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An Administrative Meter Maid: Using Inter Partes Review and Post-Grant Review to Curb Exclusivity Parking via the "Failure to Market" Provision of the Hatch-Waxman Act

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NOTE

AN ADMINISTRATIVE METER MAID: USING INTER PARTES REVIEW AND POST-GRANT REVIEW TO CURB EXCLUSIVITY PARKING VIA THE “FAILURE TO MARKET” PROVISION OF THE HATCH-WAXMAN ACT

Brian T. Apel*

Congress created the unique Hatch-Waxman framework in 1984 to increase the availability of low-cost generic drugs while preserving patent incentives for new drug development. The Hatch-Waxman Act rewards generic drug companies that successfully challenge a pharmaceutical patent: 180 days of market exclusivity before any other generic firm can enter the market. When a generic firm obtains this reward, sometimes drug developers agree to pay generic firms to delay entering the market. These pay-for-delay agreements give rise to exclusivity parking and run counter to congressional intent by delaying full generic drug competition. The Medicare Prescription Drug, Improvement, and Modernization Act created several statutory forfeiture provisions that proved only marginally effective at curbing the practice of exclusivity parking. More recently, Congress created new quasi-judicial administrative proceedings that effectively replace certain kinds of district court patent litigation. This Note describes the complex statutory scheme that gave rise to exclusivity parking, explains why previous and current attempts to curtail exclusivity parking were and remain ineffective, and suggests amending the “failure to market” provision to include these new administrative proceedings as a way to help curb exclusivity parking.

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INTRODUCTION

Legal protections that affect pharmaceutical drug prices involve a tale of two competing interests: innovation and competition.¹ Pharmaceutical drug developers need to recoup large up-front development costs through above-cost pricing. On the other hand, lower pricing from greater competition would increase consumers' access to current drugs but would diminish investment returns and curtail the development of new drugs.² Congress attempted to balance these competing interests in 1984 when it enacted the Drug Price Competition and Patent Term Restoration Act,³ more commonly known as the Hatch-Waxman Act.⁴ Congress designed the Act to increase access to drugs at competitive prices.⁵ At the same time, the Hatch-Waxman Act fortified the incentives of "pioneers"—pharmaceutical companies that research, create, and market new drugs—by extending the term of pharmaceutical patents. Pioneers rely on patent protection for new drugs (as well as methods of making and using new drugs) to help recoup the cost of developing the drug and to finance future drug development.⁶ Although issued patents enjoy a presumption of validity,⁷—that is, compliance with the patent laws—it is not uncommon for courts to determine that some patents are

1. See generally Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417 (2011) (discussing how the Hatch-Waxman Act serves competing interests).

2. See *infra* Section I.A.

3. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

4. The Act is named for two of the statute's sponsors: Sen. Orrin Hatch and Rep. Henry Waxman.

5. H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984).

6. See, e.g., WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RS21129, PHARMACEUTICAL PATENT TERM EXTENSIONS: A BRIEF EXPLANATION 1 (2002), <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS21129.pdf>.

7. 35 U.S.C. § 282(a) (2012).

invalid in the course of patent infringement litigation.⁸ Congress was concerned that potentially invalid patents might be blocking generic entry into certain drug markets.⁹ To address this concern, Congress created an incentive for generic firms to challenge pioneer patents as part of the Hatch-Waxman Act: the first generic firm to initiate and lawfully maintain a challenge to a pioneer patent (a “first filer”) receives 180 days of market exclusivity, enforced by the U.S. Food and Drug Administration (FDA).¹⁰ Effectively, Congress was willing to give the first filer a 180-day head start before it would face competition from other generics in order to promote patent challenges.¹¹

This scheme created an unintended consequence: “exclusivity parking.” Exclusivity parking occurs when a first filer that can otherwise enter the market refrains from doing so. Because of the statutory scheme, no other generic firm can enter the market until after the first filer’s 180-day market exclusivity elapses.¹² Exclusivity parking became common in the context of patent litigation settlement agreements between the pioneer and the first filer. Specifically, the pioneer would pay the first filer to delay entering the market, allowing the pioneer to charge above-cost prices for a longer period of time than if the first filer prevailed in the litigation. These types of settlements are known as “pay-for-delay” settlements.

Delaying full generic competition more than 180 days upsets the balance Congress sought to achieve with the Hatch-Waxman Act and delays full generic competition and the lower prices that necessarily follow. Naturally, other generic firms waiting to enter the market became frustrated with first filers parking their exclusivity. In 2003, Congress attempted to remedy the situation with several amendments to the Hatch-Waxman Act.¹³ Effectively, Congress wanted the first filer to use it or lose it. One of these amendments, the “failure to market” provision, is triggered if the first filer *or any other generic firm waiting to enter the market* prevails in litigation against the pioneer.¹⁴ Unfortunately, the failure to market provision was poorly drafted and has proven toothless.¹⁵ Today, other generics frequently lack the incentive to incur litigation costs to attempt to unpark the first filer, and exclusivity parking continues largely unaffected.¹⁶

8. See, e.g., *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 966, 970 (Fed. Cir. 2014); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 741 (Fed. Cir. 2013); *Novo Nordisk A/S v. Caraco Pharm. Labs.*, 775 F. Supp. 2d 985, 1018 (E.D. Mich. 2011), *aff’d in relevant part*, 719 F.3d 1346 (Fed. Cir. 2013).

9. See *infra* Section I.A.

10. 21 U.S.C. § 355(j)(5)(B)(iv) (2012).

11. See *infra* Section I.A.

12. See *infra* Section I.A.

13. See *infra* Section I.A.

14. 21 U.S.C. § 355(j)(5)(D)(i)(I).

15. See *infra* notes 129–130 and accompanying text.

16. See FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1 (2010) [hereinafter FTC, PAY-FOR-DELAY], <http://www.ftc.gov/sites/default/files/docu>

In 2011, Congress enacted major reforms to the patent laws when it passed the Leahy-Smith America Invents Act (AIA).¹⁷ Among its many provisions, the AIA created several quasi-judicial administrative proceedings in the U.S. Patent and Trademark Office (PTO) that permit a party to challenge the validity of a duly issued patent.¹⁸ These proceedings present patent challengers, including generic firms, with alternatives to litigation. This Note focuses on two of the AIA's new administrative proceedings—inter partes review (IPR) and post-grant review (PGR)—and addresses a question the AIA did not answer: Can a party that prevails in one of these proceedings trigger the failure to market provision in the Hatch-Waxman Act, thereby unparking the first filer's exclusivity?

No court or agency has addressed this question.¹⁹ This Note argues that IPRs and PGRs, as alternatives to litigation, can and should trigger the failure to market provision of the Hatch-Waxman Act. Because neither the FDA nor a court is likely to construe the Hatch-Waxman Act's language broadly enough to incorporate IPRs and PGRs, however,²⁰ the failure to market provision requires an amendment. Part I explains the complex statutory and administrative structures that govern pharmaceutical patents and the circumstances that gave rise to the practice of exclusivity parking. Part II shows that past and current attempts to eliminate exclusivity parking have been ineffective. Part III argues that IPRs and PGRs present workable alternative forums to challenge a patent's validity, and that Congress should incorporate IPRs and PGRs into the Hatch-Waxman framework with a simple statutory amendment.

I. THE STATUTORY FRAMEWORK

The Hatch-Waxman Act provides a detailed statutory and regulatory framework that attempts to balance the incentives of the patent system with the benefits of easier generic drug entry. Section I.A describes the unique features of pharmaceutical patents and lays out the relevant portions of the Hatch-Waxman framework as it exists today. Section I.B describes the new administrative proceedings created by the AIA.

ments/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

17. Pub. L. No. 112-29, 125 Stat. 284 (2011).

18. See *infra* Section I.B.

19. See *infra* notes 177–180 and accompanying text.

20. See *infra* Section III.B.

A. *Pharmaceutical Patents and The Hatch-Waxman Act*

Due to the high cost of drug development,²¹ the pharmaceutical industry heavily relies on the patent system as part of its business model.²² Because the patent laws prohibit an inventor from obtaining a patent on an invention that is used more than one year before the inventor applies for the patent,²³ drug developers must often obtain a patent on a new drug well before FDA approval,²⁴ which can take up to twelve years.²⁵ Thus, while the standard patent term is twenty years,²⁶ “the *effective* patent term [for pharmaceuticals] is frequently less than 20 years because patents are often obtained before products are actually marketed.”²⁷

Before 1984, companies seeking to market generic versions of previously approved drugs were required to complete the same safety and efficacy testing in clinical trials as the pioneer drug developer.²⁸ Before the Hatch-Waxman Act, approximately 150 pioneer drugs with expired patents had no generic equivalent.²⁹ Consequently, pioneer drug developers could continue to charge above-cost prices beyond the term of the drug’s patent because the pioneer drug did not face any direct competition.³⁰ By comparison, once a drug is no longer patent protected, consumers can purchase generic drugs that can cost up to 85 percent less than the branded drug.³¹ Substituting generic drugs for pioneer drugs reduces government spending on health

21. SHEIN-CHUNG CHOW & JEN-PEI LIU, DESIGN AND ANALYSIS OF CLINICAL TRIALS: CONCEPTS AND METHODOLOGIES 5 (3d ed. 2014) (noting that drug development can cost up to \$1 billion per drug).

22. See Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93 (2004).

23. 35 U.S.C. § 102(a) (2012).

24. E.g., *Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994).

25. CHOW & LIU, *supra* note 21, at 5.

26. 35 U.S.C. § 154(a)(2).

27. *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, FDA, <http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm> (last updated Mar. 31, 2009) (emphasis added).

