

Winter 2017

Big Pharma Versus Inter Partes Review: Why the Pharmaceutical Industry Should Seek Logical Hatch-Waxman Reform over Inter Partes Review Exemption, 50 J. Marshall L. Rev. 337 (2017)

Francisco Javier Espinosa

Follow this and additional works at: <https://repository.law.uic.edu/lawreview>



Part of the [Food and Drug Law Commons](#), and the [Intellectual Property Law Commons](#)

Recommended Citation

Francisco Javier Espinosa, Big Pharma Versus Inter Partes Review: Why the Pharmaceutical Industry Should Seek Logical Hatch-Waxman Reform over Inter Partes Review Exemption, 50 J. Marshall L. Rev. 337 (2017)

<https://repository.law.uic.edu/lawreview/vol50/iss2/7>

This Comments is brought to you for free and open access by UIC Law Open Access Repository. It has been accepted for inclusion in UIC Law Review by an authorized administrator of UIC Law Open Access Repository. For more information, please contact repository@jmls.edu.

BIG PHARMA VERSUS *INTER PARTES* REVIEW: WHY THE PHARMACEUTICAL INDUSTRY SHOULD SEEK LOGICAL HATCH-WAXMAN REFORM OVER *INTER PARTES* REVIEW EXEMPTION

FRANCISCO JAVIER ESPINOSA*

I.	INTRODUCTION.....	338
II.	BACKGROUND.....	342
	A. The FDA, the Process for Approving New Drugs, and Generic Drugs Entry under the Hatch-Waxman Act	342
	1. The FDA and Approving New Drugs	342
	2. The Hatch-Waxman Act, ANDA Litigation, and Generic Drugs	344
	a. Identical Active Ingredient and Bioequivalence to the NDA	345
	b. ANDA Certification Framework.....	346
	c. ANDA Notification to the NDA Holder and Adjudication	347
	B. Patents and IPR	348
	1. Patents, Novelty, and Obviousness	349
	2. IPR, an Overview.....	352
	C. Reverse Payment Agreements and Product Hopping...354	
	D. Reviewing Kyle Bass’s “Short Activist Strategy” and His War on Drug Patents.....	358
	E. The Drug Industry’s Response to Kyle Bass and Their Request for IPR Exemption	361
	1. The Difficulty in Making a New Drug, Big Pharma’s Reasons for High Drug Prices.....	361
	2. The Drug Industry’s Plea to PTAB to Stop Kyle Bass	362
	3. A Request for IPR Exemption	363
III.	ANALYSIS.....	363
	A. Hatch-Waxman versus IPR.....	365
	1. ANDA Litigation and IPR: Filings and Court Differences	365
	2. ANDA versus IPR: Cost and Time to Litigate	367
	3. The Exclusivity Benefit, Patent Infringement, and Article III Standing	368
	4. ANDA versus IPR: A Patent’s Presumptive Validity	369
	B. IPR Statistics on Patent and Bio/Pharma Patents: Patent Kill Rates.....	370
	C. PTAB’s Decisions on CFAD’s IPRs—the Effectiveness of Kyle Bass’s Strategy.....	372
	1. A Review of PTAB’s Decision Not to Institute CFAD IPRs	373
	2. PTAB Institutes Several CFAD IPR Challenges and Their Final Written Decisions	375
	D. No IPR Exemption for Hatch Waxman, But Reverse Payments Are Still an Issue	377
	1. Kyle Bass’s Losing Battle	377
	2. IPRs and Reverse Payment Agreements Are Still an Issue for Hatch-Waxman	379
IV.	PROPOSAL	382
	A. Amendment Inspiration: Verizon Communications Inc. v.	

Law Offices of Curtis V. Trinko, LLP and the Telecommunications Act of 1996.....	383
B. Creating a New Paragraph V Challenge to Re-incentivize the Hatch-Waxman Act	385
C. USPTO Rule and the Telecommunication Act Remedial Framework Can Be a Model to Create an Effective Remedy Section for the Hatch-Waxman Act.....	389
D. Why Should Big Pharma Accept This Hatch-Waxman Amendment?	392
V. CONCLUSION	394

I. INTRODUCTION

In this modern tale of Robin Hood, Robin Hood invalidates drug patents from the rich and gives to the poor, to himself, and to other rich people.¹ That is the reputation that hedge fund² manager Kyle Bass³ and his hedge fund subsidiary, the Coalition for Affordable Drugs (CFAD), have garnered.⁴ In January 2015 Kyle Bass declared war on the pharmaceutical industry by making it his goal to challenge and invalidate what he calls their “BS patents” through *inter partes* review (IPR).⁵ Kyle Bass and CFAD own no patents and produce no products, yet IPR rules allow him and others, sans Article III standing, to challenge a pharmaceutical patent’s validity.⁶ Big Pharma⁷ claims that Kyle Bass’s

* J.D. June 2017, The John Marshall Law School, Chicago, Illinois, Professional Master in Biology July 2013, The Illinois Institute of Technology, Chicago, Illinois, Master in Public Health May 2010, Benedictine University, Lisle, Illinois, B.S. in Health Science August 2008, Benedictine University, Lisle, Illinois. This comment would not have been possible without the unconditional support and love from the love of my life, Beth, and my family, Gina, Pancho, and Jessica. Thank you for always being there for me.

1. Kyle Bass views himself as the “Robin Hood of the modern world” and claims his plan to challenge drug patents to lower drug prices and health care costs is “a rare example of hedge funds aligning themselves with the public good.” Mark Melvin, *Kyle Bass Wants to Be the Robin Hood of Drug Prices*, VALUEWALK (Jan. 7, 2015, 4:30 PM), www.valuewalk.com/2015/01/kyle-bass-wants-robin-hood-drug-prices.

2. Hedge funds “are alternative investments using pooled funds that may use a number of different strategies in order to earn active return, or alpha, for their investors.” *Hedge Fund*, INVESTOPEDIA, www.investopedia.com/terms/h/AIAhedgefund.asp.

3. Kyle Bass is the founder and head of a hedge fund called Hayman Capital Management LP. Joseph Walker & Rob Copeland, *New Hedge Fund Strategy: Dispute the Patent, Short the Stock*, WALL ST. J. (Apr. 7, 2015, 7:24 PM), www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408. In 2007, Mr. Bass successfully predicted the subprime mortgage meltdown and earned 212% return by betting on the short of the subprime mortgages. *Id.* In January 2015, Kyle Bass formed his subsidiary, the Coalition for Affordable Drugs (hereinafter CFAD), which he uses to challenge and invalidate drug patents to lower drug prices for the public. *Id.*

4. See Mark Melvin, *supra* note 1.

5. Julia La Roche, *Hedge Fund Manager Kyle Bass Is Going After Big Pharma and Its ‘BS Patents’*, BUSINESS INSIDER (Jan. 7, 2015, 10:47 AM), www.businessinsider.com/kyle-bass-going-after-us-pharma-2015-1.

6. See 35 U.S.C. § 311.

7. The name “Big Pharma” is used in this comment to generally refer to the

motivation is far from altruistic and that he is simply abusing the IPR process to get rich by negatively influencing pharmaceutical stocks when his IPR challenges to those specific drug patents become public.⁸ Kyle Bass counters by professing to use the IPR process to attack wrongly validated patents to lower drug costs for the public.⁹ Whatever Kyle Bass's true motivation may be, it is undeniable that his novel way of using IPR is contrary to what was intended when the America Invents Act (AIA) of 2011¹⁰ was enacted.¹¹

While some have clamored for IPR to carry an Article III standing requirement¹² and others have suggested making IPR rules parallel to stricter federal court standards,¹³ the drug industry has asked Congress to exempt¹⁴ it from IPR proceedings altogether, arguing that its drug

pharmaceutical industry as a whole but it has referred to specific pharmaceutical groups. *See generally Big Pharma Manufacturers*, DRUG WATCH, www.drugwatch.com/manufacture (last modified May 12, 2017, 3:30:43 PM). "Big Pharma is the nickname given to the world's vast and influential pharmaceutical industry and its trade group, the Pharmaceutical Research and Manufacturers of America or PhRMA. These powerful companies make billions of dollars every year by selling drugs and medical devices." *Id.*

8. Lisa Shuchman, *Big Pharma: Let's Shift Patent Debate Away from Trolls*, CORP. COUNS. (May 20, 2015), www.corpcounsel.com/id=1202726911929/Big-Pharma-Lets-Shift-Patent-Debate-Away-From-Trolls#ixzz3ISTCWgDD. Discussing the concern over alleged IPR abuse in the pharmaceutical industry, Big Pharma claims Kyle Bass's use of IPRs by betting on the short of a stock for financial gain is an abuse of process that was never intended by Congress when it passed the American Invents Act in 2011. *Id.*

9. *See* Mark Melvin, *supra* note 1. Kyle Bass claims that the pharmaceutical industry has kept drug prices high and generic manufacturers out of the market by using patent law loopholes. *Id.*

10. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); 35 U.S.C. § 101 et seq. (2013). The AIA, a federal statute signed into law by Former President Barack Obama, was designed to "modernize the U.S. patent system and strengthen America's competitiveness in the global economy." *Leahy-Smith America Invents Act Implementation*, U.S. PAT. & TRADEMARK OFFICE, www.uspto.gov/patent/laws-and-regulations/leahy-smith-america-invents-act-implementation (last visited May 5, 2017). The AIA was enacted in 2011, some 221 years after the first Patent Act was passed. *See generally* Patent Act of 1790, 1 Stat. 109 (1790).

11. *See* Gene Quinn, *Inter Partes Review and the Controversial Implications of the Kyle Bass petitions*, IP WATCHDOG (Sept. 15, 2015), www.ipwatchdog.com/2015/09/15/inter-partes-review-and-the-controversial-implications-of-the-kyl-e-bass-peti-tions/id=-61691 (stating it is "undeniable that Congress did not intend for hedge fund billionaires to challenge drug patents using [IPR]. It is equally undeniable that the law clearly does allow for anyone, including hedge fund billionaires, to challenge patents they believe were improvidently granted.>").

12. Lionel M. Lavenue, R. Benjamin Cassady & Michael Liu Su, *A Review of Patent Bills in the 114th Congress*, LAW 360 (June 15, 2015, 11:08 PM), www.law360.com/articles/664670/a-review-of-patent-bills-in-the-114th-congress.

13. Peter J. Pitts, *Patent 'Death Squads' v. Innovation*, WALL ST. J. (June 10, 2015, 7:23 PM), www.wsj.com/articles/patent-death-squads-vs-innovation-1433978591. The Patent Trial and Appeal Board (PTAB) uses softer standards than federal courts, for example, PTAB follows the "preponderance of the evidence" standard in contrast to the "clear and convincing" standard the federal court system uses to determine a patent's validity. *Id.* This has led to former Chief Judge Randall Rader of the Federal Circuit to call PTAB a potential patent death squad. *Id.*

14. Mathew Bultman, *Pharma Lobby Wants Some Patents Exempt from AIA Review*, LAW 360 (July 16, 2015, 7:43 PM), www.law360.com/articles/680005/pharma-lobby-wants-

patents are already subject to a patent invalidating process under the Hatch-Waxman Act.¹⁵ The prevailing fear is that IPR may render Hatch-Waxman litigation useless.¹⁶ The Big Pharma lobbyists, in their argument for exemption from IPR, stated that IPR could destroy the development of new drugs: “These challenges take money away from research and development of new medicines, ultimately hurting the patient.”¹⁷ Also, Big Pharma has argued that there is no evidence that IPRs will bring generics faster to the pharmaceutical market place and at lower prices.¹⁸

But, pro-generic drug lobbyists and Medicare lobbyists vehemently oppose pharmaceutical exemption from IPR.¹⁹ In letters to Congress, Medicare lobbyists wrote, “Soaring prescription drug prices threaten to undermine their stability and an [*inter partes* review] carve-out for brand drug manufacturers would only make matters worse.”²⁰ Medicare lobbyists argued that IPRs are a useful, quick, and inexpensive alternative to litigation for generic companies to invalidate bad pharmaceutical patents to get their generic product on the market.²¹

Whether Kyle Bass’s IPR challenges are meritless or an abuse of IPR, his stated reasons for challenging drug patents are not completely off base. His criticisms of the drug industry bring focus on its questionable practices to maintain high profits. In 2014, Americans spent approximately one thousand dollars per person per year on pharmaceuticals, more than any other country in the world.²² That number has increased 13.1% in 2015.²³ Further, the drug industry has taken some hits to its reputation because of these high drug prices. From a former CEO increasing the drug price of an already available medication by 5,000%²⁴ to a drug company increasing the price of an EpiPen from

some-patents-exempt-from-aia-review.

15. *Id.*; Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Commonly referred to as the Hatch-Waxman Act. Construction and Application of Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994)), 180 A.L.R. Fed. 487, 2a. The Act is known as the Hatch-Waxman Act because of its two co-sponsors, Senator Orrin Hatch and Representative Henry Waxman. *Id.*

16. See Gene Quinn, *Senators Mistaken, IPRs Do Not Frustrate Hatch-Waxman*, IP WATCHDOG (June 4, 2015), www.ipwatchdog.com/2015/06/04/senators-mistaken-iprs-do-not-frustrate-hatch-waxman/id=58397.

17. See Bultman, *supra* note 14.

18. *Id.*

19. See Mathew Bultman, *Medicare Group Opposes Carveout for Drug Patents*, LAW 360 (Sept. 22, 2015, 8:11 PM), www.law360.com/articles/705730/medicare-group-opposes-carveout-for-drug-patents.

20. *Id.*

21. *Id.*

22. Valerie Paris, *Why Do Americans Spend So Much on Pharmaceuticals?*, PBS NEWSHOUR (Feb. 7, 2014, 12:15 PM), www.pbs.org/newshour/updates/americans-spend-much-pharmaceuticals.

23. *Pharmaceutical Pricing: Crippling*, THE ECONOMIST (June 4, 2015), www.economist.com/blogs/democracyinamerica/2015/06/pharmaceutical-pricing.

24. Meghana Keshavan, *Revenge of the Hoodie: Marti Shkreli Fires Back at the Drug Industry*, STAT (Jan. 23, 2017), www.statnews.com/2017/01/23/shkreli-revenge-drug-industry.

\$57 a shot to more than \$600 for a two-pack,²⁵ the drug industry has garnered a reputation that cares more about profits than patient healthcare.²⁶ What has helped fuel this profit mongering are drug companies that employ generic drug blocking strategies such as reverse payment agreements and product hopping, both, which opponents argue, unfairly extends a drug patents term and keeps drug prices high.²⁷ These practices can keep drugs expensive and inaccessible.²⁸

In a drug patent system that is currently flawed, logical Hatch-Waxman reform may be the compromise needed to foster drug innovation but also keep drug prices fair. Part II of this comment provides background information on how new drugs get approved by the U.S. Food and Drug Administration²⁹ (FDA) and the process for approving generic drugs through the Hatch-Waxman Act. Then a short explanation of how a patent is obtained and how they can be challenged under the new IPR process. After a discussion of reverse payment agreements and product hopping, this section will also look at Kyle Bass's IPR strategy and how it could affect the drug industry. Finally, this last part of the background section will look at the drug industry's response to Kyle Bass's IPR use and their request IPR exemption.

Part III begins by comparing the pros and cons of the Hatch-Waxman process of invalidating drug patents to how IPR operates. Then, IPR statistics on patent invalidation rates will be examined, in particular the statistics that pertain to bio/pharma patents. Next, an analysis of the Patent Trial and Appeal Board's (PTAB's) review of some of Kyle Bass's

25. David McLaughlin, Sara Forden, and Jared S. Hopkins, *Mylan Faces U.S. Antitrust Investigation on Epipen*, BLOOMBERG (Jan. 30, 2017, 2:14 PM), www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices.

26. See Ed Silverman, *Drug Industry Ad Campaign May Be Too Late to Save Its Reputation*, STAT (Jan. 23, 2017), www.statnews.com/pharmalot/2017/01/23/pharma-ad-campaign-drug-industry (“[A] new Harris Poll reported that only 9 percent of Americans believe drug makers place more value on patients than profits.”). *Id.*

27. JOHN R. THOMAS, CONG. RESEARCH SERV., R44222, PHARMACEUTICAL PATENT-ANTITRUST: REVERSE PAYMENT SETTLEMENTS AND PRODUCT HOPPING 1 (2015). Under a reverse payment agreement, a brand-name pays a generic brand to not compete by “neither challeng[ing] the brand-name’s patent nor sell[ing] a generic version of the patented drug for a period of time.” *Id.* Product Hopping involves the practice of releasing a “new patent-protected version of existing drugs—while simultaneously discontinuing an earlier drug that is near patent expiration—with the primary goal of delaying generic entry into the marketplace.” *Id.*

28. See Amy Nordrum, *Drug Prices: World’s Most Expensive Medicine Costs \$440,000 a Year, but Is It Worth the Expense?*, IB TIMES (Feb. 13, 2016, 8:37 AM), www.ibtimes.com/drug-prices-worlds-most-expensive-medicine-costs-440000-year-it-worth-expense-2302609 (finding that a drug that treats rare blood disorders costs \$400,000, cancer therapies can cost up to \$100,000 per year, and hepatitis C drugs can cost up to \$94,500 per treatment).

29. The Food and Drug Administration, an agency of the United States Department of Health and Human Services, was created to protect the public health “by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and ensuring the safety of our nation’s food supply, cosmetics, and products that emit radiation.” *About FDA: What We Do*, U.S. FOOD & DRUG ASS’N, www.fda.gov/AboutFDA/WhatWeDo/default.htm (last visited May 30, 2017).

challenges and the overall success rate of these challenges will show that drug patent exemption from IPR is excessive. Part IV proposes that logical Hatch-Waxman reform, rather than IPR exemption, is needed to solve the current issues involving the drug industry. This includes incorporating a new IPR-type challenge into the Hatch-Waxman system and creating a new regulatory regime to punish Act violators. The purpose of this proposal, in reforming the Hatch-Waxman Act, is to create a system that is fair system for both drug companies and consumers alike. Overall, its goal is to do for the Hatch-Waxman Act what the AIA did for patent law: modernize it for the 21st century.

II. BACKGROUND

A. *The FDA, the Process for Approving New Drugs, and Generic Drugs Entry under the Hatch-Waxman Act*

1. *The FDA and Approving New Drugs*

The FDA, along with the rules set by the Hatch-Waxman Act,³⁰ regulate the manufacture and distribution of pharmaceutical drugs.³¹ The FDA ensures, through a lengthy process, that prospective drug meet strict safety and efficacy standards.³² If a drug is worth pursuing after these safety and efficacy tests, the drug maker files an Investigational New Drug Application (IND) to the FDA.³³ If, after reviewing the IND for thirty days, the FDA approves the application, the drug manufacturer can begin testing the drug through physician supervision at hospitals and other approved medical facilities.³⁴ If the FDA finds that the IND data shows the drug is safe for humans, clinical trials can begin.³⁵ Thereafter, if the drug

30. The Hatch-Waxman Act, or the Drug Price Competition and Patent Term Restoration Act, amended the Food, Drug, and Cosmetic Act to allow fairness in competition between brand name drug companies and generic brand companies. *See generally* Martha M. Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809. The Hatch-Waxman protects a brand name company's patented drug while giving a generic company an opportunity to work on creating a generic version of the patented drug through an abbreviated new drug application (ANDA) without infringing on the patented drug. *Id.*

31. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (2012).

32. JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 7 (2d ed. 2011) (stating that to test if a drug is effective and reasonably safe for humans, the drug must pass several phases of preclinical evaluation like laboratory tests on tissue cell culture, computer based analysis, and live animals to determine if a drug has an effect on a disease or symptoms of the disease).

33. *Id.* An IND application contains the drug's chemical composition, pre-clinical study data, the drug's intended use, and full description of all of the testing to ensure the drug is safe and effective. *Id.*

34. 21 C.F.R. §§ 312.23, 312.40(b) (2016). The Institutional Review Board (IRB) provides oversight to the human testing by evaluating the ethical aspects of the study. THOMAS, *supra* note 32, at 7.

35. THOMAS, *supra* note 32, at 8. Phase I helps determine toxicity levels and clinical

passes three phases of clinical trials, the drug manufacturer must then comply with the Hatch-Waxman Act and file a New Drug Application (NDA) with the FDA for evaluation.³⁶ If approved, the drug manufacturer may market the drug to the public.³⁷ As a reward for complying with the Hatch-Waxman Act, the FDA grants the NDA holder marketing exclusivity and data exclusivity for its new drug, depending on the new drug's categorization.³⁸ All approved NDAs are listed in the FDA's "Orange Book" of federally approved drugs.³⁹ From inception to market, on average it takes twelve years and \$350 million for a new drug to reach consumers.⁴⁰

During pre-clinical testing of the drug, or as early in the clinical trial testing as possible, the drug manufacturer must file a patent application to avoid forfeiting potential patent rights as a result of a one-year statutory bar.⁴¹ This is important because there is uncertainty in the law concerning when a pharmaceutical company's actions, in complying with FDA regulations to receive drug-marketing approval, will be considered

dosage range; Phase II determines if the drug is effective or not; Phase III involves testing the drug in controlled and uncontrolled studies to determine the drug's secondary effects or side effects to particular portions of the population. *Id.*

36. *Id.* FDA officials have 180 days to do their own tests on the drug's safety; checking the phase trials data and conducting inspections to ensure the drug is manufactured properly. *Id.* If they approve the NDA, the drug is monitored through a "Med Watch" surveillance program or Phase IV studies to acquire additional information to determine the drug's long-term safety and efficacy. *Id.* An NDA application also requires the filer to include patent application information. *Id.*

37. *Id.*

38. See 21 C.F.R. § 314.108 (New Drug Product Exclusivity). Orphan Drugs exclusivity (ODE) is seven years, New Chemicals exclusivity is five years, "other" exclusivity is three years, pediatric exclusivity is six months added to an existing patent term or exclusivity, and Abbreviated New Drug Applications, if approved, receive 180 days of exclusivity. U.S. FOOD AND DRUG ADMIN., FREQUENTLY ASKED QUESTIONS ON PATENTS AND EXCLUSIVITY (last updated Dec. 5, 2016), www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#How%20long%20does%20an%20applicant%20holder%20have%20to%20submit%20patent%20information?. As part of the deal for brand name drug manufacturers to receive market exclusivity of new drugs, brand name drug manufacturers must participate in the Hatch-Waxman Act so that generic companies can rely on the safety and efficacy data of a brand name company's NDA. *Id.* The brand name drug companies also receive a period of data exclusivity and patent term extension based on agency delays of NDA approval. THOMAS, *supra* note 32, at 4 (citing EDWIN MANSFIELD, PATENTS AND INNOVATION: AN EMPIRICAL STUDY, 2 MANAGEMENT SCI. 13 (Feb. 1986)).

