

A Prescription for Biopharmaceutical Patents: A Cure for *Inter Partes* Review Ailments

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INTRODUCTION

In Delhi, under British rule, the government provided a bounty on dead cobras in an attempt to reduce the population of the deadly snake. Eventually, some people employing the motto of “work smarter, not harder,” began breeding cobras for the bounty, leading to an increase in the cobra population when the cobras inevitably escaped. History is replete with examples of these well-intentioned laws that either exacerbated the existing problem or created even larger auxiliary issues. Such instances have become known as “the cobra effect”;¹ other examples come from the French “rat-tail” bounty of Hanoi² and essentially every animal importation decision that concerned the colonization of Australia.³ To this infamous list can be added the *inter partes* review proceeding recently developed in the American patent system: by trying to limit the amount of meritless patent infringement suits, the system has increased the number of meritless administrative *inter partes* review challenges to patents.

The patent system in the United States was forever changed with the introduction of the Leahy-Smith America Invents Act (AIA) in September of 2011. The AIA brought sweeping changes to American patent law in

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1. See generally HORST SIEBERT, DER KOBRA-EFFEKT (2002).

2. See Michael G. Vann, *Of Rats, Rice, and Race: The Great Hanoi Rat Massacre, an Episode in French Colonial History*, in 4 FRENCH COLONIAL HISTORY 191, 191–93 (2003). A law in French-ruled Hanoi aimed to decrease the rampant rat population. In order to collect the bounty, one needed to provide the government with a rat tail as proof. Unfortunately, humans rarely do more than the bare minimum, and eventually many tailless rats were roaming the streets, doing little to stem the population. *Id.*

3. See generally *Feral Animals in Australia*, AUSTL. GOV'T DEP'T ENV'T & ENERGY, <http://www.environment.gov.au/biodiversity/invasive-species/feral-animals-australia> [https://perma.cc/L9VU-WQNJ]. Especially prominent was the introduction of the cane toad, which was initially introduced to combat beetles but has caused millions of dollars' worth of damage to the Australian ecosystem. *Id.*

order to align the U.S. with much of the rest of the world by changing the invention priority from a “first to invent” to a “first to file” system. Among the many other changes included in the AIA, two of particular import to this Note are the *inter partes* review and the transitory covered business method patent review.

Understanding this Note will necessitate having knowledge of multiple patent review procedures, which I postulate can be combined to create a workable solution for the current issues that have arisen with *inter partes* reviews. Therefore, in the first section I will provide a brief overview of the substance of *inter partes* reviews and some of the most critical negatives that have become apparent since 2013. I will also give a brief look at the similarities and key differences between *inter partes* reviews and the covered business method patent reviews, and the advantages they give to certain classes of patents. The section will conclude by looking at the European equivalent procedure of *inter partes* reviews, known as oppositions.

The second section of this Note will highlight the imperfections and abuses that have become apparent with the *inter partes* review process, especially in how the biotechnology and biopharmaceutical industries⁴ have been negatively impacted or threatened. Next, I will give reasons why the biotechnology and biopharmaceutical industries need to have further protections from *inter partes* review abuses to continue providing technologies that help make the world a better place.

This Note will then conclude with proposed amendments to the *inter partes* review procedure, combining elements of covered business method reviews and oppositions that could be used to ease the burden on the biotech industry, to provide a better system for ensuring that developers of drugs can spend more time in the laboratory and less time in the court room. This system should help correctly incentivize companies to continue spending the incredible amount of capital required to bring a drug to market with proper patent protections intact, but it would further the goal of *inter partes* reviews in providing an efficient way of invalidating meritless patents.

I. POST-ISSUANCE CHALLENGES TO PATENTS

The original intent in creating post-issuance reviews in the AIA⁵ was to reduce the cost and timeline of litigating challenges to patents in the

4. Throughout this Note, for ease of reading and because there is a significant amount of overlap between the industries, I will be using the term “biotech” to cover the biotechnology, biopharmaceutical, and pharmaceutical industries.

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

courtroom.⁶ While still a lengthy and costly process, *inter partes* reviews do fulfill that purpose by drastically reducing the timeline of the proceedings. Another intention was to decrease the amount of frivolous lawsuits brought by “patent trolls.”⁷ Patent trolls are hard to uniformly define, but are largely viewed as non-practicing entities (NPE), or patent-asserting entities,⁸ that purchase patents—not to profit from making a product—but as a business strategy to then sue manufacturers for infringing on those patents.⁹

In order to develop a better system for efficiently challenging any administrative post-issuance challenge, it is necessary to have a better understanding of the way things currently stand. While there are many procedures that may be performed to challenge a patent after it has been issued, the three at issue for this Note are (1) *Inter Partes* Review (IPR),¹⁰ (2) the related Covered Business Method (CBM) patent reviews,¹¹ and (3) oppositions.¹² The first two come from the AIA, whereas oppositions have been in effect with the European Patent Office long before the AIA took effect. Of the other two post-grant proceedings under the AIA, post-grant reviews are seldom utilized due to time constraints,¹³ and *ex parte* reexaminations are almost exclusively used by the patentee, or patent holder, to either broaden or limit the scope of the patent.¹⁴

A. *Inter Partes* Reviews

IPRs and CBMs are relatively recent proceedings, having been introduced in the AIA in 2011 and going into effect in 2013 with the intent of providing a quick, cost-effective way to invalidate meritless patents.