28. H.R. REP. NO. 98-857, pt. 2, at 4 (1984).

29. David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 168–69 (2005).

30. See *id.*

31. See *Facts About Generic Drugs*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm> (last updated Sept. 19, 2012). This assumes, however, full generic competition. See *Generic Competition and Drug Prices*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (last updated Mar. 1, 2010).

care³² and could mean the difference between a five dollar and a twenty dollar copay on prescription drugs for consumers.³³

The Drug Price Competition and Patent Term Restoration Act of 1984,³⁴ colloquially referred to as the Hatch-Waxman Act,³⁵ was a landmark piece of legislation intended to make low-cost generic drugs more readily available.³⁶ In particular, the Act significantly reduced generic firms' entry barriers through the creation of the Abbreviated New Drug Application (ANDA).³⁷ By utilizing an ANDA, a generic firm is not required to submit detailed clinical trial data to demonstrate the drug's safety and efficacy.³⁸ Instead, a generic firm utilizing an ANDA must certify that its drug will have the same active ingredients, dosage, strength, form, and packaging as the already approved pioneer drug³⁹ (also known as "reference listed drug" or "RLD").⁴⁰ The firm must also demonstrate that its generic drug is "bioequivalent" to the RLD by having similar chemical interactions in the human body as the RLD.⁴¹

Because ANDAs effectively allow generic firms to "piggyback[]" or "short-cut" the extensive clinical trial work financed by the pioneer drug developer,⁴² the Hatch-Waxman Act provided for extension of the pioneer's patent term beyond the twenty-year baseline to account for regulatory delays that occur during drug development.⁴³ In this way, the Act "struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market."⁴⁴

In addition to the bioequivalence requirement, an ANDA applicant must certify one of the following four criteria with respect to each patent that covers the pioneer drug

32. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE 4 (2012), <http://www.gao.gov/assets/590/588064.pdf>.

33. See Virgil Dickson, *Reform Update: Generic Drugs' High Prices Spur Fears of Failed Drug Adherence*, MODERN HEALTHCARE (Oct. 9, 2014), <http://www.modernhealthcare.com/article/20141009/NEWS/310099962>.

34. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

35. *E.g.*, FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013).

36. H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984).

37. Hatch-Waxman Act § 101, 98 Stat. 1585, 1585–92 (codified at 21 U.S.C. § 355(j) (2012)).

38. 21 U.S.C. § 355(j)(2)(A) (2012).

39. *Id.*

40. 21 C.F.R. § 314.94(a)(3) (2014).

41. 21 U.S.C. § 355(j)(8). See generally *Abbreviated New Drug Application (ANDA): Generics*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/> (last updated Sept. 18, 2014).

42. *Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008).

43. 35 U.S.C. §§ 154(b), 156(a)(4) (2012).

44. *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

- (I) that such patent information has not been filed [with FDA],
- (II) that such patent has expired,
- (III) . . . the date on which such patent will expire, or
- (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted⁴⁵

Paragraph I and II certifications are for drugs without patent protection. If the applicant makes a paragraph III certification, the ANDA will be approved upon patent expiration.⁴⁶

If an ANDA applicant makes a paragraph IV certification that the patent is invalid—that is, not in compliance with the patent laws—or would not be infringed by the ANDA product, the statute provides an intricate framework for resolving the dispute. First, the generic firm must notify the pioneer of the paragraph IV certification.⁴⁷ Then, the pioneer can sue the generic firm for patent infringement.⁴⁸ If the pioneer sues for patent infringement within forty-five days, the FDA must delay approval of the generic firm’s ANDA for thirty months to allow for the resolution of the litigation.⁴⁹ If the pioneer does not sue for patent infringement within that forty-five day period, the generic firm can sue the pioneer for declaratory judgment of patent invalidity or noninfringement to obtain certainty before entering the market.⁵⁰ Consequently, “patent litigation is an integral part of a generic drug company’s business,”⁵¹ and the number of challenges to pioneer patents by generic firms is on the rise.⁵²

The Hatch-Waxman Act created a reward for generic firms that challenge pioneer patents, thereby incurring litigation costs and risking liability for patent infringement. Specifically, the Act provides a 180-day generic exclusivity window for the first ANDA filer that challenges a pioneer patent with a paragraph IV certification and prevails in the ensuing litigation.⁵³ As Senator Hatch explained, “[i]n order to give an incentive for vigorous patent challenges, the 1984 law granted a 180-day head start over other generic drug firms when the pioneer firm’s patents failed or were simply not infringed.”⁵⁴ This 180-day exclusivity window begins when the first filer enters

45. 21 U.S.C. § 355(j)(2)(A)(vii).

46. *Id.* § 355(j)(5)(B)(ii); see H.R. REP. NO. 98-857, pt. 1, at 46 (1984) (“[I]mmediate competition should be encouraged.”).

47. 21 U.S.C. § 355(j)(2)(B).

48. 35 U.S.C. § 271(e)(2) (2012).

49. 21 U.S.C. § 355(j)(5)(B)(iii).

50. *Id.* § 355(j)(5)(C).

51. *AstraZeneca AB v. Mylan Pharm., Inc.*, No. 14-696-GMS, 2014 WL 5780213, at *7 (D. Del. Nov. 5, 2014).

52. Ed Silverman, *Sue Me, Sue You Blues: More Generic Patent Litigation is Being Filed*, WALL ST. J. (Nov. 5, 2014, 10:54 AM), <http://blogs.wsj.com/pharmalot/2014/11/05/sue-me-sue-you-blues-more-generic-litigation-is-being-filed/>.

53. 21 U.S.C. § 355(j)(5)(B)(iv).

54. 149 CONG. REC. S16104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).

the market.⁵⁵ The 180-day period is worth millions of dollars, vastly exceeding litigation costs.⁵⁶ “In general, most generic drug companies estimate that 60% to 80% of their potential profit for any one product is made during this exclusivity period.”⁵⁷

The 180-day exclusivity period in the Hatch-Waxman Act gave rise to a practice known as exclusivity parking, which occurs when a first filer that otherwise could enter the market refrains from doing so, usually because of an agreement with the pioneer.⁵⁸ Exclusivity parking delays not only the *start* of the first filer’s generic exclusivity, but also its *end*. This practice extends the time that the pioneer can charge monopoly prices on the drug—a portion of which is usually paid to the first filer. Since the first filer’s exclusivity starts only after the first filer enters the market,⁵⁹ the first filer retains almost the full economic benefit of its generic exclusivity; the benefit just comes later. Exclusivity parking occurs most frequently as a result of patent litigation settlements.⁶⁰ Generally these settlements involve a payment from the pioneer to the first filer in exchange for a promise by the first filer to delay marketing its generic drug for some period of time.⁶¹ These settlements are colloquially called “pay-for-delay” settlements.⁶²

The practice of exclusivity parking upsets the balance between innovation and competition that Congress chose. Congress precisely quantified its intended balance; it only wanted full generic competition reduced by 180 days.⁶³ Any further delay runs counter to congressional intent.⁶⁴ Additionally, pay-for-delay settlements cost consumers an estimated \$3.5 billion annually⁶⁵ and have drawn heavy scrutiny from the Federal Trade Commission (FTC) for possibly violating federal antitrust laws.⁶⁶ While some might try to

55. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

56. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1560 (2006).

57. Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing From a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who’s on First*, 25 BIOTECHNOLOGY L. REP. 525, 525–26 (2006).

58. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067 (D.C. Cir. 1998); *No Parking? USPTO Relief for Subsequent ¶ IV Filers*, SUGHRUE MION, PLLC (Apr. 27, 2012), <http://www.sughrue.com/resources/PublicationDetail.aspx?publication=877f6d53-1e0b-458c-bd0c-4e5639fedaa1>.

59. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

60. *FTC v. Actavis*, 133 S. Ct. 2223, 2227 (2013).

61. *Id.* Compensation to the generic can involve more than just a cash payment. See, e.g., *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180, 186 (D.R.I. 2014) (noting that the pioneer agreed not to launch its own competing generic and allowed the first filer to sell the drug internationally).

62. E.g., Michael L. Fialkoff, Note, *Pay-for-Delay Settlements in the Wake of Actavis*, 20 MICH. TELECOMM. & TECH. L. REV. 523 (2014).

63. See *supra* notes 53–54 and accompanying text.

64. See 149 CONG. REC. S15884–85 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) (discussing the intended process of the 180-day exclusivity period).

65. FTC, PAY-FOR-DELAY, *supra* note 16, at 10.

66. See *infra* Section II.A.

justify pay-for-delay agreements given the high cost of drug development, these agreements still upset Congress's chosen policy preferences.

Congress did not foresee the problem of exclusivity parking; it was an unintended consequence.⁶⁷ In 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Congress amended the Hatch-Waxman Act, creating six provisions under which the first filer forfeits its 180-day exclusivity.⁶⁸ Two of those forfeiture provisions—the antitrust provision and the failure to market provision—specifically targeted the practice of exclusivity parking. In 2003, Congress utilized the only then-available forum for the resolution of patent disputes: litigation in federal court.⁶⁹ Today, new administrative proceedings offer an alternative solution that is quicker and less costly than litigation.

B. *New Administrative Proceedings Created by the America Invents Act*

In 2011, Congress enacted the most comprehensive changes to the patent laws since 1952.⁷⁰ Among other things, the Leahy-Smith America Invents Act⁷¹ (AIA) created new quasi-judicial administrative proceedings before the Patent Trial and Appeal Board (PTAB), an adjudicative body within the PTO, for a party to challenge a patent's validity.⁷² These new administrative proceedings attempt to decrease the time, cost, and uncertainty of patent litigation by placing patent disputes before a technically competent agency rather than a lay judge or jury.⁷³ Two of the new proceedings are inter partes review (IPR)⁷⁴ and post-grant review (PGR).⁷⁵

IPRs and PGRs are very similar to traditional patent litigation in both procedure and substance. Any person who is not the patent owner can file a petition for IPR or PGR,⁷⁶ and the patent owner can file a preliminary response.⁷⁷ This is roughly analogous to the complaint and answer phase of

67. Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1794 n.34 (2011).

68. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in relevant part at 21 U.S.C. § 355(j)(5)(D)(i)(I)–(IV) (2012)). For a more detailed discussion of the MMA's forfeiture provisions, see *infra* Part II.

