

NOTES

STRANGE BEDFELLOWS: NATIVE AMERICAN TRIBES, BIG PHARMA, AND THE LEGITIMACY OF THEIR ALLIANCEDANIEL C. KENNEDY[†]

ABSTRACT

Lost in the cacophony surrounding the debate about high drug prices is the fundamental principle that pharmaceutical innovation will not occur without the prospect of outsized returns enabled through market exclusivity. Biopharmaceutical patents are currently under siege, subject to challenge both in inter partes review (“IPR”) proceedings and in Hatch-Waxman actions. These twin assaults threaten to eliminate the incentives necessary for biotechnological innovation—particularly for discoveries made upstream in the innovation pipeline—thus imperiling the development of new drug therapies. But a fascinating solution has emerged: invoking tribal immunity to shield pharmaceutical patents from IPR before the Patent Trial and Appeal Board (“PTAB”). This serves two critically important objectives: promoting tribal self-sufficiency, and encouraging investment in life-saving and life-improving new drugs. Contractual partnerships between Native American tribes and pharmaceutical companies not only provide the tribes with a steady stream of royalty revenue, but also insulate biopharmaceutical patents from challenge in IPR proceedings through the invocation of long-established principles of tribal sovereign immunity. This Note is the first piece of scholarship to comprehensively analyze, and advocate for, the right to invoke tribal sovereign immunity in IPR proceedings.

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INTRODUCTION

In June 2017, the St. Regis Mohawk Tribe (“St. Regis Tribe”) adopted a Tribal Council Resolution endorsing the creation of a “‘technology and innovation center for the commercialization of existing and emerging technologies,’ called the Office of Technology, Research, and Patents.”¹ Effective September 8, 2017, the St. Regis Tribe entered into a contractual relationship with Allergan Inc. (“Allergan”), a biopharmaceutical company.² Allergan, pursuant to the parties’ agreement, assigned to the St. Regis Tribe a portfolio of patents related to Restasis (collectively, the “Restasis patents”), a prescription drug for the treatment of dry eye.³ Allergan also agreed to pay the St. Regis Tribe \$13.75 million immediately, as well as a royalty of up to \$15 million per year until the patents expire in 2024.⁴ For its part, the St. Regis Tribe granted Allergan “an irrevocable, perpetual, transferable and exclusive license” in the Restasis patents.⁵ Allergan was thus “granted the first right to sue for infringement with respect to ‘Generic Equivalents,’ while the Tribe [was granted] the first right to sue for infringement unrelated to such Generic Equivalents.”⁶

At the time that Allergan assigned the Restasis patents to the St. Regis Tribe, the Patent Trial and Appeal Board (“PTAB”) had instituted inter partes review (“IPR”) of those patents, based on petitions filed by Mylan Pharmaceuticals, Inc.⁷ On September 22, 2017, the St. Regis Tribe asked the PTAB to dismiss the pending IPR proceedings, arguing that tribal sovereign immunity inoculated those patents from challenge before the PTAB.⁸

1. Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe, Nos. IPR2016-01127, -01128, -01129, -01130, -01131, -01132, 2018 WL 1100950, at *2 (P.T.A.B. Feb. 23, 2018) (per curiam) (citation omitted).

2. *Id.*

3. *Id.*; the patent numbers for these patents are U.S. Patent Nos. 8,685,930, 8,629,111, 8,642,556, 8,633,162, 8,648,048, and 9,248,191.

4. *Mylan*, 2018 WL 1100950, at *3, *12.

5. *Id.* at *3 (citation omitted).

6. *Id.* The license between the St. Regis Tribe and Allergan states that a “Generic Equivalent” is “a drug product that requires [Food and Drug Administration (“FDA”)] approval for sale in the United States, including those products covered by an Abbreviated New Drug Application (ANDA) for which Allergan’s Restasis product is the listed reference drug.” *Id.* at *8.

7. *Id.* at *1.

8. *Id.*

On February 23, 2018, the PTAB instead issued a decision denying the St. Regis Tribe’s motion to terminate proceedings.⁹ It held that tribal immunity does not apply to IPR proceedings given that such proceedings were created by statute, and because they are “not the type of ‘suit’ to which an Indian tribe would traditionally enjoy immunity under the common law.”¹⁰ The PTAB concluded, moreover, that the St. Regis Tribe had not identified any statute or controlling precedent requiring the application of tribal sovereign immunity in IPR proceedings.¹¹ In addition, although the panel recognized that previous PTAB decisions had concluded that state sovereign immunity could be applied to shield patents from IPR review, it held that these decisions were distinguishable—a conclusion this Note argues is erroneous.¹²

Following the St. Regis Tribe’s and Allergan’s appeal of the PTAB’s holding, on July 20, 2018, the Federal Circuit issued an opinion incorrectly concluding that tribal sovereign immunity does not apply to IPRs.¹³ The Federal Circuit panel relied primarily on the Supreme Court’s analysis in *Federal Maritime Commission v. South Carolina State Ports Authority* (“*FMC*”),¹⁴ in determining that “[g]enerally, [sovereign] immunity does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action.”¹⁵ Yet, the panel conceded that, “IPR is neither clearly a judicial proceeding instituted by a private party nor clearly an enforcement action brought by the federal government.”¹⁶ It also acknowledged Supreme Court precedent that sovereign immunity is applicable during administrative adjudications between private parties.¹⁷ The panel, however, ultimately determined that “IPR is more like an agency enforcement action than a civil suit brought by a private party,” and thus concluded that “tribal immunity is not implicated” in IPR proceedings.¹⁸

9. *Id.* at *2.

10. *Id.* at *6.

11. *Id.* at *3–6.

12. *Id.* at *3 n.4.

13. *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327–29 (Fed. Cir. 2018).

14. *Fed. Mar. Comm’n v. S.C. State Ports Auth.*, 535 U.S. 743 (2002).

15. *Mylan*, 896 F.3d at 1325.

16. *Id.* at 1326.

17. *Id.* at 1326–27.

18. *Id.* at 1327.

But, contrary to the Federal Circuit's rejection of the applicability of sovereign immunity, courts and the PTAB have repeatedly allowed state universities that own and license patents to assert sovereign immunity from IPRs.¹⁹ Yet, apparently, Native American tribes have no corresponding right to deploy sovereign immunity to shield their patents from IPR scrutiny.²⁰ By drawing such a distinction, the PTAB and Federal Circuit departed from well-established precedent on the scope of tribal immunity. As the Supreme Court has made clear, Native American tribes possess "inherent sovereign authority."²¹ Therefore, "[a]s a matter of federal law, an Indian tribe is subject to suit only where Congress has authorized the suit, or the tribe has waived its immunity."²²

Although many have criticized the partnership as a "sham,"²³ the St. Regis Tribe's contract with Allergan is a proper exercise of its sovereign authority, serving both to protect the Restasis patents and to provide the tribe with a much-needed revenue stream. Moreover, using tribal sovereign immunity to shield pharmaceutical patents from IPR scrutiny protects and promotes biotechnological innovation; more broadly, strong patents—like the Restasis patents—are critically important in encouraging investment in the development of life-saving and life-enhancing drug therapies.²⁴ The costs associated with biotechnological innovation are high,²⁵ and allowing tribal immunity to be used to protect pharmaceutical patents would help to ensure that

19. See, e.g., *Reactive Surfaces Ltd. v. Toyota Motor Corp.*, No. IPR2016-01914 (P.T.A.B. July 13, 2017) (holding that Regents of the University of Minnesota could not be compelled to join the proceeding); *NeoChord, Inc. v. Univ. of Md.*, No. IPR2016-00208 (P.T.A.B. May 23, 2017) (granting the University of Maryland immunity from the proceeding); *Covidien LP v. Univ. of Fla. Research Found. Inc.*, No. IPR2016-01274, -01276, -01276 (P.T.A.B. Jan. 25, 2017) (determining that the University of Florida Research Foundation was entitled to sovereign immunity as an arm of Florida).

20. *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, Nos. IPR2016-01127, -01128, -01129, -01130, -01131, -01132, 2018 WL 1100950, at *2 (P.T.A.B. Feb. 23, 2018) (per curiam).

21. *Okla. Tax Comm'n v. Citizen Band Potawatomi Tribe of Okla.*, 498 U.S. 505, 509 (1991).

22. *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 754 (1998).

23. See, e.g., *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-cv-1455-WCB, 2017 WL 4619790, at *2-3 (E.D. Tex. Oct. 16, 2017) (noting that Allergen's transactions with the St. Regis Tribe have circumstances that are "frequently encountered in sham transactions").

24. See PHRMA, *BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES* 6 (2015), http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure.pdf [<https://perma.cc/FC2G-WG2T>] (noting the importance of intellectual property for pharmaceutical research and development).

25. See *id.* at 1 (estimating the "average cost to research and develop each successful drug . . . to be \$2.6 billion").

the enormous costs associated with new drug development can be recouped.

Part I of this Note sketches the legal background of IPR proceedings. Part II discusses the threats facing biopharmaceutical innovation from IPR proceedings, including IPR petitions brought by hedge funds. Part III argues that both the Federal Circuit and the PTAB incorrectly determined that tribal sovereign immunity could not be used to shield patents owned by the St. Regis Tribe from IPR challenge. Finally, Part III also contends that sovereign immunity can and should be used to protect biopharmaceutical patents and to encourage new investments in drug innovation and development.

I. A BRIEF OVERVIEW OF IPR AND SOVEREIGN IMMUNITY

This Part provides critical background information on the patent system and the type of post-grant proceeding at issue in this Note: IPR. It then provides a primer on the concept of tribal sovereign immunity, upon which the St. Regis Tribe contends that the Restasis patents are not subject to IPR review.

A. *IPR Challenges*

The federal government's power to issue patents stems from a constitutional provision that authorizes Congress "[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."²⁶ The Patent Act of 1790 granted the Secretary of State, the Secretary of War, and the Attorney General the authority to examine patent applications and issue patents.²⁷ Congress then created the Patent Office in 1836, giving it broad power to "execute, and perform, all such acts and things touching and respecting the granting and issuing of patents for new and useful discoveries, inventions, and improvements."²⁸ And in 1952, Congress provided the Patent and Trademark Office ("PTO") with the authority to promulgate rules "for the conduct of proceedings in the Patent Office."²⁹

26. U.S. CONST. art I, § 8, cl. 8.

27. Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 109–10.

