COMMENT

HEDGE FUNDS SHOULD BE ABLE TO CHALLENGE PATENT VALIDITY USING INTER PARTES REVIEW DESPITE MIXED MOTIVES*

ABSTRACT

On February 10 and February 27, 2014, The Coalition for Affordable Drugs ("CFAD") filed petitions with the United States Patent and Trademark Office ("USPTO") challenging the validity of two patents covering Ampyra, a prescription drug that improves multiple sclerosis patients' ability to walk. Acorda Therapeutics, which owns the two patents, watched its stock drop 9.7% on February 10 and 4.8% on February 27 in reaction to news of CFAD's patent challenges. The patent challenge and ensuing stock drop comprise the initial steps of a new investment strategy developed by hedge fund manager Kyle Bass. Mr. Bass created CFAD to search for potentially invalid patents and file petitions requesting the USPTO to reassess the validity of these patents in an administrative process called inter partes review ("IPR").

CFAD states it is targeting patents that lack social value. The USPTO should have never issued the targeted patents in the first place because the patents fail to disclose anything novel and accomplish little more than keeping drug prices artificially high. However, CFAD's motives for challenging drug patents are not purely altruistic. It stands to make a profit by shorting the shares of companies holding the challenged patents and taking a long position on the shares of companies who stand to benefit from the challenged

* J.D. Candidate, University of Houston Law Center, 2017; M.S. Biomedical Engineering 2010, Tulane University; B.S. Biomedical Engineering 2008, University of Virginia. This Comment received the Heim, Payne & Chorush LLP Award for Best Overall Paper. I would like to thank the members and editors of the *Houston Law Review* for their careful editing and Rhett Carter for his love and endless support.

patent's invalidation. Opponents accuse CFAD of exploiting loopholes in the patent system and manipulating financial markets primarily for profit at the expense of biotechnological innovation. Critics urge the USPTO and Congress to amend laws or introduce new laws to prevent CFAD and other financial opportunists from challenging patents.

This Comment uncovers the merits of the biotechnology sector and CFAD's arguments, ultimately concluding that Congress should not create any legal barriers that would prevent hedge funds from challenging the validity of biotechnology patents. It is important for third parties who represent the interests of the public domain to have an opportunity to participate in the discussion over a patent's validity—even in instances where public interests are subordinated by personal motives. By allowing third parties who represent the public interest to challenge patents, Congress prevents biotechnology companies and their direct competitors from entrenching the patent system with patent owner's interests without any balancing consideration for public domain interests. Instead, Congress should introduce legislation that prevents parties' financial motives from abusing IPR's settlement provisions. Even third parties motivated primarily by personal gain can serve an important "ecological role" in maintaining the integrity of the U.S. patent system, ensuring invalid patents do not slip through the cracks.

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I. INTRODUCTION

On February 10 and February 27, 2014, The Coalition for Affordable Drugs ("CFAD") filed several petitions with the United States Patent and Trademark Office ("USPTO") challenging the validity of two patents covering Ampyra, a prescription drug that improves multiple sclerosis patients' ability to walk.[1] Acorda Therapeutics, which owns the two patents, watched its stock drop 9.7% on February 10 and 4.8% on February 27 in reaction to news of the patent challenges.[2]

The patent challenge and ensuing stock drop comprise the initial steps of a new investment strategy developed by a well-known hedge fund manager Kyle Bass.[3] Mr. Bass created CFAD—which is owned by Bass's hedge fund, Hayman Capital Management—to search for potentially invalid patents and file petitions requesting the USPTO to reassess the validity of these patents in an administrative process called inter partes review ("IPR").[4]

CFAD states it is targeting patents that lack social value.[5] The USPTO should have never issued the targeted patents in the

1. Susan Decker, *Kyle Bass's Challenge to Two Acorda Drug Patents Rejected*, BLOOMBERG BUS. (Aug. 24, 2015, 4:12 PM), http://www.bloomberg.com/news/articles/2015-08-24/kyle-bass-s-petitions-challenging-two-acorda-patents-rejected [https://perma.cc/G2L6-EF8Q].

2. *Id.*

3. Mr. Bass rose to fame as one of the investors who made a fortune in 2007 betting against subprime mortgage securities. Jess Delaney, *Hedge Fund Manager Kyle Bass Declares War on Drug Prices*, INSTITUTIONAL INV. (Oct. 22, 2015), http://www.institutionalinvestor.com/Article.aspx?ArticleId=3499918. Bass's fund earned a 212% return the year of the mortgage crisis. *Id.*

4. *Id.*

5. Joseph Walker & Rob Copeland, *New Hedge Fund Strategy: Dispute the Patent,*

first place because the patents fail to disclose anything novel and accomplish little more than keeping drug prices artificially high.[6] CFAD states it is focusing on companies who are inappropriately extending their patents' period of exclusivity beyond the allotted twenty-year term by making simple, non-innovative changes to dosage or packaging.[7] Mr. Bass believes invalidating these patents will open the market for generic manufacturers to offer the drug at a lower price, driving drug prices down for all.[8]

CFAD's challenges coincide with mounting criticism of U.S. drug prices. For example, Acorda raised the price of Ampyra by 11% in 2015; a single prescription now costs more than $23,650 per year.[9] Top drugmakers Pfizer, Amgen, Allergan and Horizon Pharma raised the 2014 list price of many of its brand-name drugs between 9–10% at the beginning of 2015.[10] Many politicians, healthcare payers, doctors and patients complain that high drug prices are barring patient access to drugs and pushing the limits of healthcare budgets.[11] In response, drug industry representatives rationalize high prices and post-launch price increases as a reflection of newly discovered "clinical benefits" and as necessary for "continued scientific innovation."[12]

CFAD's motives for challenging drug patents are not purely altruistic. In addition to the goal of driving down drug prices, CFAD stands to make a hefty profit by shorting (i.e., betting against)[13] the shares of companies holding the challenged patents and taking a long position on the shares of companies who stand to benefit from the challenged patent's invalidation.[14] Between February 10 and September 28, 2015, CFAD filed thirty-two IPR petitions against

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Short the Stock; Hayman Capital Seeks to Invalidate Patents While Betting on a Drop in Target's Shares, Apr. 7, 2015, WALL ST. J., at B1. "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." *Big Pharma: Let's Shift Patent Debate Away From Trolls*, MAYER BROWN (May 20, 2015), https://www.mayerbrown.com/en-US/Big-Pharma-Lets-Shift-Patent-Debate-Away-From-Trolls-05-20-2015/.

6. *Id.*

7. Matthew Harper, *Solving the Drug Patent Problem*, FORBES (May 2, 2002, 8:00 AM), https://www.forbes.com/2002/05/02/0502patents.html; *U.S. Hedge Fund Plans to Take on Big Pharma Over Patents*, REUTERS (Jan. 7, 2015), http://www.reuters.com/article/pharmaceuticals-haymancapital-idUSL3N0UM42O20150107 [https://perma.cc/KZ3V-V9B9].

8. Walker & Copeland, *supra* note 5.

9. Peter Loftus, *Drugmakers Raise Prices Despite Criticisms*, WALL ST. J. (Jan. 10, 2016, 8:03 PM), http://www.wsj.com/articles/drugmakers-raise-prices-despite-criticisms-1452474210 [https://perma.cc/3CBL-JNMR].

10. *Id.*

11. *Id.*

12. *Id.*

13. *See infra* notes 95–122 (discussing short-selling).

14. Walker & Copeland, *supra* note 5.

various biopharmaceutical companies' patents.[15] The Patent Trial and Appeal Board ("PTAB"), the panel responsible for reviewing IPR petitions,[16] instituted IPR and issued a final written decision on eighteen of the petitions.[17]

CFAD targeted the biotechnology sector because biotechnology companies and their inventions are especially vulnerable to patent invalidation. First, biotechnology companies are typically small and derive their revenue from only a few key products.[18] Invalidation, or even the prospect of invalidation, of a biotechnology patent is particularly likely to affect the stock price of the company that holds only a few key patents.[19] For example, Ampyra accounts for about 90% of Acorda's revenue.[20] Second, unlike technologies in other fields, where a single product is often protected by hundreds of patents, a single biotech invention is typically covered by only a few patents.[21] Invalidating one out of a few patents protecting a biotechnology weakens the product's patent protection more significantly than in other areas of technology and thus is more likely to open the entire technology to competitors.[22] Finally, quickly developing a new product to replace the revenue lost from the invalidated patent is difficult for biotechnology companies, because it takes between ten and fifteen years for companies to develop a marketable drug.[23] A biotechnology company's fragile patent portfolio creates the potential for a major loss in the company's share price—and a major win for hedge funds betting against the stock—if the USPTO invalidates any one patent from the company's portfolio.[24]

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15. USPTO PAT. TRIAL & APPEAL BOARD, https://ptab.uspto.gov/#/login (last visited Jan. 22, 2017) (search "Coalition for Affordable Drugs" in Party Name field) [hereinafter Petitions Filed by the Coalition for Affordable Drugs].

16. *See infra* notes 74–76 and accompanying text (explaining the Patent Trial and Appeal Board's role during IPR).

17. Petitions Filed by the Coalition for Affordable Drugs, *supra* note 15. CFAD has not filed any more petitions since September 2015.

18. *The Impact of Abusive Patent Litigation Practices on the American Economy: Hearing Before the S. Comm. On the Judiciary*, 114th Cong. 1 (2015) (statement of Hans Sauer, Deputy General Counsel for Intellectual Property, Biotechnology Industry Association) [hereinafter *BIO Hearing*].

19. *Id.*

20. Decker, *supra* note 1.

21. Jim Greenwood & John Castellani, *Congress Must Keep Trolls Away from Medical Patents*, THE HILL (July 20, 2015, 6:19 PM), http://thehill.com/opinion/op-ed/248567-congress-must-keep-trolls-away-from-medical-patents [https://perma.cc/7N6F-4ZPS].

22. *BIO Hearing*, *supra* note 18.