69. 28 U.S.C. § 1338 (2000) (amended 2011).

70. H.R. REP. NO. 112-98, pt. 1, at 38 n.4 (2011).

71. Pub. L. No. 112-29, 125 Stat. 284 (2011).

72. *Id.* § 6 (codified at 35 U.S.C. §§ 311–329 (2012)).

73. H.R. REP. NO. 112-98, pt. 1, at 43–48.

74. 35 U.S.C. §§ 311–319 (2012). In an IPR, a patent's validity may only be challenged with respect to novelty, *id.* § 102, or nonobviousness, *id.* § 103, and only based on patents or printed publications, *id.* § 311(b).

75. *Id.* §§ 321–329. In a PGR, a patent's validity may be challenged on almost any legal ground. *Id.* § 321(b).

76. 35 U.S.C. §§ 311(a), 321(a) (2012).

77. *Id.* §§ 313, 323.

litigation.⁷⁸ The scope of the proceeding, however, is strictly limited to questions of patent validity; IPRs and PGRs do not determine questions of patent infringement.⁷⁹ If the PTAB institutes the IPR or PGR, the parties submit evidence and take limited discovery, including depositions.⁸⁰ IPRs and PGRs culminate in an oral hearing, similar to a trial or oral argument.⁸¹ Afterward, the PTAB must issue a final written decision within one year of instituting the IPR or PGR.⁸² Finally, like traditional litigation, the parties can settle by joint stipulation at any time before the PTAB issues its final written decision.⁸³ In these ways, IPRs and PGRs reduce the strain on the federal judiciary effectively by replacing certain patent validity disputes that the parties might otherwise litigate in district court. IPRs and PGRs are not ideal for every patent challenger, but they can be superior to litigation depending on the circumstances.⁸⁴ Unfortunately for both pioneer and generic pharmaceutical firms, the AIA's provisions for IPRs and PGRs contain no reference to the Hatch-Waxman Act and leave practitioners uncertain about how these two statutes interact.

II. CURRENT STATUTORY FORFEITURE PROVISIONS ARE INEFFECTIVE AT CURBING EXCLUSIVITY PARKING

While Congress attempted to eliminate exclusivity parking in 2003, the practice continues largely unabated. When it enacted the MMA, Congress rejected proposed changes to the Hatch-Waxman Act's major elements.⁸⁵ Instead, Congress retained the basic Hatch-Waxman framework and created several forfeiture provisions designed to make the original framework operate more effectively.⁸⁶ For example, the first filer forfeits its exclusivity if the patent in question expires,⁸⁷ if the first filer amends its ANDA to no longer

78. See FED. R. CIV. P. 8.

79. See *infra* notes 149–150 and accompanying text.

80. 37 C.F.R. §§ 42.51–42.65 (2014); see FED. R. CIV. P. 26–37. This discovery, however, is limited. See *infra* notes 167–170 and accompanying text.

81. 37 C.F.R. § 42.70 (2014).

82. 35 U.S.C. §§ 316 (a)(11), 326(a)(11) (2012). This timeframe is shorter than in traditional patent litigation. See *infra* notes 160–166 and accompanying text.

83. 35 U.S.C. §§ 317, 327.

84. See *infra* Section III.A.

85. See Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 FOOD & DRUG L.J. 287, 309–13 (2004). For example, Senator Hatch advocated giving the 180-day market exclusivity to the first successful challenger rather than the first ANDA filer. *Examining the Senate and House Versions of the “Greater Access to Affordable Pharmaceuticals Act”: Hearing on S. 1 and H.R. 1 Before the S. Comm. on the Judiciary*, 108th Cong. 2–3 (2003) (statement of Sen. Orrin G. Hatch, Chairman, S. Comm. on the Judiciary).

86. See Shashank Upadhye, *There’s a Hole in My Bucket, Dear Liza, Dear Liza: The 30-Year Anniversary of the Hatch-Waxman Act: Resolved and Unresolved Gaps and Court-Driven Policy Gap Filling*, 40 WM. MITCHELL L. REV. 1307, 1326 (2014).

87. 21 U.S.C. § 355(j)(5)(D)(i)(VI) (2012) (“All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.”).

challenge the patent,⁸⁸ or if the first filer withdraws its ANDA entirely.⁸⁹ Two additional provisions targeted exclusivity parking⁹⁰: the antitrust provision and the failure to market provision. The effect of these provisions, however, has been marginal at best.⁹¹ Section II.A explains why the antitrust provision and antitrust actions generally fail to curtail exclusivity parking. Section II.B explains why the failure to market provision has similarly failed.

A. *The Antitrust Provision is Ineffective at Curbing Exclusivity Parking*

“Pay-for-delay” settlements have attracted antitrust scrutiny from the FTC since they became more common in the early 2000s.⁹² Naturally, when Congress enacted the MMA, it wanted the first filer to lose its exclusivity if a court found the agreement illegal.⁹³ The antitrust provision results in forfeiture of the 180-day exclusivity when, in an action brought by one of the antitrust agencies, a court finds the pay-for-delay agreement violates the antitrust laws.⁹⁴ While fairly straightforward, this provision, and antitrust litigation generally, have proven ineffective at combating exclusivity parking.

First, plaintiffs face an uphill battle to prove a pay-for-delay settlement violates the antitrust laws. In *FTC v. Actavis* in 2013, the Supreme Court held that pay-for-delay settlements—even those within the scope of a valid patent—are not per se legal and could be subject to antitrust scrutiny.⁹⁵ Many view the *Actavis* decision as a victory for antitrust plaintiffs because cases are more likely to go beyond the motion to dismiss stage.⁹⁶ The implications of *Actavis*, however, still make these cases very difficult for plaintiffs

88. *Id.* § 355(j)(5)(D)(i)(III) (“The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.”).

89. *Id.* § 355(j)(5)(D)(i)(II) (“The first applicant withdraws the application or the [FDA] considers the application to have been withdrawn as a result of a determination by the [FDA] that the application does not meet the requirements for approval . . .”).

90. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102, 117 Stat. 2066, 2457–60 (2003) (codified in relevant part at 21 U.S.C. § 355(j)(5)(D)(i)(I)–(VI) (2012)); 149 CONG. REC. S16104–05 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch) (praising the conference committee for adopting statutory language meant to curb exclusivity parking).

91. See Matthew Avery, Note, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171 (2008).

92. Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1794 (2011).

93. See 149 CONG. REC. S15884 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy). Interestingly, Congress did not outright ban pay-for-delay settlement agreements, but rather tied their legality to the antitrust laws.

94. 21 U.S.C. § 355(j)(5)(D)(i)(V).

95. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

96. Joshua D. Wright, Commissioner, FTC, Remarks at the Concurrences Journal Annual Dinner 3 (Sept. 26, 2013) [hereinafter Remarks of Wright], http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf.

to win. Specifically, the Court held that plaintiffs must prove their case under a “rule of reason” analysis.⁹⁷ The rule of reason employs an overall balancing of harms, benefits, and alternatives to decide whether the challenged agreement is illegal.⁹⁸ A rule of reason antitrust case will involve complex economic questions about the market in which the defendant operates, the scope of the defendant’s power or influence in that market, and how much and to what extent consumers are harmed by the defendant’s conduct compared with potential efficiencies of or justifications for the defendant’s conduct.⁹⁹ Unlike pay-for-delay cases after *Actavis*, other types of antitrust cases employ burden-shifting, presumptions, or rules of per se illegality, which make it easier for plaintiffs to prevail.¹⁰⁰

Rule of reason cases are hard for plaintiffs to win generally,¹⁰¹ and pay-for-delay cases will likely prove particularly difficult. Even before *Actavis*, pay-for-delay settlements often contained provisions that appeared to mask their underlying anticompetitive effects, making an antitrust case difficult to prove.¹⁰² After *Actavis*, settlements will likely become more complex, making it difficult for plaintiffs to articulate the distinct anticompetitive effects of the agreements.¹⁰³ For example, some settlements have involved forgiving past liability in previous disputes between the same parties but involving different drugs.¹⁰⁴ Furthermore, post-*Actavis* plaintiffs will need more economic evidence of anticompetitive harm than simply the size of the payment for delay.¹⁰⁵ Unfortunately, evidence of market effects will be difficult to obtain. Pay-for-delay settlements, “by their very structure and the fact entry has not yet occurred, [mean that] courts typically will be unable to measure the actual effect of the settlement on prices at trial.”¹⁰⁶

Second, the *Actavis* Court did not provide a clear framework for evaluating pay-for-delay settlements under the rule it announced: “We therefore

97. *Actavis*, 133 S. Ct. at 2227, 2236.

98. 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1500 (3d ed. 2010).

99. *Id.*

100. *See, e.g.*, 11 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1911c (3d ed. 2011).

101. Michael A. Carrier, *The Rule of Reason: An Empirical Update for the 21st Century*, 16 GEO. MASON L. REV. 827, 830 (2009) (finding that defendants won 99 percent of all rule of reason cases between 1999 and 2009).

102. *See* Amanda P. Reeves, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis*, 28 ANTITRUST, no. 1, Fall 2013, at 9, 10.

103. Remarks of Wright, *supra* note 96, at 11; *see* Reeves, *supra* note 102, at 12 (suggesting the settling companies will include joint development provisions and a desire for patent certainty among their procompetitive reasons for a pay-for-delay arrangement).

104. *E.g., In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 384 (D. Mass. 2013).

105. Remarks of Wright, *supra* note 96, at 9–10; *e.g., In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389 (PGS), 2014 WL 4543502, at *19–21 (D.N.J. Sept. 12, 2014).

