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

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Congress created the unique Hatch-Waxman framework to increase the availability of low-cost generic drugs while preserving patent incentives for new drug development. The Hatch-Waxman Act provides a reward for generic drug companies that successfully challenge a pharmaceutical patent: 180 days of market exclusivity before any other generic can enter the market. When a generic obtains this reward, sometimes drug developers agree to pay generics 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 which 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 the practice of 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 their large up-front development costs through above-cost pricing. On the other hand, lower pricing from more 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 Hatch-Waxman 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—to develop new drugs by extending the term of drug patents. Pioneers rely on patent protection for new drugs (as well as methods of making and using new drugs) in order 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]—i.e. compliance with the patent laws—it is not uncommon for courts to determine that some patents are 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, as part of the Hatch-Waxman Act, an

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[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] 98 Stat. 1585, Pub. L. 98-417 (1984).
[4] The Act is named for two of the statute's sponsors: Sen. Orrin Hatch and Rep. Henry Waxman.
[5] H.R. REP. 98-857, pt. 1, at 14–15.
[6] *E.g.*, WENDY H. SCHACHT & JOHN R. THOMAS, PHARMACEUTICAL PATENT TERM EXTENSIONS: A BRIEF EXPLANATION 1, Cong. Research Service (Jan. 31, 2002), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RS21129.pdf.
[7] 35 U.S.C. § 282 (2012).
[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, 1352 (Fed. Cir. 2013).
[9] *See infra* Section I.A.

incentive for generics to challenge—e.g. litigate—pioneer patents: 180 days of market exclusivity, enforced by the United States Food & Drug Administration (FDA) for the first generic to challenge to a pioneer patent (a "first-filer"). 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.[10]

This scheme created an unintended consequence: "exclusivity parking." Exclusivity parking occurs when a first-filer who can otherwise enter the market refrains from doing so. Because of the way the statute is worded, no other generics can enter the market until after the first-filer's 180-day market exclusivity elapses.[11] 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 generics waiting to enter the market became frustrated with first-filers parking their exclusivity. In 2003, Congress attempted to close some of the loopholes that allowed first-filers to park their exclusivity.[12] Effectively, Congress wanted the first-filer to use it or lose it. One of these provisions, the "failure to market" provision, is triggered if the first-filer *or any other generic waiting to enter the market* prevails in litigation against the pioneer.[13] The failure to market provision, however, was poorly drafted and has proven toothless.[14] Today, other generics frequently lack the incentive to incur litigation costs in an attempt to unpark the first-filer, and the practice of exclusivity parking continues largely unaffected.[15]

In 2011, Congress enacted major reforms to the patent system when it passed the Leahy-Smith America Invents Act (AIA).[16] Among its many provisions, the AIA created several quasi-judicial administrative proceedings in the United States Patent & Trademark Office (USPTO) to permit a party to challenge the validity of a

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[10] *See infra* Section I.A.
[11] *See infra* Section I.A.
[12] *See infra* Section I.A.
[13] 21 U.S.C. § 355(j)(5)(D)(i)(I) (2012).
[14] *See infra* notes 128–129 and accompanying text.
[15] *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 1 (2010) [hereinafter FTC, *Pay-for-Delay*], *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.
[16] Pub. L. No. 112-29, 125 Stat. 284 (2011).

duly issued patent.[17] These proceedings present patent challengers, including generics, with an alternative 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 new quasi-judicial administrative proceedings trigger the failure to market provision in the Hatch-Waxman Act and unpark the first-filer's exclusivity?

No court or agency has addressed this question.[18] 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 FDA nor a court is likely to construe the Hatch-Waxman Act's language broad enough to incorporate IPRs and PGRs,[19] the failure to market provision will likely require 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 current attempts to eliminate exclusivity parking remain ineffective. Part III argues that IPRs and PGRs present workable alternative forums for challenging 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 ease of 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 patent administrative proceedings created by the AIA.

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

Due to the high cost of drug development,[20] the pharmaceutical industry relies heavily on the patent system as part of its business model.[21] Because the patent laws prohibit an inventor from obtaining a patent on an invention that was used more than one year before applying for a patent,[22] drug developers must often obtain

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[17] *See infra* Section I.B.
[18] *See infra* notes 169–171 and accompanying text.
[19] *See infra* Section III.B.
[20] 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 over $1 billion per drug).
[21] Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93 (2004).
[22] 35 U.S.C. § 102(a) (2012).

a patent on a new drug well before FDA approval[23] which can take up to twelve years.[24] Thus, while the standard patent term is twenty years,[25] "the *effective* patent term [for pharmaceuticals] is frequently less than [twenty] years because patents are often obtained before products are actually marketed."[26]

Before 1984, companies seeking to market generic versions of previously approved drugs were required to complete the same safety and efficacy testing (i.e. clinical trials) as the pioneer drug.[27] At the time, approximately 150 pioneer drugs with expired patents had no generic equivalent.[28] Consequently, the 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 competition.[29] By comparison, once a drug is no longer patent-protected and competes head-to-head with generics, the price reduces by an average of eighty to eighty-five percent.[30] Substituting generic drugs for pioneer drugs reduces government spending on healthcare[31] and could mean the difference between a $5 and $20 copay for consumers.[32]

