Taking Your Medicine: Applying the Fifth Amendment to Pharmaceutical Patents During Inter-Partes Review

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ABSTRACT

The rate of patent invalidation has climbed since the America Invents Act's creation of the Patent Trial and Appeals Board. Some see this as a victory against large corporations who attempt to patent obvious inventions to create large monopolies. On the other hand, opponents advocate for small-time inventors by claiming the new process disenfranchises them of their original ideas. These debates tend to revolve around the idea that patents possess strong private property interests and invalidating a patent results in an unconstitutional regulatory taking. This comment discusses whether the Fifth Amendment's Takings Clause should apply when the PTAB invalidates patents through PTAB's inter partes review, specifically using the pharmaceutical industry as an example.

INTRODUCTION

Josh Malone crouched soaking wet at the garden spicket watching his eight children play water balloons without him as he continuously replenished their ammo.[1] Tired of spending valuable hours observing his children from the garden hose, Josh began experimenting with new and creative ways to fill the balloons until one day he invented something that worked—100 balloons that fill within 60 seconds and self-seal before falling away from the spout.[2] After perfecting his creation, Josh filed a provisional patent with the United States Patent and Trademark Office ("USPTO") and his invention was approved.[3] After selling his product on "Kick Starter" and winning "Toy of the Year," Josh found himself fighting against blatant infringement from a mega corporation who purchased his product, reverse engineered it, and beat him to market.[4] Even after a federal court enjoined

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1. Paul Morinville, *Water Balloons, Weapons of Mass Destruction and the PTAB*, IP WATCHDOG (Jan. 27, 2017), http://www.ipwatchdog.com/2017/01/27/water-balloons-weapons-mass-destruction-ptab/id=77637/ [https://perma.cc/QSQ6-ZMG8].

2. *Id.*

3. *Id.*

4. *See id.*; *ZURU's Bunch-O-Balloons Wins Prestigious "Outdoor Toy of the Year"*, PR NEWSWIRE (Feb. 18, 2018, 11:29 ET), https://www.prnewswire.com/news-releases/zurus-bunch-o-balloons-wins-

the infringer from further use of the patent, the corporation challenged the validity of Josh's patent with the USPTO.[5] The company successfully argued that the patent be completely invalidated, and Josh was left with nothing but a worthless sheet of paper.[6]

America lead in innovation for decades.[7] Even the United States Constitution prioritizes protection and promotion of scientific progress.[8] So why has the United States fallen from first place in terms of patent protection to tenth?[9] The answer lies within the numerous court rulings that re-define the very essence of a patent[10], and unending legislative shifts.[11] A majority of these legislative changes originate in the America Invents Act (AIA) passed June 1, 2011.[12] The AIA's changes to the patent system bring both praise and criticism in the way it impacts intellectual property and the rights of inventors.

Critics point out that the rate of patent invalidation has climbed higher than ever before after the AIA created the Patent Trial and Appeals Board ("PTAB").[13] Some see this as a victory against large corporations, who

prestigious-outdoor-toy-of-the-year-award-for-second-consecutive-year-300600476.html [https://perma.cc/LGC6-ETPT].

5. *See* Morinville, *supra* note 1.

6. *Id.* Telebrands filed a post-grant review in front of the Patent Trial and Appeals Board and invalidated Josh's patent by arguing that the patent's claim of "substantially filling" the balloons with water (which causes them to fall off the spout) could not be technically proven as accurate. *Id.* The PTAB ruled for Telebrands, holding that the patent should never have been granted which allowed Telebrands to freely market Josh's design and reap the benefits. *Id.*

7. Richard Nelson, *U.S. Technological Leadership: Where Did It Come From and Where Did It Go?*, 19 RESEARCH POLICY 2, 119 (1990) (the United States was a global leader in technology after World War II for a quarter century before other nations began to catch up).

8. U.S. CONST. art. I, § 8, cl. 8 (stating that Congress shall "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries ...").

9. Rana Foroohar, *Big Tech vs. Big Pharma: The Battle Over U.S. Patent Protection*, FINANCIAL TIMES (Oct. 16, 2017), https://www.ft.com/content/6c5b2cca-ae8b-11e7-beba-5521c713abf4 [https://perma.cc/K3AA-HQLX].

10. *See infra* Part I.

11. Hermant Gupta, *Making Heads and Tails Out of the Patent Reform Act*, 58 MISS. LAW. 21, 22 (2012).

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

13. Tahir Amin, *America's Current Patent System Inhibits Innovation. Here's How to Fix It*, QUARTZ (Sept. 22, 2017), https://qz.com/1084383/americas-current-patent-system-inhibits-innovation-heres-how-to-fix-it/ [https://perma.cc/THL6-J3CZ] ("Instead of being paralyzed by paranoia, corporate interests and inventors should instead be welcoming programs like PTAB aimed at strengthening market competition and the value of their deserved patents. Junk patents don't belong in the American story of innovation, ingenuity, and free market competition."); Peter Huber, *Junk Patents*, FORBES (June 16, 1997), https://www.forbes.com [https://perma.cc/8DVY-JP4K] (explaining junk patents as poorly written, broad patents and include small claims that, if patented, result in a broad range of coverage for the patent owner thus making it difficult for courts to determine where the inventor's interests begin and end); *see* BakerDonelsonOnline, *Patent Trial and Appeals Board Proceedings: Friend or Foe?*, YOUTUBE (Apr. 23, 2018), https://www.youtube.com/watch?v=vwzujWGWCnw [https://perma.cc/ZN2C-GTG9] (citing to *PTAB Statistics*, US Patent and Trademark Office, www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/statistics [https://perma.cc /6EXR-7PLX]) (explaining that between September 16, 2012 and March 31, 2018, 92% of PTAB petitions have been for inter partes reviews, and of these petitions during the same period, 65% of the petitions were granted and the patent invalidated).

attempt to patent obvious[14] inventions and create large monopolies.[15] On the other hand, opponents of the AIA advocate for small-time inventors, like Josh, claiming the new process disenfranchises them of their original ideas.[16] These debates tend to revolve around two issues: if patents possess a strong private property interest, and if that interest can and should be taken through invalidation of the patent.

This comment discusses whether the Fifth Amendment's Takings Clause[17] should apply when the PTAB invalidates patents through inter partes review ("IPR")[18], specifically using the pharmaceutical industry as an example. Part I examines the legislative, judicial, and regulatory history of patents within the United States, in addition to the evolution of the Supreme Court's application of the Fifth Amendment. Part II analyzes the legal classification of patents as personal property, and examines whether such property is subject to the Takings Clause, using pharmaceutical patents as an example. Part III concludes that patent invalidation in PTAB proceedings should be categorized as a "taking" under the Takings Clause, and proposes what the USPTO should do to comply with the Fifth Amendment.

I. BACKGROUND

A. HISTORY OF PATENTS WITHIN THE UNITED STATES

Today, United States patents are defined solely by their negative right to exclude others from an invention,[19] but history shows that this has not always been the case. Protection of property is a primary concept included

14. 35 U.S.C. § 103 ("A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains . . .").

15. Foroohar, *supra* note 9 (explaining that the problem with monopolies is "[f]ew will have too much sympathy for Big Pharma. The industry has long been in the line of fire over drug pricing and its monopolistic power. But the large drug companies are only one voice among many that have begun to complain about how shifts in the US patent system over the past decade have weakened the ability of companies to protect their innovations.").

16. Michele Nash-Hoff, *Has the America Invents Act Been Beneficial or Harmful?*, INDUSTRYWEEK (Feb. 18, 2015), https://www.industryweek.com/intellectual-property/has-america-invents-act-been-beneficial-or-harmful [https://perma.cc/F6CC-LW8V] ("Opponents argued that there was no reason to change the U.S. system, and inventors and small businesses complained that switching to a 'first-to-file' system would give large companies an advantage and hurt individual inventors."); *see also* Gupta, *supra* note 11, at 21. The USPTO distinguishes different types of reexamination proceedings to determine the validity of a patent—post-grant reviews ("PGRs"), and inter partes reviews ("IPRs") being two of them—and identify the main difference at the time of the patent's issuance. *Id.* PGR proceedings determine the validity of patents that were issued before the "first-to-file" system was implemented by the AIA, and IPRs are available for third-party challengers to question the validity of any patent issued either before or after the AIA changes. *Id.*

17. U.S. CONST. amend. XV.

18. James A. Johnson, *Patent Trial and Appeal Board*, INTELLECTUAL PROPERTY TODAY, May 2015, at 1 (explaining that any person who is not the owner of the patent may file an IPR with the USPTO and petition to cancel one or more of a patent's claims as unpatentable, and such petition must be based upon 35 U.S.C. §§ 102 (novelty) or 103 (non-obviousness), and even then, only on the basis of prior art or printed publication).

19. Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J. OF LAW & TECH. 321, 322 (2009).

within the United States Constitution as an essential element of our democracy.[20] Article I, Section Eight of the United States Constitution allows Congress to promote the progress of science, specifically by securing to inventors the exclusive right to their inventions.[21] The United States patent system traces its roots back even further, however, to sixteenth-century England.[22] During the emergence of modern Europe in the sixteenth century, the Crown granted patents to establish monopolies, benefiting the rapidly developing English economy.[23] The Crown bestowed a patent upon an inventor which imposed affirmative rights and duties to use his patent to introduce new trades into the marketplace, thus creating jobs.[24] The patent-holder, with his monopoly, was expected to set up shop to sell the new product, which in turn required employment and training of apprentices in the new industry.[25] If an inventor did not use his patent to the best of his ability by manufacturing and distributing his product, the monarchy would revoke the patent and bestow it upon someone else.[26]

This theory, known as "use-rights,"[27] established in a patent an affirmative property right to make, use, and sell.[28] The patent consisted of both a monopolistic exclusion and the obligation to use the invention.[29] The United States Patent Act of 1790 embraced the theory of "use rights," that granted broad rights to the patent holder.[30] Enacted shortly after the formation of Congress, the Patent Act of 1790 provided the first legal definition of a patent in the United States.[31] A patent was defined as "any useful art, manufacture, engine, machine, or device, or any improvement there on not before known or used."[32] Most importantly, the Patent Act of 1790 granted the applicant the "sole and exclusive right and liberty of making, constructing, using, and vending to others to be used" of his invention.[33]

Changing theories in American property law during the early twentieth century significantly altered the type of property rights associated with patents, causing the use-rights theory to devolve from affirmative rights to

20. U.S. CONST. art. 1, § 8, cl. 8.

21. *Id.*

22. Mossoff, *supra*, note 19, at 366.

23. *Id.*; *see also* Ira Milton Jones, *United States Patent Law System*, 17 MARQ. L. REV. 125, 126 (1933) (explaining the monopolistic functions of patents in a more modern era).

24. Mossoff, *supra* note 19, at 366.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. Mossoff, *supra* note 19, at 366.

30. *See id.*

31. *See id.*

32. Press Release, U.S. Patent and Trademark Office, The U.S. Patent System Celebrates 212 Years (Apr. 9, 2002) (available at https://www.uspto.gov/about-us/news-updates/us-patent-system-celebrates-212-years [https://perma.cc/9KWK-MDKW]).

33. Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 109 (1790); P.J. Federico, *Operation of the Patent Act of 1790*, 18 J. PAT. OFF. SOC'Y 237, 237 (1936).

use and manufacture the idea, into a mere requirement that an inventor disclose his idea to obtain only the negative right to exclude.[34] This change is reflected in the twenty-first century as courts uphold the idea that a government-granted patent establishes only a monopolistic, negative exclusionary right, as opposed to affirmative use-rights.[35] Compared to a patent as defined in the Patent Act of 1790, today's patent is more limited in its scope.[36] A patent today still grants a negative right to exclude others from producing and selling the patented invention, but it is no longer interpreted as granting positive "use-rights" duties to use and manufacture the invention as was the case in sixteenth-century England.[37]

Beginning as early as 1899, courts have found that, in addition to any positive or negative private property rights patents possess, they also involve "public rights."[38] Although courts have not clearly defined the difference between "public rights" and "private rights," it has been established that the public rights doctrine applies to agreements arising between a party and the government.[39] This "public" emphasis on patents further compromises the private interests of inventors, as their interest is not solely private but now more "public" in nature.[40] Because patents grant almost an exclusive monopoly from the government to the inventor, the Supreme Court

34. Mossoff, *supra* note 19, at 323; Adam Mossoff, *Patents as Constitutional Private Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 691 (2007). Use rights are different than the right to exclude that current patents hold, because current patents do not grant the inventor an affirmative right to use his invention. *Id.* For example, an inventor can invent a new atomic bomb, but international treaties and laws do not permit him to implement and use his invention, they only stop others from claiming his idea as their own. Mossoff, *supra* note 19, at 367.

35. Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1373 (2018) (explaining the detailed history of patent law precedent in the United States); *see also* Section A, *infra* Part II.

36. Mossoff, *supra* note 19, at 367 (explaining how modern property theory evolved from positive "use-rights" in patent law to negative "exclusionary" rights; under the right to exclude theory, the right is negative which means the inventor does not have any positive property interest of which regulation may infringe upon—however, if patents establish positive "use-rights," regulation of the patent would infringe upon the inventor's property interest).

37. *Id.*

38. United States v. Duell, 172 U.S. 576, 582–83 (1899) (stating that, "The legislation based on this provision regards the right of property in the inventor as the medium of the public advantage derived from his invention; so that in every grant of the limited monopoly two interests are involved—that of the public, who are the grantors, and that of the patentee. There are thus two parties to every application for a patent. . ." (quoting Butterworth v. Hoe, 112 U.S. 50, 59 (1884))); *Oil States*, 138 S. Ct. at 1373 (holding that patents are considered "public franchises" due to their nature as a "public right," although admitting that, "this Court has not 'definitively explained' the distinction between public and private rights" (quoting Northern Pipeline Constr. Co. v. Marathon Pipe Line Co., 458 U.S. 50, 69 (1982)), and the Court's precedent applying the public rights doctrine has not been consistently applied).

39. *Oil States*, 138 S. Ct. at 1373 ("Our precedents have recognized that the [public rights] doctrine covers matters 'which arise between the Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments' (citing Crowell v. Benson, 285 U.S. 22, 50 (1932))."). Because IPR reconsiders if the USPTO's decision to grant a "public franchise" was proper, *Oil States* reasons that these tribunals have a hand in such "public rights." *Id.* Thus, if something is classified as a "public right," regulatory entities other than Article III courts, such as the PTAB, can act as tribunals over such subject matter. *Id.*

40. *Compare* McCormick Harvesting Machine Co. v. Aultman, 169 U.S. 606, 609 (1898) (holding a granted patent becomes the private property of the patentee), *and* United States v. American Bell Telephone Co., 128 U.S. 315, 370 (1888) (holding a patent is "private property of a patentee"), *with Oil States*, 138 S. Ct. at 1373 (holding patents are now more public in nature than private).

concluded that the rights associated with a patent are "public rights."[41] On this basis, patents have recently been categorized as "public franchises," but only in application to Article III and the Seventh Amendment.[42] Therefore, the debate is still unsettled as to the true nature of constitutional property rights associated with patents.[43]

B. HISTORY OF THE PATENT TRIAL AND APPEALS BOARD

In 1836, Congress created the Patent and Trademark Office ("PTO"), as a division within the Department of Commerce.[44] For centuries, the USPTO functioned on a "first-to-invent" system for patenting, granting patents to an inventor who could provide extensive proof that she was the initial creator and designer of her idea.[45] In September 2011, Congress passed the Leahy–Smith America Invents Act and significantly changed the patent process. [46] The AIA shifted patent awards from "first-to-invent" to "first-to-file."[47] This allows an inventor a patent to his invention only if he can file his paperwork before anyone else and prove his invention is novel, useful, and nonobvious compared to "prior art."[48] As the last remaining country not using the "first-to-file" system, this change was meant to catapult the United States into the twenty-first century and change the 200-year-old

41. *Duell*, 172 U.S. at 582–83.