39. THOMAS, *supra* note 32, at 8. Both NDA approved brand name drugs and approved generic drugs are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is also known as the "Orange Book" of FDA-approved drugs. *Id.*

40. *New Drug Approval Process*, DRUGS.COM, www.drugs.com/fda-approval-process.html (last modified May 3, 2017). Phase I takes one year, Phase II takes two years, Phase III takes three years, and finally, the FDA takes two-and-a-half years to review an NDA. *Id.*

41. 35 U.S.C. § 102(b) (2012). Section 102(b) denies a patent if the invention was "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the" filing date of the U.S. patent application. *Id.* The inventor can trigger these activities or by other activities performed by others. THOMAS, *supra* note 32, at 123. "Pharmaceutical firms would do well to coordinate the timing of their clinical trials and patent filings as closely as possible." *Id.* at 138.

experimental use⁴² or a trigger for a section 102 statutory bar.⁴³ In addition to being granted a twenty-year monopoly on the patent drug, a pharmaceutical company may receive an extension on the patent term based on the delays associated with FDA regulations.⁴⁴

2. *The Hatch-Waxman Act, ANDA Litigation, and Generic Drugs*

Prior to the passage of the Hatch-Waxman Act, it was very complicated and difficult for brand name drug companies to obtain both a patent and FDA marketing approval of a new drug.⁴⁵ But, the process was even harder for generic drug companies that wanted to introduce unpatented, generic version of drugs into the marketplace.⁴⁶ In the 1980s, if generic companies wanted to introduce their own formulations of an existing drug, they had to undergo the same FDA NDA procedures that a brand name drug had already completed.⁴⁷ This brought about a conflict between patent law and the FDA because a generic company would be liable for patent infringement merely for conducting the necessary experimentation required to satisfy and complete an NDA for the FDA prior to the termination of a drug patent's period of exclusivity.⁴⁸

42. See KENNETH L. DORSNEY ET AL., *ANDA LITIGATION: STRATEGIES AND TACTICS FOR PHARMACEUTICAL PATENT LITIGATORS* 3 (2012).

43. See *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals Inc.*, 471 F.3d 1369 (Fed. Cir. 2006) (rejecting that a drug's clinical trials constituted public use because the trials had experimental purposes based on the testing on healthy volunteers, experimenters restrictions, security, monitoring, and secrecy of the trials); *contra* *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004) (holding that "an experimental use negates a statutory bar when the inventor was testing claimed features of the invention," thus testing a drug's primary intended use, efficacy and safety for FDA approval does not constitute experimental use.), *vacated*, 403 F.3d 1328 (Fed. Cir. 2005) (en banc), *on remand*, 403 F.3d 1331 (Fed. Cir. 2015) (avoiding the experimental use issue and decided that the patent was invalid by inherent anticipation); see *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877) (finding that if the use of the invention is for experimental purposes to find the inventions best embodiment, then this use is not considered public use under 35 U.S.C. § 102(b)); *accord* *EZ Dock, Inc. v. Schafter Sys., Inc.*, 276 F.3d 1347 (Fed. Cir. 2002) ("This Court has repeatedly stressed that evidence of experimental use . . . operates to negate the application of section 102(b)[.]."). *Id.*; *compare* *In re Smith*, 714 F.2d 1127, 1135 (Fed. Cir. 1983) (ruling that if the predominant purpose of the testing of an invention is to predict if an invention will be successful in the marketplace, that testing will not constitute experimentation under the experimental use doctrine).

44. See 35 U.S.C. § 156 (2012). Patent holder is entitled to one half the time starting from the IND testing and the submission of NDA, and in addition, the time spent by the FDA to approve the NDA. *Id.* The extension must not exceed five years. *Id.* Ordinarily, a patent term lasts twenty years. See 35 U.S.C. § 154 (2012).

45. See *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 860-61 (Fed. Cir. 1984) (determining if generic firm infringed brand name firm's pharmaceutical patent because it conducted FDA-required premarketing tests of a generic version of the drug patent six months before patent term ended).

46. *Id.*

47. THOMAS, *supra* note 32, at 10.

48. *Id.*; See *Roche Products*, 733 F.2d at 863-64 (concluding that the defendants committed patent infringement because their testing of a patented drug was for "business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" and thus was not experimental use).

This scenario forced generic drug companies to wait for a patented drug's twenty-year monopoly to end just to be able to begin drug experimentation and to file an NDA.⁴⁹ In addition to FDA regulation delays in processing a generic company's NDA, these delays would also inadvertently give a brand name drug company an extension on their patent past the statutory term allowed.⁵⁰ In response to this problem, Congress passed amendments to the Federal Food, Drug, and Cosmetic Act called the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.⁵¹ The Hatch-Waxman Act was meant to "strike a balance between two potentially competing policy interests, inducing pioneering development of pharmaceutical formulations and methods, and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term."⁵² Paragraph IV of the Hatch-Waxman Act "streamlines" a generic drug's market entry by allowing the generic drug to rely on the brand name drug's NDA safety and efficacy data.⁵³ This process is called an Abbreviated New Drug Application, or ANDA.⁵⁴

All ANDA applications require (1) bioequivalence data,⁵⁵ (2) certification, and (3) notice to the patent owner of the patented drug that the generic drug company has filed an ANDA for a generic version of the patented drug.⁵⁶

a. Identical Active Ingredient and Bioequivalence to the NDA

For the bioequivalence requirement, a generic drug company must prove through corroborative data that its new drug is therapeutically equivalent to a previously approved new drug, namely "that the same generic drug will function in the same manner if the two drugs are identical."⁵⁷ Part of the benefit of this process is that a generic drug company can rely on the safety and efficacy testing of the patented drugs

49. THOMAS, *supra* note 32, at 10–11. The FDA regulatory delays to get NDA approval delayed generic drug entry, which extended a drug company's patent on a drug. *Id.*

50. THOMAS, *supra* note 32, at 11.

51. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)) as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). Congress concluded "that the [Federal Food, Drug, and Cosmetic Act] was cumbersome to the drug approval process and delayed the entry of relatively inexpensive generic drugs into the market place." See Construction and Application of Hatch-Waxman Act, *supra* note 15.

52. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010) (citing *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)) *rev'd on other grounds*, 2012 U.S. LEXIS 3106 (U.S. Apr. 17, 2012) (No. 10-844).

53. *Caraco Pharm. Labs., Ltd.*, 601 F.3d at 1361. All the provisions related to the Hatch-Waxman Act and ANDA certification are codified as 15 U.S.C. §§ 68b–68c, 70b; 21 U.S.C. §§ 301, 355(j), 360cc; 28 U.S.C. § 2201; and 25 U.S.C. §§ 156, 271, 282.

54. *Id.*

55. 21 U.S.C. § 355(j).

56. DORSNEY, *supra* note 42, at 10–24.

57. DORSNEY, *supra* note 42, at 18.

NDA application.⁵⁸ The only scientific data a generic company must supply is that the active ingredient⁵⁹ in its generic drug is identical and is the bioequivalent⁶⁰ to the NDA drug to demonstrate that the generic drug is just as safe and effective as the NDA drug.⁶¹ This can save a generic company millions of dollars associated with preclinical and clinical studies.⁶² Other than these scientific requirements, the ANDA application has to mirror the NDA regarding labeling, usage, dosage, route of administration, and manufacturing information.⁶³

b. ANDA Certification Framework

This ANDA certification requirement is the most notable difference between IPR and ANDA. As previously mentioned, the Hatch-Waxman Act provides several exclusivity incentives to both generic and brand name drug companies to spend money on creating and testing new drugs.⁶⁴ As part of receiving the exclusivity benefit for participating in Hatch-Waxman litigation, an ANDA applicant and an NDA applicant agree to participate in a framework that organizes a deliberate adversarial dispute between generic companies and brand name companies, and generic companies against other generic companies.⁶⁵ This framework requires an ANDA applicant to assert one of the following four certifications in its ANDA application: (Paragraph I) the drug is not patented, (Paragraph II) the patent on the drug has expired, (Paragraph III) the drug will not be introduced into the market until after the twenty-year patent term of a patented drug ends, or (Paragraph IV) there is no patent infringement or the patent is invalid.⁶⁶

58. *Id.*; see 21 U.S.C. § 355(j). An ANDA applicant does not have to submit any preclinical or clinical testing data in an ANDA application. *Id.*

59. DORSNEY, *supra* note 42, at 18. The active ingredient identity is used to determine the similarity in the chemical composition of the generic drug and the NDA drug. *Id.* The active ingredient of a generic drug is allowed to and is still considered identical to the NDA drug if the generic drug has different physical characteristics than the NDA drug active ingredient. *Id.*

60. *Id.* at 19. Bioequivalence of the NDA drug and generic drug is proven by showing that the rate and extent the generic's active ingredient, after ingestion or intravenous injection, becomes available to the body or works on the intended active site in the body, is the same as the NDA drug's activity in the body. *Id.*

61. *Id.*

62. *Id.* Calculations estimate that it can "cost more than \$1 billion to bring one product to the market, including approximately \$50-840 million to bring treatments through the stages of Basic Research/Drug Development and Pre-Clinical/Translational Research, and approximately \$50-970 million to complete the Clinical Trials (Phases 1, 2, and 3)." BRIGHT FOCUS FOUND., FDA APPROVAL PROCESS (last modified Oct. 19, 2015, 5:01:17 PM), www.brightfocus.org/clinical-trials/how-clinical-trials-work/fda-approval-process.

63. See DORSNEY, *supra* note 42, at 19.

64. DORSNEY, *supra* note 42, at 4. For brand name drug companies, the FDA will promise to delay the review or approval of a competing drug. *Id.*

65. *Id.*

66. See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2002); see also 21 C.F.R. § 314.94(a)(12). Generic companies who file under paragraphs I, II, and III do not trigger any patent infringement repercussions because they do not challenge any patent rights. DORSNEY, *supra*

When an ANDA applicant files a paragraph IV certification, the ANDA applicant is (1) asserting that the generic drug does not violate the NDA drug or (2) claiming the NDA's patent is invalid.⁶⁷ Under the Hatch-Waxman Act, filing a paragraph IV certification is considered an "artificial" act of patent infringement.⁶⁸ The "artificial infringement" action is required to provide the patent holder with the Article III "case or controversy" standing necessary to sue in federal court.⁶⁹ This is the "price" a generic company has to pay if it wants to receive the 180-day market exclusivity reward from the FDA.⁷⁰ Essentially, paragraph IV was designed for generic companies to aggressively introduce their generic drug by attacking patented drugs they think are weak and potentially vulnerable to an invalidity challenge.⁷¹

c. ANDA Notification to the NDA Holder and Adjudication

When a generic drug company files an ANDA with a paragraph IV certification for FDA approval, the generic company is required, within twenty days after filing the ANDA, to notify the drug patent owner that an ANDA challenge was made against their drug.⁷² If the drug patent owner does not respond or file suit against the ANDA applicant within forty-five days of receiving notice of the ANDA's paragraph IV challenge, the ANDA applicant can file a motion in court for the entry of a declaratory judgment for patent invalidity or noninfringement.⁷³ If the drug patent holder sues the ANDA applicant within the forty-five-day window, the drug patent

note 42, at 30 n.51.

67. DORSNEY, *supra* note 42, at 30.

68. 35 U.S.C. § 271(e)(2) (2016).

69. DORSNEY, *supra* note 42, at 10. The "safe harbor" provision of the Hatch-Waxman Act prevents patent owner from suing generic drug manufacturers for using the patent in their clinical experiments and studies. *Id.* Justiciability issues would arise in the form of a lack of standing if the patent owner sued the generic company and so the Hatch-Waxman Act makes the filing of an ANDA an act of infringement and gives the patent owner standing to resolve their issues in federal court. *Id.*; see generally Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1249 (Fed. Cir. 2000).

70. DORSNEY, *supra* note 42, at 22. The first generic company to file a paragraph IV certification has a 180-day market exclusivity against all other generic companies that filed later ANDAs. *Id.* Even more beneficial, is that the first generic to file a paragraph IV certification is entitled to the 180-day market exclusivity regardless if the ANDA applicant wins or loses its litigation case against the NDA/patent holder. Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1356–57 (Fed. Cir. 2008).

71. DORSNEY, *supra* note 42, at 22.

72. Medicare Prescription Drug, Improvement, and Modernization Act (MMA). Pub. L. No. 108-173, 117 Stat. 2066 (2003). The ANDA applicant must give notice of a paragraph IV certification that the generic company is seeking to market the generic drug before a drug's patent term has ended. *Id.* The notice must also contain explanations, in detail, the facts and legal reasons why the patent holder has an invalid patent or why the generic company's drug does not infringe the patent. See 21 U.S.C. § 355(j)(2)(B).

73. MMA § 1101(a)(2)(C); 21 U.S.C. § 355(j)(5)(i)(I); 35 U.S.C. § 271(e)(5). Declaratory judgment will be entered if the forty-five-day period has expired, the ANDA applicant was not sued in court for patent infringement within the forty-five-day period, and the ANDA applicant gave notice to the NDA/patent holder and offered confidential access to the ANDA application in the notification. *Id.*

holder has the benefit of the FDA staying approval of the ANDA application for thirty months, pending litigation.⁷⁴ FDA ANDA approval can occur in three scenarios: (1) the patent's twenty-year term ends, (2) a final federal court decision finds that the ANDA applicant's drug did not infringe the patent or that the patented drug is invalid,⁷⁵ or (3) the FDA mandated thirty-month stay ends.⁷⁶ On average, the FDA takes eighteen to twenty-four months to approve an ANDA application.⁷⁷ ANDA applicants and drug patent holders prefer to that any litigation issues be resolved and conclude within the thirty-month stay to forgo any additional complicated matters.⁷⁸

B. Patents and IPR

United States Patent law has undergone many changes in its two hundred year history,⁷⁹ but none greater than the passing of the AIA in 2011.⁸⁰ The enactment of the AIA has been labeled "the most significant overhaul to our patent system, since the founding fathers first conceived of codifying a grand bargain between society and invention."⁸¹ PTAB, the patent adjudicating agency, was created on September 16, 2012, one year after President Obama signed the AIA into law.⁸²

74. DORSNEY, *supra* note 42, at 14. The FDA requires strict compliance with the forty-five-day period because if the NDA/patent holder does not respond the FDA may approve the ANDA immediately despite any actual patent or exclusivity issues. *Id.* If the NDA/patent owner sues, then the FDA will delay the ANDA approval for thirty months. *Id.*

75. 21 U.S.C. § 355(j)(4)(B)(iii)(I). Thus, an NDA/patent owner can litigate an ANDA challenge before the generic drug reaches the market. *See e.g.*, Glaxo, Inc. v Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997).

76. DORSNEY, *supra* note 42, at 15.

77. *Id.*

78. *Id.* at 77. NDA/patent holders prefer to delay generic entry as long as possible so if it has a weak patent, it would prefer that litigation end as close the end of the thirty-month stay, to keep the current market price on the branded drug as long as possible. *Id.* at 87. If the NDA/patent holder has a strong claim, then it would seek a trial in hope of winning and being granted an injunction against the introduction of the generic drug into the market place. Generic companies prefer the opposite because the end of litigation in their favor would activate the one of the three scenarios to end of the thirty-month stay and allow them to introduce their drug to the market as soon as possible. *Id.* Litigating past the thirty-month stays introduces complicated decisions regarding NDA/patent holders filing injunctions or generic companies making the risk to market the drug with the possibility of facing an injunction. *Id.*

79. *See generally* Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 10 (1966) (stating that patent law has been "amended, revised or codified 50 times since 1790.").

80. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); 35 U.S.C. § 101 et seq. (2013). *See also* text accompanying *supra* note 10.

81. David Kappos, *Re-Inventing the U.S. Patent System*, DIRECTOR'S FORUM: DAVID KAPPOS'S PUBLIC BLOG (Sept. 16, 2011, 5:45 PM), www.uspto.gov/blog/director/entry/re_inventing_the_us_patent.

82. Gene Quinn, *Inter Partes Review: Overview and Statistics*, IP WATCHDOG (Feb. 9, 2014), www.ipwatchdog.com/2014/02/09/inter-partes-review-overview-and-statistics/id=47894.

The AIA created vast changes in patent law,⁸³ including three brand new patent reexamination procedures,⁸⁴ IPR being the most relevant of those procedures.⁸⁵ IPR, was created for two reasons: (1) to offer a quicker and more cost-effective alternative to federal court litigation⁸⁶ and (2) to replace IPR's predecessor, the overly cumbersome *inter partes* reexamination (IPX).⁸⁷

The language of the AIA would incrementally come into effect—for example IPRs were not available until PTAB was created.⁸⁸ Applying that same incremental plan, the U.S. Patent and Trademark Office (USPTO) announced that any patent application filed on or after March 16, 2013, would be reviewed under the new AIA rules.⁸⁹ Pre-AIA, the substantive patent law was mostly developed through the federal court system's interpretations of the 1952 Patent Act.⁹⁰

1. Patents, Novelty, and Obviousness

Patent law, in its ideal form, is a *quid pro quo* system that provides inventors with a powerful and government-protected financial business

83. LEGAL PUB, THE NEW UNITED STATES PATENT LAW 7 (Black Line ed. 2011). United States patent law transitioned from a first-to-invent system to a first-to-file system, it instituted three brand new post-grant review proceedings, it allows third party submissions during the examination of a patent application, and it replaces current interferences proceedings with derivation proceedings among other changes. *Id.* The AIA also created PTAB to replace the Board of Patent Appeals and Trial Interferences. *Id.*

84. 35 U.S.C. §§ 311–319 (2013). Derivation proceedings, Covered Business Methods (CBM), and Post-Grant Review (PGR) are the other new post-grant procedures that were introduced when the AIA was enacted. U.S. PATENT AND TRADEMARK OFFICE, INTER PARTES DISPUTES (last modified Apr. 2, 2013, 2:39 PM), www.uspto.gov/patent/laws-and-regulations/america-invents-act-aia/inter-partes-disputes.

85. See Ryan Lynch & Peter Geier, *New Patent Rules Pit Wall Street Against Big Pharma*, FORBES (Oct. 21, 2015, 1:07 PM), www.forbes.com/sites/mergermarket/2015/10/21/new-patent-rules-pit-wall-st-against-big-pharma.

86. See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIR. B.J. 539, 600–01 (commenting on the motivation behind creating IPR as an alternative to patent litigation because, depending on the value of the challenged patent, the average cost of patent litigation, including the costs of discovery, ranges between \$500,000 and \$3,995,000 per party).

87. See Robert Shang, Article, *Inter Partes Reexamination and Improving Patent Quality*, 7 NW. J. TECH. & INTELL. PROP. 185 (2009) (“[O]ne should be aware that a hard-fought inter partes reexamination between the patent owner and the challenger may take a long time to complete.”). *Id.*

88. See Quinn, *supra* note 82.

89. USPTO announced that first to file patents applications that are filed on or after March 16, 2013 will have the AIA substantive law applied to it. U.S. PATENT & TRADEMARK OFFICE, AMERICA INVENTS ACT EFFECTIVE DATES 6 (2011), www.uspto.gov/aia_implementation/aia-effective-dates.pdf.

90. See Sarah Tran, Article, *Patent Powers*, 25 HARV. J.L. TECH. 609, 616 (2012) (“The Federal Circuit has developed for itself an enviable role in patent law. It has assumed exclusive responsibility for making substantive interpretations of the Patent Act and has historically chosen not to defer to agencies on issues of patent law.”) (internal quotations omitted) (quoting Sapna Kumar, Article, *Expert Court, Expert Agency*, 44 U.C. DAVIS L. REV. 1547, 1550 (2011)).

tool, in exchange for the inventors' relinquishment of trade secret rights⁹¹ by fully disclosing their inventions' workings for public knowledge and future public use.⁹² Incentives in patent law, such as monetary gain, motivate an inventor to file a patent for their invention.⁹³ If granted a patent, the inventor has sole control over the patent through "a right to exclude," and can profit off of the patent through licenses, royalties or by marketing and selling the invention.⁹⁴ However, it can cost thousands of dollars to acquire a patent and, realistically, only 2%–10% of patents turn a profit.⁹⁵ For perspective, the drug industry spends close to \$5 billion a year in research and development to ensure it has an FDA-approved drug.⁹⁶

To acquire a patent, an inventor must satisfy five elements: (1) the invention must be patentable,⁹⁷ (2) the invention must be useful,⁹⁸ (3) the invention must be fully disclosed,⁹⁹ (4) the invention must be novel, and

91. See *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 155, 160–61, 165–67 (1989) (discussing the relationship between patent law and trade secret law); see also *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 493–94 (1974) (Marshall, J., concurring) (stating that an inventor discloses their invention for patent protection in exchange for "withdrawing any alternative possibility of [Trade Secret] protection for their invention . . .").

92. Gene Quinn, *Why Do You Want a Patent?*, IP WATCHDOG (Feb. 8, 2014), www.ipwatchdog.com/2014/02/08/why-do-you-want-a-patent/id=45621.

93. *Id.*

94. *Kewanee Oil Co.*, 416 U.S. at 480–81.

95. See Gene Quinn, *The Cost of Obtaining a Patent in the US*, IP WATCHDOG (Apr. 4, 2015), www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485.

Depending on the complexity of the invention, acquiring a patent can cost anywhere from \$300–\$800 in filing fees, \$5,000–\$20,000 in attorney's fees for filing the patent. *Id.*

96. See Mathew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES: PHARMA & HEALTHCARE (Aug. 11, 2013, 11:10 AM), www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine (finding that current pharmaceutical research and development trends are making it difficult and impractical to sustain growth in an industry that relies on discovering successful drugs).

97. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (affirming the patentability of a genetically modified bacteria that was designed by its inventor to break down crude oil). In essence, patentable inventions include "anything under the sun that is made by man." *Id.* An invention must be manmade and cannot be an abstract idea, something that already exists in the laws of nature, or a natural phenomenon. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). For example, $E = mc^2$, the formula created by Einstein, is unpatentable because it is considered a law of nature. *Id.* at 309. A new earth mineral or a new plant discovered in nature or mental processes or abstract intellectual processes are unpatentable because holding a patent on a broad principle would encompass too much control on a subject matter and halt scientific discoveries. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012).

98. 35 U.S.C. § 101 (2000). In cohesion with the patentable subject matter requirement, a patent must also be a "useful process, machine, manufacture or composition of matter." ROBERT MERGES & PATRICK DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 209–54 (LexisNexis, 6th ed. 2013). Patent law requires an invention to be useful, by having some benefit to society or have a practical application, to receive protection. *Id.* USPTO categorizes useful inventions, like pharmaceutical drugs, into utility patent category. Amy L. Landers, *Understanding Patent Law* § 7.01 (2d ed. 2012).

