PATENT SYSTEM MANIPULATION: HEDGE FUNDS ABUSING IPR, POOR PATENT QUALITY & PHARMACEUTICAL MONOPOLIES♦

INTRODUCTION

What if a corporation had nonpublic information about another company and used that information to make profits in the stock market by significantly affecting the stock price through their subsequent actions? That would be illegal insider trading and market manipulation.[1] Yet, this is exactly what hedge funds are doing, and it is completely

[1] *Insider Trading*, INVESTOPEDIA, http://www.investopedia.com/terms/i/insidertrading.asp (last visited Aug. 24, 2016); *see also*, *Manipulation*, INVESTOPEDIA, http://www.investopedia.com/terms/m/manipulation.asp (last visited Aug. 24, 2016) (Stock market manipulation, or simply, manipulation, is the "act of artificially inflating or deflating the price of a security[,]" and is an illegal practice).

legal. In April 2015, hedge fund manager Kyle Bass of Hayman Capital Management ("Hayman") devised a new and novel strategy by which he and his shareholders could profit by challenging patents.[2] This strategy begins with the filing of an action with the United States Patent and Trademark Office (USPTO) to invalidate certain pharmaceutical drug patents by seeking an *inter partes* review (IPR) by the Patent Trial and Appeal Board (PTAB).[3] Mr. Bass's hedge fund then takes a position shorting the stock for the pharmaceutical company that owns the patent they are seeking to challenge. After Mr. Bass has taken one of these positions, he publicly announces the pharmaceutical company whose patent is being challenged. When this happens, the stock price drops, and Mr. Bass profits from having shorted that stock. This act is blatant illegal market manipulation.[4] As of February 2016, Mr. Bass has filed thirty-seven such actions.[5]

While some hedge funds have profited off of this strategy by settling with the pharmaceutical company, Mr. Bass claims to have more altruistic motives, and has stated that he will not settle.[6] The Coalition for Affordable Drugs ("Coalition"), a subsidiary of Hayman, has filed the IPRs, claiming that their goal is to benefit patients by increasing competition in the market place, thus causing prescription

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

[3] The PTAB is an administrative body that operates under the USPTO and performs the review of post-grant challenges such as inter partes review, post grant review, and covered business method review. It decides whether or not a challenge will proceed to trial. If it decided that a petition merits it, it will hold an oral hearing to decide the validity of the patent claims being challenged. *See* Tim Bianchi, *What is the Patent Trial and Appeal Board or PTAB?*, REELLAWYERS, https://www.reellawyers.com/minnesota/minneapolis-patent-and-intellectual-property-attorneys/tim-bianchi/patent-trial-appeal-board-ptab/ (last visited Sept. 11, 2016).

[4] The Securities and Exchange Commission (SEC) defines stock market manipulation as "intentional conduct designed to deceive investors by controlling or artificially affecting the market for a security." It includes acts such as: "spreading false or misleading information about a company; improperly limiting the number of publicly-available shares; or rigging quotes, prices or trades to create a false or deceptive picture of the demand for a security." *Manipulation*, SEC (Mar. 28, 2008), http://www.sec.gov/answers/tmanipul.htm.

[5] Most of these actions were filed in 2015. 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; *see also* John Aquino, *Kyle Bass Challenges 'Zombie Drug' Patents That Won't Die*, PATENT TRADEMARK AND COPYRIGHT JOURNAL (Dec. 2, 2015), https://www.bloomberglaw.com/product/blaw/document/XA1RTJU0000000?resource_id=b78b590909a7d44d1859014580626f0f [hereinafter Aquino, *Zombie Drug*].

[6] *See* Rich Hung & Alex Hadduck, Defendants, *Non-Profits, Defensive Aggregators and Hedge Funds: Common Uses of Inter Partes Review*, INTELL. PROP. WATCH (July 16, 2015), http://www.ipwatch.org/2015/07/16/defendants-non-profits-defensive-aggregators-and-hedge-funds-common-and-less-common-uses-of-inter-partes-review/; *see also* William Greider, *Can Wall Street Take Down Big Pharma?*, THE NATION (Jan. 20, 2015), http://www.thenation.com/article/can-wall-street-take-down-big-pharma/.

prices to decrease for Medicare patients and everyone else.[7] Mr. Bass publicly announced he only plans on targeting pharmaceutical corporations that hold bad patents or patents, that are extended by a change in the dosage or some other minute detail, such as the packaging.[8] However, pharmaceutical companies claim his methods are an abuse of process and stock manipulation.[9] They are responding by, among other things, filing motions for sanctions when the Coalition files an IPR petition.

There are two reasons the hedge funds are challenging pharmaceutical drug patents. First, the pharmaceutical corporations make for an easy target because of the numerous "bad patents" they hold which are susceptible to invalidation through IPR.[10] The drug companies misuse the patent system by filing and receiving these so-called bad patents. The hedge funds can be stopped by reducing the number of bad patents in the market place. This can be done by subjecting pharmaceutical corporations to more rigorous patent approval processes so as to prevent bad patents from being approved by the USPTO in the first place. With higher quality patents, hedge funds will not challenge pharmaceutical corporations in IPR because they will be less likely to win. Moreover, the stock market will not react as much when an IPR is filed because they will have more faith in the system and the strength of the patents.[11]

The second reason hedge funds are targeting the pharmaceutical industry is because they believe the stocks of pharmaceutical companies are overvalued.[12] This overvaluation is a direct consequence of the pharmaceutical companies' exploitation of the regulatory system to maintain their monopolies and the high prices they charge for their

---

[7] *See* Ed Silverstein, *Should hedge funds have standing in IPR?*, INSIDE COUNSEL (July 22, 2015), http://www.insidecounsel.com/2015/07/22/should-hedge-funds-have-standing-in-ipr*; see also* Hung & Hadduck *supra* note 6.

[8] Scott McKeown, *The PTAB as a Hedge Fund Tool?*, PATENTS POST-GRANT (Jan. 15, 2015), http://www.patentspostgrant.com/the-ptab-as-a-hedge-fund-tool.

[9] *See* Hung & Hadduck *supra* note 6; *see also Acorda Fires Back at Kyle Bass's IPR Strategy*, FIN ALTERNATIVES (May 29, 2015, 3:01 PM), http://www.finalternatives.com/node/30947.

[10] A bad patent is one that is likely to be found invalid because it is questionable, of poor quality, contains overly broad claims, or obvious as defined by 35 U.S.C. § 103, which is discussed *infra* in Part I.A. *See* Patrick Doody, *What is a Bad Patent*, PATENTS AND INNOVATION ECON. (2010), http://www.ipadvocate.org/mibj/pdfs/ Doody_Bad%20Patent.pdf.

[11] *See* Maulin Shah, *Challenge the Patent and Short the Stock – Does it Really Work?*, PATENTVUE (Oct. 20, 2015, 7:23PM), http://patentvue.com/2015/10/20/challenge-the-patent-and-short-the-stock-does-it-really-work/.

[12] When an investor shorts a stock they are anticipating a decrease in the stock's price, therefore they believe the stock is overvalued. *See* Elvis Picardo, *What Is Short Selling?*, INVESTOPEDIA, http://www.investopedia.com/university/shortselling/shortselling1.asp (last visited Sept. 11, 2016). When one thinks the market has overvalued a corporation's stock, that is when one would short that stock. *See* Patrick Watson, *Short Selling 101: How to Short a Stock and Make Money As It Falls*, MAULDIN ECON. (Oct. 15, 2015), http://www.mauldineconomics.com/resources/short-selling-101-how-to-short-a-stock-and-make-money-as-it-falls.

products.[13] Pharmaceutical companies use the unregulated prescription drug market to achieve absurdly high profit margins on their products, which leads to an artificially inflated price of the companies' stock.[14] For example, in 2015, the price for the drug Daraprim rose from $13.50 to $750 a pill.[15] This practice of drug "price gouging" is all too common and leads to further inflation of stock prices.[16] Drug companies get away with this because of tactics they use to extend their monopolies on the market.[17] If the monopolistic tactics of the drug companies were to be prevented their stocks would not be overvalued, and hedge funds would cease to target them for short selling.

Congress must facilitate an environment where generic drug companies can enter the market place more quickly, thus increasing competition and decreasing prices for prescription drugs.[18] With this will come more stable market conditions in which pharmaceutical share prices are appropriate instead of overvalued. This can be achieved by preventing the pharmaceutical industry's tactics of pay-for-delay, patent extensions, and product hopping.[19]

This Note explores the abuses to IPR and the stock market by hedge funds, and abuses by pharmaceutical companies to the patent system as a whole, and poses a solution that will prevent these abuses. In Part I, this Note will discuss patent basics, the PTAB's role, and the IPR process. It will also examine, in detail, the patent trolling technique hedge funds are using. Additionally, it will address what actions the PTAB has taken, and is likely to take, if any, to prevent the hedge funds' conduct. Lastly, Part I will explore the monopolistic hold the pharmaceutical industry has on drug pricing. Part II of this Note will examine the legislative responses to hedge funds' abuse of IPR by analyzing proposed patent reform bills in Congress, and whether those bills will affect the problem at hand. This Part will also address the pharmaceutical industry's push for an exception to IPR. In Part III of this Note, a policy solution will be proposed that advocates for higher standards for pharmaceutical companies to obtain drug patents, and for regulatory changes that allow for quicker entry to the market by generics. Moreover, Part III will discuss how these policies can be implemented and why they will work.

---

13 Greider, *supra* note 6.

14 *Id.*

15 Heather Long, '*Hated' CEO Lowering Price of $750 AIDS Drug Daraprim*, CNN MONEY (Sept. 24, 2015, 9:34 AM), http://money.cnn.com/2015/09/22/investing/daraprim-aids-drug-price/.

16 *Id.*

17 Greider, *supra* note 6.

18 *See* discussion *infra* Part III.B.

19 *See* discussion *infra* Part III.B.

I. BACKGROUND

A. *What Are Patents, and What Do They Require?*

Patents are authorized by the U.S. Constitution, which expressly gives Congress the power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[20] Obtaining a patent allows the patent holder to exclude all others from making, selling, or using their invention in the U.S.[21] A patent essentially creates a government-sponsored, time-limited monopoly for the inventor over the item covered by the patent.[22] What is and is not covered by the patent is described in one or more sentences known as the claims of the patent.[23] "Reading and understanding the claims of a patent is the key to determining if a given product or process infringes the patent."[24] There are three types of patents: design patents,[25] plant patents,[26] and utility patents.[27] Utility patents can be used for "processes ([including inter alia] a chemical, mechanical or electrical procedure . . .); machines . . . ; articles of manufacture . . . ; and compositions of matter (chemical compounds, combinations or mixtures, such as a plastic)."[28] Patents incentivize research and development that would not occur but for the protection they are given and, in that sense, they stimulate innovation.[29]

Patents require novelty and non-obviousness.[30] During patent prosecution,[31] the USPTO will perform a search of what is essentially

---

[20] Stephanie A. Diehl, Note, *Treating the Disease: A First Amendment Remedy for the Problem of Patent Trolls and Overbroad Business Methods*, 33 CARDOZO ARTS & ENT. L. J. 1, 5 (2015) (quoting 35 U.S.C. § 154(a)(2)).

