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

INTRODUCTION

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

off a radio broadcast segment highlighting a hedge fund manager who made

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

Inter Partes Review (

has granted a patent.[4] This third-party method of challenging a patent became effective September 16, 2012, one year after the America Invents Act statute was passed by Congress.[5]
hedge fund managers to file an IPR petition and in turn receive financial gain,[6] this is exactly what is occurring.

Hedge funds managers now use the IPR process as a tool in their investment portfolio.[7] They will short stock the company whose patent is being challenged and simultaneously invest in a company that will benefit if the patent is declared invalid.[8] Specifically, pharmaceutical (pharma) and biotechnology (biotech) industries are targeted by hedge fund managers because posing a challenge to one or more drug patent claims through the

adversely affects its stock.[9] The tfolio:tt srttBT1 0 0oETb2(nd si)-s5(hosef)-3(6(f)-3(u)11(r)-3(t)-4(sbr)-3(]

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

PART I: HISTORICAL BACKGROUND ON PATENTS AND THE IPR PROCESS

discoveries.[12] The Constitution explicitly grants Congress the right to ring for limited times to . . . inventors the exclusive right to their respective . . . [13] Patent owners may enjoy the protection of their intellectual

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

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

To best understand the changes associated with patent reform through the AIA, it is essential to understand the historical context surrounding the Act. n age when thousands of overly broad software

the subject matter and a lack of existing software patents (also known as prior art) to compare the pending patent applications.[22] Specifically, these unwarranted patents were notoriously granted to software products that lacked novelty.[23]

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

For example, in May of 2001, Ultramercial Inc. filed a patent for a method of viewing free copyrighted media over the Internet in exchange for watching an advertisement.[25] On September 9, 2009, Ultramercial sued

be uploaded.[26] Although Ultramercial argued that their patent claims were

[27] The lower court held that the patent was invalid.[28] In reaching its decision, the court agreed

[29]

Additionally, the court agreed

[30]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition to filing the petitions, Bass has simultaneously bet against [68]

those involved with the development of IPR.[69] Jim Greenwood, the President and CEO of Biotechnology I

-selling [70]

lains that a short

delivery of a borrowed security.[71] Essentially, short sellers aim to profit from [72]

This investment strategy has been profitable for Bass, as the very news that

tumbling.[73]

64. *Id.*

65.

medicines that . . . should be available in generic form . . . [83] Although has purported that IPRs resulting in his favor valuable purpose of reducing drug prices artificially priced above the socially [84] [85] According to the Coalition priced products serve a socially redeeming value.[86]

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

Industry trade groups such as PhRMA and Bio are not persuaded by

PART III. REASONABLE SOLUTIONS

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

A. The Right to Amend Claims During an IPR Proceeding

Patent owners may submit a motion to amend challenged patent claims in lieu of filing a preliminary response to an IPR petition.[100] Claim amendment allows patent owners to narrow the scope of their claims in order to avoid prior art infringement.[101] They may also present evidence before the PTAB that demonstrates patentability of the proposed amended claims.[102] If

and the IPR proceeding will come to a halt.[103]

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

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

98. *See supra* Section II.

99. *See supra* Section II.

100.0 [illegible]

enacted.[110] Desp

claims using this proceeding, the application must be filed within two years [125]

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

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

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

1. Evidentiary Standard

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

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

125. 35 U.S.C. § 251 (d) (2012).

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

127. *Id.*

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

129. 35 U.S.C. § 316 (e) (2012).

130. Laird, *supra* note 126.

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

132. *Id.* at 95.

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

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

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

For patents challenged during an IPR proceeding, however, the PTAB of

[146]

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

to uphold the broadest reasonable interpretation standard and petitioned for writ of certiorari,[157] which was granted.[158] In part, Cuozzo challenged whether the statute that governs inter partes review authorizes the Patent Office to mandate the construal of patent claims using the broadest reasonable interpretation.[159] In its reasoning, Cuozzo proclaimed that the

[164] Because the

of the district court, it does not logically follow that the PTAB standard should be more relaxed.

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

The submission of declarations with an IPR petition is a tactic that favors the petitioner.[165] The petitioner can spend several months preparing declarations to submit simultaneously with their petition. However, if a patent owner wishes to submit a preliminary response, they must do so within

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

D. Standing Requirement

A standing requirement will help combat non-practicing entities

which is something that the AIA intended.[174] NPEs do not engage in the related business of the patent, yet acquire patent ownership.[175] These entities then use their ownership rights, not to further innovation or product manufacture, but to accuse other entities of infringement and to collect damages accordingly.[176] Today there exists a phenomenon known as

[177]

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

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

173. *Id.*

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

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

176. *Id.*

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

178. 37 CFR 42.100 (a), (c) (2015), Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,766 (Apr. 1, 2016) (to be codified at 37 C.F.R. § 42.100(b)); 37 CFR 42.200 (a), (c), (d) (2015), Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Boad A-3(a)-6(l)21 0 0 1Tm[(-)] TJETBT1o(e)7(d)7( )-

[182] This, in companies and their shareholders.[183]

Amending section 311 of the AIA, which pertains to IPR, will effectively ensure that patent invalidity challenges are meritorious. The STRONG Patents Act of 2015 was introduced to the Senate on March 3, 2015 in efforts

innovator by amending title 35 United States Code, to protect the property [184] This Act proposes two additional sections that define a standing requirement for