42. *Oil States*, 138 S. Ct. at 1365. The Court's holding that patents are "public franchises" significantly contradicted and overruled the standing precedent that concluded tribunals like the Patent Trial and Appeals Board should not act as a valid tribunal to determine patent validity. Precedent states, "[t]he only authority competent to set a patent aside, or to annul it, or to correct it for any reason whatever, is vested in the courts of the United States, and not in the department which issued the patent." *McCormick*, 169 U.S. at 609. The Supreme Court concluded such precedent could not stand because the previous holdings were reasoned on old law from the Patent Act of 1790. *Oil States*, 138 S. Ct. at 1365. However, the Court also argued that their holding in *Oil States* does not contradict the holdings of previous cases under the Patent Act of 1790. *Id.* at 1375. Rather, the Court's new holding simply redefines a patent's property right as the granting of a public franchise (even though the holdings of such cases define the property interest of the patent as private). *Id.* Most importantly, the *Oil States* holding was narrow and stated:

> We emphasize the narrowness of our holding. We address the constitutionality of inter partes review only. We do not address whether other patent matters, such as infringement actions, can be heard in a non-Article III forum. . . moreover, we address only the precise constitutional challenges that Oil States raised here. Oil States does not challenge the retroactive application of inter partes review. . . nor has Oil States raised a due process challenge. Finally, our decision should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause of the Takings Clause.

Id. at 1379.

43. *Oil States*, 138 S. Ct. at 1379.

44. ALAN L. DURHAM, PATENT LAW ESSENTIALS: A CONCISE GUIDE 2 (4th ed. 2013).

45. Gupta, *supra* note 11, at 21.

46. Leahy–Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (codified as amended at 35 U.S.C. §§ 1-390 (2012)).

47. Gupta, *supra* note 11, at 21.

48. M. HENRY HEINS, FIRST TO FILE: PATENTS FOR TODAY'S SCIENTISTS AND ENGINEERS 9 (2014). A patentable invention must pass the following tests: utility, novelty (as a new idea that has not been filed before or part of an already-patented invention's claims), and non-obviousness (if so unique that not many laypeople would consider its claims common-knowledge). *Id.* Obviousness tends to be a more subjective test and many IPRs focus on the obvious nature of a patent, questioning if an invention is monopolizing an obvious product that the public tends to use at large. *Id.* at 9–10. Prior art refers to everything an invention can be compared to, including prior patent applications, common knowledge, or even information that has not yet been verified as true. *Id.*

process of "first-to-invent."[49] Not only did the AIA make changes to its filing system, but the AIA broadened the spectrum of what qualifies as "prior art,"[50] and replaced the review process for a patent's validity by creating the Patent Trial and Appeals Board from the entity formerly known as the Board of Patent Appeals and Inferences.[51]

The Act also created the IPR process, which allows any person to challenge a patent in whole or in part.[52] The PTAB oversees IPRs, and ultimately decides if the patent should be invalidated, and if so, whether it is invalidated in whole or in part.[53] Advocates of these reforms applaud the use of IPRs to ensure that patents (like those attached to pharmaceuticals) are truly valid.[54] Others, however, accuse the PTAB of stifling innovation and making it harder to defend patents.[55]

The majority of the proceedings seen by the PTAB are IPRs.[56] The PTAB also has a notably lower standard of review than regular district court proceedings.[57] One function of IPR hearings is to allow any third party to question the validity of a patent for up to nine months after a patent's grant.[58] These proceedings must be concluded within eighteen months—sometimes

49. Gupta, *supra* note 11, at 22.

50. 35 U.S.C. § 102; *2152 Detailed Discussion of AIA 35 U.S.C. 102(a) and (b) [R-11.2013]*, USPTO.GOV, https://www.uspto.gov/web/offices/pac/mpep/s2152.html [https://perma.cc/8ZBH-L7E9] (last modified Jan. 24, 2018 at 5:18 PM) ("Under AIA 35 U.S.C. 102(a)(1), there is no geographic limitation on where prior public use or public availability occurs.").

51. Gupta, *supra* note 11, at 22. Previously, the Board of Patent Appeals and Inferences was used to determine which inventor had actually been the first to invent; however, when the "first-to-file" system replaced the "first-to-invent" system, such board was no longer necessary and the PTAB was created for IPR proceedings to reexamine already issued patents for validity. *Id.*

52. Leahy–Smith America Invents Act, sec. 6, § 311, Pub. L. No. 112–29, 125 Stat. 284 (2011) (codified as amended at 35 U.S.C. § 311 (2012)); *see generally* Johnson, *supra* note 18 (briefly summarizing the functions of the PTAB).

53. 35 U.S.C. § 6(a) (2012); *see also* Johnson, *supra* note 18, at 1 ("The duties of the board are as follows. . . conduct inter partes reviews and post-grant reviews pursuant to chapters 31 and 32.").

54. Max Nisen, *Big Pharma Wins If a Speedy Patent-Challenge Process Dies*, BLOOMBERG: BLOOMBERGOPINION (Nov. 28, 2017), https://www.bloomberg.com/gadfly/articles/2017-11-28/inter-partes-review-supreme-court-decision-could-help-big-pharma [https://perma.cc/CG3Y-E9S8] (explaining, "IPR is faster, cheaper, and friendlier to patent plaintiffs than going to court. That makes it particularly worrisome to pharma companies, which want market exclusivity for their drugs to last as long as possible. Since IPR became available in 2012, 550 biopharma patent petitions have been filed with the U.S. Patent and Trademark Office, 337 of which have been accepted by the Patent Trial and Appeal Board (PTAB) for review.").

55. Foroohar, *supra* note 9 (explaining that, "Indeed, some would argue that the system of adjudication for patents introduced under the Obama administration has become a 'powerful shield' for those accused of patent infringement. Most of the verdicts go against the patent holder, leading former chief judge Randall Rader, who led the court in charge of patent appeals, to label it the 'death squad' for IP.").

56. BakerDonelsonOnline, *supra* note 13 (explaining that between September 16, 2012 and March 31, 2018, IPRs comprised 92% of PTAB petitions).

57. Michael J. Flibbert & Maureen D. Queler, *5 Distinctions Between IPRs and District Court Patent Litigation*, FINNEGAN (Dec. 16, 2015), https://www.finnegan.com/en/insights/5-distinctions-between-iprs-and-district-court-patent-litigation.html [https://perma.cc/YX9C-3XVZ] ("Issued patents receive fundamentally different levels of deference in district court and PTAB proceedings. In district court, patents enjoy a statutory assumption of validity and challengers must prove each patent claim invalid by clear and convincing evidence—the highest burden of proof in U.S. litigation. But no such presumption of validity applies in PTAB proceedings. Petitioners need only establish unpatentability by a preponderance of the evidence . . . this is a significantly reduced burden of proof compared to litigation.").

58. DURHAM, *supra* note 44, at 49.

a better alternative than drawn out and expensive litigation in the federal circuits.[59]

C. HISTORY OF THE FIFTH AMENDMENT'S TAKINGS CLAUSE

The Takings Clause of the Fifth Amendment states, "No person. . . shall [have] private property be taken for public use, without just compensation." [60] This amendment has seen many interpretations throughout the judicial history of the United States, as one of the more controversial issues that the Supreme Court has reversed, overturned, or questioned throughout the decades.[61] For most of the first 100 years of United States history, the Takings Clause only prohibited the taking of real or personal property against *direct* appropriation.[62] Now, courts identify the taking of private property as either a physical taking or a taking by regulation.[63]

Taking by regulation results when the government so severely limits the use of private property that the property is effectively and economically worthless.[64] When presented before the Supreme Court, the Court answered the question of regulatory taking by proposing an "ad hoc" test of factual inquiries.[65] The factors under the proposed test included the type of governmental action at the time of the taking, the economic impact of the regulation, and the impact upon investment backed expectations.[66] After finding these factors satisfied, the Court permits such regulatory taking if for public use and after just compensation.[67]

59. Gupta, *supra* note 11, at 22.

60. U.S. CONST. amend. XV.

61. *See* Horne v. Dep't of Agric., 135 S. Ct. 2419, 2427 (2015) (explaining the complex history of judicial interpretation of the "Takings Clause" in the Fifth Amendment).

