INTER PARTES REVIEW: SHOULD HEDGE FUND MANAGERS BE able TO PROFIT FROM CHALLENGING A PATENT'S VALIDITY?

INTRODUCTION

Imagine that you have spent time, energy, and investor's money into developing an innovative drug that treats a life-threatening illness. You have hired reputable counsel and submitted a patent to the Patent Office. Eventually, a patent examiner declares that your invention is patentable and you are overjoyed that you have the proprietary right to your invention and can enforce that right against infringing parties.

Elated with the Patent Office's grant of your patent, you lightly brush off a radio broadcast segment highlighting a hedge fund manager who made substantial financial gain during the housing market collapse by short stocking its market. You find the story interesting, but pay it no mind as the subject matter is far removed from your drug developing endeavors. The next thing you know, the same hedge fund manager you have heard about in passing has shorted your company's stock, instituted a proceeding to challenge the validity of your patent, and invested in companies that have everything to gain if he succeeds. It is to your frustration and detriment that this challenge bestowed upon your invention is completely legal.

The scenario above is a reality for many companies in the biotechnology and pharmaceutical industries. At the core of protection for intellectual property is the encouragement for researchers and scientists alike to innovate; not to stifle innovation with litigious loopholes.[1] While patent reform occurred with the passing of the Leahy-Smith America Invents Acts (AIA)

1. *See* President Barack Obama, State of the Union Address (Jan. 28, 2014) (stating that "a patent reform bill that allows . . . businesses to stay focused on innovation, not costly, needless litigation" should be passed).

in 2011,[2] the need for further reform has been addressed by the President of the United States,[3] practitioners, and innovators.

Inter Partes Review (IPR) is a review of a patent's validity that takes place after the United States Patent and Trademark Office ("Patent Office") has granted a patent.[4] This third-party method of challenging a patent became effective September 16, 2012, one year after the America Invents Act statute was passed by Congress.[5] While it may not have been Congress's intent for hedge fund managers to file an IPR petition and in turn receive financial gain,[6] this is exactly what is occurring.

Hedge funds managers now use the IPR process as a tool in their investment portfolio.[7] They will short stock the company whose patent is being challenged and simultaneously invest in a company that will benefit if the patent is declared invalid.[8] Specifically, pharmaceutical (pharma) and biotechnology (biotech) industries are targeted by hedge fund managers because posing a challenge to one or more drug patent claims through the IPR process pose an "existential threat" to a drug company's portfolio and adversely affects its stock.[9] The process is troublesome for both industries because once investors and shareholders become aware of potential patent invalidation, a decrease in investments and innovation are likely to occur.[10]

Rather than opposing IPR as a whole, this paper discusses why there is a need to modify this post-grant review process to ensure that innovation is

2. Leahy-Smith America Invents Act, H.R. REP. NO. 112-98, 112th Cong. (2011).

3. *See* State of the Union Address, *supra* note 1.

4. 35 U.S.C. § 311(a) (2011).

5. *Id.*

6. *See supra* note 2 at 40 (stating that the United States needs a modernized and improved patent system "that will support and reward all innovators with high quality patents." Additionally, The America Invents Act was designed to "limit unnecessary and counterproductive litigation costs").

7. Gene Quinn, *Patent Abuse or Genius? Is Kyle Bass Abusing the Patent System?*, IP Watchdog (Apr. 8, 2015), http://www.ipwatchdog.com/2015/04/08/is-kyle-bass-abusing-the-patent-system/id=56613.

8. *Id.*

9. Susan Decker & Caroline Chen, *Hedge Funds Found a New Way to Attack Drug Companies and Short Their Stock*, BLOOMBERG BUSINESS (Mar. 20, 2015), http://www.bloomberg.com/news/articles/2015-03-20/hedge-funds-take-advantage-of-patent-rules-to-target-drugmakers; Lorelei Laird, *Patent Holders Allege Financial Companies are Misusing New Post-Grant Review Process for Profit*, ABA J. (Dec. 1, 2015), http://www.abajournal.com/magazine/article/patent_holders_allege_financial_companies_are_misusing_new_post_grant_revie.

10. Decker & Chen, *supra* note 9.

the top priority of a nation that thrives on innovation.[11] Part I provides an educational background on patents and the IPR process. Part II discusses the effects that IPR has on biotech and pharma industries and the implications that can arise if the system remains unchanged. Part III proposes reasonable changes to the IPR process that uphold the issuance of high quality, legitimate patents.

PART I: HISTORICAL BACKGROUND ON PATENTS AND THE IPR PROCESS

Our country's forefathers gave express protection to innovative discoveries.[12] The Constitution explicitly grants Congress the right to "promote the progress of science and useful arts, by securing for limited times to . . . inventors the exclusive right to their respective . . . discoveries."[13] Patent owners may enjoy the protection of their intellectual property for a predetermined number of years if they are willing to disclose their invention to the public (i.e. through the issuance of a publicly available patent).[14]

Today, patent examiners at the Patent Office are the gatekeepers of patent grants.[15] Even though the Patent Office is equipped with qualified examiners, patent examination is not without its flaws. One consistent obstacle in the process is handling the sheer number of patent applications that examiners review each year.[16]

In 2014, each patent examiner processed approximately 70 patents.[17] Provided that applications can be hundreds to thousands of pages long, mistakes are inevitable.[18] Until a perfect world exists where adequate resources are available and patents are examined with 100% efficiency, IPR is one way to posthumously catch non-meritorious patents that may have slipped through the cracks during the examination process.[19]

Unwarranted patent claims that pass under the examiner's radar during an examination should be invalidated for drug development's sake. Once a

11. A STRATEGY FOR AMERICAN INNOVATION: NATIONAL ECONOMIC COUNCIL AND OFFICE OF SCIENCE AND TECHNOLOGY POLICY (Oct. 2015) (discussing strategies to ensure that innovation in America continues to thrive).

12. U.S. CONST. art. I, § 8, cl. 8.

13. *Id.*

14. H.R. REP. NO. 112-98, *supra* note 2, at 38.

15. *General Information Concerning Patents*, USPTO (Oct. 2015), http://www.uspto.gov/patents-getting-started/general-information-concerning-patents.