106. Remarks of Wright, *supra* note 96, at 14. For a summary of post-*Actavis* pay-for-delay antitrust litigation, *see* Melissa Lipman, *Law360’s Pay-for-Delay Cheat Sheet for 2015*, LAW360 (Jan. 25, 2015, 8:21 PM), <http://www.law360.com/articles/608357/law360-s-pay-for-delay-cheat-sheet-for-2015>.

leave to the lower courts the structuring of the present rule-of-reason anti-trust litigation.¹⁰⁷ In dissent, Chief Justice Roberts took particular issue with the majority's failure to provide guidance to lower courts: "Good luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.'"¹⁰⁸ This leaves many questions unanswered and leaves antitrust plaintiffs unable to predict how their cases might unfold.¹⁰⁹ The difficulty in winning a rule of reason pay-for-delay antitrust case combined with uncertainty after *Actavis* means later-filing generic firms lack a predictable and reliable way to break the logjam created by the first filer's parked exclusivity.¹¹⁰

Third, the FTC will not scrutinize most pay-for-delay settlements. Although the FTC has publicly stated its intention to continue aggressively enforcing the antitrust laws in pay-for-delay situations,¹¹¹ the FTC's resources are limited; it cannot pursue every pay-for-delay settlement.¹¹² Since 2004, the number of pay-for-delay settlements has slowly risen.¹¹³ Today, the FTC estimates that approximately thirty settlements each year take on a pay-for-delay character.¹¹⁴ Despite these increasing numbers, only two FTC pay-for-delay suits are currently pending.¹¹⁵ If the threat of FTC action were an effective deterrent to pay-for-delay agreements, one would expect the number of pay-for-delay settlements to be on the decline.

Finally, fighting the rule of reason battle without clear guidance draws out litigation for extended periods of time.¹¹⁶ For example, the FTC filed suit

107. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2238 (2013).

108. *Id.* at 2245 (Roberts, C.J., dissenting) (quoting *id.* at 2231 (majority opinion)).

109. Remarks of Wright, *supra* note 96, at 15–16.

110. Reeves, *supra* note 102, at 14–15; see Fialkoff, *supra* note 62.

111. Remarks of Wright, *supra* note 96, at 7–8.

112. See Reeves, *supra* note 102, at 14.

113. BUREAU OF COMPETITION, FTC, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2013, at 4 (2014), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf>.

114. *Id.* This number is based on the settlement agreements that parties are required to submit to the FTC. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 §§ 1112–1113, 117 Stat. 2066, 2461–63 (codified at 21 U.S.C. § 355(j)(5)(D) (2012)).

115. Edith Ramirez, Chairwoman, FTC, Statement to the Senate Committee on the Judiciary, Subcommittee on Antitrust, Competition Policy & Consumer Rights 3 (July 23, 2013), http://www.ftc.gov/sites/default/files/documents/public_statements/statement-chairwoman-edith-ramirez-pay-delay-settlements/130923pfdopeningstatement_0.pdf. The cases are, (1) the Supreme Court's *Actavis* decision remanded back to the Northern District of Georgia, *FTC v. Actavis, Inc.*, No. 1:09-CV-955-TWT, 2014 WL 1600331 (N.D. Ga. April 21, 2014), and (2) *FTC v. Cephalon, Inc.*, 36 F. Supp. 3d 527 (E.D. Pa. 2014).

116. See Daniel A. Crane, *Optimizing Private Antitrust Enforcement*, 63 VAND. L. REV. 675, 692 (2010) (noting that the average antitrust case today takes six years from filing to disposition).

against a pioneer company in 2008,¹¹⁷ and the court ruled on summary judgment motions over six years later.¹¹⁸ As of March 2015, the litigation that resulted in *Actavis*, initially filed in 2009, is scheduled to complete discovery in mid-2016.¹¹⁹ Antitrust actions are unlikely to be instituted by the FTC, but even when they are instituted, they are difficult to win and lengthy to resolve. The combination of plaintiffs' difficulty prevailing in rule of reason cases, the uncertainty after *Actavis*, the lack of FTC resources, and the long duration of antitrust litigation, make antitrust actions, and the corresponding forfeiture provision, ineffective at curbing exclusivity parking.¹²⁰

B. *The Failure to Market Provision Is Ineffective at Curbing
Exclusivity Parking*

With the failure to market provision, as with the other MMA forfeiture provisions, Congress intended to retain the overall structure of the Hatch-Waxman Act, but incentivize the first filer to use its exclusivity or lose it.¹²¹ The result, however, is a poorly drafted nuanced web of "earlier than" and "later than" language that, when formally applied, leaves a pioneer and first filer almost completely in control and able to thwart Congress's goals.¹²² The provision provides for forfeiture if

- [t]he first applicant fails to market the drug by the later of—
- (aa) [a date determined by the first filer's submission and final approval dates]; or
 - (bb) with respect to the first applicant or any other applicant . . . the date that is 75 days after . . . at least 1 of the following has occurred:
 - (AA) In an infringement action . . . or in a declaratory judgment action . . . a court enters a final decision from which no appeal . . . has been or can be taken that the patent is invalid or not infringed.

117. *FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 22 (D.D.C. 2008).

118. *Cephalon, Inc.*, 36 F. Supp. 3d 527. For a summary of FTC actions in the field, see MARKUS H. MEIER ET AL., HEALTH CARE DIVISION, BUREAU OF COMPETITION, FEDERAL TRADE COMMISSION, OVERVIEW OF FTC ANTITRUST ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS (2013), <http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf>.

119. Consent Order Modifying Schedule at 2, *FTC v. Actavis, Inc.*, No. 1:09-cv-00955-TWT (N.D. Ga. Feb. 2, 2015), ECF No. 330.

120. While a private antitrust suit cannot trigger forfeiture, 21 U.S.C. § 355(j)(5)(D)(i) (2012), it could potentially act as a deterrent to pay-for-delay settlements. Private antitrust actions must still proceed under the rule of reason, *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013), and are likely to take several years as well. Crane, *supra* note 116, at 692.

121. 149 CONG. REC. 31,200 (2003) (statement of Sen. Schumer) ("If it forfeits, then the exclusivity is lost and any other generic applicant that is ready to be approved and go to market can go.").

122. See Upadhye, *supra* note 86, at 1325.

(BB) In an infringement action or a declaratory judgment action . . . a court signs a settlement order . . . that includes a finding that the patent is invalid or not infringed.¹²³

The statute provides for forfeiture for failure to market upon the *later of* two events: an event pursuant to subpart (aa) (a “submission/approval event”) or an event pursuant to subpart (bb) (a “litigation event”).¹²⁴ While the submission/approval event is a straightforward date determination based on the first filer’s ANDA submission and final approval dates, the litigation event depends on the ensuing litigation triggered by “the first applicant or any other applicant.”¹²⁵ This flexibility in the statute means that any paragraph IV ANDA filer can trigger the litigation event for the first filer, unpark the exclusivity, and force the first filer to either enter the market within seventy-five days or forfeit the 180-day exclusivity period. Using this provision, another generic firm can force the first filer to use it or lose it.

The flexibility of the litigation event combined with the overall “later than” framework of the provision initially left an important question unanswered: How long does the FDA wait to decide whether another generic firm might trigger a litigation event? The FDA’s answer: as long as the occurrence of a litigation event is a “possibility,” forfeiture is not triggered.¹²⁶ The FDA has not expanded upon what exactly “possibility” means, except that actual pending litigation with another generic firm is not required.¹²⁷ Thus, the failure to market provision triggers only upon the occurrence of *both* a submission/approval event *and* a litigation event.¹²⁸

The seemingly indefinite length during which a litigation event can occur leaves the failure to market provision almost entirely within the control of the parties. By settling the litigation, the pioneer and first filer avoid the first possible litigation event—an event that falls within item (bb)(AA)—because there is no final judgment on the merits. If that settlement contains no stipulation of the patent’s invalidity or noninfringement, the parties avoid the second possible litigation event—an event that falls within item (bb)(BB)—unless a later filer initiates litigation against the pioneer. Consequently, the failure to market provision lacks any real teeth,¹²⁹ and the FDA acknowledges this loophole:

123. 21 U.S.C. § 355(j)(5)(D)(i)(I). For a more detailed discussion of the failure to market provision, see David E. Korn et al., *A New History and Discussion of 180-Day Exclusivity*, 64 *FOOD & DRUG L.J.* 335, 371–82 (2009).

124. 21 U.S.C. § 355(j)(5)(D)(i)(I).

125. *Id.* § 355(j)(5)(D)(i)(I)(bb) (emphasis added).

126. Letter from Gary J. Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, FDA, to Marc A. Goshko, Exec. Dir., Teva N. Am. 5–6 (Jan. 17, 2008) [hereinafter Granisetron Letter], www.fda.gov/ohrms/dockets/dockets/07n0389/07n-0389-let0003.pdf.

127. *Id.*

128. *Id.* at 4–5.

129. Chad A. Landmon & Jay B. Sitlani, *FDA Removes Teeth from Exclusivity Forfeiture*, IP *LAW360* (Jan. 24, 2008), http://www.axinn.com/media/article/101_CALJBS-ip360-FDA%20Removes%20Teeth.pdf.