6. See generally *id.*

7. 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/> [https://perma.cc/2C9C-7E3X].

8. Although NPEs often get a negative reputation, there are many nonmalicious reasons to assert a patent that a party does not own. For example, if a party gains a patent through a bankruptcy and has neither the expertise nor the resources to practice the technology, it is often forced to pursue actions in order to keep from being estopped from asserting the rights later.

9. Gene Quinn, *In Search of a Definition of the Term “Patent Troll,”* IPWATCHDOG (July 18, 2010), <http://www.ipwatchdog.com/2010/07/18/definition-patent-troll/id=11700/> [https://perma.cc/2BCB-HX4Q].

10. 35 U.S.C. § 311 (2012 & Supp. I 2013).

11. 37 C.F.R. § 42.300 (2018).

12. Convention on the Grant of European Patents art. 99, Oct. 5 1973, 1065 U.N.T.S. 199 (as amended Nov. 29, 2000).

13. PGRs must be filed within nine months of a patent being granted. 35 U.S.C. § 321(b) (2012). Although this is the same time frame as oppositions, unsuccessful PGR proceedings carry wide estoppel provisions and are therefore risky to bring without extensive review of the prior art.

14. Scott McKeown, *Is There Value to Ex Parte Patent Reexamination After the AIA?*, PATENTS POST GRANT (Feb. 14, 2013), <http://www.patentspostgrant.com/is-there-value-in-ex-parte-patent-reexamination-after-the-aia> [https://perma.cc/NQ9R-TXA9].

Recently, IPRs, and to a lesser extent post-grant reviews,¹⁵ have come under intense scrutiny because of their ability to invalidate patents without requiring a full trial or patent examiner review.¹⁶ Instead, these reviews are judged by a panel of three members from the Patent Trial and Appeals Board (PTAB).¹⁷ To understand the controversy surrounding these procedures, there must first be an understanding of how such procedures operate and what advantages and disadvantages are faced by patentees and third parties.

Because it was introduced with the AIA, IPRs may only be initiated on patents that have effective filing dates on or after March 16, 2013.¹⁸ IPRs may be instituted by *any* third party looking to invalidate any number of claims disclosed in the patent and may be filed any time between nine months after the patent has been issued and its expiration.¹⁹ The subject matter that may be challenged with an IPR is limited in scope, and only issues concerning novelty²⁰ and obviousness²¹ may be considered.²² The evidence used to challenge a claim with an IPR is also limited, with only earlier patents and publications allowed; the on-sale bar²³ and patentability²⁴ issues are not applicable in IPR hearings. Because IPRs are an expedited proceeding, the process may only take up to eighteen months to proceed.²⁵ Once a petition for an IPR has been filed, the patentee may file a response as to why the petition should be denied.²⁶ Additionally, the patentee also has the one-time opportunity to amend or remove the challenged claims, or substitute new claims to replace the challenged claims.²⁷

Once an IPR has been requested, the United States Patent and Trademark Office (USPTO) must grant such request if it is “more likely than not that a claim is unpatentable or if the IPR raises any novel legal questions.”²⁸ The proceeding goes before the PTAB and runs much like

15. 35 U.S.C. § 321 (2012).

16. Matt Levy, *Three Crucial Words in Patent Reform: Inter Partes Review*, PAT. PROGRESS, <http://www.patentprogress.org/2015/05/14/three-crucial-words-in-patent-reform-inter-partes-review-part-1/> [https://perma.cc/W4UJ-EBSN].

17. *Id.*

18. MARTIN J. ADELMAN ET AL., *PATENT LAW* 627 (4th ed. 2015).

19. *Id.*

20. 35 U.S.C. § 102 (2012 & Supp. IV 2016).

21. 35 U.S.C. § 103 (2012).

22. *Id.* § 311(b).

23. Essentially, if a patented object has been sold for more than a year before the filing of a patent, it may not be patented. *See* 35 U.S.C. § 102(a)(1) (2012 & Supp. IV 2016).

24. 35 U.S.C. § 101 (2012).