The Drug Price Competition and Patent Term Restoration Act,[33] colloquially referred to as the "Hatch-Waxman Act,"[34] was a landmark piece of legislation intended to make low-cost generic drugs more available.[35] Specifically, the Hatch-Waxman Act significantly reduced generic entry barriers through the creation of the Abbreviated New Drug Application (ANDA).[36] By utilizing an ANDA, a generic is

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[23] *E.g.*, Scott v. Finney, 34 F.3d 1058, 1063 (Fed. Cir. 1994).
[24] CHOW & LIU, *supra* note 20, at 5.
[25] 35 U.S.C. § 154(a)(2) (2012).
[26] *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).
[27] H.R. REP. 98-857, pt. 2, at 4 (1984).
[28] 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).
[29] *Id.*
[30] *Facts About Generics*, FDA, http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm#_ftnref3 (last updated Sept. 19, 2012).
[31] John E. Dicken, *Drug Pricing: Research on Savings from Generic Drug Use*, GAO (Jan. 31, 2012) at 4, *available at* http://www.gao.gov/assets/590/588064.pdf.
[32] Virgil Dickson, *Reform Update: Generic Drugs' High Prices Spur Rears of Failed Drug Adherence*, MODERN HEALTHCARE (Oct. 9, 2014), http://www.modernhealthcare.com/article/20141009/NEWS/310099962.
[33] Pub. L. 98-417, 98 Stat. 1585 (1984).
[34] *E.g.*, F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013).
[35] H.R. REP. 98-857, pt. 1, at 14–15 (1984).
[36] Pub. L. 98-417, § 101, 98 Stat. 1585, 1585–92 (1984) (codified at 21 U.S.C. § 355(j)).

not required to submit detailed clinical trial data to show safety and efficacy.[37] Instead, a generic utilizing an ANDA must certify that their drug will have the same active ingredients, dosage, strength, form (e.g. pill, intravenous, surgical implant, etc.), and packaging as the already-approved pioneer drug[38] (also known as reference listed drug or RLD),[39] and that the generic drug is "bioequivalent" to the RLD—i.e. has similar chemical interactions in the human body as the pioneer drug.[40]

Because ANDAs effectively allow generics to "piggyback" or "short-cut" the extensive clinical trial work financed by the pioneer drug developer,[41] the Hatch-Waxman Act provided for extension of the pioneer patent term beyond the twenty-year baseline to account for regulatory delays during drug development.[42] In this way, the Hatch-Waxman 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."[43]

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:

> (I) that such patent information has not been filed [with FDA],
> (II) that such patent has expired,
> (III) of 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 submitted.[44]

Paragraph (I) and (II) certifications are for drugs without patent protection. If the applicant makes a paragraph (III) certification, the ANDA will be approved when the patent expires,[45] allowing for immediate generic entry upon patent expiration.[46]

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[37] 21 U.S.C. § 355(j)(2)(A) (2012).
[38] *Id.* § 355(j)(2)(A).
[39] 21 C.F.R. 314.94(a)(3) (2014).
[40] 21 U.S.C. § 355(j)(8) (2012). *See generally Abbreviated New Drug Application (ANDA): Generics*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ (last updated Sept. 18, 2014).
[41] Teva Pharm., USA, Inc. v. Leavitt, 548 F.3d 103, 104 (D.C. Cir. 2008).
[42] 35 U.S.C. § 154(b), 156 (2012).
[43] Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002).
[44] 21 U.S.C. § 355(j)(2)(A)(vii) (2012).
[45] *Id.* § 355(j)(5)(B)(ii).
[46] H.R. REP. 98-857, pt 1, at 46 (1984) ("[I]mmediate competition should be encouraged.").

If an ANDA applicant makes a paragraph (IV) certification that the patent is invalid—i.e. 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 must notify the pioneer of the paragraph (IV) certification.[47] Then, the pioneer can sue the generic for patent infringement.[48] If the pioneer sues for patent infringement within forty-five days, FDA must stay approval of the generic's ANDA for thirty months to allow for the resolution of the dispute.[49] If the pioneer does not sue for patent infringement within that forty-five day period, the generic can sue the pioneer for declaratory judgment of patent invalidity or non-infringement in order 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 generic challenges to pioneer patents is on the rise.[52]

The Hatch-Waxman Act created a reward for generics that challenge pioneer patents, incur litigation costs, and risk liability for patent infringement. Specifically, the Hatch-Waxman Act provides a 180-day generic exclusivity window for the first ANDA filer that challenges a pioneer patent with a paragraph (IV) certification followed by litigation against the pioneer.[53] As Senator Hatch explained, "In 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 begins when the first-filer enters the market.[55] The value of this 180-day exclusivity 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 employment of a 180-day exclusivity period in the Hatch-Waxman Act gave rise to a practice known as exclusivity parking. Exclusivity parking occurs when