[21] *See* JANE GINSBURG, JESSICA LITMAN & MARY KEVLIN, TRADEMARK AND UNFAIR COMPETITION LAW: CASES AND MATERIALS 27–28 (5th ed. 2013).

[22] *See* Diehl, *supra* note 20, at 499.

[23] *How do I Read a Patent? – The Claims*, BROWN & MICHAELS, http://www.bpmlegal.com/howtopat5.html (last visited Aug. 25, 2016).

[24] *Id.*

[25] Design patents are obtained "for a new original and ornamental design for an article of manufacture." GINSBURG ET AL., *supra* note 21, at 28.

[26] Plant patents are obtained "for a new variety of seed or plant or any of its parts." *Id.*

[27] Utility patents can be used for "processes ([including inter alia] a chemical, mechanical or electrical procedure . . .); machines . . . ; articles of manufacture . . . ; and compositions of matter (chemical compounds, combinations or mixtures, such as a plastic)." GINSBURG ET AL., *supra* note 21, at 28.

[28] GINSBURG ET AL., *supra* note 21, at 28.

[29] *See* Diehl, *supra* note 20, at 499.

[30] *See* 35 U.S.C. § 102(a)(1)–(2); *see also* 35 U.S.C. § 103.

[31] Patent prosecution is:

> [t]he administrative process of obtaining a patent from the [USPTO]. Prosecution includes filing the application with the [USPTO], office action, amending the application in response to objections and rejections from the examiner, responding to objections and rejections without amendment to the application, telephone and personal interviews with the examiner, appeals, and timely payment of the appropriate fees.

Arnold B. Silverman and George K. Stacey, *Understanding 'Patentese' – A Patent Glossary*, THE

the entire body of knowledge surrounding that invention to ensure the uniqueness required by law.[32] This body of technological information is known as prior art.[33] Prior art is defined by 35 U.S.C. § 102, which states,

> A person shall be entitled to a patent unless – (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) . . . was described in a patent . . . or in an application for patent published or deemed published . . . .[34]

The second condition for patentability is that the invention is non-obvious. According to 35 U.S.C. § 103, a patent may not be obtained when the difference between the prior art and the claimed invention would be obvious "to a person having ordinary skill in the art to which the claimed invention pertains."[35]

B. *The Leahy-Smith America Invents Act, the PTAB, and IPR*

The Leahy-Smith America Invents Act (AIA) established the PTAB in 2012 as a replacement for the Board of Patent Appeals and Interferences with a largely expanded jurisdiction.[36] Under the AIA, the PTAB holds trials for three new procedures established for challenging patent claims: IPR,[37] Post-Grant Review (PGR),[38] and Covered Business Method (CBM) Review.[39] The purpose of creating IPR was to establish a quick and efficient alternative to costly and lengthy patent infringement litigation in federal court.[40] IPR consists of an administrative hearing conducted at the PTAB rather than a full-blown

---

MINERALS, METALS AND MATERIALS SOCIETY, http://www.tms.org/pubs/journals/jom/matters/matters-9609.html (last visited Aug. 25, 2016).

[32] *See* Walter J. Blenko, Jr., *Considering What Constitutes Prior Art in the United States*, THE MINERALS, METALS AND MATERIALS SOCIETY, http://www.tms.org/pubs/journals/jom/matters/matters-9106.html (last visited Aug. 25, 2016).

[33] *Id.*

[34] 35 U.S.C. § 102(a)(1)–(2).

[35] 35 U.S.C. § 103.

[36] Quinn, *Patent Abuse or Genius*, *supra* note 2.

[37] IPR is a "trial proceeding conducted at the Board to review the patentability of one or more claims in a patent only on a ground that could be raised under §§ 102 or 103, and only on the basis of prior art consisting of patents or printed publications." *Inter Partes Disputes*, U.S. PATENT & TRADEMARK OFF., http://www.uspto.gov/patent/laws-and-regulations/america-invents-act-aia/inter-partes-disputes.

[38] PGR is a "trial proceeding conducted at the Board to review the patentability of one or more claims in a patent on any ground that could be raised under § 282(b)(2) or (3)." *Inter Partes Disputes*, *supra* note 37.

[39] CBM is a "trial proceeding conducted at the Board to review the patentability of one or more claims in a covered business method patent." *Inter Partes Disputes*, *supra* note 37; Quinn, *Patent Abuse or Genius*, *supra* note 2.

[40] *See* Hung & Hadduck, *supra* note 6.

trial.[41] Typically, an IPR is not instituted by the PTAB unless the petitioner is likely to prevail on one of the claims.[42] One of the most controversial features of the system under the AIA is that the PTAB's decision of whether to institute an IPR "under 35 U.S.C. [§] 314 is final and not appealable."[43]

IPR proceedings, when conducted to completion, have been very beneficial for petitioners.[44] In its first year of IPR, the PTAB granted 87% of petitions, and in its second year, it granted 76% of petitions.[45] The overall claim cancellation rate, as of March 2014, was 96.4%.[46] Thirty months into the creation of IPR, the overall claim cancellation rate was 80.9%,[47] leading some to call IPR a "death squad" for patents.[48]

In addition to allowing petitioners to challenge patent claims as unpatentable under 35 U.S.C. §§ 102 or 103,[49] IPR allows petitioners to file a request to cancel those claims "on the basis of prior art consisting of patents or printed publications," or obviousness.[50] An IPR or a PGR may be initiated by any party, whether they own a patent or not. This allows those who have "no direct interest in the patent either as an alleged infringer, licensee or prospective licensee" to challenge the patent in IPR or PGR.[51] These parties are referred to as non-practicing

---

41 *See id.*

42 *See id.*

43 Quinn, *Patent Abuse or Genius*, *supra* note 2; *see also* Hung & Hadduck, *supra* note 6 ("[W]hether to institute IPR proceedings (or not) is unappealable under 35 U.S.C. § 314(d)."); Gene Quinn, *USPTO denies Kyle Bass IPR patent challenge against Acorda Therapeutics,* IPWATCHDOG (Aug. 25, 2015) [hereinafter Quinn, *USPTO denies Kyle Bass IPR*], http://www.ipwatchdog.com/2015/08/25/uspto-denies-kyle-bass-ipr-patent-challenge-against-acorda-therapeutics/id=61016/ ("[T]he way the law is written decisions not to institute cannot be appealed." (citing 35 U.S.C. § 314(d) (2012))).

44 Hung & Hadduck, *supra* note 6.

45 *See id.*; *see also 30 Months of IPR Practice – By the Numbers*, IPR-PGR, http://ipr-pgr.com/30-months-of-ipr-practice-by-the-numbers/ (last visited Aug. 25, 2016).

46 When a patent claim is found to be invalid the court will cancel that claim. The rate at which this occurs is the claim cancellation rate. *See* Hung & Hadduck, *supra* note 6.

47 *See* Hung & Hadduck, *supra* note 6.

48 The

> [F]ormer Federal Circuit Chief Judge Randall Rader previously remarked, IPR proceedings have acted as a 'death squad' for the majority of claims brought before the PTAB. For this reason, litigation defendants, non-profit entities, for-profit membership-based organization, and now even hedge and venture funds have increasingly availed themselves of these proceedings.

Hung & Hadduck, *supra* note 6. "[T]he PTAB institutes too many reviews and they kill too many patent claims, being all too willing to find claims obvious." Quinn, *USPTO denies Kyle Bass IPR*, *supra* note 43.

49 Meaning that an IPR challenge seeks to invalidate a patent by proving the patent to be in violation of 35 U.S.C § 102, which establishes that an invention is unpatentable upon a showing of the existence of prior art, and § 103, which establishes that a claimed invention must be non-obvious to a person with ordinary skill in the art. *See* 35 U.S.C. §§ 102–103 (2012).

50 Quinn, *Patent Abuse or Genius*, *supra* note 2.

51 *Id.*

entities (NPE) or patent assertion entities (PAE).[52] By contrast, CBM requires that "[a] person may not file a petition for a transitional proceeding with respect to a [CBM] patent unless the person or the person's real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under that patent."[53] Thus, while IPR and PGR petitioners can challenge patents in the PTAB, they would not be able to bring these claims to a federal district court because they would not have standing, as "there is no case or controversy."[54] Indeed anyone who pays the filing fee is allowed to submit a petition for an IPR.[55] This lack of a standing requirement allows for patent trolling since it permits NPEs, and in this case the hedge funds, to bring an IPR action.

C. *The Kyle Bass Shorting Strategy and the PTAB's Response*

A recent patent trolling technique, started by hedge fund manager Kyle Bass of Hayman, has the potential to shake up the pharmaceutical patent industry. Because of the current lack of standing requirements, Mr. Bass has embarked on an opportunity that legislators have failed to consider.[56] Mr. Bass files a petition for IPR seeking invalidation of one or multiple patent claims as raised under 35 U.S.C. §§ 102 or 103 on the basis of the prior art or obviousness requirement.[57] He then takes a position shorting the stock of the company against which he instituted the IPR. When he subsequently announces that he has filed a challenge to the pharmaceutical company's patent, the company's stock drops and his hedge fund profits from the shorting position they have taken on the stock.[58]

When hedge funds short sell the stock of a patent owner, as Mr. Bass does, they have a potentially high yield for return on investment.[59] The cost to prepare and file an IPR is relatively low, approximately $23,000, and the cost to pursue it to completion is approximately $250,000—much less than filing an action in federal district court.[60] When news broke that Hayman had filed an IPR action against Acorda Therapeutics' ("Acorda") Ampyra, a drug designed to treat multiple sclerosis, the pharmaceutical company's stock initially dropped 10%,

---

[52] Ivy Wigmore, *Non-Practicing Entity*, WHATIS.COM, http://whatis.techtarget.com/definition/non-practicing-entity-NPE (last updated Oct. 2013).
[53] Quinn, *Patent Abuse or Genius*, *supra* note 2 (quoting 35 U.S.C. § 311(a) (2012), 35 U.S.C. § 321(a) (2012), and America Invents Act (AIA) § 18(a)(1)(B) (2012)).
[54] *Id.*
[55] *See* Silverstein, *supra* note 7.
[56] *See* Quinn, Patent Abuse or Genius, *supra* note 2.
[57] *Id.*
[58] *Id.*
[59] Hung & Hadduck, *supra* note 6.
[60] *See id.*

and dropped another 4.8% when news of a second IPR action broke.[61] A similar Hayman action against Shire PLC[62] caused its stock to drop 5.2 percent.[63] So far, Mr. Bass has filed thirty-seven IPRs against various pharmaceutical corporations.[64] Other hedge funds are starting to use the strategy as well.[65] Ferrum Ferro Capital, LLC ("FFC") has filed an IPR action against Allergan,[66] and Mangrove Partners has filed an IPR against VirnetX.[67]

Hayman and other hedge funds claim that they only challenge bad patents, those that were obtained through an abuse or manipulation of the patent system.[68] Mr. Bass has argued the IPRs Hayman has initiated are "fully in line with Congress's desire to allow the quick invalidation of allegedly questionable patents," and, thus, the company only seeks "to invalidate bad pharmaceutical patents that improperly promote higher drug prices."[69] Similarly, FFC has insisted it is motivated purely by a "desire to invalidate a bad pharmaceutical patent."[70] The "bad," "questionable," and so-called phony patents to which these companies refer are the patents pharmaceutical companies obtain through an abuse or manipulation of the system.[71] Normally, pharmaceutical drug patents expire after twenty years and generic brand substitutes come into the market. Pharmaceutical companies often extend their patents by simply changing the dosage, the packaging, or reformulating a newer version of an old drug.[72] Such actions represent manipulation of the system.