99. See *Eldred v. Ashcroft*, 537 U.S. 186, 216 (2003) (attributing the patent disclosure obligation as part of the deal in securing exclusive rights on a patent). In exchange for the limited monopoly, an inventor is required to disclose his invention. *Id.* To properly disclose

(5) the invention must be nonobvious.¹⁰⁰ After the government grants a patent, competitors or other indirect third party interests that do not agree with USPTO's decision can challenge a patent's validity under several proceedings, including IPR.¹⁰¹ Per the statute's requirements, IPR challenges can only be raised to invalidate a patent under the novelty¹⁰² and nonobviousness¹⁰³ tests.¹⁰⁴

an invention, the inventor, as part of the specification requirement of a patent application, is required to disclose (1) a written description of the invention, (2) enable a person of ordinary skill in the art how to make and use the invention, (3) disclose the invention's best mode (best iteration/version), and (4) have definite claims of what the invention covers. 35 U.S.C. § 112 (2000). Definite claims are covered in § 112(b). The claims must be definite to inform the public of the protected features of the monopoly. *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931); *see generally* *Gottschalk v. Benson*, 409 U.S. 63, 69 (1972) (finding "the chemical process or the physical acts which transformed the raw material are, sufficiently definite to confine the patent monopoly within rather definite bounds."). Failure to disclose the four requirements results in a rejected patent application or an invalid patent. AMY L. LANDERS, UNDERSTANDING PATENT LAW § 7.01 (2d ed. 2012).

100. *See* *Merges supra* note 98, at 605.

101. *See* *Tran, supra* note 90, at 626–36.

102. An invention must be new and never have existed before receiving a patent. *Merges supra* note 98, at 340. Novelty is defined by the critical date—also known as the date the applicant created the invention. *Id.* The invention will be considered novel as long as there is no reference that predates the invention. 35 U.S.C. § 102 (2000). A reference is considered a piece of prior art that invalidates a patent. *Id.* Prior art is best described as a "piece of knowledge" that was available in the public before the invention existed, and that a patent examiner can legally use to determine if it can reject one or more of the claims in a patent application. *Id.* Prior art can be an already existing patent or a printed publication like information displayed on a power point presentation or information in a published book, something that is already used or known by others. *Id.* For a reference to anticipate an applicant's invention, a single reference must "enable the invention, and disclose each and every element of the invention" that is expressly or inherently described. Jason Brewer, Comment, *Updating the Patent System's Novelty Requirement to Promote Small-Molecule Medicinal Progress*, 45 J. MARSHALL L. REV. 1151, 1157 (2012). Thus, novel inventions are patentable because they promote and advance scientific discovery of inventions that do not already exist in public. *Merges supra* note 98, at 337–38.

103. LANDERS, *supra* note 99, at § 21.01. An invention must "represent more than an obvious advance to the existing state of the art" to a person having ordinary skill in the art. *Id.* The nonobviousness requirement is often referred to as the "final gatekeeper" in determining if an invention is patentable or not. *John Deere*, 383 U.S. at 11. The nonobvious requirement is justified for three reasons. First, to avoid inventions that do not require much effort because they are an obvious next step in an industry. *Merges supra* note 98, at 609. Second, granting obvious patents would undermine the incentives to develop nonobvious inventions. *Id.* Finally, granting obvious patents would create a "proliferation of economically insignificant patents that are expensive to search and to license." *Id.* An invention is unpatentable if the subject matter, in light of a combination of all pertinent prior art, would be obvious to a person having ordinary skill in the pertinent art. 35 U.S.C. § 103(a) (2000).

104. 35 U.S.C. § 311(b) (2013). "A petitioner for an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." *Id.*

2. IPR, an Overview

After a patent is granted, USPTO has a continuing role in almost everything concerning a patent.¹⁰⁵ When the AIA was passed, three new post-grant review (reexamination) procedures were added: post-grant review (PGR), IPR, and covered business methods (CBM).¹⁰⁶ IPR can be used by anyone who is not the owner of a patent who wants to challenge a patent's validity.¹⁰⁷ Strategically, IPR can be used by defendants in an infringement action to attack patent's validity, or by any outside third party (likely a competitor) to attack the claims of the patent.¹⁰⁸ Thus, competitors or outside third party interests—or anyone else with the means to do so—can file an IPR.¹⁰⁹ IPR was designed to be less expensive and less time consuming than district court proceedings.¹¹⁰ The creation of IPR was motivated by the high cost of federal court litigation in the patent industry and the fact the knowledge of these high costs were being used, by larger companies, as a threat to force licenses or settlements on smaller businesses who could not afford it.¹¹¹ IPR was not only meant to alleviate the financial burden that results from litigation, but also to provide a specialized forum to resolve complex, scientific issues associated with an invention.¹¹² In an IPR proceeding, PTAB may correct, modify or cancel single claims, many claims or all the claims of a patent.¹¹³

IPR petitions can only be filed (1) nine months after a patent was granted or immediately after a PGR proceeding concludes or is canceled, whichever occurs later, and (2) after PTAB institutes an IPR petition,¹¹⁴ which includes a panel of three administrative judges that review the

105. LANDERS, *supra* note 99, at § 3.01. Post-patent grant, USPTO collects patent maintenance fees, corrects and reissues patents, and resolves inventorship disputes. *Id.*

106. Scott A. McKeown, *Is There Value in Ex Parte Reexamination After the AIA?*, PATENTS POST-GRANT (Feb. 14, 2013), www.patentspostgrant.com/is-there-value-in-ex-parte-patent-reexamination-after-the-aia. After the AIA was passed, IPX was replaced by IPRs and reports show that IPX petitions dropped 50% in one year from 2012–2013. *Id.* IPR replaced IPX. Kenneth N. Nigon, *Post Grant Review, Inter Partes Review and Transitional Program for Covered Business Method Patents*, IP WATCHDOG (Aug. 29, 2012), www.ipwatchdog.com/2012/08/29/post-grant-review-inter-partes-review-and-transitional-program-for-covered-business-method-patents/id=27668.

107. 35 U.S.C. § 311(a).

108. *Id.*

109. *Id.*

110. See Matt Cutler, *Inter Partes Review—Not Just an Anti-Troll Proceeding*, LAW 360 (July 21, 2015, 9:52 AM), www.law360.com/articles/679716/inter-partes-review-not-just-an-anti-troll-proceeding.

111. Michael Gulliford, *If Patent Reform Is Meant to Starve Patent Trolls, Why Is It Feeding Them Instead*, IP WATCHDOG (Sept. 8, 2015), www.ipwatchdog.com/2014/09/08/if-patent-reform-is-meant-to-starve-patent-trolls-why-is-it-feeding-them-instead/id=51067.

112. Matal, *supra* note 86, at 601.

113. 35 U.S.C. §§ 302–311 (2000).

114. The USPTO director must make a decision to institute an IPR petition three months after an IPR is filed. 35 U.S.C. § 314(b). The director's decision to institute an IPR is based on the "reasonable likelihood" standard. *Id.* at § 316(a). The director's scope is limited to novelty and obviousness issues. *Id.*

petitions and make a final written judgment on the merits.¹¹⁵ IPR proceedings are limited to questions about novelty and obviousness.¹¹⁶ Also, all real parties of interest to the proceeding must be identified in an IPR petition for fairness and to ensure that they “[have] not previously filed a civil action challenging the validity of a claim of the patent, and has not been served with a complaint alleging infringement of the patent more than 1 year prior” to filing an IPR (exception for joinder).¹¹⁷ For the three-judge panel to review an IPR, the petitioner must show that there “is a reasonably likelihood of success that the requester would prevail” against at least one of the claims in the challenged patent.¹¹⁸ An IPR challenge would likely be granted if (1) an administrative judge finds, on first glance, that the challenger submitted sufficient anticipatory or obvious prior art evidence that would render the patent invalid and (2) an administrative judge would reject a patent owner’s response to the challenger’s prior art evidence.¹¹⁹ If an IPR petition is granted, PTAB will fully review the patent and prior art evidence, and then issue a final unappealable written decision about the patent’s validity.¹²⁰ If the claims are held invalid or valid, PTAB will issue a certificate of the canceled or upheld claims.¹²¹

Finally, the federal courts have become more deferential to PTAB’s rule-making authority and IPR decisions, a move that has empowered PTAB and its application of IPR, giving PTAB a stronger solitary voice as an agency.¹²² In fact, this authority was recognized in a recent U.S.

115. 35 U.S.C. § 6(c) (2000); 35 U.S.C. § 311(c).

116. 35 U.S.C. § 311(b). There is a different obviousness test for pharmaceuticals and other chemical compounds. *Brewer*, *supra* note 102, at 1158 (citing *In re Hass*, 141 F.2d 122, 125 (ruling that a homolog could not be patented unless it possessed some “unobvious or unexpected beneficial properties not possessed by a homologous compound disclosed in the prior art.”)). Pharmaceuticals and other types of chemical compounds that have similar chemical structures “only supports a prima facie case of obviousness and shifts the burden of proof to the [patent] applicant to show that the compound possesses unexpectedly improved properties.” *Brewer*, *supra* note 102, at 1159 (citing *In re Grabiak*, 769 F.2d 729, 731 (Fed. Cir. 1985)); see *In Re Papesch*, 315 F.2d 381, 390–92 (Fed. Cir. 1963) (holding that the discovery of unexpected physical properties of a slightly changed homolog of an obvious chemical compound is patentable because a person of ordinary skill in the art would not have determined that the differences in structure resulted in different chemical properties). Thus, trying to analyze obviousness of a chemical compound on structure alone would be improper, because the properties of a compound cannot be predicted on the similarity of structures alone. Kristen C. Buteau, *Deuterated Drugs: Unexpectedly Nonobvious?*, 10 J. HIGH TECH L. 22, 38 (2009).

117. 35 U.S.C. § 311(a). The patent owner cannot bring an IPR petition against its own patent. *Id.*

118. 35 U.S.C. § 314(b).

119. See Allison J. Baldwin, *Inter Partes Review and Inter Partes Reexamination: More Than Just a Name Change*, INTEL. PROP. TODAY (Feb. 2014), www.iptoday.com/issues/2014/02/inter-partes-i-review-and-inter-partes-i-reexamination-more-than-just-name-change.asp.

120. 35 U.S.C. § 318(a).

121. 35 U.S.C. § 318(b).

122. *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268 (Fed. Cir. 2015) (affirming the rulemaking authority of USPTO and that a decision to institute an IPR is not judicially reviewable by statute nor are PTAB final written decision on the matter). Using the broadest

Supreme Court case, fortifying PTAB's IPR decisions and authority in patent law.¹²³

C. Reverse Payment Agreements and Product Hopping¹²⁴

Two of the most common generic drug blocking/patent extending methods are (1) reverse payment agreements¹²⁵ and (2) product hopping.¹²⁶ These methods appear to be in direct contradiction to the purpose of the Hatch-Waxman Act: to facilitate the "efficient transition to a market with low-cost, generic copies of those pioneering inventions"¹²⁷ Likewise, these methods contravene the purpose of patent law: a benefit to the public through scientific progress and innovation.¹²⁸

A reverse payment agreement is when brand name pharmaceutical company pays a rival generic drug company to abandon its challenge to the brand name's patent or to delay the release of its generic drug into the market.¹²⁹ This not only blocks a generic from entering the market, but artificially extends a drug patent's term.

In 2003, Congress attempted to address reverse payment agreements with the Medicare Prescription Drug, Improvement, and

reasonable interpretation standard is inherently unfavorable to patent owners because more prior art can be brought in to invalidate a patent. A change of the standard would have to be made in Congress. Ryan Davis, *Fed. Cir. Signoff on PTAB Rules Boosts Patent Challengers*, LAW 360 (Feb. 4, 2015, 7:40 PM), www.law360.com/articles/618330/fed-circ-signoff-on-ptab-rules-boosts-patent-challengers. When it comes to IPR or PGR, specifically cases involving novelty and obviousness, the Federal Circuit has upheld the majority of PTAB decisions concerning the validity of challenged patents. Adam Floyd & Derrick Carman, *PTAB's 3-Year Check-Up: How Rulings Hold Up at Fed. Cir.*, LAW 360 (Sept. 11, 2015, 4:01 PM), www.law360.com/articles/699863/ptab-s-3-year-check-up-how-rulings-hold-up-at-fed-circ.

123. See *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016); Jennifer A. Mauri, *A Different Route: Challenging Orange Book Patents via Inter Partes Review*, MICHELMAN & ROBINSON LLP (July 18, 2016), www.mrlp.com/blog-a-different-route-challenging-orange-book-patents-via-inter-partes-review.

124. Although this comment presents both product hopping and reverse payment agreements as methods that block generic drug market entry, this purpose is merely informational. This comment's focus is on reducing the negative effect of reverse payment agreements.

125. These agreements are considered "reverse" because in contrast to patent licensing agreements where the patent holder gets paid to let others use the patent, the patent holder pays the generic brand not to compete. CHRISTOPHER L. SAGERS, *ANTITRUST* 246-48 (2d ed. 2014).

126. Thomas, *supra* note 27, at 1.

127. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010) (citing *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)), *rev'd on other grounds*, 2012 U.S. LEXIS 3106 (U.S. Apr. 17, 2012).

128. See generally *Time to Fix Patents*, THE ECONOMIST (Aug. 8, 2015), www.economist.com/news/leaders/21660522-ideas-fuel-economy-todays-patent-systems-are-rotten-way-rewarding-them-time-fix.

129. Edward Wyatt, *Supreme Court Lets Regulators Sue Over Generic Drug Deals*, N.Y. TIMES (June 17, 2013), www.nytimes.com/2013/06/18/business/supreme-court-says-drug-makers-can-be-sued-over-pay-for-delay-deals.html?_r=0.

Modernization Act (MMA).¹³⁰ The MMA gave the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) the power to review these agreements.¹³¹ But, the MMA did not impose antitrust scrutiny on reverse payment agreements.¹³² Thereafter, reverse payment agreements became popular when the Eleventh Circuit, in *Schering-Plough Corp. v. FTC*, rejected the notion that these agreements are inherently suspect.¹³³ After *Schering-Plough*, there were three reverse payment agreements in 2005, fourteen in 2007, and then forty in 2012.¹³⁴

Eight years later, the Supreme Court took on reverse payment agreements in *FTC v. Actavis* to determine whether these agreements “can sometimes unreasonably diminish competition in violation of antitrust laws.”¹³⁵ In *Actavis*, two generic brands filed a paragraph IV challenge against a brand name’s patent certifying that “listed patent was invalid and their drugs did not infringe it.”¹³⁶ Even though the brand name initiated patent litigation against the generic brands to start the FDA thirty-month stay, the litigation took longer, and the FDA approved the first to file generic’s drug.¹³⁷ However, in 2006, the brand name and the first to file generic entered into a reverse payment agreement, which terms stated that (1) the generic brand would not bring its generic version of the drug to market until 2015, in other words, “65 months before [the brand name’s] patent expired (unless someone else marketed a generic sooner),” and (2) the brand name agreed to pay the first to file generic “\$19–\$30 million annually, for nine years” as well as a one-time payment of approximately \$72 million to the other generic brand.¹³⁸ Although the parties attempted to explain that the payments were for other services, the payments were used to “compensate the generics for agreeing not to compete”¹³⁹ FTC filed an antitrust suit against the

130. Pub. Law No. 108-173, 117 Stat. 2066.

131. *Id.*

132. Thomas, *supra* note 27, at 8.

133. See generally, *Schering-Plough Corp. v. FTC.*, 402 F.3d 1056 (11th Cir. 2005) (finding that reverse payment agreement terms were within the scope of a patent’s exclusionary rights and demonstrated a reasonable use of the protections afforded by the law); Dennis Crouch, *Economics: Explaining Reverse Payment in ANDA Litigation*, PATENTLY-O (Oct. 28, 2014), <https://patentlyo.com/patent/2014/10/economics-explaining-litigation.html> (finding that there was a surge in reverse payment agreements after the 11th Circuit’s *Schering-Plough* decision).

134. Trace Staton, *FTC Stats Show Pharma Backing OFF Pay-for-Delay Deals After SCOTUS Ruling*, FIERCE PHARMA (Jan. 14, 2016), www.fiercepharma.com/legal/ftc-stats-show-pharma-backing-off-pay-for-delay-deals-after-scotus-ruling.

135. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013). For a more detailed discussion of the *Actavis* case, patent law and antitrust law and their conflicting relationship, see Joel S. Sprout, Note, *Presumptively Illegal: The Supreme Court’s Missed Opportunity in FTC v. Actavis, Inc.*, 42 CAP. U.L. REV. 763, 770–80 (2014).

136. *Actavis*, 133 S. Ct. at 2229.

137. *Id.* The \$72 million were divided between two generic brands who shared litigation costs, Par Pharmaceutical and Paddock, in an arrangement through which Par received \$60 million and Paddock received \$12 million.

138. *Actavis*, 133 S.Ct. at 2229.

139. *Id.*

brand name, but the United States District Court for the Northern District of Georgia dismissed the claims and the Eleventh Circuit affirmed.¹⁴⁰

This led to the Supreme Court holding that reverse payment agreements may sometimes violate antitrust laws, and that “patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”¹⁴¹ The Court reasoned that because the paragraph IV challenge to the brand name’s patent put the patent’s validity at issue, and because said litigation was halted before its resolution, the patent “may or may not be valid, and may or may not be infringed.”¹⁴² And while a patent may give its owner the right to exclude others from using it, an invalid patent does not.¹⁴³ As such, because the settlement ended the determination of the drug patent’s validity, the fear is that a patent that is actually invalid is nevertheless keeping drug prices at “supracompetitive levels,” resulting in brand names and generic brands winning, while consumers lose.¹⁴⁴ Overall, the Court pointed out that Hatch-Waxman’s “procompetitive thrust” did not support anticompetitive reverse payment agreements.¹⁴⁵

Product hopping is when a pharmaceutical company comes out with “new” version of an “old” drug and immediately ends the production of the older, cheaper version.¹⁴⁶ This forces consumers to purchase the new version of the drug (e.g., going from capsule to tablet) at a higher price, despite the new drug having the same therapeutic benefits as the old drug.¹⁴⁷ State drug distribution laws contribute to the effectiveness of product hopping.¹⁴⁸ Depending on the state, “pharmacists are either permitted or required to dispense a therapeutically equivalent generic drug in place of a brand-name drug unless the prescribing physician has stipulated otherwise.”¹⁴⁹ Essentially, when a brand name “product hops” to the newly patented drug and withdraws the old unpatented drug from the market, the generic version of the old unpatented drug that the generic brand was in the process of developing no longer becomes “therapeutically equivalent” under state law, and as a result, it “will not

140. *Id.*

141. *Id.* at 2227, 2231. Thus, reverse payment agreements should be reviewed under the rule of reason analysis. *Id.* at 2237.

142. *Id.* at 2231.

143. *Id.*

144. *Id.* at 2234–35.

145. *Id.* at 2234. For continued development on reverse payment agreements and antitrust law, see *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015).

146. Thomas, *supra* note 27, at 12.

147. Adam Kurtz, *Product Hopping, Big Pharma and the High Cost of Prescription Drugs*, POMERANTZ MONITOR (Mar. 2015), <http://pomerantzlawfirm.com/publications/2015/6/25/product-hopping-big-pharma-and-the-high-cost-of-prescription-drugs>.

148. Thomas, *supra* note 27, at 13.

149. *Id.* (“A generic drug must be designated as “AB”-rated within the Orange Book to be deemed therapeutically equivalent to a brand-name drug.”). *Id.*

be substituted for brand-name prescriptions.”¹⁵⁰ This would delay generic drug entry.

Since the *Actavis* decision, pay-for-delay settlements have decreased to twenty-one in 2014.¹⁵¹ In 2015, FTC recorded the largest settlement of \$1.2 billion against Teva Pharmaceuticals because of its seven-year history of spending over \$300 million in settlements to block generic entry of its sleep disorder drug.¹⁵² On March 16, 2016, FTC, for the first time, sued ENDO Pharmaceuticals and several other drug companies, “over an agreement not to compete through an authorized generic,” a pay-for-delay settlement with an estimated worth \$112 million.¹⁵³ This FTC activity does not mean that pay-for-delay settlements will be obsolete. ANDA filings have increased from 234 in 2012 to 432 in 2014, leaving the potential for more settlement opportunities.¹⁵⁴ Essentially, drug companies will have to maneuver under “reasonable and justified” language to legitimize their settlements.¹⁵⁵

In 2015, the Second Circuit, in *New York ex rel. Schneiderman v. Actavis PLC*, determined whether antitrust laws applied to product hopping.¹⁵⁶ The *Schneiderman* case involved the product hopping of a brand name’s Alzheimer’s drug, going from the old version (Namenda IR, taken twice daily) to its newly patented version (Namenda XR, once-daily extended release.¹⁵⁷ Before the switch, Namenda IR generated about “\$1.5 billion in annual sales in 2012 and 2013.”¹⁵⁸ When Namenda XR was introduced, Namenda IR and Namenda XR became the only two specific Alzheimer-type drugs of its kind, and represented 100% of the market.¹⁵⁹ Namenda IR’s patent term was set to end in 2015, and Namenda XR’s patent term does not end until 2029.¹⁶⁰ The Second Circuit justified applying antitrust law to product hopping patented drugs citing the Supreme Court’s reasoning in *Actavis*.¹⁶¹ In finding that antitrust laws could be violated because product hopping can be anti-competitive and exclusionary, the Second Circuit stated that the brand name’s actions in *Schneiderman* were a violation of antitrust laws because:

150. *Id.*

151. Staton, *supra* note 134.

152. Rebecca R. Ruiz & Katie Thomas, *Teva Settles Cephalon Generics Case with FTC for \$1.2 Billion*, N.Y. TIMES (May 28, 2015), www.nytimes.com/2015/05/29/business/teva-cephalon-provigil-ftc-settlement.html?_r=1.

153. Jeff Zalesin, *FTC Sues Endo, Generics for Pay-For-Delay Agreements*, LAW 360 (Mar. 31, 2016), www.law360.com/ip/articles/778572.

154. BRIAN C. HOWARD, LEX MACHINA, PATENT LITIGATION YEAR IN REVIEW 18 (2014), <https://pages.lexmachina.com/rs/lexmachina/images/2014%20Patent%20Litigation%20Report.pdf>.

155. Michael A. Carrier, *Actavis and “Large and Unjustified” Payments*, SCOTUS BLOG (July 25, 2013, 4:09 PM), www.scotusblog.com/2013/07/actavis-and-large-and-unjustified-payments.

156. *New York v. Actavis PLC*, 787 F.3d 638, 647 (2d Cir. 2015).

157. *Id.* at 646–47.

158. *Id.* at 647.

159. *Id.* at 651–52.

160. *Id.* at 647.

161. *Id.* at 659–60.

[The] hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer’s patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws. . . . [W]ithout a legitimate business justification, [this] violates § 2 of the Sherman Act.¹⁶²

Ultimately, like reverse payment agreements in *Actavis*, the Second Circuit held that product hopping could violate antitrust laws and thus should be analyzed under the rule of reason.

D. Reviewing Kyle Bass’s “Short Activist Strategy” and His War on Drug Patents

Kyle Bass has always been forthcoming about his intentions using IPR: he wants to make money and to make drugs more affordable by invalidating weak patents.¹⁶³ Bass alleges drug companies obtained these weak patents by abusing the system through statutory loopholes, like the use of reverse payment agreements and product hopping, stating that “[a] small minority of drug companies are abusing the patent system to sustain invalid patents that contain no meaningful innovations but serve to maintain their own anti-competitive, high-price monopoly, harming Americans suffering from illnesses.”¹⁶⁴ Using methods like reverse payment agreements or product hopping, the drug industry has been accused of “taking advantage of a mix of laws” and “exploiting these fault lines.”¹⁶⁵

162. *Id.* at 654.