16. DEAN BAKER, CENTER FOR ECONOMIC AND POLICY RESEARCH, THE IMPACT OF EXEMPTING THE PHARMACEUTICAL INDUSTRY FROM PATENT REVIEWS 2 (2015).

17. *Id.* at 4.

18. *Id.*

19. *Id.* at 7.

patent is granted, other competing entities spend resources to invent around the patent in order to produce a similar product while avoiding infringement.[20] Allowing an invention to have unjustifiable protection permits companies to charge consumers reprehensible amounts for their product and wrongfully uphold a monopoly by earning revenue on a product that should be shared by other pharma and biotech companies in generic form.[21] In this respect, consumers and competing companies in the pharma and biotech industries may have a solid reason to pursue any action that can invalidate a questionable patent.

A. Problems Associated with Overbroad Patent Claims Prior to the AIA

To best understand the changes associated with patent reform through the AIA, it is essential to understand the historical context surrounding the Act. The 1990's were an age when thousands of overly broad software patents were approved, mostly due to the Patent Office's lack of expertise in the subject matter and a lack of existing software patents (also known as prior art) to compare the pending patent applications.[22] Specifically, these unwarranted patents were notoriously granted to software products that lacked novelty.[23]

Due to the overbroad language of software patents, determining patent claim limits became virtually impossible.[24] The effect was essentially this: if an overbroad patent was issued, any subsequent, related inventions would fall within the scope of the overbroad patent and be deemed to have infringed the overbroad patent.

For example, in May of 2001, Ultramercial Inc. filed a patent for a method of viewing free copyrighted media over the Internet in exchange for watching an advertisement.[25] On September 9, 2009, Ultramercial sued Hulu, LLC, YouTube, LLC, and Wild Tangent for infringement of the method despite lacking specificity as to how the copyrighted material would

20. *Id.*

21. *See* Andrew Pollack, *Drug Goes from $13.50 a Tablet to $750, Overnight*, N.Y. TIMES (Sept. 20, 2015), http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html (discussing that the price of Daraprim, a medication used to treat HIV, was raised 5,000 percent after it was acquired by a pharmaceutical start-up company run by former hedge fund manager Martin Shkreli).

22. Kris Frieswick, *The Real Toll of Patent Trolls*, INC (Feb. 14, 2013), http://www.inc.com/magazine/201202/kris-frieswick/patent-troll-toll-on-businesses.html.

23. *Id.*; an invention that is already in use sets forth a statutory bar and prevents another from filing a patent on the previous invention. Conditions for patentability; novelty, 35 U.S.C. § 102(a)(1).

24. *See* Frieswick, *supra* note 22.

25. U.S. Patent No. 7,346,545 (filed May 29, 2001).

be uploaded.[26] Although Ultramercial argued that their patent claims were directed to a novel method "previously unknown and never employed on the Internet before," the Supreme Court remanded the case.[27] The lower court held that the patent was invalid.[28] In reaching its decision, the court agreed with the alleged infringers' contentions that the simple break down of "abstract idea[s] into basic steps" was underserving of protection.[29] Additionally, the court agreed that the claims "add[ed] no meaningful limitations to convert the abstract idea into patent eligible subject matter."[30]

With respect to computer technology companies in the 1990's, IPR would have been a cheaper and more effective method for getting rid of lawsuits such as Ultramercial's, which took a little over five years to come to an end.[31] Ultramercial's case demonstrates instances where a company was forced to spend a large sum of money to fend off infringement allegations from a patent that should have never been granted in the first place.[32] Patent reform was desperately needed to avoid expensive and lengthy litigation.

B. The Post-Grant Review Process Prior to the AIA

As an efficient and cost-effective alternative to district court litigation, Congress enacted an administrative reexamination process to review a patent's validity after it was granted.[33] Reexamination required the Patent Office to review validity in light of a "substantial new question of patentability" that was not provided to the patent examiner in his or her initial patent examination.[34]

This procedure weighed in favor of patent holders and made it difficult for a petitioner to initiate a reexamination request because he or she could not base their request on statutory bar violations: prior inventions (prior art), prior public use or sales of the invention, utility of the invention, or patent specification requirements.[35] Although patent owners are required to

26. Ultramercial, Inc. vs. Hulu, 772 F.3d 709, 714 (Fed. Cir. 2014).

27. *Id.*

28. *Id.* at 711.

29. *Id.* at 714.

30. *Id*. According to the district court, the abstract idea of Ultramercial's patent was "that one can use [an] advertisement as an exchange or currency." Ultramercial, Inc. v. Hulu, No. 09-CV-06918 (RGK), 2010 WL 3360098, at *17 (C.D. Cal. Aug. 13, 2010).

31. Ultramercial, Inc., 772 F.3d at 709.

32. In 2011, patent trolls cost companies approximately $29 billion in legal fees and settlement costs. James Bessen & Michael J. Meurer, *The Direct Costs from NPE Disputes*, 99 CORNELL L. REV. 387, 389 (2014).

33. 35 U.S.C. § 302 (1982) (amended 2011).

34. 35 U.S.C. § 303 (1982) (amended 2011).

35. Leahy-Smith America Invents Act, *supra* note 2, at 45.

overcome these "statutory bars" before a patent is granted,[36] evidence of a violation may have been overlooked due to the number of patents pending examination. In addition to evidentiary restrictions, a third-party petitioner had no role in the proceeding once it was initiated and could not appeal the outcome.[37]

C. The Post-Grant Review Process After Implementation of the AIA

Prior to the AIA, substantial patent reform had not taken place since 1952.[38] In 2011, Congress produced an improved patent system designed to enhance "support and [to] reward all innovators with high quality patents."[39] To ensure that only worthy patents remained protected for their entitled statutory life-span,[40] the post grant review process was modified.

The AIA notably changed its post grant proceeding of allowing third parties to challenge the validity of one or more patent claims that may not have had initial grounds for being granted.[41] Rather than being heard in federal court, the post-grant process was to be conducted by a panel comprised of Administrative Patent Judges, all of which are or have been experienced patent attorneys in the relevant field.[42]

As a final modification to the post-grant procedure, the inter partes reexamination proceeding was renamed "inter partes review" (IPR) and provided a change in the threshold for initiating an inter partes reexamination proceeding.[43] Rather than allow a question of patent validity to occur whenever there was a substantial new question of patentability, an IPR proceeding would not be granted unless there was a "reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition."[44]

36. 35 U.S.C. § 102 (a)(1) (1982) (amended 2011).