25. *Id.*

26. ADELMAN ET AL., *supra* note 18, at 628.

27. *Id.*

28. *Id.*

any other litigation with motions, discovery, and eventually a “trial.”²⁹ At the end of such trial, the PTAB either certifies that the claims, original or amended, are valid or invalidates the challenged claims.³⁰ Any decisions by the PTAB are appealable to the district court, assuming the party has standing.³¹

There are risks to a challenger in petitioning for IPRs if the claim is eventually found to be valid, however. If the PTAB declares claims to be valid, the petitioner and its privies forever lose the ability to not only raise the same issues again but also the ability to raise any issues that “reasonably could be raised.”³² While this is a great boon to patentees, much controversy exists over the procedural differences between arguing the validity of a patent in front of the PTAB and the more traditional route of defending patents in federal court,³³ with the greatest of these controversies being centered on the standard of proof for invalidity.³⁴

B. *Covered Business Method Patent Review*

The transitory program for covered business method patent reviews is a special type of subset of post-grant reviews that covers, not surprisingly, business method patents. As the name implies, the process is not intended to be in effect permanently and will sunset in 2020.³⁵ Business method patent reviews are a special proceeding carved out in response to perceived abuses of business method patents.³⁶ In particular, the federal circuit has limited covered business method patents to “a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions.”³⁷ Whether a patent is for

29. *Id.*

30. *Id.*

31. Levy, *supra* note 16.

32. 35 U.S.C. § 315(e)(1)–(2) (2012).

33. *A Closer Look at the PTAB’s New Post-Issuance Review Procedures*, INTELL. ASSET MGMT., Mar.–Apr. 2016, at 44, <https://www.finnegan.com/images/content/9/1/v3/910/ACloserLookatthePTABsNewPostIssuanceReviewProcedures.pdf> [<https://perma.cc/TG9C-9CRA>].

34. In IPRs, invalidity need only be shown by a preponderance of evidence. 35 U.S.C. § 316(e) (2012). At trial, invalidity must be shown by clear and convincing evidence. *Microsoft v. i4i Ltd. P’ship*, 564 U.S. 91 (2011).

35. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18(a)(3)(A), 125 Stat. 284, 330 (2011).

36. Joshua Zarabi, *Covered Business Method—Is There a Limit to What Is “Covered”?*, CARTER DELUCA FARRELL & SCHMIDT LLP (Oct. 23, 2015), <http://www.cdfslaw.com/publications/covered-business-method-limit-covered-2/> [<https://perma.cc/KB6H-DR5P>].

37. Leahy-Smith America Invents Act § 18(d)(1), 125 Stat. 284, 329; *see also* *Versata Dev. Grp. v. SAP Am., Inc.*, 793 F.3d 1306, 1326 (Fed. Cir. 2015) (noting that a technological patent is one in

a technological invention or a business method is determined on a case-by-case basis.³⁸

CBMs have slightly different qualifications than IPRs for who may bring an action and what may be used to attempt to invalidate a claim. In order to initiate a CBM proceeding, a plaintiff must be someone who has been either sued or charged with infringement of a CBM patent.³⁹ Compare this to IPRs, where any third party can initiate a proceeding. The prior art that is allowed to challenge a CBM is also slightly narrower than IPRs, limiting any § 102 art to § 102(a).⁴⁰ Challenges may still be maintained using patents or printed publications or § 101.⁴¹

The trade-off for having a more stringent standing requirement compared to IPRs is the lesser extent that a petitioner is estopped after an unsuccessful CBM proceeding. Parties who unsuccessfully challenge a business method are only estopped from raising the same issue in the future but are free to challenge based on different issues in a future proceeding.⁴²

C. Oppositions

Oppositions are procedures in the European Patent Office (EPO) that are very similar to *inter partes* reviews. The two main procedural differences are in the timeline the procedure is available and in the party allowed to initiate the opposition. The window to initiate an opposition is a scant nine months after a patent has issued, similar to post-grant reviews,⁴³ but far narrower than the years available for IPRs.⁴⁴

The other key difference is who may initiate an opposition. Unlike the United States, a party may remain anonymous in bringing an opposition in the European Union.⁴⁵ Comparatively, an initiation of an IPR must state the real parties in interest.⁴⁶

which “the claimed subject matter as a whole recites a technological feature that is novel and unobvious over the prior art; and solves a technical problem using a technical solution”).

38. 37 C.F.R. § 42.301(b) (2018).

39. Leahy-Smith America Invents Act § 18(a)(1)(B).

40. *Id.* § 18(a)(1)(C)(ii).

41. *Id.* § 18(a)(1)(C).

42. *Id.* § 18(a)(1)(D).

43. 35 U.S.C. § 321 (2012).

44. Michael J. Flibbert et al., *Coordinating European and U.S. Post-Grant Patent Opposition*, FINNEGAN (Nov. 4, 2014), <https://www.finnegan.com/en/insights/coordinating-european-and-u-s-post-grant-patent-opposition.html> [<https://perma.cc/4B6E-4T29>].