62. *Id.*

63. Steven J. Eagle, *Property Rights After Horne*, 10 N.Y.U. J. L. & LIBERTY 669, 670 (2016).

64. Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1018–19 (1992) (holding that there are "good reasons for our frequently expressed belief that when the owner of real property has been called upon to sacrifice all economically beneficial uses in the name of the common good, that is, to leave his property economically idle, he has suffered a taking.").

65. Penn Central Transp. Co. v. New York City, 438 U.S. 104, 123–24 (1978).

66. *Penn Central*, 438 U.S. at 124 (reasoning that physical takings by the government are more readily identifiable as a taking, but interferences with property as a result of a public program benefitting economic and public good can prove harder to identify, though still categorized as a regulatory taking).

67. U.S. CONST. amend. V; Kelo v. City of New London, Conn., 545 U.S. 469, 484–91 (2005) (holding a city's decision to take private property for the purpose of economic development and confer said property to another private owner satisfies the "public use" requirement of the Fifth Amendment because "public use" can be defined as conferring a public benefit for "public purpose" in the form of an economic boost to the community, however the Court's concurring opinion advises of a caveat to such taking stating, "a court applying rational-basis review under the Public Use clause should strike down a taking that, by a clear showing, is intended to favor a particular private party, with only incidental or pretextual public benefits," thus a clear transfer of private property to another private party for such party's singular benefit would be an abuse of the takings clause). *Compare* Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 415 (1922) (setting previous precedent that demanded compensation for a regulatory taking, thus holding that government regulation—if taken too far—can be classified as a taking), *with Horne*, 135 U.S. at 2427 (holding, "Nothing in this history suggests that personal property was any less protected against physical appropriation than real property. As this Court summed up in *James v. Campbell*, 104 U.S. 356, 358 (1882), a case concerning the alleged appropriation of a patent by the Government: '[A patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use

II. ANALYSIS

Even though patents can trace their lineage to sixteenth-century England, in the twenty-first century their definition as property remains heavily debated.[68] Until 2018, courts entertained the idea of patents as personal private property relatively often, though never setting binding precedent that they be treated as such on a broad scale. [69] When the America Invents Act replaced the examination and petition process of a patent, courts began to realize the need for deeper interpretation of the property interest associated with a patent.[70] Today, the Supreme Court still generally refers to patents as private property,[71] but includes a new sub-category: public franchise.[72] Because the Fifth Amendment only applies to private property, it is essential to determine if a patent categorized as a "public franchise" is indeed private property. Because *Oil States* recognizes "public franchise" as a private property subcategory, the regulation of patents indeed triggers Fifth Amendment scrutiny.[73]

A. IPR INVALIDATION AS REGULATORY TAKING OF PHARMACEUTICAL PATENTS

One industry claiming significant repercussions by the implementation of IPR is the pharmaceutical industry.[74] Determining whether IPR invalidations qualify as a regulatory taking could significantly affect the way this industry functions. Thus, this analysis will use the pharmaceutical industry to help explain the types of consequences that would stem from labeling invalidation proceedings in IPRs as regulatory takings under the Fifth Amendment.

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without compensation land which has been patented to a private purchaser'"; setting a more recent precedent that the Taking Clause imposes a "categorical duty" that the government pay just compensation for the taking of real or personal property, implying there is no distinction between the two.).

68. John Golden, *Private Property and Public Franchise: Patents Under the Supreme Court's Public-Rights Doctrine*, NEW PRIVATE LAW BLOG (Apr. 30, 2018), https://blogs.harvard.edu/nplblog/2018/04/30/private-property-and-public-franchise-patents-under-the-supreme-courts-public-rights-doctrine/ [https://perma.cc/ZQ3L-QMMA]; *see supra* Part I, Section A.

69. Gregory Dolin & Irina D. Manta, *Taking Patents*, 73 WASH. & LEE L. REV. 719, 721–75 (2016); *see also* Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1373 (2018) (where the court again took up the discussion of what private property interest patents convey).

70. *See generally Oil States*, 138 S. Ct. 1365 (2018) (where the Court further debated what property interest patents possess and ultimately redefined such interest as a public franchise).

71. Horne v. Dep't of Agric., 135 S. Ct. 2419, 2427 (2015).

72. *Oil States*, 138 S. Ct. at 1373.

73. *Id.*

74. Foroohar, *supra* note 9. Opinions on the patent system vary wildly, but the pharmaceutical industry has been a loud voice in opposition to the changes made by the AIA, claiming that the changes have weakened innovation and have essentially made their patents utterly useless, as explained by Foroohar:

> The industry has long been in the line of fire over drug pricing and its monopolistic power. But the large drug companies are only one voice among many that have begun the complain about how shifts in the US patent system over the past decade have weakened the ability of companies to protect their innovations.

Foroohar, *supra* note 9.

1. Penn Central Analysis

The Supreme Court relies on the ad hoc analysis provided by *Penn Central Transp. Co. v. New York City* in determining if a regulatory taking has occurred.[75] The *Penn Central* analysis includes a three-factor balancing test courts use to determine whether a taking is a regulatory taking: the character of the governmental action; the economic impact of such action; and the action's interference with reasonable investment-backed expectations.[76] *Ruckelshaus v. Monsanto Co.*'s application of the *Penn Central* factors to the Environmental Protection Agency's ("EPA") regulations is most analogous to what a *Penn Central* analysis would look like in application to a USPTO regulation.[77] Though not identical, *Ruckelshaus*'s analytical application of *Penn Central* factors to the EPA oversight of a regulatory partnership between the government and a private entity is useful in analyzing the USPTO's relationship with an inventor after conferring a patent.

a. Character of governmental action

One of *Penn Central*'s first analytical prongs is the character of the governmental action.[78] Regulatory taking proves harder to identify than a physical taking of land.[79] A key factor in determining if the governmental action fits the character of a taking is whether the public program interferes with economic benefits or burdens by adjusting them to promote common good.[80] PTAB IPR proceedings can significantly interfere with the economic interests of the patent holder in the name of the public good, suggesting the character of the governmental action leans toward excess regulation that equals a taking.[81]

Such economic interferences can occur in the pharmaceutical industry due to the high volume of patent applications filed, and the high cancellation rate of such patents' claims by the PTAB.[82] In July 2018, the PTAB issued fifty-one IPR and Covered Business Method ("CBM") Final Written Decisions, cancelling 79% of the challenged instituted claims.[83] The adverse

75. Penn Central Transp. Co. v. New York City, 438 U.S. 104 (1978).

76. *Id.* at 124.

77. Ruckelshaus v. Monsanto Co., 467 S. Ct. 986 (1984) (applying *Penn Central*'s regulatory taking analysis to the pesticide industry's requirements for trade secret disclosure to the EPA, who would then determine if such information should be disseminated).

78. *Penn Central*, 438 U.S. at 124.

79. *Id.*

80. *Id.*

81. *See infra* Part II, Section B.

82. Daniel F. Klodowski, David C. Seastrunk, & Michael R. Galgano, *IPR and CBM Statistics for Final Written Decisions Issued in July 2018*, FINNEGAN AIA BLOG (Sept. 10, 2018), https://www.finnegan.com/en/insights/blogs/america-invents-act/ipr-and-cbm-statistics-for-final-written-decisions-issued-in-July-2018.html [https://perma.cc/3JKJ-54KM].