Many drug companies also engage in an abusive tactic called pay-for-delay.[73] This occurs when a brand name pharmaceutical company pays a generic drug company to keep their generic drug off the

61 Joseph Gulfo, *Hedge funds, 'reverse trolls' crushing biopharma innovation*, CNBC (July 22, 2015, 10:16 AM), http://www.cnbc.com/2015/07/22/biopharma-hammered-by-hedge-funds-reverse-trolls-commentary.html.

62 Hayman filed an IPR action against Shire PLC's colitis drug, Lialda. *See* Susan Decker, *Bass Joins Mangrove Showing Hedge Funds Can Challenge Patents*, BLOOMBERG (Oct. 7, 2015) https://www.bloomberg.com/news/articles/2015-10-07/bass-joins-mangrove-showing-hedge-funds-can-challenge-patents.

63 Hung & Hadduck, *supra* note 6.

64 *See* Aquino, Zombie Drug, *supra* note 5.

65 Hedge funds Ferrum Ferro Capital, LLC ("FFC") and Mangrove Partners have both began using the tactic. *See* Decker, *supra* note 62; *see also* Gulfo, *supra* note 61.

66 *See* Gulfo, *supra* note 61. There has not been any word of them succeeding on these charges. FFC's IPR petition was later denied on the merits. *See* John Aquino, *PTO Denies Hedge Fund Challenge of Allergan Glaucoma Patent*, PATENT TRADEMARK & COPYRIGHT J., Sept. 29, 2015; *see also* Hung & Hadduck *supra* note 6 ("Allergan also recently sued FFC, alleging civil extortion, unfair competition, and malicious prosecution.").

67 *See* Decker, *supra* note 62.

68 Greider, *supra* note 6.

69 Hung & Hadduck, *supra* note 6.

70 *Id.*

71 Greider, *supra* note 6.

72 *See id.*

73 *See id.*

market.[74] Sometimes the brand name company may even buy the start-up rival who is a threat to their monopolistic pricing.[75] By engaging in such tactics, they not only suppress lesser priced competitors, but continue to raise the price for their own pharmaceuticals, or the price for the cheaper generic brand after they buy the company.[76] These are the abuses and manipulations upon which the hedge funds capitalize.

The pharmaceutical companies argue that the hedge funds are using IPR to manipulate markets and earn private financial gains, which constitutes an abuse of process, as described by 37 C.F.R. § 42.12(a)(6),[77] and should be dismissed as such.[78] In response to IPR actions filed against it, the pharmaceutical corporation Celgene has argued that filing an IPR for financial benefit is a misuse of the system.[79] In response, Mr. Bass argued that the motivation behind every patent and IPR is profit and "[h]aving an economic motive for petitioning the government simply does not turn the petition into an abuse of process."[80] Bass goes on to state that his motivations are irrelevant, whether they are altruistic or not, and "[t]he U.S. economy is based largely on the notion that individual self-interest, properly

---

[74] *See* Dana A. Elfin, *OUTLOOK 2016: Busy Year Expected in Drug Patent, Antitrust Law*, PHARM. LAW & INDUS. REP. (Jan. 11, 2016), http://www.bna.com/outlook-2016-busy-n57982066063/.

[75] *See* Greider, *supra* note 6.

[76] *See id.*

[77] 37 C.F.R. § 42.12 (stating "(a) The Board may impose a sanction against a party for misconduct, including: (1) Failure to comply with an applicable rule or order in the proceeding; (2) Advancing a misleading or frivolous argument or request for relief; (3) Misrepresentation of a fact; (4) Engaging in dilatory tactics; (5) Abuse of discovery; (6) Abuse of process; or (7) Any other improper use of the proceeding, including actions that harass or cause unnecessary delay or an unnecessary increase in the cost of the proceeding.").

[78] *See* Gulfo, *supra* note 61; *Acorda Fires Back at Kyle Bass's IPR Strategy*, *supra* note 9; *see also* Hung & Hadduck *supra* note 6.

[79] *See* Gene Quinn, *Inter Partes Review and the Controversial Implication of the Kyle Bass Petitions*, IPWATCHDOG (Sept. 15, 2015), http://www.ipwatchdog.com/2015/09/15/inter-partes-review-and-the-controversial-implications-of-the-kyle-bass-petitions/id=61691/ [hereinafter Quinn, *Controversial Implication*].

[80] *Id.*

> [A]t the heart of nearly every patent and nearly every IPR, the motivation is profit. Celgene files for and acquires patents to profit from the higher drug prices that patents enable. Generic pharmaceutical companies challenge patents to profit from generic sales. Celgene's argument is in conflict with Supreme Court precedent expressly finding it in the public's interest for economically motivated actors to challenge patents. *See* Lear v. Adkins, 395 U.S. 653, 670 (1969) (holding public interest requires permitting licensees to challenge validity because they "may often be the only individuals with enough economic incentive to challenge the patentability" and "[i]f they are muzzled, the public may continually be required to pay tribute to would-be monopolists"). Having an economic motive for petitioning the government simply does not turn the petition into an abuse of process.

Id. (quoting Gene Quinn, *PTAB to Determine Whether to Sanction Kyle Bass for Filing IPRs*, IPWatchdog (Aug. 17, 2015), http://www.ipwatchdog.com/2015/08/17/ptab-to-determine-whether-to-sanction-kyle-bass-for-filing-iprs/id=60722/ (quoting Lear v. Adkins, 395 U.S. 653, 670 (1969))).

directed, benefits society writ large."[81] Bolstering this argument, Mr. Bass cites to Celgene's tumor treatment drug, Revlimid, which costs over $580 per pill resulting in costs of over $200,000 per year to just a single patient, and totaling sales of nearly $5 billion a year.[82]

The PTAB has several options to which it can resort to prevent abuse by both NPE's and patent owners. As one deterrent, it is allowed to impose sanctions against companies, and can deny suits for abuse of process as another.[83] The PTAB also has rulemaking authority, which allows it to "guard against petitions that undermine the integrity of the patent system and that tax the USPTO's resources."[84] Consequently, pharmaceutical corporations are responding to the Coalition's IPR petitions against them by, among other things, turning to the PTAB for relief by filing motions for sanctions.[85] In June 2015, the PTAB allowed Celgene to file a motion to dismiss the IPR petition filed against it by the Coalition and a motion for sanctions against the Coalition on the grounds of abuse of process.[86]

In late August 2015, the USPTO released proposed changes to their trial rules and proceedings for notice and comment from the public.[87] While as of yet they have not adopted any of these changes,[88] one such proposed rule "reinforces the duty of candor" for PTAB trials.[89] This requirement essentially provides that anyone who files an action with the USPTO makes a representation he is not bringing the action "for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of the proceeding."[90] The PTAB has not defined what "improper purpose" means, but some are calling it a "catch-all" provision that they could use in a variety of ways, including as a way to prohibit hedge funds from filing IPRs if they are

---

81 *Id.*

82 *Id.* ("The U.S. economy is based largely on the notion that individual self-interest, properly directed, benefits society writ large. Celgene's motive is to profit from consumers and taxpayers from drug sales. Celgene's patent-conferred monopoly results in Revlimid prices that exceed $580 per pill— creating costs in excess of $200,000 per patient year. Revlimid sales were nearly $5 billion in 2014. Celgene is not giving Revlimid or its profits away."); *see also Revlimid*, DRUGS, http://www.drugs.com/revlimid.html (last visited Mar. 18, 2016).

83 37 C.F.R. § 41.12(a).

84 Hung & Hadduck, *supra* note 6.

85 Gulfo, *supra* note 61; *Acorda Fires Back at Kyle Bass's IPR Strategy*, *supra* note 9; *see also* Hung & Hadduck *supra* note 6.

86 Hung & Hadduck, *supra* note 6.

87 Bernard Knight, *Inside Views: USPTO Proposes New PTAB Trial Rules*, INTELL. PROP. WATCH (Aug. 22, 2015), http://www.ip-watch.org/2015/08/22/uspto-proposes-new-ptab-trial-rules/.

88 *See PTAB Extends Time for Comments on Proposed Rules*, U.S. PATENT AND TRADEMARK OFF. (2015), http://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/about-ptab/ptab-extends-time-comments.

89 Knight, *supra* note 87.

90 *See id.* (citation omitted).

in a position to profit from the action.[91]

On August 24, 2015, pharmaceutical companies received what appeared to be good news when the PTAB declined to initiate the IPRs Mr. Bass had filed against the pharmaceutical corporation, Acorda.[92] Instead of denying the action as an abuse of process, the PTAB simply denied it on the merits without any reference to the overall actions and motives of the Coalition.[93] This decision left many wondering what the PTAB's stance was on this patent trolling issue.

On October 23, 2015, the PTAB concluded that the Coalition's IPR filed against Shire, another pharmaceutical corporation, offered sufficient evidence of an unpatentable claim, and it should proceed to trial.[94] While this marked the third out of eight IPR challenges from the Coalition that the PTAB has granted, they still avoided announcing a stance on the Coalition's actions.[95]

In a shocking turn of events, the PTAB held that, in regards to Celgene's motion for sanctions, any profit motives behind a challenge to the validity of a patent are irrelevant.[96] The PTAB stated that the AIA was intended to encourage meritorious patent challenges by third parties and non-patent owners in efforts to improve patent quality.[97] They continued by adding that the AIA was designed not just to provide a less costly alternative to federal court litigation, but also to enable "a more efficient and streamlined patent system that improved patent quality, while at the same time limiting unnecessary and counterproductive litigation costs."[98] Thus, the hedge fund's goals "to improve patent quality is in keeping with the purpose of the AIA."[99]

Based on this position, it appears the PTAB will continue to allow hedge funds to file IPRs even when they hold a position shorting the stock of the patent owner, and it will now only rule on the merits of such filings. Because the PTAB denied both Celgene's motion for sanctions and their motion to dismiss, this suggests there could be some merit to the IPR action.[100] It also suggests the PTAB does not want to

---

91 *See id.* The proposed provision also establishes "new procedural rules for sanction motions, including allowing the other party to first correct the challenged document." *Id.*

92 *See* Quinn, *USPTO denies Kyle Bass IPR*, *supra* note 43.

93 *See id.* ("[T]he PTAB substantively denied the Bass petitions finding that the prior art relied upon to challenge . . . patents was not sufficiently available to the public to qualify as prior art.").