163. See generally Balazs Koranyi *U.S. Hedge Fund Plans to Take On Big Pharma over Patents*, REUTERS (Jan. 7, 2015), www.reuters.com/article/pharmaceuticals-haymancapital-idUSL3N0UM42O20150107.

164. Julia La Roche, *Kyle Bass Scored a Huge Win in His Big Short Strategy*, BUSINESS INSIDER (Sept. 25, 2015, 4:35 PM), www.businessinsider.com/no-sanctions-for-kyle-bass-ipr-2015-9. Kyle Bass calls Horizon Pharma’s (Horizon Pharma PLC) arthritis drug, Vimovo, a “ridiculous” and anti-Patent-Act type of drug that IPRs were meant to invalidate, because the drug, according to Bass, combines two cheap over the counter drugs (Nexium and Aleve) in an obvious way. Ryan Davis, *Hedge Fund Hits “Ridiculous” Horizon Patent with AIA Review*, LAW 360 (May 22, 2015, 5:40 PM), www.law360.com/articles/659301/hedge-fund-hits-ridiculous-horizon-patent-with-aia-review. CFAD attacks Pharmacyclics’s leukemia drug, claiming a published research paper anticipates the drug and thus the information is already in the public domain. Ryan Davis, *Hedge Fund’s Latest Patent Attack Targets Pharmacyclics*, LAW 360 (Apr. 21, 2015, 9:07 PM), www.law360.com/articles/645849/hedge-fund-s-latest-patent-attack-targets-pharmacyclics.

165. See generally Peter B. Bach, *Why Drugs Cost So Much*, N.Y. TIMES (Jan. 14, 2015), www.nytimes.com/2015/01/15/opinion/why-drugs-cost-so-much.html?_r=0 (“Frivolous patent—like a method of exercising a cat and a crustless peanut butter and jelly sandwich—have riveted the public’s attention.”); see MICHAEL A. CARRIER, *INNOVATION FOR THE 21ST CENTURY* 200 (2009). The blame for abuses in the patent industry has been placed on the executive branch and the judicial branch of the federal government for two reasons: (1) the USPTO’s lack of resources to comprehensively examine approximately four thousand patents issued each week and (2) the Federal Circuit’s creation of formalistic rules on issues of obviousness, experimental use, and injunctive relief among other rules that have made

As aforementioned, IPR can be used by anyone with the means to do so. This includes hedge funds. Even though Kyle Bass and his hedge fund subsidiary, CFAD, are not the first group to use IPRs for financial gain,¹⁶⁶ Kyle Bass and CFAD are the first to publicly admit that they are using the “short activist strategy” which has angered the drug industry.¹⁶⁷

Kyle Bass’s proclaimed “short activist strategy” is simply betting that a pharmaceutical company’s stock will fall and that his hedge fund will profit from that fall because of one of two outcomes that go against the challenged drug company: (1) an IPR challenge against that company’s patented drug is made public or (2) a patent challenged by an IPR is instituted and invalidates that patent.¹⁶⁸ There is speculation that Kyle Bass will not go after every pharmaceutical patent because he stands to profit by investing in the direct competitors of the pharmaceutical companies against which he has filed IPRs.¹⁶⁹ This “short activist strategy” can be explained in a simple analogy.

For example, Kyle and Sam are neighbors. Sam recently bought a printer for \$200. One day, Kyle asks Sam if he can borrow Sam’s printer to print an important assignment for work. Sam agrees, and hands the printer to Kyle to take home and use. While Kyle waits for his documents to be printed, Kyle reads a magazine ad and also sees a TV commercial from an electronics store. Both advertisements for the business say that new merchandise is coming in its store and for one day it will pay customers back the difference in any recently purchased product that has dropped in price. Realizing that Sam recently purchased the printer from

litigation complicated and rigid. *Id.*

166. Michelle Carniaux and Michael E. Sander, *The Curious Case of New Bay Capital LLC and VirnetX Inc.*, IPR BLOG (Nov. 22, 2015, 5:15 PM), <https://interpartesreviewblog.com/curious-case-new-bay-capital-llc-virnetx-inc>. New Bay Capital LLC was rumored to have taken the short against a publicly traded patent licensing entity, VirnetX Holding Corporation, after New Bay had filed IPRs against VirnetX. *Id.* The rumor was never substantiated because short selling is privately conducted. *Id.*

167. Beth Winegarner, *Celgene Calls Kyle Bass’ AIA Review Bids “Harassment,”* LAW 360 (Sept. 11, 2015), www.law360.com/articles/701833/celgene-calls-kyle-bass-aia-review-bids-harassment-. Celgene Corp. claims CFAD’s has no interest in invalidating patents and that CFAD’s IPR bids constitute “harassment” for profits. *Id.* Wall Street hedge funds have “exploited” the IPR process against congressional intent. Lisa Shuchman, *Big Pharma: Let’s Shift Patent Debate Away From Trolls*, CORP. COUNS. (May 20, 2015), www.corpcounsel.com/id=1202726911929/Big-Pharma-Lets-Shift-Patent-Debate-Away-From-Trolls#ixzz3lSTCWgDD (discussing the concern of IPR abuse in the pharmaceutical industry). MCM Portfolio LLC, the owner of a now invalid patent, argued in federal court that USPTO’s IPR proceedings are unconstitutional because patents are property rights that should be adjudicated in court and not in administrative agencies. Jimmy Hoover, *Patent Owner Calls IPR Process Unconstitutional at Fed. Cir.*, LAW 360 (Sept. 11, 2015, 4:06 PM), www.law360.com/articles/701764/patent-owner-calls-ipr-process-unconstitutional-at-fed-circ-.

168. Gene Quinn, *Patent Abuse or Genius? Is Kyle Bass Abusing the Patent System?*, IP WATCHDOG (Apr. 8, 2015), www.ipwatchdog.com/2015/04/08/is-kyle-bass-abusing-the-patent-system/id=56613; Dr. Kristel Schorr, Dr. Jason N. Mock & Lydia B. Choi, *The Road Ahead for Kyle Bass’s IPRs*, LAW 360 (Aug. 28, 2015, 5:39 PM), www.law360.com/articles/696911/the-road-ahead-for-kyle-bass-s-iprs. Christopher R. Walker, Article, *Deadly Delay/Postponed Pills*, 10 J. MARSHALL REV. INTEL. PROP. L. 253, 255–56 (2010).

169. Quinn, *supra* note 168. This may be why Kyle Bass is not targeting every single Orange Book-listed patent for a given drug or even drug patents that are almost ending. *Id.*

that store, Kyle does his research and finds the printer on the electronics store's website. Kyle sees that the printer's price had dropped \$100. Unbeknownst to Sam, Kyle takes the printer to the electronics store as proof of purchase and receives \$100 in cash for the difference between the original price and the price decrease. Without Sam noticing, John pockets the \$100 in cash.¹⁷⁰ Although it is a simplified example, this "shorting the stock" strategy is completely legal and regulated by the Securities and Exchange Commission.¹⁷¹

This is Kyle Bass's "short activist strategy" in effect. But instead of taking back a reduced price printer, Bass anonymously borrows pharmaceutical stocks from a broker, and profits off of the difference when a drug company's stock price plummets because of the institution of an IPR against a drug patent or when an IPR invalidates a drug patent.¹⁷² However, shorting the stock is risky and can prove costly.¹⁷³ Using our printer price example, let us say the price goes up \$10, then a trader would have to buy back at \$210 (for a loss) to replace what he borrowed when the broker demands that the trader return the borrowed stocks.¹⁷⁴ A lot of research and care must go into this strategy.

This financial strategy against drug companies could prove highly lucrative if Kyle Bass were to successfully invalidate a drug company's patent. For example, Kyle Bass's IPR challenge filed against a Jazz Pharmaceuticals' cancer drug Imbruvica threatens to invalidate a patented drug that makes up two-thirds of Jazz's \$800 million total revenue.¹⁷⁵ So far, Kyle Bass and CFAD have launched over thirty IPRs against more than fifteen publicly traded pharmaceutical companies.¹⁷⁶

170. Brigitte Yuille, Short Selling Tutorial, INVESTOPEDIA, www.investopedia.com/university/shortselling/ (last updated Apr. 28, 2017, 1:34 PM). Shorting a stock is when an investor or trader, based on market predictions that a stock will decline, borrows, for example, one hundred shares for \$50 a share from a willing broker. *Id.* The trader then will close the short position and buy one hundred shares back to replace the borrowed shares when the stocks drop to \$45 a share, as predicted, and then pockets \$500 for the difference. *Id.*

171. 17 C.F.R. § 201. After the market crash and the Great Depression of the 1920s and 1930s, Congress investigated and researched short selling as a potential problem but ultimately declined to perform any action making it illegal. When Congress passed the Securities and Exchange Act in 1934, Congress gave the Securities and Exchange Commission broad powers to regulate short selling to prevent abuse of the stock market. Adam Hayes, *Why Is Short Selling Legal? A Brief History*, INVESTOPEDIA (Nov. 6, 2014), www.investopedia.com/articles/investing/110614/why-short-selling-legal-brief-history.asp.

172. *Id.*

173. *Id.*

174. *Id.*

175. Rich Steeves, *Hedge Fund, IPR Rocking the Pharma Patent Space*, INSIDE COUNS. (May 12, 2015), www.insidecounsel.com/2015/05/12/hedge-funds-ipr-rocking-the-pharma-patent-space. Jazz Pharmaceuticals can breathe easy as PTAB has denied instituting Kyle Bass's IPR challenge against its cancer drug Imbruvica. Kelly Knaub, *PTAB Denies Another Kyle Bass Petition for Drug Review*, LAW 360 (Oct. 20, 2015, 4:41 PM), www.law360.com/articles/716375/ptab-denies-another-kyle-bass-petition-for-drug-review.

176. Julia La Roche, *Kyle Bass Scored a Huge Win in His Big Short Strategy*, BUSINESS INSIDER (Sept. 25, 2015, 4:35 PM), www.businessinsider.com/no-sanctions-for-kyle-bass-ipr-2015-9.

E. The Drug Industry's Response to Kyle Bass and Their Request for IPR Exemption

1. The Difficulty in Making a New Drug, Big Pharma's Reasons for High Drug Prices

Generally, a “pioneering drug” is deserving of a patent because of the amount of time and money spent researching it and testing it during clinical trials.¹⁷⁷ Patents are important to brand name pharmaceutical companies because “the pharmaceutical industry is an innovation-dependent industry, and so the intellectual property rights, specifically patents, are much more important in this industry than in others.”¹⁷⁸ On average, patented drugs make up 70% of total drug sale revenues for Big Pharma.¹⁷⁹ A drug's price decreases almost 90% once its patent term ends or it is invalidated under the Hatch-Waxman Act.¹⁸⁰ In 2011 and 2012, when sixteen major patents expired, this resulted in \$12 billion and \$30 billion in lost revenue, respectively.¹⁸¹

Research and development is “likely the most vital part of big pharma.”¹⁸² The cost of developing a new drug can range from \$800 million to \$5 billion.¹⁸³ But spending this money does not always guarantee success: “95% of the experimental medicines that are studied in humans fail to be both effective and safe” and thus never pass the FDA's regulations.¹⁸⁴ Obtaining FDA approval to market a new drug is a long and difficult process. Big Pharma claims this is the reason why acquiring a patent, maintaining a patent, and having high drugs prices are acceptable.¹⁸⁵

177. See *supra* Part IIA; ECONOMIST, *supra* note 128.

178. Mike Benson, *Patents Mean Big Business to Big Pharma*, MARKET REALIST (Feb. 20, 2015, 12:29 PM), <https://marketrealist.com/2015/02/patents-big-pharma>.

179. *Id.*

180. Natalie Stoltz, Comment, *Reverse Payment Agreements: Why a “Quick Look” Properly Protects Patents and Patients*, 58 ST. LOUIS L.J. 1189, 1190 (2014).

181. Benson, *supra* note 178. Patents that are soon expiring are estimated to cause even higher losses of revenue in 2014 (\$34 billion) and 2015 (\$66 billion). *Id.*

182. Mike Benson, *Big Pharma Invests Big Money in Research and Development*, MARKET REALIST (Feb. 20, 2015, 12:29 PM), <https://marketrealist.com/2015/02/patents-big-pharma>. “A single drug to market can expect to have spent \$350 million before the medicine is available for sale. In part because so many drugs fail, large pharmaceutical companies that are working on dozens of drug projects at once spend \$5 billion per new medicine.” See Herper, *supra* note 96.

183. DORSNEY, *supra* note 42, at 3. Any use or production of a patented product for experimental, noncommercial uses was permitted and not considered patent infringement. *Id.* There is a statutory research exemption for research and development of drugs and medical devices. 35 U.S.C. § 271(e) (2012); see, e.g., *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002) (ruling that the experimental use defense is limited to acts taken for amusement, to satisfy idle curiosity, or strictly for philosophical inquiry and not applicable for the purpose to further an infringer's legitimate business interests).

184. Herper, *supra* note 96.

185. With cancer medicine ranging from \$13,000 to \$64,000 a month for a prescription, drug companies blame the costly and lengthy research and development process, while

2. *The Drug Industry's Plea to PTAB to Stop Kyle Bass*

Frustrated by Kyle Bass and his “short activist strategy,” one drug company eventually asked PTAB to reject Kyle Bass’s use of IPR. After having four of its drug patents challenged by Kyle Bass through CFAD, Celgene asked PTAB to sanction CFAD for what Celgene alleges is an abuse of the IPR proceedings.¹⁸⁶ In response, PTAB requested memoranda from Celgene and CFAD as to why the “short activist strategy” is or is not an abuse of the IPR proceedings, and whether this type of “strategy” is sanctionable.¹⁸⁷ Three months later, PTAB responded by denying Celgene’s motion for the following reasons:

Profit is at the heart of nearly every patent and nearly every *inter partes* review. As such, an economic motive for challenging a patent claim does not itself raise abuse of process issues. We take no position on the merits of short-selling as an investment strategy other than it is legal, and regulated Accordingly, consistent with the proposition that Article III standing is not a requirement to appear before this administrative agency, we hold that Congress did not limit *inter partes* reviews to parties having a specific competitive interest in the technology covered by the patents.¹⁸⁸

Frankly speaking, this means that it is open season on the drug industry.¹⁸⁹ PTAB will not aid the drug patent industry to prevent IPR use in any “shorting” strategies, nor will it help Big Pharma by making any Article III standing rules to narrow third party standing.¹⁹⁰ From now on, all of Kyle Bass’s IPR filings will be reviewed on the merits. The pharmaceutical industry is now left with two choices: ask Congress to either pass patent reform, or be granted exemption from IPR proceedings.

other claim that drug companies are “taking advantage of a mix of laws that force insurers to include essentially all expensive drugs in their policies,” as well buying rights to old and inexpensive drugs and shut out other competitors. Peter B. Bach, *Why Drugs Cost So Much*, N.Y. TIMES (Jan. 14, 2015), www.nytimes.com/2015/01/15/opinion/why-drugs-cost-so-much.html?_r=0.

186. Lisa Schuchman, *PTAB Allows Challenge to Inventor's Patent Strategy*, CORP. COUNS. (June 22, 2015), www.corpcounsel.com/id=1202730002109/PTAB-Allows-Challenge-to-Investors-Patent-Strategy.

187. 37 C.F.R. § 42.1(d).

188. *Coalition For Affordable Drugs VI, LLC, v. Celgene Corporation*, No. 571.272.7822, Paper 19 at 3–4 (P.T.A.B. Sept. 25, 2015); see *Sierra Club v. E.P.A.*, 292 F.3d 895, 899 (D.C. Cir. 2002) (stating that an administrative agency is not subject to Article III of the Constitution of the United States, so a petitioner would have no need to establish standing to participate in proceedings before the agency); see also *Consumer Watchdog v. Wis. Alumni Res. Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014) (citing *Sierra Club*).

189. Ryan Davis, *Bass 'Patent Troll' Ally Seeks Help Targeting Depomed IP*, LAW 360 (Sept. 29, 2014, 10:17 PM), www.law360.com/articles/708511/bass-patent-troll-ally-seeks-help-targeting-depomed-ip. In response to the USPTO sanction ruling, Erich Spangenberg praised USPTO’s decision and called upon every member of the public, willing and able, to file IPRs against the pharmaceutical industry. *Id.*

190. See Gene Quinn, *BIO, PhRMA Lobby for IPR Fix to Insulate Their Patents from Challenge*, IP WATCHDOG (July 25, 2015), www.ipwatchdog.com/2015/07/26/bio-pharma-lobby-for-ipr-fix/id=59965.

3. A Request for IPR Exemption

Finally, Big Pharma requested that Congress exempt its drug patents from AIA post-grant reviews.¹⁹¹ Big Pharma argues that because its drug patents are subject to invalidity challenges through Hatch-Waxman litigation,¹⁹² its patents should not have to be subject to AIA review, which drug makers claim “usurps” the purpose of the Hatch-Waxman Act.¹⁹³ Most importantly, IPR ignores a patent’s presumption of validity and the clear and convincing evidence standard needed to rebut that presumption.¹⁹⁴ One argument is that methods like reverse payments agreements offset the financial risk of producing a new drug, thereby allowing brand name companies to secure profits to recoup NDA and patent expenditures and funnel those profits into continued research and development, which results in the continued creation of new and innovative drugs.¹⁹⁵

As abovementioned, getting a patent for an FDA NDA is an important business model, and now after the recent *Actavis* and *Schneiderman* decisions, drug patents are not only just subject to IPR and Hatch-Waxman patent invalidating procedures—they are subject to antitrust scrutiny. The argument is that this increased scrutiny against drug patents will scare potential investors and future settlement talks, which will lead to less innovation and drugs on the market.¹⁹⁶

III. ANALYSIS

Recently, PTAB has instituted CFAD’s challenge against Cosmos Technologies’ patent, the first among CFAD’s IPR challenges against the pharmaceutical industry.¹⁹⁷ Cosmos Technologies’ patent, a drug called

191. Ryan Davis, *Drugmakers Have Tough Task in Quest for AIA Exemption*, PHARMACEUTICAL (Sept. 11, 2015, 4:28 PM), www.law360.com/articles/700894/drugmakers-have-tough-task-in-quest-for-ai-a-exemption.

192. See Quinn, *supra* note 16.

193. See Bultman, *supra* note 19. The Hatch-Waxman provides generic drug companies the ability to compete with brand name drugs by allowing it to bypass having to file a complete new drug application and conduct clinical studies of their drug with the FDA. Construction and Application of Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994)), 180 A.L.R. Fed. 487, 2a. Generic drug companies only need to complete an Abbreviated New Drug Application (ANDA), which use a brand name drug company’s NDA clinical trial information and labeling information. *Id.*

194. T. Chet Compton, Comment, *Redrawing the Line Between Patent Rights and Antitrust Law: How the U.S. Supreme Court’s Over-Extension of Antitrust Law Harms Patent Holders, Damages Innovation, and Discourages Settlements*, 53 WASHBURN L.J. 365, 389–90 (2014).

195. *Id.* at 393–95.

196. *Id.* at 399–401.

197. Lisa Shuchman, *Kyle Bass Wins One as the Patent Trial and Appeal Board Agrees to Review a Drug Patent*, CORP. COUNS. (Oct. 8, 2015), www.corpcounsel.com/id=1202739363823/Kyle-Bass-Wins-One-as-the-Patent-Trial-and-Appeal-Board-Agrees-to-Review-Drug-

Lialda, is used to combat ulcerative colitis.¹⁹⁸ Prior to the IPR challenge, Actavis PLC certified a paragraph IV challenge against Lialda under the Hatch-Waxman Act to introduce a generic version of Lialda to the market.¹⁹⁹ This is a good example of a drug company having to fight invalidity challenges on two fronts, and there is a prevailing fear that this dual attack will deter investors because there the higher risk is not worth the reward.²⁰⁰ Moreover, more questions arise concerning whether IPR has an effect on certain Hatch-Waxman provisions because of the different invalidating standards at PTAB and the federal court, and the fact that Hatch-Waxman precedes the AIA and it may not be interpreted to allow IPR decisions to “trigger” Hatch-Waxman provisions.²⁰¹

Big Pharma is pushing for legislation that would exempt it from being challenged by IPR altogether.²⁰² But after taking a closer look of how IPR is affecting the bio/pharma patents, including Kyle Bass’s challenges, the drug industry will see that their request for exemption is unsupported.

Part III consists of three sections. The first section compares the pros and the cons of both IPR and Hatch-Waxman litigation and reviews IPR’s effect on patents and in particular to bio/pharma patents. This will

Patent?slreturn=20150913145749.

198. The drug is licensed to Shire Pharmaceuticals PLC. Tracy Staton, *Shire’s Lialda, Gattex are Hedge Funder’s Latest Patent Targets*, FIERCE PHARMA (Apr. 6, 2015), www.fiercepharma.com/story/shires-lialda-gattex-are-hedge-funders-latest-patent-targets/2015-04-06. Lialda, Shire’s second best-selling drug, makes up 10% of Shire’s revenue and earned it \$633 million in sales in 2014. *Id.*

199. Tracy Staton, *Shire’s Bid to Block Lialda Copies Hits Another Snag*, FIERCE PHARMA (June 4, 2015), www.fiercepharma.com/story/shires-bid-block-lialda-copies-hits-another-snag/2015-06-04. In Shire’s case against Actavis, the Federal Court of Appeals narrowed the scope of the Lialda patent through interpretation of its claims. *Id.* This paved the way for generic version of Lialda to enter the market. *Id.* Shire filed an appeal, and the case was remanded from the Supreme Court in response to the Supreme Court decision in *Teva v. Sandoz*. *Id.* In response, the Federal Court of Appeals still found Shire’s patent rights were narrower than the District Court had determined, and remanded the case back to trial to apply the standard. *Id.* Kyle Bass and CFAD have also challenged the patent validity of Gattex, Shire’s short bowel treatment drug, which Shire acquired in February 2015 for \$5.2 billion. *Id.* The Gattex patent expires in 2022. *Id.*; *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015) (ruling that on appeal, a court must give deference to the trial courts factual findings unless the trial court has committed clear error).

200. See Lisa Schuchman, *Big Patent Problems for Big Pharma and Biotech*, CORP. COUNS. (Aug. 4, 2015), www.corpcounsel.com/id=1202733863100/Big-Patent-Problems-for-Big-Pharma-and-Biotech?slreturn=20150917121834 (Big Pharma fears that the way IPR is used by groups like CFAD, will “discourage future investments in new medicines,” while others allege the pharmaceutical industry is simply trying to insulate and protect itself excessively).