28. Patent Act of 1836, ch. 357, § 1, 5 Stat. 117, 117–18.

29. Patent Act of 1952, Pub. L. No. 82-593, § 6, 66 Stat. 792, 793.

More recently, the Leahy-Smith America Invents Act³⁰ (“AIA”) was signed into law on September 16, 2011.³¹ Put simply, it was the most significant overhaul of patent law in more than half a century.³² The AIA gives the PTO expanded authority to reconsider the patentability of claims in issued patents.³³ It replaced inter partes reexamination with IPR, an administrative procedure that allows a third-party challenger³⁴ to petition the PTO to reexamine the claims in an issued patent and to cancel any claims the agency finds to be unpatentable in light of the prior art.³⁵

IPRs proceed in two phases.³⁶ In the first phase, the PTO determines whether to institute IPR.³⁷ In the second phase, the PTAB conducts the IPR proceeding and issues a final written decision.³⁸ A party in an IPR proceeding who is “dissatisfied with the final written decision of the [PTAB] may appeal the decision” to the United States Court of Appeals for the Federal Circuit.³⁹ Critically, an IPR can be requested at any point during a patent’s term, beginning nine months after its issuance.⁴⁰ A petition for IPR will be granted by the PTO if the petitioner can show with “reasonable likelihood” that it will “prevail with respect to at least 1 of the claims challenged in the petition.”⁴¹ IPR proceedings—typically heard before three administrative patent judges of the PTAB—are conducted on an expedited basis and are subject to a statutorily imposed requirement that disputes be resolved within twelve to eighteen months.⁴²

30. Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 28 and 35 U.S.C.).

31. See 157 CONG. REC. D979 (daily ed. Sept. 16, 2011) (noting the signing of the AIA into law).

32. See Clark D. Asay, *Patenting Elasticities*, 91 S. CALIF. L. REV. 1, 49 (2017) (noting that “[t]he AIA has been called the most important patent law reform since the 1952 Patent Act”).

33. 35 U.S.C. §§ 311–19 (2012).

34. The AIA provides that “a person who is not the owner of a patent may file with the [PTO] a petition to institute an inter partes review of the patent.” *Id.* § 311(a).

35. *Id.* § 311; *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2136 (2016).

36. See *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375–76 (Fed. Cir. 2014) (explaining the IPR process mandated by statute).

37. 35 U.S.C. § 314(a).

38. *Id.* § 318(a).

39. *Id.* § 319; see, e.g., *Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1314–15 (Fed. Cir. 2015) (providing an example of an appealed PTAB decision).

40. 35 U.S.C. § 311(c)(1).

41. *Id.* § 314(a).

42. *Id.* § 316(a)(11).

IPR proceedings differ from district court proceedings in important ways, and these differences can dramatically increase the likelihood that a challenger will succeed in invalidating a patent.⁴³ In district court litigation, a patent enjoys a presumption of validity,⁴⁴ with clear and convincing evidence required to demonstrate invalidity.⁴⁵ By contrast, a petitioner in an IPR proceeding only carries “the burden of proving a proposition of unpatentability by a preponderance of the evidence.”⁴⁶ Moreover, the PTAB applies a broader claim-construction standard than that which is applied in district courts. In district court proceedings, the language of a patent claim is given its “ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.”⁴⁷ In IPR proceedings, however, the language of a patent claim is “given its broadest reasonable construction in light of the specification of the patent in which it appears.”⁴⁸ The impact of this distinction can be profound: a broadly construed claim is far more likely to be invalidated for infringing upon prior art because the more generally a claim is constructed, the more likely it is that its specific novelty will be overlooked. Furthermore, construing identical claims in different ways, solely based upon the forum, is “troubling, especially when claim construction takes place at the same time in parallel district court proceedings and USPTO proceedings.”⁴⁹

43. See David Hricik, *Will Patenting Make As Much Sense in the New Regime of Weakened Patent Rights and Shorter Product Life Cycles?*, 20 VAND. J. ENT. & TECH. L. 457, 489–91 (2017) (discussing how IPRs have made it easier to challenge patents because the patents do not have a presumption of validity, claims are given broad interpretations, and litigation can be stayed if an IPR is instituted).

44. 35 U.S.C. § 282(a).

45. *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 97 (2011).

46. 35 U.S.C. § 316(e).

47. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

48. 37 C.F.R. § 42.100(b) (2017); see *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016) (affirming the Patent Office’s authority to use the “broadest reasonable construction” standard in § 42.100(b)).

49. KEVIN GREENLEAF ET AL., INTELL. PROP. OWNERS ASS’N, *HOW DIFFERENT ARE THE BROADEST REASONABLE INTERPRETATION AND PHILLIPS CLAIM CONSTRUCTION STANDARDS?* 3 (July 2018), <https://www.ipo.org/wp-content/uploads/2018/07/BRI-v-Phillips-Final.pdf> [<https://perma.cc/N3LE-HY9U>].

The costs of challenging a patent are generally much lower at the PTAB.⁵⁰ It is estimated that post-grant-review challenges before the PTAB “on average cost from \$350,000 to \$450,000 through any appeal, whereas patent litigation in federal court is estimated to cost between \$1 [million] and \$1.5 million through any appeal for matter[s] in which \$1 [million] to \$10 million are at stake.”⁵¹ Where more money is at stake, the costs associated with challenging a patent in federal court are even higher.⁵²

The AIA’s new post-grant proceedings, including IPR, were designed to be “quick and cost effective alternatives to litigation.”⁵³ One of the motivating policy justifications for enacting the AIA was the sense that the PTO had granted too many “bad” patents that were doing little to incentivize innovation, and that were instead being asserted by so-called “trolls” in an extortionist manner.⁵⁴ IPRs were instead intended to provide “a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court.”⁵⁵

IPRs have provided a highly effective avenue for challenging patents.⁵⁶ In fact, petitioners have been so successful in invalidating patents before the PTAB that Randall Rader, then Chief Judge of the U.S. Court of Appeals for the Federal Circuit, referred to the PTAB as a “death squad[] killing property rights.”⁵⁷ And the statistics bear this

50. Teague I. Donahey, *The Patent Trial and Appeal Board (PTAB) and the Supreme Court: How Oil States Threatens to Reverse Congressional Efforts to Reform Patent Litigation*, 60 *ADVOCATE* 22, 22 (2017).

51. *Id.*

52. *Id.*

53. H.R. REP. NO. 112-98, pt. 1, at 48 (2011), as reprinted in 2011 U.S.C.C.A.N. 67, 78 [hereinafter “House Report”].

54. See Asay, *supra* note 32, at 3 (“From fueling the business models of so-called patent trolls, to diverting valuable resources into patent ‘wars,’ to otherwise failing to live up to their purported theoretical justifications, the increasing number of patents flooding the U.S. marketplace is of growing concern to scholars and policymakers alike.” (citations omitted)); Michael A. Carrier, *Post-Grant Opposition: A Proposal and a Comparison to the America Invents Act*, 45 *U.C. DAVIS L. REV.* 103, 108–09 (2011) (noting that nearly half of all litigated patents that make it through trial were eventually invalidated by the courts).

55. House Report, *supra* note 53, at 48.

56. See Donahey, *supra* note 50, at 22 (“Over the past five years, parties have been widely successful at invalidating patents before the PTAB . . .”).

57. Brian Nolan & Michael Martinez, *New Enemy Challenging Biopharma Patents: Investment Firms*, 22 *No. 8 WESTLAW J. INTELL. PROP.* *1, *1 (Aug. 5, 2015); see also Susan Decker, *Apple Likes the ‘Patent Death Squad.’ Allergan Pays to Avoid It*, *BLOOMBERG* (Sept. 20, 2017, 4:00 AM), <https://www.bloomberg.com/news/articles/2017-09-20/apple-likes-the-patent->

out: between 2012 and 2017, in instances when the PTAB instituted IPR review, it found all claims unpatentable in 65 percent of instances and at least one claim unpatentable in 82 percent of proceedings.⁵⁸

A recently published study demonstrates that IPRs pose a very real threat to biopharmaceutical innovation. On March 13, 2018, the PTO issued a special report on trial outcomes for pharmaceutical patents.⁵⁹ The report focuses on the “institution rate” metric of how often a challenged patent gets upheld; it states that “[t]he cumulative institution rate for [pharmaceutical patent] petitions (66%) is essentially the same as the cumulative overall institution rate (68%).”⁶⁰ Although the PTAB’s institution rate on pharmaceutical patents is similar to its overall institution rate, in cases where the PTAB issued a final written decision related to pharmaceutical patents, it found that none of the challenged claims were patentable in 46 percent of those cases.⁶¹ This means that if a challenger can convince the PTAB to review an Orange Book patent, there is a nearly 50 percent chance that all the challenged claims will ultimately be invalidated.⁶²

Although IPRs may be useful in eliminating low-quality patents in certain fields, the system, as it is currently structured, fails to recognize that “[t]echnology is anything but uniform . . . and it displays highly diverse characteristics across different sectors.”⁶³ In the pharmaceutical sector, the IPR system is not only unnecessary, but it also places potentially catastrophic burdens on the future of new drug development.

B. *A Primer on Sovereign Immunity*

Sovereign immunity has been a bedrock principle of our federal system since the founding: “Although the Constitution establishes a National Government with broad, often plenary authority over matters

death-squad-allergan-pays-to-avoid-it [<https://perma.cc/7R7F-WLNS>] (noting that the PTAB has been “dubbed a ‘death squad’”).

58. Donahy, *supra* note 50, at 22.

59. U.S. PAT. & TRADEMARK OFF., CHAT WITH THE CHIEF, NEW PTAB STUDIES IN AIA PROCEEDINGS: EXPANDED PANELS AND TRIAL OUTCOMES FOR ORANGE BOOK-LISTED PATENTS (2018), https://www.uspto.gov/sites/default/files/documents/chat_with_the_chief_march_2018.pdf [<https://perma.cc/548P-N3XM>].

60. *Id.* at 34.