45. *Id.*

46. *Id.*

II. WHY BIOTECHNOLOGY PATENTS ARE VULNERABLE TO CHALLENGE UNDER *INTER PARTES* REVIEW

Recently, pharmaceutical companies have been facing a large number of difficulties, even beyond problems from IPRs. The ongoing pharmaceutical “patent cliff”⁴⁷ is estimated to cost the industry over \$200 billion worth of patent expiration.⁴⁸ Recent controversies have arisen from the pricing of medical devices and drugs.⁴⁹ Disputes involving health care and the coverage of very expensive drugs have made headlines.⁵⁰ In short, public perception of pharmaceutical companies has seldom—if ever—been lower than it is today. And yet, the public needs biotech companies to continue to cure diseases and solve the world’s problems, and the outstanding cost of discovering drugs must be covered by a relatively high price of such drugs.

The greatest enemy facing biotechnology companies, however, is the IPR. Biotech companies are acutely vulnerable to patent challenges, and *inter partes* review in particular, because (1) biotech patents have limited ways of extracting value from innovations without patent protection; (2) massive regulatory oversight in biotech products slows innovation; (3) fewer patents in biotechnology expose companies to substantial risk if one of them is blocked; and (4) the expense and risk of developing patentable pharmaceutical products is substantial. This vulnerability comes at a great risk: the public relies on lifesaving developments from the biotechnology industry.

A. *Biotech Patents Are Limited in Ways to Make a Profit*

Biotech patents can be readily differentiated from many other types of high-tech products like computer software, robotics, and computer technologies in a few key ways. Unlike software and many electronic

47. “A ‘patent cliff’ occurs when a relatively large number of blockbuster prescription drugs lose their patent protection within the same year.” 2016: *A ‘Mini-Cliff’ for Drug Patents*, UNITEDHEALTHCARE (June 9, 2016), <https://consultant.uhc.com/articleView-16864> [<https://perma.cc/7RNW-UABB>].

48. Angela Sands, *Top 10 Patent Losses to Watch out for*, TOTAL BIOPHARMA, <http://www.totalbiopharma.com/2014/06/06/top-10-patent-losses-watch/> [<https://perma.cc/R3AW-4Q5V>].

49. See, e.g., Christie Smythe & Keri Geiger, *Shkreli, Drug Price Gouger, Denies Fraud and Posts Bail*, BLOOMBERG (Dec. 17, 2015), <http://www.bloomberg.com/features/2015-martin-shkreli-securities-fraud/> [<https://perma.cc/Y4M4-QTNZ>] (detailing the public outcry concerning the CEO who raised the price of an AIDS drug over 5,000%); Brad Tuttle, *Why the EpiPen Price Scandal Sums up Everything We Hate About Big Business & Politics*, TIME: MONEY (Sept. 21, 2016), <http://time.com/money/4502891/epipen-pricing-scandal-big-pharma-politics/> [<https://perma.cc/A25V-UN9F>] (describing the outrage involved in the sudden increase in the EpiPen price).

50. See Jake Harper, *States Deny Pricey Hepatitis C Drugs to Most Medicaid Patients*, NPR (Dec. 27, 2015), <http://www.npr.org/sections/health-shots/2015/12/27/460086615/states-deny-pricey-hepatitis-c-drugs-to-most-medicaid-patients>.

patents, there are few ways for a pharmaceutical company to recoup the capital spent in developing a product without the monopoly protection of a patent.⁵¹ Many drugs are relatively easy to reverse engineer,⁵² so there is little possibility of keeping them protected by trade secrets. In addition, since few people ever become truly brand loyal to drug companies when it affects their wallets, being first to market provides little advantage against generics and biosimilars.⁵³

B. *Government Oversight Stifles Biotech Innovation*

Biotech patents also differ from other high-tech patents in the sheer amount of governmental regulation involved. For example, in order to introduce a drug to market, a drug must pass through a lengthy three-step process of clinical trials with the FDA. After years spent developing a promising candidate, the clinical trials take, on average, eight to twelve years.⁵⁴ There is little that can be done to shortcut this process without sacrificing patient safety. The public good is served best when the drugs that are sold have been found to be safe or at least acceptably dangerous compared to the alternative of withholding treatment. However, this means that there should be a presumption of usefulness and necessity for any drug that eventually gets to market; no rational developer would risk the time and money on a product that has no value to the public.

C. *The Small Number of Biotech Patents Exposes Companies to Risk If Patents Are Challenged*

Another reason biotech companies are particularly susceptible to patent challenges is the relatively small number of patents a single company will rely on. Unlike software or hardware companies, most innovative biotech companies operate with a very small patent portfolio.⁵⁵ While the large companies still carry a significant portfolio, the identity of

51. See generally Himanshu Gupta et al., *Patent Protection Strategies*, J. PHARMACY & BIOALLIED SCI., Jan.–Mar. 2012, at 2.

52. See Esteban Burrone, *Patents at the Core: The Biotech Business*, WORLD INTELL. PROP. ORG. (2006), http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html#P25_4185 [<https://perma.cc/KJ6L-P8ZC>].

53. Denise Myshko, *The Rise of Biosimilars*, PHARMAVOICE (Sept. 2014), <http://www.pharmavoices.com/article/biosimilars/> [<https://perma.cc/28JF-7V9Z>].

