

ALLERGAN'S BATTLE TO STAY IN COURT: DOES *INTER PARTES* REVIEW VIOLATE THE CONSTITUTION BY CIRCUMVENTING COURTROOM ADJUDICATION?

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Abstract: Since its institution in 2011, *inter partes* review has caused considerable disruption in the intellectual property world, with some industry players questioning the process' constitutionality. One of these players is Dublin-based pharmaceutical company Allergan, Inc., which asserts that it is unfair to force patent owners to defend their USPTO-granted patent rights before the Patent Trial and Appeal Board ("PTAB"), a non-Article III sanctioned forum. Central to this debate is the question of whether patents confer private or public rights. This article discusses both sides of the dialogue over *inter partes* review constitutionality, and postulates that the process is likely unconstitutional. The Supreme Court is set to rule on whether *inter partes* review is constitutional this year.

I. INTRODUCTION

The pharmaceutical industry has long been a target of public distaste.¹ In fact, the pharmaceutical industry comes only second to the federal government as the public's least-favored industry in the United States.² This fervent aversion stems from drugs' high prices in light of pharmaceutical companies' billion-dollar revenues and lack of transparency.³ Nonetheless, pharmaceutical company Allergan, Inc. has recently compelled extensive media coverage due precisely to its transparency in selling a number of its patents to a Native American tribe in an effort to employ the tribe's sovereign

¹ See Jim Norman, *Americans' View of Pharmaceutical Industry Take A Tumble*, GALLUP NEWS (Sept. 14, 2015), <http://news.gallup.com/poll/185432/americans-views-pharmaceutical-industry-tumble.aspx>.

² See Lydia Saad, *Restaurants Again Voted Most Popular U.S. Industry*, GALLUP NEWS (Aug. 15, 2016), <http://news.gallup.com/poll/194570/restaurants-again-voted-popular-industry.aspx>.

³ See Zachary Brennan, *Why Don't People Like Pharma Companies? Pfizer and Regeneron CEOs Discuss*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Dec. 1, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/12/01/26289/Why-Don%E2%80%99t-People-Like-Pharma-Companies-Pfizer-and-Regeneron-CEOs-Explain/>.

immunity to avoid *inter partes* review (“IPR”).⁴ In doing so, Allergan has shone light on a system the company believes to be undermining the protection of intellectual property and innovation.⁵ Allergan is not alone in its criticism of IPR.⁶ In fact, patent holders have been questioning the constitutionality of the system since before its formal institution.⁷ In recent years, the debate has proven so divisive that the Supreme Court of the United States has granted certiorari in *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC* on whether IPR “violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.”⁸ Oral arguments are set to take place on November 27, 2017.⁹

⁴ See *id.* Davidson, *Why Is Allergan Partnering With the St. Regis Mohawk Tribe?*, THE NEW YORKER (Nov. 20, 2017), <https://www.newyorker.com/magazine/2017/11/20/why-is-allergan-partnering-with-the-st-regis-mohawk-tribe>; Eric Sagonowsky, *Allergan CEO Saunders Claims ‘Tenacity’ Led Company Into Tribal Licensing Deal*, FIERCE PHARMA (Nov. 3, 2017), <https://www.fiercepharma.com/pharma/allergan-ceo-saunders-says-tenacity-led-company-into-tribal-licensing-deal>; Brent Saunders, *Opinion, Reverse Patent Trolls Are Harming Drug Innovation – And Patients*, WALL ST. J., Oct. 8, 2017, <https://www.wsj.com/articles/reverse-patent-trolls-are-harming-drug-innovationand-patients-1507487600>; Meg Tirrell, *Senators Question Allergan CEO on Tribe Patent Deal*, CNBC NEWS (Nov. 7, 2017), <https://www.cnbc.com/2017/11/07/senators-question-allergan-ceo-on-tribe-patent-deal.html>.

⁵ See Saunders, *supra* note 4.