61. *Id.* The PTAB found some claims patentable in another 3 percent of cases. *Id.*

62. *Id.*

63. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577 (2003).

within its recognized competence, the founding document ‘specifically recognizes the States as sovereign entities.’”⁶⁴ By its plain terms, the Eleventh Amendment provides state governments with immunity from suits brought in federal court by citizens of other states and citizens or subjects of foreign states.⁶⁵ In *Hans v. Louisiana*, however, the Supreme Court extended this immunity to preclude *all* suits against a state, including those suits brought by citizens of the same state.⁶⁶

Unlike state sovereign immunity, which is constitutionally guaranteed under the Eleventh Amendment, tribal immunity is grounded in federal common law.⁶⁷ In 1919, the Supreme Court explicitly embraced the doctrine of tribal sovereign immunity, stating that tribal governments—like local or state governments—cannot be sued “for injuries to persons or property due to mob violence or failure to keep the peace.”⁶⁸ In the ensuing years, the Supreme Court made clear that as “domestic dependent nations,”⁶⁹ Indian tribes “exercise inherent sovereign authority over their members and territories.”⁷⁰ Accordingly, although Congress exercises “plenary control” over them, the tribes maintain their sovereign authority up to the point at which Congress acts. Furthermore, “[a]lthough Congress has plenary authority over tribes, courts will not lightly assume that Congress in fact intends to undermine Indian self-government.”⁷¹ At a base level, the Supreme Court has asserted that, “[a]mong the core aspects of sovereignty that tribes possess—subject, again, to congressional action—is the ‘common-law immunity from suit traditionally enjoyed by sovereign powers.’”⁷² Specifically, this sovereign tribal immunity applies to suits brought by both states and individuals.⁷³ And any

64. *Alden v. Maine*, 527 U.S. 706, 713 (1999) (quoting *Seminole Tribe of Fla. v. Florida*, 715 U.S. 44, 71 n.15 (1996)).

65. U.S. CONST. amend. XI (“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.”).

66. *Hans v. Louisiana*, 134 U.S. 1, 16 (1890) (noting that a state can only be sued with its consent).

67. *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 759 (1998).

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

69. *Cherokee Nation v. Georgia*, 30 U.S. (5 Pet.) 1, 17 (1831).

70. *Okla. Tax Comm’n v. Citizen Band Potawatomi Indian Tribe of Okla.*, 498 U.S. 505, 509 (1991).

71. *Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2032 (2014).

72. *Id.* at 2030 (quoting *Santa Clara Pueblo v. Martinez*, 436 U.S. 49, 58 (1978)).

73. *Id.* at 2031.

waiver of sovereign immunity by a tribe must be unequivocally expressed.⁷⁴

There is no blanket prohibition on asserting sovereign immunity in agency proceedings involving the federal government.⁷⁵ But there *is* an exemption from sovereign immunity for suits brought by the United States; however, that exemption only subjects tribes to proceedings that are “commenced and prosecuted” by the United States.⁷⁶ In general, sovereign immunity applies in agency proceedings when such proceedings “can indeed be characterized as a lawsuit” in that they involve adverse parties, examination and cross examination, deposition discovery, and an impartial federal adjudicator.⁷⁷

Tribal sovereign immunity has no exception for commercial activity,⁷⁸ allowing tribes to engage in commerce with corporate partners without waiving the protections this immunity offers. In determining whether a commercial entity enjoys the benefits of tribal immunity, courts look to see whether the entity is an “arm of the tribe.”⁷⁹ In doing so, they consider whether the entity “is chartered under tribal law, whether its proceeds serve to further the aims of tribal self-governance, and whether the tribe intended to confer its immunity.”⁸⁰ Casinos and other businesses on reservations routinely receive this protection.⁸¹ And significantly, Allergan and the St. Regis Tribe structured their contract in such a way that their partnership has never been challenged under this test.

II. IPRs: AN IMPROPER FORUM FOR REVIEW OF PHARMACEUTICAL PATENTS

The costs and difficulties associated with drug development, the vital importance of patents to the pharmaceutical industry—especially

74. *C & L Enters., Inc. v. Citizen Band Potawatomi Tribe of Okla.*, 532 U.S. 411, 418 (2001) (“[T]o relinquish its immunity, a tribe’s waiver must be ‘clear.’” (quoting *Okla. Tax Comm’n*, 498 U.S. at 509)).

75. *See Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1326 (Fed. Cir. 2018) (“There is not, however, a blanket rule that immunity does not apply in federal agency proceedings.” (citing *Fed. Mar. Comm’n v. S.C. State Ports Auth.*, 535 U.S. 743, 754–56 (2002))).

76. *Alden v. Maine*, 527 U.S. 706, 755 (1999).

77. *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376, 1382 (Fed. Cir. 2007).

78. Gregory Ablavsky, *Tribal Sovereign Immunity and Patent Law*, LEGAL AGGREGATE (Sept. 13, 2017), <https://law.stanford.edu/2017/09/13/tribal-sovereign-immunity-and-patent-law> [<https://perma.cc/UP4U-9Y3A>].

79. *Id.*

80. *Id.*

81. *Id.*

early in the innovation pipeline—and the already successful, but delicate, legislative framework allowing generic entry into the market, all make IPR the improper forum to review pharmaceutical patents.

A. *The Nature of Drug Development*

Strong patents have been described as the “lifeblood of the biotechnology industry,”⁸² and with good reason. The costs associated with innovation in the biotechnology realm are typically far higher than in other fields,⁸³ in part because “of the labyrinthine regulatory process and the detailed study that is required to sell a drug for consumption by humans.”⁸⁴ In 2014, it cost drug manufacturers an estimated average of \$2.6 billion to bring a new drug to market.⁸⁵ This “is based on an average out-of-pocket cost of \$1.4 billion and an estimate of \$1.2 billion in returns that investors forego” during the decade the drug is in development.⁸⁶

Before marketing a new drug to the public, pharmaceutical companies must first obtain approval from the Food and Drug Administration (“FDA”).⁸⁷ The FDA approval process requires time-consuming and expensive clinical testing, typically including “three phases of human trials designed to test whether a drug is safe and effective for general public consumption.”⁸⁸ Furthermore, much of the “low-hanging fruit”—the relatively easy-to-develop molecules for which there is great demand—has already been picked, forcing firms to “focus their R&D [research and development] where the science is difficult and the failure risks are higher.”⁸⁹ Consequently, the practice of creating new medicines “is growing in difficulty and length” as well as in expense.⁹⁰ It typically takes *at least* a decade to bring a potentially

82. Sommer Nicole Louie, *The Inadequacy of Bankruptcy Protection for the Biotechnology Industry*, 22 EMORY BANKR. DEV. J. 337, 339 (2005) (citation omitted).

83. Burk & Lemley, *supra* note 63, at 1581–82.

84. *Id.*

85. Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5B*, SCI. AM. (Nov. 24, 2014), <https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b> [<https://perma.cc/3BW9-HL56>].

86. *Id.*

87. 21 U.S.C. § 355(a) (2012).

88. Caitlyn Martin, *Questioning the “Right” in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws*, 77 OHIO ST. L.J. 159, 168 (2016).

89. PHRMA, *supra* note 24, at 1.

90. *Id.*

therapeutic discovery from its nascent stage to the market, “with clinical trials alone taking six to seven years on average.”⁹¹

The apparent purpose of IPRs is to rid the system of useless patents writ large. But even the most suspect component of any drug from a patentability perspective has already had to prove its safety and efficacy to the FDA to a greater extent than the most comprehensive PTO review could require: less than 12 percent of drugs survive clinical testing, and *thousands* more never advance beyond the in vitro stage of testing.⁹² Because FDA-approved pharmaceutical components have all been so thoroughly vetted by that industry, and because the FDA process guarantees that the component is functional, allowing these patents to be retroactively invalidated is particularly unfair.

Producing any first-in-class drug, like Restasis, requires “the best scientific minds, highly sophisticated technologies, ever-evolving manufacturing processes, and complex project management.”⁹³ Developing a lucrative drug requires dogged persistence through scores of failures, but in the end, the drug “brings hope and relief to millions of patients.”⁹⁴ At bottom, it is estimated that new drug discoveries accounted for 40 percent of the increase in American lifespan between 1986 and 2000.⁹⁵

However, the “best scientific minds” can no longer be certain they will be rewarded for their discoveries, even in a field where discovery has provided more life-saving benefits than almost any other. Presumably, the best and brightest should continue to be encouraged to enter the pharma-innovation field and provide society with breakthrough therapies like penicillin or the polio vaccine. But myriad environmental factors are not providing these pharmaceutical innovators with effective incentives. “[T]he unprecedented combination of reduced R&D output in the form of successfully launched truly innovative” new molecular entities, together with reduced market exclusivity and massive revenue loss from generic competitors, “suggest[s] that we may be moving closer to a pharmaceutical ‘ice age’ and the potential extinction of the industry.”⁹⁶

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. Steven M. Paul et al., *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, 9 NATURE REV. DRUG DISCOVERY 203, 204 (2010).

96. *Id.*

According to one estimate, for every dollar of profit that branded pharmaceuticals miss out on because of patent expirations, they only recoup twenty-six cents through the sale of new products.⁹⁷ Thus, in the absence of a massive boost in productivity, branded pharmaceuticals simply “cannot sustain sufficient innovation to replace the loss of revenues due to patent expirations for successful products.”⁹⁸

B. The Critical Role of Patents in Drug Development

Given the enormous amount of money and time it takes to bring a new drug to market, the financial rewards of patent protection are of paramount importance to the pharmaceutical sector. Investment in the biotech space “is predicated on an expected return in the form of patent-protected products or services that ultimately reach the market.”⁹⁹ Furthermore, “biotech companies often rely on just a handful of highly valuable patents to protect their products and massive investment therein.”¹⁰⁰ Even compared to other industries that rely heavily on research and development (“R&D”), biotechnology companies spend a far greater share of their resources on R&D.¹⁰¹ In the chemical industry, for example, “the ratio of R&D expenditure to total revenues is approximately 5%,” but in the biotechnology arena, companies tend to plow between 40 and 50 percent of their revenues back into R&D.¹⁰²

Moreover, while it is incredibly expensive to bring new drugs to market, it is quite cheap to imitate them.¹⁰³ Compared to the billions that pharmaceutical companies are forced to spend to develop first-in-class drugs, it typically costs generics only \$1 million to \$2 million to gain FDA approval, based on a study in the year 2000.¹⁰⁴ This is because the present reality in drug development is that “[a]lmost any

97. *Id.* at 203.

98. *Id.*

99. *The Impact of Abusive Patent Litigation Practices on the American Economy: Hearing Before the S. Comm. on the Judiciary*, 114th Cong. 3–4 (2015) (Statement of Hans Sauer, Deputy General Counsel for Intellectual Property, Biotechnology Industry Association) [hereinafter Sauer Testimony].

100. *Id.* at 18.

101. Esteban Burrone, *Patents at the Core: The Biotech Business*, WORLD INTELL. PROP. ORG. (2006), http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html#P4_83 [https://perma.cc/5YMN-GW42].

102. *Id.*

103. *Id.*

104. Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUB. POL’Y REV. 7, 13 (2003).

technology or compound can rapidly be reverse engineered,”¹⁰⁵ making strong intellectual property protection the most significant motivation that companies have to invent new drugs.