37. 35 U.S.C. §§ 302–303 (1982) (amended 2011).

38. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 435 (2012).

39. Leahy-Smith America Invents Act, *supra* note 2, at 40.

40. 35 U.S.C. § 154(a)(2) (1952) (amended 2011) (stating that the patent term begins on the patent issue date and ends 20 years from the date in which the patent application was filed in the Unites States).

41. Leahy-Smith America Invents Act, *supra* note 2, at 45.

42. Matt Levy, *Three Crucial Words in Patent Reform: Inter Partes Review (Part 1)*, PATENT PROGRESS (May 14, 2015), http://www.patentprogress.org/2015/05/14/three-crucial-words-in-patent-reform-inter-partes-review-part-1.

43. Leahy-Smith America Invents Act, *supra* note 2, at 15.

44. *See id.*; 35 U.S.C. § 314(a) (2012).

Nearly all inter partes petitions include evidence to support the contention that the challenged patent is invalid, known as a declaration.[45] Declarations can be very effective when arguing unpatentability under the theory that the claimed invention would have been obvious to make in light of existing inventions[46] (i.e. combining prior invention A with prior invention B would yield the result of the challenged invention; hence, the challenged invention is obvious to invent and is not patentable[47]).

1. Limited Patent Owner Power in an IPR Proceeding

Currently, the preliminary response to an IPR petition does not allow patent owners to include their own declaration that could rebut the petitioner's research used to allege a patent's invalidity.[48] Even if patent owner declarations were permitted, he or she has only three months to file a preliminary response to an IPR petition,[49] which is inadequate time to perform research necessary to directly attack the petitioner's findings. If the patent owner's declaration is insufficient or not filed at all, the Patent Office will take a one-sided consideration in favor of the moving party when making the decision as to whether a patent claim should be invalidated.[50]

PART II. WHY IPR IS BENEFICIAL, YET HAS DANGEROUS IMPLICATIONS.

Post-grant review in any form can serve as a low-cost approach to invalidate a patent that is deemed unworthy of protection. Because IPR may only be initiated within nine months of a patent grant, the process may "enable early challenges to patents" and "improve the quality of patents and the patent system."[51] While there is a need and interest in reform,[52] Biotech and Pharma industries should not be exempt from the process.

Not all pharmaceutical patents are worthy of protection. In 2012, Gnosis SpA (Gnosis) challenged the validity of a dietary supplement patent owned

45. 37 C.F.R. § 1.132 (2015).

46. John M. Bird & Margaret M. Welsh, *Strategic Considerations Before Filing an IPR*, 7 LANDSLIDE (2014), http://www.americanbar.org/publications/landslide/2014-15/november-december/strategic_considerations_filing_ipr.html (stating that declarations may contribute to success of an obviousness issue).

47. 35 U.S.C. § 103 (2012).

48. Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,766 (Apr. 1, 2016) (to be codified at 37 C.F.R. § 42.107(a)).

49. *Id.*

50. *See* 81 Fed. Reg. 81,750, 81,766 (Apr. 1, 2016) (to be codified at 37 C.F.R. § 42.108(c)).

51. Leahy-Smith America Invents Act, *supra* note 2, at 48.

52. *See* State of the Union Address, *supra* note 1.

by Swiss Merck KgaA (Merck).[53] Merck's patent[54] related to a reduced folate dietary supplement, and Gnosis was accused of infringing by producing the product in generic form.[55] Gnosis, the alleged infringer, filed an IPR petition arguing that twenty-eight of Merck's claims were invalid due to a lack of novelty.[56] Additionally, Gnosis argued that the same twenty-eight claims were invalid because they were obvious to invent.[57] The prior art references used to challenge Merck's validity were a European patent application and U.S. Patent No. 5,194,611.[58]

For purposes of the obviousness argument, Gnosis argued that it would be obvious for a person of ordinary skill in the art to combine both prior art references to arrive at the subject matter claimed in several of Merck's patent claims.[59]

Gnosis prevailed on each of its claims despite Merck's argument that patent protection should remain intact because there was commercial success of the product and because the dietary supplement was licensed.[60] Counsel for Gnosis labeled this decision as the first IPR outcome of a pharma patent[61] and described it as "a win for customers and the American health care consumer."[62] Merck's patent invalidity is illustrative of the opportunity that IPR gives companies to manufacture a generic form of a drug without infringing.

Although typically used by drug manufacturers accused of infringement, IPR filings are now used by hedge fund managers as part of an investment strategy.[63]

53. Ryan Davis, *Merck Supplement Patents Nixed In 1st Pharma AIA Reviews*, LAW 360 (June 23, 2014, 5:09 PM), http://www.law360.com/articles/550733/merck-supplement-patents-nixed-in-1st-pharma-aia-reviews.

54. U.S. Patent No. 5,997,915 (filed Jan. 31, 1997).

55. Bill Donahue, *Merck Drops ITC Probe Into Patented Folate Supplements*, LAW 360 (June 11, 2013, 7:25 PM), http://www.law360.com/articles/449309/merck-drops-itc-probe-into-patented-folate-supplements.

56. Petition for Inter Partes Review, Gnosis S.p.A. v. South Alabama Med. Sci. Found., No. IPR 2013-00116, 2013 WL 5402330, *9-10 (P.T.A.B. Jan. 23, 2013).

57. *Id.* at 28-41.

58. *Id.* at 8.

59. *Id.* at 28.

60. Davis, *supra* note 53, at 2-3.

61. *Id.* at 1.

62. *Id.* at 3.

63. Jim McTague, *Kyle Bass' Comeback Plan: Oil, Argentina and Patents*, BARRON'S (Aug. 13, 2015), http://www.barrons.com/articles/kyle-bass-comeback-plan-oil-argentina-and-patents-1439489572.