94 John Aquino, *Board Moves Bass's Bowel Treatment Patent Challenge to Trial*, PHARMACEUTICAL LAW AND INDUS. REP. (Oct. 30, 2015), https://www.bloomberglaw.com/product/blaw/document/XBPFMTAK000000?resource_id [hereinafter Aquino, *Board Moves*].

95 *Id.* (stating the PTAB denied the other five IPR petitions it has reviewed).

96 *See* John Aquino, *Patent Board Says Bass's IPR Motive Irrelevant*, PATENT TRADEMARK AND COPYRIGHT J. (Sept. 29, 2015), https://www.bloomberglaw.com/product/blaw/document/XC3PP6AC000000?resource_id= [hereinafter Aquino, *IPR Motive Irrelevant*].

97 *Id.*

98 *Id.*

99 Aquino, *Board Moves*, *supra* note 94.

100 *See id.*; *see also* Aquino, IPR Motive Irrelevant, *supra* note 96.

curb hedge funds' behavior through sanctioning. Echoing Mr. Bass' position, the PTAB stated that "profit is at the heart of nearly every patent," and "having an economic motive for challenging a patent claim 'does not itself raise abuse of process issues.'"[101] If changes to hedge fund practices are to occur, they will have to come from Congress.

D. *The Deeper Problem: The Pharmaceutical Monopolies and Over Priced Prescriptions*

The inflated stock prices and overvaluation of large pharmaceutical companies are a result of profits that are derived from their monopolistic practices. Such practices are maintained through a manipulation of the system, and allow companies to "double or triple prices by extending their legal claims to exclusive production of widely prescribed and essential drugs."[102] Pharmaceutical companies take advantage of a variety "of laws that force insurers to include essentially all expensive drugs in their policies, and a philosophy that demands that every new health care product be available to everyone, no matter how little it helps or how much it costs."[103]

The extent to which drug companies take advantage of the system is staggering and has led to skyrocketing prices for drugs in the U.S.[104] For example, Albendazole, a drug for parasitic infections, cost $5.92 per day in 2010.[105] By 2013, it cost $119.58 per day, over a 1,920% increase.[106] In 2012, the Food and Drug Administration (FDA) approved twelve cancer drugs, eleven of which cost over $100,000 per year.[107] One popular cancer drug is Gleevec, which is produced by Novartis.[108] When it was first produced in 2001, Gleevec sold for $28,000 per year; by 2012 that figure rose to $92,000.[109] In 2015, Daraprim, an AIDS treatment pill, rose from $13.50 per pill to $750—a 5,500% increase.[110] The high cost of these drugs is passed on to

---

101 Aquino, *IPR Motive Irrelevant*, *supra* note 96 ("Profit is at the heart of nearly every patent and nearly every inter partes review. As such, an economic motive for challenging a patent claim does not itself raise abuse of process issues. We take no position on the merits of short-selling as an investment strategy other than it is legal, and regulated[.]").

102 Greider, *supra* note 6.

103 Peter Bach, *Why Drugs Cost So Much*, N.Y. TIMES (Jan. 14, 2015), http://www.nytimes.com/2015/01/15/opinion/why-drugs-cost-so-much.html?_r=0.

104 *See* Michelle Llamas, *Big Pharma Cashes in on Americans Paying (Higher) Prices for Prescription Drugs*, DRUG WATCH (Oct. 15, 2014), http://www.drugwatch.com/2014/10/15/americans-pay-higher-prices-prescription-drugs/.

105 *See* Bach, *supra* note 103.

106 *Id.*

107 Amy Nordrum, *Why Are Prescription Drugs So Expensive? Big Pharma Points to the Cost of Research and Development, Critics Say That's No Excuse*, INT'L BUS. TIMES (May 19, 2015, 11:59 AM), http://www.ibtimes.com/why-are-prescription-drugs-so-expensive-big-pharma-points-cost-research-development-1928263#discussion.

108 Llamas, *supra* note 104.

109 *See id.*

110 Annalisa Merelli, *The way to fix outrageous drug pricing in the US is simply to do what all*

patients.[111] The result, as a 2013 study shows, is that one in five Americans fail to fill a prescription or skip a dose because the medication is too expensive.[112] The percentage of those with private health insurance who put off treatment has risen from 25% in 2013 to 34% in 2014—a steep rise in only one year.[113]

Pharmaceutical companies often cite to billion-dollar research and development (R&D) costs as the reason for the high cost of medications.[114] Current figures estimate the R&D of a single drug costs around $1.2 billion.[115] However, these purportedly high costs are misleading and have been labeled as "myths of the industry."[116] This is because the R&D figures are "based on only the most expensive drugs with extensive clinical trials."[117] The actual cost for developing just one drug is less than $60 million.[118] The high figures are partly due to the fact that they include both failed and successful experiments, and do not take into account massive tax breaks companies receive for R&D.[119]

The patent protections available for pharmaceutical companies result in regulatory conditions, inhibiting normal market forces and trends that would otherwise exist in a free, capitalist market.[120] Patent protection for these pharmaceutical companies' drugs usually lasts for

other rich countries do, QUARTZ (Sept. 15, 2015), http://qz.com/509344/the-way-to-fix-outrageous-drug-pricing-in-the-us-is-simply-to-do-what-all-other-rich-countries-do/.

111 Bach, *supra* note 103; "[H]igh drug prices result in higher premiums." Annalisa Merelli, *supra* note 110. Insurance companies are increasingly requiring patients to cover 40 to 50 percent of high medication costs out of pocket. *See* Brianna Ehley, *Obamacare Insurers Hit High-Cost Patients with High Drug Prices*, THE FISCAL TIMES (July 10, 2014), http://www.thefiscaltimes.com/Articles/2014/07/10/Obamacare-Insurers-Hit-High-Cost-Patients-High-Drug-Prices.

112 Llamas, *supra* note 104 (comparing the U.S. to countries like Germany, Canada, and Australia where less than one in ten citizens have the same problem).

113 Rebecca Riffkin, *Cost Still a Barrier Between Americans and Medical Care*, GALLUP (Nov. 28, 2014), http://www.gallup.com/poll/179774/cost-barrier-americans-medical-care.aspx.

114 *See* Nordrum, *supra* note 107.

115 Llamas, *supra* note 104; *see also Cost to Develop and Win Marketing Approval for a New Drug Is $2.6 Billion*, TUFTS CENTER FOR THE STUDY OF DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (calculating the average out-of-pocket cost for one drug to be $1.395 Billion). *But see* Jason Millman, *Does It Really Cost $2.6 Billion to Develop a New Drug?*, THE WASH. POST (Nov. 18, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/11/18/does-it-really-cost-2-6-billion-to-develop-a-new-drug/.

116 This is partly due to the fact that the figures include both successful and failed experiments, and do not take into account massive tax breaks companies receive for research and development. Nordrum, *supra* note 107; *see also* Llamas, *supra* note 104; Millman, *supra* note 115.

117 Llamas, *supra* note 104.

118 *See id.*

119 Nordrum, *supra* note 107; *see also* Millman, *supra* note 115.

120 *See* Nordrum, *supra* note 107; *see also* James Surowiecki, *Taking on the Drug Profiteers*, THE NEW YORKER (Oct. 12, 2015), http://www.newyorker.com/magazine/2015/10/12/taking-on-the-drug-profiteers (quoting Gerard Anderson, a professor at John Hopkins University, who stated that "[w]ithout price competition, the generic model fails," and "[w]ithout competition, there are no market forces that limit price increases."); Merelli, *supra* note 110 (explaining the problem with pharmaceutical drug pricing is that you have a free, unregulated market).

twenty years.[121] However, the current practice of the FDA has extended such protection further by prohibiting rival products from entering the market for an additional five to seven years *on top* of the twenty-year protection already afforded.[122] These regulatory conditions create a market with monopolies that have free reign for an unnecessarily extended period of time, and a market where product cost is divorced from the equation.[123] Because the two primary forces that keep goods and services in check in other markets are not present here, there are no other market forces to keep prices in line.[124] When companies calculate a price for their drug, they determine what the highest possible price is by comparing what it would cost patients to go untreated, inevitably resulting in astronomical prices.[125]

The price of pharmaceutical drugs needs to be brought down. American patients pay far more for pharmaceutical prescriptions than any other country.[126] Unfortunately, the Affordable Care Act does not address this problem, so another solution is needed.[127]

---

121 Keith Maskus, *Intell. Prop. Rights and Econ. Dev.*, 32 CASE WESTERN RESERVE J. INT'L L. 471, 474 (Summer 2000).

122 Nordrum, *supra* note 107.

123 *See id.*; *see generally* Surowiecki, *supra* note 120 (discussing how pharmaceutical monopolies can charge any price they choose and how prices do not reflect the cost of production).

124 *See* Nordrum, *supra* note 107 (stating that the two primary forces that are missing are competition and affordability); *see also* Surowiecki, *supra* note 120 (quoting Gerard Anderson, a professor at John Hopkins University, who stated that "[w]ithout price competition, the generic model fails," and "[w]ithout competition, there are no market forces that limit price increases."); Merelli, *supra* note 110 (explaining the problem with pharmaceutical drug pricing is that you have a free, unregulated market).

125 *See* Nordrum, *supra* note 107; *see also* Merelli, *supra* note 110.

126 Merelli, *supra* note 110.

127 Americans are putting off medical treatment due to the high cost of prescriptions, which is the highest it has ever been in the past 14 years. *See* Riffkin, *supra* note 113; "[Obamacare] isn't designed to save money." Meghan Foley, *Here's How Obamacare Is (and Isn't) Lowering Health Care Spending*, THE CHEAT SHEET (Dec. 27, 2014), http://www.cheatsheet.com/politics/heres-how-obamacare-is-and-isnt-lowering-health-care-spending.html/?a=viewall (quoting MIT health economist Jonathan Gruber);

> [T]he current system has proved ineffective not only in providing access to affordable care, but also in saving public resources. Although the Affordable Care Act might help in reducing costs for the government, the US government is currently in the paradoxic position of spending more in healthcare than any other in terms of GDP percentage, while covering a much smaller percentage of the overall health costs.

Merelli, *supra* note 110; "Americans still find themselves unable to access the care they desperately need due to high out of pocket costs" for prescription drugs. Ehley, *supra* note 111; "Health reform represents a decline in medication coverage inasmuch as the average drug copayments and co-insurance fees are higher than the averages found in the pre-reform market." Kev Coleman, *Drug Coverage and the Affordable Care Act*, HEALTHPOCKET (Feb. 13, 2014), https://www.healthpocket.com/healthcare-research/infostat/prescription-drug-coverage-and-affordable-care-act#.ViWQR9bQeoU.

