaskill-sovereign-immunity-bill/id=89007>.

¹³⁵ Savee, *supra* note 109; *see also* *PTAB Permits Amicus Briefing in Connection with the St. Regis Mohawk Tribe’s Motion to Terminate IPRs Based on Tribal Sovereign Immunity*, GOODWIN (Nov. 4, 2017), <https://www.bigmoleculewatch.com/2017/11/04/ptab-permits-amicus-briefing-in-connection-with-the-st-regis-mohawk-tribes-motions-to-terminate-iprs-based-on-tribal-sovereign-immunity>.

¹³⁶ GOODWIN, *supra* note 135.

¹³⁷ Brief for U.S. Inventor, LLC, as Amicus Curiae Supporting Patent Owner, Mylan Pharms., Inc. v. Saint Regis Mohawk Tribe, No. IPR2017-01127 (P.T.A.B. 2016).

¹³⁸ *Id.*

¹³⁹ *Id.* at 6.

¹⁴⁰ *Id.* at 10.

¹⁴¹ Brief of Askeladden, LLC, as Amicus Curiae Opposing Patent Owner, Mylan Pharms. v. Saint Regis Mohawk Tribe, No. IPR2017-01127 (P.T.A.B. 2016).

subsequent transaction by the Patent Owner and the Tribe cannot and should not be entitled to divest PTAB of its rights and duty to complete these proceedings, and (4) the transaction is nothing more than a sham.¹⁴² The arguments put forth by Askeladden LLC align with those of Mylan, Judge Bryson, and Senator McCaskill, in reasoning that the transaction between Allergan and the Tribe is a sham and this behavior should not be allowed to prevent PTAB from arriving at its final written decisions in IPR proceedings. For those reasons, Askeladden LLC urged PTAB to deny the Tribe's motion to dismiss and to complete its second look at the patents it previously granted, with or without the Tribe's participation.¹⁴³

As for the public at large, many practitioners working in the industry or related fields have written articles, created blog posts, and taken to social media to voice their opinions about this unprecedented transaction. Steve Brachmann, a freelance writer for IPWatchdog, seems to favor the transaction as an innovative way to protect Allergan's patents.¹⁴⁴ In his piece surrounding the Allergan deal, he states that:

The unintended problems and abuses of the IPR process at PTAB would concern any patent owner and naturally drive a party like Allergan to seek out an arbitrage opportunity with the St. Regis Mohawk Tribe to protect assets from the PTAB while engaged in Hatch-Waxman litigation.¹⁴⁵

On the other side of the debate, Joe Nocera, a columnist for *Bloomberg View*, characterized the deal between Allergan and the Tribe as Allergan's way of evading the law.¹⁴⁶ He used the word 'sleazy' to describe the transaction.¹⁴⁷ Nocera went on to criticize Allergan for potentially paving the way to the end of the patent review process.¹⁴⁸ In addition to his reaction to the deal itself, Nocera went on to explain that the Restasis® patents should have expired in 2014 meaning low-cost generic alternatives should have been available to consumers years ago.¹⁴⁹ He combines this with the transaction and Allergan's social contract to consumers of not raising its drug prices to reach his less than reputable opinion of the company.¹⁵⁰

¹⁴² *Id.*

¹⁴³ *Id.* at 15.

¹⁴⁴ Brachmann, *supra* note 102.

¹⁴⁵ *Id.*

¹⁴⁶ Joe Nocera, *Allergan Patent Deal Isn't Just Unusual. It's Ugly.*, BLOOMBERG (Sept. 11, 2017, 7:25 AM), <https://www.bloomberg.com/view/articles/2017-09-11/allergan-patent-deal-isn-t-just-unusual-it-s-ugly>.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

Along the same lines, Brad Loncar, a prominent biotech investor, was similarly upset by the transaction and felt it reflected poorly on the industry as a whole.¹⁵¹ He posted his opinion on his Twitter account about the transaction on the day the deal went public.¹⁵² Loncar said, “[t]his is going to impact all of us. Will be the next major black eye pharma story. Thanks [Allergan].”¹⁵³ It is easy to see how this controversial deal has caused a large divide within the industry. Some praise the deal as an innovative way to escape the review of patents at PTAB. Others are shocked by the tactic calling it “sleazy” and a sham. Needless to say, there are many proponents and opponents of this transaction, all with varying opinions of how to handle tribal sovereign immunity as it relates to patents that a sovereign tribe obtains at the end of the IPR proceeding.