Kyle Bass is a hedge fund manager with Hayman Capital Management LP.[64] Bass gained popularity in 2008 due to his financial stock market gain during the housing market crisis.[65] Today, he has gained a newfound notoriety within the patent, biotech, and pharma industries by adding IPR petitions as an investment strategy to his hedge fund's portfolio.[66] As a part of this strategy, Bass formed the Coalition for Affordable Drugs (Coalition) which, as of late-February 2016, has now filed at least thirty seven IPR petitions with the Patent Office.[67]

In addition to filing the petitions, Bass has simultaneously bet against the targeted company's stock.[68] Bass's use of IPR proceedings in "effort[s] to move stock" or as "an investment vehicle" even comes as a surprise to those involved with the development of IPR.[69] Jim Greenwood, the President and CEO of Biotechnology Industry Organization ("BIO"), has described Bass's IPR use as an abuse of the patent system that "[exploits] the Patent Office's patent challenge proceeding as part of his cynical short-selling strategy."[70]

The Securities and Exchange Commission ("SEC") explains that a short sale is the act of selling a borrowed stock that is completed upon the seller's delivery of a borrowed security.[71] Essentially, short sellers aim to profit from a decline in a company's stock by betting against a company's performance.[72] This investment strategy has been profitable for Bass, as the very news that his coalition has filed an IPR petition has sent patent owner's stocks tumbling.[73]

64. *Id.*

65. *Id.*

66. *Id.*

67. Julia La Roche, *Kyle Bass Gave Back Most of the Investor Money he Raised for His Big Pharma Short, But He's Not Giving up the Fight*, BUSINESS INSIDER, (Feb. 23, 2016, 8:31 AM), http://www.businessinsider.com/kyle-bass-to-return-most-of-money-from-hayman-pharma-vehicle-2016-2.

68. *See* McTague, *supra* note 63.

69. Susan Decker and Caroline Chen, *Hedge Funds Found a New Way to Attack Drug Companies and Short Their Stock*, BLOOMBERG BUSINESS (Mar. 20, 2015, 2:00 AM), http://www.bloomberg.com/news/articles/2015-03-20/hedge-funds-take-advantage-of-patent-rules-to-target-drugmakers (Bernard Knight, former general counsel for the Patent Office, stating that those involved with patent reform at the Patent Office never anticipated the IPR system to be used as an investment and stock market tool).

70. *BIO Statement Following Kyle Bass' IPR Petition*, BIO, (Feb. 11, 2015), https://www.bio.org/media/press-release/bio-statement-following-kyle-bass-ipr-petition-0.

71. SEC Concept Release: Short Sales, SEC (Oct. 21, 1999), https://www.sec.gov/rules/concept/34-42037.htm.

72. *Id.*

73. *See BIO Statement Following Kyle Bass' IPR Petition*, *supra* note 70.

Acorda Therapeutics Inc. is one of several companies that has been affected by Bass's IPR petitions.[74] Bass's Coalition filed IPR petitions on February 10[75] and 27 [76] in 2015, challenging the validity of Acorda's multiple sclerosis drug from which the company bases 93 percent of its revenue.[77] Although the Patent Trial and Appeal Board (PTAB) ultimately denied both inter partes petitions, Acorda's stock fell 10 percent after the first petition was filed, and an additional five percent once the second petition was filed.[78]

The abrupt decline in stock activity caused by Bass's petitions may serve as a deterrent for investors to provide pharma and biotech companies with the funds necessary to develop new, effective, and innovative drugs to patients in need.[79] Should stock prices continue to decrease with every IPR petition, and with a possibility of a lack of return on investment, the pharma and biotech industry may see a decrease in investor dollars.[80] The current IPR system allows this risk to continue.

A. Drug Development Costs vs. Possible Lack of Investment Return

Costs associated with prescription drug medication is substantial.[81] Tufts Center for the Study of Drug Development has estimated that $2.5 billion is required for each approved product.[82] With a substantial amount of money poured into each drug, investors and companies that develop drugs could reasonably expect a financial return so that they may continue to produce innovative products.

While the high cost of drug development may lead to high drug prices, Bass contends that approximately one percent of pharma companies are "gam[ing] the patent system in order to keep charging top dollar for

74. *See* Petition for Inter Partes Review, Coal. for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. 2015-00720, 116 U.S.P.Q.2d 1066 (P.T.A.B Feb. 10, 2015).

75. *Id.*

76. Petition for Inter Partes Review, Coal. for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. 2015-00817, 116 U.S.P.Q.2d 1064 (P.TA.B. Feb. 27, 2015).

77. Ryan Davis, *Hedge Fund's AIA Attack Should Have Biotech Cos. Wary*, LAW 360 (Mar. 9, 2015, 2:16 PM), http://www.law360.com/articles/628691/hedge-fund-s-aia-attack-should-have-biotech-cos-wary.

78. *Id.*

79. Leanne Miller, *Biotech CEO: Bass Exploiting Weakness in System*, CNBC (Sep. 19, 2015), http://www.cnbc.com/2015/09/19/biotech-ceo-bass-exploiting-weakness-in-system.html (Dr. Ron Cohen stating that if the system remains unchanged, investors will be unable to contribute to research funding).

80. *Id.*

81. *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion*, TUFTS CSDD (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

82. *Id.*

medicines that . . . should be available in generic form . . . ."[83] Although Bass concedes that IPRs are part of the Coalition's investment strategy, he has purported that IPRs resulting in his favor "would serve the socially valuable purpose of reducing drug prices artificially priced above the socially optimum level."[84] He continued to say that even an IPR petition loss "knocks down a barrier to generic entry [that] benefits the public."[85] According to the Coalition's counsel, the act of invalidating poor quality patents of artificially priced products serve a socially redeeming value.[86]

While there is a concern for artificially priced medications,[87] Bass's efforts ought to be placed with regulating drug prices as opposed to engaging in a system that may very well stifle innovation and, in return, reduce the variety of medical drugs available to consumers.

Industry trade groups such as PhRMA and Bio are not persuaded by Bass's claim that he is primarily driven to use the IPR process as a tool to combat artificially high drug prices.[88] Referred to as a "wonderful ruse" by PhRMA's CEO, Bass's coalition strives to "make money on failure," and his IPR use is akin to an arsonist who decides to enter the extinguisher business, and subsequently claims to be an expert in fire safety.[89]

Although Bass has not yet been successful in patent claim invalidation, his petitions force small companies like Acorda to "divert their time, attention and limited resources to fighting these improper attacks rather than focusing on bringing new cures to patients."[90]

83. McTague, *supra* note 63.

84. Petitioner's Response in Opposition to Patent Owner Motion for Sanctions at 2, Coal. for Affordable Drugs LLC v. Celgene Corporation. No. 2015-01096, paper 14 (P.T.A.B. Aug 13, 2015).