Inherent in the structure of the “failure to market” forfeiture provisions is the possibility that a first [filer] would be able to enter into a settlement agreement with the [pioneer] or patent owner in which a court does not enter a final judgment of invalidity or non-infringement (i.e., without a [litigation] event . . . occurring), and that subsequent applicants would be unable to initiate a forfeiture with a declaratory judgment action. This inability to force a forfeiture of 180-day exclusivity could result in delays in the approval of otherwise approvable ANDAs owned by applicants that would market their generic drugs if they could but obtain approval. *This potential scenario is not one for which the statute currently provides a remedy.*¹³⁰

Furthermore, the use of declaratory judgment actions by later-filing generic firms is ineffective at curbing exclusivity parking. First, the later filer lacks the same incentive as the first filer to litigate any patents covering the drug in question. Even if the later filer prevails in a declaratory judgment action, the later filer does not obtain the lucrative 180-day exclusivity.¹³¹ Although incurring similar risks and costs, the only benefit to the later filer from a successful declaratory judgment action would be earlier market entry. But the later filer would still be competing with all the other generic firms now able to enter the market.¹³²

Second, a later-filing generic firm pursuing a declaratory judgment action faces a battle just to establish standing. Article III of the U.S. Constitution limits the jurisdiction of federal courts to “cases” and “controversies.”¹³³ To demonstrate Article III standing, a plaintiff must show injury, a causal connection between the injury and the defendant, and likelihood that the injury will be redressed by a favorable court action.¹³⁴ In the context of patent disputes, a declaratory judgment plaintiff used to be required to show “reasonable apprehension of *imminent* suit.”¹³⁵ This required showing “(1) acts of [the patent owner] indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement.”¹³⁶ In *MedImmune, Inc. v. Genentech, Inc.*,¹³⁷ the Supreme Court clarified the scope of Article III standing for declaratory judgment actions in

130. Granisetron Letter, *supra* note 126, at 5 n.6 (emphasis added).

131. 21 U.S.C. § 355(j)(5)(D)(iii) (2012) (“If all first [filers] forfeit the 180-day exclusivity period . . . no applicant shall be eligible for a 180-day exclusivity period.”).

132. See *Avery*, *supra* note 91, at 193. To be sure, later-filing generics still have significant incentives to enter the market. See, e.g., *Apotex, Inc. v. Daiichi Sankyo, Inc.*, No. 2014-1282, 2015 WL 1423624, at *6 (Fed. Cir. Mar. 31, 2015) (“If the judgment issues, there is every likelihood that [the pioneer and first filer] will lose substantial revenues, and [the later filer] will gain substantial revenues.”).

133. U.S. CONST. art. III, § 2, cl. 1.

134. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992).

135. *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005), *abrogated by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

136. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 737 (Fed. Cir. 1988).

137. 549 U.S. 118 (2007).

patent suits and rejected the reasonable apprehension test.¹³⁸ Subsequent court decisions have made it easier for later filers to establish standing,¹³⁹ but the standard remains unsettled.¹⁴⁰ For example, the Federal Circuit recently held that a generic firm that has begun testing its drug but not yet submitted an ANDA to the FDA lacks Article III standing.¹⁴¹

A more recent case likely puts this issue to rest. In *Apotex, Inc. v. Daiichi Sankyo, Inc.*,¹⁴² the Federal Circuit allowed a later-filing generic firm to pursue a declaratory judgment action of noninfringement against the pioneer for a patent that the pioneer disclaimed—that is, legally surrendered.¹⁴³ The court acknowledged that a declaratory judgment of noninfringement would trigger the failure to market provision for the first filer.¹⁴⁴ The court held that the economic consequences of exclusivity forfeiture and the later filer's earlier market entry created a case or controversy, despite the fact that the pioneer could never sue the later filer (or anyone else for that matter) for infringement of the patent in question.¹⁴⁵

The rationale of *Apotex v. Daiichi* will likely extend to a later filer that successfully employs an IPR or PGR. After an IPR or PGR that invalidates a patent (and after affirmance on appeal), the pioneer can no longer sue for infringement. This has the same effect as disclaiming the patent: the property right no longer exists.¹⁴⁶ Furthermore, the same sizeable economic stakes will likely be in play. Consequently, a later-filing generic firm may be able to establish Article III standing to obtain a declaratory judgment of invalidity or noninfringement after an IPR or PGR invalidates a pioneer patent.¹⁴⁷

138. *MedImmune*, 549 U.S. at 132 n.11; see also *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 505 n.1 (Fed. Cir. 2012) (“The Supreme Court in *MedImmune, Inc. v. Genentech, Inc.*, rejected our ‘reasonable apprehension of suit’ test for declaratory judgment standing and held that the proper test is whether ‘there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.’” (citation omitted) (quoting *MedImmune*, 549 U.S. at 127)).

139. See, e.g., *Apotex, Inc. v. Daiichi Sankyo, Inc.*, No. 2014-1282, 2015 WL 1423624 (Fed. Cir. Mar. 31, 2015) (holding exclusivity parking sufficient injury to satisfy Article III standing for later filer's declaratory judgment action); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293–94 (Fed. Cir. 2008) (same). But see *Janssen Pharm., N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1360–61 (Fed. Cir. 2008) (distinguishing *Caraco* and holding later filer's stipulation of patent validity, infringement, and enforceability failed to create adequate controversy).

140. Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1, 18 (2013).

141. *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1278–79 (Fed. Cir. 2014).

142. *Apotex*, 2015 WL 1423624.

143. *Id.* at *14.

144. *Id.* at *9.

145. *Id.* at *4.

146. See 35 U.S.C. § 253(b) (2012) (allowing a patent owner “to disclaim or dedicate [the patent] to the public”).

147. See *Apotex*, 2015 WL 1423624, at *4–14.

III. MODIFYING THE FAILURE TO MARKET PROVISION TO INCLUDE IPRs

Though well-intentioned, the MMA's forfeiture provisions remain ineffective at curbing exclusivity parking. The newly created quasi-judicial administrative proceedings before the PTAB offer an alternative process for challenging a patent's validity, and thus can and should also trigger the failure to market provision. Because courts and the FDA are unlikely to interpret the failure to market provision as including the new PTAB proceedings, however, a statutory change is required to achieve that inclusion. Section III.A describes how IPRs and PGRs present alternative forums for challenging the validity of a pharmaceutical patent. Section III.B argues that courts and the FDA are unlikely to construe the failure to market provision to include IPRs or PGRs in light of the statutory language. Section III.C proposes an amendment to the failure to market provision that would accommodate IPRs and PGRs and argues that this amendment is faithful to congressional intent.

A. *IPRs and PGRs: The Alternative Forum to Patent Litigation*

Although IPRs and PGRs bear striking similarities to litigation,¹⁴⁸ certain differences will alter their attractiveness to a generic firm that wants to challenge a pioneer patent. First, the scope of IPRs and PGRs is limited strictly to issues of patent validity; IPRs and PGRs cannot be used to determine questions of infringement.¹⁴⁹ Thus, a generic firm that intends to claim that its product does not infringe the pioneer patent *and* that the pioneer patent is invalid might choose to keep all its claims in a single district court rather than fight on two fronts.¹⁵⁰

Second, IPRs and PGRs have different standards of proof than traditional litigation. A declaratory judgment plaintiff needs only a "short and plain statement" showing the party is entitled to relief.¹⁵¹ To successfully institute an IPR or PGR, the challenger must show a "reasonable likelihood" of success,¹⁵² or "that it is more likely than not" that the petitioner will prevail,¹⁵³ very similar to the standard for a preliminary injunction.¹⁵⁴ Thus, IPRs and PGRs require more initial work than a complaint for declaratory judgment and contain a higher probability of early failure.¹⁵⁵ Once the IPR

148. See *supra* notes 76–84 and accompanying text.

149. 35 U.S.C. §§ 311(b), 321(b) (2012).

150. See Eric S. Walters & Colette R. Verkuil, *Patent Litigation Strategy: The Impact of the America Invents Act and the New Post-Grant Patent Procedures*, PRACTICAL LAW CO. 6 (2012), <http://media.mofo.com/files/Uploads/Images/120307-Patent-Litigation-Strategy.pdf>.

151. FED. R. CIV. P. 8(a)(2).

152. 35 U.S.C. § 314(a).

153. *Id.* § 324(a).

154. See *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) ("A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits.")

155. It should be noted, however, that a later filer would likely spend significant resources evaluating a patent's validity in advance of filing an IPR or declaratory judgment action.

or PGR is instituted, however, a generic firm must prove invalidity by only a preponderance of the evidence¹⁵⁶—a lower standard than the “clear and convincing” standard a district court requires to overcome the patent owner’s statutorily mandated presumption of validity.¹⁵⁷ While some commentators suggest standards of proof are amorphous and highly subjective,¹⁵⁸ a subtle difference in the standard of proof could be dispositive in some patent cases.¹⁵⁹

Third, IPRs and PGRs are often shorter than patent litigation. According to a recent study, the median time to trial in patent litigation is two-and-a-half years.¹⁶⁰ By contrast, an IPR or PGR is statutorily required to conclude within twelve months.¹⁶¹ The PTAB decides whether to institute an IPR or PGR within six months of the filed petition, resulting in a maximum eighteen-month start-to-finish timeline for IPRs and PGRs.¹⁶² This faster timeline could prevent courts from hearing issues too late to afford the relief sought.¹⁶³ Furthermore, given their shorter duration and more limited scope, IPRs and PGRs are estimated to cost a challenger \$300,000 to

156. 35 U.S.C. §§ 316(e), 326(e).

157. *Id.* § 282(a), construed in *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2246 (2011).

158. See, e.g., Kevin M. Clermont, *Standards of Proof Revisited*, 33 VT. L. REV. 469, 470 (2009) (suggesting it is “contestable” that a fact finder assigns the appropriate probability for a given standard of proof); cf. *Dickinson v. Zurko*, 527 U.S. 150, 162–63 (1999) (finding the difference between the Administrative Procedure Act’s “substantial evidence” standard and Federal Rule of Civil Procedure 52(a)’s “clearly erroneous” standard is “subtle” and that the Federal Circuit “overstate[d] the difference that a change of standard will mean in practice”).

159. See, e.g., *Allergan, Inc. v. Apotex, Inc.*, No. 1:10-CV-681, 2013 WL 286251, at *9–10 (M.D.N.C. Jan. 24, 2013) (holding defendant failed to prove invalidity by clear and convincing evidence), *rev’d in relevant part by a divided panel*, 754 F.3d 952, 966 (Fed. Cir. 2014).

160. CHRIS BARRY ET AL., PRICEWATERHOUSECOOPERS LLP, 2014 PATENT LITIGATION STUDY: AS CASE VOLUME LEAPS, DAMAGES CONTINUE GENERAL DECLINE 16 (2014), http://www.pwc.com/en_US/us/forensic-services/publications/assets/2014-patent-litigation-study.pdf.