54. See generally Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BOARD FAM. PRAC. 362 (2001).

55. *The Impact of Abusive Patent Litigation Practices on the American Economy: Hearing Before the S. Comm. on Judiciary*, 114th Cong. 1–2 (2015) [hereinafter Sauer Testimony] (testimony of Hans Sauer, Ph.D., Deputy Gen. Counsel for Intellectual Property, Biotechnology Industry Association), <https://www.judiciary.senate.gov/meetings/the-impact-of-abusive-patent-litigation-practices-on-the-american-economy>.

who is actually innovating and discovering new drugs has changed significantly in the past few years.⁵⁶

A significant change in the biotech and pharmaceutical world is who is coming up with new drugs and how those drugs are being marketed. Recently, there has been drastically less innovation from large companies, such as Roche and Pfizer, and much more innovation from small biotech startups.⁵⁷ In 2015, over sixty percent of new approved drugs came from small biotech firms.⁵⁸

Part of the reason less innovation is coming from large corporations is the amount of overhead involved in running bulky, bureaucratic entities.⁵⁹ Small companies have the luxury of devoting their complete time and attention to developing useful products, while large companies must deal with management, overhead, and feuding departments.⁶⁰ One study found that in larger corporations, most research and development (R&D) employees will put personal and departmental priorities over team and innovation goals.⁶¹ This amount of bureaucratic headache leads to the formation of many small biotech companies as top scientists leave management to return to the laboratory.

While smaller companies can allow innovative scientists more freedom to concentrate on developing drugs, they are also highly susceptible to any threats to their patents and income streams. These companies have no “blockbuster drugs”⁶² to carry them financially while fighting any patent challenges, and they often rely solely on investment from venture capitalists.⁶³ Challenges to such patents can lead to the death of a company because the cost to defend against such claims can total upwards of \$1 million.⁶⁴ The lifecycle and goal of small companies is to innovate, patent, and either make all of their money through licensing their

56. Jennifer Alsever, *Big Pharma Innovation in Small Places*, FORTUNE (May 13, 2016), <http://fortune.com/2016/05/13/big-pharma-biotech-startups/> [https://perma.cc/KF8U-9FMS].

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. Peter Tollman et al., *Can R&D Be Fixed?: Lessons from Biopharma Outliers*, BOS. CONSULTING GROUP (Sept. 6, 2011), <https://www.bcg.com/publications/2011/biopharmaceuticals-innovation-can-r-and-d-be-fixed.aspx> [https://perma.cc/HZ52-VFHD].

62. Defined as a drug “where annual global turnover for that medicine exceeds US\$ 1 billion.” *Preliminary Report of the Directorate-General for Competition on the Pharmaceutical Sector Inquiry*, at 7 (Nov. 28, 2008), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf [https://perma.cc/E6FK-VVW2].

63. Alsever, *supra* note 56.

64. Gene Quinn, *BIO, PhRMA Lobby for IPR Fix to Insulate Their Patents from Challenge*, IPWATCHDOG (July 26, 2015), <http://www.ipwatchdog.com/2015/07/26/bio-pharma-lobby-for-ipr-fix/id=59965/> [https://perma.cc/8FSL-YVLQ].

technology⁶⁵ or being swallowed up by larger companies with the manufacturing capability to capitalize the technology.⁶⁶

D. Expense in Researching and Developing a New Drug

A fourth reason biotech products are so sensitive to patent challenges is the expense and risk involved in developing a new drug. The average cost of developing a new drug and getting it to market is a staggering \$2 billion.⁶⁷ The problem is apparent from an earlier report showing a funding gap of over \$1 billion in the European market.⁶⁸ Coupled with the expense, developing a new drug is an incredibly risky financial undertaking. The percentage of drugs that make it to clinical trials is only about 30%, and only 0.02% of all drugs developed ever make it to market.⁶⁹ Because it takes over a decade to begin to recoup such costs, biotech companies must rely heavily on patent certainty in the future.⁷⁰ With less certainty of a return on investment comes a far more difficult time enticing venture capitalists to finance a new business.⁷¹

E. Biotech Companies Provide a Valuable Service to the Public

Beyond the mere financial benefit for biotech companies,⁷² the global public is profoundly dependent on biotech products. The world's population is expanding, and new advances in genetically modified (GM) food will allow for more food growth using fewer resources.⁷³ Humanity is experiencing the longest life expectancy in history, and it depends on new drugs to cure a variety of maladies from diabetes to arthritis to cancer.⁷⁴ While weaker patent protection may seem beneficial because it

65. Burrone, *supra* note 52.

66. This is evidenced by the massive surge in mergers and acquisitions (M&A) activity within the biotech industry in the last few years. In 2015 alone, over \$300 billion worth of M&A activity was carried out in the pharmaceutical sector. See *An All-Time Record Year for Pharma/Biotech M&A in 2015*, THEPHARMALETTER (July 1, 2016), <https://www.thepharmaletter.com/article/an-all-time-record-year-for-pharma-biotech-m-a> [<https://perma.cc/NAU6-8PU8>].