85. *Id.*

86. *Id.*

87. *See* Pollack, *supra* note 21.

88. Carly Helfand, *Drugmakers to Congress: You Want Patent Reforms? Stop Pharma Challenger Bass*, FIERCE PHARMA (May, 5, 2015), http://www.fiercepharma.com/story/drugmakers-congress-you-want-patent-reforms-stop-pharma-challenger-bass/2015-05-05.

89. *Id.*

90. Daniel Seaton, *Kyle Bass Continues Abuse of Patent Challenge System*, BIO (Sept. 3, 2015), https://www.bio.org/media/press-release/kyle-bass-continues-abuse-patent-challenge-system.

B. Bass's Purported Primary Concerns for Low Drug Costs Have Already Been Addressed by Congress.

Low drug cost has become available via generic drugs pursuant to an Act that was passed over three decades ago.[91] In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act also known as the Hatch-Waxman Act.[92] It provides that "any person may file . . . an abbreviated application for the approval of a new drug."[93] This type of application, Abbreviated New Drug Application ("ANDA"), is submitted to the FDA and requests review and approval of a generic drug.[94] Once proven to be bioequivalent,[95] the applicant may "manufacture and market the generic drug product to provide a safe, effective, low cost alternative" to brand-name drugs.[96]

Dr. Ron Cohen, Acorda's President and CEO, maintains that the Hatch-Waxman Act effectively allows brand drugs to become available in generic form, thereby making drugs affordable and "preserv[ing] the incentives that [allow] an explosion of new drugs, better drugs, to come on the market over time."[97] The danger with having IPR proceeding for the purpose of making drugs affordable while the existing Hatch Waxman system is available is that IPR proceedings create an additional system for pharma and biotech companies to "deal with." It is this dual system that creates a danger to the medical drug industry.

If the Coalition's primary focus is to ensure that affordable drugs are available to all Americans, its time and energy may be better served by fixing any potential weaknesses within the Hatch-Waxman Act. Focusing on the Act, as opposed to IPR proceedings may result in Bass's goal of drug cost reduction and the pharma and biotech industries goal of producing innovative drugs.

91. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

92. *Id.*

93. *Id.* at 1585.

94. *Abbreviated New Drug Application (ANDA): Generics*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics (last updated Feb. 5, 2016).

95. Bioequivalent means that the generic drug "performs in the same manner as the innovator drug." *Id.*

96. *Id.*

97. Miller, s*upra* note 79.

PART III. REASONABLE SOLUTIONS

As discussed above, IPR can be effective if used in the rights hands.[98] However, the proceeding may have a significant impact on the pharma and biotech industries.[99] Due to this fluctuation between benefits and detriments, further reform is needed.

A. The Right to Amend Claims During an IPR Proceeding

Patent owners may submit a motion to amend challenged patent claims in lieu of filing a preliminary response to an IPR petition.[100] Claim amendment allows patent owners to narrow the scope of their claims in order to avoid prior art infringement.[101] They may also present evidence before the PTAB that demonstrates patentability of the proposed amended claims.[102] If successful, the PTAB will allow the patent owner's claims to be amended and the IPR proceeding will come to a halt.[103]

Ideally, the patent owner will strive to amend his or her claims in accordance with the petitioner's allegations.[104] For example, in *International Flavors & Fragrances Inc.*, the patent owner provided several publications and declarations from scientists to overcome Petitioner's claim that the patented invention was obvious in light of prior similar inventions.[105] The PTAB held that the amended claims did not impermissibly enlarge the scope of the patent[106] and that the patent owner provided adequate support to demonstrate patentability of all but one of the amended claims.[107]

While a patent owner may amend challenged claims by statute, the PTAB infrequently permits this.[108] In fact, the PTAB did not grant a motion to amend until May 20, 2014,[109] nearly three years after the AIA was

98. *See supra* Section II.

99. *See supra* Section II.

100. 35 U.S.C. § 316(d) (2012).

101. *Id.*

102. *Id.*

103. 35 U.S.C. § 318(b) (2012).

104. 35 U.S.C. § 316(d) (2012).

105. Int'l Flavors & Fragrances Inc. v. U.S. Sec'y of Agric., No. 2013-00124, 2014 WL 2120542, at *12 (P.T.A.B. May 20, 2014) (final written decision).

106. *Id.* at *10-11.

107. *Id.* at *19.

108. *See* Allissa Wickham, *USPTO Allows Gov't to Amend Patent Claims in AIA Review*, LAW 360 (May 22, 2014, 10:22 PM), http://www.law360.com/articles/540789/uspto-allows-gov-t-to-amend-patent-claims-in-aia-review.

109. *Int'l Flavors & Fragrances Inc.*, 2014 WL 2120542, at *1.

enacted.[110] Despite PTAB Chief Judge James Smith's statement that "making an amendment may be easier than is currently perceived by many,"[111] only six out of 86 motions to amend have been granted.[112]

Patent owners have complained about the burdensome requirements for substituting claims during an IPR proceeding in comparison to other post-grant review proceedings conducted at the Patent Office, where owners have a "freer hand to amend claims."[113] These proceedings include ex parte reexamination (reexaminations)[114] and reissue application filings.[115]

As an alternative to amending claims during an IPR proceeding, patent owners may request a reexamination of their patent,[116] which essentially "tests" their patent's validity,[117] while also providing the opportunity to amend claims.[118] In this proceeding, patent owners may propose any amendment to their patent and add new claims to distinguish their patent from prior art.[119] In general, after paying a $12,000 fee,[120] the patent owner may utilize this proceeding upon the realization that prior art raises a new, substantial question of patentability.[121] A patent owner is entitled to a reexamination as long as a new, substantial question of patentability arises during the enforceability period of the patent.[122]

Patent owners may also amend patent claims by filing a reissue application.[123] In this proceeding, claims can be amended when there is a defective specification or drawing, or in instances where the "patentee claim[ed] more or less than he had a right to claim in the patent."[124] If a patent holder wishes to broaden, as opposed to narrow, the scope of any

110. Leahy-Smith America Invents Act, 125 Stat. 284 (2011).

111. Wickham, *supra* note 108.

112. Harness Dickey, *Harnessing Patent Office Litigation: A Look at Forty-Five Months of* Inter Partes *Review Proceedings Before the United States Patent and Trademark Office*, 14 IPR-PGR Report, 2 n.3 (2016), http://ipr-pgr.com/wp-content/uploads/2016/08/IPR-PGR-Report-Vol-14.