201. See Brian T. Apel, Note, *An Administrative Meter Maid: Using Inter Partes Review and Post-Grant Review to Curb Exclusivity Parking via the “Failure to Market” Provision of the Hatch-Waxman Act*, 114 MICH. L. REV. 107 (2015) (arguing and amendment should be made to the Hatch-Waxman Act that would allow IPR decisions to “trigger” the forfeiture provision of the Act to curb “exclusivity parking.”); see also Jaiman Shah, Article, *Pulling the ‘Trigger’ on the Hatch-Waxman Act’s 180-Exclusivity Using Inter Partes Review*, 14 J. MARSHALL REV. INTELL. PROP. L. 453 (2015).

202. See Bultman, *supra* note 19.

determine whether IPR is a better generic drug delivery system than Hatch-Waxman and if PTAB's patent "death squad" moniker means bad news bio/pharma patents. Finally, a review of IPR recent decisions on some of CFAD's IPR challenges will show that the drug patent industry is seeking the wrong type of legislation in IPR exemption. In fact, after taking a look at a comparison of IPR and ANDA litigation side by side, the drug industry should consider updating the Hatch-Waxman Act.

A. Hatch-Waxman versus IPR

Generally, both ANDA and IPR have a purpose of challenging a patent's validity. Also, the noninfringement²⁰³ benefit generic drug companies receive for conducting drug patents experiments, as long as these experiments in using a patented drug are reasonably related to the development and FDA approval of their generic drug, applies whether a generic decides to file an ANDA or an IPR.²⁰⁴

That is where its similarities end and their differences begin with these two procedures. There are several different substantive and policy differences that distinguish Hatch-Waxman litigation from IPR. The following section demonstrates how both IPR and ANDA litigation have advantages and disadvantages.

1. ANDA Litigation and IPR: Filings and Court Differences

Procedurally, whether you are a generic brand that filed an ANDA-certified paragraph IV challenge or a generic that files an ANDA certification and a separate IPR challenge, all ANDA applications require (1) bioequivalence data,²⁰⁵ (2) certification, and (3) notice to the patent owner of the patented drug that the generic drug company has filed an ANDA for a generic version of the patented drug.²⁰⁶ In comparison, whether you are a generic brand or a third party that files an IPR, the IPR petition has to be made by a person or entity who is not the owner of a patent,²⁰⁷ and must contain (1) a pleading of patent invalidity only on a ground of anticipation or obviousness or both and only on the basis of

203. 35 U.S.C. § 271(e). This statutory exception, also known as the "FDA Safe Harbor," can be applied broadly and thus a patent holder cannot sue others for using the patent for "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." *Id.* A patent holder can sue others for patent infringement if the non-patent holders make, use, sell, offer to sell, or import the patented invention into the U.S. without the patent holder's permission. 35 U.S.C. § 271(a). *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (holding that the scope of § 271(e) is broad and can apply to scientific research on a drug that is intended to be submitted to the FDA and scientific research on patented compounds that are not submitted to the FDA).

204. *Id.*

205. 21 U.S.C. § 355(j).

206. DORSNEY, *supra* note 42, at 10–24.

207. 35 U.S.C. § 311(a).

prior art consisting of patents or printed publications,²⁰⁸ (2) an identification of all real parties in interest,²⁰⁹ and (3) an identification, in detail, of each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the challenges to each claim.²¹⁰ In contrast, any person or entity that wants to file an IPR does not have to supply any kind of bioequivalence data or comply with an ANDA or NDA to file an IPR.²¹¹

IPR is a “mini-trial” administrative proceeding that is meant to be less expensive and a less time-consuming alternative to federal court litigation.²¹² ANDA litigation, in contrast, is adjudicated in federal court and is directly tailored for generic drug companies to quickly introduce their generic drugs to the marketplace.²¹³

ANDA litigation mirrors traditional patent infringement cases in federal court where there is a pleading, forum selection, case scheduling,²¹⁴ discovery,²¹⁵ claim construction,²¹⁶ a trial, and appeal.²¹⁷ Similar to IPR cases, ANDA cases are litigated without a jury, but unlike an IPR proceeding where there is a panel of three administrative judges, a single Article III judge reviews the ANDA case.²¹⁸ Also, while IPR final written decisions are unappealable to PTAB,²¹⁹ ANDA decisions are appealable under the Federal Rules of Civil Procedure.²²⁰ While a patent infringement trial lasts one to two weeks, on average ANDA litigation cases can last twenty-seven months.²²¹ Damages are generally not available since the NDA/patent holder is asking for equitable relief in the

208. 35 U.S.C. § 311(b).

209. 35 U.S.C. § 312(a)(2).

210. 37 C.F.R. § 43.104.

211. *See supra* Part II.A.1.a.

212. *See* Cutler, *supra* note 110; *see also* Baldwin, *supra* note 119 (creating IPR set a “mini-trial” proceedings that takes less time to adjudicate and costs less than a trial in the federal court system).

213. DORSNEY, *supra* note 42, at 17. The policy goal was to quickly introduce generic drugs to the market to drive down drug costs. *Id.* at 5.

214. *Id.* at 77–80. Case scheduling occurs early within the thirty-month stay. *Id.*

215. *Id.* at 80. Some jurisdictions have adopted specific ANDA related procedural rule, which relate to timing and discovery orders. *Id.* at 81. The District Court of New Jersey is known to have the most comprehensive pretrial rules. *Id.* The District Court of New Jersey and the District Court of Delaware are the courts where the most ANDA cases are litigated. PRICEWATERHOUSECOOPERS, 2013 PATENT LITIGATION STUDY: BIG CASES MAKE HEADLINES, WHILE PATENT CASES PROLIFERATE (2013), www.pwc.com/us/en/forensic-services/publications/assets/2013-patent-litigation-study.pdf.

216. DORSNEY, *supra* note 42, at 81.

217. *Id.* at 75–88.

218. *Id.* at 86–87.

219. DORSNEY, *supra* note 42, at 77–80. Case scheduling occurs early within the thirty-month stay. *Id.*

220. *Id.* at 87. An appeal can delay the 180-day exclusivity if the trial court finds that a patent is valid or infringed. *Id.* In this scenario, the 180-day market exclusivity would occur if the Federal Court of Appeals reverses and finds a patent is valid or noninfringement. *Id.* at 88.

221. PRICEWATERHOUSECOOPERS, A CLOSER LOOK: 2008 PATENT LITIGATION STUDY: DAMAGES AWARDS, SUCCESS RATES, AND TIME-TO-TRIAL (2008), www.pwc.com/us/en/forensic-services/assets/2008_patent_litigation_study.pdf.

form of a permanent injunction.²²² In contrast, IPR challenges are simply a forum for patent invalidation.

2. ANDA versus IPR: Cost and Time to Litigate

The lifespan of an IPR challenge from petition institution to possible invalidation by a final written decision by PTAB usually takes twelve months to complete, up to a maximum of eighteen months.²²³ Including attorney's fees, an IPR can cost anywhere from \$300,000 to \$1 million depending on the firm.²²⁴ This beats the time it complete an ANDA case, which on average, including attorney's fees, can cost up to \$10 million and take up to twenty-seven months to complete.²²⁵

When a generic drug company files an ANDA paragraph IV certification, subsequently notifies the brand name of that challenge,²²⁶ and the brand name appropriately responds, the brand name has the benefit of the FDA staying approval of the ANDA application for thirty months, pending litigation²²⁷ or other events.²²⁸ On average the FDA takes eighteen to twenty-four months to approve an ANDA application.²²⁹ ANDA applicants and drug patent holders prefer that any litigation issues be resolved and concluded within the thirty-month stay to forgo any additional complicated matters.²³⁰ An IPR challenge does not trigger a thirty-month stay.²³¹

222. DORSNEY, *supra* note 42, at 241. Compensatory damages are not awarded because the generic company usually refrains from making, using, or selling the generic drug commercially until ANDA litigation ends. *Id.* Several forms of injunctive relief are available. *See id.* at 245–71.

223. 37 C.F.R. § 42.100(c) (2015).

224. Quinn G., *supra* note 190.

225. Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011).

226. MMA. Pub. L. No. 108-173, 117 Stat. 2066.

227. DORSNEY, *supra* note 42, at 14. The FDA requires strict compliance with the forty-five-day period because if the NDA/patent holder does not respond the FDA may approve the ANDA immediately despite any actual patent or exclusivity issues. *Id.* If the NDA/patent owner sues, then the FDA will delay the ANDA approval for thirty months. *Id.*

228. *See supra* Part II.A.2.c.

229. DORSNEY, *supra* note 42, at 15.

230. *Id.* at 77. NDA/patent holders prefer to delay generic entry as long as possible so if they have a weak patent, they would prefer that litigation end as close to the end of the thirty-month stay, to keep the current market price on the branded drug as long as possible. *Id.* at 87. If the NDA/patent holder has a strong claim, then it would seek a trial in hope of winning and being granted an injunction against the introduction of the generic drug into the market place. Generic companies prefer the opposite because the end of litigation in their favor would activate one of the three scenarios terminating the thirty-month stay and allowing them to introduce their drug to the market as soon as possible. *Id.* Litigating past the thirty-month stay introduces complicated decisions such as NDA/patent holders filing injunctions, or generic companies taking the risk to market the drug with the possibility of facing an injunction. *Id.*

231. *See* 37 C.F.R. § 42.105 (2015).

3. *The Exclusivity Benefit, Patent Infringement, and Article III Standing*

Under the Hatch-Waxman framework,²³² paragraph IV certification “authorizes and streamlines” a generic drug’s market entry by allowing the generic drug to rely on the brand name drug’s NDA safety and efficacy data.²³³ The generic who is the first to file and successfully challenges the brand name’s patent receives the 180-day market exclusivity right against all other generic drug companies.²³⁴ This is the most significant difference between ANDA and IPR. The 180-day market exclusivity is supposed to be the most important incentive for generic companies to challenge a patented drug under the Hatch-Waxman Act.

Another big difference between ANDA and IPR is the Article III standing requirement.²³⁵ Under a paragraph IV challenge, a generic notifies the FDA and the brand name company that it is challenging the brand name’s patented drug, and asserting that it is not committing patent infringement or that the patent is invalid.²³⁶ This assertion is unique to Hatch-Waxman because of the need for an “artificial” act of patent infringement.²³⁷ The “artificial infringement” provides the patent holder with the Article III “case or controversy” standing needed to sue in federal court.²³⁸ Essentially a generic drug company “risks” being subjected to a permanent injunction if the patent is deemed valid and infringed, having to wait until the drug patent’s term ends before it can market its generic product.²³⁹ Conversely, if the generic were to not infringe or invalidate the patent, as the first filer it gains the 180 days of market exclusivity.²⁴⁰ Because of this high risk and high reward challenge,

232. *Supra* Part II.A.2.

233. 15 U.S.C. §§ 68b–68c, 70b; 21 U.S.C. §§ 301, 355(j), 360cc; 28 U.S.C. § 2201; and 25 U.S.C. §§ 156, 271, 282.

234. DORSNEY, *supra* note 42, at 22.

235. *See supra* Part II.A.2.b.

236. *See* 21 U.S.C. § 355(j)(2)(A)(viii)(I)–(IV) (2002); *see also* 21 C.F.R. § 314.94(a)(12). Generic companies who file under paragraphs I, II, and III do not trigger any patent infringement repercussions because they do not challenge any patent rights. DORSNEY, *supra* note 42, at 30 n.51.

237. 35 U.S.C. § 271(e)(2).

238. DORSNEY, *supra* note 42, at 10. The “safe harbor” provision of the Hatch-Waxman Act prevents a patent owner from suing generic drug manufacturers for using the patent in their clinical experiments and studies. *Id.* Justiciability issues would occur if the patent owner sued the generic company because they would not have standing in federal court. *Id.* The Hatch-Waxman Act makes the filing of an ANDA an act of infringement and gives the patent owner standing to resolve their issues in federal court. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000).

239. DORSNEY, *supra* note 42, at 207 (compensatory damages are not awarded because the generic company usually refrains from making, using, or selling the generic drug commercially until ANDA litigation ends).

240. DORSNEY, *supra* note 42, at 22. The first generic company to file a paragraph IV certification has a 180-day market exclusivity against all other generic companies that filed later ANDAs. *Id.* Even more beneficial, is that the first to file a paragraph IV certification is entitled to the 180-day market exclusivity regardless if the ANDA applicant wins or loses its litigation case against the NDA/patent holder. *See, e.g., Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008).

a generic drug company usually attacks drug patents it thinks are weak and vulnerable to a challenge.²⁴¹

In contrast, under IPR, there is no Article III standing requirement “which means that anyone can bring an IPR for any reason.”²⁴² But while a generic drug company may avoid an injunction under IPR, it may forgo the 180-day market exclusivity to another generic drug company that is the first to file a paragraph IV litigation.²⁴³ As above mentioned, there are many questions regarding what would happen to the 180-day exclusivity right if a paragraph IV first to file generic were to successfully file an IPR.²⁴⁴ However, it is important for generic brands to remember that, by filing an IPR and not being the first to file a paragraph IV certification, it can be subjected to market exclusion by the first file generic, no matter if its IPR challenge is successful.²⁴⁵

4. *ANDA versus IPR: A Patent’s Presumptive Validity*

Substantively, in ANDA litigation, the sitting judge can evaluate a generic’s challenge to a drug patent’s validity under patentability, utility, disclosure, novelty, and nonobviousness.²⁴⁶ For the IPR judges to review an IPR, the petitioner must show that there “is a reasonable likelihood of success that the requester would prevail” against at least one of the claims in the challenged patent.²⁴⁷ Truly, an IPR challenge would be granted if a judge finds the challenger submitted sufficient anticipatory or obvious prior art evidence that would render the patent invalid.²⁴⁸ In this aspect, the advantage goes to ANDA litigation in the number of opportunities and ways to attack a drug patent.

But, drug patents in ANDA litigation enjoy a presumption of patent validity, which means a challenger has the higher burden of proving a patent is invalid with “clear and convincing evidence.”²⁴⁹ In contrast, PTAB does not presume the drug patent invalid.²⁵⁰ As a result, PTAB

241. DORSNEY, *supra* note 42, at 22.

242. Quinn, *supra* note 190.

243. See Vicki G. Norton, Siegfried J.W. Ruppert, & Michael Swit, *Successful Use of Inter Partes Review to Cancel Claims Asserted in Parallel Litigation*, Duane Morris Blog (Mar. 26, 2014), <http://blogs.duanemorris.com/lifescienceslaw/2014/03/26/successful-use-of-inter-partes-review-to-cancel-claims-asserted-in-parallel-litigation>.

244. See Apel, *supra* note 201.

245. See Norton, *supra* note 243 (stating why IPR “remains a viable option for later filing generic companies.”).

246. *Supra* Part II.B.1.

247. 35 U.S.C. § 314(b).

248. 35 U.S.C. § 316(a)(11). IPR challenges are limited to using evidence of other patents or printed publications as prior art to challenge a patent’s validity under novelty or nonobviousness. *Id.*

249. See generally Rob Sterne & Gene Quinn, *PTAB Death Squads: Are All Commercially Viable Patents Invalid?*, IP WATCHDOG (Mar. 24, 2014), www.ipwatchdog.com/2014/03/24/ptab-death-squads-are-all-commercially-viable-patents-invalid/id=48642/ (“The biggest safeguard that a patentee enjoys at the district court is a presumption of validity, which is not present to protect the patentee in proceedings before PTAB.”).

250. See 35 U.S.C. § 282(a) (2016).

invalidates patents under a preponderance of the evidence standard.²⁵¹ What is even more favorable to IPR users is the fact that federal courts have been more deferential to PTAB and its ability to make rules, enforce those rules, and make decisions based on those rules.²⁵² Also, based on PTAB's use of the broadest reasonable interpretation to patent claims,²⁵³ patents challenged under IPR are more likely to be invalidated by PTAB than a drug patent in federal court because PTAB may consider "a broader range of prior art than the district court."²⁵⁴

B. IPR Statistics on Patent and Bio/Pharma Patents: Patent Kill Rates

Even before the Federal Court of Appeals endorsed PTAB regarding its rules and procedures,²⁵⁵ two years of IPR reporting have shown that IPRs are quite combative to patents.²⁵⁶ One study reviewing the first two years of IPR proceedings has shown that (1) USPTO institutes IPR petitions for at least one challenged claim 84% of the time, (2) USPTO institutes IPRs for all challenged claims 74% of the time, and (3) PTAB reached a final written decision, on the merits, and invalidated or disclaimed all instituted claims more than 77% of the time.²⁵⁷ As of September 30, 2014, IPRs, on average, are filed at the rate of 75.1 per month, for a total of 1,841 IPRs filed in IPR's first two years.²⁵⁸ This IPR filing per month rate is six times the IPX filing rate in IPX's entire history.²⁵⁹ In total, IPRs in the first two years have nearly totaled the maximum number of IPX filings in IPX's thirteen-year history.²⁶⁰

251. See e.g., *Bio-Rad Laboratories, Inc. v. California Institute of Technology*, No. IPR2015-00010, Paper 29 at 2 (P.T.A.B. Apr. 21, 2016) ("For the reasons that follow, we determine that Petitioner has met its burden to prove by a preponderance of the evidence that claims 1-5 and 10-17 of the '539 patent are unpatentable.>").

252. Bob Steinberg, Michael Morin & Davis Frazier, *Let PTAB Decide: Federal Courts Are Increasingly Deferring to the Patent Trial and Appeal Board*, CORP. COUNS. (Apr. 1, 2015), www.corpcounsel.com/id=1202720053044/Let-the-PTAB-De

[cide?slreturn=20150904215414](http://www.corpcounsel.com/id=1202720053044/Let-the-PTAB-De). USPTO and its predecessor have applied the broadest reasonable interpretation standard "to reduce the possibility that, after the patent is granted, the claims may be interpreted as giving broader coverage than is justified." *In re Reuter*, 670 F.2d 1015, 756 (C.C.P.A. 1981); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268 (Fed. Cir. 2015) (affirming the rulemaking authority of USPTO and that a decision to institute an IPR is not judicially reviewable by statute nor are PTAB final written decision on the matter).

253. See 37 C.F.R. § 42.100(b) (2016).

254. Mauri, *supra* note 119.

255. See text accompanying *supra* note 123.

256. The Patent Trial and Appeal Board began accepting petitions for IPR on September 16, 2012. See Leahy-Smith America Invents Act § 319(c)(2)(A), Pub. L. No. 112-29, 125 Stat. 284, 304 (2011), see also Brian J. Love & Shawn Ambwani, Dialogue, *Inter Partes Review: An Early Look at the Numbers*, 81 U. CHI. REV. 93 n.1 (2014).

257. Love, *supra* note 256, at 97.

258. *Id.*

259. *Id.*

260. *Id.*

In February 2015, PTAB “invalidated 93% of the claims from all industries that reached a final written decision.”²⁶¹ In a new study that analyzed over four hundred final written decisions by PTAB from September 2012 through August 1, 2015, 88% of final written decisions resulted in at least one claim being invalidated; 21% of all final written decisions resulted in a complete patent invalidation; 82% of instituted IPRs result in final written decisions that result in some type of patent invalidation, thus “PTAB’s first impression of the petitions strength appears to affect the entire proceeding and ultimate outcome.”²⁶² If IPRs are so effective in invalidating patents, the concern is that if an IPR invalidates a patented drug that is financially important to a pharmaceutical company, it could seriously deter potential investors from providing the funding that is needed to complete an NDA. These results could potentially destroy an entire business and thereby result in thousands of lost jobs.²⁶³

In February 2015, it was reported that IPR challenge rates against biotech/pharmaceutical patents have tripled and the total number of IPRs already filed in 2015 (73 as of March 26) has exceeded the total number of combined IPRs filings against biotech/pharmaceutical patents from 2012 to 2014.²⁶⁴ During the 2015 fiscal year, 167 of the total 1,897 AIA petitions have been petitions to challenge bio/pharma patents.²⁶⁵ That is an increase from the 2012–2014 combined totals of 111 petitions.²⁶⁶ Pharmaceutical companies alone have filed a combined total of 115 IPRs.²⁶⁷

Broken down further, of the bio/pharma petitions filed in the past three years: 45 IPRs were filed in 2013, 91 IPRs were filed in 2014, and

261. Irena Royzman and Zhiqiang Liu, *IPR Puts Biotech in the Crosshairs: A Forum to Invalidate Patents Is Now Being Used on Biotech Firms; From the Experts*, CORP. COUNS. (June 12, 2015), www.corpcounsel.com/id=1202726050369/IPR-Puts-Biotech-in-the-Crosshairs.

262. Amy Simpson & Hwa Lee, *PTAB Kill Rates: How IPRs Are Affecting Patents*, LAW 360 (Sept. 15, 2015, 9:44 AM), www.law360.com/articles/699860/ptab-kill-rates-how-iprs-are-affecting-patents. This study “analyzed all of the approximately 404 final written decisions on instituted IPRs from September 2012 through Aug. 1, 2015, to explore the factors behind IPR kill rates.” *Id.* The results ultimately represented “the number of patents that have been invalidated in their entirety via IPRs,” as well as “the statistical impact that certain aspects of the IPR petition have on the kill rate, including petitions to invalidate all claims in a patent and petitions under § 102, § 103 or both.” *Id.*

263. See Gene Quinn, *The Looming Patent Nightmare Facing the Pharmaceutical Industry*, IP WATCHDOG (July 8, 2015), www.ipwatchdog.com/2015/07/08/the-looming-patent-nightmare-facing-the-pharmaceutical-industry/id=51428.

264. Royzman, *supra* note 261.

265. UNITED STATES PATENT, TRIAL AND APPEAL BOARD, PATENT TRIAL AND APPEAL BOARD STATISTICS (2015), www.uspto.gov/sites/default/files/documents/2015-12-31%20PTAB.pdf.

266. Love, *supra* note 256, at 97.

267. Austin Donohue, *IP Sessions at BIO 2015: The Impact of the Inter Partes Review on (BIO)Pharma*, BIOTECHNOW (June 24, 2015), www.biotech-now.org/public-policy/patently-biotech/2015/06/ip-sessions-at-bio-2015-the-impact-of-the-inter-partes-review-on-biopharma.

176 were filed in 2015, a yearly increase.²⁶⁸ With respect to bio/pharma IPRs: 51 are not yet decided, 61 have fallen under the settled/dismissed category, and 193 have been instituted on the merits.²⁶⁹ However, PTAB is less likely to institute a bio/pharma petition, holding a 61% institution rate compared to 72% all other tech challenges.²⁷⁰ Even if instituted, bio/pharma claims are more likely to survive than any other technical field.²⁷¹ Their survival rate is still low because bio/pharma patents have a 34.4% survival rate compared to the 13.4% survival rate in all other technical fields.²⁷² This is because pharmaceutical drugs are seen as the “unpredictable arts,” and thus patent owners can argue more effectively to save the patent.²⁷³

In 2016, PTAB began issuing its first PGR final decisions.²⁷⁴ This means an increase in bio/pharma challenges by both IPR and PGR.²⁷⁵ In 2016, IPR and PGR institution rates have increased.²⁷⁶ Examining a combined 254 IPR and PGR decisions against bio/pharma patents, PTAB instituted these petitions 65.7% of the time.²⁷⁷ On all other patents, institution rates have been at 66.8%.