67. Sauer Testimony, *supra* note 55, at 4.

68. Burrone, *supra* note 52.

69. *Id.*

70. *Id.*

71. *Id.*

72. Obviously, it is also good for the economy to have profitable companies who are able to hire more employees. It is estimated that biotech companies spend over \$20 billion on research alone, not to mention the jobs created in manufacturing, distribution, etc. See *id.*

73. See generally NUFFIELD COUNCIL ON BIOETHICS, THE USE OF GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES (2003), <http://nuffieldbioethics.org/wp-content/uploads/GM-Crops-Discussion-Paper-2003.pdf> [<https://perma.cc/UVD4-54VS>] (highlighting the benefits of GM crops in growing more crops in harsher environments and using GM crops to alleviate nutritional deficiencies in developing countries).

74. Max Roser, *Life Expectancy*, OUR WORLD DATA, <https://ourworldindata.org/lifeexpectancy/> [<https://perma.cc/GY3F-WQPY>].

creates lower prices in the short-term, fewer venture capitalists would be willing to invest in innovative companies without the ability to recoup R&D expenses.

III. IPRs SUBSTANTIALLY HARM BIOTECHNOLOGY INNOVATION AND GROWTH

Inter partes and post-grant reviews were created for a worthy purpose: to decrease the cost and time involved in litigating against baseless patent trolls. Specifically, legislative history indicates that the intent was to prevent these baseless cases primarily in the technology sector.⁷⁵ Whatever the original intent, it seems that the greatest harm from IPRs is being felt in the biopharmaceutical industry.

The extent of IPR abuse has become so prevalent it was covered in the *Wall Street Journal*⁷⁶ and is largely attributable to one company in particular.⁷⁷ The technique of shorting a company's stock and then filing an IPR is completely legal and available because of the lack of a standing requirement for an IPR; "a person who is not the owner of a patent may file with the Office a petition to institute an *inter partes* review of the patent."⁷⁸ In addition, the requirement to get an IPR instituted is a very low bar: a petitioner need only demonstrate a "reasonable likelihood" that it will prevail in showing at least one challenged claim to be unpatentable.⁷⁹ This has been construed to be low enough that the likelihood could be even *less* than a 50% chance of a claim being unpatentable.⁸⁰

Even without an IPR invalidating a patent, the mere filing of an IPR has been shown to have dramatic consequences. For example, when the Coalition for Affordable Drugs (CFAD) first *filed* an IPR against Acorda Therapeutics looking to invalidate its patent on Ampyra, a drug that

75. 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/> [<https://perma.cc/XC9A-5D9M>].

76. Joseph Walker & Rob Copeland, *New Hedge Fund Strategy: Dispute the Patent, Short the Stock*, WALL ST. J. (Apr. 7, 2015, 7:24 PM), <https://www.wsj.com/articles/hedge-fund-manager-kyle-bass-challenges-jazz-pharmaceuticals-patent-1428417408>.

77. Much of the abuse of IPRs has been brought to light by the actions of one company, the Coalition for Affordable Drugs (CFAD). While the company's stated goal is to decrease drug prices and increase the availability of generics, its strategy has been to short a company's stock, file an IPR against that company's best-selling product, and reel in the profits. See Quinn, *supra* note 75; Kyle Bass: *The U.S. Still has a Drug Problem*, VALUEWALK (Nov. 9, 2016, 9:57 AM), <http://www.valuewalk.com/2016/11/kyle-bass-iprs-the-u-s-still-has-a-drug-problem/> [<https://perma.cc/CJ9Q-MRGT>].

78. 35 U.S.C. § 311(a) (2012 & Supp. I 2013).

79. 35 U.S.C. § 314(a) (2012).

80. Scott E. Kamholz, *The Death Valley for Petitioners in IPR*, PTAB BLOG (Oct. 26, 2015), <http://www.ptab-blog.com/2015/10/26/the-death-valley-for-petitioners-in-ipr/> [<https://perma.cc/X2PG-X7UD>].

allowed multiple sclerosis patients greater mobility, the company's stock prices dropped 9.7%.⁸¹ When the IPR was later instituted, the stock dropped an additional 7.8%.⁸² This stock drop was not due to a final decision or invalidation of a claim but simply from the PTAB *instituting* the hearing and looking into the allegations. Although no claims were invalidated, Acorda's investors lost over \$150 million in response to the IPR.⁸³

IV. A NOVEL APPROACH TO "FIXING" THE *INTER PARTES* REVIEW PROCEEDINGS IN BIOTECHNOLOGY PATENTS BY A HYBRIDIZATION OF COVERED BUSINESS METHOD REVIEWS, OPPOSITIONS, AND COMMON SENSE