There are some recent cases that have been brought before PTAB which also provide insight into the rationale of PTAB and how it views its role in these cases. The recent decision and rationale of PTAB in *Ericsson Inc. and Telfonaktiebolaget LM Ericsson v. Regents of the Univ. of Minnesota* is one of those cases. The *Ericsson* and *Allergan* cases share many similarities and yielded the same outcome despite the fact that Minnesota’s sovereign immunity is constitutionally protected and tribal sovereign immunity is not.¹⁵⁴ The question before PTAB was the same as the question in the *Allergan* case: Does sovereign immunity provide a defense for a patent owner against IPR challenges?¹⁵⁵ On December 19, 2017, PTAB issued an order dismissing the University of Minnesota’s sovereign immunity challenge and asserted its right to review the validity of the University’s patents.¹⁵⁶ PTAB reasoned that the University had waived its own right to immunity from administrative review when it filed suits in district court against Ericsson and other companies accusing them of infringing on the same patents.¹⁵⁷ PTAB stated:

it would be unfair and inconsistent to allow a State to avail itself of the federal government’s authority by filing a patent infringement action in federal court, but then

¹⁵¹ Sy Mukherjee, *Botox Maker Allergan’s CEO Defends Selling Drug Patents to Native American Tribe to Thwart Rivals*, FORTUNE (Sept. 9, 2017), <http://fortune.com/2017/09/09/allergan-drug-patents-native-american>.

¹⁵² *Id.*

¹⁵³ Brad Loncar (@bradloncar), TWITTER (Sept. 8, 2017, 12:27 PM), https://twitter.com/bradloncar?ref_src=twsrc%5Etfw&ref_url=http%3A%2F%2Ffortune.com%2F2017%2F09%2F09%2Ffa%2Fllergan-drug-patents-native-american%2F.

¹⁵⁴ Kevin E. Noonan, *PTAB Decides Patent Infringement Lawsuit Waives Eleventh Amendment Sovereign Immunity to Inter Partes Review*, PATENT DOCS (Dec. 19, 2017), <http://www.patentdocs.org/2017/12/ptab-decides-patent-infringement-lawsuit-waives-eleventh-amendment-sovereign-immunity-to-inter-parte.html>.

¹⁵⁵ Order Denying Patent Owner’s Motion to Dismiss, *Ericsson Inc. and Telfonaktiebolaget LM Ericsson v. Regents of the Univ. of Minn.*, No. IPR2017-01186 (P.T.A.B. Dec. 19, 2017).

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

selectively invoke its sovereign immunity to ensure that a defendant is barred from requesting an IPR of the asserted patent from a different branch of the same federal government.¹⁵⁸

It is clear through this decision and PTAB's dismissal of the Tribe's motion to dismiss in the *Allergan* case that PTAB intends to limit the use of sovereign immunity as a defense to IPR challenges and that it believes it rightfully has jurisdiction to decide these matters. Due to these decisions, Allergan's transaction with the Tribe will not be of use in shielding the Restasis® patents from IPR.

If Allergan's transaction were allowed to proceed, it could have had serious consequences on the patent legal framework Congress has put in place. Put another way, a tribe's sovereign immunity would essentially be rendered a commodity that could be bought and sold in order for patent owners to evade IPR making IPR proceedings useless. The consequences are amplified when put in the context of the pharmaceutical industry. While this scheme may be beneficial to tribes who are looking for new sources of income as well as for innovators who hold patents for valuable brand name drugs, it is very detrimental to potential generic competitors and, in turn, consumers of drugs who may need a low-cost alternative.

One main reason Congress created IPR proceedings was to create an efficient system for challenging wrongly issued patents.¹⁵⁹ In the *Allergan* case, the IPR process Congress intended has been undermined and made inefficient through Allergan's tactic. PTAB has been forced to push its statutory deadline for reaching its final decision from December of 2017 to June of 2018. Not only can this be interpreted as contrary to Congress's intent when creating PTAB, but Allergan will also reap the benefits of having its blockbuster drug on the market exclusively for at least an extra four months. Taking into consideration that annual profits of Restasis® are approximately \$1.5 billion, Allergan will make approximately \$500 million in those four months disregarding any royalties owed to the Tribe.¹⁶⁰ While this affects potential generic competitors, the ultimate loser in this case is the consumers who are left with no low-cost alternatives to the medication they need for a much longer time than should be allowed by law.

IV. CONCLUSION

Allergan's tactic for delaying the expiration of its patents for the branded drug Restasis® is exactly what Congress in enacting the Hatch-Waxman Act sought to avoid. For the pharmaceutical industry to thrive, there needs to be a balance between the innovators who produce brand name drug products and the generic companies which seek to provide customers with inexpensive alternatives. Brand name manufactures must be incentivized to innovate by enjoying patent protection long

¹⁵⁸ *Id.* at 8, 9.

¹⁵⁹ Landau, *supra* note 27 (quoting the House Report on the AIA).

¹⁶⁰ Mukherjee, *supra* note 151.

enough to recoup the expenses that went into the research and development of a new drug while making a profit. However, generic competitors must be allowed to enter the market through Congressionally created mechanisms such as IPR in order to provide consumers with low-cost options to the medications they desperately need.