161. 35 U.S.C. §§ 316 (a)(11), 326(a)(11). The PTAB can extend this twelve-month period by an additional six months for “good cause.” *Id.*

162. A patent owner’s preliminary response must be filed within three months of the petition, 37 C.F.R. § 42.107 (2014), and the PTAB must decide whether to institute the IPR or PGR within three months of the preliminary response, 35 U.S.C. §§ 314(b), 324(c).

163. E.g., *Merck & Co. v. Apotex, Inc.*, 292 F. App’x 38, 41 (Fed. Cir. 2008) (per curiam) (affirming dismissal for lack of standing under *MedImmune*) (“Even with prompt action by this panel, the final judgment sought by Apotex cannot be provided in time to be meaningful.”).

\$500,000,¹⁶⁴ while patent litigation can cost several million dollars.¹⁶⁵ Ultimately, a generic firm would be well advised to carefully consider the full implications of its particular situation before pursuing an IPR or PGR.¹⁶⁶

Fourth, the scope of discovery available to the parties in an IPR or PGR is much more limited than in a district court action. In an IPR, discovery is limited to deposing witnesses who submitted affidavits or declarations and “what is otherwise necessary in the interest of justice.”¹⁶⁷ In a PGR, “discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding.”¹⁶⁸ By contrast, in district court “any nonprivileged matter that is relevant to any party’s claim or defense” is generally discoverable.¹⁶⁹ Thus, IPRs and PGRs might be attractive to generic firms that wish to challenge a pioneer patent on only a specific and narrow ground, making additional discovery unnecessary.¹⁷⁰ Whether a generic firm will find an IPR or PGR suitable will depend on its individual circumstances.¹⁷¹

Many patent challengers already utilize these new proceedings, and their popularity is quickly growing.¹⁷² Patent challengers are on pace to file nearly 2,000 IPRs in fiscal year 2015.¹⁷³ In the biochemistry/organic chemistry field, patent challengers are on pace for approximately 150 IPRs in fiscal year 2015.¹⁷⁴ Although these figures fall short of the nearly 6,500 total patent lawsuits filed in district courts in 2013¹⁷⁵ (approximately 260 of which were filed pursuant to the Hatch-Waxman Act),¹⁷⁶ it remains to be seen how prominent a role PTAB proceedings will play in the resolution of patent disputes, particularly Hatch-Waxman disputes. Additionally, in December

164. Tom Engellenner, *Comparison of Federal Court, ITC, and USPTO Proceedings in IP Disputes*, AIPLA 31 (Jan. 2014), http://www.aipla.org/committees/committee_pages/IP-Practice-in-Japan/Committee%20Documents/2014%20MWI%20Presentations/Tom%20Engellenner%20-%20IP%20Dispute%20Cost%20Comparison.ppt.

165. AM. INTELLECTUAL PROP. LAW ASS’N, 2013 REPORT OF THE ECONOMIC SURVEY, <http://www.patentinsurance.com/custdocs/2013aipla%20survey.pdf>.

166. Walters & Verkuil, *supra* note 150, at 7.

167. 35 U.S.C. § 316(a)(5).

168. *Id.* § 326(a)(5).

169. FED. R. CIV. P. 26(b)(1).

170. Walters & Verkuil, *supra* note 150, at 4.

171. For example, small entities could be at a disadvantage in the “complex procedural web” of the new PTAB proceedings. Mark Consilvio & Jonathan R.K. Stroud, *Unraveling the USPTO’s Tangled Web: An Empirical Analysis of the Complex World of Post-Issuance Patent Proceedings*, 21 J. INTEL. PROP. L. 33, 36–37 (2013).

172. See USPTO, AIA PROGRESS STATISTICS, http://www.uspto.gov/ip/boards/bpai/stats/aia_trial_statistics.jsp (last updated Mar. 19, 2015).

173. See *id.*

174. *Id.*

175. BARRY ET AL., *supra* note 160, at 5.

176. BRIAN C. HOWARD & JASON MAPLES, LEX MACHINA, HATCH-WAXMAN/ANDA LITIGATION REPORT 3 (2014).

2014 the PTAB issued its first set of final written decisions in a pharmaceutical patent dispute that could otherwise be the subject of Hatch-Waxman litigation.¹⁷⁷ The patent owner prevailed,¹⁷⁸ and the challenger did not appeal the PTAB's decision.¹⁷⁹ Thus, neither the FDA nor a court has addressed how an IPR or PGR final written decision interacts with the failure to market provision.¹⁸⁰

B. *IPRs and PGRs Are Unlikely to Fall Within the Failure to Market Provision*

Whether the failure to market provision extends to IPRs and PGRs is fundamentally a question of statutory interpretation. Adopting an inclusive interpretation would be consistent with the broad scope of estoppel that attaches to IPRs and PGRs and would effectuate the same result as a legislative change. Given the language of the Hatch-Waxman Act and the AIA, however, neither the FDA nor a court is likely to adopt an inclusive interpretation, especially in a highly regulated field.

1. The Language of Both the Hatch-Waxman Act and the AIA Strongly Supports an Exclusive Construction

The plain text of the failure to market provision does not support including IPRs or PGRs within its scope. The statute's triggering event is a determination of noninfringement or invalidity from "an infringement action or a declaratory judgment action."¹⁸¹ Neither an IPR nor a PGR is an infringement action; IPRs and PGRs determine questions of patent *validity*,

177. Aaron Vehling, *PTAB Backs 3 Oracea Patents in 1st-Ever Pharma AIA Ruling*, *Law 360* (Dec. 10, 2014, 2:12 PM), <http://www.law360.com/articles/603169/ptab-backs-3-oracea-patents-in-1st-ever-pharma-aia-ruling>; see *Amneal Pharm., LLC v. Supernus Pharm., Inc.*, No. IPR2013-00368, 2014 WL 6998034, at *8 (P.T.A.B. Dec. 9, 2014) (holding challenged patent claims not invalid); *Amneal Pharm., LLC v. Supernus Pharm., Inc.*, No. IPR2013-00371, 2014 WL 6998035, at *8 (P.T.A.B. Dec. 9, 2014) (same); *Amneal Pharm., LLC v. Supernus Pharm., Inc.*, No. IPR2013-00372, 2014 WL 6998115, at *8 (P.T.A.B. Dec. 9, 2014) (same). None of these decisions appear docketed for appeal in the Federal Circuit.

As of March, 2015, four pharmaceutical IPRs settled before the PTAB issued a final written decision: IPR2013-00012, IPR2013-00015, IPR2013-00024, and IPR2014-00160. Fourteen pharmaceutical IPRs are due for final written decisions in 2015: IPR2014-00115, IPR2014-00325, IPR2014-00360, IPR2014-00376, IPR2014-00377, IPR2014-00378, IPR2014-00379, IPR2014-00549, IPR2014-00550, IPR2014-00652, IPR2014-00654, IPR2014-00656, IPR2014-00784, and IPR2014-00876. Numerous pharmaceutical IPRs are pending and awaiting PTAB action in 2016.

178. *Amneal*, 2014 WL 6998034, at *8; *Amneal*, 2014 WL 6998035, at *8; *Amneal*, 2014 WL 6998115, at *8.

179. Most appeals take nine to twelve months. *Median Disposition Time for Cases Decided by Merits Panels*, U.S. CT. APP. FED. CIR., http://www.cafc.uscourts.gov/images/stories/Statistics/med%20disp%20time%20merits_chart.pdf (last visited Mar. 27, 2015).

180. See Matias Ferrario et al., *The Use of Inter Partes Review Petitions in ANDA Litigation*, ABA (Aug. 4, 2014), <http://apps.americanbar.org/litigation/committees/intellectual/articles/summer2014-0814-use-inter-partes-review-petitions-anda-litigation.html>.

181. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) (2012).

not patent *infringement*.¹⁸² Thus, the issue would be whether IPRs or PGRs are “declaratory judgment actions.” The statute frequently uses the term “declaratory judgment” with specific reference to the Declaratory Judgment Act,¹⁸³ suggesting that the term should not be broadened to include IPRs or PGRs.¹⁸⁴ Although IPRs, PGRs, and infringement actions all originate pursuant to title 35,¹⁸⁵ declaratory judgment actions originate pursuant to title 28.¹⁸⁶ The explicit references to title 28 in the failure to market provision strongly suggest that neither IPRs nor PGRs fall within the plain meaning of the forfeiture statute.¹⁸⁷

The backdrop against which the MMA-enacting Congress legislated supports excluding IPRs and PGRs from any judicial or agency construction of the forfeiture statute. When Congress enacted the MMA in 2003, a third party could challenge the validity of an issued patent in two other PTO administrative proceedings: “ex partes reexamination”¹⁸⁸ and “optional inter partes reexamination.”¹⁸⁹ Congress did not include these older proceedings in the MMA forfeiture provisions in 2003.¹⁹⁰ Thus, the MMA-enacting Congress presumably intended for only litigation to trigger forfeiture. It is also possible, however, that this was a simple oversight.

Next, the IPR and PGR statutes do not support an interpretation that either proceeding is a “declaratory judgment action.” Sections 315 and 325 of title 35 frequently use the words “proceeding” and “matter” to reference the IPR or PGR, while referring separately to “civil actions.”¹⁹¹ There is no reference in the IPR or PGR statutes to the Hatch-Waxman Act, the MMA, or any other related statute that would suggest an IPR or PGR triggers the failure to market provision—a provision that existed in 2011 when Congress created IPRs and PGRs. This clear delineation between litigation and administrative proceedings strongly suggests that Congress did not intend the two to be interchangeable.

The presence of another provision in the AIA, separate from the IPR and PGR provisions, supports excluding IPRs and PGRs from the failure to market provision. Section 12 of the AIA, though not directly related to IPRs

182. 35 U.S.C. §§ 311(b), 321(b) (2012). Infringement of patents is governed by §§ 271–273 of title 35.