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[47] 21 U.S.C. § 355(j)(2)(B) (2012).
[48] 35 U.S.C. § 271(e)(2) (2012).
[49] 21 U.S.C. § 355(j)(5)(B)(iii) (2012).
[50] *Id.* § 355(j)(5)(C).
[51] AstraZeneca AB v. Mylan Pharmaceuticals, Inc., No. 14-696-GMS, slip. op at 15 (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) (2012).
[54] 149 CONG. REC. S16104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch).
[55] 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2012).
[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*, 25 BIOTECH. L. REP. 525, 525–26 (2006).

a first-filer, who 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 extends the time that the pioneer can charge monopoly prices on the drug—a portion of which are 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 nearly the full economic benefit of its generic exclusivity—it just occurs later. Exclusivity parking occurs most frequently as a result of patent litigation settlements.[60] Generally, these settlements involve (1) a promise by the first-filer to delay marketing their generic for some period of time, and (2) payment from the pioneer to the first-filer.[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 their intended balance; they only wanted full generic competition reduced by 180 days. Consequently, any further delay runs counter to Congressional intent.[63] Additionally, pay-for-delay settlements cost consumers an estimated $3.5 billion annually,[64] and these agreements have received significant attention from the Federal Trade Commission (FTC) for possibly being in violation of federal antitrust laws.[65] While some might try to 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.[66] In 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Congress amended the Hatch-Waxman Act by creating six provisions under which the first-filer forfeits its 180-day

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[58] Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1067 (D.C. Cir. 1998); Ken Burchfeil, *No Parking? USPTO Relief for Subsequent ¶ IV Filers*, USPTO PATENT TRIALS (Apr. 27, 2012), http://usptopost-grant.com/2012/04/27/1328/.

[59] 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2012).

[60] F.T.C. v. Actavis, 133 S. Ct. 2223, 2227–28 (2013).

[61] *Id.* at 2227. Compensation to the generic can involve more than just a cash payment. *FTC Briefing on Pharmaceutical Pay-For-Delay Settlements*, at 3 (Apr. 25, 2012), http://usptopost-grant.com/wp-content/uploads/2012/04/FTC-Briefing-04-25-2012.pdf.

[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] 149 CONG. REC. S15885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) (discussing the intended process of the 180-day exclusivity period).

[64] FTC, *Pay-for-Delay*, *supra* note 15, at 10.

[65] *See infra* Section II.A.

[66] 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).

exclusivity.[67] 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.[68] Today, new administrative proceedings in the USPTO offer an alternative solution that is quicker and less costly than litigation.

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

In 2011, Congress enacted the most comprehensive changes to the patent laws since 1952.[69] Among other things, the Leahy-Smith America Invents Act[70] (AIA) created new quasi-judicial administrative proceedings in the USPTO where a party can challenge a patent's validity.[71] These new administrative proceedings served 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.[72] Two of these new proceedings are inter partes review (IPR)[73] and post-grant review (PGR).[74]

For challenging a patent's validity, 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 of a patent,[75] and the patent owner can file a preliminary response.[76] This is analogous to the complaint and answer phase of litigation.[77] The scope of the proceeding, however, is limited strictly to questions of patent validity; IPRs and PGRs do not determine questions of patent infringement.[78] If the USPTO institutes the IPR or PGR, the parties submit evidence and take limited discovery including depositions.[79] IPRs and PGRs culminate in an

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[67] Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 21 U.S.C. § 355(j)(5)(D)(i)(I)–(IV)). The MMA's forfeiture provisions are discussed in more detail in Part II, *infra*.
[68] *See* 28 U.S.C. § 1338 (2000).
[69] H.R. REP. No. 112-98, pt. 1, at 38 (2011).
[70] Pub. L. No. 112-29, 125 Stat. 284 (2011).
[71] *Id.* at § 6 (codified at 35 U.S.C. §§ 311–329).
[72] H.R. REP. No. 112-98, pt. 1, at 45–48 (2011).
[73] 35 U.S.C. §§ 311–319 (2012). In an IPR, a patent's validity may only be challenged with respect to novelty, *id.* § 102, and/or nonobviousness, *id.* § 103, and only based on patents or printed publications. *Id.* § 311(b).
[74] *Id.* §§ 321–329. In a PGR, a patent's validity may be challenged on any legal ground. *Id.* § 321(b).
[75] 35 U.S.C. §§ 311(a), 321(a) (2012).
[76] *See id.* §§ 313, 323.
[77] *See* FED. R. CIV. P. 8.
[78] *See infra* notes 143–144 and accompanying text.
[79] 37 C.F.R. §§ 42.51–42.65 (2014); *see* FED. R. CIV. P. 26–37. This discovery, however, is limited. *See infra* notes 160–163 and accompanying text.

oral hearing, similar to a trial or oral argument.[80] Afterwards, the USPTO issues its final decision, which is required by statute to be issued within one year of instituting the IPR or PGR.[81] Finally, similar to traditional litigation, an IPR or PGR can be settled by a joint stipulation of the parties at any time before the Board issues its final decision.[82] In these ways, IPRs and PGRs effectively replace certain invalidity claims that the parties might otherwise litigate in district court, reducing the strain on the federal judiciary. IPRs and PGRs will not be ideal for every patent challenger, but they will be superior to litigation for some challengers depending upon their circumstances.[83] Unfortunately, however, the AIA's provisions for IPRs and PGRs contain no reference to the Hatch-Waxman Act and leave practitioners uncertain how these two statutes interact.