113. Wickham, *supra* note 108.

114. 35 U.S.C. § 302 (2012).

115. 35 U.S.C. § 251 (2012).

116. 35 U.S.C. § 302 (2012).

117. 35 U.S.C. § 303 (2012).

118. 35 U.S.C.S. § 305 (2012).

119. *Id.*

120. *USPTO Fee Schedule*, USPTO (July 1, 2016), https://www.uspto.gov/sites/default/files/documents/USPTO%20fee%20schedule_current.pdf.

121. U.S. Patent & Trademark Office, MPEP § 2240 (9th ed. rev. 7, Nov. 2015).

122. *Id.*

123. 35 U.S.C. § 251 (a) (2012).

124. *Id.*

claims using this proceeding, the application must be filed within two years of the patent's grant.[125]

Considering that a patent owner may amend claims in other post-grant proceedings, they should likewise be able to amend during an IPR proceeding.

B. Patent Validity Determinations Should Be Treated Equally In Both District Court and IPR Proceedings

The standard for determining patent validity differs between challenges heard at the District Court versus the PTAB,[126] but should be equivalent. Currently, both the evidentiary and claim construction standards vary between the two fora.[127]

1. Evidentiary Standard

Although patents are presumptively valid in district court,[128] during an IPR proceeding, the petitioner's burden of proving unpatentability is preponderance of the evidence,[129] a "challenger-friendly evidentiary standard."[130] The district court, on the other hand, applies the higher standard of clear and convincing evidence.[131] This standard was confirmed in *Microsoft Corp. v. i4i Limited Partnership*,[132] and applies only to factual inquiries of invalidation,[133] such as patent invalidity based on statutory bars.[134]

The difference in evidentiary standards essentially creates a second bite at the apple for those challenging patent invalidity. If challengers fail to invalidate a patent in district court, they may file an IPR petition with the PTAB where the evidentiary standard is lower and, while arguing the same

125. 35 U.S.C. § 251 (d) (2012).

126. Lorelei Laird, *Patent Holders Allege Financial Companies Are Misusing New Post-Grant Review Process for Profit*, ABA J., Dec. 1, 2015, 3:20 AM), http://www.abajournal.com/magazine/article/patent_holders_allege_financial_companies_are_misusing_new_post_grant_revie.

127. *Id.*

128. *See* 35 U.S.C. § 282 (2012) (indicating that patent claims are presumed valid in district court proceedings).

129. 35 U.S.C. § 316 (e) (2012).

130. Laird, *supra* note 126.

131. Microsoft Corp. v. i4i Ltd. P'ship, 564 U.S. 91, 97 (2011).

132. *Id.* at 95.

133. *Id.* at 114 (Breyer, J. concurring).

134. 35 U.S.C. §102 (b) (2012) (providing that a patent may not be granted if the invention was on sale for more than one year prior to filing the patent application).

factual matter, prevail.[135] Additionally, if one party fails in district court, a separate third party can challenge patent validity using the IPR system.[136]

Both parties should "be allowed to use the same weapons."[137] In *Corning v. Burden*, Justice Grier reasonably argued:

> It is evident that a patent . . . issued after an . . . examination, made by skilful [sic] and sworn public officers, appointed for the purpose of protecting the public against false claims . . . is entitled to much more respect . . . than those formerly issued without any such investigation. . . . [I]t is not easy to perceive why the defendant . . . should not have the benefit of a like presumption in his favor . . . .[138]

The petitioner and patent owner should be placed on a level playing field[139] throughout different stages of challenging or upholding patent claim validity.[140]

2. Claim Construction Standard

Patent claim interpretation is essential to define what the invention is and to what the patent holder is entitled.[141] Courts are required to interpret claims based on how a person having ordinary skill in the art ("PHOSITA") understands the claims.[142] PHOSITAs are deemed to have an understanding of a particular scientific field, the ability to read the claim language, and knowledge of the meaning and use of the term within the field.[143]

135. *See generally* Jason E. Stach & Jeffrey A. Freeman, *District Court or the PTO: Choosing Where to Litigate Patent Invalidity*, FINNEGAN, http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=e7ad4528-cec4-4889-a23d-d17bca527ca2 (last visited Oct. 31, 2016) (explaining the potential factors that can play into a defendant's decision in choosing whether to litigate in district court or with the USPTO).

136. *See* David R. Heckadon, *New Ways to Challenge Patents Both Before and After They Issue*, GORDON & REES (Oct. 2012), http://www.gordonrees.com/newsroom/2012/new-ways-to-challenge-patents-both-before-and-after-they-issue.

137. Corning v. Burden, 56 U.S. 252, 271 (1854).

138. *Id.*

139. *See Intellectual Property Key to Protecting Pharma and Biotech Innovation*, COMMERCE.GOV (Jun. 26, 2014, 11:00 AM), https://www.commerce.gov/news/blog/2014/06/intellectual-property-key-protecting-pharma-and-biotech-innovation (expressing that "strong intellectual property is key to protecting innovation" and that the Patent Office is dedicated to leveling the playing field for relevant parties involved).

140. *Corning*, 56 U.S. at 271.

141. 35 U.S.C. § 112(b) (2012).

142. U.S. Patent & Trademark Office, *supra* note 121, § 2141.

143. *Ex parte Hiyamizu*, 10 U.S.P.Q.2d 1393, 1394 (B.P.A.I. Feb.8, 1988); U.S. Patent & Trademark Office, *supra* note 121, § 2141.03

When a patent is initially examined by the Patent Office, the patent examiner construes claims using the "Phillips standard."[144] This standard requires the Patent Office to construe claims within a customary meaning that is equivalent to how a PHOSITA would interpret the claim at the time the invention was created.[145]

For patents challenged during an IPR proceeding, however, the PTAB uses "[the] broadest reasonable construction in light of the specification of the patent."[146] Although the AIA created IPR proceedings, the statute governing IPR does not dictate which standard the PTAB must adhere during claim interpretation.[147] By federal statute, the Director of the Patent Office has the authority to "prescribe regulations establishing and governing inter partes review."[148] Pursuant to this authority, the Patent Office promulgated 37 C.F.R. § 42.100(b), which provides that an unexpired patent claim shall be given its broadest reasonable construction.[149]

The difference in claim construction standards between the two fora results in claims that are easier to invalidate during IPR since the claims will be allowed to encompass much more subject matter than in district court proceedings. This brings a greater possibility of finding infringement of a previously issued patent.