23. Leanne Miller, *Biotech CEO: Bass Exploiting Weakness in System*, CNBC (Sept. 19, 2015, 4:13 PM), http://www.cnbc.com/2015/09/19/biotech-ceo-bass-exploiting-weakness-in-system.html [https://perma.cc/6ZRQ-8NHT].

24. *BIO Hearing*, *supra* note 18.

Opponents accuse CFAD of abusing the patent system and manipulating financial markets primarily for profit.[25] The media calls members of CFAD "financial predators that exploit loopholes in patent law to fatten their wallets at the expense of great American science."[26] In a hearing before the Senate, Deputy General Counsel for Intellectual Property for the Biotechnology Industry Organization ("BIO") Hans Sauer[27] criticized hedge funds for attacking patents for the illegitimate reason of financial gain rather than a legitimate reason such as promoting innovation.[28] The pharmaceutical industry believes CFAD is using IPR as a fear tactic to scare away investors.[29] It thinks CFAD is actually trying to drive the stock price down through decreases in biotechnology funding rather than trying to rid the system of unfair patents.[30] Critics warn that CFAD's tactics will stifle innovation.[31] To address these issues, critics are urging Congress to introduce legislation that prevents financial opportunists such as CFAD from practicing this investment strategy, either by statutorily limiting financial institutions' ability to practice these investment strategies[32] or by exempting biopharmaceutical patents from IPR altogether.[33]

This Comment uncovers the merits of the biotechnology sector and CFAD's arguments, ultimately concluding that Congress should not create any legal barriers that would prevent hedge funds from challenging the validity of biotechnology patents. It is important for third parties who represent the interests of the public domain to have an opportunity to participate in the discussion over a patent's validity—even in instances where public interests are subordinated by personal motives. By allowing third parties who represent the public interest to challenge patents, Congress prevents biotechnology companies and their direct competitors from entrenching the patent system with patent

25. Greenwood & Castellani, *supra* note 21.

26. *See id.*

27. *BIO Hearing*, *supra* note 18.

28. *See id.*

29. Walker & Copeland, *supra* note 5.

30. *Id.*

31. Greenwood & Castellani, *supra* note 21, at 1–2.

32. *BIO Hearing*, *supra* note 18.

33. Bipartisan Letter to House Leadership Regarding *Inter Partes* Review and H.R. 9 (July 24, 2015); Letter to the House and Senate Judiciary Committees from the President & CEO of BIO and the President & CEO of PhRMA (July 15, 2015), http://thehill.com/sites/default/files/final_joint_phrma_bio_letter_on_ipr_071515.pdf [https://perma.cc/VCV8-LDCA] (arguing that the Hatch–Waxman Act and Biologics Price Competition and Innovation Act already provide carefully calibrated and specialized patent challenge procedures for biopharmaceutical patents).

owners' interests by allowing public interests to provide a counterbalance. Instead, Congress should introduce legislation that prevents parties' financial motives from abusing IPR's settlement provisions. Even financially motivated third parties can serve an important "ecological role" in the patent system.[34]

Part II breaks down the main aspects of CFAD's investment strategy, explaining the key concepts of the patent system and financial system that CFAD is using in its attempt to make a profit and decrease drug prices. Part III presents how CFAD's strategy fits into the patent system and the financial system's current legal framework and then describes CFAD opponents' proposed changes to the system. Part IV elaborates upon why Congress should continue to permit hedge funds to challenge patents.

II. BREAKING DOWN CFAD'S STRATEGY

This Part discusses each component of CFAD's investment strategy separately, and then explains how the components interplay. CFAD's strategy is interdisciplinary, utilizing aspects of both the legal system and financial system. This Part begins by discussing two legal concepts, invalid patents and IPR, and then provides an overview of the financial concept of short selling. It sets the framework for Part III, which explains how CFAD opponents seek to reform laws related to these concepts to prevent CFAD and other types of third parties from challenging patents.

A. Invalid Patents

To appreciate CFAD's investment strategy, which targets potentially invalid patents, it is important to understand what an invalid patent is and how it is possible for the USPTO to issue invalid patents.[35] The USPTO grants an invalid patent when a patent application survives the registration process despite its failure to meet all of the eligibility requirements, because the invalidating evidence never made it before the examiner.[36]

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34. *Kyle Bass, IPR and Shorting Big Pharma*, ALL ABOUT ALPHA (Sept. 22, 2016), http://www.allaboutalpha.com/blog/2016/09/22/kyle-bass-ipr-and-shorting-big-pharma/ [https://perma.cc/2K75-NNKY].

35. For an in depth discussion about how invalid patents slip through the cracks at the USPTO, see Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. UNIV. L. REV. 1495–96 (2001).

36. Professor Robert Merges describes a bad patent as "a patent that should have been weeded out after a reasonable investment of effort, but was not." Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 581 n.6 (1999). To meet the

Invalid patents undermine Congress's intent for creating the patent system.[37] Once the USPTO grants a patent, the patent owner has a time-limited monopoly to "exclude others from making, using, offering for sale, or selling the invention" in the United States.[38] Until a party successfully challenges and invalidates an improvidently granted patent in federal court or before the USPTO, owners of invalid patents can enforce their right to exclude against their competitors just as owners of valid patents can.[39] This is a problem because Congress only meant to confer the right to exclude to owners of patents that have something "new and useful" to offer to the public in exchange.[40] "[W]hen the PTO mistakenly grants a patent on something that is already public knowledge, the inventor gets his reward, but society gets nothing in return because the invention was not actually new or useful."[41]

There are many reasons why the USPTO issues a patent despite its invalidity.[42] First, the USPTO carries the burden of proving nonpatentablity as opposed to establishing patentability; the examination process is skewed from the start in the applicant's favor.[43] Second, the burden of proving nonpatentability falls on a single person, the patent examiner. The patent examiner:

> [H]as the burden of reading the application, searching for and identifying the relevant prior art, reading the relevant prior art, deciding whether the application should be allowed by comparing the claims to the prior art, and writing an "Office Action" explaining the reasons why any claims are rejected. . . . It is not very surprising, therefore, that the PTO issues many patents that would have been rejected had the examiner possessed perfect knowledge. This is particularly true since much of the most relevant prior art isn't easy to

statutory requirements for patentability, a claim must define an invention that is useful, novel and nonobvious and the specification must adequately describe and enable the claimed invention. 35 U.S.C. §§ 101–103, 112 (2012).

37. Megan M. La Belle, *Patent Law as Public Law*, 20 GEO. MASON L. REV. 41, 42 (2012).

38. 35 U.S.C. § 154(a)(1)–(2).

39. *See infra* note 75 and accompanying text (explaining the challenger must prove a reasonable likelihood of unpatentability, otherwise the Patent Trial and Appeal Board will not institute review).

40. 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

41. La Belle, *supra* note 37, at 42.

42. *See infra* notes 43–58 and accompanying text (pointing out flaws with the patent registration process and concessions the USPTO makes, which cause invalid patents to slip through the cracks at the USPTO).

43. *See* 35 U.S.C. § 102(a) (providing "A person shall be entitled to a patent unless . . .").

> find—it consists of sales or uses by third parties that don't show up in any searchable database and will not be found by examiners in a hurry.[44]

Third, examination quality tends to be poor due to high examiner turnover.[45] Fourth, many examiners are inadequately experienced in the breadth of the technical field covered by patent applications they are charged with examining.[46]

Fifth, all participants in patent registration process—the applicant and the examiner—are primarily interested in obtaining patent issuance.[47] Patent applicants are not motivated to provide evidence invalidating their own invention and in fact are under no duty to submit relevant prior art.[48] The USPTO scrutinizes the quality of patent applications yet one of its primary concerns is encouraging inventors to continue to file more patent applications.[49] During examination, third parties who would like to challenge the patent application have minimal opportunity to submit relevant prior art or arguments against issuance.[50]

Finally, the USPTO imposes a number of economic and time constraints on patent examiners' searches for invalidating prior art.[51] The USPTO only allots so much time and money to registration, otherwise the process becomes economically inefficient.[52] In 2014, the

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44. Lemley, *supra* note 35, at 1499–1500.

45. Merges, *supra* note 36, at 606 ("A recurring theme in the assessment of PTO performance is poor examination quality due to high examiner turnover.").

46. Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 107 (2006).

47. Rochelle Cooper Dreyfuss, *Dethroning Lear: Licensee Estoppel and the Incentive to Innovate*, 72 VA. L. REV. 677, 755 (1986).

48. FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 526 n.6 (Fed. Cir. 1987) ("As a general rule, there is no duty to conduct a prior art search, and thus there is no duty to disclose art of which an applicant could have been aware."); Lemley, *supra* note 35, at 1499–1500 ("While patent applicants must submit to the PTO relevant prior art of which they are aware, they are under no obligation to search for prior art, and most do not.").

49. *See* Merges, *supra* note 36, at 607, 609 (explaining how patent examiner's compensation structure is based in part on the number of final allowances and rejections of applications and how the structure of the registration process "skew[s] incentives in favor of granting patents.").

50. Dreyfuss, *supra* note 47, at 755 ("[T]he absence of an interested party adverse to the patentee makes it improbable that every argument against patentability will be considered in every case.").

51. *See* Leslie, *supra* note 46, at 106 (asserting "[e]ven the most rational, cost-effective patent system would issue some invalid patents, but flaws in the American system unnecessarily increase that number."); Merges, *supra* note 36, at 596 ("Our patent system envisions a mixture of public and private expenditures to determine the validity of patents. Indeed, it is part of a larger theme in patent law: the division of labor between the public and private sectors in the issuance and enforcement of these property rights."); *cf. id.* at 593–94 (explaining how even if the PTO raised examination standards, a certain number of invalid patents would still survive the examination process).