183. 28 U.S.C. §§ 2201–2202 (2012).

184. 21 U.S.C. § 355(c)(3)(D)(i)(I) (“No action may be brought under section 2201 of title 28 . . . for a declaratory judgment . . .”); *id.* § 355 (j)(5)(C)(i)(I) (same).

185. 35 U.S.C. §§ 271–273, 311–319, 321–329.

186. 28 U.S.C. §§ 2201–2202.

187. *See Sullivan v. Hudson*, 490 U.S. 877, 894 (1989) (White, J., dissenting) (concluding that the plain meaning of “civil action” in 28 U.S.C. § 2412(d)(1)(A) excludes administrative proceedings).

188. 35 U.S.C. §§ 301–307.

189. *Id.* §§ 311–319.

190. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in relevant part at 21 U.S.C. § 355(j)(5)(D)(i)(I)–(IV) (2012)).

191. 35 U.S.C. §§ 315, 325.

or PGRs, specifically references litigation pursuant to the Hatch-Waxman Act.¹⁹² Thus, the AIA-enacting Congress presumably legislated with full awareness of the Hatch-Waxman Act and was capable of amending the forfeiture provisions to include the new PTAB proceedings, but chose not to.¹⁹³ Furthermore, because IPRs and PGRs are different from declaratory judgment actions,¹⁹⁴ Congress arguably could have wanted it to be easier to invalidate patents generally, but not easier to trigger forfeiture of exclusivity for pharmaceutical patents. Although this too was probably an oversight by Congress in a complex area of law, a court or the FDA would be unlikely to adopt an inclusive interpretation in light of the powerful textual arguments available.

2. Neither a Court nor the FDA Would Be Likely to Adopt an Inclusive Construction of the Failure to Market Provision

The strongest arguments for an inclusive construction flow from the broad estoppel effect of IPRs and PGRs. After an IPR or PGR, a patent challenger “may not assert . . . that the [patent] claim is invalid on any ground that the petitioner raised or reasonably could have raised” during the IPR or PGR.¹⁹⁵ This estoppel attaches to any future PTO proceeding, action before the International Trade Commission, or declaratory judgment action,¹⁹⁶ and an IPR or PGR final decision is only appealable directly to the Court of Appeals for the Federal Circuit.¹⁹⁷ The estoppel also operates in reverse: if the patent challenger files for declaratory judgment of patent invalidity, the challenger may not pursue an IPR or PGR.¹⁹⁸ In effect, the AIA directly replaced certain types of declaratory judgment actions with IPRs and PGRs to reduce the amount of patent litigation.¹⁹⁹ Without the estoppel attached to IPRs and PGRs, litigation in district court might not be reduced.

Interpreting the forfeiture provision to *exclude* IPRs and PGRs could lead to an unusual result—an IPR or PGR final decision of invalidity affirmed on appeal could actually *prevent* the challenger from triggering a forfeiture event.²⁰⁰ If neither the PTAB’s final decision nor the Court of

192. *Id.* § 257(c)(2)(A) (“Paragraph (1) shall not apply to . . . a notice received by the patent owner under . . . the Federal Food, Drug, and Cosmetic Act . . .”).

193. *See* 157 CONG. REC. S5405 (daily ed. Sept. 8, 2011) (statement of Sen. Grassley) (“Congress certainly should not expect nor allow mistakes by the bureaucracy to up-end the rights and provisions included in the Hatch-Waxman Act.”).

194. *See supra* Section III.A.

195. 35 U.S.C. §§ 315(e), 325(e).

196. *Id.*

197. *Id.* §§ 319, 329.

198. *Id.* §§ 315(a)(1), 325(a)(1). This form of estoppel does not apply if the declaratory judgment action is a counterclaim to an infringement action. *Id.* §§ 315(a)(3), 325(a)(3).

199. *See supra* Section I.B.

200. *See* H. Keeto Sabharwal & Dennies Varughese, *How Inter Partes Review Impacts Hatch-Waxman Exclusivity*, LAW360 (Feb. 27, 2013), <http://www.law360.com/articles/417119/how-inter-partes-review-impacts-hatch-waxman-exclusivity>.

Appeals's decision falls within the bounds of the forfeiture statute, the prevailing patent challenger would be forced to go back to a district court to obtain a consistent declaratory judgment *pro forma*—to the extent that the case is not moot—to trigger forfeiture.²⁰¹ But, as described above, the challenger is estopped from bringing the action and may not even have a justiciable case or controversy.²⁰²

Arguing for a broad statutory construction would not be unprecedented in this context, but would likely be unsuccessful. In *Sullivan v. Hudson*,²⁰³ the Supreme Court construed the phrase “civil action” in a fee-shifting statute to include related administrative proceedings because the administrative proceedings were “intimately tied to the resolution of the judicial action and necessary to the attainment of the results Congress sought to promote.”²⁰⁴ An IPR or PGR by a later-filing generic firm might meet these two criteria. Not only is the IPR or PGR “intimately tied” to a potential co-pending district court action, but the IPR effectively replaces it.²⁰⁵ Also, using an IPR effectuates the results that the MMA-enacting Congress sought to promote. Congress envisioned that “[u]nder the failure to market provision, the conditions for forfeiture [would] be satisfied when a generic company has resolved patent disputes on all the patents that earned the [first filer] its exclusivity.”²⁰⁶ Due to the estoppel that attaches to IPRs and PGRs, an invalidity ruling from the PTAB resolves the patent dispute, thereby satisfying the condition Congress thought sufficient to trigger forfeiture and force the first filer to enter the market. The analogy to *Sullivan v. Hudson* fails, however, because neither an IPR nor PGR is a *necessary* condition to resolve the patent dispute; it is simply a sufficient one. A patent challenger can choose whether to file a declaratory judgment action or a PTAB proceeding. Both lead to a resolution of the dispute, but neither one is necessary to resolve the dispute.

A later-filing generic firm that prevails in an IPR or PGR could petition the FDA to determine whether the PTAB's decision falls within the language of the forfeiture provision. If the FDA adopts an interpretation that excludes IPRs and PGRs from the statutory language, the later filer would face a tremendous obstacle if a reviewing court affords the FDA *Chevron* deference for its interpretation.²⁰⁷ The FDA has a track record of strictly interpreting

201. *See id.*

202. *Id.* *But see, infra* notes 142–147 and accompanying text.

203. 490 U.S. 877 (1989).

204. *Sullivan*, 490 U.S. at 888. *But see* *Schindler v. Sec'y of Dep't of Health & Human Servs.*, 29 F.3d 607, 609–11 (Fed. Cir. 1994) (construing the phrase “civil action” to exclude a probate proceeding, even though the construction would lead to double recovery contrary to congressional intent).

205. 35 U.S.C. § 315(e) (2012).

206. 149 CONG. REC. S15885 (daily ed. Nov. 25, 2003) (statement of Senator Kennedy) (discussing the intended purpose of the failure to market provision).

207. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). When a court reviews an agency interpretation of law, it first asks if Congress has directly spoken to the question at hand. If not, then the court simply inquires if the agency's interpretation is a

the Hatch-Waxman Act.²⁰⁸ For example, the FDA interpreted a different part of the failure to market provision²⁰⁹ to effectively allow a pioneer to “pull the rug” out from under the first filer by removing the patent from the FDA’s official list of patents on approved drugs, triggering forfeiture of the first filer’s 180-day exclusivity.²¹⁰ The Court of Appeals for the D.C. Circuit overturned the FDA’s interpretation, determining that removal of a patent from the FDA’s official list only triggers forfeiture if done by court order, rather than by the voluntary act of the pioneer.²¹¹ The FDA also strictly interpreted one of the MMA’s other forfeiture provisions: the “failure to obtain tentative approval” provision.²¹² Under this provision, the exclusivity is forfeited if the first filer “fails to obtain tentative approval . . . within 30 months after . . . the [ANDA] is filed, unless the failure is caused by a change in or a review of the requirements . . . imposed after . . . the [ANDA] is filed.”²¹³ This provision was designed to prevent generic firms from quickly filing poor quality ANDAs in order to obtain the 180-day exclusivity when final approval might come several years later.²¹⁴ Initially, the FDA construed the second half of the provision (excusing a delay stemming from a change in review requirements) in a “very narrow and draconian” fashion.²¹⁵ Applying an *expressio unius* argument, the FDA stated:

reasonable one. *Id.* at 842–43. A recent Federal Circuit case suggests the FDA would receive *Chevron* deference. *See Apotex, Inc. v. Daiichi Sankyo, Inc.*, No. 2014-1282, 2015 WL 1423624, at *9 (Fed. Cir. Mar. 31, 2015) (“[The parties] do not suggest that, were a non-infringement judgment to issue [to the later-filer] in this case, the FDA would nonetheless consider it inadequate to trigger forfeiture of [the first filer]’s exclusivity period based on a restrictive view of the forfeiture provisions *that is entitled to judicial deference.*” (emphasis added)).

208. *See, e.g., Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1317–18 (D.C. Cir. 2010); Letter from Gary Buehler, Dir., Office of Generic Drugs, Ctr. For Drug Evaluation and Research, FDA, to ANDA Applicant 8–9 (Oct. 28, 2008) [hereinafter *Dorzolamide Letter*], <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CenterforDrugEvaluationandResearch/ucm119602.pdf>; *Granisetron Letter*, *supra* note 126, at 5–6.

209. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) (2012).

210. *Teva*, 595 F.3d at 1305. The FDA’s official list of patents that protect approved drugs is colloquially called the “Orange Book.” FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS: PUBLICATIONS, <http://www.accessdata.fda.gov/scripts/cder/ob/eclink.cfm>.

211. *See Teva*, 595 F.3d at 1317.

212. 21 U.S.C. § 355(j)(5)(D)(i)(IV).