Inter partes reviews were surely not meant to be abused for financial gain and were not designed to help invalidate otherwise valid patent claims. Unfortunately, this has been the result, and while there is consensus that the system is broken, there seems to be little consensus on how to fix it. A recent proposal raised in the House Judiciary Committee was designed to shield pharma patents from IPR review; however, it never made it out of committee.⁸⁴ Other attempts have been made to contest the constitutionality of post-issuance reviews, though they too have been largely unsuccessful.⁸⁵ Although the Supreme Court has been deliberating the constitutionality of IPRs in the *Oil States* case, the consensus among patent professionals is that the Court will likely uphold IPRs as constitutional.⁸⁶ Other legislative attempts have focused on amending

81. Michael Loney, *Kyle Bass IPRs End up with 57% Institution Success Rate*, MANAGING INTELL. PROP. (June 13, 2016), <http://www.managingip.com/Article/3561885/Kyle-BassIPRsendupwith57institutionsuccessrate.html>.

82. *Id.*

83. Jim Greenwood & John Castellani, *Congress Must Keep Trolls Away from Medical Patents*, THE HILL (July 20, 2015), <http://thehill.com/opinion/op-ed/248567-congress-must-keep-trolls-away-from-medical-patents> [https://perma.cc/BX3D-8MM7].

84. Quinn, *supra* note 64.

85. *See, e.g.,* *Cuozzo Speed Tech. v. Lee*, 136 S. Ct. 2131, 2146 (2016) (denying any ability of a patentee to appeal the PTAB's decision to *institute* an IPR, whether as an interlocutory or final appeal, and upholding the PTAB's practice of interpreting claim language in their "broadest reasonable construction."); *MCM Portfolio v. Hewlett-Packard Co.*, 812 F.3d 1284 (Fed. Cir. 2015), *cert. denied*, 137 S. Ct. 292 (2016). In *MCM*, the court upheld the rule that patents are seen as public rights and are therefore justiciable in non-Article III courts. *See id.* at 1289. In addition, the court held that Congress had given the PTO rights to exterminate patents in reviews under the AIA, and that because IPRs are akin to administrative proceedings there is no issue with Seventh Amendment jury trial rights. *See id.* at 1293. By denying certiorari, the Supreme Court demonstrated its unwillingness to hear a constitutional argument against the IPR system itself.

86. Gene Quinn, *Predicting Oil States after Supreme Court Oral Arguments*, IPWATCHDOG (Nov. 28, 2017), <http://www.ipwatchdog.com/2017/11/28/predicting-oil-states-supreme-court-oral-arguments/id=90558/> [https://perma.cc/K2MN-Q8WL].

patent litigation laws, but because the issues arise during IPRs—not litigation—such reforms are unlikely to be of any help.⁸⁷

In light of the lack of solutions to the current problem, I endeavor to put forward a novel approach to improve IPRs by borrowing from other procedures in order to cure the most egregious defects of the IPR process: the standing requirement is too low, the amendment procedure is too draconian, and the claim interpretation is too biased towards the patent challenger.

One of the greatest criticisms for IPRs is that, unlike cases in Article III courts, there is no standing requirement to initiate an IPR. Anyone who has unearthed allegedly invalidating prior art may file a review with the PTAB.⁸⁸ Because the Supreme Court has largely avoided any challenges of IPRs on constitutional grounds,⁸⁹ the duty to solve the standing issue must fall upon Congress. Abuse of IPRs in meritless cases can be addressed most simply by creating a requirement that those who intend to initiate an IPR must either be defendants in an infringement suit or must have been sent a cease-and-desist order by the patentee, similar to a CBM. This keeps the process of invalidating unworthy patents relatively inexpensive but assures that only parties with some legitimate interest in the validity of the patent can move forward with an IPR.

Another harsh aspect of the current IPR proceedings is the difficulty of getting a challenged claim amended. Although statutes permit patentees to cancel a challenged claim and make a reasonable number of amendments,⁹⁰ the amount of amendments that the PTAB has granted is incredibly low—around seven percent of amended claims have been allowed by the PTAB.⁹¹ In oppositions with the EPO, however, amendments are looked at more favorably, leading some companies to attempt amendments with the EPO in order to discern which amendments to bring with the PTAB.⁹² Compared to the “kill rate” of over seventy-five

87. *See, e.g.*, Patent Abuse Reduction Act of 2013, S. 1013, 113th Cong. (requiring increased pleading requirements for patent infringement action and easier fee shifting); Saving High-Tech Innovators from Egregious Legal Disputes (SHIELD) Act of 2013, H.R. 845, 113th Cong. (attempting to deter patent trolls by allowing defendants to declare the plaintiff a patent troll and then force a fee shift to the loser); End Anonymous Patents Act, H.R. 2024, 113th Cong. (2013) (forcing the disclosure of the real party in interest when initiating an infringement suit).

88. 35 U.S.C. § 311(a) (2012 & Supp. I 2013).

89. *See supra* text accompanying note 85.