52. Merges, *supra* note 36, at 605–09.

USPTO received 618,330 patent applications.[53] Additionally, there was a backlog of approximately 605,646 unexamined patent applications at the end of the USPTO's 2014 fiscal year.[54] The USPTO has employed only 9,302 patent examiners to examine these patents.[55] In an effort to keep examination costs down, the Patent Office minimizes the amount of time examiners spend per application.[56] An examiner only spends eighteen hours on average examining a single patent application over the two to three year prosecution period.[57] This amount of time is insufficient for a patent examiner to find all of the relevant prior art that could defeat a patentability requirement. Additionally, the likelihood an examiner will miss important prior art increases as the complexity of the application increases.[58]

Invalid patents issue because the USPTO does not have the time or resources to determine the full scope of relevant art contained in the vast ocean of information in the public domain.[59] The USPTO is not to blame for issuing invalid patents; invalid patents are simply a necessary byproduct of the USPTO's attempt to efficiently address the hundreds of thousands of applications that arrive at its front door.[60] Like most systems, the patent system cannot escape false positives. Professor Mark Lemley suggests "society ought to resign itself to the fact that bad patents will issue, and attempt to deal with the problem *ex post*, if the patent is asserted in litigation."[61] The next section discusses administrative procedures Congress has introduced to address improvidently-granted patents *ex post*, which CFAD uses to execute its investment strategy.

B. Inter Partes Review

In 2011, Congress created several new ways for third parties to administratively challenge issued patents at the USPTO under the

53. UNITED STATES PATENT AND TRADEMARK OFFICE: FISCAL YEAR 2014 PERFORMANCE AND ACCOUNTABILITY REPORT 144 (2014), http://www.uspto.gov/about/stratplan/ar/USPTOFY2014PAR.pdf [https://perma.cc/75SW-PET9].

54. *Id.* at 2.

55. *Id.* at 11.

56. "[T]he PTO doesn't do a very good job of examining patents, but we probably don't want it to. . . . [I]t is too costly for the PTO. . . ." Lemley, *supra* note 35, at 1497. "[W]e simply cannot afford to perfect decision making in each of the hundreds of thousands of cases on which the PTO has to make decisions." *Id.* at 1511.

57. Brenda Sandburg, *Speed Over Substance?*, INTELL. PROP. MAG., Mar. 1999.

58. Leslie, *supra* note 46, at 106–07.

59. Jay P. Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 765 (2002).

60. Susan Hansen, *Power to the People*, IP L. & BUS., Apr. 2007, at 36, 42.

61. Lemley, *supra* note 35, at 1510.

America Invents Act ("AIA"): inter partes review, post-grant review ("PGR") and Covered Business Method ("CBM") patent review.[62] An additional post-grant proceeding, *ex parte* reexamination, has also been available since the 1980's.[63] Congress designed post-grant proceedings to provide a quicker, lower-cost alternative to litigation.[64] Most importantly for third parties like CFAD, IPR, PGR, and *ex parte* reexamination allow almost any member of the public to challenge the validity of a patent.[65] This Comment specifically focuses on IPR because CFAD has only used IPR in its investment strategy.

To institute an IPR, a challenger must file a petition with the USPTO requesting cancellation of one or more claims of a patent as unpatentable.[66] IPR grants broad statutory standing: any "person who is not the owner of a patent" can file a petition.[67] However, petitioners can only request cancellation on invalidity grounds under the Patent Act's novelty or obviousness requirements.[68] In addition, the Patent Act limits petitioners' prior art submissions to patents or printed publications.[69]

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62. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 299–304 (2011) (codified as amended in scattered sections of 35 U.S.C.). Third parties must wait until after a patent has issued to challenge validity, because Congress has barred third party pre-grant oppositions. *See* 35 U.S.C. § 122(c) (2012) ("The Director shall establish appropriate procedures to ensure that no protest or other form of pre-issuance opposition to the grant of a patent on an application may be initiated after publication of the application without the express written consent of the applicant.").

63. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 302–307).

64. *BIO Hearing*, *supra* note 18. Before Congress enacted IPR, PGR and CBM, many representatives of intellectual property interests complained that litigation costs too much time and money to be an effective vehicle for challenging bad patents. *Patent Quality Improvement: Post-Grant Opposition: Hearing before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 108th Cong. 8–13 (2004) [hereinafter *2004 Hearing*].

65. Under both IPR and PGR, any "person who is not the owner of a patent" may file a petition to institute a review of the patent. 35 U.S.C. §§ 311(a); 321(a). Under *ex parte* reexamination, "[a]ny person at any time may file a request for reexamination." § 302. CBM reviews are a narrow and specialized category of PGR limited to challenges to the validity of patents covering business methods and will not be further discussed in this Comment. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18(a)(1)(B), 125 Stat. 284, 329 (2011) (limiting the scope of CBM reviews to patents covering business methods).

66. 35 U.S.C. § 311(a)–(b).

67. § 311(a).

68. § 311(b); *see also* §§ 102–103 (setting out the novelty and obviousness requirements for patentability). Challengers cannot request cancellation based on failure to meet the written description and enablement requirements provided in § 112. *See supra* note 36 (describing the requirements for patentability during examination).

69. § 311(b). During registration, examiners can also reject patent applications upon discovery that the claimed invention was "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." § 102(a)(1). The Patent Trial and Appeal Board may not consider this type of evidence during IPR. § 311(b).

The challenger's IPR petition must meet a number of requirements.[70] The petition must identify "each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim. . . ."[71] The USPTO must make the petition available to the public in a timely fashion.[72] Patent owners have the opportunity to file a preliminary response to petitions, which provides reasons why the petition fails to meet the requirements to institute an IPR.[73]

The Patent Trial and Appeal Board ("PTAB") conducts IPRs.[74] After considering the challenger's petition and the patent owner's preliminary response (if filed), the PTAB decides whether to institute a review depending upon whether the petition demonstrates a reasonable likelihood the challenger will prevail with respect to at least one of the challenged claims.[75] The PTAB's decision whether to institute an IPR is final and non-appealable.[76]

During the IPR, the petitioner bears the burden of proving unpatentability by a preponderance of the evidence.[77] The patent owner may file one motion to amend the patent to "cancel any challenged claim" or "propose a reasonable number of substitute claims."[78] The PTO may sanction either party for "abuse of discovery, abuse of process, or any other improper use of the proceeding," such as harassment, causing an unnecessary delay or causing an unnecessary increase in the cost of the proceeding.[79]

Finally, the PTAB issues a final written decision, canceling claims deemed invalid, confirming patentable claims and incorporating new or amended claims.[80] The PTAB must issue a

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70. *See generally* § 312 (explaining IPR petition requirements).

71. § 312(a)(3).

72. § 312(b).

73. § 313.

74. § 316(c).

75. § 314(a). The PTAB denied institution of IPR based on fourteen of CFAD's thirty-two petitions. *See* PTAB USPTO, https://ptab.uspto.gov/#/login (last visited Apr. 26, 2017).

76. § 314(d).

77. § 316(e).

78. § 316(d).

79. § 316(a)(6).

80. § 318(a)–(b). The PTAB issued a final written decision based on eighteen of CFAD's thirty-two petitions. *See* PTAB USPTO, https://ptab.uspto.gov/#/login (last visited Apr. 26, 2017). Eight of CFAD's petitions succeeded in showing that the claims of patents owned by Celgene, NPS Pharmaceuticals, and Anacor Pharmaceuticals were unpatentable. *See, e.g.*, Coal. for Affordable Drugs VI LLC v. Celgene Corp., No. IPR2015-01169 (P.T.A.B. Nov. 16, 2015). In the remaining ten petitions, the PTAB determined that CFAD failed to show by a preponderance of the evidence that the claims at issue were unpatentable. *See, e.g.*, Coal. For Affordable Drugs XI LLC v. Insys Pharma, Inc., No. IPR2015-01800 (P.T.A.B. Mar. 10, 2016). The relevant patents are owned by Cosmo Technologies, NPS Pharmaceuticals, Pozen, Acorda Therapeutics, Biogen, and the Trustees of the University of Pennsylvania.

final determination no later than one year after the date it institutes a review.[81] Final written decisions estop petitioners from requesting another proceeding or civil action "on any ground that the petitioner raised or reasonably could have raised" against the claims challenged during the IPR.[82]

Post-grant proceedings before the PTAB are a more favorable environment for patent challengers compared to invalidity actions in federal courts. The PTAB applies the "broadest reasonable construction" standard during IPR proceedings,[83] which is broader than the standard applied by federal courts.[84] When the PTAB is considering whether to institute IPR, the petitioner bears the burden of proving unpatentability by a "preponderance of the evidence,"[85] in contrast to district court cases where the burden of proving unpatentability is by "clear and convincing evidence."[86] Unlike in IPR proceedings, patents enjoy a "presumption of validity" in federal court.[87] The application of these different standards by the PTAB and federal courts when determining the validity of a claim could cause a federal court to interpret the same claim as valid and the PTAB to determine the opposite in parallel proceedings.[88]

Since the AIA's enactment in 2012,[89] IPR has quickly become a popular litigation alternative across all technology fields.[90] Between September 16, 2012 (the date of enactment of the IPR provision of the AIA) and March 31, 2014,[91] 11.3% of IPR petitions filed challenged biotechnology and pharmaceutical patents.[92] Out of all the petitions challenging these patents, the

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81. § 316(a)(11). However, the PTO may, for good cause, grant a six-month extension. *Id.*

82. § 315(e).

83. Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2139 (2016).

84. *In re* Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1285 (Fed. Cir. 2015) (Newman, J., dissenting).

85. § 316(e).

86. Eric C. Cohen, *A Primer on Inter Partes Review, Covered Business Method Review, and Post-Grant Review Before the Patent Trial and Appeal Board*, 24 FED. CIR. B.J. 1, 15 (2014).

87. *Id.*

88. *But see In re Cuozzo*, 793 F.3d at 1285 ("The [AIA], in authorizing the PTO to determine validity by conducting adversarial proceedings . . . is designed to reach the correct result in the PTO, the same correct result as in the district courts.").

89. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 299–304 (2011) (codified as amended in scattered sections of 35 U.S.C.).

90. In 2015, challengers filed 1,737 IPR petitions, compared to seventeen petitions filed in 2012. USPTO, PATENT TRIAL AND APPEAL BOARD STATISTICS 4–5 (2015), http://www.uspto.gov/sites/default/files/documents/2015-10-31%20PTAB.pdf [https://perma.cc/5LS4-QV6G].