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

While Congress attempted to eliminate the practice of exclusivity parking in 2003, the practice continues largely unabated. When it enacted the MMA, Congress rejected major changes to the Hatch-Waxman Act's major elements.[84] Instead, Congress retained the basic Hatch-Waxman framework and created several forfeiture provisions designed to make the original Hatch-Waxman framework operate more effectively.[85] For example, the first-filer forfeits its exclusivity if the patent in question expires;[86] if the first-filer amends its ANDA to no longer challenge the patent;[87] or if the first-filer withdraws its ANDA entirely.[88] Two provisions in

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[80] 37 C.F.R. § 42.70 (2014).

[81] 35 U.S.C. §§ 316 (a)(11), 326(a)(11) (2012). This timeframe is shorter than traditional patent litigation. *See infra* notes 153–159 and accompanying text.

[82] *Id.* § 317, 327.

[83] *See infra* Section III.A.

[84] 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, 309–313 (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 (Aug. 1, 2003) (statement of Sen. Orrin G. Hatch, Chairman, S. Comm. on the Judiciary).

[85] 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 WILLIAM MITCHELL L. REV. 1307, 1326 (2014).

[86] 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.").

[87] *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.").

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

particular targeted the practice of exclusivity parking[89]: the antitrust provision and the failure to market provision. The effect of these provisions has been marginal at best.[90] Section II.A. explains why the antitrust provision and antitrust actions generally fail to solve the exclusivity parking problem. 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.[91] Naturally, when Congress enacted the MMA, they wanted the first-filer to lose its exclusivity if a court found the agreement illegal.[92] The antitrust provision results in forfeiture of the 180-day exclusivity when, in an action brought by the antitrust agencies, a Federal Court of Appeals finds the pay-for-delay agreement violates the antitrust laws.[93] While fairly straightforward, this provision, and antitrust litigation generally, have proven ineffective at combating exclusivity parking.

First, plaintiffs face an uphill battle in order to prove a pay-for-delay settlement violates the antitrust laws. In 2013, in *Federal Trade Commission v. Actavis*, 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.[94] Many view the *Actavis* decision as a victory for antitrust plaintiffs because these cases can now go forward rather than failing at the motion-to-dismiss stage.[95] The implications *of* the Court's holding in *Actavis*, however, still make these cases very difficult for plaintiffs to win. Specifically, the Court held that plaintiffs must prove their case under a "rule of reason" analysis.[96] The rule of reason employs an overall balancing of harms, benefits, and alternatives to decide whether or not the

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

[90] *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).

[91] 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).

[92] *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.

[93] 21 U.S.C. § 355(j)(5)(D)(i)(V) (2012).

[94] F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

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

[96] Actavis, 133 S. Ct. at 2227.

challenged agreement is illegal.[97] A rule of reason case will involve complex economic questions about the market in which the defendant operates, the scope of how much power or influence the defendant has in that market, and how much and to what extend consumers are harmed by the defendant's conduct compared with potential efficiencies or justifications of the conduct.[98] Unlike pay-for-delay cases after *Actavis*, other types of antitrust cases employ burden-shifting, presumptions, and/or *per se* illegality rules that make them easier for plaintiffs to win.[99]

Rule of reason cases are hard for plaintiffs to win generally.[100] Pay-for-delay cases prove particularly difficult for plaintiffs to win. 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.[101] After *Actavis*, settlements likely will become more complex, making it difficult for plaintiffs to articulate the distinct anticompetitive effects of the agreement.[102] For example, some settlements have involved forgiving past liability in previous disputes between the same parties but involving different drugs.[103] Furthermore, post-*Actavis* plaintiffs will likely need more economic evidence of anticompetitive harm than simply the size of the payment for delay.[104] Unfortunately, evidence of market effects is nearly impossible to obtain because the antitrust defendants have not entered the market.[105]

Second, the *Actavis* Court did not provide a clear framework for evaluating pay-for-delay settlements under the rule of reason announced: "[w]e therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation."[106] In dissent, Chief Justice Roberts took particular issue with the majority for failing 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,

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[97] 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW, AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATIONS ¶ 1500 (3rd ed. 2010).
[98] *Id.*
[99] *E.g.*, 11 HERBERT HOVENKAMP, ANTITRUST LAW, AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATIONS ¶ 1911c (3rd ed. 2011).
[100] 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 over 99% of all rule of reason cases between 1999 and 2009).
[101] Amanda P. Reeves, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following* FTC v. Actavis, 28 ANTITRUST, no. 1, Fall 2013, at 10.
[102] Remarks of Wright, *supra* note 95, at 11. *See* Reeves, *supra* note 101, 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).
[103] *In re* Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 384 (D. Mass. 2013).
[104] Remarks of Wright, *supra* note 95, 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).
[105] Remarks of Wright, *supra* note 95, at 14.
[106] F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2238 (2013).

redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.' "[107] This leaves many questions unanswered and antitrust plaintiffs unable to predict how their cases might unfold.[108] The difficulty in winning a rule of reason pay-for-delay antitrust case combined with uncertainty after *Actavis* leaves later-filing generics without a predictable and reliable way to break the logjam of the first-filer's parked exclusivity.[109]

Third, most pay-for-delay settlements will not receive significant antitrust scrutiny from the FTC. Although the FTC has publicly stated their intention to continue aggressively enforcing antitrust laws in pay-for-delay situations,[110] the FTC's resources are limited; they cannot pursue every pay-for-delay settlement.[111] Since 2004, the number of pay-for-delay settlements has slowly risen.[112] Today, the FTC estimates that approximately thirty settlements each year take on a pay-for-delay character[113] based on the settlement agreements that parties are required to submit to FTC.[114] Despite these increasing numbers, the FTC currently only has two pending suits of this nature.[115] If the threat of FTC action were an effective deterrent to pay-for-delay agreements, one would have expected 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 against a pioneer company in 2008,[117] and the court ruled on summary judgment motions over

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[107] *Id.* at 2245 (Roberts, C.J., dissenting) (quoting *id.* at 2231 (majority opinion)).
[108] Remarks of Wright, *supra* note 95, at 15–16.
[109] Reeves, *supra* note 101, at 14–15; *see* Michael L. Fialkoff, Note, *Pay-for-Delay Settlements in the Wake of Actavis*, 20 MICH. TELECOMM. & TECH. L. REV. 523 (2014).
[110] Remarks of Wright, *supra* note 95, at 7–8.
[111] *See* Reeves, *supra* note 101, at 14.
[112] *FTC Briefing on Pharmaceutical Pay-For-Delay Settlements*, FTC 11 (Apr. 25, 2012), http://usptopost-grant.com/wp-content/uploads/2012/04/FTC-Briefing-04-25-2012.pdf.
[113] FTC, *Pay-for-Delay*, *supra* note 15, at 10.
[114] Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173 § 1112–1113, 117 Stat. 2066, 2461–63 (2003).
[115] Statement of Chairwoman Edith Ramirez, Senate Committee on the Judiciary, Subcommittee on Antitrust, Competition Policy & Consumer Rights (July 23, 2013), *available at* 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, Docket No. 1:09-CV-00955, and (2) *FTC v. Cephalon, Inc.*, pending in the Eastern District of Pennsylvania, Docket No. 2:08-CV-2141.
[116] *See* Daniel A. Crane, *Optimizing Private Antitrust Enforcement*, 63 VAND. L. REV. 675, 692 (noting that the average antitrust case today takes six years from filing to disposition).
[117] F.T.C. v. Cephalon, Inc., 551 F. Supp. 2d 21, 22 (D.D.C. 2008).

six years later.[118] As of this writing, the litigation that resulted in *Activis*, initially filed in 2009, has just entered discovery.[119] Antitrust actions are unlikely to be instituted, difficult to win when they are instituted, and lengthy to resolve. The combination of the difficulty for plaintiffs to prevail in a rule of reason case, the uncertainty after *Actavis*, the lack of FTC resources, and the long duration 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 wanted to keep the overall structure of the Hatch-Waxman Act, but make the first-filer take its exclusivity and use it or lose it. The result is a poorly drafted nuanced web of "earlier than" and "later than" language that, when formally applied, leaves the pioneer and first-filer almost completely in control and able to thwart Congress's goals.[121] 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 ANDA 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 [one] 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.
>
> (BB) In an infringement action or a declaratory judgment action . . ., a court signs a settlement

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[118] F.T.C. v. Cephalon, Inc., No. 2:08-CV-2141 (E.D. Pa. July 29, 2014). For a summary of FTC actions in the field, see Markus H. Meier et. al., *Overview of FTC Antitrust Actions in Health Care Services and Products*, HEALTH CARE DIVISION, BUREAU OF COMPETITION, FEDERAL TRADE COMMISSION (Mar. 2013), http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/hcupdate.pdf.

[119] F.T.C. v. Actavis, Inc., Docket No. 1:09-CV-00955-TWT (N.D. Ga.).

[120] While a private antitrust suit cannot trigger forfeiture, 21 U.S.C. § 355(j)(5)(D)(i)(V) (2012), it could potentially act as a deterrent to pay-for-delay settlements. Private antitrust actions must still proceed under the rule of reason, F.T.C. 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] *See* Upadhye, *supra* note 85, at 1325.