In *In re Cuozzo Speed Technologies, LLC*, the Federal Court of Appeals upheld the broadest reasonable interpretation standard for an IPR proceeding.[150] Petitioner Cuozzo argued that the Patent Office lacked authority to promulgate a statute that mandated the use of the broadest reasonable interpretation standard.[151] However, the court disagreed, finding that the broadest reasonable interpretation had been applied in various Patent Office proceedings for more than 100 years.[152] The court also stated that the broadest reasonable interpretation standard "reduce[s] the possibility that, after the patent is granted, the claims may be interpreted as giving broader coverage than is justified."[153] In response, Cuozzo argued that the broadest interpretation standard was approved in earlier proceedings because those

144. *See generally* Phillips v. AWH Corp., 415 F.3d 1301, 1313 (Fed. Cir. 2005) (offering an objective baseline to construe patent claims from which the *Phillips* test is derived).

145. *Id.* at 1313.

146. 37 C.F.R. § 42.100(b) (2012).

147. *See* 35 U.S.C. § 316 (2012).

148. 35 U.S.C. § 316(a)(4) (2012).

149. Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,766 (Apr. 1, 2016) (to tbe codified at 37 C.F.R. sec. 42.100(b)).

150. *In re* Cuozzo Speed Techs., LLC, 793 F.3d 1268, 1271 (Fed. Cir. 2015).

151. *Id.* at 1275-76.

152. *Id.*

153. *Id.* at 1277 (quoting *In re* Reuter, 670 F.2d 1015, 1019 (C.C.P.A. 2015)).

earlier decisions "relied on the availability of amendment, and the AIA limits amendments in IPR proceedings."[154]

Judge Newman's dissenting opinion acknowledged that the broadened interpretation does not always result in the correct construction of a claim and, that by not adopting the correct construction, the majority had frustrated the statutory plan of the AIA.[155] The broadened interpretation approach was originally approved in conjunction with the opportunity to amend challenged claims during a reexamination proceeding—an opportunity which is not always granted during an IPR proceeding.[156] Whether the effect was anticipated or not, the broadened interpretation hurts patent owners battling a petitioner during an IPR proceeding.

On October 6, 2015, Cuozzo challenged the Court of Appeal's decision to uphold the broadest reasonable interpretation standard and petitioned for writ of certiorari,[157] which was granted.[158] In part, Cuozzo challenged whether the statute that governs inter partes review authorizes the Patent Office to mandate the construal of patent claims using the broadest reasonable interpretation.[159] In its reasoning, Cuozzo proclaimed that the difference in claim construction standard between the Patent Office and the district court may result in inconsistent rulings and overall confusion.[160] The Court recognized the potential for inconsistencies due to different evidentiary standards between the Patent Office and district court and declared the inconsistencies as being "inherent to Congress' regulatory design."[161] Additionally, the Court did not find that the Patent Office's decision to prefer "a degree of inconsistency" between the different standards was unreasonable.[162] Ultimately, the Court did not decide whether there was a better alternative to the broadest reasonable interpretation standard but decided to defer to the legislature as to whether the standard should be changed or remain the same.[163]

The standard of interpreting claims in district court should mimic the patent examiner's standard. IPR was designed to serve the purpose of

154. *Id.*

155. *In re* Cuozzo Speed Techs., LLC, 778 F.3d 1271, 1287 (Fed. Cir. 2015) (Newman, P., dissenting).

156. *Id.*

157. Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016), *petition for cert. filed* (U.S. Oct. 6, 2015) (No. 15-446).

158. *Id.* at 2139.

159. *Id.*

160. *Id.* at 2146.

161. *Id.*

162. *Id.*

163. *Id.*

"providing quick and cost effective alternatives to litigation."[164] Because the "PTAB serves as a surrogate for district court litigation" and is an extension of the district court, it does not logically follow that the PTAB standard should be more relaxed.

C. Allowing a Patent Owner to File New Testimonial Evidence in Response to an IPR Petition

The submission of declarations with an IPR petition is a tactic that favors the petitioner.[165] The petitioner can spend several months preparing declarations to submit simultaneously with their petition. However, if a patent owner wishes to submit a preliminary response, they must do so within three months after notification that an IPR petition has been filed.[166] Additionally, the response may not contain information that is beyond the original patent file history or the IPR petition, such as expert declarations.[167] The patent owner's inability to thoroughly respond puts the patent owner at an evidentiary disadvantage.[168]

On July 29, 2015, the Committee on the Judiciary for the 144th Congress submitted its report on The Innovation Act, which makes a reasonable modification to preliminary responses in an IPR petition.[169] It suggests the insertion of a clause allowing a patent owner to submit "affidavits or declarations of supporting evidence and opinions."[170]

In addition to the Innovation Act, law associations have requested modifications.[171] In response to the Patent Office's request for opinions, the New York Intellectual Property Law Association ("NYIPLA") suggested allowing the submission of a patent owner's new testimonial evidence in an IPR preliminary response.[172] Allowing these modifications will level the

164. Leahy-Smith America Invents Act, H.R. Rep. No. 112-98, at 48 (2011) (Comm. Rep.).

165. *See* 35 U.S.C. §282 (2012) (indicating that patent claims are presumed valid in district court proceedings); *See* 35 U.S.C. §316(e) (2012) (stating that the evidentiary standard in inter partes review proceedings is a preponderance of the evidence).

166. 37 C.F.R. § 42.207(b) (2015).

167. OBLON SPIVAK, POST-GRANT PROCEEDINGS BEFORE THE PATENT TRIAL AND APPEAL BOARD 92 (2013).

168. *Id.*

169. The Innovation Act, H.R. REP. NO. 114-235, 114th Cong. (2015).

170. *Id.* at 16.