II. ANALYSIS

A. *Examining the Current Patent Reform Bills in Congress*

Since the PTAB has not taken any significant steps to prevent patent trolls from abusing the patent system, Congress has taken up the issue by proposing multiple patent reform bills.[128] The two bills most likely to be passed[129] are the Innovation Act,[130] and the PATENT Act.[131] These proposed bills each have measures that could affect the PTAB and the IPR abuse by the Coalition. The House of Representative's Innovation Act is the counterpart to the Senate's PATENT Act, and so, due to their similarity, they will be evaluated simultaneously.[132]

The Innovation Act and the PATENT Act both require significant specificity in infringement pleadings before the PTAB and U.S. district courts, and, in particular, the Innovation Act requires:

> [I]dentification of each patent . . . identification of *all claims* necessary to produce the identification . . . of each process, machine, manufacture, or composition of matter (referred to in this section as an 'accused instrumentality') that is alleged to infringe *any claim* of *each patent* . . . an identification of *each accused instrumentality* alleged to infringe the claim . . . an identification with particularity, if known, of— the name or model number (or a representative model number) of each accused instrumentality; or . . . a description of each accused instrumentality. For each accused instrumentality identified . . . a clear and concise statement of— where each element of each claim identified . . . is found within the accused instrumentality; and with detailed specificity, how each limitation of each claim identified . . . is met by the accused instrumentality. For each claim of indirect infringement, a description of the acts of the alleged indirect infringer that contribute to or are inducing the direct infringement. A description of the authority of the party alleging

---

128 There are currently eight proposed bills in Congress addressing patent reform. These bills include the Innovation Act (H.R. 9), PATENT Act (S. 1137), STRONG Patents Act (S. 632), Venue Equity and Non-Uniformity Elimination Act (S. 2733), Demand Letter Transparency Act (H.R. 1896), Targeting Rogue and Opaque Letters Act (H.R. 2045), Trade Protection Not Troll Protection Act (H.R. 4829), and Innovation Protection Act (H.R. 1832). *Patent Progress's Guide to Federal Patent Reform Legislation*, PATENT PROGRESS, http://www.patentprogress.org/patent-progress-legislation-guides/patent-progresss-guide-patent-reform-legislation/ (last visited Nov. 15, 2016).

129 The Innovation Act and the PATENT Act are the only patent bills to have made it out of committee and recommended for further consideration by the House and Senate respectively. *See S. 1137: PATENT Act*, GOVTRACK, https://www.govtrack.us/congress/bills/114/s1137 (last visited Aug. 25, 2016); *see H.R. 9: Innovation Act*, GOVTRACK, https://www.govtrack.us/congress/bills/114/hr9 (last visited Aug. 25, 2016).

130 H.R. REP. NO. 114-524 (2015-2016).

131 S. 114-1137 (2015-2016).

132 *See* Brian Pomper, *PATENT Act Still Ominous for Startups and Small Inventors*, IPWATCHDOG (June 4, 2015), http://www.ipwatchdog.com/2015/06/04/patent-act-still-ominous/id=58407/ [hereinafter Pomper, *PATENT Act*].

> infringement to assert each patent identified . . . and of the grounds for the court's jurisdiction.[133]

This pleading standard would thus require an identification of each patent and claim being challenged, and "an element-by-element analysis of how the accused instrumentality meets all the claim limitations."[134] By requiring that *all* claims of *all* the infringing patents be identified with particularity to *all* the accused instrumentalities in the pleadings, the bar to permit discovery would be set so high it would be impossible to reach.[135] This overly broad and burdensome standard would require plaintiffs to prove the majority of their case before even filing a complaint with the PTAB or district courts.[136] "Imagine if there were twenty product models alleged to infringe five patents, each with ten specific infringement claims. A patent holder would have to do heightened pleading on a thousand categories of information (twenty products times fifty claims) and patent complaints could easily run over a hundred pages long."[137] A patent owner may have a good faith basis for believing a product infringes on their own product, but the particularities would be unknown because typically not all of the information this proposed statute requires would be available through public information, and as a consequence they would be prohibited from seeking discovery.[138]

Another effect of these increased pleading standards would be an increased cost of litigation, and a delay in the resolution of disputes both at the PTAB and district courts.[139] Such pleading requirements would lead defendants to challenge the sufficiency of complaints filed against them as failing to plead facts that the plaintiff "should have known or that were readily accessible" had the plaintiff conducted a reasonable investigation.[140] This will lead to cycles of plaintiffs submitting amended complaints that defendants then challenge repeatedly as insufficient, leading to long delays and more attorney fees.[141] While this could help protect pharmaceutical corporations from patent trolls, such as the Coalition, this would be particularly prohibitive for small business, startups, and other venture capital backed companies with

133 H.R. 9, § 3(a); The language in the PATENT Act is almost identical. *See* S. 1137 § 3.

134 Lionel Lavenue, R. Benjamin Cassady & Michael Su, *A Review of Patent Bills in The 114th Congress*, LAW360 (June 15, 2015), https://advance.lexis.com/document/?pdmfid=1000516&crid.

135 Brian Pomper, *Innovation Act makes patents harder to enforce, easier to infringe*, IPWATCHDOG (Apr. 16, 2015), http://www.ipwatchdog.com/2015/04/16/innovation-act-makes-patents-harder-to-enforce-easier-to-infringe/id=56860/ [hereinafter Pomper, *Innovation Act*].

136 Pomper, *Innovation Act*, *supra* note 135.

137 Pomper, *PATENT Act*, *supra* note 132.

138 Pomper, *Innovation Act*, *supra* note 135.

139 *See id.*

140 *See id.*

141 *See id.*

limited resources.[142] The cumulative effect to all U.S. patent rights by these overly broad measures would result in a system where patents are tougher to enforce and easier to infringe.[143]

One detractor of the proposed pleading requirements is the USPTO's own Director, Michelle Lee.[144] She has publicly expressed concern for the effects the provision would have and advocates for further revision.[145] Ms. Lee stated:

> A concern we have is that requiring the pleading of additional claims with greater specificity at the beginning of the litigation might unduly burden a patent owner, might encourage needless and early procedural motions in the form of motions to dismiss, and not materially advance the case, when all that is required is an appropriately plead single claim in order for the case to move forward.[146]

An additional concern being raised is over the claim construction standard the Innovation Act and PATENT Act would require of the PTAB. District courts currently evaluate disputed patent claim terms by the "ordinary and customary meaning" standard established by the Federal Circuit in *Phillips v. AWH Corp*.[147] Under this standard, district courts are required to *presume* the claims of an issued patent as valid.[148] In order for these claims to be declared invalid, the district court must overcome this presumption of validity by showing *clear and convincing evidence*.[149]

The PTAB, however, is held to the lower standard of "broadest reasonable interpretation," under which there is *no presumption* of validity, but rather, validity is determined by a preponderance of the evidence.[150] Under this standard of preponderance of the evidence, the PTAB examines whether a given patent claim is more likely than not to be valid or invalid, which does *not* require clear and convincing evidence.[151] The Innovation Act and the PATENT Act both narrow the claim construction standard for IPR and PGR to the "ordinary and customary meaning" standard that district courts use, rather than the

142 Pomper, *PATENT Act*, *supra* note 132.
143 Pomper, *Innovation Act*, *supra* note 135.
144 *See* Pomper, *PATENT Act*, *supra* note 132.
145 *See id.*
146 *See id.*
147 *See* Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005); *see also* Grant Ford, *Broadest Reasonable Interpretation vs. Ordinary and Customary Meaning: - Challenges Introduced by Applying Different Claim Construction Standards at the PTAB and District Courts*, MARTINDALE-HUBBELL (Sept. 24, 2014), http://www.martindale.com/intellectual-property-law/article_Sughrue-Mion-PLLC_2178908.htm.
148 *See* Ford, *supra* note 147.
149 *See id.*
150 *See id.*
151 *See id.*

PTAB's current standard of "broadest reasonable interpretation."[152]

Because the "ordinary and customary meaning" standard increases the difficulty of invalidating patents, implementing it at the PTAB would extend the length of the IPR process and increase costs.[153] This would defeat the purpose for which the PTAB and IPR were created in the first place, to wit, to be a low cost, and expeditious solution to patent litigation.[154] While pharmaceutical corporations would benefit from the increased difficulty of invalidating patents, they, unlike small businesses, have the monetary resources available to be able to meet the increased costs under the proposed system. The USPTO has publicly explained that, by contrast, the current "broadest reasonable interpretation" standard provides a clear understanding of the outer limits applicants and patentees can attribute to their claims.[155] They add that this standard produces patents that are well-defined and defensible at the "lowest cost point in the system."[156]

Another overly broad provision in both the PATENT Act and the Innovation Act is the "customer stay" provision.[157] The customer stay provision allows district courts and the PTAB to indefinitely postpone "patent infringement suits against 'retailers' and 'end users' in favor of suits involving manufacturers higher up the supply chain."[158] Although the goal of the provision is to protect innocent customers, such as mom-and-pop stores, from patent infringement accusations when liability ultimately belongs to the manufacturer of the infringing product, almost any party could qualify as a "customer," including Fortune 500 companies.[159] This is because both Acts define customer more broadly than necessary.[160] Under each Act, a customer is defined as a retailer, which is further defined as an entity that generates "revenues predominantly through the sale to the public of consumer goods and services . . . ."[161] Almost any entity would fall into this definition "because almost all manufacturers are also retailers of other

152 Lavenue et al., *supra* note 134; *see also* H.R. 9, § 9(b); S. 1137, § 11.

153 Lavenue et al., *supra* note 134.

154 *See* Aquino, IPR Motive Irrelevant, *supra* note 96; *see also* Eric Cohen, *Should PTAB Apply Broadest Construction In IPR?*, LAW360 (Sept. 22, 2014, 10:11 AM), http://www.law360.com/articles/574722/should-ptab-apply-broadest-reasonable-construction-in-ipr.

155 *See* Tom Engellenner, *Does the Broadest Reasonable Interpretation Standard Make Sense*?, POSTGRANT-COUNSEL (Jan. 6, 2015) http://postgrant-counsel.com/2015/01/06/does-the-broadest-reasonable-interpretation-standard-make-sense/.

156 *See id.*; *see also* Cohen, *supra* note 154.

157 S. 114-1137, § 4 (2015-2016); H.R. 114-9, § 5 (2015-2016).

158 Devlin Hartline, *Unintended Consequences of "Patent Reform": The Customer Suit Exception*, CENTER FOR THE PROT. OF INTELL. PROP. (June 16, 2015), http://cpip.gmu.edu/2015/06/16/unintended-consequences-of-patent-reform-the-customer-suit-exception/; *see also* Pomper, *PATENT Act*, *supra* note 132.

159 *See* Hartline, *supra* note 158; *see also* Pomper, *PATENT Act*, *supra* note 132.

160 *See* Hartline, *supra* note 158; *see also* Pomper, *PATENT Act*, *supra* note 132.