83. *Id.* The Patent Trial and Appeal Board issued fifty-one IPR and CBM Final Written Decisions in July, including decisions following remands from the Federal Circuit, cancelling (holding non-patentable) 617 (79%) instituted claims while declining to cancel (remaining valid patents) 143 (18.31%) instituted claims. *Id.* Patent owners conceded twenty-one (2.69%) claims through motions to amend or disclaimer in cases reaching a final decision. *Id.* For comparison, the cumulative average rate of instituted claims cancelled in IPR and CBM Final Written Decisions is about 75%. *Id.*

parties in these IPRs usually argue that the challenged patent is too vague, a stolen idea, or an obvious claim.[84]

Since 2012, there have been 550 biopharma patent petitions filed with the PTAB, which make up a large portion of the average 75% cancellation rate of instituted claims from IPR proceedings.[85] In 2018, only 47.65% of these biotech and organic chemistry patent claims survived PTAB IPR and CBM.[86] Because pharmaceutical patents make up a large portion of patents held invalid by the PTAB, it may be concluded that such government action significantly interferes with the market, categorizing the PTAB's action as a regulatory taking. Thus, the next analytical step is weighing the economic impact felt by the pharmaceutical companies who hold the patent.

b. Economic Impact

Critics of the process argue that most patent invalidations deprive the original patent owner of some type of economic interest, but not all economic impacts rise to the level of a regulatory taking.[87] To claim a regulatory taking, the property owner must show a severe economic impact directly resulting from the taking.[88] The severity of the economic impact is judged on the whole property as opposed to the specific piece of property that may be directly affected by the taking.[89] Thus, the economic value of a patent is not necessarily weighed by the actual product's monetary return. A patent's property value can be found solely in the right to exclude and create a competitive advantage within the market, regardless of the product's actual creation and sales.[90]

As discussed previously in Part I, patents allow exclusivity for the inventor to stop others from using his patented invention.[91] The right to exclude others from making and selling the patent-holder's invention makes

84. Daniel Siegal, *Corrected: PTAB Rejects Mylan's Challenge To Gilead's Viread Patent*, LAW360, (Dec. 11, 2014, 4:36 PM), https://www.law360.com/articles/603306/corrected-ptab-rejects-mylan-s-challenge-to-gilead-s-viread-patent [https://perma.cc/58MA-CEA2].

85. Klodowski, Seastrunk & Galgano, *supra* note 82; *see also* Nisen, *supra* note 54 ("IPR is faster, cheaper, and friendlier to patent plaintiffs than going to court. That makes it particularly worrisome to pharma companies, which want market exclusivity for their drugs to last as long as possible. Since IPR became available in 2012, 550 biopharma patent petitions have been filed with the [PTO], 337 of which have been accepted by the [PTAB] for review.").

86. Klodowski, Seastrunk & Galgano, *supra* note 82.

87. Penn Central Transp. Co. v. New York City, 438 U.S. 124 (1978); Robert S. Mangiaratti, *Regulatory Taking Claims in Massachusetts Following the* Lingle *and* Gove *Decisions*, 90 MASS. L. REV. 54, 58 (2007).

88. *Penn Central*, 438 U.S. at 124 (1978).

89. Mangiaratti, *supra* note 87, at 58.

90. Ruckelshaus v. Monsanto Co., 467 S. Ct. 986, 1010 (1984). *Ruckelshaus* discusses that the exclusivity of the patent owner's right—in this specific case, the rights of the Monsanto Company—to a market monopoly can far outweigh any monetary gain from sales of the actual invention. *Id.* The property right's economic value lies in the competitive advantage that companies possess in exclusive access to patented formulas or designs. *Id.* Thus, any disclosure of those formulas and designs would take away the competitive advantage most patent holders enjoy, thus decreasing the economic value of the patent. *Id.*

91. Dean Baker, *End Patent Monopolies on Drugs*, N.Y. TIMES (Jan. 10, 2016), https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/end-patent-monopolies-on-drugs [https://perma.cc/DY3W-4DY5] (although the right to exclude may not necessarily grant the right to "use" in the patent system, large companies like those in the pharmaceutical industry have the resources to actually produce their patented drugs); *see supra* Part I.

his invention unique, thus increasing the economic value of the patent via simple supply and demand.[92] The leading United States biopharmaceutical company Gilead Science, for example, holds roughly 560 patents and has applications for roughly 329 patents pending in 2018.[93] On January 1, 2018, Gilead Science's market capitalization was estimated at $95 billion (including international markets), and the course of treatment for its highest selling hepatitis C drug, *Sovaldi*, is valued at $84,000, which suggests the patent's worth is much more.[94] A successful IPR petition to challenge Gilead's hepatitis C treatment drugs could be considered a severe economic impact should the PTAB invalidate the patent, allowing more generic drugs to enter the marketplace.[95] Thus, invalidation also meets this "taking" criteria.

c. Interference with Reasonable Investment Backed Expectations

The last of the three *Penn Central* factors is the reasonable expectations of the patent holder with regard to their investment in the property.[96] Such investments are made with the expectations that the patent will be held valid and after production will yield high returns.[97] Invalidating a patent after successfully completing the application process and receiving higher rates of investment for the production stage can fully interrupt expectations investors had in the product's rate of return.[98] However, the Court in *Ruckelshaus* held that a property owner that has notice of the governmental action cannot have a reasonable investment-backed expectation that his property will not be taken.[99]

92. Baker, *supra* note 91 ("United States stands out among wealthy countries in that we give drug companies patent monopolies on drugs that are essential for people's health or lives and then allows them to charge whatever they want.").

93. JUSTIA COMPANY PROFILES, https://companyprofiles.justia.com/company/gilead-sciences [https://perma.cc/VLD6-35PA] (last visited Sept. 11, 2018).

94. David Crow, *Drugmakers Alarmed by Trump Pricing Threat*, FINANCIAL TIMES (Jan. 14, 2017), https://www.ft.com/content/e664a97e-d920-11e6-944b-e7eb37a6aa8e [https://perma.cc/ W9KC-4BFN] ("Alexion . . . makes a drug for rare blood disorders that costs roughly $500,000 a year per patient."); Susan Decker & Cynthia Koons, *Gilead's Patents on Hepatitis C Drug Challenged by Consumer Group*, BLOOMBERG (Oct. 25, 2017, 8:01 AM), https://www.bloomberg.com/news/ articles/2017-10-25/gilead-patents-on-sovaldi-drug-challenged-by-consumer-group [https://perma.cc/ QT6T-7YE5]; Preston Pysh, *The Intrinsic Value of Gilead Science*, FORBES (Jan. 1, 2018, 12:01 PM) https://www.forbes.com/sites/prestonpysh/2018/01/01/the-intrinsic-value-of-gilead-science/ #3c4394b6f86b [https://perma.cc/HQ4Z-KAQL].

95. Decker & Koons, *supra* note 94.

96. Penn Central Transp. Co. v. New York City, 438 U.S. 124 (1978); Ruckelshaus v. Monsanto Co., 467 S. Ct. 986, 1010 (1984) (also reasoning that such reasonable expectation must be more than a unilateral expectation or abstract need).

97. Foroohar, *supra* note 9. Patents often require venture capitalists to invest in their product throughout the patent application process, and small to mid-sized companies "live or die on the ability to protect a handful of patents, and thus monetize their years of investment." *Id.* Being able to defend a patent increases the securing of venture capital funding by 53%. *Id.*

98. *Id.*

99. *Ruckelshaus*, 467 S. Ct. at 1008–09 (explaining, "Monsanto was on notice of the manner in which EPA was authorized to use and disclose any data turned over to it by an applicant for registration . . . If . . . Monsanto chose to submit the requisite data in order to receive a registration, it can hardly argue that its reasonable investment backed expectations are disturbed when EPA acts to use or disclose the data in a manner that was authorized by law at the time of the submission.").

Estimated at $50 billion invested annually in research and development, pharmaceutical companies have high investment-backed expectations in their patents.[100] Such investments in patents for drugs like *Sovaldi*, are reasonable, considering Gilead's success in becoming the leading pharmaceutical manufacturer in the United States. However, IPR proceedings and post-grant invalidations are not new to the pharmaceutical industry. The AIA's IPR proceedings have been in full effect since 2012. *Ruckelshaus*'s reasoning would suggest that a company like Gilead may have enough notice of these invalidation proceedings to negate any type of "reasonable" investment backing that IPR invalidation may upset.[101]

2. Is Invalidation for Public Use?

If the *Penn Central* factors are satisfactorily met, courts may conclude that the government has taken private property by regulation, triggering the Fifth Amendment's public use requirement. To prove public use in a regulatory taking, the legislative history of the regulation's statutory authority provides guidance as to the law's public purpose.[102] Dependent on the legislative intent, a taking does not require the property to be given directly from one person to the public as a whole, as long as the taking inadvertently benefits the public.[103]

The AIA intended that only facially defective patents be subject to IPR review.[104] The driving factor behind the AIA's creation of IPR proceedings—allowing the public to more directly alert the USPTO of possibly invalid patents—promotes public interest.[105] Such public interest rests at the core of the procedural aspects of IPRs.[106] The Court may consider public interest as a reason to allow the taking of pharmaceutical patents that are challenged in IPR proceedings if such patents are not "kept within their legitimate scope."[107]

100. INT'L TRADE ADMIN, 2016 TOP MARKETS REPORT: PHARMACEUTICALS 7 (2016), https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Top_Markets_Reports.pdf [https://perma.cc/2ENF-HQPU].