> order . . . that includes a finding that the patent is invalid or not infringed. . . .[122]

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").[123] While the submission/approval event is a straightforward date determination based upon the first-filer's ANDA submission and final approval dates, the litigation event is (obviously) dependent upon the ensuing litigation triggered by "the first applicant *or any other applicant*."[124] This flexibility in the statute means that *any* paragraph (IV) ANDA filer could trigger the litigation event for the first-filer and unpark the exclusivity by forcing the first-filer to enter the market within seventy-five days. Using this provision, another generic 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 leaves an important question unanswered: how long does FDA wait to decide whether or not another generic might trigger a litigation event? FDA's answer: as long as the occurrence of a litigation event is "possible," forfeiture is not triggered.[125] For now, FDA refuses to expand upon what exactly "possible" means, except that actual pending litigation with another generic is not required.[126] Thus, the failure to market provision is only triggered upon the occurrence of *both* a submission/approval event *and* a litigation event.[127]

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 litigation event because there is no final judgment from the Court of Appeals. If that settlement contains no stipulation of the patent's invalidity or non-infringement, the parties avoid the second litigation event unless a later-filer initiates litigation against

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[122] 21 U.S.C. § 355(j)(5)(D)(i)(I) (2012). 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).

[123] *Id.*

[124] *Id.* § 355(j)(5)(D)(i)(I)(bb) (emphasis added).

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

[126] Granisetron Letter, *supra* note 125, at 5–6.

[127] *Id.* at 4.

the pioneer. Consequently, the failure to market provision lacks any real teeth,[128] and FDA acknowledges this loophole:

> Inherent in the structure of the "failure to market" forfeiture provisions is the possibility that a first applicant 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.[129]

Furthermore, the use of declaratory judgment actions by later-filing generics is ineffective at curbing exclusivity parking. First, the later-filing generic lacks the same incentive to litigate any patents covering the drug in question as the first-filer. Even if the later-filing generic prevails in a declaratory judgment action, the later-filer does not obtain the lucrative 180-day exclusivity; it remains with the first-filer.[130] Although incurring similar risks and costs, the only benefit the later-filer would accrue from a successful declaratory judgment action would be earlier market entry, but in competition with all other generics now able to enter the market who have effectively ridden the coattails of the later-filer's action absent some joint defense agreement with other later-filing generics.[131]

Second, later-filing generics pursuing a declaratory judgment action face an uphill battle just to establish standing. Article III limits the jurisdiction of federal courts to "cases" and "controversies."[132] To demonstrate Article III standing, a plaintiff must show some sort of injury, a causal connection between the injury and the defendant, and likelihood that the injury will be redressed by a favorable court action.[133] In the context of patent disputes, a declaratory judgment plaintiff used to be required to show that she was in "reasonable apprehension of imminent suit."[134]

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[128] 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.
[129] Granisetron Letter, *supra* note 125, at 5, n.6.
[130] 21 U.S.C. § 355(j)(5)(D)(iii)(II) (2012).
[131] *See* Avery, *supra* note 90, at 193.
[132] U.S. CONST. art. III, § 2, cl. 1.
[133] Lujan v. Defenders of Wildlife, 504 U.S. 555, 560–61 (1992).
[134] Teva Pharm. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1333 (Fed. Cir. 2005).

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."[135] In *MedImmune, Inc. v. Genetech, Inc.*,[136] the Supreme Court clarified the scope of Article III standing for declaratory judgment actions and discredited the Federal Circuit's reasonable apprehension test.[137] Subsequent court decisions have made it easier for later-filing generics to establish standing,[138] but the question is far from resolved.[139] For example, the Federal Circuit recently held that a generic that has begun testing their drug but not yet submitted an ANDA to FDA lacks sufficient Article III standing.[140]

III. MODIFYING THE FAILURE TO MARKET PROVISION TO INCLUDE IPRS AND PGRS

Though well-intentioned, the forfeiture provisions remain ineffective at curbing exclusivity parking. The newly-created quasi-judicial administrative proceedings in the USPTO[141] offer an alternative process for challenging a patent's validity, and thus can and should also trigger the failure to market provision. Because the failure to market provision is unlikely to be construed to include the new USPTO proceedings, statutory change would be required. Section III.A. describes how IPRs and PGRs present alternative forums for challenging the validity of a pharmaceutical patent. Section III.B. argues that the failure to market is unlikely to be construed 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 similarity to litigation,[142] certain differences might make them a more or less attractive forum for a generic desiring to

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135 Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 737 (Fed. Cir. 1988).
136 549 U.S. 118 (2007).
137 Medimmune, Inc. v. Genentech, Inc., 549 U.S. 118, 132 n.11 (2007).
138 *See* Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1293 (Fed. Cir. 2008) (holding exclusivity parking sufficient injury to satisfy Article III standing for later-filer's declaratory judgment action). *But see* Janssen Pharm. 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); Merck & Co. v. Apotex, Inc., 287 F. App'x 884 (Fed. Cir. 2008) (per curiam).
139 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).
140 Sandoz, Inc. v. Amgen, Inc., No. 2014-1693, slip op. at 2 (Fed. Cir. Dec. 5, 2014).
141 *See supra* Section I.B.
142 *See supra* notes 75–83 and accompanying text.

challenge a pioneer patent. First, the scope of IPRs and PGRs is limited strictly to issues of patent validity; IPRs and PGRs may not be used to determine questions of infringement.[143] Thus, a generic that intends to claim both that their product does not infringe the pioneer drug patent *and* that the pioneer patent is invalid might choose to keep all their claims in a single district court rather than fighting on two fronts.[144]