161 Hartline, *supra* note 158.

manufacturers . . . ."[162] For example, a smartphone company that receives its components from a third-party, if sued for patent infringement, could claim to be a "customer," because it is a "retailer" that generates its revenue predominantly through the sale of goods to the public, and could be granted a stay.[163] Thus, in fact, it is the large corporations, including pharmaceutical corporations, that would be able to avoid patent infringement suits through use of the customer stay provision, while the ability of small innovators and inventors to seek remedies or procedures to enforce their patent rights would be hindered.[164]

In addition, the Innovation Act and the PATENT Act contain a fee-shifting provision.[165] This provision allows judges at the PTAB and district courts "to order the losing party to pay the attorneys' fees and other costs of the prevailing party."[166] Generally, in litigation, the traditional rule is that each party pays their own fees.[167] The fee-shifting provision would codify the Supreme Court's ruling in the 2014 case, *Octane Fitness LLC v. ICON Health & Fitness Inc*,[168] where the Supreme Court held that "attorney fees and costs may be awarded to a prevailing party, where the substantive strength of a party's position 'stands out from others,' as shown by a preponderance of the evidence."[169]

The fee-shifting provision of the Innovation Act and the PATENT Act would make it even easier for parties to recover fees and costs.[170] It would empower the PTAB to penalize any party who brings a frivolous case by requiring them to pay the attorney fees for the other party.[171] The Innovation Act would always award the prevailing party reasonable fees and other expenses, making fee-shifting the default rule. Unless the non-prevailing party could show it was reasonably justified or there were special circumstances, such as economic hardship, this would make the award unjust.[172] By contrast, the PATENT Act would only

---

162 *See id.*

163 *See id.*

164 *See* Hartline, *supra* note 158; *see also* Pomper, *PATENT Act*, *supra* note 132; *see also* Pomper, *Innovation Act*, *supra* note 135.

165 *See* H.R. 114-9, § 285 (2015-2016); *see also* S. 114-1137, § 285 (2015-2016).

166 Gene Quinn, *Patent Reform 101: A Comparison of Current Fee-shifting Language*, IPWATCHDOG (June 11, 2015), http://www.ipwatchdog.com/2015/06/11/patent-reform-101-a-comparison-of-current-fee-shifting-language/ id=58638/ [hereinafter Quinn, *Patent Reform 101*].

167 Lavenue et al., *supra* note 134.

168 *See id.*

169 *Id.*

170 *See id.*

171 *See* Bob Zeidman, *An inventor's perspective on patent reform*, THE HILL (Aug. 10, 2015, 3:00 PM), http://thehill.com/blogs/congress-blog/technology/250593-an-inventors-perspective-on-patent-reform.

172 *See* H.R. 114-9, § 285(a) (2015-2016); *see also* Lavenue et al., *supra* note 134; *see also* Quinn, *Patent Reform 101*, *supra* note 166.

allow fee shifting upon a motion made by the prevailing party.[173] Then, the PTAB would look to whether or not the non-prevailing party's position and conduct was objectively reasonable.[174] If that party's position or conduct was found to be objectively unreasonable, the party would then have to pay reasonable attorney fees to the prevailing party, absent any special circumstances that would make the award unjust.[175]

It is unlikely that fee shifting would stop the challenges brought by the hedge funds. Since accused infringers face the high fees and costs of litigation, "this rule arguably drives wrongly accused parties to settle, especially when settlement costs less than the total attorney fees and costs required to defend the case."[176] In addition, the PTAB would only shift fees as a penalty to those bringing frivolous suits deemed to be objectively unreasonable.[177] The problem with this standard is that the claims the hedge funds are bringing are arguably not frivolous, but legitimate, and objectively reasonable IPR challenges with merit.[178] Proof of this is that the PTAB has allowed three of the challenges through, and has even stated they are not concerned with the monetary incentives of the hedge funds, which indicates they too think the challenges are not all without merit but are objectively reasonable.[179]

The Innovation Act contains one amendment to the PTAB's IPR proceedings which would preclude any party who fails to certify "it does not own a financial instrument designed to profit from a decrease in the patentee's stock value," and "it has not demanded payment from the patentee in exchange for foregoing an IPR unless the party has been sued for patent infringement."[180] Under this provision, hedge funds like Hayman would still be able to initiate an IPR, but they would be prevented from short-selling stock of the patentee at the same time.[181] However, passing the bill in its current form with its broad drafting would do more harm than good.

Neither the Innovation Act nor the PATENT Act are tailored enough to stop the abusive behavior of patent trolls. In fact, their overly broad measures will harm innovation, the economy, and increase patent litigation.[182] Both Acts benefit large corporations, such as

173 *See* S. 114-1137, § 285(a) (2015-2016); *see also* Quinn, *Patent Reform 101*, *supra* note 166.
174 *See* S. 114-1137, § 285(a) (2015-2016); *see also* Quinn, *Patent Reform 101*, *supra* note 166.
175 *See* S. 114-1137, § 285(a) (2015-2016); *see also* Quinn, *Patent Reform 101*, *supra* note 166.
176 Lavenue et al., *supra* note 134.
177 *See* S. 114-1137, § 285(a); *see also* H.R. 114-9, § 285(a); *see also* Quinn, *Patent Reform 101*, *supra* note 166.
178 *See* Aquino, *Board Moves*, *supra* note 94; *see also* Aquino, *IPR Motive Irrelevant*, *supra* note 96; *see also* Decker, *supra* note 62.
179 *See* Aquino, *Board Moves*, *supra* note 94; *see also* Aquino, *IPR Motive Irrelevant*, *supra* note 96; *see also* Decker, *supra* note 62.
180 H.R. 114-9, § 9(b)(1); *see also* Hung & Hadduck, *supra* note 6.
181 *See* Hung & Hadduck, *supra* note 6.
182 See Pomper, Innovation Act, *supra* note 135.

pharmaceutical corporations, but harm startups and small inventors due to the burdensome enforcement requirements they place on patent owners.[183]

Although it is not the most popular patent reform bill and is unlikely to be passed, the Support Technology and Research for Our Nation's Growth (STRONG) Patents Act is worth mentioning for one of the good ideas it proposes.[184] Congress currently diverts USPTO fees away from the USPTO and towards other projects. In 2003, Congress diverted $162 million of the $237 million budgeted to the USPTO.[185] The STRONG Patents Act would eliminate this fee diversion.[186] This would allow the USPTO to abolish the budget restrictions it currently has and use the fees it collects without limitation, including, most importantly, for improvements in the patent examination process.[187] This provision would be a step in the right direction to protecting both pharmaceutical corporations and small patent owners from hedge fund patent trolls.

*****

The chart below illustrates the pros and cons of the changes proposed by the PATENT Act, Innovation Act, and STRONG Patents Act:

Proposed Change / Act	**Pros**	**Cons**
Significant specificity in pleadings / Innovation Act, PATENT Act	• More difficult to initiate an infringement suit	• Increased costs of litigation • Delay in resolutions
Ordinary and customary standard / Innovation Act, PATENT Act	• Increased difficulty of invalidating patents	• Extends length and costs of IPR
Customer stay provision / Innovation Act, PATENT Act	• Could indefinitely postpone infringement suits against small business retailers and end users	• Would also apply to big businesses thus hindering remedies of enforcement available for small businesses

183 *See* Pomper, *PATENT Act*, *supra* note 132.

184 *See* Dennis Crouch, *The Strong Patent Act of 2015 from Senator Coons*, PATENTLY-O (Mar. 3, 2015), http://patentlyo.com/patent/2015/03/strong-patent-senator.html; *see also* Andrew Williams, *STRONG Patents Act of 2015 -- An Alternative Patent Reform Bill*, PATENT DOCS (Mar. 4, 2015), http://www.patentdocs.org/2015/03/strong-patents-act-of-2015-an-alternative-patent-reform-bill.html.

185 *See* Mandy Barbara Seuffert, *Soft-Science Examiners at the USPTO: A Non-Obvious Solution to Reduce Erroneous Patent Grants*, 10 MARQ. INTELL. PROP. L. REV. 111, 124-25 (2006) (discussing the need to improve the quality of patents issued by the USPTO).

186 *See* S. 114-632, § 107 (2015-2016); *see also* Zeidman, *supra* note 171.

187 See Gene Quinn, *Pro-patentee Patent Reform, the STRONG Patents Act Introduced in Senate*, IPWATCHDOG (Mar. 3 2015), http://www.ipwatchdog.com/2015/03/03/strong-patents-act-introduced-in-senate/id=55384/; *see also* Zeidman, *supra* note 171.

Fee shifting provision / Innovation Act, PATENT Act	• Potential to penalize parties who bring frivolous suits • Easier for parties to recover fees and costs	• Would not stop patent trolls because not all suits they initiate are frivolous
Certification that one will not profit off of an IPR / Innovation Act	• Patent trolls prevented from short-selling stock of the patentee	• Passing the bill in its current form, with all other provisions, would do more harm than good
Eliminates fee diversion / STRONG Patents Act	• Would allow for improvements in the patent examination process at the USPTO	• Not likely to pass

B. *An IPR Carve-out for the Pharmaceutical Industry*

Although the requirements proposed by the Innovation Act and the PATENT Act might be enough to stop the hedge funds from attacking pharmaceutical companies, this is not enough for the pharmaceutical industry. They are now demanding a complete exemption from IPR and PGR.[188] Absent this carve-out for IPR, the pharmaceutical and biotech industries will not support any patent reform bill, and without their support patent reform will likely not pass.[189] Such an exemption is estimated to cost $1.3 billion over a decade.[190] This would in part be due to a decrease in competition, as generic drug companies would be delayed from entering the market.[191] The Center for Economic and Policy Research has stated "the failure to remove improperly awarded patents at an early date could lead to substantially higher drug costs."[192] This would in turn result in higher payments for Medicare, Medicaid, and other government-run health programs.[193] The IPR carve-out is not the right solution to the problem and it would be a huge benefit only to the pharmaceutical industry, which would stand to profit immensely as their patents would be unchallengeable by IPR.

---

188 *See* Gene Quinn, *Fat cats have the patent system perpetually on the brink*, IPWATCHDOG (Sept. 22, 2015) http://www.ipwatchdog.com/2015/09/22/fat-cats-have-the-patent-system-perpetually-on-the-brink/id=61868/ [hereinafter Quinn, *Fat cats*].

189 *See id.*

190 Brett Norman & Sarah Karlin, *As Congress returns, patent reform hits the skids*, POLITICO (Sept. 8, 2015, 12:01 PM), http://www.politico.com/tipsheets/prescription-pulse/2015/09/pro-prescriptionpulsesept8-karlin-norman-210101#ixzz3lCCbduhm.

191 *Id.*

192 Lawrence B. Ebert, *The debate about the proposed IPR carve-out for pharma patents*, IPBIZ (Aug. 31, 2015), http://ipbiz.blogspot.com/2015/08/the-debate-about-proposed-ipr-carve-out.html.

193 *Id.*

C. *Another Solution is Needed*

Congress' proposed patent reform solutions, including the Innovation Act, the PATENT ACT, and the IPR carve-out, benefit large corporations, such as the pharmaceutical corporations, but harm startups and small inventors due to the burdensome enforcement requirements they place on patent owners.[194] Neither the Innovation Act nor the PATENT Act are tailored enough to stop the abusive behavior of hedge fund patent trolls. In fact, Congress' overly broad proposals will harm innovation, the economy, and increase patent litigation.[195] Thus, these proposals are not the right solution.

It is possible that this problem facing the pharmaceutical industry will work itself out over time. Hedge funds are successfully making money by shorting the stocks because the market continues to react in a volatile way once it is announced that an IPR has been filed against a company. Once, and if, the novelty of this approach wears off, it is possible that the market will not react to the filing of an IPR in such a way.[196] If that were to happen, the hedge funds' approach would be useless, because they would have no profit incentive. However, it is unlikely that this will occur any time soon, and another solution is needed.