An important—but often overlooked—factor in the debate surrounding high drug prices is that, for many biotech companies, “intellectual property rights are actually the *final* product.”¹⁰⁶ Because such companies lack the resources to bring their drugs to market, many firms either license out their patents to, or are acquired by, larger companies.¹⁰⁷ The profound implications of this are poorly addressed in the popular discourse surrounding big pharma and rising drug costs. Instead, the pharmaceutical industry is broadly criticized for reaping huge profits at the expense of public health, and it “comes only second to the federal government as the public’s least-favored industry.”¹⁰⁸ Consequently, attempting to defend the industry, much less expand its protections, is not a popular position to take.

However, unbeknownst to most casual observers, the lion’s share of innovation in the pharmaceutical industry does not occur within large companies.¹⁰⁹ Smaller companies, often funded by venture capitalist (“VC”) investors, direct nearly 90 percent of their funding in the space into novel drug R&D—research focused on diseases with an unmet medical need.¹¹⁰ This stands in stark contrast to the “low technical risk” investment model prominent at many large

105. *Why Patents are the Lifeblood of Biotech Companies*, BIOSPACE (Apr. 26, 2016), <https://www.biospace.com/article/around-the-web/why-patents-are-the-lifeblood-of-biotech-companies-> [https://perma.cc/83TU-CN3F].

106. *Id.* (emphasis added).

107. *Id.*

108. Ashley E. Petrarca, Note, *Allergan’s Battle to Stay in Court: Does Inter Partes Review Violate the Constitution by Circumventing Courtroom Adjudication?*, B.C. INTELL. PROP. & TECH. F. 1, 1 (Dec. 20, 2017); Peter Loftus, *Drugmakers Raise Prices Despite Criticisms*, WALL ST. J. (Jan. 10, 2016, 8:03 PM), <http://www.wsj.com/articles/drugmakers-raise-prices-despite-criticisms-1452474210> [https://perma.cc/3CBL-JNMR] (noting that high drug prices mean that certain patients will be denied access to life-saving drugs).

109. *Cf.* THE BUSINESS OF HEALTHCARE INNOVATION 148 (Lawton Burns ed., 2d ed. 2012) (“While larger firms may (or may not) undertake the bulk of innovative investment, they are not the source of the majority of innovations, or at least the most distinctive innovations in a therapeutic area.”).

110. David Thomas & Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO INDUSTRY ANALYSIS 9 (June 1, 2017), <https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf> [https://perma.cc/BHH5-SBMC] (“The majority of the venture funding continues to flow into novel drug R&D, reaching a peak of 92% in 2015 and down slightly to 83% in 2016.”).

pharmaceutical firms.¹¹¹ By and large, VCs are professional investors, not scientists. Accordingly, in this knowledge-intensive industry, “emerging firms that seek external financ[ing] can be difficult to” value.¹¹² Patents provide an important signaling function to VCs, and they are a useful heuristic for these investors in making their valuations. Studies have documented “that patents attract prominent VC[s], prompt VC[s] to invest faster and generally increase the amounts” they invest.¹¹³ In essence, many VCs *rely on the PTO* in making their investment decisions—particularly in early rounds of funding,¹¹⁴ where the majority of funding “has gone toward early stage assets”¹¹⁵ like drug discovery, among the furthest upstream research in the innovation pipeline. This is significant because “discovery research and early translational medicine” are the most significant factors in producing “highly innovative medicines that result in markedly improved health outcomes.”¹¹⁶ Further, it is in these early rounds that VCs rely most heavily on the PTO’s grant of a patent. Unfortunately, many feel they can no longer do so.¹¹⁷

In 1996, the United States financed 83 percent of the world’s venture capital.¹¹⁸ But by 2015, its market share had been reduced to 54 percent.¹¹⁹ As investment in the space continues to decrease, the “US should be working to improve its innovation ecosystem, providing stable and effective property rights,” especially intellectual property rights, “so that VCs can once again feel confident” in their

111. Bruce Booth, *Where Does All That Biotech Venture Capital Go?*, LIFESCIVC (Feb. 9, 2015), <https://lifescivc.com/2015/02/where-does-all-that-biotech-venture-capital-go> [https://perma.cc/WPY7-QDVS].

112. Sebastian Hoenen, Christos Kolympiris, Wilfred Schoenmakers & Nicholas Kalaitzandonakes, *The Diminishing Signaling Value of Patents Between Early Rounds of Venture Capital Financing*, 43 RES. POL’Y 956, 956 (2014).

113. *Id.* at 957.

114. Eric K. Steffe & Timothy J. Shea, Jr., *Protecting Innovation in Biotechnology Startups*, NATURE: BIOENTREPRENEUR (June 23, 2003), <https://www.nature.com/bioent/2003/030601/full/bioent741.html> [https://perma.cc/YF9Z-VUC3].

115. Booth, *supra* note 111.

116. Paul, *supra* note 95, at 213.

117. See Kevin Madigan, *As Investment Moves Overseas, The US Must Restore Its Gold-Standard Patent System*, CTR. FOR PROTECTION INTELL. PROP. (June 22, 2017), <https://cpip.gmu.edu/2017/06/22/as-investment-moves-overseas-the-us-must-restore-its-gold-standard-patent-system> [https://perma.cc/86L7-B3TL] (explaining how the weakening of patent rights is a factor causing venture capital investment to decline in the United States and move overseas).

118. *Id.*

119. *Id.*

investments.¹²⁰ However, the American intellectual property regime is “doing just the opposite.”¹²¹ For this reason, especially in the research-intensive biotechnology sector where strong patents are “absolutely vital,” investment has been flowing out of American firms and into Chinese ones at an alarming rate. This trend could soon allow China to take the lead “in the development of lifesaving therapeutics and cancer treatment drugs.”¹²²

Research suggests that possessing patents is among the most significant factors in securing early stage venture funding in the life sciences industry.¹²³ This makes sense, as “[v]ery few biotechnology startups actually have products to sell; their primary assets are usually proprietary technologies”—that is, these companies’ value is usually directly tied to their ability to safeguard their innovations through patent protection.¹²⁴ For this reason, many VCs hire patent consultants to assess the strength of a company’s patent portfolio before making an investment.¹²⁵

But the IPR “death squad[.]” of the PTAB is increasingly undermining the confidence VCs can place in biotech patents.¹²⁶ This is problematic because VC investing is risky enough to begin with: the majority of venture capital funds do not break even,¹²⁷ and around 75 percent of the companies they invest in fail outright.¹²⁸ To turn a profit, VCs need to hit a home run on a small portion of their investments, and in doing so, make up for their high number of strikeouts, which are especially expensive in the pharmaceutical industry. But who would swing for the fences on every pitch, given that the umpire—the PTAB—can far too easily “invalidate” any pharmaceutical home run? Put simply, according to a letter signed by some of the nation’s top VCs, “the injection of this type of [IPR] uncertainty into the patent system puts in doubt [our] future funding of” the life sciences sector

120. *Id.*

121. *Id.*

122. *Id.*

123. See Steffe & Shea, *supra* note 114 (noting that “a strong patent position is a crucial ingredient for successfully raising venture capital”).

124. *Id.*

125. *Id.*

126. Nolan & Martinez, *supra* note 57, at *1.

127. Diane Mulcahy, *Six Myths About Venture Capitalists*, HARV. BUS. REV. (May 2013), <https://hbr.org/2013/05/six-myths-about-venture-capitalists> [<https://perma.cc/6HVW-KN92>].

128. Max Nisen, *Bill Gates Says the Success Rate on Venture Capital Is “Pathetic” Compared to Development*, QUARTZ (Mar. 14, 2014), <https://qz.com/187959/bill-gates-says-the-success-rate-on-venture-capital-is-pathetic-compared-to-development> [<https://perma.cc/6SBE-ASXJ>].

because “no matter how groundbreaking an innovation may be, without the guarantee of a strong patent, the risk cannot be justified.”¹²⁹

It could be argued that the pharmaceutical patents challenged in IPR proceedings are not the same sort of patents that VCs rely on in making their investment decisions. Instead, so the reasoning goes, the challenged patents are the so-called “evergreening” patents,¹³⁰ obtained by large pharmaceutical firms after a drug has been launched. Such “secondary” patents pertain to “ancillary aspects of drug innovation,” such as formulations and compositions, as opposed to active ingredients.¹³¹ The data on Orange Book-related patents in IPR proceedings has not been broken down into active-ingredient patents and secondary patents, but in district court proceedings, secondary patents are the subject of a greater proportion of preexpiration challenges, where they are invalidated at higher rates than active ingredient patents.¹³² Even assuming, *arguendo*, that secondary patents make up the lion’s share of patents in IPR proceedings, and assuming that these secondary patents are obtained after the venture funding stage, it does not necessarily follow that the invalidation of secondary patents will have a *de minimis* impact on upstream innovation. Importantly, if large pharmaceutical companies are unable to extend the patent-protected life of their blockbuster drugs by relying on secondary patents, they will be less likely to acquire active-ingredient patents from venture-backed companies in the first place. Because of the “current pressures on existing patents and the uncertain[] future of pharmaceutical patent protection . . . an unintended downward

129. Letter from Members of Life Sciences Venture Capital Community to Chuck Grassley, Chairman, Senate Comm. on the Judiciary, Patrick J. Leahy, Ranking Member, Senate Comm. on the Judiciary, Bob Goodlatte, Chairman, House Comm. on the Judiciary, John Conyers, Ranking Member, House Comm. on the Judiciary (Sept. 9, 2015), https://califesciences.org/wp-content/uploads/2015/09/VC-Letter-on-IPR-Reform-H-R-9_FINAL.pdf [<https://perma.cc/6PHC-5WA5>].

130. See Cynthia M. Ho, *Should All Drugs Be Patentable? A Comparative Perspective*, 17 VAND. J. ENT. & TECH. L. 295, 297 (2015):

In recent years, companies are increasingly seeking and obtaining a series of patents on different *aspects* of a drug, with each patent having a later expiration date to effectively result in a longer period of market exclusivity. Critics call this “evergreening,” in that the patent term appears “evergreen,” even if the commercial exclusivity is technically achieved through different patents.