Second, IPRs and PGRs have different standards of proof compared to litigation. In order to file a complaint for declaratory judgment of patent invalidity, the challenger needs only a "short and plain statement" showing the party is entitled to relief.[145] In order to successfully institute an IPR or PGR, the challenger must show a "reasonable likelihood" of success[146] or "that it is more likely than not" that the petitioner will prevail,[147] similar to the standard for a preliminary injunction.[148] Thus, IPRs and PGRs require more initial work than a complaint for declaratory judgment and contain a higher probability of early failure. Once the IPR or PGR is instituted, however, a generic needs to prove invalidity only by a preponderance of the evidence[149]—a lower standard than the clear and convincing standard a district court requires to overcome a patent owner's statutorily-mandated presumption of validity.[150] While some commentators suggest standards of proof are highly subjective,[151] a subtle difference in the standard of proof could be dispositive in the patent context.[152]

Third, IPRs and PGRs are likely to be shorter than patent litigation. According to a recent study, the median time to trial in patent litigation is two and a

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143 35 U.S.C. §§ 311(b), 321(b) (2012).
144 *See* Eric S. Walters & Colette R. Verkuil, *Patent Litigation Strategy: The Impact of the America Invents Act and the New Post-Grant Patent Procedures*, PRACTICING LAW CO. 5 (2012) http://media.mofo.com/files/Uploads/Images/120307-Patent-Litigation-Strategy.pdf.
145 FED. R. CIV. P. 8(a)(2).
146 35 U.S.C. § 314(a) (2012).
147 *Id.* § 324(a).
148 *See* Winter v. Natural Res. Def. Council, Inc. 557 U.S. 7, 20 (2008) ("A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits. . . .").
149 35 U.S.C. §§ 316(e), 326(e) (2012).
150 *Id.* § 282(a); Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2246 (2011).
151 *See, e.g.*, Kevin M. Clermont, *Standards of Proof Revisited*, 33 VT. L. REV. 469, 470 (2009) (suggesting that it is "contestable" that a fact-finder assigns the appropriate probability for a given standard of proof).
152 *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).

half years.[153] By contrast, an IPR or PGR is statutorily required to conclude within twelve months.[154] The Board decides whether or not to institute an IPR or PGR within six months of the filing of the petition, resulting in a maximum 18-month start-to-finish timeline for IPRs and PGRs.[155] This faster timeline could prevent courts from being presented with issues too late to afford the relief sought.[156] Given their shorter duration and more limited scope, IPRs and PGRs are estimated to cost a challenger $300,000 to $500,000[157] while patent litigation can cost several million dollars.[158] Ultimately, generics would be well-advised to carefully consider timing implications for their particular situation before pursuing an IPR or PGR.[159]

Fourth, the scope of discovery available to the parties in an IPR or PGR is much more limited than in district court. In an IPR, discovery is limited to deposing witnesses who submitted affidavits or declarations and "what is otherwise necessary in the interest of justice."[160] In a PGR, "discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding."[161] In district court, "any nonprivileged matter that is relevant to any party's claim or defense" is generally discoverable.[162] Thus, IPRs and PGRs might be attractive only to generics who wish to challenge a pioneer patent on a specific and narrow ground where additional discovery would be unnecessary.[163] Whether a generic will find an IPR or PGR suitable will depend upon its individual situation.

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153 Chris Barry et al., PricewaterhouseCoopers LLP, *2013 Patent Litigation Study, Big Cases Make Headlines While Patent Cases Proliferate* (2013) at 21, *available at* http://www.pwc.com/en_us/us/forensic-services/publications/assets/2013-patent-litigation-study.pdf.

154 35 U.S.C. §§ 316 (a)(11), 326(a)(11) (2012). The UPSTO can extend this twelve-month period by an additional six months for "good cause." *Id.* To date, the UPSTO has not invoked this authority for any IPR or PGR final decision in tech center 1600.

155 *See* 35 U.S.C. §§ 314(b), 324(c) (2012).

156 *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.").

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

158 American Intellectual Property Law Association, *2013 Report of the Economic Survey*, *available at* http://www.patentinsurance.com/custdocs/2013aipla%20survey.pdf.

159 Walters & Verkuil, *supra* note 144, at 7.

160 35 U.S.C. § 316(a)(5) (2012).

161 *Id.* § 326(a)(5).

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

163 Walters & Verkuil, *supra* note 144, at 4–5.

Many patent challengers are already utilizing these new proceedings, and their popularity is quickly growing.[164] Patent challengers are on pace to file nearly 2,000 IPRs in fiscal year 2015.[165] In the biochemistry and organic chemistry field, patent challengers on pace for over 200 IPRs in fiscal year 2015.[166] Although these figures currently fall short of the 6,500 total patent lawsuits filed in district courts in 2013,[167] (of which approximately 300 or so were pursuant to the Hatch-Waxman Act),[168] it remains to be seen how prominent of a place USPTO proceedings will occupy in the resolution of patent disputes, particularly Hatch-Waxman patent disputes. Additionally, in December, 2014, the USPTO issued their first final decisions in a pharmaceutical patent dispute that could otherwise be the subject of Hatch-Waxman litigation.[169] No appeal has been filed in that dispute, but most appeals take nine to twelve months.[170] Thus, neither FDA nor a court has yet been presented the opportunity to address how an IPR or PGR final decision interacts with the failure to market provision.[171]

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164 *See* USPTO, *AIA Progress Statistics*, http://www.uspto.gov/ip/boards/bpai/stats/aia_trial_statistics.jsp (last visited Nov. 8, 2014).