171. *See* Letter from Dorothy R. Auth, President of the New York Intellectual Property Law Association, to Susan Mitchell, Lead Judge, USPTO (Nov. 18, 2015), http://www.uspto.gov/sites/default/files/documents/PTAB%20Rules%20Aug%202015%20IPO%20NYIPLA%20Comments.pdf.

172. *Id.* at 3.

playing field between the patent owner and petitioner and provide for swift factual development in the early stages of the proceeding.[173]

D. Standing Requirement

A standing requirement will help combat non-practicing entities ("NPEs"), also known as patent trolls, from filing excessive IPR petitions, which is something that the AIA intended.[174] NPEs do not engage in the related business of the patent, yet acquire patent ownership.[175] These entities then use their ownership rights, not to further innovation or product manufacture, but to accuse other entities of infringement and to collect damages accordingly.[176] Today there exists a phenomenon known as "reverse patent trolling" whereby an NPE announces the challenge of a patent's validity and frequently follows through with an IPR petition.[177]

There are currently three post-AIA procedures available for petitioners to challenge a patent's validity under the AIA: Post-Grant Review, Covered Business Method Review (CBM), and Inter Partes Review.[178] Of the three options, CBM is the only method that requires a petitioner to have standing before challenging a patent's validity.[179] The lack of required standing for IPR in combination with the processes weighing in favor of the petitioner,[180] "encourages organizations, activists, and individuals with less than a definite and concrete dispute with the patent owner" to challenge patent validity.[181]

If third parties can initiate IPR proceedings, Bass and others like him will continue to generate profit through the short sale of pharma or biotech

173. *Id.*

174. H.R. REP. NO. 114-235, at 54.

175. *See* Joe Nocera, Op-Ed., *The Patent Troll Smokescreen*, N.Y. TIMES (Oct. 23, 2015), http://nyti.ms/1KvDFOg.

176. *Id.*

177. Joseph Gulfo, *Hedge Funds, "Reverse Trolls" Crushing Biopharma Innovation*, CNBC (July 22, 2015), http://www.cnbc.com/2015/07/22/biopharma-hammered-by-hedge-funds-reverse-trolls-commentary.html.

178. 37 CFR 42.100 (a), (c) (2015), Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,766 (Apr. 1, 2016) (to be codified at 37 C.F.R. § 42.100(b)); 37 CFR 42.200 (a), (c), (d) (2015), Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,766 (Apr. 1, 2016) (to be codified at 37 C.F.R. § 42.200(b)); 37 C.F.R 42.300 (a), (c), (d) (2015), Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,766 (Apr. 1, 2016) (to be codified at 37 C.F.R. § 42.300(b)).

179. 37 C.F.R. § 42.302 (2015).

180. *See supra* part III (A)-(C).

181. Andrew Wilson, *The Relaxed Standing Requirements For Institution of Inter Partes Review*, BAKER BOTTS (Oct. 2014), http://files.bakerbotts.com/file_upload/PostGrantReport102014-TheRelaxedStandingRequirementsforInstitutionofInterPartesReview.htm.

stocks and the PTAB "will be inundated with similar petitions."[182] This, in turn, will place an "unwarranted burden on the [PTAB]" as well as innovative companies and their shareholders.[183]

Amending section 311 of the AIA, which pertains to IPR, will effectively ensure that patent invalidity challenges are meritorious. The STRONG Patents Act of 2015 was introduced to the Senate on March 3, 2015 in efforts to "strengthen the position of the United States as the world's leading innovator by amending title 35 United States Code, to protect the property rights of the inventors that grow the country's economy."[184] This Act proposes two additional sections that define a standing requirement for persons who wish to petition a patent's claim by way of IPR.[185]

The section entitled "Standing" provides that a person may not file a petition unless the real party in interest has been sued for infringement of the patent or has been "charged with infringement under the patent."[186] The second section entitled "Discovery of Real Party In Interest" expands discovery to include evidence that identifies the petitioner's real parties in interest.[187]

Properly identifying the real party in interest will not only ensure that NPEs are not filing petitions solely for financial gain, it will also "[estop] the petitioner . . . from asserting in a district court proceeding . . . that the claim is invalid or unpatentable on any ground that the petitioner 'raised or reasonably could have raised' during [an IPR proceeding]."[188] This would essentially prevent a petitioner from having a "second bite at the apple."

A standing requirement will still allow a petitioner to challenge patent claim validity while creating an equal level of fairness for both the petitioner and patent owner. The only thing that will change is the inability for hedge fund managers to exploit the IPR system as a vehicle for pecuniary gain from stock market fluctuation.

182. Cary Miller and Matthew I. Kreeger, *A Win for Kyle Bass's Hedge Fund as the PTAB Dismisses Celgene's Sanctions Motion*, MORRISON FOERSTER (Oct. 2, 2015), https://media2.mofo.com/documents/151001awinforkylebassshedgefund.pdf.

183. *Id.*

184. STRONG Patents Act of 2015, S.632, 114th Cong. (2015).

185. *Id.*

186. *Id.* at § 102 (d)(2)(B).

187. *Id.* at § 102(e).

188. Xiaoying Zhang, *Patent Ownership Disclosure and Real Party-in-Interest Regulation*, JURIST (Nov. 25, 2015), http://www.jurist.org/dateline/2015/11/Xiaoying-Zhang-patent-ownserhips-disclosure.php.

CONCLUSION

If America wishes to remain a leader in innovation, it must protect legitimate patents and encourage innovation. Innovation can only continue if investors are willing to risk giving large sums of money to pharma and biotech companies so that they may conduct research, development, and adequately perform FDA testing so that the product can reach consumers.

Concerns for overpriced medications have already been addressed by the enactment of the Hatch Waxman Act and IPR should not serve as a vehicle for NPEs to make a profit by challenging patent invalidity. If the IPR system remains unchanged, the result may be a rise of NPEs whose sole purpose of operation is to use IPR proceedings as a means to achieve financial gain.

Although Bass and others like him have yet to succeed on any of their IPR petitions, if the trend of using the proceeding as an investment tool remains unchanged, many pharma and biotech companies will continue to be forced to spend much needed time and money in litigation as opposed to innovation. Additionally, investors may become wary and elect to invest in companies that are less risky. Rather than being reactive to a point in time where drug product innovation is stifled, Congress must be proactive because America must continue to thrive.

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