Institution rates are understood to mean one, more, or all of a patent’s claims will likely be invalidated, which means a win for the patent challenger.²⁷⁸ In contrast, an IPR petition that is not instituted means the patent is strong and it is a win for the patent holder.²⁷⁹

C. PTAB’s Decisions on CFAD’s IPRs—the Effectiveness of Kyle Bass’s Strategy

A review of some of Kyle Bass’s IPR challenges, through CFAD, will determine if they are consistent with the above-mentioned IPR statistics.

268. Mellissa Gibson & Ruben Munoz, *IPR and Biopharma Patents: What the Statistics Show*, LS IPR (Nov. 11, 2015), www.akingump.com/images/content/3/9/v2/39881/IPR-and-biopharma-patents-what-the-statistics-show-GF.pdf.

269. *Id.*

270. *Id.*

271. *Id.*

272. *Id.*

273. Thomas L. Irving et al., *Nonobviousness in the U.S. Post-KSR for Innovative Drug Companies*, FINNEGAN (Oct. 2009), www.finnegan.com/resources/articles/articlesdetail.aspx?news=72b65383-ff4e-4d71-a15c-019ca60e1d30.

274. Mathew Bultman, *In 1st-Ever PGR Decisions, PTAB Nixes Livestock Patents*, LAW 360 (June 13, 2016), www.law360.com/articles/806355/in-1st-ever-pgr-decisions-ptab-nixes-livestock-patents.

275. *PTAB Analytics Indicate Record Highs for Bio/Pharma IPR/PGR Institution Rates*, DOCKET REPORT (Nov. 2, 2016), <http://docketreport.blogspot.com/2016/11/ptab-analytics-indicate-record-highs.html>.

276. *Id.*

277. *Id.*

278. John T. Aquino, *Inter Partes Review Patent Challenges Bedevil Biopharmas*, BLOOMBERG BNA (Nov. 21, 2016), www.bna.com/inter-partes-review-n73014447528.

279. *Id.*

1. *A Review of PTAB's Decision Not to Institute CFAD IPRs*²⁸⁰

In PTAB's first review of CFAD's first IPR petition, PTAB decided that the prior art references that CFAD presented were not sufficient to be considered printed publications that would invalidate Acorda's patent under the nonobviousness requirement.²⁸¹ Even though PTAB did not mention Kyle Bass and CFAD's "short activist strategy," PTAB's reasons for siding against CFAD raises the question of whether PTAB took into account who the IPR petitioners were and thereby stretched its substantive findings to not institute CFAD's IPR.²⁸² One day after PTAB denied instituting CFAD's IPR challenge against Acorda, Acorda's stock increased from \$28.96 per share to \$35.15 per share, likely resulting from confidence in the patent's strength.²⁸³

Similar criticisms were directed to PTAB's rejection of CFAD's subsequent IPR challenge of Biogen's patents.²⁸⁴ Specifically, in CFAD's challenge against Biogen's MS drug, PTAB rejected CFAD's contention that Biogen's MS patent claims were obvious because of the public availability of clinical information on a similar drug's phase II trials.²⁸⁵ PTAB reviewed the information on the phase II drug trials and ruled that it was not the type of printed publication that would breach the "likelihood of success" standard threshold of invalidating the patent

280. Institution decisions are final and not appealable. See 35 U.S.C. § 314(d).

281. Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. IPR2015-00817, Paper 12 (PTAB Aug. 14, 2015). CFAD issued an IPR against two of Acorda's patents related to its multiple sclerosis drug. *Id.* PTAB first ruled that Acorda's information disclosure statements (IDS) about two posters it had presented at industry meetings did not constitute an admittance of material prior art. *Id.* The two posters at the Acorda industry meeting had detailed information about Acorda's MS drug Ampyra. *Id.* Also after reviewing the two posters, PTAB found that CFAD presented "insufficient evidence" that these two posters were sufficient prior art printed publications that would invalidate Acorda's drug patents. *Id.*; *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004) (ruling that there are four considerations for a prior art to qualify as a printed publication: (1) the length of time the display was exhibited, (2) the expertise of the target audience, (3) the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and (4) the simplicity or ease with which the material displayed could have been copied).

282. See Gene Quinn, *USPTO Denies Kyle Bass IPR Patent Challenge against Acorda Therapeutics*, IP WATCHDOG (Aug. 25, 2015), www.ipwatchdog.com/2015/08/25/uspto-denies-kyle-bass-ipr-patent-challenge-against-acorda-therapeutics/id=61016 ("I have to wonder whether this decision represents a shift in the worldview of PTAB or whether they sought out a reason to deny the petition because it was filed by Kyle Bass. Unfortunately, I suspect these two denials have everything to do with who was behind the challenge and little to do with the merits of the challenge.").

283. *Id.*

284. Gene Quinn, *With Dubious Logic and Inaccurate Statements of Law, PTAB Denies Another Kyle Bass IPR Petition*, IP WATCHDOG (Sept. 2, 2015), www.ipwatchdog.com/2015/09/02/ptab-denies-another-kyle-bass-ipr-petition/id=61333; Gene Quinn, *Kyle Bass IPR Challenge Moves Forward, What Does It Mean?*, IP WATCHDOG (Oct. 12, 2015), www.ipwatchdog.com/2015/10/12/kyle-bass-ipr-challenge-moves-forward-what-does-it-mean-for-patent-reform/id=62449.

285. Coalition for Affordable Drugs (ADROCA) LLC v. Biogen MA, Inc., No. IPR2015-01136, Paper 23 at 16 (P.T.A.B. Sept. 2, 2015). CFAD challenged Patent Claims 1–20. *Id.*

claims CFAD sought to invalidate.²⁸⁶ Again, PTAB denied instituting the IPR on what may be considered faulty reasoning.²⁸⁷ PTAB determined that the written description of the phase II studies was not a printed publication, yet without explanation, it still relied on its contents to decide that the phase II trials constituted public use, when it was clear that the drug studied in the phase II trials was used to find MS (as that is exactly what the written description said the trials were meant for).²⁸⁸ Thus, PTAB's use of the phase II trials' written description to deny the institution of IPR "can be described only as [. . .] horribly disingenuous" because the written description is prior art publication that can be used to invalidate Biogen's patent.²⁸⁹ Once again, PTAB's decision appears to be based more on denying CFAD than on denying the IPR pursuant to established law.²⁹⁰

PTAB also denied CFAD's IPR petitions against Jazz Pharmaceuticals' narcolepsy drug Xyrem²⁹¹ and Pharmacyclics Inc.'s cancer drug Imbruvica.²⁹² PTAB rejected CFAD's claim that the Xyrem patent was obvious because the prior art was not publicly available and the combination of the prior art would not be sufficient for a person having ordinary skill in the art (PHOSITA)²⁹³ to practice the patented drug.²⁹⁴ In a change of tone, PTAB criticized CFAD's efforts in providing

286. *Id.* at 9–11. Challenge 1—Kappos et al. Pilot study: Kappos concerned a pilot study. The Board identified multiple deficiencies associated with the pilot study of Kappos, ultimately finding that "Petitioner [had] failed to establish that Kappos teaches that DMF would be useful for treating MS. *Id.* Challenge 2—ClinicalTrials as prior art: PTAB found that ClinicalTrials was not prior art printed publication. As a test, PTAB assumed it was prior art, and even under this assumption the Board found ClinicalTrials to be "deficient as a prior art teaching of DMF being useful to treat MS for many of the same reasons that Kappos is deficient." *Id.* at 12–14. Challenge 3—Admissions said to have been in the '514 Patent and ICH Guideline: the Board declined to address the issue of whether an "admission" per se can form the basis of an IPR challenge. Instead, the Board indicated that even if an "admission" could be relied upon for this purpose, the alleged "admission" in the instant proceeding failed as prior art like the Kappos and ClinicalTrials challenges. *Id.* at 14–16.

287. See Quinn, *supra* note 284. "Clearly, one of skill in the art familiar with FDA processes and clinical trials would have thought it obvious to try DMF for treating multiple sclerosis after having read the description in the Kappos reference." *Id.*; see generally *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007). "In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.*

288. Quinn, *supra* note 284.

289. *Id.*

290. *Id.*

291. Vin Gurrieri, *PTAB Again Rejects Kyle Bass AIA Review of Drug Patent*, LAW 360 (Oct. 16, 2015, 4:40 PM), www.law360.com/lifesciences/articles/715126.

292. Kelly Knaub, *PTAB Denies Another Kyle Bass Petition for Drug Review*, LAW 360 (Oct. 20, 2015, 4:41 PM), www.law360.com/ip/articles/716375.

293. A person having ordinary skill in the art is similar in theory to the reasonable person standard but in this case it refers to a person in a particular technical field, for example, in the drug field it could be an ordinary pharmacologist or an ordinary organic chemist or an ordinary inorganic chemist who has available to them all present knowledge about pharmacology and whether that hypothetical person could come up with the invented drug in question. See text accompanying *supra* note 103.

294. *Coalition For Affordable Drugs III LLC v. Jazz Pharms., Inc.*, No. IPR2015-01018 Paper 17 at 12, 18–21 (P.T.A.B. Oct. 15, 2015). The Drug Advisory Committee (DAC)

sufficient evidence to warrant the institution of IPR, stating that CFAD “does not offer reasons why a [PHOSITA] would ‘cobble together disclosures from these disparate references’ that are not related to the same endeavor.”²⁹⁵ The prior art failed to anticipate or make Imbruvica obvious because it was insufficient to be considered a printed publication.²⁹⁶

2. PTAB Institutes Several CFAD IPR Challenges and Their Final Written Decisions

In October of 2015, PTAB, for the first time, instituted an IPR filed by Kyle Bass and CFAD against Cosmo Technology’s patent on Mesalazine, a drug used to treat Crohn’s disease and ulcerative colitis.²⁹⁷ PTAB agreed, for the most part, with CFAD that a PHOSITA would find the Mesalazine patent obvious because a prior-existing patent and a printed publication teach several claims of the Mesalazine patent.²⁹⁸

But approximately one year later, PTAB sided against CFAD and held that the prior art was not enough to meet the preponderance of the evidence standard to invalidate Cosmo’s patent.²⁹⁹ Particularly, PTAB found that CFAD’s definition of a disputed term in the claims of the patent were “outweighed significantly by non-patent extrinsic evidence in the form of relevant treatises, textbooks, and dictionaries that chemically define [that term,]” and thus, CFAD’s prior art did not apply to Cosmo’s patent.³⁰⁰ Ultimately, PTAB stated CFAD’s obvious challenge against

transcripts were prior art in question. *Id.*

295. *Id.* at 20. Even though PTAB denied CFAD’s IPR, PTAB once again came to CFAD’s defense by saying that CFAD’s “short activist strategy” is not contrary to the AIA’s Congressional intent, nor is there anything illegal with CFAD’s strategy because having a financial motivation for filing IPR occurs all the time and is not sanctionable. *Id.* at 10–12. PTAB’s rejection of CFAD’s IPR against Pharmacyclics was based on their decision that NCT00849654, a published clinical phase I trial document, describing the clinical trials conducted by Pharmacyclics did not anticipate nor make the Imbruvica patent obvious. *Id.* at 2.

296. *Id.* at 6. CFAD failed to provide “probative evidence that supports its assertions, or that is sufficient to support a reasonable inference that NCT00849654 was publically accessible before the critical date.” *Id.* PTAB found that CFAD failed to explain the meaning of certain dates found on the website where NCT00849645 was available and CFAD failed to provide evidence of the websites publishing practices, including how the website disseminates its information and thus, “[w]ithout such information, there is no support for a conclusion that NCT00849654 was publicly accessible by February 2, 2009, as Petitioner asserts.” *Id.* at 8.

297. Coalition for Affordable Drugs II LLC v. Cosmo Technologies LTD., No. IPR2015-00988, Paper 8 at 2–3 (P.T.A.B. Oct. 7, 2015).

298. *Id.* at 3. The patent is the Leslie, U.S. Patent No. 3,965,256, filed June 5, 1974, issued June 22, 1976 (Leslie) (Ex. 1003) and the printed publication is Groenendaal et al., EP Appl. Publ. No. 0 375 063 A1, filed Dec. 18, 1989, published on June 27, 1990 (Groenendaal) (Ex. 1005). *Id.*

299. Coalition for Affordable Drugs II LLC v. Cosmo Technologies LTD., No. IPR2015-00988, Paper 55 (P.T.A.B. Oct. 5, 2016).

300. *Id.* at 10–12. CFAD argued that the term “waxes” in the patent’s first claim referred to cetyl alcohol and cetostearyl alcohol, but PTAB sided with Cosmo in that “waxes” “has a specific chemical definition that does not include cetyl alcohol” and cetostearyl alcohol. *Id.*

Cosmo's patent was "a close call, but certainly not a strong case."³⁰¹ According to PTAB, CFAD's prior art is unpersuasive in making Cosmo's patent obvious, and criticized its attempted attack by stating that its "challenge is more akin to 'merely throw[ing] metaphorical darts at a board filled with combinatorial prior art possibilities' when the prior art gave little or conflicting indications as to which parameters were critical or which of many possible choices were likely to be successful."³⁰²

In another case, PTAB instituted, in part, CFAD's IPR against NPS Pharmaceuticals Inc.'s patent covering Gattex, a drug used to treat short bowel syndrome.³⁰³ In this case, PTAB found that the combination of prior-existing patents, which disclosed information on the Gattex drug, would have been obvious to a PHOSITA with respect to how to create the drug.³⁰⁴ One year later, PTAB ultimately agreed and invalidated most of the patent claims covering Gattex.³⁰⁵ NPS has appealed the final written decision to the Federal Circuit.³⁰⁶

In another win for Kyle Bass and CFAD, PTAB decided to institute an IPR against two Celgene patents related to the cancer drugs Thalomid, Revlimid, and Pomalyst.³⁰⁷ PTAB held that a combination of journal articles and the fact that the three drugs may contain thalidomide (or are similar to it) would make Celgene's patented method obvious to a PHOSITA.³⁰⁸ In a final written decision, PTAB ultimately "found that Celgene Corp. patents related to the cancer drugs Thalomid, Reylimid, and Pomalyst are invalid."³⁰⁹ Celgene has yet to appeal the decision to the Federal Circuit.³¹⁰

at 11–13.

301. *Id.* at 23.

302. *Id.* at 18–19 (quoting *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009)).

303. *Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals Inc.*, No. IPR2015-00990 and IPR2015-01093, Paper 26 (P.T.A.B. Oct. 23, 2015).

304. *Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals Inc.*, No. IPR2015-01093 Paper 26 at 19 (P.T.A.B. Oct. 23, 2015); see Vin Gurrieri, *Kyle Bass-Backed Group Gets PTAB to Review Gattex Patent*, *Law 360* (Oct. 26, 2015, 5:25 PM), www.law360.com/ip/articles/718885.

305. See *Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals Inc.*, No. IPR2015-00990, Paper 68 (P.T.A.B. Oct. 21, 2016); *Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals Inc.*, No. IPR2015-01093, Paper 67 (P.T.A.B. Oct. 21, 2016).

306. *Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals Inc.*, No. IPR2015-01093, Notice of Appeal (P.T.A.B. Dec. 20, 2016).

307. Ryan Davis, *Kyle Bass Group Gets PTAB to Review 2 Celgene Patents*, *Law 360* (Oct. 27, 2015, 8:38 PM), www.law360.com/articles/719428/kyle-bass-group-gets-ptab-to-review-2-celgene-patents.

308. *Id.* CFAD challenged patents that cover a computerized method of distributing the three drugs to keep them from being used by pregnant women. *Id.* PTAB said the claims of the patent are "likely obvious in view of earlier systems for ensuring that pregnant women cannot access drugs that could harm a fetus." *Id.*

309. Davis *supra* note 307; *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, No. IPR2015-01102, IPR2015-01103, IPR2015-01092, and IPR2015-01096 (P.T.A.B. Oct. 27, 2016).

310. An IPR final written decision may be appealed directly to the Federal Circuit. 35 U.S.C. § 319 (2016). A notice of appeal must be made within 63 days of the final written decision. See 37 C.F.R. § 90.3 (2016).

D. No IPR Exemption for Hatch Waxman, But Reverse Payments Are Still an Issue

1. Kyle Bass's Losing Battle

As of October 2015, Kyle Bass has experienced mixed results in his IPR challenges, most of which have been unfavorable. Kyle Bass and CFAD have filed thirty-three IPRs,³¹¹ and PTAB has decided seventeen of those petitions.³¹² Out of the seventeen decisions, PTAB has agreed to institute seven of Kyle Bass's and CFAD's IPRs and to reject ten.³¹³ This essentially shows a 59% denial rate with respect to CFAD's IPR challenges.³¹⁴ Overall, USPTO statistics have shown that PTAB has denied IPRs on the merits at a 30% rate, and thus instituted IPRs at a 70% rate, on average.³¹⁵ At this point in time, based on this sample size, CFAD, on the merits of these decisions, has "been denied [institution] approximately 2 times more than the average."³¹⁶ In comparison to how many IPRs are instituted against the bio/pharma industry overall, CFAD is faring slightly better.³¹⁷

Of the six challenges that reached a final written decision, five resulted in having a drug patent's claims (some or all) invalidated.³¹⁸ On paper, Kyle Bass's strategy appears to be a success, but not an "overwhelming success."³¹⁹ But, after two years, others argue that Kyle Bass's "short activist strategy" has been a "failure."³²⁰ Despite his success at invalidating five patents as well as achieving a higher IPR institution rate compared to other bio/pharma challenges, Kyle Bass's strategy has

311. Katherine L. Neville, *Coalition for Affordable Drugs PTAB Scorecard*, PTAB WATCH (Oct. 30, 2015), www.ptabwatch.com/2015/10/coalition-for-affordable-drugs-ptab-scorecard. In these cases, multiple IPR challenges have been filed against the same patent. *Id.*

312. *Id.*

313. *Id.*

314. Ryan Davis, *USPTO Asks Congress to Change Some AIA Petition Rules*, LAW 360 (Oct. 2, 2015, 4:48 PM), www.law360.com/ip/articles/710386 (USPTO has asked Congress to pass legislation to relax the "real parties of interest" (RPI) requirement that USPTO currently identifies as "too strict" because it terminates a petition for failing to identify the correct RPI in their IPR, PGR, or CBM petition.). This also can be seen as an institution rate of 41%. *Id.*

315. Neville, *supra* note 311.

316. *Id.*

317. Tasha M. Francis, *Kyle Bass Group Gets PTAB to Review 4 Celgene Patents*, LEXOLOGY (Oct. 28, 2015), www.lexology.com/library/detail.aspx?g=f426cc1a-ce41-4347-8640-9e1049f5a6c4. Approximately, a total of 74 bio/pharma IPRs were filed so far in 2015. *Id.* IPRs were instituted in 28.4% of the cases, granted in part in 20.3% of the cases, and denied in 51.4% of the cases. *Id.*

318. Tasha M. Francis and Tucker N. Tehufen, *Kyle Bass Is on a Roll: Four More Wins at PTAB*, FISH & RICHARDSON (Nov. 1, 2016), www.fr.com/fish-patent/kyle-bass-is-on-a-roll-four-more-wins-at-the-ptab.

319. Mathew Bultman, *Hedge Fund Drug Patent Challenges in Doubt after Bass' Test*, LAW 360 (Mar. 31, 2017), www.law360.com/articles/908491.

320. *Id.*

had “a lack of apparent success betting against pharmaceutical companies’ stock.”³²¹

While stock prices initially dropped when Kyle Bass filed his first few challenges, “subsequent filings and final decisions invalidating patents did not seem to cause major fluctuations in the stock price. In some instances, the price actually went up.”³²² Someone who “shorts the stock” would not benefit from these results, and this trend does not appear likely to change because “as time wore on, the stock market better understood the uncertainties that come along with filing an IPR petition and were less influenced by it.”³²³ Also, the lack of financial success in the strategy has not led to copycats, further suggesting that the shorting strategy is not successful.³²⁴

Besides PTAB rejecting CFDA’s IPRs under questionable reasoning,³²⁵ some have argued against the merit of CFAD’s challenges, stating that CFAD simply may not be submitting strong evidence to invalidate these pharmaceutical patents, which “suggests that CFAD may be less about making a strong case against the validity of the patents and more about the quick monetary gain of their ‘short activist strategy.’”³²⁶

There is also an inherent flaw in Kyle Bass’s strategy. A drug company defending against an IPR challenge still has the opportunity to appeal the final written decision to the Federal Circuit because there is an identifiable harm to its patent property.³²⁷ CFAD may not. For example, if one of CFAD’s IPR challenges reaches a final written decision, CFAD may be denied appellate review because CFAD “cannot identify any harm that it has suffered by losing the IPR,” and thus lacks standing to argue the case at the Federal Circuit.³²⁸

321. *Id.* PTAB instituted CFAD challenges 56% of the time while the overall institution rate for bio/pharma is at 61%. *Id.* In CFAD cases that reached a final written decision, 54% of the challenged claims were held unpatentable, compared to the overall invalidation rate of 39%. *Id.*

322. *Id.*

323. *Id.*

324. *Id.*

325. See Quinn, *supra* note 284; see also Bultman, *supra* note 319 (CFAD finding that PTAB demonstrated a “cynical attitude” in their decisions against instituting CFAD’s IPR petitions).

326. Neville, *supra* note 311.

327. See generally Mathew Bultman, *Fed. Cir. Overturns PTAB in 2nd-Ever AIA Reversal*, LAW 360 (Nov. 5, 2015, 6:57 PM), www.law360.com/ip/articles/723756 (reporting that the Federal Circuit disagreed with PTAB’s invalidation of only four patent claims, ruling on appeal that all six claims of Belden Inc.’s patent on a method for making a communications cable); see also Ryan Davis, *3 Takeaways from First-Ever Fed. Cir. AIA Reversal*, LAW 360 (June 19, 2015, 8:53 PM), www.law360.com/articles/670203/3-takeaways-from-first-ever-fed-circ-aia-reversal (reporting that the Federal Circuit reversed PTAB’s final written decision invalidating several claims of Proxyconn’s data access patent by way of prior art anticipation or obviousness because the Federal Circuit found that PTAB “relied on incorrect claim constructions and remanded for further proceedings.”).

328. Scott Kamholz, *Can Kyle Bass Appeal His IPR Loss? Not If Consumer Watchdog Is on the Prowl*, PTAB BLOG (Oct. 8, 2016), www.ptab-blog.com/2016/10/08/can-kyle-bass-appeal-his-ipr-loss-not-if-consumer-watchdog-is-on-the-prowl; see generally *Consumer Watchdog v. WARF*, 753 F.3d 1258, 1261 (Fed. Cir. 2014).