⁶ See *e.g.*, *MCM Portfolio, LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1289 (Fed. Cir. 2015) (discussing whether IPR violates Article III of the Constitution and the Seventh Amendment), *cert. denied*, 137 S. Ct. 292 (2016).

⁷ See *e.g.* *McCormick Harvesting Mach. Co. v. C. Aultman & Co.*, 169 U.S. 606, 608–09 (1898) (finding that patents are private rights and thus cannot be rescinded by any non-Article III court).

⁸ *Oil States Energy Serv.’s, LLC v. Greene’s Energy Grp., LLC*, 639 F. App’x 639 (Fed. Cir. 2016), *cert. granted*, 137 S. Ct. 2239 (2017); *Petition for Certiorari, Oil States*, 639 F. App’x 639 (No. 16-712), 2016 WL 6995217; Gaston Kroub, *Supreme Court, Patent Saviors?*, ABOVE THE LAW (June 13, 2017), <https://abovethelaw.com/2017/06/supreme-court-patent-saviors/>.

⁹ See *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/oil-states-energy-services-llc-v-greenes-energy-group-llc/>.

II. BACKGROUND

A. What is Inter Partes Review?

Historically, challenges to the validity of patents have been adjudicated in the federal courts established by Article III of the Constitution.¹⁰ In September 2011, Congress instituted IPR as part of the Leahy-Smith America Invents Act (“AIA”) as an alternative to adjudication in federal court.¹¹ In contrast to federal court, IPR provides a quicker, more efficient, and less costly forum of challenging patent validity.¹²

IPR proceedings allow a petitioner to challenge the validity of any patent based on failures of the patent to comply with conditions for patentability, and on prior art, such as other patents or printed publications, beginning nine months after the patent is issued.¹³ A panel of administrative law judges at the Patent Trial and Appeal Board (“PTAB”) oversees the IPR process.¹⁴ The PTAB may institute a proceeding only if it finds that there is “a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition.”¹⁵ Neither party can appeal an institution decision; however, a dissatisfied party may request a rehearing before the PTAB.¹⁶

¹⁰ See U.S. CONST. art. III, §§ 1-2; MARTIN A. VOET, *THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT* 53 (BrownWalker Press, 5th ed. 2016).

¹¹ Voet, *supra* note 10, at 48.

¹² Voet, *supra* note 10, at 48; *A Practice Guide to Inter Partes Review*, WILMER CUTLER PICKERING HALE AND DORR, LLP (June 20, 2013), https://www.wilmerhale.com/uploadedFiles/WilmerHale_Shared_Content/WilmerHale_Files/Events/WilmerHale-webinar-IPR1-20Jun13.pdf.

¹³ 35 U.S.C. §§ 311(b)–(c)(1) (2013).

¹⁴ See Voet, *supra* note 10, at 48; *Inter Partes Review*, UNITED STATES PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review>.

¹⁵ *Inter Partes Review*, *supra* note 14.

¹⁶ 37 C.F.R. § 42.71(d) (2012); *America Invents Act (AIA) Frequently Asked Questions*, UNITED STATES PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/patent/laws-and->

If an IPR is instituted, the petitioner need only prove “preponderance of the evidence” as opposed to the higher standard of “clear and convincing evidence” employed in the federal courts.¹⁷ In further distinction from federal courts, the PTAB interprets a patent’s claims as broadly as possible and limits discovery.¹⁸ Following a final decision on a patent’s validity, the petitioner is barred from filing a new action on the same basis in federal court.¹⁹ However, either party may bring an appeal of the final decision in federal court.²⁰ If a petitioner files a federal court action for patent invalidation prior to filing an IPR, the petitioner is thereafter barred from filing an IPR.²¹ Conversely, if a patent owner files a federal court action for patent infringement prior to the filing of an IPR, the accused infringer may file an IPR within one year of service of the patent owner’s complaint.²²

Since IPR proceedings have become available, there have been a total of 4,563 petitions filed with the PTAB and 1,577 decisions rendered across all industries.²³ Of these decisions, 80% have deemed at least one claim of the challenged patent invalid.²⁴

regulations/america-invents-act-aia/america-invents-act-aia-frequently-asked#3224 (Nov. 14, 2017).