III. PROPOSAL

A. *Policy Proposals to Solve the Problem*

What the hedge fund patent trolls are doing is, in fact, a good thing, because it has the effect of eliminating the bad pharmaceutical patents in the market. However, their method should be prohibited for being illegal stock market manipulation.[197] Once hedge funds are removed from the equation, there will be no well-funded organizations to challenge the bad patents obtained by pharmaceutical companies. Therefore, the solution will need to establish long-term changes that prevent abuse of the patent system, prevent market manipulation, and reduce the number of bad patents.

This problem can be solved in two steps. First, pharmaceutical prescription drug patents should be required to undergo a more rigorous approval process, making it more difficult for them to receive bad patents. With fewer bad patents in existence, the hedge funds would not

194 *See* Pomper, *PATENT Act*, *supra* note 132.

195 *See* Pomper, Innovation Act, *supra* note 135.

196 *See* Tony Dutra, *Stakeholders Don't Want Major Changes to PTAB Rules*, BLOOMBERG BNA: PATENT TRADEMARK AND COPYRIGHT J. (Oct. 16, 2015), https://www.bloomberglaw.com/product/blaw/document/X58KCG94000000?resource_id=079316a0809282999d088ffbe3a1b42c.

197 Stock market manipulation, or simply, manipulation, is the "act of artificially inflating or deflating the price of a security[,]" and is an illegal practice. *Manipulation*, *supra* note 1.

be able to attack the pharmaceutical companies to the same extent, and this could bring some stabilization to the stock market such that if an IPR action is filed, the market may not overreact as it currently does. Tougher standards would breed stronger patents, and, with stronger patents, companies would have a higher incentive to innovate.[198]

Second, there must be a regulatory change addressing the tactics of the pharmaceutical industry to maintain their monopolistic hold over drug pricing. This will also facilitate an environment which allows manufacturers of generics to enter the market more quickly. As it would be easier for such manufacturers to enter the market, there would be an increase in competition, which will lead to lower drug prices.[199] As drug prices fall more in line with the market, it would be less likely for pharmaceutical companies' stocks to be overvalued, and thus hedge funds would be less likely to take a position shorting the stock.

B. *Increasing the Quality Standards for Drug Patents*

A novel solution to the problem would be to strengthen the patent system by creating stricter standards. That does not mean that it should be harder to challenge patents, but rather it should be more difficult for pharmaceutical companies to obtain patents. By creating stricter standards for drug patent approval, the quality and strength of patents will be higher and this will result in fewer challenges.[200] In addition, as the quality and strength of patents increases, what will result is an increase in innovation, growth, investment, and prosperity.[201]

The direction the patent system is heading is one that incentivizes patent infringement, rather than transactions for patent rights.[202] The Coase theorem, which describes economic efficiencies, provides that when faced with an external situation affecting the parties involved, the

198 *See generally* Michelle Lee, Deputy Under Sec'y of Commerce for IP and USPTO Deputy Dir., Speaking Truth to Patents: The Case for a Better Patent System, Address Before Stanford Law School (June 26, 2014), *in* U.S. PATENT AND TRADEMARK OFF., http://www.uspto.gov/about-us/news-updates/speaking-truth-patents-case-better-patent-system (discussing how the best course of action for improving the patent system would be to improve patent quality).

199 *See* JOANNA BROUGHER, INTELL. PROP. AND HEALTH TECH.: BALANCING INNOVATION AND THE PUBLIC'S HEALTH 130–133 (2014), https://books.google.com/books?id=TuC5BAAAQBAJ&pg=PA130&lpg=PA130&dq=allow+generics+into+market+sooner&source=bl&ots.

200 *See generally* Lee, *supra* note 198.

201 *See id.*; see *also* Gene Quinn, *Reality Check: Patents Foster Innovation and Economic Activity*, IPWATCHDOG (May 8, 2014), http://www.ipwatchdog.com/2014/05/08/reality-check-patents-foster-innovation-and-economic-activity/id=49452/ [hereinafter Quinn, *Reality Check*]; Quinn, *Fat cats*, *supra* note 188; Gene Quinn, *Celebrating Presidents Who Advocated for the U.S. Patent System*, IPWATCHDOG (Feb. 18, 2013), http://www.ipwatchdog.com/2013/02/18/celebrating-presidents-who-advocated-for-the-u-s-patent-system/id=34896/.

202 *See* Gene Quinn, *Fixing the patent system requires a return to strong patent rights*, IPWATCHDOG (Sept. 15, 2015), http://www.ipwatchdog.com/2015/09/15/fixing-the-patent-system-requires-a-return-to-strong-patent-rights/id=61684/ [hereinafter Quinn, *Fixing the patent system*].

externality will be solved by negotiations between the parties, resulting in the most efficient outcome to the externality.[203] The theorem only holds true when there are free market forces and conditions, and negotiation is possible.[204] However, as previously discussed, free market forces are prevented,[205] which results in an inefficient marketplace where people are less willing to trade, invest, and negotiate.[206] In addition, when patent protections are easy to overcome, there is no incentive to negotiate for the rights to a patent.[207] Therefore, businesses infringe patents, rather than negotiate with inventors and patent holders for the rights.[208]

As a result, innovation is disincentivized because there is no protection for those who invent.[209] When patent quality is poor, patents are less capable of being enforced and more likely to be successfully challenged.[210] Jay Walker, inventor and founder of Priceline.com, has stated that when one does not own the rights to the problems one solves, they will get copied.[211] He followed with, "[i]f [I] can't own the solution to the problem the last thing I want to do is invest in the solution."[212]

While the reason for creating IPR itself was to eliminate the bad patents in the market and strengthen the patent system, the overall IPR system is largely inefficient and a waste of government resources. [213] It would be much more efficient to increase the quality of patents that are granted by the USPTO. Instead of flooding the market with bad patents, increasing the quality initially would be a cheaper solution, compared to pouring more money into the operation of the PTAB and IPR trials to

---

203 *See* Robin Hahnel & Kristen A. Sheeran, *Misinterpreting the Coase Theorem*, 43 J. OF ECON. ISSUES 215, 218 (2009).

204 *See id.* at 218–219 (discussing the necessity of enabling market forces through the establishment of strong property rights); *see also Interview with Ronald Coase*, THE RONALD COASE INSTITUTE (Sept. 17, 1997) http://www.coase.org/coaseinterview.htm.

205 *See supra* notes 120–125 and accompanying text.

206 *See* Interview with Ronald Coase, THE RONALD COASE INSTITUTE (Sept. 17, 1997), http://www.coase.org/coaseinterview.htm.; *see also* Quinn, *Fixing the patent system*, *supra* note 202; *see also* Hahnel & Sheeran, *supra* note 203 at 218–219; Lee, *supra* note 198.

207 *See* Quinn, *Fixing the patent system*, *supra* note 202; *see also* Lee, *supra* note 198.

208 *See* Quinn, *Fixing the patent system*, *supra* note 202; *see also* Hahnel & Sheeran, *supra* note 203 at 218–219; *see also* Lee, *supra* note 198.

209 *See* Quinn, *Fixing the patent system, supra* note 202; *see also* Lee, *supra* note 198; *see also* Elfin, *supra* note 74 (stating that enforcement of a patent against an infringer has become increasingly difficult).

210 *See* Quinn, *Fixing the patent system, supra* note 202; *see also* Hahnel & Sheeran, *supra* note 203 at 218–219.

211 *See* Quinn, *Fixing the patent system*, *supra* note 201.

212 Quinn, *Fixing the patent system*, *supra* note 201.

213 *See* Aquino, *IPR Motive Irrelevant*, *supra* note 96 ("[T]he 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. The AIA was designed to encourage the filing of meritorious patentability challenges, by any person who is not the patent owner, in an effort to further improve patent quality.").

sift through the bad patents as challenges arise.[214] Additionally, this would increase faith in the patent system and create more incentives for inventors and corporations.[215] John M. Whealan, the associate dean for intellectual property law at George Washington University and counsel to the U.S. Senate Committee on the Judiciary, has stated that PTAB decisions would be held more valuable if patent quality were to increase.[216] "It makes little sense to issue a patent that will likely be invalidated in an IPR[,]"[217] Whealan said, adding that "[i]f the PTAB changes the way people pay attention to patent applications, everybody wins . . . ."[218]

Significantly, the patent system, with its combination of broad property rights over inventions and requirements for public disclosure, has been deemed to be extremely effective at stimulating and promoting technological growth.[219] Studies show that increases in the strength of patent protection correlate positively and significantly to expenditures on research and development, as well as an influx of high-tech products.[220] Even over the long term, patent protection systems as a whole are "*strongly correlated* with increased technology innovation, knowledge diffusion, and economic growth."[221] Patent systems are essential to providing incentives and ensuring access to capital.[222]

The reason strong patent systems lead to success is because they protect inventors' ability to profit.[223] One must spend money to create and invent, and, in order to profit, one must recoup that initial investment.[224] Without patent rights, others could copy an invention from the moment of its creation without spending the initial money on development, and therefore, they would be able to make a profit at a substantially lower price point.[225] Indeed, infringing companies could make a profit at such a low selling point that the original inventor would not be profitable because he would not be able to compete.[226] If inventors could not make money selling what they created while those

214 *See generally* Seuffert, *supra* note 185 (discussing the need to improve the quality of patents issued by the USPTO).
215 *See* Lee, *supra* note 198.
216 *See* Dutra, *supra* note 196.
217 *See id.*
218 *See id.*
219 David Kline, *Do Patents Truly Promote Innovation*?, IPWATCHDOG (April 15, 2014), http://www.ipwatchdog.com/2014/04/15/do-patents-truly-promote-innovation/id=48768/.
220 *Id.*
221 *Id.*; *see also* Lee, *supra* note 198.
222 *See* Gene Quinn, *Mark Cuban is an Idiot, Patents Do NOT Impede Innovation*, IPWATCHDOG (March 7, 2013), http://www.ipwatchdog.com/2013/03/07/mark-cuban-is-an-idiot-patents-do-not-impede-innovation/id=36851/ [hereinafter Quinn, *Mark Cuban*]; *see also* Lee, *supra* note 198.
223 *See generally* Seuffert, *supra* note 185.
224 *See id.*; *see also* Quinn, Mark Cuban, *supra* note 222.
225 *See* Quinn, Mark Cuban, *supra* note 222.
226 *See id.*

who copied their inventions could make money, no one would have the incentive to innovate or invest in research and development.[227] This is why great leaders, such as Abraham Lincoln, advocated for a strong patent system stating it "added the fuel of interest to the fire of genius."[228] Even George Washington urged Congress, in his first State of the Union Address, to pass a patent act as quickly as possible.[229]

While there has been an IPR abuse problem, the issue has caused misdirected blame, faulting the patent system itself. Former Chief Judge Rader of the U.S. Court of Appeals for the Federal Circuit explains that "[t]here is nothing wrong with the patent system."[230] The patent system has one objective, as defined by the Constitution, which is to "promote the progress of science."[231] The purpose of the patent system is to create opportunities for investment and incentives for innovation and invention.[232] "The things that the patent system is criticized for is not its job."[233] It is not the system, but the manner in which it has been manipulated that must be criticized and corrected.