91. Brian J. Love & Shawn Ambwani, Inter Partes *Review*: *An Early Look at the Numbers*, 81 UNIV. CHI. L. REV. DIALOGUE 93, 96 (2014).

92. *Id.* at 101.

PTAB instituted a review 83.2% of the time.[93] Of the instituted IPRs reviewing the validity of biotechnology and pharmaceutical patent claims, the PTAB invalidated all instituted claims in 87% of the decisions.[94]

C. Short Selling

After reviewing aspects of CFAD's strategy related to the patent system, we now turn to its financial side: shorting a biotechnology company's stock.[95] Short selling is an investment strategy recognized and regulated by the Securities and Exchange Commission ("SEC").[96] Investors have practiced short selling since the seventeenth century.[97] In contrast to the conventional investor who purchases a security with the expectation the security price will increase,[98] investors short securities with the expectation the stock price will decrease.[99]

A traditional short sale requires three players—an owner, a borrower (the short-seller), and a purchaser—and multiple steps to achieve its intended effect.[100] In the first step of the transaction, the short seller borrows a security from the true owner.[101] In the second step, the short seller delivers the same security to a purchaser in exchange for payment.[102]

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93. *Id.*

94. *Id.* at 106.

95. *See supra* notes 96–122 and accompanying text (explaining how CFAD shorts the stocks of same companies whose patents it is challenging).

96. H.R. REP. NO. 102-414, at 6 (1991).

97. James Surowiecki, *In Praise of Short Sellers*, NEW YORKER (Mar. 23, 2015), at 40.

98. This type of stock purchase is referred to as taking a "long" position. DAVID FABER, THE FABER REPORT 44 (2002); *UnAmerican Activities*, THE ECONOMIST (Oct. 4, 2001), http://www.economist.com/node/808860 [https://perma.cc/UQ7V-WZK4].

99. James W. Christian et al., *Naked Short Selling: How Exposed are Investors?*, 43 HOUS. L. REV. 1033, 1042 (2006). The Code of Federal Regulations defines a short sale as "any sale of a security which the seller does not own or any sale which is consummated by the delivery of a security borrowed by, or for the account of, the seller." 17 C.F.R. § 242.200 (2010).

100. Christian et al., *supra* note 99, at 1041. After this initial step, the short-seller is now "short" the stock, because the short seller is now obligated to return to the lender at some point in time the same number of shares it had initially borrowed. H.R. REP. NO. 102-414, at 2 (1991).

101. H.R. REP. NO. 102-414, at 2 (1991); *see also* Securities Exchange Commission Concept Release and Request for Comments, 64 Fed. Reg. 57,996, 57,996–97 (defining a short sale).

102. Securities Exchange Commission Concept Release and Request for Comments, 64 Fed. Reg. at 57,996–97; *see also* Christian et al., *supra* note 99, at 1041. The key to understanding the mechanics of a short sale is keeping in mind that the short seller does not own the stock it has sold but has merely borrowed the stock from the lender; the short seller is obligated to return the security that it sold to the lender at some later point in time. Christian et al., *supra*.

The act of returning the borrowed shares to the true owner—also referred to as "closing out" the position or "covering" the short sale—is the last step in the transaction.[103] The original owner does not require the short seller return the identical stock that it originally borrowed back to the owner, simply its equivalent.[104] The short seller buys these equivalent shares at the current market price from whomever is willing to sell them and returns these shares to the true owner, as a replacement for the shares it originally borrowed.[105]

The overall transaction is designed to return a profit if the stock price decreases between the time the short seller sold the borrowed shares to the buyer and the time the short seller returned the equivalent shares to the lender.[106] The short seller keeps the difference in value of (i) the original stock the short seller borrowed then sold to the market at a high price and (ii) the replacement stock the short seller bought at a cheaper price from the market and returned to the lender.[107]

Stigma surrounds short selling.[108] Because short sellers are betting against the growth of a company, the public and many members of the investment community view short selling as "UnAmerican,"[109] rooting against the home team, or bad manners.[110] Short selling is even illegal in some countries.[111] Company management dislikes onlookers who poke holes in how they run their company.[112] Some companies suspect short sellers are saboteurs willing to spread rumors about their enterprise to cause a stock price drop.[113]

Short sellers who have practiced "shorting and distorting"—shorting a company's stock while simultaneously spreading negative rumors about the company in order to cause a stock price decrease—have rightfully increased public skepticism of short selling,[114] but the same can be said of traditional investors who

103. Christian et al., *supra* note 99, at 1041.

104. *Id.*

105. *Id.*

106. *Id.* at 1038.

107. *Id.*

108. Surowiecki, *supra* note 97, at 40.

109. *UnAmerican Activities*, *supra* note 98.

110. *Id.*

111. Surowiecki, *supra* note 97, at 40.

112. Deirdre Fanning, *Profits of Doom*, SPY, Sept. 1991, at 53.

113. Brian A. Ochs, *When Does Short Selling Become Manipulation?*, K&L GATES 1, 5 (Nov. 24, 2008), http://www.klgates.com/files/tempFiles/901e34d6-b3ee-4ac4-bdad-3b6cabd7060b/Alert_SEC_ShortSelling.pdf [https://perma.cc/R7WM-4WX6].

114. Surowiecki, *supra* note 97, at 40. In fact, the first recorded short seller in history, a Dutchman named Isaac Le Maire, shorted Dutch East India Company stock and spread

"pump and dump"—taking a long position then spreading rumors that causes the stock price to increase.[115] Importantly, short selling is legally distinguishable from shorting and distorting: short selling is legal in the United States while shorting and distorting is not.[116]

Despite general suspicion and uneasiness directed toward short selling, it has many positive attributes.[117] It can be of valuable service by "provid[ing] an antidote to unrealistic expectations, reminding investors that stocks aren't on some unending march to ever greener pastures."[118] Short sellers provide liquidity to the markets, adding to the supply of stock by selling shares to buyers and buying falling shares from sellers.[119] They are often the first to point out financial fraud.[120] One 2012 study found that "[s]tock prices are more accurate when short sellers are more active."[121] Another 2007 study concluded markets in countries where short selling is legal and commonplace are more efficient than countries where short selling is illegal or rarely practiced.[122]

D. Combining IPR and Short Selling to Create a New Investment Strategy

CFAD brought together the concepts of invalid patents, IPR, and short selling to create its novel investment strategy.[123] First, it looks for patents that it believes grant exclusivity to non-innovative products.[124] As a result, these patents offer little value other than driving up drug prices, because patent protection closes off the opportunity for generic drug manufacturers to offer the product at a lower price.[125] Second, it searches for patents or

misrepresentations about the health of the company to drive the stock price down during the 17th century. *Episode 598: The Very First Short*, NPR (Jan. 23, 2015 7:21 PM ET), http://www.npr.org/templates/transcript/transcript.php?storyId=379416223.

115. Ochs, *supra* note 123, at 5.

116. Surowiecki, *supra* note 97, at 40.

117. *See* FABER, *supra* note 98, at 65 (noting short sellers' unique contributions to the health of financial markets).

118. *Id.* Short sellers serve as a much-needed counterbalance to overly bullish outlook of the United States' capitalist market. *Id.* at 64–65.

119. *UnAmerican Activities*, *supra* note 109.

120. FABER, *supra* note 98, at 65; Walker & Copeland, *supra* note 5 ("[Mr. Bass] was one of the handful of hedge-fund managers to spot trouble in the subprime mortgage markets before the finance crisis."); Surowiecki, *supra* note 97, at 40 (explaining how short seller James Chanos was one of the first people to tip off the public about Enron's fraudulent accounting practices in 2001).

121. Surowiecki, *supra* note 97, at 40.

122. *Id.*

123. Walker & Copeland, *supra* note 5.

124. *Id.*

125. Non-novel patents upset the quid pro quo exchange between the public and patent owner and consequently, fail to add any social value. *See supra* notes 37–41 and

printed publications the examiner failed to consider during examination that might prove the technology is obvious or not novel, which would show the patent is invalid.[126] Third and fourth, CFAD files an IPR petition—using these new patents and printed publications to present arguments for why the patent fails novelty or obviousness requirements—and simultaneously shorts the stock of the company holding the patent.[127]

There are several points where the stock price could react to news about the patent challenge: the day the IPR petition is filed, the day the PTAB decides whether to institute review of the challenged patent, and the day the PTAB issues a final decision determining the patent's validity.[128] On the days CFAD filed challenges against two patents covering Ampyra, Acorda's stock price dropped 9.7% and 4.8% respectively.[129] Acorda's stock price rose 27.7% on the day the PTAB declined to review CFAD's petitions.[130] Theoretically, CFAD stands to make the most profit when it successfully invalidates one of the key patents of a company whose revenue is largely derived from its patents.[131]

CFAD's interdisciplinary strategy combines aspects of the patent system and financial system to target specific patents that

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accompanying text (explaining how invalid patents undermine Congress's intent for creating the patent system). One way this can occur is through the grant of an invalid patent, because invalidating prior art is overlooked during examination. *See supra* notes 42–61 and accompanying text (discussing how invalid applications become invalid patents). A patent-protected invention that isn't actually new and original can upset this balance, because the USPTO gives the inventor exclusivity over something that should belong to the public domain. *See* 35 U.S.C. §§ 102–103 (2012) (setting out the novelty obviousness requirements for patentability). Another way companies upset the exchange is by extending patent protection covering a true innovation beyond its 20-year term through a process called "evergreening." Joanna T. Brougher, *Evergreening Patents: The Indian Supreme Court Rejects Patenting of Incremental Improvements*, 19 J. COM. BIOTECHNOLOGY 54, 55 (2013) (Drug companies engage in evergreening by "extend[ing] the market exclusivity of a drug beyond the life of its original patent by obtaining multiple patents that cover different aspects of that drug, including the active ingredient, formulations, methods of manufacturing, chemical intermediates, mechanisms of actions, packaging, screening methods, and biological targets.").