¹⁷ Voet, *supra* note 10, at 48.

¹⁸ See Adriana L. Burgy, *Five Considerations Before Filing An IPR*, FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP (May 1, 2013), <https://www.finnegan.com/en/insights/blogs/america-invents-act/five-considerations-before-filing-an-ipr.html>.

¹⁹ See *America Invents Act (AIA) Frequently Asked Questions*, *supra* note 16.

²⁰ *See id.*

²¹ 35 U.S.C. § 315(a)(1).

²² *Id.* § 315(b).

²³ *Patent Trial and Appeal Board Statistics*, UNITED STATES PATENT AND TRADEMARK OFFICE (Mar. 31, 2017), https://www.uspto.gov/sites/default/files/documents/AIA%20Statistics_March2017.pdf.

²⁴ *See id.*

B. Allergan's Unprecedented Maneuver

Allergan is a Dublin-based pharmaceutical company and the maker of Restasis®, a treatment for chronic dry-eye.²⁵ In 2015, Allergan brought suit in the United States District Court for the Eastern District of Texas against Teva Pharmaceuticals USA, Inc., Akorn, Inc., and Mylan Pharmaceuticals, Inc. and Mylan, Inc. (collectively “Mylan”).²⁶ The complaint alleged patent infringement of Allergan’s six patents protecting Restasis® on the basis that each of the Defendants had filed an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration.²⁷ If granted, the ANDAs would allow the Defendants to manufacture and market generic versions of Restasis® at a lower price than the brand-name drug.²⁸ In their answers to Allergan’s complaint, the Defendants alleged that the patents are invalid and thus cannot be infringed.²⁹ Consequently, in 2016, the Defendants each filed patent-specific IPR proceedings in hopes of invalidating Allergan’s six patents protecting Restasis®.³⁰

²⁵ *Company Profile*, ALLERGAN, PLC, <https://www.allergan.com/about/company-profile>; ALLERGAN, INC., <https://www.Restasis.com/> (last visited October 9, 2017).

²⁶ *Allergan, Inc. v. Teva Pharm., USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4803941, at *13 (E.D. Tex. Oct. 16, 2017).

²⁷ *See id.* at *13; U.S. Pat. Nos. 8,685,930, 8,629,111, 8,642,556, 8,633,162, 8,648,048 and 9,248,191.

²⁸ *See* Abbreviated New Drug Application (ANDA), UNITED STATES FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (Nov. 14, 2017).

²⁹ *See Teva*, 2017 WL 4803941, at *13.

³⁰ *See* Search Returning IPRs Filed Against Allergan, PATENT TRIAL AND APPEAL BOARD, <https://ptab.uspto.gov/#/login> (enter “Allergan” as “Party Name;” uncheck all “AIA Review/Case Type” except for “IPR;” uncheck all “Filing Party” except “Petitioner;” check “I am not a robot” and search).

In 2016 alone, Restasis® sales brought Allergan \$1.4 billion in revenue, making it the company's second highest selling product.³¹ In light of this sizeable profit, it is understandable why Allergan is seeking to protect its Restasis® patents from being scrutinized through IPR.³² If the proceedings were to result in invalidation and the ANDAs were granted, the petitioners would be authorized to produce lower-priced generic versions of the drug that may devastate Allergan's sales of Restasis® within months.³³ In an effort to prevent this potential outcome, in September 2017, Allergan entered into an unprecedented deal with the St. Regis Mohawk Tribe of upstate New York.³⁴ Allergan sold its six IPR-challenged Restasis® patents to the tribe, paid \$13.75 million upfront, and further agreed to pay the tribe \$15 million annually in royalties until the patents expire in 2024.³⁵ In exchange, the tribe will invoke its status as a sovereign government to free the patents from USPTO jurisdiction by asserting sovereign immunity.³⁶ If successful, the maneuver will effectively circumvent the IPR proceedings, and preclude the Restasis® patents from being challenged before the PTAB.³⁷