Nevertheless, reform measures that seek to improve the quality of patents across the board are often overreaching, which leads to more harm than good.[234] Since the problem of "bad patents" lies with only a small group of patent holders, to wit, the pharmaceutical companies, it would be best if only those companies were held to a higher standard, and subjected to a more rigorous approval process for their patents. "The goal of any patent legislation should be to narrowly target abusive behavior without harming America's innovation economy."[235] Additionally, "PTAB decisions will be more valuable if they increase the quality of issued patents."[236]

Since IPR is a challenge on the basis of prior art or obviousness, the easiest way to increase the quality of patents and to hold the pharmaceutical industry to more rigorous standards would be to require the USPTO to conduct more extensive searches for prior art and obviousness during the patent prosecution process.[237] There have been many invalidations of patent claims due to the discovery of prior art and

227 *See id.*; *see also* Lee, *supra* note 198.
228 Quinn, *Mark Cuban*, *supra* note 222.
229 *See id.*
230 *Id.*
231 *Id.*; *see also* Lee, *supra* note 198.
232 *See* Lee, *supra* note 198.
233 Quinn, *Mark Cuban*, *supra* note 222.
234 *See* Doody, *supra* note 10, at 25 n.35.
235 Pomper, *Innovation Act*, *supra* note 135.
236 Dutra, *supra* note 196.
237 *See generally supra* notes 30–35 and accompanying text (discussing prior art and obviousness); *see generally* Seuffert, *supra* note 185 (discussing the need to improve the quality of patents issued by the USPTO).

obviousness during IPR, as discussed previously in this Note.[238] This indicates that a numerous amount of prior art was missed by the USPTO during patent prosecution and that many patent claims were erroneously deemed non-obvious.[239] Performing more thorough searches for prior art and furthering their investigations into the obviousness of claims will ensure that there is less of a chance the patent will be found invalid through an IPR. And thus, a higher quality patent will be issued.[240]

To achieve this system of higher quality patents, there will have to be an increase in well-educated, experienced patent examiners at the USPTO, and an increase in oversight.[241] Those who oversee the examiners could conduct quality checks of the examiners' work by performing a secondary search for prior art or supplementary investigations for obviousness on questionable applications.[242] This will ensure that prior art is not missed and that more time is spent on investigations for obviousness.[243]

In order to pay for the higher quality examinations, there should be a partial fee diversion ban that allows the USPTO to keep more of the fees it acquires. With this additional funding, the USPTO will be able to implement appropriate changes with ease and will be able to hire the additional personnel needed.[244] This partial fee diversion would garner more support than a full fee diversion because Congress would get the remainder of the fees to use as it sees fit.

If the USPTO did not grant so many bad patents to pharmaceutical companies, and instead began issuing higher quality patents, bad patents would eventually be reduced and hopefully eliminated completely. Without bad patents on the market, hedge funds would hesitate to target the pharmaceutical companies because the possibility that they would win an IPR challenge would be significantly diminished.[245] As a result, even if hedge funds occasionally file an IPR against a pharmaceutical company, the market will not react as volatilely because the market will know that the IPR challenge would be less likely to succeed based on the company's history of holding strong patents.

---

238 *See supra* notes 44–48 and accompanying text (discussing how the PTAB's overall claim cancellation rate was 80.9%).

239 *See generally* Seuffert, *supra* note 185.

240 This would also help to eliminate bad patents. *See generally id.*

241 *See generally id.*

242 *See* Seuffert, *supra* note 185, at 122–127.

243 *See id.*

244 *See generally id.*

245 *See generally* Seuffert, *supra* note 185, at 122 (discussing how increased patent quality would lead to less litigation over patent validity).

C. *Over-Priced Prescription Drugs, Generics, and Monopolistic Strategies*

There have been different solutions proposed for the problem of overpriced prescription drugs in America,[246] but the one that is most relevant to this discussion is the idea of allowing generic drug companies to enter the market place more quickly.[247] Kyle Bass has attempted to call attention to this issue by filing several IPRs in his own name against what he calls "zombie drugs," which he explains are pharmaceutical patents that do not expire, but live on endlessly, regardless of innovation, through extensions to the patents.[248]

One such "zombie drug" Mr. Bass seeks to invalidate, through an IPR, as being obvious is Propofol, an anesthetic produced by Fresenius Kabi USA LLC's ("Fresenius").[249] The Propofol patent extension covers the container the drug is stored in, which has a non-reactive or inert closure, such as siliconized butyl-rubber stoppers.[250] This is nothing more than a commonly used rubber stopper.[251] Additionally, it has long been known that siliconized stoppers have advantages over unsiliconized stoppers.[252] Bass argues that such a "minor and routine substitution" would be obvious "to a person having ordinary skill in the art[,]"[253] and Fresenius could have easily used such closures when they first began using the current containers.[254] Bass contends that the only thing standing between the high price for Propofol and the discounted generic price is a rubber stopper.[255]

When generic drug companies can enter the market sooner, there is increased competition in the market.[256] As a result of that increase in competition, the brand name companies will be forced to lower prices to competitive levels.[257] If a patent extension is found invalid, generic companies can then begin to produce the drug and this will lower the price of the prescription to average market levels. When Lipitor, a pill that treats high cholesterol, was faced with the threat of generic competition, the price per pill dropped ninety five percent, from $5.00

246 *See* Llamas, *supra* note 104 (discussing how preventing pay for delay tactics would also help solve some of the issues).
247 *See* BROUGHER, *supra* note 199.
248 In November 2015, Mr. Bass filed petitions against Fresenius Kabi USA LLC and Alpex Pharma. *See* Aquino, *Zombie Drug*, *supra* note 5.
249 *See id.* The other IPR filed is against Alpex Pharma for a patent of an orally disintegrating tablet with speckled appearance and is also being challenged as obvious, and thus, invalid. *See id.*
250 *See id.*
251 *See id.*
252 *See id.*
253 35 U.S.C. § 103 (2015).
254 *See* Aquino, *supra* note 5.
255 *See id.*
256 *See generally* Surowiecki, *supra* note 120.
257 *Id.*

to $0.31.[258] Sovaldi, a drug that cures hepatitis C if taken daily for twelve weeks, currently costs $1,000 a pill in the U.S.[259] A study by the University of Liverpool found that the pill could be manufactured for as little as $68 to $136 per pill.[260] In fact, Sovaldi is expected to go on sale in Europe at a price of $285 per pill, and a generic version of the pill is selling in India for just $10.[261] These examples illustrate that in order for generics to enter the market place sooner there must be regulatory change.

Related to the patent extension problem is a tactic called "product hopping". Product hopping, also known as a forced switch, occurs when a brand name pharmaceutical creates a small formulation change to an older product and rebrands it as a new product right before the patent expires and the generics are about to enter the market.[262] This tactic artificially inflates drug costs and delays generic drugs' entry to the market. For example, Allegran switched patients who were on their product Namenda, an Alzheimer's drug, to Namenda IR, the same drug branded as new because it contained a time-release formula.[263] This was a blatant move to maintain their monopoly and prevent generics from selling Namenda.[264] This tactic has become so prevalent that even the Federal Trade Commission (FTC) has become involved, publicly stating that through drug hopping, a pharmaceutical manufacturer's well-timed tweaks to their products can endlessly forestall generic competition at the expense of consumers.[265]

To facilitate the faster entry of generic products into the marketplace, there must be a nationwide ban on the types of patent extensions described above and especially on the product hopping tactic. By allowing the drug companies to extend patents when all they do is change the dosage, packaging, coloring, or add a time-release formula, the government is protecting the monopolistic power these companies have to the detriment of the people. Artificially extending the patents in such ways unfairly delays entry into the market for generic drug companies, and thus, sustains the ever-rising costs of pharmaceuticals.

An alternative that might enable generics to enter the market sooner would be to place a ban on pay-for-delay tactics.[266] These tactics

258 *See* Nordrum, *supra* note 107.
259 *See id.*
260 *See id.*
261 *See id.*
262 *See* Elfin, *supra* note 74.
263 *See id.*
264 *See id.* The U.S. Court of Appeals for the Second Circuit, upholding a district court injunction, found that the product hopping tactic of Allegran could violate antitrust laws, as the main reason for switching patients was to thwart generic competition. *See id.*
265 *See id.*
266 *See supra* notes 73–76 and accompanying text.

are just another way pharmaceutical corporations maintain their monopolies on the market place, by allowing them to continue to charge high, unjustified prices for their products and unfairly limit competition.[267] Consequently, conditions closer to that of a real market will be created, i.e. by increasing competition, and thus, helping to lower the price of pharmaceutical drugs to consumers.

CONCLUSION

While patent reform bills in the House of Representatives and Senate seek to fix and revamp a large portion of the patent system, they propose overly broad provisions that will harm innovation and the economy. However, hedge funds' abuses can be prevented with just a simple and acute policy change that will be easier to implement than a complete overhaul. That policy change can be achieved by placing a ban on pharmaceutical corporations' tactics involving patent extensions, product hopping, and pay-for-delay. Additionally, a partial fee diversion should be instituted so the USPTO can train and use more skilled patent examiners to perform more thorough searches on drug patents for prior art and obviousness, thus increasing the quality of drug patents that come out of the USPTO. This targeted policy will cost little to implement and will continue to incentivize pharmaceutical companies to innovate. With fewer bad patents, hedge funds like Hayman will stop abusing the system because their odds of winning an IPR challenge will be so low that they will not even attempt the challenge. This solution will also stabilize market reactions if an IPR is filed, because the market will have more faith in the strength of patents held by pharmaceutical companies and in the decisions of the PTAB. By facilitating an environment where generics can enter the market sooner, competition will increase and the prices for prescription drugs will decrease for everyone. As a result of the decrease in prescription drug prices, pharmaceutical corporations' stock prices will fall back in line with the market, and hedge funds will likely be further disincentivized to short pharmaceutical corporations' stocks because they will no longer be overvalued.

Kenneth J. Costa∗

---

267 *See* Greider, *supra* note 6.

∗ Acquisitions Editor, CARDOZO ARTS & ENT. L.J. Vol. 35, J.D. Candidate, Benjamin N. Cardozo School of Law (2017); B.A. Political Science, B.S. Biomedical Sciences, University of South Florida (2011). I would like to thank Professor Lisa Volpe for her input and the legal writing skills she helped to foster during his first year of law school. Special thanks to Dr. Susan MacManus whose tutelage in politics and law sparked the interests and motivations which lead down this most exciting career path. Thanks to the Vol. 34 Editorial Board members Michael Weiss, James Gaskill, Kenneth W. Eng, Tatsuya Adachi, and Katherine M. Dineen. And thanks to the best colleagues one could ask for and the Vol. 35 Editorial Board members Elina Rakhlin, Justine Amy Park, Katie Thalen, and Kerrijane John.