Finally, Kyle Bass is not reaching his stated goal of lowering drug prices for the public by helping generic drugs enter the market.³²⁹ The drug patents that CFAD did challenge and obtain a final written decision invalidating claims, like the Gattex patent, have multiple different patents covering it, and are thus robustly protected.³³⁰ Records indicate that of the drugs CFAD challenged that are protected by multiple different patents, CFAD only challenged “a subset” of those patents, putting into question whether they truly followed through with their goal helping generic drugs enter the market.³³¹

2. *IPRs and Reverse Payment Agreements Are Still an Issue for Hatch-Waxman*

Kyle Bass’s strategy has so far failed to help introduce generic drugs into the market place to lower healthcare costs, and it is unlikely that others will follow his model due to its lack of success.³³² But, IPR can still be an issue for the drug industry. Overall, ANDA litigation was created to provide a much simpler way to receive FDA drug approval by bypassing the cumbersome and lengthy requirements associated with filing a NDA.³³³ But IPR on paper (and possibly in practice), can do a better job. IPRs cost \$300,000 and may take up to eighteen months for a final written decision to be issued.³³⁴ Litigation to invalidate a patent through the federal court system may cost up to \$3 million and take years to complete.³³⁵ Further, under IPR, there is no Article III standing requirement or risk of infringement.³³⁶

Generic brands that are not the first to file may use IPR to challenge drug patents.³³⁷ Compared to filing an IPR petition, a generic company faces more risks when filing a paragraph IV ANDA application. Generally, a generic brand that loses a paragraph IV challenge can be faced with an injunction that would prevent it from introducing its generic drug into the

329. Bultman, *supra* note 319.

330. *Id.*

331. *Id.*

332. *Id.*

333. DORSNEY, *supra* note 42, at 17.

334. See Herman, *supra* note 225, at 1795 n.41. IPR, including attorney’s fees can cost anywhere from \$300,000 to \$1 million depending on the firm. *Id.* In contrast ANDA litigation in federal court on average, including attorney’s fees, can cost up to \$10 million. *Id.*

335. Ed Silverman, *Innovate or Else: Kyle Bass Strikes Again and Challenges Shire Patents*, WALL ST. J. BLOG PHARMALOT (Apr. 2, 2015, 5:15 PM), <http://blogs.wsj.com/pharmalot/2015/04/02/innovate-or-else-kyle-bass-strikes-again-and-challenges-shire-patents>.

336. Quinn, *supra* note 190 (discussing the drug industry lamenting IPR process and wanting drugs to be insulated from it because “the IPR provisions do not include a standing requirement, which means that anyone can bring an IPR for any reason.”).

337. Gurpreet Singh Walia, *Inter Partes Review as an Option as a Substitute for Hatch-Waxman Litigation*, INS. COUNS. (Nov. 7, 2014), www.insidecounsel.com/2014/11/07/inter-partes-review-an-option-as-a-substitute-for. “Petitioning for an IPR may be a very attractive route to potentially invalidate patent claims for generics” who were not first to file a paragraph IV ANDA and thus “do not have the 180-day market exclusivity incentive.” *Id.*

market until the NDA/patent expires.³³⁸ Under the right circumstances a trial court, in addition to granting an injunction, can award damages against a generic infringer “only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.”³³⁹ This scenario is called an “at risk” launch, which may result in a generic brand being “financially destroyed.”³⁴⁰

Under IPR, generic brands can initially avoid the ANDA risk by employing a dual-pronged attack strategy to take multiple shots at a drug patent.³⁴¹ While parties are estopped from bringing IPR final written decisions into district court and final district court judgments into PTAB, IPR institution decisions are not estopped from bringing those claims into district court.³⁴² So if a generic fails at getting an IPR instituted, it can take those claims into district court.³⁴³ Also, with IPR having more technically proficient judges, a generic may employ the strategy of filing its most complex arguments with PTAB, while filing its patentability and disclosure arguments in federal court.³⁴⁴ Finally, many questions remain as to whether an IPR final written decision can trigger the 180-day market exclusivity period or trigger the “failure to market” forfeiture provision.³⁴⁵

Despite Kyle Bass’s perceived failure, these IPR questions, IPR strategies, IPR statistics towards bio/pharma, and IPR overall, still have the drug industry concerned.³⁴⁶ The drug industry thinks IPR’s high bio/pharma patent invalidation rates are too high and that there needs to be more patent certainty.³⁴⁷ The “patent cliff” is real, as a brand name drug company drug “often loses more than 80 to 90% of the market within six months” of a patent’s expiration.³⁴⁸ Also, now that drug patents are subject to IPR, Hatch-Waxman, and antitrust scrutiny, drug patent investors may be scared off from investing in new drugs, which can shut down funding for scientists who may be on the verge of discovering life-changing medicine.³⁴⁹

338. DORSNEY, *supra* note 42, at 242; 35 U.S.C. § 271(e)(4)(B). See generally In re Omepirone Patent Litig., 536 F.3d 1361, 1367 (Fed. Cir. 2008).

339. 35 U.S.C. § 271(e)(4)(C).

340. DORSNEY, *supra* note 42 at 17.

341. Mauri, *supra* note 123.

342. *Id.*

343. *Id.*

344. *Id.*

345. *Id.* Under the forfeiture provision, a first file generic forfeits 180-exclusivity if it fails to market its generic drug within the time proscribed by statute. *Id.*

346. Aquino, *supra* note 278.

347. *Id.*

348. *New York v. Actavis PLC*, 787 F.3d 638, 647 (2d Cir. 2015).

349. Leanne Miller, *Biotech CEO: Bass Exploiting Weakness in System*, CNBC FAST MONEY (Sept. 19, 2015), www.cnbc.com/2015/09/19/biotech-ceo-bass-exploiting-weakness-in-system.html; see also Austin Frakt, *How Patent Law Can Block Even Lifesaving Drugs*, N.Y. TIMES (Sept. 28, 2015), www.nytimes.com/2015/09/29/upshot/how-patent-law-can-block-even-lifesaving-drugs.html?_r=0 (discussing the high cost of creating a new drug as well as issues in the drug industry that affect how companies avoid to create risk in the industry).

But IPR exemption is not the solution because it is estimated that “federal spending would increase by \$1.3 billion over 10 years because the exemption would delay” generic drug entry.³⁵⁰ Invalidating a pharmaceutical patent “would save the government money as the result of cheaper generics becoming immediately available on the market if a patent were to fall.”³⁵¹ USPTO believes that the IPR process is doing its job and that the high patent invalidity rates are a result of the previous patent law regime that “approved way too many ‘bad’ patents in the past that should never have made it out the door.”³⁵²

Reverse payment agreements are still an issue that places doubts on whether Hatch-Waxman can deliver generic drugs to market. As Senator Hatch, a co-sponsor of the Act stated, the Hatch-Waxman Act was not meant to “encourage” Reverse payment agreements where generic brands are paid “not to sell generic drugs and not to allow multi-source competition.”³⁵³ Brand names know that only the paragraph IV challenge matters because paragraphs I–III do not include any incentive, and thus “no one wants to pay for the patent litigation where the results will wind up benefitting many free riders that did not fund the litigation.”³⁵⁴ As a result, reverse payment agreements “reversed” the Hatch-Waxman incentive framework by targeting the first to file generic brands. Brand names were successful at delaying entry because “brand firms value deterring entry, on average, at \$4.6 billion . . . generic firms value the right to enter [with the 180-day market exclusivity] at \$236.8 million dollars.”³⁵⁵

In 2013, FTC reported consumers had to pay over \$3 billion in higher drug prices because of reverse payment agreements.³⁵⁶ Also, there are doubts as to whether the antitrust scrutiny from *Actavis* will have an impact on curbing these agreements. Post-*Actavis*, several district courts opinions upheld reverse payment agreements as lawful.³⁵⁷ Finally, there are doubts that the rule of reason analysis, as applied in *Actavis*, will be sufficient to police reverse payment agreements. In one study looking at over several hundred antitrust cases, focusing on rule of reason cases that were decided on the merits, courts sided with the defendant 96% of the time.³⁵⁸

350. Joseph Walker, *Drug Industry Rule Would Raise Medicare*, WALL ST. J. (Aug. 31, 2015, 7:20 PM), www.wsj.com/articles/drug-industry-bill-would-raise-medicare-costs-1441063248.

351. *Id.*

352. See Pitts, *supra* note 13.

353. 148 CONG. REC. S7566 (daily ed. July 30, 2002) (Statement of Se. Hatch).

354. Quinn, *supra* note 16.

355. Dennis Crouch, *Economics: Explaining Reverse Payments in ANDA Litigation*, PATENTLY-O (Oct. 28, 2014), <http://patentlyo.com/patent/2014/10/economics-explaining-litigation.html>.

356. U.S. FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), <http://ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

357. Thomas, *supra* note 27, at 10.

358. Michael A. Carrier, *The Rule of Reason: An Empirical Update for the 21st Century*, 16 GEO. MASON L. REV. 827, 829–30 (2009).

Considering the drug industries' qualms with PTAB's "Death Squad" reputation,³⁵⁹ and the continued issues with reverse payment agreements, there is a legitimate need to pass logical Hatch-Waxman reform to curb the high price of generic drugs while avoiding the plausible negative drug industry trends that can interrupt pharmaceutical innovation.³⁶⁰ Instead of asking for exemption, Big Pharma, generic brands, and consumers should seek comprehensive Hatch-Waxman reform.

IV. PROPOSAL

A compromise between Big Pharma and IPR supporters is the best way to preserve Congressional intent of the Hatch-Waxman Act. I propose an amendment to the Hatch-Waxman Act that will create a new regulatory regime in two parts. First, the IPR process and procedure should be integrated into the Hatch-Waxman Act as a new paragraph V challenge to invigorate and modernize the outdated Act, much like IPR invigorated the AIA. This new paragraph V challenge, which will be discussed below, will act as an alternative to paragraph IV challenges and provide incentives to complete ANDA adjudication. Furthermore, a separated administrative agency that solely focuses on pharmaceutical patents alone will need to be created. This new drug patent approval administration (DPAA) will work with the FDA and FTC and review and adjudicate all ANDA drug challenges to help alleviate the ANDA backlog that is plaguing the FDA, which can lead to an increase in lower-priced drugs for the public.³⁶¹

Second, the next part of the new Hatch-Waxman regulatory regime will be to add a new remedies section to the Act. This remedies section will not only allow the DPAA to police parties' behaviors, but it will also provide financial penalties for violators. Where PTAB is limited in its ability to investigate IPR abuse, the DPAA, under this newly proposed remedies section, will have the ability to examine the quality all pharmaceutical patent challenges. This remedy section will be further discussed below.

These amendments are purposely designed to combat the issues of reverse payment systems, penalties for Act violations, and provide a regulatory barrier between drug companies and antitrust scrutiny. However, before proceeding with a more detailed description of these new elements and how this new drug patent system will generally work,

359. See Pitts, *supra* note 13.

360. See Quinn, *supra* note 11.

361. Zachary Brennan, *What FDA Can and Can't Do to Help Lower Rising Drug Prices*, RAPS (Nov. 18, 2015), www.raps.org/Regulatory-Focus/News/2015/11/18/23635/What-FDA-Can-and-Can%E2%80%99t-Do-to-Help-Lower-Rising-Drug-Prices. "[The] FDA is having some issues addressing the gargantuan backlog of nearly 3,000 ANDAs and the median approval time for an ANDA has increased from about 30 months in 2011 to 48 months in 2014." *Id.*

an explanation for the inspiration of this new system is first described below.

*A. Amendment Inspiration: Verizon
Communications Inc. v. Law Offices of Curtis V. Trinko, LLP
and the Telecommunications Act of 1996*

In *Trinko*, a New York based telephone service customer (the “Customer”) sued Verizon Communications Inc. (Verizon), alleging that Verizon violated the Telecommunications Act of 1996³⁶² (1996 Act) and in turn violated section 2³⁶³ of the Sherman Antitrust Act.³⁶⁴ Before the filing and the resolution of this case, the New York Public Service Commission (PSC) and the Federal Communications Commission (FCC) investigated the alleged violation and ultimately imposed financial penalties on Verizon, among other available remedial measures under the 1996 Act.³⁶⁵ However, while these penalties were applied, the Customer continued with its complaint.³⁶⁶

Essentially, the Customer alleged that Verizon, as the “incumbent local exchange carrier” (also known as the “established network provider” in New York State), had a duty under the 1996 Act to share its network with other “new entrant” competitors, and breached this duty when it failed to meet these obligations.³⁶⁷ Specifically, this breach occurred because Verizon filled orders on a “discriminatory basis as part of an anticompetitive scheme to discourage customers from becoming or remaining customers of [competitors] in violation of § 2 of the Sherman Act.”³⁶⁸ Without access to Verizon’s network, a competitor cannot fill its customers’ orders, and Verizon devised this anticompetitive scheme to prevent its own customers from switching to other carriers or deter potential customers from choosing its competitors.³⁶⁹

The District Court for the Southern District of New York dismissed the complaint, finding that the Customer’s allegations of “deficient assistance to rivals failed to satisfy § 2’s requirements.”³⁷⁰ The Second Circuit reversed and reinstated the Customer’s complaint.³⁷¹ Upon grant of certiorari, the Supreme Court reversed and remanded the Second Circuit’s ruling, concluding that the Customer’s complaint that Verizon’s

362. 47 U.S.C. § 251 (2017).

363. 15 U.S.C. § 2 (2017).

364. *Verizon Communs., Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 402–05 (2004).

365. *Id.* at 403–04 (“Verizon undertook to make a ‘voluntary contribution’ to the U.S. Treasury in the amount of \$3 million; under the PSC orders, Verizon incurred liability to the competitive LECs in the amount of \$10 million.” (citations omitted)).

366. *Id.* at 404. The Customer filed a complaint on behalf of a class of similar customers in the District Court of the Southern District of New York. *Id.*

367. *Id.* at 404–05; 47 U.S.C. § 251(c).

368. *Id.* at 404.

369. *Id.* at 405.

370. *Id.*

371. *Id.*

breach of its duty to share under the 1996 Act did not constitute a recognizable cause of action under section 2 of the Sherman Act.³⁷²

The *Trinko* decision describes several important principles that are especially important to structuring this comment's proposal to amend the Hatch-Waxman Act. First, of important note, is the regulatory scheme of the 1996 Act. The 1996 Act, which applies to local incumbent multibillion-dollar telecommunication networks like Verizon and AT&T,³⁷³ established a "complex regime for monitoring and enforcement" that imposes sharing duties on incumbent local telecommunication companies to give its competitors a fair opportunity to compete in that market.³⁷⁴ The court recognized that the 1996 Act made sharing compulsory between "rivals and at considerable expense and effort."³⁷⁵ This was supported by the fact that "[n]ew systems must be designed and implemented simply to make that access possible . . ."³⁷⁶

Moreover, this also relates to an important aspect of the Court's decision concerning whether there is a duty to deal or compete. Specifically, the Court found that, absent the duties imposed by the 1996 Act, antitrust law did not impose on competitors a duty to deal or impose Sherman section 2 liabilities on competitors who refused to deal with each other.³⁷⁷

Finally, the last aspect of *Trinko* that is important to this comment's Proposal is the Court's recognition of the 1996 Act's regulatory scheme. More exactly, the Act did not utterly preclude antitrust scrutiny,³⁷⁸ but simply asserted that alleged injured parties can pursue remedies available under the Act before filing antitrust claims in federal court.³⁷⁹

The existence of a regulatory structure was important to the Court:

One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such structure exists, the additional benefit to competition provided by antitrust

372. *Id.* at 414–16.

373. See generally Liyan Chen, *The World's Largest Telecom Companies: China Mobile Beats Verizon, AT&T Again*, FORBES (June 1, 2015), www.forbes.com/sites/liyanchen/2015/06/01/the-worlds-largest-telecom-companies-china-mobile-beats-verizon-att-again/#fe5658a4df4d (showing that China Mobile's market value is estimated at \$250 billion compared to Verizon \$206.2 billion and AT&T at \$234.2 billion).

374. *Trinko*, 540 U.S. at 401.

375. *Id.* at 410.

376. *Id.*

377. *Id.* at 408; *but cf.* *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985) (ruling, under limited circumstances, competitors who refuse to cooperate with each other can be subject to antitrust liability).

378. See 47 U.S.C. § 601(b)(1) (2017); *but cf.* *Trinko*, 540 U.S. at 406. "In some respects the enforcement scheme set up by the 1996 Act is a good candidate for implication of antitrust immunity, to avoid the real possibility of judgments conflicting with the agency's regulatory scheme 'that might be voiced by courts exercising jurisdiction under the antitrust laws.'" *Id.* (citing *United States v. Nat'l Ass'n of Sec. Dealers, Inc.*, 422 U.S. 694, 734 (1975)). While the 1996 Act did not preclude antitrust scrutiny, it did not impose new antitrust standards on litigating parties. *Id.* at 407.

379. *Trinko*, 540 U.S. at 406; 47 U.S.C. § 152 (2017).

enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.³⁸⁰

Under the 1996 Act, Verizon was already subject to FCC and PSC oversight, and both agencies effectively responded to Verizon's violations under the Act by imposing fines and other burdens on it.³⁸¹ As the Court concluded, the 1996 Act presented a complex regulatory scheme that employed stricter anticompetitive regulation, much more than what antitrust law provided, in preventing the formation of anticompetitive monopolies.³⁸² This demonstrated that the 1996 Act's regulatory regime was more suited to deal with anticompetitive issues and violations made by the parties involved in this particular telecommunication industry.³⁸³

Implementation of these principles learned from *Trinko* and the 1996 Act through a Hatch-Waxman amendment will become clearer in the following section.

B. Creating a New Paragraph V Challenge to Re-incentivize the Hatch-Waxman Act

Prior to the passing of the Hatch-Waxman Act, Congress concluded "that the [Federal Food, Drug, and Cosmetic Act] was cumbersome to the drug approval process and delayed the entry of relatively inexpensive generic drugs into the market place."³⁸⁴ Now, reverse payment agreements have caused the Hatch-Waxman Act to become the most cumbersome problem for low-cost generic drug entry.³⁸⁵ As some patent experts have asserted, Hatch-Waxman has been a "failure" and "is not the answer" in ensuring quick generic drug market entry.³⁸⁶ In contrast, there are several advantages to IPR that make it "undeniably far more effective at achieving the stated goal of Hatch-Waxman."³⁸⁷

As aforementioned,³⁸⁸ one of the main concerns that reverse payment agreements present is that these agreements may protect invalid patents, which could result in artificially high drug prices.³⁸⁹ Remember, when a paragraph IV challenge is made, the challenger asserts either that their generic drug does not infringe or that the

380. *Trinko*, 540 U.S. at 412.

381. *Id.* at 412–13.

382. *Id.* at 412, 416. "The regulatory framework that exists in this case demonstrates how, in certain circumstances, regulation significantly diminishes the likelihood of major antitrust harm . . . [t]he 1996 Act is in an important respect much more ambitious than the antitrust laws." *Id.*

383. *Id.*

384. Construction and Application of Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C.A. § 355 and 35 U.S.C.A. § 271(e) (1994)), 180 A.L.R. Fed. 487, 2a.

385. See *supra* Part II.C. and Part III.D.2.

386. Quinn, *supra* note 16.f

387. *Id.*

388. See *supra* Part II.C.

389. *Actavis*, 133 S. Ct. at 2230–31.

patented drug is actually invalid.³⁹⁰ Because the reverse payment agreement halts the ANDA litigation before its completion, the determination of that drug patent's validity remains unresolved in perpetuity.³⁹¹ Reverse payment agreements also created a problem called "exclusivity parking" where the generic brand that was first to file refrained from entering the market as a result of the reverse payment, thereby making other generic brands wait until 180-day exclusivity ended.³⁹²

To solve this problem, several ideas have been implemented or proposed to fix the incentive system within the Hatch-Waxman Act so that adjudication of a patent's validity is completed. First, Congress tried to rectify the problem by creating a failure-to-market provision for the generic brand that is the first to file an ANDA.³⁹³ Essentially, the failure-to-market provision dictates that a generic brand can forfeit the 180-day exclusivity right "in one of the ways specified by statute."³⁹⁴ One of the ways that can "trigger" the forfeiture provision is if a subsequent paragraph IV filer sees the patent validity litigation to its completion.³⁹⁵ The provisions would force a first filer to either choose to market their generic drug within 75 days or lose its 180-day exclusivity.³⁹⁶ However, this provision failed because the poorly drafted language "leaves a pioneer and first filer almost completely in control and able to thwart Congress's goals."³⁹⁷

As a solution to the forfeiture provision's ineffectiveness, two comments, one by Brian T. Apel and the other by Jaimin Shah, agree that a statutory amendment to the Hatch-Waxman should be made to allow IPR challenges of drug patents to trigger the forfeiture provision, effectively using the quick adjudicating procedures of IPR to force generic first filers to choose to market a generic drug or forfeit the 180-day exclusivity and allow other generic brands to enter the market.³⁹⁸ For clarity, my comment's purpose and proposal do not seek to argue against these solutions. It presents them merely to distinguish what this comment is trying to accomplish in preventing the harm caused by anticompetitive reverse payment agreements, which is to completely overhaul the Hatch-Waxman system.

The first part of overhauling the system is to create a brand-new paragraph V challenge. Essentially, IPR will no longer apply to drug patents and USPTO will not have jurisdiction over drug patent challenges.

390. *Id.* at 2228 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

391. *Id.* at 2231.

392. Apel, *supra* note 201, at 109.

393. See 21 U.S.C. § 355(j)(5)(D) (2016).

394. *Actavis*, 133 S. Ct. at 2229 (citing 21 U.S.C. § 355(j)(5)(D)).

395. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2016). Congress rejected an amendment that would have changed the award of the 180-day exclusivity period to the first successful challenger instead of the first to file. Apel, *supra* note 201, at 114 n.85.

396. See 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2016).

397. See Apel, *supra* note 201, at 120. For a more detailed discussion of how the failure to market provision failed to curb exclusivity parking, see Apel, *supra* note 201, at 120–23.

398. *Id.* at 124, 132; Shah, *supra* note 201, at 469–74.

That will fall on the newly created DPAA, the agency that will also work both with the FDA and FTC to monitor ANDA litigation and antitrust enforcement, respectively. The DPAA would handle paragraph IV and V challenges, but mirror the procedures as if they were brought in federal court and an administrative court. Hence, paragraph V will mirror IPR in almost every way,³⁹⁹ and as in the Apel and Shah comments, language in the Act will allow paragraph V to trigger the forfeiture provision against a first filer. However, my proposal goes a step further in providing greater incentives to parties to successfully complete litigation. Frankly, this proposal's goal is to do for the Hatch-Waxman Act what the AIA did for patent law with IPR.

First, paragraph V will be available to a first to file or the next subsequent filer and grant the party who succeeds in invalidating a drug patent, a period of exclusivity of forty-five to ninety days or less.⁴⁰⁰ An exclusivity period is probably one of the most ingenious ways to incentivize parties to litigate, creating a prize at the end of the litigating road.⁴⁰¹ Paragraphs I–III are considered useless word fillers in the Hatch-Waxman Act because generic drug companies that are not the first to file do not gain that 180-day incentive to challenge a drug patent.⁴⁰² By creating a brand new paragraph V challenge that mirrors IPR, generic drug companies can take advantage of a system is at a relatively low cost, quickly decided, and does not subject them to infringement claims. The paragraph V challenge would reflect a lower exclusivity period, because one can pay more and taker higher risk under paragraph IV challenge to get the longer and more financially beneficial 180-day market exclusivity.