Exactly one month after the controversial deal was announced, the chairman and CEO of Allergan, Brent Saunders, penned an opinion for The Wall Street Journal.³⁸ In this opinion, he expressed his hope that the drug-maker's maneuver to avoid the "unfair

³¹ Jonathan D. Rockoff, *Allergan Partners With Indian Tribe to Protect Drug Patents*, WALL ST. J., Sept. 8, 2017, <https://www.wsj.com/articles/allergan-partners-with-indian-tribe-to-protect-drug-patents-1504892222>; *Allergan Reports Strong 2016 Finish with 7% Increase in GAAP Net Revenues to \$3.9 Billion in Fourth Quarter 2016*, ALLERGAN, PLC (Feb. 8, 2017), <https://www.allergan.com/news/news/thomson-reuters/allergan-reports-strong-2016-finish-with-7-increas>.

³² See Rockoff, *supra* note 31.

³³ *Id.*

³⁴ *Id.*

³⁵ See Saunders, *supra* note 4; Rockoff, *supra* note 31.

³⁶ See Rockoff, *supra* note 31.

³⁷ See *id.*

³⁸ Saunders, *supra* note 4.

challenges” to the patents would place a microscope on the flaws inherent in IPR.³⁹ Mr. Saunders offered his support for federal court adjudication and made issue of IPR’s lower burden of proof.⁴⁰ Mr. Saunders further proposed that IPR might not be lawful at all under the Constitution.⁴¹ As a result, Mr. Saunders urged Congress to take action against IPR and its destructive handling of biopharmaceutical patents while we await the Supreme Court’s decision on the matter.⁴²

On October 16, 2017, Judge Bryson of the United States District Court for the Eastern District of Texas invalidated the Restasis® patents on grounds of obviousness.⁴³ On November 1, 2017, Allergan appealed the decision.⁴⁴ The company’s appellate brief is due January 2, 2018.⁴⁵ Despite Judge Bryson’s ruling, trial has been instituted in the IPR proceedings currently before the PTAB.⁴⁶ The IPRs will likely progress independent of the appellate court proceedings.⁴⁷ Nevertheless, Allergan’s efforts to circumvent the IPR proceedings may prove to be moot, as federal court decisions normally supersede those made by the PTAB.⁴⁸ Despite Judge Bryson’s decision, IPR constitutionality

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *See* 35 U.S.C. § 103; *Teva*, 2017 WL 4803941, at *65.

⁴⁴ *See* Docket, *Allergan, Inc. & The Saint Regis Mohawk Tribe v. Teva Pharmaceuticals USA, Inc., et al.*, No. 18-1130 (Fed. Cir. Nov. 1 2017) (“Allergan Appeal”).

⁴⁵ *See id.*

⁴⁶ *See* Search Returning IPRs Filed Against Allergan, PATENT TRIAL AND APPEAL BOARD, <https://ptab.uspto.gov/#/login> (enter “Allergan” as “Party Name;” uncheck all “AIA Review/Case Type” except “IPR;” uncheck all “Filing Party” except “Petitioner;” check “I am not a robot” and search).

⁴⁷ *See* Katie Thomas, *Patents for Restasis Are Invalidated, Opening Door to Generics*, N.Y. TIMES, Oct. 16, 2017, <https://www.nytimes.com/2017/10/16/health/allergan-restasis-patent-.html>.