101. Rana Foroohar, *A Better US Patent System Will Spur Innovation*, FINANCIAL TIMES (Sept. 3, 2017), https://www.ft.com/content/74114a6c-8f28-11e7-9084-d0c17942ba93 [https://perma.cc/ XLQ2-LV6L] ("In fact . . . most investors are beginning to realize the danger and investments have sharply decreased. Venture capital money into biotech is sharply down from 2015 to 2016); Foroohar, *supra* note 9 ("If companies can't defend their intellectual property, they won't invest.").

102. *Ruckelshaus*, 467 S. Ct. at 1008–09.

103. *Id.* at 1014 ("So long as the taking has conceivable public character . . . the means by which it will be attained is for Congress to determine.").

104. 35 U.S.C. § 316(b); Phil Johnson, *A Look Back at the Legislative Origins of IPRs*, IPWATCHDOG (Sept. 20, 2017), http://www.ipwatchdog.com/2017/09/20/look-back-legislative-origin-iprs/id=88075/ [https://perma.cc/SD5K-EEJ3] (explaining patent owners' "reliance rights" would be considered as a factor in deciding whether the institution of a post-grant proceeding would have an adverse effect "on the economy, integrity of the patent system, the efficient administration of the Office, and ability of the Office to timely complete proceedings instituted.").

105. Johnson, *supra* note 18 (explaining that the overall structure of the AIA was influenced by encouraging the public to bring any patent challenges early).

106. *Id.*

107. Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1374 (2018) (". . . the Board's inter partes review protects 'the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope.'").

Many parties in IPR proceedings against pharmaceutical patents argue that the patent does not meet the non-obviousness standard established under 35 U.S.C. § 103.[108] Such an obvious patent can create too strong of an exclusive and undue patent right for one company.[109] Through a successful challenge, the invalidity of such a patent would create a more diverse and competitive market, decreasing the cost of the drug for the consumer and allowing more options for treatment.[110] For example, Gilead Science initially priced *Sovaldi* at $1,000.00 per pill.[111] A successful obviousness challenge of *Sovaldi*'s patents could break through the monopoly, which would offer cheaper drugs for consumers. There are others, however, who argue the new patent process actually protects Big Pharma companies[112] by allowing them to infringe and obtain medication patents already in existence, creating a difficult task for the courts reviewing the issue of whether a PTAB taking benefits public use.[113]

3. Is there Just Compensation?

Even more complicated in regulatory takings is assigning just compensation in accordance with the Fifth Amendment.[114] Especially considering that a patent's economic value can vary, justly compensating the taking of a patent for public use can prove tricky. 28 U.S.C.A. § 1491, the Tucker Act, could solve this dilemma, as the Act allows for the United States Court of Federal Claims to render judgement on any claim against the United States founded upon the Constitution.[115] The Court in *Ruckelshaus* determined that this separate act allows a property owner to obtain just

108. Siegal, *supra* note 84.

109. *Id.*

110. Foroohar, *supra* note 9; *but see* Nisen, *supra* note 54 (explaining that generic drug makers lean on patent challenges in anticipation that their competing product will make it to the market, and would suffer if IPRs were abolished or changed, thus these manufacturers rely on IPRs to grant them speedier access to the market and use the proceedings to target legal threats to their own products resulting in consumers having less options for cheaper drugs).

111. Ricardo Alonso-Zaldivar, *Maker of $1,000 Hepatitis C Pill Was Focused on Profits, Not Patients, Report Finds*, PBS NEWS HOUR (Dec. 1, 2015), https://www.pbs.org/newshour/health/ maker-of-1000-hepatitis-c-pill-was-focused-on-profits-not-patients-report-finds [https://perma.cc/Q3X E-K2Q4]; *see also* Crow, *supra* note 94 ("Alexion, which makes a drug for rare blood disorders that costs roughly $500,000 a year per patient.").

112. *Big Pharma*, MERRIAM-WEBSTER ONLINE DICTIONARY, https://www.merriam-webster.com/dictionary/Big%20Pharma [https://perma.cc/8BK9-8HMJ] (last updated 2019) ("Large pharmaceutical companies considered especially as a politically influential group.").

113. Foroohar, *supra* note 101 (explaining, "Indeed, some would argue that the system of adjudication for patents introduced under the Obama administration has become a 'powerful shield' for those accused of patent infringement. Most of the verdicts go against the patent holder, leading former chief judge Randall Rader, who led the court in charge of patent appeals, to label it the 'death squad' for IP."); *see also* Jessica Dye, *Jury Orders Gilead to Pay Merck $2.54bn in Damages in Patent Trial*, FINANCIAL TIMES (Dec. 15, 2016), https://www.ft.com/content/2857f437-5882-33ec-a1f3-7cc7cf8292b3 [https://perma.cc/76R5-7UKK] ("Gilead . . . disputed that it had relied on Indenix's intellectual property in making its blockbuster drugs, and said the patent was invalid. Jurors, however, found that Gilead had willfully infringed the patent at issue.").

114. *Ruckelshaus*, 467 S. Ct. at 1008–09.

115. 28 U.S.C.A. § 1491.

compensation through required arbitration at the Court of Federal Claims.[116] Thus, the same remedy may be applied to patents.[117]

III. PROPOSAL

As the wave of new technology advances and countries battle to lead in innovation, defining the true essence of a patent's property interest as it relates to United States constitutional rights becomes increasingly important. Based on the "public franchise" holding in *Oil States*,[118] it is relatively clear that courts still consider patents as personal, not public, property. Additionally, under a *Penn Central* analysis, PTAB IPR invalidations may qualify as regulatory taking of personal property by the government.

However, applying these principles to USPTO procedures as they stand today would cause significant problems. Because almost every action by the PTAB could qualify as a "public purpose," the Fifth Amendment would demand an outpouring of compensation to every inventor who loses a patent.[119] Alternatively, simple changes in PTO procedures could lead to constitutional protections that equally benefit both the inventor and the public.

A. PRE-GRANT EXAMINATION PROCEEDINGS

As discussed previously in Part II, the AIA intended for the PTAB to review and invalidate only facially invalid patents.[120] The PTO assumes that pre-grant examination proceedings thoroughly and properly filter through only nonobvious and novel patents.[121] Presumably, challenged claims in IPR should never have been patented in the first place. Yet the PTAB cancels over 70% of challenged claims.[122] Therefore, logic suggests that USPTO examiners should have never approved over 70% of challenged claims. To limit the regulatory taking of patents, and ensure invalidation of only facially flawed claims, the USPTO should adopt higher standards in their pre-grant

116. Ruckelshaus v. Monsanto Co., 467 S. Ct. 986, 1019 (1984) (explaining that courts do not require just compensation be given directly by the entity taking the private property if a suit can be brought against the government for equitable relief beforehand via the Act); Larson v. Domestic & Foreign Commerce Corp., 337 U.S. 682, 697 (1949); Hurley v. Kincaid, 285 U.S. 95, 104 (1932) (explaining the Fifth Amendment does not require that compensation precede the taking).

117. *Ruckelshaus*, 467 S. Ct. at 1017. If determined that IPR does take by regulation the private property of an inventor, the Tucker Act may possibly apply and allow an avenue to provide just compensation to the taking. *Id.*

118. Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1373 (2018).

119. Johnson, *supra* note 18. As explained previously in Part II, the entire point of the AIA is to make safe, consumer-friendly, and marketable patents; thus, each invalidation can be considered a taking for public use. *See supra* Part II.

120. Johnson, *supra* note 18; *see supra* Part II.

121. Josh Landau, *FTC Hearings #4: Patents, Intellectual Property, and Innovation*, DISRUPTIVE COMPETITION PROJECT (Oct. 31, 2018), http://www.project-disco.org/competition/103118-ftc-hearings-4-patents-ip-innovation/#.W-IDt5NKiUk [https://perma.cc/Y2N5-HT9D] ("If the PTO had known at the time of grant what it knows now, [would it] have issued the patent?").