213. *Id.* Section 1133 of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, 126 Stat. 993, 1122 (2012), extended this thirty-month period to forty months for some applications and thirty-six months for others to allow the FDA to process a backlog of ANDAs, *US FDA Extends Timeline for Generic Drug Approval*, *BioSPECTRUM* (last updated Oct. 29, 2012), <http://www.biospectrumasia.com/biospectrum/news/121139/us-fda-extends-timeline-generic-drug-approval>.

214. *See Upadhye*, *supra* note 86, at 1326.

215. Kurt R. Karst, *OGD Management Review Results in Forfeiture of Generic ACTONEL 180-Day Exclusivity Eligibility*, *FDA L. BLOG* (Sept. 1, 2014, 4:34 PM), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/09/ogd-management-review-results-in-forfeiture-of-generic-actonel-180-day-exclusivity-eligibility-.html.

This express description of the circumstances in which exclusivity will not be forfeited for failure to obtain tentative approval makes it clear that, under other circumstances in which an applicant has failed to obtain tentative approval, *regardless of what party might be responsible for that failure*, the first applicant will forfeit exclusivity.²¹⁶

The FDA's hard-line stance has been dubbed "our failure is your failure."²¹⁷ Although the FDA has been lenient in some circumstances,²¹⁸ the FDA remains committed to this position.²¹⁹

Finally, pharmaceuticals are a highly regulated industry, and courts usually defer to Congress and agencies in such instances.²²⁰ Congress has spoken frequently and recently in matters related to pharmaceutical approval and patent disputes: the Hatch-Waxman Act in 1984, the America Inventors Protection Act of 1999,²²¹ the MMA in 2003, and the AIA in 2012. Furthermore, the "balance between incentives . . . for innovation[] and . . . for quickly getting lower-cost generic drugs to market" is "quintessentially a matter for legislative judgment, [and] the court must attend closely to the terms in which the Congress expressed that judgment."²²² Thus, an amendment to the statute by Congress is the only workable solution.²²³

C. Using IPRs and PGRs to Trigger Forfeiture Would Likely Require Congressional Action

Because neither a court nor the FDA is likely to construe the failure to market provision to include IPRs and PGRs, statutory change is required to bring IPRs and PGRs within the failure to market provision. Amending the

216. Dorzolamide Letter, *supra* note 208, at 9 (emphasis added).

217. Karst, *supra* note 215.

218. See e.g., Letter from Gary Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, FDA, to Marcy Macdonald, Dir., Regulatory Affairs, Sandoz, Inc. 2–3 (Mar. 31, 2010), http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/040445s000ltr.pdf (determining exclusivity not forfeited when drug's labeling requirement remained under review); Letter from Gary Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, FDA, to Nicholas Tantillo, Senior Dir., Regulatory Affairs, Barr Labs., Inc. 2 (July 30, 2009), http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2009/078104s000ltr.pdf (declining to determine if a first filer forfeited exclusivity until another applicant becomes eligible for approval); Letter from Janet Woodcock, Dir., Ctr. For Drug Evaluation and Research, FDA, to Stephen Auten, Vice President, Sandoz, Inc. 9 (Sept. 20, 2011), <http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0632-0017> (determining exclusivity was not forfeited when first filer chose to change drug's formulation from a sealed glass ampule to a stoppered glass vial).

219. See Memorandum from Robert L. West, Deputy Dir., Office of Generic Drugs, FDA, to ANDA 079215, Teva Pharmaceuticals USA (June 10, 2014), <http://www.fdalawblog.net/AC-TONEL%20-%20180-Day%20Exclusivity%20Forfeiture%20FDA%20Letter%20Decision.pdf>.

220. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142–45 (2000); *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–44 (1984).

221. American Inventors Protection Act of 1999, Pub. L. 106-113 app. I, 113 Stat. 1501A–521.

222. *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005).

223. See *Brown & Williamson*, 529 U.S. at 155–56.

failure to market provision would remove uncertainty from a field in which so much is at stake, and an appropriate amendment would further the goals of both the Hatch-Waxman framework and the AIA. Adding the following italicized words to the failure to market provision at 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) would effectuate this result:

In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent *or in an administrative proceeding with respect to the patent*, a court *or agency* enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.²²⁴

First, this amendment would provide greater procedural certainty for later filers that wish to unpark a first filer's exclusivity. Utilizing an IPR or PGR avoids potential uncertainty concerning standing in a declaratory judgment action and the uncertainty of how to prove a pay-for-delay rule of reason antitrust violation. More to the point, this amendment would confirm that IPRs and PGRs can be used to trigger forfeiture under the failure to market provision. Uncertainty, especially in the pharmaceutical industry, can cause huge fluctuations in stock prices, making business executives and investors particularly anxious.²²⁵

Second, this amendment would further the goals of the Hatch-Waxman Act as amended by the MMA. This amendment would assure later filers that their successful IPR or PGR will unpark a first filer's exclusivity, consistent with Congress's intent.²²⁶ For some generic firms, this amendment would provide a preferable alternative to litigation as a way of triggering forfeiture. Ultimately unparking the first filer's exclusivity facilitates Congress's original goal of getting cheaper drugs to consumers via full competition after the first filer's exclusivity elapses.²²⁷

Third, this amendment would further the goals of the AIA. The AIA-enacting Congress wanted to remove some patent disputes from district courts and put them in front of a more technically competent agency.²²⁸ If an IPR or PGR of a pharmaceutical patent lacks the effect of a declaratory judgment action for Hatch-Waxman purposes, neither first filers nor later

224. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (2012). Although this Note proposes legislative change, a court or agency decision that adopts an inclusive interpretation would effectuate the same result.

225. See John Osborn, *Supreme Court Punts on Pay For Delay, But Will Generic Filings Under Hatch-Waxman Decline?*, FORBES (June 26, 2013, 5:37 PM), <http://www.forbes.com/sites/johnosborn/2013/06/26/will-the-supreme-courts-opinion-on-patent-settlements-deter-generic-filings-under-hatch-waxman/> (discussing the business and economic harms from patent uncertainty in the litigation context).

226. See 149 CONG. REC. S15885 (daily ed. Nov. 25, 2003) (statement of Senator Kennedy).

227. See *supra* notes 58–69 and accompanying text.

228. See H.R. REP. NO. 112-98, pt. 1, at 38–40 (2011).

filers will pursue the new PTAB proceedings. Consequently, pharmaceutical patent disputes will remain in district courts.

Other options for reducing exclusivity parking remain viable, but involve more sweeping change. For example, Congress could legislatively modify *Actavis* to afford the FTC (and private parties too, potentially) greater leverage in fighting pay-for-delay settlements under the antitrust laws.²²⁹ Another option would be to reduce the ability of the pioneer to market its own “authorized generic” which competes with the first filer during the 180-day exclusivity period, depriving the first filer of its full reward.²³⁰ Yet another option would be to tie the 180-day exclusivity to the first generic firm to prevail in court, rather than the first to submit its ANDA to the FDA.²³¹ These options, however, propose a similar kind of overhaul to the one the MMA-enacting Congress rejected.²³² Significantly reforming these statutes risks unintended consequences.

This proposed amendment is by no means a complete fix to the exclusivity parking problem. As mentioned, IPRs and PGRs can be settled,²³³ meaning that later-filing generic firms could use IPRs as leverage to extract their own settlements from the pioneer companies. While settlements that do not unpark the first filer’s exclusivity do not lead to timely full competition, the prospect of paying off multiple later filers might incentivize the pioneer and first filer to refrain from entering into a pay-for-delay settlement in the first instance.

Furthermore, this proposed amendment allows a *first filer* to defeat a pioneer patent more quickly and more cheaply. If it were easier to defeat a pioneer patent, Congress should reduce the length of the exclusivity for first filers that defeat pioneer patents in an administrative proceeding; less “reward” would be needed for less expense and risk, and full generic competition could occur sooner.

This amendment is a modest change and a good first step. It would clarify one ambiguity in a complex statutory scheme without overhauling the basic regulatory process. This amendment advances the goals of both the Hatch-Waxman Act and the AIA and contains a relatively low risk of unintended consequences. Exclusivity parking itself was an unintended consequence of major reform, so Congress should proceed cautiously with even moderate reforms. This specific, narrow amendment can be done now.

CONCLUSION

Patents incentivize pioneer drug developers to search for treatments for medical conditions and help offset the substantial cost of ensuring new

229. See Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 94–96 (2009).

230. See *id.* at 97–99.

231. See *id.* at 99–103.

232. See *supra* notes 85–86 and accompanying text.

233. See *supra* note 83 and accompanying text.

drugs are both safe and effective. Greater patent protection fuels innovation for life-saving drugs, but at the cost of some affordability. With the Hatch-Waxman Act, Congress struck a balance between innovation and competition. The practice of exclusivity parking upsets that balance. Although some scholars argue that the 180-day exclusivity period should not be used as a way to effectuate greater generic competition,²³⁴ it is the mechanism Congress has chosen and reaffirmed.²³⁵

Congressional efforts to close the loopholes that allow exclusivity parking have proven marginal at best. Antitrust plaintiffs face a multiyear uphill battle to prevail in rule of reason cases and significant uncertainty about courts' receptiveness to various types of evidence and arguments. Similarly, the MMA's poorly drafted failure to market provision has proven toothless for later filers attempting to unpark a first filer's exclusivity with declaratory judgment actions.

New administrative proceedings before the PTAB offer an alternative solution. Under the present statutory language, however, these new proceedings will likely prove ineffective for later-filing generic firms at triggering the failure to market provision. Neither a court nor the FDA is likely to adopt a broad enough construction of the failure to market statute to accommodate the new PTAB proceedings. Thus, amending the failure to market provision to include administrative proceedings would remove the uncertainty in the field and help return the Hatch-Waxman Act to its originally intended balance.

234. See Upadhye, *supra* note 86, at 1325–26 n.70 (noting that other countries without a generic exclusivity period maintain a robust generic drug industry base and that exclusivity is “not a necessary predicate to generic drug development”).

235. See *supra* notes 85–86 and accompanying text.