⁴⁸ *See id.*

remains a significant issue in intellectual property law, as evidenced by the Supreme Court's granting of certiorari in *Oil States*.⁴⁹

III. CONSTITUTIONALITY OF *INTER PARTES* REVIEW

A. Historical Precedent

In 1898, in *McCormick Harvesting Machine Co. v. C. Aultman & Co.*, the Supreme Court held that administrative bodies such as the USPTO did not have the authority to revoke a patent, declaring that once a patent was granted, it could no longer be controlled by the issuing office.⁵⁰ The Court further stated that once granted, a patent was the patentee's property, and as such commanded legal protection equivalent to that of any other property.⁵¹ In correctly recognizing the need for a forum of action, the Court provided that challengers of patents could bring an action before an Article III court, as these courts exclusively held the authority and competency required to invalidate a patent.⁵² In reaching its decision, the Supreme Court implicitly branded patents as private rights in determining that Article III courts were the only proper forums for challenging their validity.⁵³ The Supreme Court's determination in this century-old case is compatible with Article III of the U.S. Constitution, which vests judicial power in the federal courts.⁵⁴ Despite the holding in *McCormick*, the USPTO has been granted the

⁴⁹ See generally *Oil States*, 137 S. Ct. 2239 (granting certiorari as to whether IPR violates Article III of the Constitution).

⁵⁰ See *McCormick*, 169 U.S. at 608.

⁵¹ See *id.* at 609.

⁵² See *id.*

⁵³ See *id.*

⁵⁴ U.S. CONST. art. III. §§ 1–2.

exact power that the Supreme Court of 1898 said that it did not have the authority to hold the ability to invalidate patents issued and approved by its own office.⁵⁵

B. Today's Case Law

In stark contrast to its historical predecessors, the U.S. Court of Appeals for the Federal Circuit held in 2016 in *MCM Portfolio, LLC v. Hewlett-Packard Company* that IPR does not violate Article III.⁵⁶ The court found patents to be public rights, as opposed to private rights as suggested by the Supreme Court of 1898, and departed from *McCormick* on the basis that Article III was not directly discussed.⁵⁷ In support of this contrary opinion, the court reasoned that patents are awarded to parties by the government and as such, the issuance of a patent is a public concern.⁵⁸ Consequently, the court in *MCM* found that Congress possesses the authority to assign adjudication regarding public rights to a non-Article III court.⁵⁹ While both the Supreme Court deciding *McCormick* and the appeals court in *MCM* concur that only those rights that are public may be adjudicated in non-Article III courts, they are in direct conflict as to whether patents are private or public rights.⁶⁰ In straying from the view of patents as private rights, the court in *MCM* determined IPR to be constitutional.⁶¹ Thereafter,

⁵⁵ See *Inter Partes Review*, UNITED STATES PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review>; see generally *McCormick* (finding that patents may only be adjudicated by an Article III court).

⁵⁶ See *MCM*, 812 F.3d at 1293.

⁵⁷ See *McCormick*, 169 U.S. at 609; *MCM*, 812 F.3d at 1289, 1293.

⁵⁸ See *MCM*, 812 F.3d at 1290–91.

⁵⁹ See *id.* at 1293.

⁶⁰ See *McCormick*, 169 U.S. at 609; *MCM*, 812 F.3d at 1293.

⁶¹ See *MCM*, 812 F.3d at 1293.

certiorari was petitioned for but was denied on the question of whether IPR violates Article III.⁶²

Fast-forwarding to 2017, the Supreme Court will soon decide this issue, as certiorari has been granted in *Oil States* on whether IPR “violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.”⁶³

IV. ANALYSIS

A. Patents As Private Rights

As discussed above, *McCormick* does not preclude non-Article III adjudicative bodies from being granted the authority to resolve disputes.⁶⁴ Instead, the Court states that the error in granting such power is committed if the property in dispute is a private right and not a public one.⁶⁵ As such, if patents are determined to be private rights, an Article III court is the only appropriate forum to adjudicate the dispute.⁶⁶ Conversely, if patents are determined to be public rights, the PTAB can properly be granted the power to oversee validity challenges.⁶⁷ Thus, the issue central to whether IPR is constitutional is whether patents are private or public property.⁶⁸

More than a century ago, the Supreme Court determined patents to confer private rights.⁶⁹ Similarly, the Constitution has echoed this determination through its Intellectual

⁶² See generally *MCM*, 812 F.3d 1284 (certiorari denied as to whether IPR is constitutional).