122. Klodowski, Seastrunk & Galgano, *supra* note 82.

examination proceedings. This would result in fewer takings, in turn, creating stronger patent protection for inventors.

Although an examiner can easily research an invention's novelty, the obviousness requirement can prove broad and difficult in pre-grant procedures.[123] Changing the subjective nature of this key requirement in most patent cases could remedy the exorbitant rate of invalidation at the PTAB.[124] Narrowing the scope of what qualifies as prior art back to pre-AIA standards offers one way to help examiners during their review.[125] When the AIA changed the definitions of prior art by removing geographic and language restrictions, it expanded the scope of public disclosures that may have prior art effect to anywhere in the world and in any language.[126] This forces the inventor and the examiner to uncover every chance of public disclosure, everywhere in the world, in every language, or risk invalidation later on when litigators at the PTAB have had the opportunity to find prior art hidden beneath an unturned rock.[127] A narrower scope allows less opportunity for "surprises" in PTAB proceedings, as the examiner has already reviewed most potential and conflicting prior art. This narrow scope may assist in bolstering later IPR defenses for a patent holder because the inventor can more easily compare his claims with all available prior art and define his claim terms to avoid ambiguity if later reviewed by the PTAB.[128]

Aside from changing the scope of prior art, extending the amount of time an examiner has to review the prior art of an invention may reinforce the validity of the patent's claims.[129] Limited turnaround time forces the examiner to grant patents that should otherwise be denied because the examiner can find no basis to reject the non-obviousness, novelty, or

123. *See generally* ARTI KANE, CRASH COURSE ON US PATENT LAW; ABA SECTION OF INTELLECTUAL PROPERTY LAW 1.

124. *Id.*

125. HEINS, *supra* note 48, at 11 (explaining that prior art under the AIA is much broader, creating a difficult task for an examiner to verify the non-obvious nature of a patent).

126. 35 U.S.C. § 102; Thomas Irving, *Top Five Dangers for the AIA Unwary*, FINNEGAN (May/June 2013), https://www.finnegan.com/en/insights/top-five-dangers-for-the-aia-unwary.html [https://perma.cc/YEB3-QGX6].

127. Irving, *supra* note 126.

128. Jason Mock, Kiri Sharon, & Tianran Yan, *IPR Proactive Defense Measures – Strategies and Considerations for Patent Owners*, FOLEY & LARDNER, LLP (May 31, 2016), https://www.foley.com/en/insights/publications/2016/05/ipr-proactive-defense-measures—strategies-and-con [https://perma.cc/E3GF-837T]; *see also* Gene Quinn, *USPTO Publishes Final Rule Adopting Phillips Standard at PTAB*, IP WATCHDOG (Oct. 10, 2018), https://www.ipwatchdog.com/2018/10/10/uspto-publishes-final-rule-phillips-standard-ptab/id=102210/ [https://perma.cc/D6W9-XAYV] (the USPTO recently changed its claim construction standard from "broadest reasonable interpretation standard" to match the *Phillips* standard in district courts during patent infringement cases, which may residually affect what previous public disclosures are considered prior art; and while this rule change does not decrease the statutory scope of prior art, many consider it a big win for inventors).

129. *The Examiner Account System: Why Patent Examiners Are On Your Side*, NUTTER UNCOMMON LAW: IP LAW BULLETIN (Nov. 18, 2014), https://www.nutter.com/ip-law-bulletin/the-examiner-count-system-why-patent-examiners-are-on-your-side [https://perma.cc/3GX9-HGEK] (describing how examiners have set expectations and time limits to complete each task during the patent application review process, and each time limit varies based on the specific task).

usefulness of the patent.[130] Even if subpar patents are being granted due to time sensitive examinations, the USPTO's grant still issues to a patent holder a personal interest in their property that the PTAB may later take due to the USPTO's own pre-grant errors. If the USPTO narrows the scope of review, and allows more time for examiners to research prior art, the PTAB will most likely hold a higher percentage of claims as valid, resulting in less taking of personal property. In addition, this change would create a solid foundation for a granted patent if ever challenged in IPRs.[131]

B. IPR EVIDENTIARY STANDARDS[132]

Federal courts and the PTAB have wildly different evidentiary standards to determine a patent's validity. Though the federal courts impose standards of clear and convincing evidence when reviewing validation of a patent, the PTAB merely requests a preponderance of the evidence.[133] For example, in *Novartis Pharm. Corp. v. Noven Pharm. Inc.*, the U.S. District Court in the District of Delaware upheld the patent at issue as valid and non-obvious, and the Federal Circuit affirmed.[134] Alternatively, the patent was challenged at an IPR proceeding and the PTAB ruled the patent invalid and obvious based on the same evidence and argument presented to the Delaware court.[135] To avoid this dilemma, PTAB standards of review should

130. Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?*, NATIONAL BUREAU OF ECONOMIC RESEARCH 2 (July 2014), https://www.nber.org/papers/w20337.pdf [https://perma.cc/3RVV-D4ES] (an August 2010 report commissioned by the Patent Office showed that examiners "consistently expressed the need for additional time," and expressed their concern that they were unable to do "high-quality" examination); *see also* KANE, *supra* note 123, at 7.

131. Mock et al., *supra* note 128.

132. Quinn, *supra* note 128. In October of 2018, the USPTO published a final rule changing the claim construction standard at IPR proceedings from "broadest reasonable interpretation standard" to now match the *Phillips* standard applied at federal district courts during patent infringement litigation. *Id.* While this means that the PTAB will now consider any prior claim construction determination previously made in a civil action or International Trade Commission proceeding, it does not change the evidentiary burdens at the PTAB which are much more lax than the heightened burdens of the federal district courts. *Id.*

133. *Id.* ("The statute requires only a preponderance of evidence to invalidate patent claims in a challenge at the PTAB, while clear and convincing evidence is required in federal courts and at the ITC to invalidate claims. Still, all tribunals using the same claim construction standard moving forward can only help. Statutory reform requiring clear and convincing evidence to invalidate patent claims in proceedings at the PTAB is still a necessity.").

134. *See generally* Novartis Pharm Corp. v. Noven Pharm., Inc., 125 F.Supp.3d 474 (D. Del. Aug. 31, 2015), *aff'd*, Novartis AG v. Watson Labs., Inc., 611 F. App'x 988 (Fed. Cir. 2015).

135. *See generally* Novartis AG v. Noven Pharm. Inc., No. 2016-1678 (P.T.A.B. Apr. 4, 2017), *aff'd*, Novartis AG v. Noven Pharm. Inc., 853 F.3d 1289, 1294 (Fed. Cir. 2017) (upholding the PTAB's invalidation because more evidence was presented during the IPR than at the federal district court, but also stating that, "even if the records were the same, Novartis's argument would fail as a matter of law" due to the PTAB's review by a preponderance of the evidence rather than by clear and convincing evidence standards of district court litigation); Elizabeth M. Crompton, *Differing Burdens of Proof in the PTAB and District Courts Can Allow Patent Challengers a Second Bite at the Apple*, HAYNESBOONE (June 13, 2017), https://www.haynesboone.com/Publications/differing-burdens-of-proof-in-the-ptab-and-district-courts [https://perma.cc/VJ9M-7EM2]. *See also* Gene Quinn & Steve Brachmann, *58 Patents Upheld in District Court Invalidated by PTAB on Same Ground*, IPWATCHDOG (Jan. 8, 2018), https://www.ipwatchdog.com/2018/01/08/58-patents-upheld-district-court-invalidated-ptab/id=91902/ [https://perma.cc/S33P-ZKUG]; *compare* Imperium IP Holdings v. Samsung, 259 F.Supp.3d 530 (E.D. Tx. Apr. 27, 2017) (holding that defendant Samsung infringed on plaintiff's valid and non-

mirror those of the federal courts, especially considering *Oil States*' holding that PTAB tribunal hearings do not violate the right to Article III courts.[136] Therefore, the PTAB should impose the Article III "clear and convincing evidence" standards, to preserve consistency.[137] Without such standard, petitioners in IPR may win challenges based on a mere argument that the claims are "more likely than not unpatentable," instead of providing extensive proof of unpatentability.[138]

Implementing this new, stricter IPR evidentiary standard would not jeopardize the integrity of patents, if coupled with the proposed pre-grant examination changes. Instead of questioning a patent's validity after the fact, a patent is less likely to be invalidated due to a more thorough, front-loaded examination by the USPTO. Therefore, after an examiner grants a patent subject to stricter examination guidelines, the PTAB may have stronger justification for any subsequent invalidation. By reviewing challenges with the same evidentiary standard as the Court of Federal Claims, invalidation could more easily meet the "public use" requirements of the Fifth Amendment. With stricter screening and standards, the PTAB will be more likely to only invalidate those patents—like obvious patents—that should never have been issued.