131. C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386 (2013).

132. See *id.* at 1386–87 (“Of . . . cases litigated to completion . . . the branded firm nearly always wins a suit asserting an active ingredient patent . . . but usually loses asserting secondary patents . . .”).

pressure [is being applied] on the incentives to undertake the most risky research,”¹³³ which is typically sponsored by VCs. If VCs conclude that a drug being developed by a small life sciences firm is unlikely to be acquired or that it will be acquired at a lower multiple than the economics of VC firms demand, the incentives for investment are sharply curtailed. An understanding of the dynamics of upstream innovation requires that “patent incentives . . . promise more than reasonable compensation for R&D effort.”¹³⁴ Instead, financing incredibly risky and potentially life-saving R&D must promise “great rewards for great advancements that will not be retroactively appropriated” by the PTO.¹³⁵

Oddly enough, and unfortunately, “[t]here’s more money to be made investing in drugs that will extend cancer patients’ lives by a few months than in drugs that would prevent cancer in the first place.”¹³⁶ Eric Budish, Benjamin Roin, and Heidi Williams effectively show why our patent system may have historically encouraged this problem by demonstrating that a drug’s commercial success is often inversely correlated with the time it takes to develop and its therapeutic value.¹³⁷ And IPRs stand to make this problem worse. Drug patents are granted by the PTO well before the FDA approves the sale of actual drugs. Before granting approval, the FDA requires years of clinical testing to show that the drugs are safe and effective.¹³⁸ While all drugs require these trials, drugs that attack diseases in their later stages, such as chemotherapeutics, tend to take proportionately less time to demonstrate safety and efficacy. This is because diseases in later stages tend to progress much more rapidly and aggressively, allowing firms to see any drug-related effects—even if insignificant—in much less time.¹³⁹ This rapidity of observable results allows late stage drugs to

133. Daniel R. Cahoy, *Rethinking Patents for Optimal Health Care Innovation*, at 87 (Apr. 2005) (unpublished manuscript), <https://www.smeal.psu.edu/fcfe/research/white/patents.pdf> [<https://perma.cc/M75L-AV2R>].

134. *Id.*

135. *Id.*

136. Austin Frakt, *Why Preventing Cancer Is Not the Priority in Drug Development*, N.Y. TIMES (Dec. 28, 2015), <https://www.nytimes.com/2015/12/29/upshot/why-preventing-cancer-is-not-the-priority-in-drug-development.html> [<https://perma.cc/G2ZA-MN7J>].

137. *See generally* Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044 (2015) (analyzing how private investment shapes cancer research).

138. *See supra* notes 87–98 and accompanying text.

139. Frakt, *supra* note 136.

obtain FDA approval faster and get to market sooner.¹⁴⁰ Accordingly, late-stage drugs have reduced *commercialization lag*—“the length of time between receipt of a patent and F.D.A. approval”—and they are much more lucrative for pharmaceutical companies because they enjoy monopoly status longer.¹⁴¹

On average, accounting for the time it takes to gain FDA approval, the effective patent term of first-in-class drugs is twelve-and-a-half years, entitling them to a mere 62.5 percent of their patent term.¹⁴² For this reason, many “compounds are never developed [into drugs] because the patent protected production time available to recoup the cost of development is too short.”¹⁴³ IPRs risk further limiting patents’ average effective term of market exclusivity—particularly if the proceedings target secondary patents that help add extensions to patent terms. Accordingly, pharmaceutical firms expect to have reduced time within which to recoup their investment, leading to fewer promising compounds being developed.

A large pharmaceutical company that acquires a drug from a small firm is in a much better position to forecast the effective life of its primary patent than the small firm was when it undertook discovery research. This is because the commercial lag between acquisition and approval is necessarily shorter than the commercial lag between discovery and approval. Also, the VCs that invest in discovery-research companies “may be more impatient than neo-classical models [of profit-maximizing behavior] would predict due to . . . agency problems”¹⁴⁴ that are the result of informational asymmetries between management and investors; these asymmetries are at their greatest when a drug’s therapeutic potential is merely theoretical.¹⁴⁵

Furthermore, because of the time value of money, small increases in the risk profile of a project exponentially discount the present value of its future cash flows, especially those that are the most remote—those furthest upstream in the innovation pipeline. According to many patent brokers, the sale price of American patents has been *reduced by*

140. *See id.* (“To secure F.D.A. approval . . . drug companies race the clock to show that their product is safe and effective.”).

141. *Id.*

142. *Id.*

143. *Id.* (citation omitted) (alteration in original).

144. Budish et al., *supra* note 137, at 2045.

145. *See infra* Part II.B.

two-thirds since the establishment of IPR proceedings.¹⁴⁶ Even if the future value of VC-funded primary patents has been reduced by a mere fraction of this amount, the present value of such a patent is worth an order of magnitude less when discounted to present value. The risk that IPRs create for pharmaceutical patents, then, may be felt most acutely far upstream. And upstream is exactly where looming risks carry the most catastrophic consequences, as that is where breakthrough therapeutic innovation typically occurs.¹⁴⁷

C. *If It Ain't Broke . . .*

Long before the advent of IPR proceedings, drug patents were already subject to specialized review. More than three decades ago, Congress, through the Hatch-Waxman Act,¹⁴⁸ devised an expedited litigation pathway for challenging pharmaceutical patents.¹⁴⁹ The Hatch-Waxman Act sought both to incentivize innovation and to facilitate the entry of cheaper generic drugs into the marketplace.¹⁵⁰ And by most accounts, it has been successful in doing so.¹⁵¹ Although generic drugs made up only 19 percent of prescriptions in 1984, they made up 88 percent of prescriptions by 2015.¹⁵² Furthermore, by 2015, the average cost of a generic drug was less than one-fifth of the price of a patented brand drug.¹⁵³

146. Richard Baker, *Guest Post: America Invents Act Cost the US Economy Over \$1 Trillion*, PATENTLY-O (June 8, 2015), <https://patentlyo.com/patent/2015/06/america-invents-trillion.html> [<https://perma.cc/TM84-UWP8>].

147. See *infra* Part II.B.

148. Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2012)).

149. The Hatch-Waxman Act does not apply to biologics or biosimilars, which are instead covered by the Biologics Price Competition and Innovation Act (“BPCIA”). 42 U.S.C. § 262.

150. See 130 CONG. REC. 24,425 (1984) (statement of Rep. Waxman) (“[T]he bill . . . assures consumers of more low-cost generic drugs when a valid patent expires and the drug industry of sufficient incentive to develop innovative pharmaceutical therapies.”); see also Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 11–14 (discussing the purposes of the Hatch-Waxman Act); Joanna Shepherd, *Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Partes Review*, 6 N.Y.U. J. INTELL. PROP. & ENT. L. 14, 16 (2016) (“With Hatch-Waxman, Congress sought to achieve a delicate balance between stimulating innovation from brand companies who hold patents and facilitating market entry from generic companies who challenge the patents.”).

151. See Carrier & Minniti, *supra* note 150, at 13 (“On the whole, the Hatch-Waxman Act has been successful.”).

152. *Id.*

153. *Id.*; see IMS INST. FOR HEALTHCARE INFORMATICS, *MEDICINES USE AND SPENDING IN THE U.S.: A REVIEW OF 2015 AND OUTLOOK TO 2020*, at 27 (2016), <https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending->

To encourage investment in new drugs, the Hatch-Waxman Act provides for “a patent-term extension for patents relating to certain products that were subject to lengthy regulatory delays and could not be marketed prior to regulatory approval.”¹⁵⁴ It also seeks to encourage generic drug manufacturers to enter the marketplace.¹⁵⁵ The Hatch-Waxman Act introduced the Abbreviated New Drug Application (“ANDA”),¹⁵⁶ which allows the manufacturers of bioequivalent generic drugs to rely on the safety and efficacy data submitted by the brand drug manufacturer when it sought FDA approval.¹⁵⁷

Importantly, the Hatch-Waxman Act gives generic drug companies a significant incentive to challenge drug patents prior to their expiration. If a generic drug company wishes to market a generic version of a drug before the Orange Book patents covering that drug expire, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), known as a Paragraph IV certification.¹⁵⁸ The Hatch-Waxman Act promotes the early resolution of patent disputes between generic and brand-name pharmaceutical companies by specifying that the mere act of filing a Paragraph IV certification constitutes an act of patent infringement.¹⁵⁹ Furthermore, “to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible, the Hatch-Waxman Act provides that the first ANDA applicant to file a Paragraph IV certification . . . [will] enjoy a 180-day period of generic marketing exclusivity.”¹⁶⁰ Significantly, the first Paragraph IV ANDA filer obtains a 180-day, or six-month, exclusivity period regardless of whether it establishes that the brand name manufacturer’s “Orange-Book-listed patents are invalid or not infringed by the drug described

2015.pdf [https://perma.cc/7JTG-J39E] (comparing branded drugs’ average list price with generic drugs’ average list price).

154. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990).

155. H.R. REP. NO. 98-857, at 14–15 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2647; see *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 396 (Fed. Cir. 1990) (“[T]he Act has two general purposes: (1) to increase the availability of low-cost drugs . . . and (2) to further encourage new drug research . . .”).

156. 21 U.S.C. § 355(j) (2012).

157. *Eli Lilly*, 496 U.S. at 676.

158. See *id.* at 677 (discussing Paragraph IV certification).

159. 35 U.S.C. § 271(e)(2); see *Eli Lilly*, 496 U.S. at 678 (“[An] act of infringement . . . consists of submitting an ANDA . . . containing the fourth type of certification . . .”).

160. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008) (citing 21 U.S.C. § 355(j)(5)(B)(iv)).

in its ANDA.”¹⁶¹ This six-month period of generic exclusivity can be extremely profitable, allowing Paragraph IV challengers to price their drug at a cost that is only slightly less than that of the branded drug.¹⁶² The data demonstrates the strength of this incentive: “81 percent of drugs facing generic entry in 2012” faced Paragraph IV challenges.¹⁶³

The IPR regime has also created a new and surprising threat: hedge funds. In 2014, a hedge fund manager named Kyle Bass, along with one of his fund’s subsidiaries—the Coalition for Affordable Drugs (“CFAD”)—entered the fray and made IPR challenges even more perilous for pharmaceutical companies.¹⁶⁴ Bass developed a scheme to reap enormous financial rewards by shorting stock in a pharmaceutical company and then petitioning to have one of that company’s important drugs invalidated in IPR proceedings.¹⁶⁵ On February 10, 2014, Bass filed IPR petitions challenging the validity of Ampyra, a prescription drug that helps multiple sclerosis patients walk.¹⁶⁶ The shares of Acorda Therapeutics, Inc., the company that owned these patents, dropped nearly 15 percent in the days that followed,¹⁶⁷ allowing Bass’s hedge fund to turn a fast profit by shorting the stock,¹⁶⁸ notwithstanding the fact that the PTAB ultimately upheld the patents’ validity.¹⁶⁹ In the months that followed, CFAD filed thirty-two more IPR petitions, all of which challenged patents in the biotechnology space.¹⁷⁰

Bass has claimed that his repeated IPR petitions were designed to bring down drug prices, asserting that “Medicare and U.S. consumers pay the ultimate price for the evergreening of bad patents by the pharma cabal.”¹⁷¹ Although Bass and his hedge fund appear to have

161. *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)).