Although I would retain paragraph IV's first to file system, the exclusivity period awarded under a paragraph V challenge would go to the first successful filer.⁴⁰³ This creates an added risk that the exclusivity can pass on to another paragraph V challenger who does not settle.⁴⁰⁴ Also, it forces any brand name that wants to enter into an agreement to consider having to "buy off" too many challengers, a consequence that the Court found was lacking in the present form of the Act.⁴⁰⁵ Any generic can

399. Paragraph V will not have an institution review like IPR does under the AIA. See 35 U.S.C. § 314.

400. I started with an exclusivity period that is half of what a first filer would get under a paragraph IV challenge, but it could be less. The idea is to have some kind of number that would appropriately reflect the risk in challenging a drug patent.

401. The exclusivity period can potentially make 60% to 80% of a generic brand's potential profit. See Apel, *supra* note 201, at 113 n.57.

402. *Id.* (without IPR, "no [generic drug company] wants to pay for the [paragraph I–III certifications] where the results will wind up benefitting many free riders that did not fund the litigation.").

403. Taking from what Sen. Hatch suggested under certain drafts of the MMA. See *supra* note 394. With the aforementioned forfeiture provision, I would suggest that paragraph V challenges could end the FDA's thirty-month stay when a paragraph IV challenge is successful.

404. DORSNEY, *supra* note 42, at 17.

405. *Actavis*, 133 S. Ct. at 2235 (finding that two special features of Hatch-Waxman prevent a brand name from having to pay off multiple challengers: (1) only the first challenger gains the 180-day market exclusivity, and (2) a subsequent paragraph IV filer

choose to start with either a paragraph IV or V challenge. While there is only one first to file under paragraph IV, paragraph V may still be available if there is no successful challenge.

A lack of Article III standing is one of the benefits of IPR, which allows any third party that is not a drug company to challenge.⁴⁰⁶ This option will still be available in paragraph V, albeit with a caveat. Any party that is not a drug company, which files a paragraph V, must do so in tandem (via joinder) with a generic brand. Hence, a third party non-generic could foot the bill, and a participating generic, added as a co-party, would receive the benefit of the exclusivity period upon the challenge's completion. This also addresses the issue that non-generic entities or parties, like CFAD, would face when they are denied appellate review of a PTAB IPR final written decision because they lack an identifiable injury to stand in the Federal Circuit.⁴⁰⁷

Settlements, in the form of reverse payment agreements, will still be allowed under the new regime, and may occur between brand names and generic brands that either file a paragraph IV or paragraph V challenge. Although there is "a general legal policy favoring the settlement of disputes," the Supreme Court recognized that reverse payment agreements are an "unusual" form of settlement.⁴⁰⁸ In fact, the Court cited *Trinko* finding that competitors that come together and agree not compete appears like some type of collusion.⁴⁰⁹ But, the Court did not find reverse payment agreements to be per se or presumptively illegal, finding that the "anticompetitive consequences" of a reverse payment agreement are not always "unjustified."⁴¹⁰ In fact, some have argued that reverse payment agreements can be pro-competitive.⁴¹¹ The Court even indicated five guidelines to help courts determine the legality of a reverse payment agreement.⁴¹² However, I propose an additional consideration, or a duty required under the Hatch-Waxman Act.

will have to wait the statutory directed thirty-month stay period, "removing the most motivated challenger and the one closest to introducing competition.").

406. See *supra* Part II.B.2.

407. See *Phigenix, Inc. v. ImmunoGen, Inc.*, No. 2016-1544 (Fed. Cir. Jan. 9, 2017) (dismissing appellants case for lack of standing and stating that the right to appeal a PTAB final written decision does not give Article III standing); see generally *Spokeo, Inc., v. Robins*, 136 S. Ct. 1540, 1547 (2016); see *Kamholz, supra* note 328. "Probably the only way out of this problem would be for the no-standing petitioner to achieve joinder with a party having standing and then to backseat-drive the joint appeal." *Id.*

408. *Actavis*, 133 S. Ct. at 2231, 2234.

409. *Id.* at 2233.

410. *Id.* at 2235-37.

411. See generally Andrew E. Podgorny, Note, *Supporting the Rationale Behind the Hatch-Waxman Act and Patent Law: How Reverse Payment Settlements under FTC v. Actavis Can Be Procompetitive*, 12 IND. HEALTH L. REV. 423, 455 (2015) (stating that a payment may be justified if it helps a generic brands to develop other drugs to benefit the public); *Compton, supra* note 194, at 396-97 (finding that ANDA success rates for generic brands hover at 48% in contrast to 67% of the generic brands that enter the market due to terms of reverse payment agreements that allow them to enter before the patent expires).

412. *Actavis*, 133 S. Ct. at 2234-37.

Under this new Hatch-Waxman regime, I propose that new language in the Act should be included to require a limitation on the number or frequency of reverse payment agreements that are allowable for a particular patented drug. This shall be known as the “limited right to settle” provision. This is not a difficult feat to accomplish. The Court in *Trinko* recognized that the 1996 Act imposed a sharing requirement between competitors, and penalties were assessed to parties who breached this duty.⁴¹³ The “limited right to settle” would have the opposite effect, limiting the interactions between brand name and generic brands, decreasing the opportunities where these agreements may “facilitate the supreme evil of antitrust: collusion.”⁴¹⁴

One helpful gauge to determine when this “limited right to settle” would end is to look at a brand name’s investment in a challenged patented drug. For example, one pro-competitive benefit that may arise from a reverse payment agreement is when a settlement secures profits for a brand name and allows it to recoup NDA and patent expenditures.⁴¹⁵ This allows the brand name to funnel those profits into research and development costs to further pharmaceutical innovation.⁴¹⁶ Thus, a “limited right to settle” may end when a brand name recoups its investment in the drug it developed. This should help quell the fear that exposure to multiple forms of patent invalidation or general liability under IPR, ANDA, and antitrust law will deter current and potential drug industry investors, which will lead to less money for research, development, and drug innovation.⁴¹⁷

The proposal section of this comment favors bringing generic drugs to market. Amending the Hatch-Waxman Act with these changes can aid in bringing the intended purpose of Hatch-Waxman back to its prominent role: facilitating the entry of low-cost generic drugs to market. But this proposal does reflect a compromise. The following section will describe how the DPAA, will enforce the new aforementioned provisions and the new remedial scheme that is designed to benefit the pharmaceutical industry.

C. USPTO Rule and the Telecommunication Act Remedial Framework Can Be a Model to Create an Effective Remedy Section for the Hatch-Waxman Act

Prior to *Actavis*, it was posited that the principles of *Trinko* and the 1996 Act’s regulatory scheme could be applied to Hatch-Waxman’s reverse payment agreement problem.⁴¹⁸ Professor Michael A. Carrier

413. *Trinko*, 540 U.S. at 412–13 (citing 47 U.S.C. § 271(d)(6)(A) (2016)).

414. *Id.* at 408.

415. Compton, *supra* note 194, at 393–95.

416. *Id.*

417. *Id.* at 399–401.

418. See Michael A. Carrier, Review, *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law: Innovation for the 21st Century: A Response to Seven Critics*, 61 ALA. L. REV. 597, 614–15 (2010); see generally Shashank Upadhye and

noted that there was some doubt as to whether the U.S. Supreme Court would apply these principles, or if the financial penalties were severe enough to sway regime violators.⁴¹⁹ However, my proposal differs in the following key aspect: while the above scholar asserted that courts should “direct some inquiry to the effectiveness of the regulatory regime” in whether antitrust scrutiny should apply to reverse payment agreements, I suggest amending the Hatch-Waxman Act to include a new remedy scheme to the Act, not unlike the remedies found in the 1996 Act, to financially punish violators who use reverse payment agreements to undermine Hatch-Waxman’s purpose.

The argument of whether financial penalties or the use of remedial measures on multi-billion-dollar drug companies is enough to curb illegal reverse payment agreements is valid. However, the Court in *Trinko* pointed to the fact that the 1996 Act created a duty that was not only already expensive for incumbents on the forced sharing level, but which cost added up when incumbents breached that duty.⁴²⁰

There is nothing that forces litigants, under the Hatch-Waxman Act, to undergo a reverse payment settlement. The “limited right to settle” implemented by my proposal in the previous section is just an assurance that the number of settlements between brand names and generics do not violate the pro-competitive purpose of the Hatch-Waxman Act. But that provision, coupled with the looming prospect of financial loss by forgoing market exclusivity granted by a paragraph IV or paragraph V challenge, in addition to financial penalties⁴²¹ under the Act, may be sufficient to preserve Hatch-Waxman’s purpose. Hence, the combination of a new remedial scheme that still exposes violators to possible antitrust scrutiny, in addition to implementing new incentives, can be enough to incentivize brand name drug companies or “first filers to refrain from entering into [illegal] [reverse payment] settlement[s] in the first instance.”⁴²²

While Professor Rebecca S. Eisenberg and Dean Daniel L. Crane suggest that the FDA should take on the responsibility of adjudicating pharmaceutical patent approval and generic drug market entry because of their familiarity and more technical expertise in the subject matter,⁴²³

Braden Lang, Article, *The FDA and Patent, Antitrust, and Property Takings Laws: Strange Bedfellows Useful to Unblock Access to Blocked Drugs*, 20 B.U. J. SCI. & TECH. L. 84, 88, 100–08 (using the essential facilities doctrine described in *Trinko* to prevent delays in the generic drug market caused by Risk Evaluation & Mitigation Strategies).

419. *Id.*

420. *Trinko*, 540 U.S. at 414. “*Amici* States have filed a brief asserting that competitive LECs are threatened with ‘death by a thousand cuts. . .’” *Id.*

421. See Part IV.A. and see *Trinko*, 540 U.S. at 403–04 (“Verizon undertook to make a ‘voluntary contribution’ to the U.S. Treasury in the amount of \$3 million; under the PSC orders, Verizon incurred liability to the competitive LECs in the amount of \$10 million.” (citations omitted)).

422. Shah, *supra* note 201, at 463.

423. See generally Rebecca S. Eisenberg and Daniel L. Crane, Article, *Patent Punting: How FDA and Antitrust Courts Undermine the Hatch-Waxman Act to Avoid Dealing with Patents*, 21 MICH. TELECOMM. TECH. L. REV. 197 (2015) (“With proper staffing and resources, FDA could use its expertise in drug regulation to make rough assessments of the relationship between particular patents and the scope of FDA approval in NDAs and ANDAs quickly and cheaply,

I propose a new agency, the DPAA, should be created to manage this new Hatch-Waxman Regulatory Regime. This agency will take on the responsibility and work with the FDA during paragraph IV or newly created paragraph V challenges. The DPAA will also work with FTC, DOJ, and state antitrust agencies to monitor the legality of reverse payment agreements and institute financial penalties provided under the Act, or pursue further antitrust liability if necessary.

Because Kyle Bass and his “short activist strategy” helped inspire the creation of this proposed new Hatch-Waxman system, it is only fitting that his strategy undergo scrutiny under the Act. The amendment to the Act itself could include a provision that makes Kyle Bass’s strategy illegal under the Act, or a provision could create a section that allows the DPAA to scrutinize challengers’ actions under the Act. This essentially would be a “check” on the use of paragraph V challenges. Because paragraph V mirrors IPR, the DPAA can have that ability to check its implementation.

The AIA grants USPTO broad authority to prescribe regulations over the entire USPTO and its proceedings:

The America Invents Act grants the USPTO a dizzying array of new powers, including powers to set forth standards and procedures for the institution of its proceedings, to set forth standards and procedures for discovery of relevant evidence, to specify when parties may amend or supplement their patents, to prescribe sanctions for abuses in discovery, and to define certain ambiguous terms.⁴²⁴

Like USPTO’s power under the AIA, I propose similar language that would allow the DPAA to create the proper procedures and regulatory standards needed to conform to the pharmaceutical industry, using the 1996 Act an example. Additionally, the AIA granted “USPTO broad regulatory authority to create and improve” post-patent issuance review proceedings such as IPR.⁴²⁵ Thus, regarding paragraph V proceedings, the DPAA would be given the power to proscribe regulations or “sanctions for abuse of discovery, abuse of process, or any other improper use of the proceeding, such as to harass or to cause unnecessary delay or an unnecessary increase in the cost of the proceeding.”⁴²⁶ These remedies should be sufficient to punish any Act violator.

Creating a new regulatory scheme although, complicated on its own, is nothing if cannot be accepted and implemented by the parties who will participate in this new scheme. My Argument for why the pharmaceutical industry would agree to and participate in this new Hatch-Waxman regulatory scheme is described below.

while leaving patent infringement remedies intact.”).

424. See Tran, *supra* note 90, at 611.

425. See generally Michelle K. Lee, *PTAB Update: Proposed Changes to Rules Governing PTAB Trial Proceedings*, DIRECTOR’S FORUM: A BLOG FROM USPTO’S LEADERSHIP (Aug. 19, 2015), www.uspto.gov/blog/director/entry/ptab_update_proposed_changes_to.

426. 35 U.S.C. § 316(a)(6).

D. Why Should Big Pharma Accept This Hatch-Waxman Amendment?

The first reason is obvious. These amendments to the Hatch-Waxman Act allow the Act to remain faithful to its original purpose of providing low-cost generic drugs to the public.⁴²⁷ An FTC report from 2010 estimated that reverse payment agreements resulted in over \$3 billion in higher prescription drug prices for Americans.⁴²⁸ Similar to the purpose of the 1996 Act, these proposed new amendments to the Hatch-Waxman Act are meant to “uproot” the anticompetitive harm reverse payment agreements have on healthcare.⁴²⁹

While recent talk from the new White House administration is focused on overhauling or streamlining “FDA operations to speed up approval decisions on new drugs and medical products[,]”⁴³⁰ this ideally would materialize more quickly by creating a new regulatory scheme that is directed by a new administrative agency. That new drug agency would then work with the drug industry, the FDA, and FTC on delivering low-cost generic drugs to the public. In 2015, the FDA reported a backlog of approximately three thousand ANDA applications, and approval time that went from thirty months in 2011, to forty-eight months in 2014.⁴³¹ Creating a new agency that that focuses on alleviating ANDA backlogs that results in lower cost drugs will further Hatch-Waxman’s purpose.

Also, the formation of a new system that can result in lower drug prices can be an important step in repairing the drug industry’s poor reputation of being profit-mongers, rather an industry that is focused on improving people’s lives.⁴³²

The second reason is that the newly amended Hatch-Waxman Act would create a new regulatory regime that is exclusive to the pharmaceutical industry. After Kyle Bass announced and implemented his “short activist strategy,” the drug industry complained that IPR was being used for an unintended purpose, and because it was already subject to the Hatch-Waxman Act, that it should be exempt from the IPR process altogether.⁴³³ But drug industry exemption from IPR without change in the Hatch-Waxman scheme can be costly because “federal spending

427. See *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1360 (Fed. Cir. 2010) (finding that the Hatch-Waxman Act was meant to facilitate the “efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term.”) (citing *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)), *rev’d on other grounds*, 2012 U.S. LEXIS 3106 (U.S. Apr. 17, 2012) (No. 10-844).

428. U.S. FED. TRADE COMM’N, *supra* note 356.

429. *Trinko*, 540 U.S. at 402.

430. Jill Wechsler, *Does Pharma Really Want to Overhaul FDA?*, PHARMEXEC.COM (Feb. 10, 2017), www.pharmexec.com/does-pharma-really-want-overhaul-fda-1. More recent statistics indicate that the backlog has decreased to 2,358, but this may be a result of a decrease in ANDA filings in the past year.

431. Brennan, *supra* note 361.

432. See Silverman, *supra* note 26 (“[A] new Harris Poll reported that only 9 percent of Americans believe drug makers place more value on patients than profits.”).

433. Rumore, *supra* note 30.

would increase by \$1.3 billion over 10 years because the exemption would delay” generic drugs that are 90% cheaper than brand-name drugs.⁴³⁴ Under my proposal, IPR would not be applied to the drug industry, but would live on as a more agency-controlled and drug industry-directed paragraph V challenge.⁴³⁵ Further, the remedies available under the Act should quell the drug industries’ concern about the unintended consequences of drug patent challenges, or Congress may simply choose to prohibit drug patent challengers from also employing Kyle Bass’s “short activist” strategy.⁴³⁶

The final major reason Big Pharma should advocate for these Hatch-Waxman changes is because of the major benefits that a self-governing regulatory regime would have on the drug industry. Specifically, the lesson learned from *Trinko* is that having a complex and intricate regime, like the 1996 Act, creates an island-type presence for the drug industry that also has several barriers that protect it from liability, or more specifically, direct antitrust scrutiny.⁴³⁷ In *Trinko*, the Supreme Court was reluctant to impose a “new layer of interminable litigation” to the telecommunication industry because of the complexity of the 1996 Act’s framework and also because of the available remedies under the Act.⁴³⁸ Because the newly proposed DPAA would be in charge of the new Hatch-Waxman regime, working with the FDA and FTC, courts would be reluctant to review claims or impose legal sanctions on parties that are already seeking remedies through the Act.

Prior to *Actavis*, Congress, through amendment, attempted but failed to create a counteractive provision that would cause generic brands to forfeit the 180-day exclusivity period for participating in illegal reverse payment agreement under antitrust law.⁴³⁹ In *Actavis*, the U.S. Supreme Court subjected reverse payment agreements to antitrust scrutiny,⁴⁴⁰ and although Congress could impose antitrust immunity,⁴⁴¹ this immunity would not serve the purpose of this comment’s proposal. This proposal’s amendment to the Hatch-Waxman Act employs the presence of potential judicial review to act as a looming specter for violators of the Act, or in cases in which the Act’s remedies have been exhausted.⁴⁴² But, in focusing on what this proposal is trying to accomplish, the goal is to create a “regulatory framework” that does would not need judicial enforcement

434. *Id.*

435. *See supra* Part IV.B.

436. *See supra* Part IV.C.

437. *Trinko*, 540 U.S. at 413.

438. *Id.*

439. *See Apel, supra* note 201 at 116–20 (describing how the antitrust provision is ineffective at curbing exclusivity parking).

440. 133 S. Ct. at 2237–38.

441. *See Trinko*, 540 U.S. at 406–07. In *Trinko*, the Supreme Court determined that Congress precluded antitrust immunity under section 601(b)(1) of the 1996 Act.

442. My proposal to amend the Hatch-Waxman Act would also include the “antitrust-specific saving clause language” of section 601(b)(1) of the 1996 Act that states that “nothing in this Act or the amendments made by this Act shall be construed to modify, impair, or supersede the applicability of any of the antitrust laws.”

because it functions as a “regulation [that] significantly diminishes the likelihood of major antitrust harm.”⁴⁴³ Also, because of this proposal’s creation of a new regulatory agency in the DPAA and a statutorily imposed “limited right to settle,”⁴⁴⁴ courts would be less apt to intervene because the proposed amendments would shield them from having to insert themselves as “central planners,” a role they have sought to avoid.⁴⁴⁵

Finally, under the doctrine of exhaustion of administrative remedies, the U.S. Supreme Court has directed parties to exhaust administrative remedies or remedies available by statute before pursuing judicial review.⁴⁴⁶ The goal would be for the newly created DPAA, supported by express language in the amended Act, to take on that administrative role, and to impose and enforce the appropriate remedies under the Act, which would need to be exhausted before there is any opportunity for judicial review.⁴⁴⁷

This new drug industry regulatory regime is designed to balance the needs and goals of both drug companies and the public. This proposed new regime’s design intends to protect pharmaceutical innovation by instilling confidence in investors, while serving the public by expeditiously introducing low-cost generic drugs to consumers. Because of the aforementioned reasons, the drug industry should support the presented proposal to amend the Hatch-Waxman Act.

V. CONCLUSION

Enacting legislation that excuses Big Pharma from IPR proceedings is premature and misguided. Kyle Bass and his “short activist” strategy, while innovative, did nothing but expose prominent issues regarding the

443. *Trinko*, 540 U.S. at 412 (quoting *Concord v. Bos. Edison Co.*, 915 F.2d 17, 25 (1st Cir. 1990)). Further, the Court indicated that it was of particular importance that there existed “a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.” *Id.* at 411.

444. *See supra* Part IV.B. Essentially the “limited right to settle” would be enforced by the DPAA to regulate the frequency and determine the legality reverse payment agreements. *Id.*

445. *Trinko*, 540 U.S. at 408. In *Trinko*, the Court was concerned that should they apply Sherman § 2 principles to enforce the 1996 Act’s sharing requirements, this application would cause them to be “central planners” and essentially have them “identify[] the proper price, quantity, and other terms of dealing—a role for which they are ill suited.” *Id.*

446. *See Reiter v. Cooper*, 507 U.S. 258, 269 (1993). “Where relief is available from an administrative agency, the plaintiff is ordinarily required to pursue that avenue of redress before proceeding to the courts; and until that recourse is exhausted, suit is premature and must be dismissed.” *Id.*; *see generally* *Seminole Tribe v. Fla.*, 517 U.S. 44, 74 (1996) “Where Congress has created a remedial scheme for the enforcement of a particular federal right, we have, in suits against federal officers, refused to supplement that scheme with one created by the judiciary.” *Id.*

447. In *Trinko*, the Supreme Court aptly stated: “careful account must be taken of the pervasive federal and state regulation characteristic of the industry.” *Trinko*, 540 U.S. at 411 (quoting *United States v. Citizens & Southern Nat. Bank*, 422 U.S. 86, 91 (1975)).

current Hatch-Waxman Act. Hatch-Waxman's original value lied with providing the proper incentives for generic companies to compete with brand name companies. But reverse payment agreements diminished those incentives. Congress has tried to revitalize those incentives to no avail, and the U.S. Supreme Court made reverse payment agreements subject to antitrust scrutiny.

Instead, Big Pharma should work with Congress to thoroughly amend the Hatch-Waxman Act to not only implement new incentives, but also create a new regulatory scheme for the drug industry. Although IPR itself would not be directed at the drug industry, the spirit of IPR, under the guise of a brand-new paragraph V challenge, will help re-incentivize generic brands to file ANDAs and see them to completion. Although settlements under the Act will not be discouraged, a new regulatory agency created under the amended Act, the DPAA, armed with new language that creates a "limited right to settle," creates a remedial scheme that not only regulates reverse payment agreements, but also allows it to discipline parties for violations under the Act. Additionally, Congress, if it so chooses, may prohibit those parties who file drug patent challenges from employing the Kyle Bass "short activist strategy", or at least create language in the Act that gives the DPAA the power and discretion to penalize parties who try and file meritless lawsuits employing Bass's shorting strategy.

This proposal's amendment to the Hatch-Waxman Act is a logical compromise. It is a compromise that would create a complex administrative regulatory framework that protects the drug industries' financial investments from direct judicial scrutiny, while serving the important purpose of ensuring that low-cost generic drugs are available to consumers to alleviate nationwide healthcare costs.