126. *See* § 311 ("A petitioner in 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."). *See* §§ 102–103 (setting out the novelty obviousness requirements for patentability).

127. Walker & Copeland, *supra* note 5.

128. *See supra* notes 1–2 (explaining how Acorda Therapeutics' stock dropped after news broke that CFAD filed petitions challenging two of Acorda's patents).

129. *Id.*

130. Joseph Walker, *Acorda Therapeutics Shares Surge After Denial of Patent Challenge*, WALL ST. J. (Aug. 24, 2015, 7:55 PM), http://www.wsj.com/articles/acorda-therapeutics-shares-surge-after-denial-of-patent-challenge-1440457321.

131. For example, Ampyra accounts for about 90% of Acorda's revenue. Decker, *supra* note 1.

it believes are non-innovative and thus should have never been issued in the first place.[132] The next Part explains the reforms CFAD opponents have proposed to prevent CFAD and other types of third parties from challenging the validity of patents.

III. HOW HEDGE FUNDS FIT INTO THE CURRENT LEGAL FRAMEWORK & PROPOSED REFORM BY CFAD OPPONENTS

Because it appears that the current law allows hedge funds to use IPR to practice their investment strategy, opponents are appealing to the legislature, USPTO and the SEC to prevent people from using IPR as an investment tool.[133] They propose a number of reforms that will prevent CFAD from continuing to implement its strategy. This Part discusses how CFAD fares with their strategy in the existing legal framework and opponents' proposed changes to the patent system and securities laws that would bar third parties like CFAD from challenging patents.

A. CFAD's Strategy is Permissible Under Patent Law's Current Legal Framework

The PTAB has allowed CFAD to practice its investment strategy.[134] In addition to instituting review of eighteen out of thirty-two of CFAD's petitions, the PTAB denied several motions for sanctions for abuse of process filed by challenged patent holders.[135] In their motions for sanctions, patent holders asserted CFAD was misusing IPR for the improper purpose of executing an investment strategy "coupled with a deceptive marketing plan."[136] Patent owners contend patent challenges motivated entirely by profit are "unrelated to the purpose of the [AIA] and unrelated to a competitive interest in the validity of the challenged patents."[137] They argue that even if the validity challenges are "legitimate,"

132. Walker & Copeland, *supra* note 5.

133. CFAD's interdisciplinary strategy is vulnerable to patent and securities rules and regulations; it uses tools from both the financial sector as well as the patent system. Walker & Copeland, *supra* note 5.

134. *See* Petitions Filed by the Coalition for Affordable Drugs, *supra* note 15 (instituting IPR on eighteen of CFAD's petitions).

135. Coal. for Affordable Drugs VI, LLC v. Celgene Corp., No. IPR2015-01092 (P.T.A.B. Sept. 25, 2015); Coal. for Affordable Drugs II LLC v. NPS Pharmaceuticals, Inc., No. IPR2015-01093, 2015 WL 6449377 *14 (P.T.A.B. Oct. 23, 2015); 37 C.F.R. § 42.12(a) (2012) ("The Board may impose a sanction against a party for misconduct. . . .").

136. *See, e.g.*, *NPS Pharmaceuticals, Inc.*, 2015 WL 6449377, at *14; *see also supra* note 114 and accompanying text.

137. *Celgene Corp.*, No. IPR2015-01092, at 2.

CFAD's profit-seeking reasons for challenging the patents are "illegitimate" and for this reason, the PTAB should dismiss the petitions.[138]

In its decisions, the PTAB notes one of the purposes of introducing post-grant procedures under the AIA was to "encourage the filing of legitimate patentability challenges . . . in an effort to improve patent quality,"[139] and CFAD filed a legitimate challenge questioning the merits of the patent.[140] "Providing a forum for legitimate patentability challenges serves a strong public interest in facilitating the removal of poor quality patents from the public arena."[141] As for CFAD's motives, "[p]rofit is at the heart of nearly every patent and nearly every [IPR]. As such, an economic motive for challenging a patent claim does not itself raise abuse of process issues."[142] The PTAB declined to take a position on using short-selling as an investment strategy in conjunction with the challenges, only remarking that short selling is legal and regulated by the SEC.[143]

The PTAB quickly dismissed the patent holder's argument that CFAD lacks a competitive interest in the validity of the challenged patents.[144] First, the PTAB responded that Congress intended to extend a broad opportunity to parties with diverse interests to challenge patent validity when it allowed any "person who is not the owner of a patent" to file in IPR petition.[145] Second, unlike in federal courts, Article III standing is not required for parties to appear before administrative agencies.[146] In summary, the PTAB maintains that parties with an economic motive for challenging patents have standing in IPR proceedings despite the

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138. *Id.*

139. *Id.* at 4 ("The purpose of the AIA was not limited to just providing a less costly alternative to litigation. Rather, the AIA sought to establish a more efficient and streamlined patent system that improved patent quality, while at the same time limiting unnecessary and counterproductive litigation costs.").

140. *Id.* at 4–5 ("The purpose of the AIA was not limited to just providing a less costly alternative to litigation. Rather, the AIA sought to establish a more efficient and streamlined patent system that improved patent quality, while at the same time limiting unnecessary and counterproductive litigation costs.").

141. *NPS Pharmaceuticals, Inc.*, 2015 WL 6449377, at *13.

142. *Celgene Corp.*, No. IPR2015-01092, at 3.

143. *Id.* at 3.

144. *Id.* at 3–4.

145. *Id.* (citing 35 U.S.C. § 311 (2012)).

146. *See* Sierra Club v. E.P.A., 292 F.3d 895, 899 (D.C. Cir. 2002) (holding parties are not required to establish an injury in fact to participate in agency proceedings because administrative agencies are not subject to Article III of the Constitution; *accord* Consumer Watchdog v. Wis. Alumni Res. Found., 753 F.3d 1258, 1261 (Fed. Cir. 2014) (quoting *Sierra Club*, 292 F.3d at 899) ("[A]lthough Article III standing is not necessarily a requirement to appear before an administrative agency, once a party seeks review in a federal court, 'the constitutional requirement that it have standing kicks in.'").

absence of a competitive interest so long as the petitioner challenges the patent on legitimate grounds.[147]

B. CFAD's Strategy from the SEC's Perspective

Few opponents have appealed to SEC rules and regulations to impede CFAD's investment strategy. Based on publicly available information, only one senator sent a letter to the SEC asking it to investigate whether CFAD's strategy violates any existing federal securities laws, particularly pointing toward the SEC's insider trading and anti-manipulation provisions.[148]

The SEC has not publicly issued any opinions specifically discussing CFAD's strategy in either a positive or negative light. With regard to the SEC's position on short selling in general, SEC Chair Mary Jo White states, "[s]hort selling has a legitimate, positive purpose in the marketplace. . . . That's very different, though, than if you manipulate by short selling."[149]

C. Proposed Patent System Reform

CFAD opponents push Congress for patent reform that either limits the types of parties who can challenge patents through post-grant proceedings,[150] raises standards applied to invalidate patents in post-grant proceedings,[151] or exempts biopharmaceutical from post-grant challenges altogether.[152] In addition to condemning CFAD's behavior as manipulative and abusive of the patent system, opponents criticize IPR for its inherent weaknesses, which subject the procedure to manipulation by profiteers.[153]

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147. *Celgene Corp.*, No. IPR2015-01092, at 4.

148. Press Release, U.S. Senator Bob Menendez of New Jersey, Menendez Calls on SEC to Crack Down on Abusive Trading (June 3, 2015), https://www.menendez.senate.gov/news-and-events/press/menendez-calls-on-sec-to-crack-down-on-abusive-trading [https://perma.cc/B2NH-WQUM]; *see also* 15 U.S.C. § 78j (prohibiting insider trading and manipulation of securities).

149. Ian Katz & Erik Schatzker, *SEC's White Says Short Selling Getting Her 'Intense Attention*,' BLOOMBERG (Nov. 10, 2015, 1:21 PM), http://www.bloomberg.com/news/articles/2015-11-10/sec-s-white-says-short-selling-getting-her-intense-attention- [https://perma.cc/Z4LH-MWXN]; *see also supra* notes 95–122 and accompanying text (describing the positive and negative aspects of short-selling); *Celgene Corp.*, No. IPR2015-01092, at 3 ("We take no position on the merits of short-selling as an investment strategy other than it is legal, and regulated.").

150. *See infra* notes 155, 160 and accompanying text (detailing provisions proposed by Congress that will limit the character of the parties who can challenge patents using IPR).

151. *BIO Hearing*, *supra* note 18 (calling entities like CFAD predators seeking to benefit off of legal advantages of IPR compared to federal court rather than the actual validity of the patent).

152. *See infra* notes 162–65 (explaining why CFAD opponents believe the Hatch–Waxman and the Biologics Price Competition and Innovation Act exempts biopharmaceutical companies' patents from IPR).

153. Acorda's CEO & President explains, "Kyle Bass is actually not the problem . . . he

In 2015 a group of senators introduced the Support Technology and Research for Our Nation's Growth ("STRONG") Patents Act,[154] which proposes an amendment allowing only parties whom patent owners have accused of infringement to file a post-grant proceeding, i.e., confining IPR to parties who otherwise have standing in federal court.[155] The bill also changes the broadest reasonable interpretation claim construction standard commonly applied by the USPTO to the standard applied by district courts.[156] It also raises the burden of proof required to invalidate a claim from preponderance of evidence to clear and convincing evidence.[157]

The House and Senate have also introduced competing patent reform bills proposing amendments to the AIA's post-grant proceedings—the Innovation Act of 2015[158] and Protecting American Talent Entrepreneurship ("PATENT") Act of 2015[159]. The Innovation Act explicitly prohibits CFAD's investment strategy by restricting post-grant proceeding standing requirements; the real parties in interest cannot "own and will not acquire a financial instrument . . . that is designed to hedge or offset any decrease in the market value of an equity security of the patent owner or an affiliate of the patent owner, during a period following the filing of the petition."[160]

Unlike the Innovation Act and the STRONG Patents Act, the PATENT Act does not introduce provisions that exclude parties like CFAD from using IPR to challenge patents. However, like the STRONG Patents Act, it revises the claim construction standard to the standard applied by district courts.[161]

Alternatively, CFAD opponents suggest that Congress should exempt life science patents from post-grant challenges, because

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is a symptom of a bigger disease here—because he's exploiting a weakness in [the patent system]." Miller, *supra* note 23.