Holding patents to a higher standard of proof would additionally stop infringing companies from using the process to invalidate patents for the underlying purpose of market access in favor of their own copied inventions. Though not on its face, the current standards of proof in the PTAB, in application, tend to favor cancelation of patents for public use based on market access. A higher standard of proof creates stronger protections for patent owners against infringers, and any fear of market monopoly in violation of public good is abated as patents only sit for fourteen to twenty years before the monopoly expires.[139]

obvious patents under 35 U.S.C. § 103), *with* Samsung v. Imperium IP Holdings, No. 2015-1232 (P.T.A.B. Dec. 1, 2016) (ruling the patent invalid and obvious under 35 U.S.C. § 103).

136. Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1373 (2018); *Substantial Evidence or Clear Error? Aligning the Standards of Review for IPR Appeals*, NAT'L L. REV. (May 27, 2016), https://www.natlawreview.com/article/substantial-evidence-or-clear-error-aligning-standard-review-ipr-appeals [https://perma.cc/3LDG-6EHZ] (explaining that, "In its Zurko decision, the Supreme Court of the United States refers to 'clear error' review as the standard for 'court/court' review, and to other standards of review contemplated by the Administrative Procedure Act as "court/agency' review. Under Zurko, if congress meant to create an adversary, party-instituted proceeding to consider what would otherwise be considered by a district court, then review of a patentability decision in an IPR would be more like court/court review.").

137. Flibbert & Queler, *supra* note 57.

138. *Id.* The standards of review differ significantly between federal courts and the PTAB:

> [I]n district court, patents enjoy a statutory presumption of validity and challengers must prove each patent claim invalid by clear and convincing evidence—the highest burden of proof in US civil litigation. But not such presumption of validity applies in PTAB proceedings. Petitioners need only establish unpatentability by a preponderance of the evidence i.e., that the claims are more likely than not unpatentable. This is a significantly reduced burden of proof compared to litigation.

Id.

139. KANE, *supra* note 123.

C. JUST COMPENSATION THROUGH TUCKER ACT CLAIMS

Just compensation proves the largest hurdle when applying the Fifth Amendment to patent invalidation. Looking to *Ruckelshaus* as an example, the Tucker Act may solve this dilemma by providing proper compensation to inventors after the taking of their property.[140] As *Ruckelshaus* explained, the compensation does not have to match the value of the patent, but merely equal "just" compensation regarding the patent holder's loss.[141] The Tucker Act provides this type of remedy to patent holders by allowing claims in the Court of Federal Claims based on constitutional violations.[142] If determined that patent claim cancellations and invalidations are unconstitutional takings without just compensation under the Fifth Amendment, the Tucker Act could apply. This would allow the Federal Claims court to independently determine the damages "justly" allowed to the inventor and compensate him without undue burden on the USPTO. If this "just" standard is applied, it may be up to the legislature to create statutory guidelines and caps for how much a patent holder may be awarded to avoid the inventor from demanding gross exaggerations of their patent's value.

Even if a patent deserves to be invalidated, inventors should not be punished for believing in the validity of their granted patent, and in turn investing further resources in it. Courts often analogize patents to written instruments such as contracts when construing patent claims.[143] They are "aptly likened to the description in a deed, which sets the bounds to the grant which it contains.[144] Written instruments like contracts allow remedy in the form of reliance damages when one party breaches.[145] Because patents are deemed valid once granted, should the same remedy not be implied when the USPTO revokes a promise of exclusivity that an inventor relied upon? Especially considering the affirmative "use rights"[146] patents once bestowed upon their owner, courts may consider re-evaluating the significant property interest patents confer, combined with the inventor's serious reliance on his exclusivity as he begins to market his product. Patent holders should be justly compensated for the taking of their personal property and not penalized for relying on its presumed validity. If the USPTO had higher standards in pre and post-grant procedures, the government could more overwhelmingly

140. Ruckelshaus v. Monsanto Co., 467 S. Ct. 1019 (1984) ("Because we hold that the Tucker Act is available as a remedy for any uncompensated taking . . .").

141. *Id.*

142. 28 U.S.C. §§ 1346(a)(2), 1491 (The Tucker Act allows the United States government to waive its sovereign immunity and expose the government to liability of certain claims, and allows for district courts to have original jurisdiction concurrent with the Federal Claims Court, stating: "Any other civil action or claim against the United States, not exceeding $10,000 in amount, founded either upon the Constitution, or any Act of Congress, or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort . . . ." capping $10,000.00 claims as the "little Tucker Act" and larger "big Tucker Act" claims as rising above $10,000.00 which also gives jurisdiction exclusively to the Court of Federal Claims).

143. Teva Pharm. US, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 837 (2015); Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 226 (1880).

144. *Teva Pharm.*, 135 S. Ct. at 837.

145. 22 Am. Jur. 2d Damages § 62.

146. *See supra* Part I.

prove public use for the taking, triggering just compensation through the Tucker Act.

CONCLUSION

Congress and the Supreme Court continuously struggle in determining what property privileges inventors gain once their idea gets the USPTO rubberstamp of approval. With each legislative act or Supreme Court opinion that attempts to clarify these rights, patent holders receive increasingly vague answers. Each change steps further away from the clear "use rights" associated with patents in the sixteenth century, to ambiguous "exclusion only" rights under the AIA. The shift from "first-to-invent" to "first-to-file" that attempted to simplify and strengthen the patent process has resulted in less protection due to vague prior art standards both before and after a patent's grant.

Although *Oil States* attempted to solve this problem by creating a new type of property interest, patent experts were left with more questions than answers.[147] The narrow holding based on the Court's new and vague "public franchise" label hurts more than helps in clarifying the private interest of an inventor. However, the Court's holding still strongly implies that patents confer personal property interests once granted, entitling patent holders to constitutional protections under the Fifth Amendment.[148]

Due to such vague patent law, courts may find it refreshing to lean on the clear structure of *Penn Central*'s analysis to characterize the nature of invalidation proceedings at the PTAB as regulatory takings. To avoid taking property via a 70% cancellation rate of challenged claims, the USPTO should place more emphasis on pre-grant procedures and heighten PTAB evidentiary standards. Inventors do not deserve the short end of the stick they often receive during IPR, created by the USPTO's lack of rigorous investigation before approving patent applications.

Creating a stronger patent system in the United States protects a working-class father, like Josh, who simply wants to invent a more creative way to play with his children, or a high-school student at her science fair who dreams of new ways to capture the inventive American spirit. Every year, billions of dollars flow through the patent industry in the United States, prioritizing the urgency to define such an unsettled area of the law.[149] The United States should lead this charge in protection of property rights, instead of stifling innovation by overregulation, easy opportunity for infringement, and habitual governmental taking. Whether it be a medical breakthrough or a toy for children, an inventor's ideas deserve recognition and protection. If

147. Adam Liptak, *Supreme Court Upholds Procedure That's Said to Combat "Patent Trolls"*, N.Y. Times (Apr. 24, 2018), https://www.nytimes.com/2018/04/24/business/scotus-patent-trolls.html [https://perma.cc/BG8U-S4YD]. Some experts interpret the opinion as stopping patent trolls, a win for inventors. *Id.* Others argue that defining patents as public franchises destabilizes the foundation patents provide to the innovation and economy of the United States. *Id.*

148. Golden, *supra* note 68.

149. INT'L TRADE ADMIN, *supra* note 100.

not, a patent's worth will only be as valuable as the paper on which it is printed.