90. 35 U.S.C. § 316(d) (2012). In practice, this has generally been understood to limit one amendment per challenged claim.

91. Greg Lantier & John LeBlanc, *Observations on Amendments in an Inter Partes Review*, WILMERHALE (Feb. 2015), https://www.wilmerhale.com/uploadedfiles/shared_content/editorial/publications/documents/2015-02-ip-today-observations-amendments-in-an-ipr.pdf [<https://perma.cc/9EV3-2ATX>].

92. Flibbert, *supra* note 44.

percent of claims challenged in IPRs at the PTAB,⁹³ seventy-one percent of opposition claims survived in either the original or amended form.⁹⁴

The major distinction between the two proceedings is who has the burden of showing the validity of amendments. In the United States, the patentee making the amended claims bears the burden of proving validity,⁹⁵ whereas in Europe, the opposition has the burden of proving invalidity.⁹⁶ The trade-off is that in oppositions there is no estoppel barring arguments that the challenger could have made in later challenges like there is in IPRs.⁹⁷ In the interest of making amendments easier, it is reasonable to trade off the possibility of having to defend further actions in order to keep a claim from being invalidated, and it would go a long way in preventing the death of legitimate patents if instituted.

The last amendment that should be made to biotech IPR proceedings, and really to every post-issuance challenge proceeding, is to have consistent claim interpretation for trials and post-issuance reviews. Though this viewpoint is neither novel nor unique, it is simply good common sense to give a patent that has been issued the presumption of validity.⁹⁸ When the PTAB construes claim language, it gives the terms the “broadest reasonable construction.”⁹⁹ However, in ordinary court proceedings, claim terms are given the “ordinary meaning . . . as understood by a person of skill in the art.”¹⁰⁰ This discrepancy allows a much lower bar to invalidate patents at the PTAB than at trial because when terms are given a broader construction there is a greater chance that prior art will cover the claims, thus invalidating them.

Most recently at the Supreme Court, Cuozzo argued that IPRs are meant to be “mini-trials” and should therefore use the same construction standard as at trial,¹⁰¹ but the Court ultimately rejected this argument claiming public policy concerns about stifling innovation.¹⁰² However, to promote innovation there has to be a reasonable assurance of a return on investment, and a presumption of validity creates a solid investment.

93. Richard Baker, *America Invents Act Cost the US Economy over \$1 Trillion*, PATENTLY-O (June 8, 2015), <http://patentlyo.com/patent/2015/06/america-invents-trillion.html> [<https://perma.cc/559D-69B9>].

94. Flibbert, *supra* note 44. Of all claims challenged in 2013 through oppositions, forty percent of amended claims survived the process. *Id.*

95. This burden is currently being litigated with the Federal circuit en banc in *In re Aqua Products* 833 F.3d 1335 (Fed. Cir. 2016).

96. Flibbert, *supra* note 44.

97. *Id.*

98. 35 U.S.C. § 282 (2012).

99. 37 CFR § 42.100(b) (2018).

100. *Cuozzo Speed Tech. v. Lee*, 136 S. Ct. 2131, 2142 (2016).

101. *Id.* at 2143.

102. *Id.* at 2145.

Making an IPR less of an unknown risk would make IPRs far less desirable to opportunists looking to bring meritless challenges without chilling parties looking to challenge truly suspect patents.

CONCLUSION

Post-issuance challenges such as *inter partes* review and post-grant reviews were created in response to a legitimate problem of patent trolls within the then-existing patent system. Unfortunately, by suppressing a problem in one area of technology, a new and significant problem has arisen in the biotech industry. By creating a system that makes it easier to invalidate a patent without any necessary standing, *inter partes* reviews have allowed uninterested third parties to throw legitimate companies with valid patents into chaos. Two of the most affected sectors from this abuse of power have been the pharmaceutical and biotech industries, and while it may seem to be advantageous to the public to have expensive drugs lose patent protection, the reality is that new innovations in pharmaceutical technology simply cannot happen if companies lose patent protection.

The most vulnerable to IPR challenges are smaller biotech firms. These companies often have only one patented drug and limited resources with which to defend any patent challenges. After putting significant resources and time into developing a drug, making it past clinical trials, and being approved by the FDA, these companies have little to no capital left to defend any legal challenges and no safety net to stay viable while the Patent Trial and Appeals Board reviews the merits of the review process. If the future of pharmaceutical development depends on the continued existence of innovative small companies, the future is fragile indeed.

Thus far, attempts to curb the abuse of IPRs have largely failed. The attempts to appeal to the courts have failed, and the legislature seems to be more concerned with the process of patent litigation than administrative proceedings. If the suggestions described above—including increasing the standing requirement for biotech patents to mirror that of covered business methods, loosening the restraints on claim amendments during reviews, and keeping claim construction consistent throughout reviews and litigation—are followed, the goal of efficiently invalidating abusive and meritless patents would still be achieved without collateral damage to the biotech industry.