162. Shepherd, *supra* note 150, at 24 (noting that the first Paragraph IV ANDA filer “can earn substantial profits by shadow pricing, or pricing slightly under the innovator’s price”).

163. *Id.*

164. See Nolan & Martinez, *supra* note 57, at *2 (suggesting that “the mere filing of the petition—and not its underlying merits—caused the [company’s stock price to drop ten percent]”).

165. *Id.*

166. Jennifer Robichaux Carter, *Hedge Funds Should Be Able to Challenge Patent Validity Using Inter Partes Review Despite Mixed Motives*, 54 HOUS. L. REV. 1315, 1317–18 (2017).

167. See *id.* (explaining that the stock price dropped 9.7 percent on February 10 and then 4.8 percent on February 27, for a total 14.5 percent drop from the original price).

168. *Id.* at 1330.

169. Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. IPR2015-00817 (P.T.A.B. Aug. 24, 2015).

170. Carter, *supra* note 166, at 1332–33.

171. Susan Decker, Bloomberg, *Dallas’ Kyle Bass Blames Big Pharma ‘Cabal’ for Lost Fights Over Drug Prices*, DALL. NEWS (Apr. 10, 2017), <https://www.dallasnews.com/business/health->

moved away from filing new IPR petitions,¹⁷² the threat to pharmaceutical companies still remains. Biotech companies are particularly vulnerable to IPR challenges filed by hedge funds and short sellers “because—in contrast to most high-tech companies—biotech companies often rely on just a handful of highly valuable patents to protect their products and massive investment therein.”¹⁷³ Hence, the mere filing of an IPR can drastically impact the stock prices of these companies.¹⁷⁴

Fighting a war on two fronts is costly and expensive. Hatch-Waxman and PTAB proceedings can force drug companies to fight validity battles in two ways, potentially eviscerating the financial incentives necessary to ensure robust drug-development efforts. It has been suggested that life science patents should be exempted from IPR challenges since Congress, through the Hatch-Waxman Act, has already established effective mechanisms for challenging such patents.¹⁷⁵ Leaders in the biotechnology and pharmaceutical industries have argued that

the IPR process threatens to disrupt the careful balance that Congress achieved over 30 years ago, by increasing business uncertainty for innovative biopharmaceutical companies having to defend their patents in multiple venues and under differing standards and procedures, ultimately diverting finite resources away from the research and development of new cures and treatments, to the detriment of patients.¹⁷⁶

Given that Congress has so far shown no real interest in exempting life sciences patents from IPR challenges, however, an alternative solution is instead for drug companies and Native American tribes to form partnerships in a manner that can effectively shield

care/2017/04/10/dallas-kyle-bass-blames-big-pharma-cabal-lost-fights-drug-prices [https://perma.cc/BFJ5-54GX].

172. *See id.* (noting that “[t]he coalition hasn’t file a new case in 18 months”).

173. Sauer Testimony, *supra* note 99, at 18.

174. *Id.* at 1.

175. *See* Letter from James C. Greenwood, President & CEO of BIO, and John J. Castellani, President & CEO of PhRMA, to Chuck Grassley, Chairman, Senate Judiciary Comm., Patrick Leahy, Ranking Member, Senate Judiciary Comm., Robert Goodlatte, Chairman, House Judiciary Comm., John Conyers, Ranking Member, House Judiciary Comm. (July 15, 2015) [hereinafter Greenwood Letter], http://thehill.com/sites/default/files/final_joint_phrma_bio_letter_on_ipr_071515.pdf [https://perma.cc/VCV8-LDCA] (arguing that the “Hatch-Waxman Act and the BPCIA already allow for generic and biosimilar companies to effectively challenge patents that are perceived as overly broad or invalid”).

176. *Id.*

biopharmaceutical patents from IPR review, as seen in *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals Inc.*¹⁷⁷

III. ALLERGAN AND THE ST. REGIS TRIBE SHOULD ENJOY SOVEREIGN IMMUNITY

The Federal Circuit and the PTAB erred in determining that tribal sovereign immunity is inapplicable to the St. Regis Tribe's patents in IPR proceedings. Their decisions mischaracterize the nature of an IPR proceeding as an administrative enforcement action, conflict with Supreme Court precedent, and fail to recognize that a congressional directive to abrogate tribal sovereign immunity must be unequivocal. Moreover, from a public policy point of view, these decisions fail to analyze the agreement *from the Tribe's perspective*, and gloss over the significant non-monetary benefits it will bring to the St. Regis community.

A. *Similarly Flawed Legal Reasoning: The Federal Circuit and the PTAB*

On July 20, 2018, the Federal Circuit issued an opinion erroneously concluding that tribal sovereign immunity does not apply to IPRs in *Saint Regis Mohawk Tribe v. Mylan Pharmaceuticals*.¹⁷⁸ In doing so, the panel relied primarily on the Supreme Court's analysis in *FMC*.¹⁷⁹ The *Mylan* court determined that “[g]enerally, [sovereign] immunity does not apply where the federal government acting through an agency engages in an investigative action or pursues an adjudicatory agency action.”¹⁸⁰ The panel did concede that “IPR is neither clearly a judicial proceeding instituted by a private party nor clearly an enforcement action brought by the federal government.”¹⁸¹ It also acknowledged Supreme Court precedent that sovereign immunity is applicable during administrative adjudications between private parties.¹⁸² The panel, however, ultimately determined that “IPR is more like an agency enforcement action than a civil suit brought by a

177. *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322 (Fed. Cir. 2018).

178. *Id.*

179. *Id.* at 1326 (citing *Fed. Mar. Comm'n v. S.C. State Ports Auth.*, 535 U.S. 743 (2002)).

180. *Id.* at 1325.

181. *Id.* at 1326.

182. *Id.* at 1326–27.

private party,” and thus concluded that “tribal immunity is not implicated” in IPR proceedings.¹⁸³

The panel’s decision is problematic for a number of reasons, providing a strong rationale for the Supreme Court to grant certiorari. First and foremost, the panel erred by failing to give sufficient weight to the many marked similarities between IPR proceedings and ordinary civil litigation. In an IPR proceeding, the private-party petitioner controls the claims challenged and the grounds of the attacks, much like a civil plaintiff who makes particularized allegations.¹⁸⁴ Indeed, an IPR cannot commence until the petitioner serves the patent owner with a petition, in line with civil service of process. Moreover, the PTAB has no authority to begin a proceeding without a private party’s petition.¹⁸⁵ And neither the PTAB nor the PTO Director is a party to the proceeding.¹⁸⁶ To the contrary, the petitioner brings forth the evidence¹⁸⁷ and carries the burden of establishing unpatentability.¹⁸⁸ Moreover, the PTAB must decide the case based on the “arguments that were advanced by a party.”¹⁸⁹

Notwithstanding these, and legion other similarities to civil adversarial proceedings, the panel justified its nonadversarial assignment by relying on the fact that the PTAB can issue a decision even if the petitioner withdraws.¹⁹⁰ But even this reasoning is flawed; significantly, the PTAB’s authority to issue a decision after the withdrawal of the petitioner is very narrow. By statute, an IPR proceeding must “be terminated with respect to any petitioner upon the joint request of the petitioner and the patent owner, unless the [PTO] has decided the merits of the proceeding before the request for

183. *Id.* at 1327.

184. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) (“Congress chose to structure a[n] IPR] process in which it’s the petitioner, not the [USPTO] Director, who gets to define the contours of the proceeding.”).

185. 35 U.S.C. § 312(a)(5) (2012).

186. *See* 37 C.F.R. § 42.2 (2018) (defining “Party” as “at least the petitioner and the patent owner and, in a derivation proceeding, any applicant or assignee of the involved application”).

187. 35 U.S.C. § 312(a)(3) (providing that a petition will only be considered if it identifies, *inter alia*, “the evidence that supports the grounds for the challenge to each claim”).

188. *Id.* § 316(e) (“In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.”).

189. *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016).

190. *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1328 (Fed. Cir. 2018) (“Once IPR has been initiated, the Board may choose to continue review even if the petitioner chooses not to participate.” (citing 35 U.S.C. § 317(a))).

termination is filed.”¹⁹¹ Thus, the PTAB can issue a decision following the withdrawal of the petitioner only if the PTAB has *already* reached a determination on the merits of the case. This is far different from an agency adjudicative action that is “commenced and prosecuted” by the United States,¹⁹² like an SEC enforcement action for violating federal securities laws.¹⁹³

A second problem with the Federal Circuit’s holding in *Mylan* is that it conflicts with *SAS Institute v. Iancu*,¹⁹⁴ where the Supreme Court specifically stated that an IPR is a “procedure allow[ing] *private parties* to challenge previously issued patent claims in an *adversarial process* before the Patent Office that *mimics civil litigation*.”¹⁹⁵ Given that *SAS Institute* characterized IPRs as “party-directed, adversarial” proceedings¹⁹⁶ with “many of the usual trappings of litigation,”¹⁹⁷ it is difficult to see how the Federal Circuit felt justified in concluding that “IPR is more like an agency enforcement action than a civil suit brought by a private party.”¹⁹⁸

Finally, the panel’s *Mylan* holding is flatly inconsistent with the Federal Circuit’s previous decision in *Vas-Cath, Inc. v. Curators of University of Missouri*.¹⁹⁹ In *Vas-Cath*, the court recognized that sovereign immunity can apply to administrative patent proceedings and pointed to a number of elements—such as the presence of “adverse parties, examination and cross-examination by deposition of witnesses,” and “findings by an impartial federal adjudicator”—that determine when an administrative proceeding “can indeed be characterized as a lawsuit.”²⁰⁰ To wit, all of these elements are indisputably present in an IPR proceeding.²⁰¹ In sum, sovereign immunity should attach in an IPR proceeding because such a

191. 35 U.S.C. § 317(a).

192. *Cf. Alden v. Maine*, 527 U.S. 706, 755 (1999) (“A suit which is commenced and prosecuted against a State in the name of the United States . . . differs in kind from the suit of an individual . . .”).

193. *See* Securities Act, § 20(b), 15 U.S.C. § 77t(b) (2012); 17 C.F.R. § 202.5(b) (2018).

194. *SAS Inst. v. Iancu*, 138 S. Ct. 1348 (2018).

195. *Id.* at 1352 (emphasis added).

196. *Id.*

197. *Id.* at 1354.

198. *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018).

199. *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376 (Fed. Cir. 2007).

200. *Id.* at 1382.