⁶³ Petition for A Writ of Certiorari, *supra* note 8.

⁶⁴ See generally *McCormick*, 169 U.S. at 608 (discussing patents as private rights).

⁶⁵ See *id.*

⁶⁶ See *id.* at 609.

⁶⁷ See *MCM*, 812 F.3d at 1293.

⁶⁸ See generally *id.* (discussing patents as public rights at length).

⁶⁹ See *McCormick*, 169 U.S. at 609.

Property Clause.⁷⁰ The Intellectual Property Clause grants innovators the absolute right to their innovations, and thus patents are exclusively held and secured property.⁷¹ Allergan and fellow pharmaceutical companies AbbVie, Inc. and Celgene Corp. discuss the implications of patents as private property in an Amici Curiae Brief in Support of Petitioner in *Oil States*.⁷² In the Brief, the parties explain that “while Congress is authorized to establish the methods by which patent rights are ‘secured,’ the Constitution does not vest Congress with similarly sweeping authority to route patent-validity disputes to a non-Article III forum without the consent of the patentee.”⁷³ The parties go on to contend that the Intellectual Property Clause undoubtedly exhibits our Founding Fathers’ recognition of patents as private rights, and in reaching this conclusion, the deduction that IPR is unconstitutional is required.⁷⁴

To conclude that patents instead confer public rights, intellectual property rights would need to be determined as public in nature.⁷⁵ Historically, however, this determination has not been found as patents have been held to confer private rights.⁷⁶ As such, IPR cannot be deemed constitutional because it allows a non-Article III adjudicative body, the PTAB, to settle disputes of private property.⁷⁷

⁷⁰ See generally U.S. CONST. art. I, § 8, clause 8 (granting Congress the power to secure innovators’ intellectual property rights).

⁷¹ See U.S. CONST. art. I, § 8, clause 8; Brief for Amici Curiae AbbVie, Inc., Allergan, Inc., and Celgene Corp. in Support of Petitioner, *Oil States*, 639 F. App’x 639 (No. 16-712), 2017 WL 3888200.

⁷² See generally Brief for Amici Curiae AbbVie, Inc., Allergan, Inc., and Celgene Corp. in Support of Petitioner, *supra* note 71 (asserting that patents are private rights and should only be adjudicated by Article III courts).

⁷³ *Id.* at 3.

⁷⁴ See *id.* at 3–4.

⁷⁵ See *MCM*, 812 F.3d at 1293.

⁷⁶ See Brief for Amici Curiae AbbVie, Inc., Allergan, Inc., and Celgene Corp. in Support of Petitioner, *supra* note 71.

⁷⁷ See *McCormick*, 169 U.S. at 609.

CONCLUSION

Fervent protection of innovators' intellectual property through patents is of the utmost importance for society's continued progression. As such, Allergan's sentiment seems particularly pertinent in its assertion that a lack of robust patent protection will impair innovation. In instituting IPR, patent protection has been effectively diminished. In subjecting patents to review by the PTAB, IPR violates Article III of the nation's oldest and most-respected text, and threatens to seize innovators' private property without proper and lawful adjudication. In waiting for the Supreme Court to weigh in on IPR's constitutionality in light of *Oil States*, Allergan and many other patent-owners seeking to protect their rights are left to wonder whether they will continue to get their day in court, or whether they will also have to fight for their rights on a second front before the PTAB.