154. STRONG Patents Act of 2015, S.632, 114th Cong. § 101(10) (2015) ("Congress finds that . . . unintended consequences of the comprehensive 2011 reform of patent laws are continuing to become evident, including the strategic filing of post-grant review proceedings to depress stock prices and extort settlements.").

155. *Id.* § 102(d).

156. *Id.* § 102(a)(3) (In an IPR proceeding, "each claim of a patent shall be construed as the claim would be construed under section 282(b) in an action to invalidate a patent. . . ."). 35 U.S.C. §§ 281–299 (2012) sets forth the guidelines for civil actions for infringement in federal court.

157. STRONG Patents Act of 2015 § 102(c)(2)(A).

158. Innovation Act of 2015, H.R. 9, 114th Cong. § 9(b)(1)(C) (2015).

159. PATENT Act, S.1137, 114th Cong. § 11 (2015).

160. Innovation Act of 2015, H.R. 9, 114th Cong. § 9(b)(1)(C) (2015).

161. PATENT Act, S.1137, 114th Cong. § 11(a)(4)(A)(vii) (2015) ("[E]ach claim of a patent shall be construed as such claim would be in a civil action to invalidate a patent under section 282(b). . . ."); STRONG Patents Act of 2015, S.632, 114th Cong. § 102(a)(3) (2015).

Congress has already established more suitable and specialized mechanisms for challenging life sciences patents, the Hatch–Waxman Act and the Biologics Price Competition and Innovation Act ("BPCIA").[162] The Hatch–Waxman Act was designed to facilitate the entry of generic drugs into the market and is available to patent challengers seeking FDA approval of a generic version of the patented drug.[163] The BPCIA is the Hatch–Waxman equivalent, available to challengers seeking FDA approval of a generic biological product.[164] Because CFAD's investment strategy does not entail seeking approval of a generic drug or biologic, it would not be able to challenge patents under Hatch–Waxman or the BPCIA.

CFAD opponents emphasize that the Hatch–Waxman Act and the BPCIA offer better systems for challenging patent validity, because both have worked for decades, and Congress customized these systems to account for the particularly fragile "balance between access to lower cost versions of medicines and preserving incentives for continued innovation" in the biotechnology sector.[165] They explain adding IPR as an additional route to challenging patent validity creates a redundancy that siphons resources away from research and development of new cures and treatments.[166] They add that IPR increases investors' uncertainty over the strength of biotechnology companies' patent portfolios, causing them to choose more certain investments in other industries.[167]

With the exception of the PATENT Act, the proposed reforms to IPR by Congress would effectively eliminate any route through which CFAD can exercise its investment strategy.[168] Enacting

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162. Letter to the House and Senate Judiciary Committees from the President & CEO of BIO and the President & CEO of PhRMA, *supra* note 33 (arguing the Hatch–Waxman Act and Biologics Price Competition and Innovation Act already provide carefully calibrated and specialized patent challenge procedures for biopharmaceutical patents).

163. 21 U.S.C. § 355(a)–(b) (2012).

164. 42 U.S.C. § 262(l)–(m).

165. Bipartisan Letter to House Leadership Regarding Inter Partes Review and H.R. 9 (July 24, 2015) ("Unlike companies in other sectors, biopharmaceutical companies are not able to immediately capitalize on the value of their patents. Instead, they must spend almost a decade and, on average, $2.6 billion, before they can receive approval from the FDA to bring new medicines to market.").

166. *Id.*

167. Ashley Keller, *Valuing Intellectual Property in an AIA World*, IP WATCHDOG (Sept. 11, 2016), http://www.ipwatchdog.com/2016/09/11/valuing-intellectual-property-aia-world/id=72597/.

168. Innovation Act of 2015, H.R. 9, 114th Cong. § 9(b)(1)(C) (2015) (Real parties in interest may not "own and will not acquire a financial instrument . . . that is designed to hedge or offset any decrease in the market value of an equity security of the patent owner or an affiliate of the patent owner, during a period following filing of the petition . . . ."); STRONG Patents Act of 2015, S. 632, 114th Cong. § 101(10) (2015) ("Congress finds that . . . unintended consequences of comprehensive 2011 reform of patent laws are continuing to

changes to IPR that would exclude hedge-fund-like companies from challenging patents would be a mistake, because as the following section explains, it would leave a group of invalid biotechnology patents that the remaining qualified challengers are unwilling or do not have the resources to challenge.

IV. WHY HEDGE FUNDS SHOULD BE ABLE TO CHALLENGE PATENTS

This Part illustrates how hedge fund controlled entities like CFAD are in a unique position to improve the integrity of the patent system by seeking out and challenging invalid patents that would otherwise confer an undeserved monopoly to patent holders. The *Myriad* case study demonstrates a situation where direct competitors are unwilling to challenge a patent despite its questionable validity and illustrates the difficulties parties who do not represent private competitive interests already face in gaining standing to challenge the validity of patents in federal court.[169] If Congress introduces legislation that prohibits parties other than direct competitors from challenging invalid patents, many patent holders will hold monopolies covering subject matter that belongs to the public domain in situations where it is not in a direct competitor's interest to challenge the patent.[170] Although part of CFAD's goal is to make a profit, it still represents the interests of the public domain, unlike a patent holder's direct competitors, who avoid situations that could undermine the validity of their own intellectual property.[171] Finally, unlike many pure public interest groups, hedge funds have formidable financial and legal resources to challenge patents, making a patent challenge between a pharmaceutical corporation and a hedge fund a more even match.[172]

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become evident, including the strategic filing of post-grant review proceedings to depress stock prices and extort settlements."); *see supra* note 162 (describing biopharmaceutical companies' requests for exemption from IPR).

169. Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1308–09 (Fed. Cir. 2012), *rev'd on other grounds*, *sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

170. *See infra* notes 186–87 (explaining situations where patent holders and their direct competitors work out mutually beneficial agreements that often leave potentially invalid patents intact).

171. *Id.*

172. *H.R. 9, The "Innovation Act": Hearing Before the H. Comm. on the Judiciary,* 114th Cong. 3 (2015) (statement of J. Kyle Bass, Chief Investment Officer, Hayman Capital Management, L.P.) (Apr. 14, 2015), http://www.valuewalk.com/wp-content/uploads/2015/04/Hayman-HR-9-Final-4-14-15-Final.pdf [https://perma.cc/VZ4R-GTW7]; *see infra* notes 217–22 and accompanying text.

A. The Myriad *Case Study*

A recent federal case illustrates the benefits of allowing non-competitors to challenge a patent's validity, especially in the biotechnology context.[173] In *Association for Molecular Pathology v. USPTO* ("*Myriad*"), a group of medical organizations, researchers, genetic counselors, and patients filed a declaratory judgment action in federal court challenging the validity of molecular diagnostic company Myriad's patents covering human genetic sequences related to increased cancer risk.[174] Some of the researchers brought the suit because they wanted to continue to provide testing services that infringed Myriad's patent; Myriad sent them cease-and-desist communications.[175] The remaining researchers and medical organization members brought suit because "knowledge of Myriad's vigorous enforcement of its patent rights against others stopped them from engaging in clinical BRCA genetic testing."[176] Although they were not infringing Myriad's patents yet, these researchers and medical organizations wanted to provide testing covered by Myriad's patents in the event a federal court found Myriad's patents invalid.[177] The patient plaintiffs brought suit because they believed Myriad's patents caused the covered genetic tests to be unaffordable and inaccessible.[178]

Myriad's plaintiff history illustrates the difficulties of challenging potentially invalid patents for financial reasons unrelated to competitive interests or general public interests in federal court.[179] Among all of the plaintiffs, the *Myriad* court held only one of the plaintiffs, a researcher interested in commercially offering genetic testing that infringed Myriad's patents, established standing to maintain the suit.[180] This holding excluded plaintiffs with affordability and accessibility concerns from standing in federal court; plaintiffs must have the commercial interest "to actually and immediately engage in allegedly

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173. Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1308–09 (Fed. Cir. 2012), *rev'd on other grounds*, *sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

174. *Id.*

175. *Ass'n for Molecular Pathology*, 689 F.3d at 1314–15.

176. *Id.* at 1315.

177. *Id.*

178. *Id.*

179. *Id.* at 1319; *cf.* Sapna Kumar, *Gene Patents and Patient Rights*, 35 WHITTIER L. REV. 363, 370–71 (2014) (explaining patient groups' difficulty in obtaining standing based on cost and accessibility).

180. *Ass'n for Molecular Pathology*, 689 F.3d at 1319.

infringing *BRCA*-related activities."[181] In other words, a general public interest in lowering the cost and increasing the availability of a biotechnological innovation does not confer standing in federal court, while an actual and immediate private, commercial, competitive interest to offer an infringing product to the public does.[182]

After the Supreme Court granted certiorari, with only one remaining researcher plaintiff challenging the patent, the Court concluded Myriad's patent claims covering naturally-occurring DNA were invalid because they covered patent ineligible products of nature.[183] Had the court excluded the remaining researcher—who was deemed only to have standing due to a minor competitive interest—on standing grounds, no plaintiffs would have remained to weed out Myriad's invalid patent claims.[184]

In *Myriad*, there is a notable absence of direct competitors who challenged the validity of Myriad's patents.[185] If Myriad's direct competitors stood to make a profit by offering Myriad's genetic tests if a court found Myriad's patents invalid, what prevented them from participating in the challenge? Patent holders and direct competitors interested in marketing an infringing product stand to benefit more by working out a settlement or even a licensing agreement than challenging the invalid patent before the PTAB or in federal court.[186] This mutually beneficial arrangement between competitors, at the very

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181. *Id.* "[A] case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*." Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1339 (Fed. Cir. 2008) (emphasis in original).