201. *See Covidien LP v. Univ. of Fla. Research Found. Inc.*, Nos. IPR2016-01274, -01275, -01276, 2017 WL 4015009, at *8 (P.T.A.B. Jan. 25, 2017) (describing arguments between patent owner and petitioner on how inter partes review is similar and dissimilar to civil litigation).

proceeding “walks, talks, and squawks very much like a lawsuit” between private parties.²⁰²

Like the Federal Circuit, the PTAB also erred when it concluded that tribal sovereign immunity does not apply to IPR proceedings.²⁰³ The Supreme Court has repeatedly made clear that a tribe, like the St. Regis, is entitled to invoke sovereign immunity unless Congress has “unequivocally” expressed its desire to abrogate this immunity.²⁰⁴ Nothing in the AIA or its legislative history even remotely suggests that tribal immunity should not apply in IPR proceedings. With this lack of any congressional directive, and with the Supreme Court’s determination that a tribe’s “baseline” condition is immunity from suit,²⁰⁵ the PTAB had no reasonable justification for refusing to grant the St. Regis Tribe’s motion to terminate IPR proceedings.

The power of an administrative agency like the PTAB “is circumscribed by the authority granted” by Congress.²⁰⁶ As several prominent scholars, including Erwin Chemerinsky, have argued, the PTAB “has no expertise or experience that would enable it to second-guess prima facie assertions of tribal sovereign immunity.”²⁰⁷ The PTAB’s “statutory jurisdiction over IPRs is limited to challenges based on prior art and obviousness” whereas tribal-immunity issues “involve sensitive legal questions that are far different from the patent issues that Congress has charged the [PTAB] with resolving.”²⁰⁸ From an institutional-competency perspective, the PTAB is simply not the right body to evaluate the legitimacy of the contract between Allergan and the St. Regis Tribe. According to one commentator, the PTAB’s “sweeping” determination that tribal sovereign immunity does not apply in IPR proceedings is “the latest and possibly most extreme example of agency overreach in the seven-year history of the PTAB under the [AIA].”²⁰⁹

202. Fed. Mar. Comm’n v. S.C. State Ports Auth., 535 U.S. 743, 757 (2002) (citation omitted).

203. *Mylan*, 896 F.3d at 1325.

204. *Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2030–31 (2014).

205. *Id.* at 2031.

206. *Stark v. Wickard*, 321 U.S. 288, 309 (1944).

207. Brief of Amici Scholars in Support of Patent Owner the St. Regis Mohawk Tribe at 12, *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322 (Fed. Cir. 2018) [hereinafter *Brief of Scholars*] (including Erwin Chemerinsky, Laurence H. Tribe, Joseph William Singer, and William N. Eskridge in the undersigned scholars).

208. *Id.*

209. Josh Malone, *Controversy Over Restasis Patents is Misplaced*, IP WATCHDOG (Mar. 21, 2018), <http://www.ipwatchdog.com/2018/03/21/controversy-restasis-patents-misplaced/id=94904> [https://perma.cc/Q32G-TPEM].

The PTAB's decision that the St. Regis Tribe had no right to assert immunity was particularly unjustifiable given that it has repeatedly allowed states to use sovereign immunity to protect patents from IPR challenge.²¹⁰ In *NeoChord, Inc. v. University of Maryland*,²¹¹ the PTAB dismissed an IPR proceeding against both a state university and the private entity that had licensed the university's patents.²¹² The PTAB held that sovereign immunity barred suit against the state university, and that the suit could not proceed without the state university because it was an indispensable party.²¹³ In concluding that the state university was an indispensable party, notwithstanding that it had licensed its patents, the PTAB focused on the fact that the state university had not transferred "substantially all" of its rights to its licensee because, like the St. Regis Tribe, the university retained the right to practice the patent, the right to royalties, and the right to respond to legal action in the event the licensee failed to do so.²¹⁴

The PTAB should have applied this same analysis to the transaction between Allergan and the St. Regis Tribe. Pursuant to the agreement between the parties, the St. Regis Tribe was given the "first right to sue for infringement unrelated to such Generic Equivalents."²¹⁵ Furthermore, although Allergan was given the sole right to use the patents in the production of drugs, the St. Regis Tribe retained the prerogative to use the patents for research, academic use, and in the care of patients, so long as it developed products that did not compete with Allergan's.²¹⁶ Most significantly, the Tribe received an initial payment of \$13,750,000 and quarterly royalties of \$3,750,000 from Allergan.²¹⁷ Because the Tribe had a very substantial financial interest in the Restasis patents, as well as the right to use and enforce the patents under certain circumstances, it was an indispensable party, and thus the PTAB had no reasonable basis for concluding that the IPR proceedings could proceed without the Tribe's participation.

210. Examples of such challenges include: *Reactive Surfaces Ltd. v. Toyota Motor Corp.*, No. IPR2016-01914, 2017 WL 2992429 (P.T.A.B. July 13, 2017); *NeoChord, Inc. v. University of Maryland*, No. IPR2016-00208 (P.T.A.B. May 23, 2017); and *Covidien LP v. University of Florida Research Foundation Inc.*, Nos. IPR2016-01274, -01275, -01276 (P.T.A.B. Jan. 25, 2017).

211. *NeoChord, Inc. v. Univ. of Md.*, No. IPR2016-00208 (P.T.A.B. May 23, 2017).

212. *Id.* at 2.

213. *Id.* at 18-19.

214. *Id.* at 19.

215. *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, Nos. IPR2016-01127, -01128, -01129, -01130, -01131, -01132, 2018 WL 1100950, at *3 (P.T.A.B. Feb. 23, 2018) (per curiam).

216. *Id.* at *10-11 (quoting Exhibit 2087 § 2.1).

217. *Id.* at *12.

The PTAB determined that there was no controlling precedent requiring the application of tribal immunity in IPR proceedings,²¹⁸ and that granting states sovereign immunity did not require a similar grant to Native American tribes.²¹⁹ But considered together, these holdings are insidiously circular and misleading. First of all, IPRs were only created in 2012, so the lack of precedent is unsurprising. But more importantly, the PTAB's assertion regarding state sovereign immunity fails to mention that in *Covidien LP v. University of Florida Research Foundation Inc.*,²²⁰ the entity granted immunity was a state university's *research foundation* that licensed intellectual property to generate revenue—meaning that its purpose was to monetize innovation, much like a pharmaceutical company.²²¹ There is little substantive difference between the university foundation in *Covidien* and the St. Regis Tribe in the Restasis proceedings; both accepted assignment of patents in order to generate revenue through royalties and licensing agreements. Consequently, to deny the Tribe's right to assert its sovereign immunity, “would constitute improper unequal treatment and discrimination against the Tribe.”²²² Furthermore, even assuming, *arguendo*, that there was no precedent directly addressing whether tribal sovereign immunity applies in IPR proceedings, the PTAB should have looked to the Supreme Court's consistent and sympathetic treatment of tribal sovereign immunity for guidance.²²³

B. Policy Considerations Also Demonstrate Why Sovereign Immunity Should Apply

Some commentators have asserted that Allergan's partnership with the St. Regis Tribe violates the public pledge by Allergan's CEO, Michael Saunders, to keep drug prices more transparent and affordable to patients.²²⁴ This argument is unpersuasive. As Saunders

218. *Id.* at *3.

219. *Id.* at *4.

220. *Covidien LP v. Univ. of Fla. Research Found. Inc.*, No. IPR2016-01274, -01275, -01276 (P.T.A.B. Jan. 25, 2017).

221. *Id.* at *3; *University of Florida Research Foundation*, OFF. RESEARCH: UNIV. OF FLA., <https://research.ufl.edu/ufrf.html> [<https://perma.cc/H688-YQXH>].

222. Amicus Curiae Brief of the Oglala Sioux Tribe in Support of Corrected Patent Owner's Motion to Dismiss Based on Tribal Sovereign Immunity at 12, *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, IPR Nos. 2016-01127, -01128, -01129, -01130, -01131, -01132, 2018 WL 1100950 (P.T.A.B. Feb. 23, 2018).

223. *See supra* Part I.B and accompanying text.

224. *See* Sy Mukherjee, *Botox Maker Allergan's CEO Defends Selling Drug Patents to Native American Tribe to Thwart Rivals*, FORTUNE (Sept. 9, 2017),

correctly contends, Allergan's partnership is not at odds with its "social contract," a core feature of which "is a focus on innovation and research to help patients."²²⁵ He argues that Allergan is not "trying to artificially extend" the Restasis patents, but instead is "just trying to protect [its] property against a system that exposes [it] to double jeopardy."²²⁶ Saunders also points out that there have been many instances of hedge funds demanding cash in exchange for not filing IPR challenges, and that "Allergan has been the target of one of these extortion-like attacks."²²⁷ If our system is to let more entities take cheap(er) shots at branded pharmaceutical companies through IPRs, it is fitting that those companies be allowed to take some additional protections, like the helmet of sovereign immunity.

What most commentators fail to analyze is the rationale for the agreement between Allergan and the St. Regis Tribe *from the Tribe's perspective*. The St. Regis Tribe's contract with Allergan is an integral part of its "economic development plan," not merely some "scheme [designed] to shield patents from review."²²⁸ As a direct consequence of its agreement with Allergan, the St. Regis Tribe, as sovereign, passed a resolution "endorsing the creation of a technology and innovation center for the commercialization of existing and emerging technologies."²²⁹ To flippantly conclude that this arrangement is a mere "sham," as many commentators have done, is to disregard the Tribe's very legitimate reasons for entering into this contract.²³⁰ And to criticize Allergan for engaging in a "rent-a-tribe" scheme trivializes not only the multimillion-dollar arrangement, but also a sovereign nation's right to act in its own interests.²³¹ The PTAB's effective nullification of the contract between Allergan and the Tribe needlessly and illegally

<http://fortune.com/2017/09/09/allergan-drug-patents-native-american> [<https://perma.cc/U7K3-456G>] (detailing patient advocates', generic drug makers', and biotech investors' concern with the St. Regis arrangement, particularly in light of the "social contract" Saunders promised to patients for fair and transparent prices).

225. *Id.* (quoting Saunders).

226. *Id.* (quoting Saunders).

227. Brent Saunders, *Reverse Patent Trolls Are Harming Drug Innovation—and Patients*, WALL ST. J. (Oct. 8, 2017, 2:33 PM), <https://www.wsj.com/articles/reverse-patent-trolls-are-harming-drug-innovationand-patients-1507487600> [<https://perma.cc/VX2K-NR8R>].

228. Brief of Scholars, *supra* note 207, at 12.

229. *Id.*

230. *See id.* at 13 (noting petitioner's argument that the Allergen/Mohawk agreement is a sham).

231. *See id.* (noting petitioner's argument that the Allergen/Mohawk agreement is a "rent-a-tribe" scheme).

injects the PTO into a “politically charged inquiry into tribal motivations and the policy wisdom of tribal economic freedom.”²³² Put another way, the assertion here is that St. Regis Tribe’s sovereign immunity can be extricated from its current dalliance with pharmaceutical patents—it cannot, for the two are inextricably intertwined.

One of the primary goals of the federal government’s policy toward Native American tribes is “to render Tribes more self-sufficient,” making them better able to finance “sovereign functions, rather than relying on federal funding.”²³³ To date, however, efforts to promote tribal economic growth have proved inadequate. For more than half of reservations, “some of the highest poverty and unemployment rates in the nation remain the norm.”²³⁴ In the words of Justice Sonia Sotomayor, “[i]f Tribes are ever to become more self-sufficient, and fund a more substantial portion of their own governmental functions, commercial enterprises will likely be a central means of achieving that goal.”²³⁵ As such, developing innovative “tribal business operations [is] critical to the goals of tribal self-sufficiency because such enterprises . . . ‘may be the only means by which a tribe can raise revenues.’”²³⁶

The St. Regis Tribe found a very creative and very lucrative means to generate much-needed revenue when it entered into its partnership with Allergan. Since Congress has not unequivocally expressed its desire to abrogate immunity in this situation,²³⁷ both the PTAB and the courts must therefore respect the Tribe’s decision to invoke tribal sovereign immunity and shield the Restasis patents.

The PTAB declared that “[e]ven assuming *arguendo* that the Tribe is entitled to assert immunity,” the IPR could proceed because Allergan is the “*effective* patent owner.”²³⁸ Although this

232. *Id.*

233. *Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2043 (2014) (Sotomayor, J., concurring).

234. Ablavsky, *supra* note 78.

235. *Bay Mills*, 134 S. Ct. at 2041 (Sotomayor, J., concurring).

236. *Id.* at 2043 (Sotomayor, J., concurring) (quoting Catherine T. Struve, *Tribal Immunity and Tribal Courts*, 36 ARIZ. ST. L.J. 137, 169 (2004)).

237. *Id.* at 2031; *see also* *C & L Enters., Inc. v. Citizen Band Potawatomi Tribe of Okla.*, 532 U.S. 411, 418 (2001).

238. *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, Nos. IPR2016-01127, -01128, -01129, -01130, -01131, -01132, 2018 WL 1100950, at *7, *13 (P.T.A.B. Feb. 23, 2018) (emphasis added).

pronouncement sounds profound, it “has no legal meaning”²³⁹ or statutory validation. The St. Regis Tribe is the sole owner of the patents. To allow the IPR to proceed without the St. Regis Tribe could be a violation of due process: no congressional authorization exists permitting “effective” patent owners to litigate on behalf of actual owners. Moreover, as Allergan points out, no unity of interest exists between the partners: “Allergan can practice the inventions in the patents whether or not they are valid but the Tribe’s property rights and right to payments from Allergan would be extinguished if the Appellees prevail in the IPRs.”²⁴⁰

The Federal Circuit has held that “a patent should not be placed at risk of invalidation by the licensee without the participation of the patentee.”²⁴¹ The Restasis patents are certainly at risk here, yet the PTAB continues to rely on its self-created “effective owner” designation in order to reach its desired result. However, as Allergan and the St. Regis Tribe detail, no statute authorizes the PTAB to conduct an IPR “against an effective patent owner in the absence of [an] ‘actual owner’” who is immune from suit.²⁴²

The AIA is clear that the right to participate as a defendant in an IPR proceeding is held by the patent owner.²⁴³ Nowhere is an “effective owner” mentioned in the statute.²⁴⁴ Because “effective” patent owners are not granted standing in the AIA, and standing in administrative proceedings is governed by statute,²⁴⁵ the PTAB’s determination that it “may proceed with an ‘effective’ patent owner exceeds its statutory authority.”²⁴⁶ Allowing PTAB judges this degree of ad hoc rulemaking authority would be contrary to the administrative structure that Congress created.

In spite of the legitimacy of the St. Regis Tribe’s contract with Allergan, for which millions of dollars of valuable consideration was exchanged, the PTAB felt it could treat Allergan, rather than the St.

239. Appellants’ Motion for Stay Pending Review at 11, *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322 (Fed. Cir. 2018) (No. 18-1638).

240. *Id.* at 11–12.

241. *Schwarz Pharm., Inc. v. Paddock Labs, Inc.*, 504 F.3d 1371, 1374 (Fed. Cir. 2007).

242. Matthew Bultman, *Tribe Asks Fed. Circ. To Pause Restasis Patent Reviews*, LAW360 (Mar. 19, 2018, 6:42 PM), <https://www.law360.com/articles/1023523/tribe-asks-fed-circ-to-pause-restasis-patent-reviews> [<https://perma.cc/HL54-AYTF>].

243. 35 U.S.C. §§ 313, 314(c), 315(a)(8)–(9) (2012).

244. See text accompanying *supra* note 243.

245. 5 U.S.C. § 702.

246. Appellants’ Motion for Stay Pending Review, *supra* note 239, at 13.

Regis Tribe, as the patent owner. However, it was the St. Regis Tribe litigating this case, and it will be the St. Regis Tribe appealing the case going forward. In terms of basic contract law, parole evidence—evidence existing outside of the text of the contract—can only be considered if there are defects in the written instrument.²⁴⁷ No one claims that such defects are present here. It is surprising, then, that the PTAB felt it was within its rights to go “under the hood” of the plain language of the St. Regis–Allergan contract. In so doing, the PTAB effectively invalidated a legitimate contract based on its *perception* of a sovereign entity’s intent, determining that the presumption of patent ownership created by an assignment was rebutted by extrinsic evidence.²⁴⁸

CONCLUSION

The patent system no longer effectively incentivizes investment in new and improved drug therapies. Lost in the cacophony surrounding the debate about high drug prices is the fundamental principle that pharmaceutical innovation will not occur without the prospect of outsized returns enabled through market exclusivity. And while the IPR system may sensibly eliminate low-quality patents in certain industries, it has the potential to derail critical investment in the biotechnology industry. VCs, who enable much of the disruptive innovation in the pharma space, rely most heavily on the signaling value of patents in early rounds of financing where therapeutic potential is greatest.²⁴⁹ IPR proceedings have upended the delicate balance that Congress struck in the Hatch-Waxman Act, and in doing so, they have “increas[ed] business uncertainty for innovative biopharmaceutical companies having to defend their patents in multiple venues and under differing standards and procedures.”²⁵⁰ These proceedings are diverting finite resources away from the research and development of new cures and treatments. The patent system may thus be “applying an unintended downward pressure on the incentives to undertake the most risky [and fruitful] research.”²⁵¹

247. *Parol Evidence Rule*, LEGAL INFO. INST., https://www.law.cornell.edu/wex/parol_evidence_rule [<https://perma.cc/3KBY-ASKK>].

248. *Mylan Pharm. Inc. v. Saint Regis Mohawk Tribe*, Nos. IPR2016-01127, -01128, -01129, -01130, -01131, -01132, 2018 WL 1100950, at *13 (P.T.A.B. Feb. 23, 2018).

249. See Hoenen et al., *supra* note 112, at 982 (finding that “patent activity before the first round of financing increases the capital invested in a firm”).

250. Greenwood Letter, *supra* note 175.

251. Cahoy, *supra* note 133, at 87.

For a myriad of reasons, the pharmaceutical industry is *different*, incurring far more in R&D costs than any other industry in order to produce products that are easily copied at a fraction of the price.

In a recent Senate Judiciary Committee hearing, Orrin Hatch, for whom the Hatch-Waxman Act is named, questioned whether PTAB proceedings “are impacting [the] Hatch-Waxman [Act] in a disproportionate way.”²⁵² The fact that Allergan felt compelled to “sell” its patents to the St. Regis Tribe provides strong evidence that PTAB proceedings are doing just that. The beleaguered pharmaceutical industry is being squeezed on all sides. It costs drug manufacturers an estimated average of \$2.6 billion to bring a new drug to market.²⁵³ And these costs are only increasing. Yet, the expected value of a drug’s patent portfolio is decreasing, thanks to the significant likelihood that some or all patent claims will be invalidated by the PTAB. Moreover, branded manufacturers are forced to fight a war against generics on two fronts, concurrently defending their patents in district court and before the PTAB, each under differing evidentiary standards. All the while, such firms must contend with hedge funds exploiting the IPR system, specifically targeting life sciences companies because they are so vulnerable. Such ills are only compounded by a shrinking R&D pipeline and by VCs deciding to move their life sciences capital abroad.²⁵⁴ Is it any wonder that Allergan turned to the St. Regis Tribe for help?

Allergan does not contend that its patents are beyond review. Nor is its partnership with the St. Regis Tribe an exploitation of the IPR regime. Rather, this partnership is a response to exploitation. Far from the “sham” or “rent-a-tribe” scheme narrative pushed by the media and commentators,²⁵⁵ Allergan’s alliance with the St. Regis Tribe is a

252. Scott Graham, *Skilled in the Art: The Brave New World of Section 101 Guidance*, LAW.COM (Apr. 20, 2018, 5:59 PM), <https://www.law.com/2018/04/20/skilled-in-the-art-the-brave-new-world-of-section-101-guidance> [<https://perma.cc/2XGJ-6797>] (quoting Andrei Iancu, Director of the United States Patent and Trademark Office, in response to prodding by Senator Orrin Hatch).

253. Mullin, *supra* note 85.

254. See Madigan, *supra* note 117 (“[T]he National Venture Capital Association . . . highlight[s] a drop [in the US share of global venture capital] from 83% of global share in 1996 to just 54% in 2015.”).

255. Roy Schestowitz, *A Sham and a Scam: How Patent Extremists Continue to Promote a Mohawks and Allergan Ploy Against PTAB, Even After Oil States*, TECHRIGHTS (May 14, 2018, 12:31 AM), <http://techrights.org/2018/05/14/watchtroll-for-allergan> [<https://perma.cc/QRX2-5FHG>]; see also, e.g., Robert Pear, *Indian Tribe Joins Big Pharma at the Supreme Court, Defending a Lucrative Deal*, N.Y. TIMES (Jan. 26, 2019), <https://www.nytimes.com/2019/01/26/>

justified effort to obtain reprieve from an IPR regime that is inherently unsuited to pass judgment on dearly acquired patent rights. In that sense, the alliance is an innovative, legitimate, and appropriate use of tribal sovereign immunity.