182. *Ass'n for Molecular Pathology*, 689 F.3d at 1323 (citing MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007)) ("Simply disagreeing with the existence of a patent on isolated DNA sequences or even suffering an attenuated, non-proximate, effect from the existence of a patent does not meet the Supreme Court's requirement for an adverse legal controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.").

183. Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2111 (2013) ("[W]e hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring."). "Laws of nature, natural phenomena, and abstract ideas are not patentable" under 35 U.S.C. § 101. *Ass'n for Molecular Pathology*, 689 F.3d at 1324 (internal quotations omitted) (quoting Mayo Collaborative Servs v. Prometheus, Inc., 132 S. Ct. 1289, 1293 (2012)).

184. In contrast, all of the excluded plaintiffs could have filed for a post-grant proceeding under the IPR and PGR statute's broad standing requirements. *See* 35 U.S.C. §§ 311(a), 321(a) (2012) (allowing any "person who is not the owner of a patent" to file a petition to institute a review of a patent).

185. *Ass'n for Molecular Pathology*, 689 F.3d at 1308–09 (determining whether "an assortment of medical organizations, researchers, genetic counselors, and patients" have standing in federal court).

186. Michael J. Burstein, *Rethinking Standing in Patent Challenges*, 83 GEO. WASH. L. REV. 498, 544 (2015).

least, gives potential challengers a handsome payment for holding off on offering an infringing product until the patent term's expiration and at the most, gives the original patent holder and licensee a level of exclusivity over remaining competitors that neither would have if the patent were invalidated.[187] Settlements also fend off the possibility of the patent holder retaliating by challenging the competitor's patents. With the knowledge that patent holders and their competitors tend to work out mutually beneficial agreements that keep invalid patents intact, Congress should create opportunities that allow other types of parties like CFAD to challenge these invalid patents that slip through the cracks.

B. Increasing the Number of Challenges Against Invalid Patents and Preventing Entrenchment of Biotech Industry Interests

In response to the STRONG Patents Act, Innovation Act, and CFAD opponents' proposal to exempt biotech companies from IPR, CFAD insists the system cannot solely rely only on generic pharmaceutical companies to police the validity of biotechnology patents through Hatch–Waxman or BPCIA litigation.[188] First, the Hatch–Waxman and the Biologics Acts do not lower drug prices.[189] Second, Hatch–Waxman and the BPCIA fail to effectively weed out many invalid patents, because pharmaceutical companies have historically been successful at persuading generic companies to accept settlement payments (known as pay-for-delay[190] agreements) and drop lawsuits challenging patent validity.[191] The brand name company will settle upon a mutually beneficial agreement rather than face the uncertainty of patent litigation.[192] Pay-for-delay agreements keep potentially invalid patents intact before a court can analyze the merits of the generic company's invalidity claims.[193] In one study, the FTC concludes that "[p]ay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices."[194]

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187. *Id.*

188. *H.R. 9, The "Innovation Act"*, *supra* note 172.

189. *See supra* notes 9–12 and accompanying text (explaining the increasing cost of drugs in the United States).

190. FEDERAL TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf [https://perma.cc/UZ8U-D3PL] [hereinafter PAY-FOR-DELAY].

191. *H.R. 9, The "Innovation Act"*, *supra* note 172.

192. PAY-FOR-DELAY, *supra* note 190.

193. *Id.*

194. *Id.*

Assuming hedge funds, like generic companies, are primarily motivated by profit, they are also vulnerable to brand name drug manufacturers' pay-for-delay tactics. CFAD attempts to refute this argument by publicly stating it will not accept settlement payments.[195] Even if CFAD sticks to this promise, the door is left open for other hedge funds willing to negotiate settlements.[196] Unlike direct competitors however, CFAD is also motivated to invalidate the patent to lower drug prices, an additional incentive that could tip the scale in favor of non-settlement.[197] There is also a chance the settlement payment that patent holders offer will be insignificant compared to the profit potential from shorting the stock of a company whose patents are invalidated.[198] Most important, Congress should focus on drafting legislation that deters abuse of IPR's settlement provisions rather than enacting overinclusive legislation that will reduce the number of people who can weed out bad patents in addition to decreasing the likelihood of settlement abuse. Abuse through settlement is already an issue between direct competitors and will continue to be one regardless of whether hedge funds are allowed to challenge patents too. Limiting IPR challenges to direct competitors will further entrench the patent system toward industry interests over the public's interest in recapturing ideas that belong in the public domain, increasing drug access, and lowering drug prices.

The Innovation Act and STRONG Patents Act (which both restrict standing requirements in post-grant proceedings)[199], as well as excluding biotechnology companies from post-grant proceedings, would limit the ability to challenge patent validity to direct competitors. Because direct competitors are often willing to accept a settlement payment or licensing agreement from patent holders in lieu of challenging their patents, these solutions would allow more patent holders to continue to enforce their invalid patents.

Congress should not prevent hedge funds from challenging patents simply because they fear hedge funds will abuse the system. It should target this already prevalent abuse by proposing

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195. *H.R. 9, The "Innovation Act"*, *supra* note 172.

196. At the joint request of the petitioner and the patent owner, the PTAB may terminate an inter partes review upon settlement between the parties. 35 U.S.C. § 317(a) (2012). Although the parties are required to file a settlement agreement in writing with the PTO, the terms of the agreement are treated as confidential and kept separate from the publically-available prosecution history of the challenged patent claims. § 317(b).

197. *See supra* note 5–7 (explaining CFAD is targeting patents it believes lack social value).

198. CFAD is targeting biotech companies' primary revenue generating products, which, if invalidated, have the potential to cause a major decrease in a company's stock price. *See* Decker, *supra* note 1 (noting Ampyra accounts for about 90% of Acorda's revenue).

199. *See supra* notes 160–62 and accompanying text.

penalties against abuse of IPR's settlement provisions or by making settlement a more transparent process.[200] A system that enables more opportunities to weed out invalid patents translates into a stronger, more efficient patent system. It also prevents entrenchment of the biotechnology's interests.[201] The legislature might find a middle ground in these proposed solutions by raising claim construction and evidentiary standards applied during post-grant proceedings to ensure more uniform results between federal courts and administrative courts without eliminating IPR's broad standing requirements.

C. CFAD: Biotech's First Formidable Threat to Improvidently Granted Patents

Hedge funds are not the first representatives of the public interest who have taken advantage of post-grant proceedings' broad statutory standing provision; some pure public interest groups have also used post-grant proceedings to challenge the validity of patents.[202] In fact, interest groups with purely public interest motives are the theoretically ideal party for weeding out invalid patents, because they are less likely to settle than challengers with profit-seeking motives, like generic companies or hedge funds.[203] Unlike the STRONG Patents Act, passage of the Innovation Act would exclude hedge funds from filing IPR petitions but would continue to allow pure public interest groups to file challenges.[204] Unfortunately, allowing parties that only have pure public interest motives to participate in post-grant proceedings is insufficient to cover the number and cost of invalidating a patent. Public interest groups need the help of organizations like CFAD, from both a numbers and a resources perspective, despite the threat their mixed motives pose.

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200. *See* 35 U.S.C. §§ 317(a)–(b) (2012) (requiring the parties to file a settlement agreement with the PTO but allowing parties to keep the terms of the agreement confidential).

201. Brand-name and generic drug companies share many of the same interests, such as keeping drug prices high in order to make a profit for their company. Jonathan D. Alpern et al., *High-Cost Generic Drugs—Implications for Patients and Policymakers*, 371 NEW ENG. J. MED. 1859, 1859 (2014) (noting that brand-name and generic drugs are extremely expensive).

202. Any "person who is not the owner of a patent" may file a petition to institute a review. § 311(a).

203. *See supra* notes 195–97 and accompanying text.

204. Innovation Act of 2015, H.R. 9, 114th Cong. § 9(b)(1)(C) (2015) (prohibiting petitioners who "acquire a financial instrument . . . that is designed to hedge or offset any decrease in the market value of an equity security of the patent owner" or "demand payment . . . from the patent owner or an affiliate of the patent owner in exchange for a commitment not to file a petition.").

Many public interest groups precede CFAD in using post-grant proceedings to challenge patents. Consumer Watchdog, a non-profit charity "dedicated to providing a voice for taxpayers and consumers in special-interest-dominated public discourse," challenged a patent covering human embryonic stem cells using inter partes reexamination.[205] The Public Patent Foundation ("PubPat") was specifically formed to challenge "[u]ndeserved [p]atents and [u]nsound [p]atent [p]olicy."[206] The Electronic Frontier Foundation ("EFF"), a nonprofit organization formed in 1990 to "defend[] civil liberties in the digital world",[207] challenges patents through its Patent Busting Project, which targets "bogus software patents."[208] Patients, medical organizations, and researchers have not used the post-grant proceeding process but attempt to challenge patents in federal court based on cost and access concerns.[209]

Unfortunately, the number of challenges brought by pure public interest groups is insufficient to identify and target all of the invalid patents granted through the USPTO's imperfect examination process.[210] Between February 10 and September 28, 2015, CFAD filed thirty-two IPR petitions against various biopharmaceutical companies' patents.[211] Although the PTAB denied institution on fourteen petitions, it instituted IPR on eighteen, which proves the number of petitions filed by CFAD is not necessarily too aggressive or frivolous.[212] Compare this number to the number of challenges filed by pure public interest groups. The embryonic stem cell patent appears to be Consumer Watchdog's first and only challenge.[213] Since its inception in 2003,[214] PubPat has challenged fifteen patents through inter

205. Consumer Watchdog v. Wis. Alumni Res. Found., 753 F.3d 1258 (Fed. Cir. 2014). *Inter partes* reexamination preceded IPR's as a post-grant proceeding option and had similar standing requirements. *See* §§ 311(a), 314(b)(2) (permitting any third party to submit a request for *inter partes* reexamination).

206. PUB. PATENT FOUND., http://www.pubpat.org/index.htm (last visited Apr. 21, 2017).

207. EFF, https://www.eff.org/about [https://perma.cc/ES9J-2EB2].

208. *Patent Busting Project*, EFF, https://www.eff.org/patent-busting [https://perma.cc/P4ZB-ALRG].

209. These groups have not used IPR to challenge patents yet but have filed challenges together in federal court, where the majority of them were dismissed based on standing issues. *See* Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1308–09 (Fed. Cir. 2012), *rev'd on other grounds*, *sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

210. *See supra* notes 42–58 and accompanying text (explaining the inefficiencies of the USPTO's patent registration process).

211. *See supra* note 15.

212. *See supra* note 17.

213. *Patent*, CONSUMER WATCHDOG, http://www.consumerwatchdog.org/tags/patent [https://perma.cc/JLU5-QWAU]. Consumer Watchdog was founded in 1985. *Id.*

214. Susan Hansen, *Power to the People*, IP L. & BUS., Apr. 2007, at 36.

partes reexamination.[215] The EFF has only filed ten reexamination requests on software and Internet patents.[216]

Another related reason why pure public interest groups can benefit from the help of hedge funds in seeking out and challenging more patents is because hedge funds have more financial resources at their disposal. Even using IPR, which is cheaper than full-blown litigation, challenging biotech patents is expensive.[217] In January 2016, Hayman Capital's assets under management were approximately $2.58 billion.[218] Consumer Watchdog's total assets hovered around approximately $3–4.8 million between 2011 and 2014.[219] The EFF's total assets have been around $11 million and $22.9 million between 2012 and 2014[220] and PubPat's total assets have steadily decreased from approximately $450,000 in 2012 to $14,000 in 2014.[221] Even comparing Consumer Watchdog's higher total asset value of $4.8 million against Hayman Capital's $2.58 billion, Hayman Capital still holds over 500 times the amount in assets of any of these public interest organizations. Although cheaper than litigation, IPR's high price tag limits the number of patents not-for-profit groups are able to challenge due to resource constraints; financial resources are much less of a limiting factor to hedge funds, many of which hold billions in assets. Other types of public interest groups have the same funding issues, especially patients who cannot afford the patented product in the first place.[222]

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215. PUB. PATENT FOUND., *supra* note 206.

216. *Patent Busting Project*, *supra* note 208.

217. Coal. for Affordable Drugs VI, LLC v. Celgene Corp., No. IPR2015-01092 (P.T.A.B. Sept. 25, 2015) (denying a motion for sanctions for abuse of IPR). The average cost of IPR ranges between $500,000 and $900,000 while patent litigation in federal court ranges between $813,000 and $3.8 million. Joseph Cwik, *The Business Case for Inter Partes Review of Patents by Generic Pharma*, HEALTHCARE L. INSIGHTS (May 27, 2014), http://www.healthcarelawinsights.com/2014/05/the-business-case-for-inter-partes-review-of-patents-by-generic-pharma/ [https://perma.cc/3QGS-T5WU].

218. *Hayman Capital Management*, CREDIO, http://investment-advisors.credio.com/l/28315/Hayman-Capital-Management-LP (last visited Apr. 26, 2017). As of the date of this Comment's publication, Hayman Capital's total assets under management has decreased to $904 million. *Id.*

219. *990 Finder: Consumer Watchdog*, FOUND. CTR., http://990finder.foundationcenter.org/990results.aspx?990_type=A&fn=Consumer+Watchdog&st=&zp=&ei=&fy=&action=Find (last visited Apr. 26,2017).

220. *990 Finder: Electronic Frontier Foundation*, FOUND. CTR., http://990finder.foundationcenter.org/990results.aspx?990_type=A&fn=Electronic+Frontier+Foundation&st=&zp=&ei=&fy=&action=Find (last visited Apr. 26,2017).

221. *990 Finder: Public Patent Foundation*, FOUND. CTR., http://990finder.foundationcenter.org/990results.aspx?990_type=A&fn=Public+Patent+Foundation&st=&zp=&ei=&fy=&action=Find (last visited Apr. 26,2017).

222. *See* Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1315 (Fed. Cir. 2012), *rev'd on other grounds*, *sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) (explaining that patients challenged Myriad's patent, because

Hayman Capital's assets under management are also more comparable to the assets of biopharmaceutical companies. As of December 31, 2015, Acorda had a market capitalization of $1.846 billion.[223] Celgene, another company whose patents CFAD has challenged, had a market capitalization of $94 billion as of December 31, 2015.[224] From a resources perspective, CFAD is one of the first formidable threats to biotechnology companies holding invalid patents, because it has more capital than pure public interest groups to compete with the legal and financial reserves of biotechnology companies.[225]

Finally, CFAD's additional motive of making a profit does not negate the social value of lowering drug prices.[226] Regardless of whether it is a pure public interest group or a profit-seeking hedge fund invalidating the patent, the general public still wins by opening up the market for generic biopharmaceutical pricing. Fear that financial incentives will cause hedge funds to abuse the system should not justify excluding parties who also have a legitimate public interest in recapturing knowledge that belongs to the public domain and lowering drug prices.

Although hedge funds' public interest motives in challenging patents are mixed with incentives for personal gain, Congress should continue to permit hedge funds to challenge patents alongside pure public interest groups by refusing to approve legislation that seeks to limit who can challenge patents. Hedge funds have more resources than pure public interest groups to seek out and challenge potentially invalid patents. In addition, their resources are more comparable to the monetary resources of biotechnology companies. There is less of a chance that one party will be able to out-finance the other. Finally, hedge funds' additional motive in no way detracts from the value the public gains by recapturing public domain information the USPTO should never have protected with a patent in the first place.

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it made the genetic screening text unaffordable and inaccessible).

223. *Acorda Therapeutics Market Cap*, YCHARTS, https://ycharts.com/companies/ACOR/market_cap (last visited Apr. 26,2017).

224. *Celgene Market Cap*, YCHARTS, https://ycharts.com/companies/CELG/market_cap (last visited Apr. 26,2017).

225. *See supra* notes 218–22 and accompanying text (comparing Hayman Capital's assets under management to the total assets of several-not-for profit groups who have challenged patents in the past).

226. Coal. for Affordable Drugs VI, LLC v. Celgene Corp., No. IPR2015-01092 (P.T.A.B. Sept. 25, 2015).

V. CONCLUSION

Hedge funds seeking to weed out invalid patents and lower healthcare prices for everyone should not be excluded from using post-grant proceedings simply because they have found a way to personally benefit from challenging patents.[227] IPR is not perfect and hedge funds are vulnerable to settlement agreements that could result in perpetuating an invalid patent, but this problem will not go away by excluding hedge funds, as generic companies are equally vulnerable to pay-for-delay settlement agreements.[228] Congress should address this problem by introducing safeguards that prevent these types of settlements and not by excluding a new group of potential challengers seeking to weed out invalid patents, albeit for a profit.

Allowing hedge funds to join pure public interest groups to find and weed out invalid patents strengthens the number of public interest representatives within the patent system, preventing entrenchment of the biotechnology industry's interest. Additionally, hedge funds are in a better position resource-wise to seek out and challenge potentially invalid patents than pure public interest groups.[229] By weeding out the invalid patents, IPR strengthens the integrity of the patent system and everyone's confidence in valid patents, which represent the majority of granted patents.[230] The more opportunities the patent system provides for public interest representatives to challenge invalid patents, the stronger the United States' patent system will be.

VI. EPILOGUE

During the preparation of this Comment for publication, the PTAB resolved all thirty-two of CFAD's petitions. It instituted IPR and released final written decisions based on eighteen of CFAD's petitions.[231] In all, the PTAB determined that CFAD showed that the claims at issue in eight of the petitions were unpatentable.[232]

Despite a promising success rate on the legal side of its strategy, CFAD has not filed any more petitions and has not offered any reasons for why it has stopped. However, there is

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227. *See supra* notes 150–66 and accompanying text (describing legislation proposed by Congress and additional suggestions from the biotechnology industry that would disallow hedge funds to participate in post-grant proceedings).

228. *See supra* notes 188–98 and accompanying text.

229. *See supra* 202–25 and accompanying text.

230. *H.R. 9, The "Innovation Act"*, *supra* note 172.

231. Petitions Filed by the Coalition for Affordable Drugs, *supra* note 15.

232. *See, e.g.*, Coal. for Affordable Drugs VI LLC v. Celgene Corp., No. IPR2015-01169 (P.T.A.B. Nov. 16, 2015).

evidence to suggest that Hayman Capital's investment strategy was not as profitable as theorized in terms of shorting the stock and lowering drug prices for all.[233] When the PTAB found most—but not all—of the claims covering Shire's patent on the gastrointestinal drug Gattex invalid, the stock price did not shift as significantly as it did when news hit that CFAD filed its first two challenges against Acorda's patents.[234] Additionally, other patents still cover the drugs at issue in CFAD's petitions and it is likely that drug makers will appeal the PTAB's decisions.[235] Although there is still a possibility that the decisions on appeal may result in lowering drug prices, short selling is preferably a short-term investment strategy. It is unlikely that investors are willing risk exposure to a potential stock increase during the time it takes to file a challenge and reach a final decision.

Without the promise of personal profit, the Patent Office may not see CFAD or any other investors bringing patent challenges in the near future. Pharmaceutical companies can breathe easy for now. However, CFAD's experience with IPR still shows us that hedge funds and other personally motivated entities can be effective in weeding out bad patents. Hedge funds may not ever try to implement CFAD's investment strategy again, but so long as the end result serves the public purpose of weeding out bad patents, no one should try to prevent hedge funds or any other personally-motivated entity from doing so.

Jennifer Robichaux Carter

233. Tony Dutra, *Hedge Fund Manager Bass Wins Shire Gattex Patent Challenge*, BLOOMBERG (Oct. 26, 2016), https://www.bna.com/hedge-fund-manager-n57982079184/.

234. Ryan Davis, *PTAB Wins for Bass May Not Move Needle on Drug Prices*, LAW360 (Oct. 28, 2016, 8:53 PM); *see supra* notes 1–2.

235. *See* Davis, *supra* note 234.