165 *See id.*

166 This information was obtained by searching the PTAB's dockets for IPRs in Technology Center 1600. Technology Center 1600 in the USPTO is the "Biochemistry and Organic Chemistry" technology center. USPTO, *Patent Technology Center 1600 Contact Information* (last updated Jun. 6, 2012) http://www.uspto.gov/about/contacts/phone_directory/pat_tech/1600.jsp. Although pharmaceutical patents are only one component of technology center 1600, *id.*, this is the finest level of detail for which IPR data is broken down.

167 Chris Barry et al., PricewaterhouseCoopers LLP, *2014 Patent Litigation Study, As Case Volume Leaps, Damages Continue General Decline* (2014) at 5, *available at* http://www.pwc.com/en_US/us/forensic-services/publications/assets/2014-patent-litigation-study.pdf.

168 Brian C. Howard & Jason Maples, Lex Machina, *Hatch Waxman / ANDA Litigation Report* (2014) at 3.

169 Amneal Pharm., LLC v. Supernus Pharm., Inc., No. IPR2013-00368, Final Written Decision (Dec. 9, 2014) (holding challenged patent claims not invalid); Amneal Pharm., LLC v. Supernus Pharm., Inc., No. IPR2013-00371, Final Written Decision (Dec. 9, 2014) (same); Amneal Pharm., LLC v. Supernus Pharm., Inc., No. IPR2013-00372, Final Written Decision (Dec. 9, 2014) (same).

Three pharmaceutical IPRs settled before the Board issued a final decision: IPR2013-00012, IPR2013-00015, and IPR2013-00024.

Fifteen pharmaceutical IPRs are ongoing (instituted and not settled) and due for final written decisions in 2015: IPR2014-00115, IPR2014-00160, IPR2014-00325, IPR2014-00360, IPR2014-00376, IPR2014-00377, IPR2014-00378, and IPR2014-00379, IPR2014-00549, IPR2014-00550, IPR2014-00652 IPR2014-00654, IPR2014-00656, IPR2014-00784, and IPR2014-00876.

Five pharmaceutical IPRs have been filed and are awaiting a Board decision on whether or not to institute: IPR2014-00998, IPR2014-01041, IPR2014-01043, IPR2014-01091, and IPR2014-01365.

170 *Median Disposition Time for Cases Decided by Merits Panels*, U.S. CT. APPEALS FED. CIRCUIT, http://www.cafc.uscourts.gov/images/stories/Statistics/med%20disp%20time%20merits_chart.pdf (last visited Feb. 1, 2015).

171 *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.

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 strong 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 AIA, however, neither 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 Support an Exclusive Construction*

The plain text of the failure to market provision likely does not support including IPRs or PGRs within its scope. The statute's triggering event is a determination of non-infringement or invalidity from "an infringement action or a declaratory judgment action."[172] Neither an IPR nor a PGR is an infringement action; IPRs and PGRs determine questions of patent *validity*, not patent *infringement*.[173] Nor are IPRs or PGRs "declaratory judgment actions," one might argue. The statute frequently uses the term "declaratory judgment" with reference to the Declaratory Judgment Act,[174] a specific reference, suggesting that the term should not be broadened to include IPRs or PGRs.[175] Although IPRs, PGRs, and infringement actions all originate pursuant to Title 35,[176] declaratory judgment actions originate pursuant to Title 28.[177] 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.[178]

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 the MMA created the forfeiture provisions in 2003, two other USPTO administrative proceedings existed whereby a third party could challenge the validity of an issued patent: "ex partes reexamination"[179] and "optional inter partes

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172 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (2012).
173 35 U.S.C. §§ 311(b), 321(b) (2012). Infringement of patents is governed by 35 U.S.C. §§ 271–273.
174 Pub. L. 80-773, 62 Stat. 964 (1948) (current version at 28 U.S.C. § 2201–2202 (2012)) (creating the declaratory judgment action).
175 21 U.S.C. § 355(c)(3)(D) (2012) ("No action may be brought under section 2201 of Title 28 . . . for a declaratory judgment"); *id.* § 355 (j)(5)(C)(i) (same).
176 35 U.S.C. §§ 271–273, 311–319, 321–329 (2012).
177 28 U.S.C. §§ 2201–2202 (2012).
178 *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).
179 35 U.S.C. §§ 301–307 (2000).

reexamination."[180] Congress did not include these administrative proceedings in the MMA forfeiture provisions in 2003.[181] Thus, one would argue, the MMA-enacting Congress presumably intended for only litigation to trigger forfeiture. It is also possible, however, that this was a simple oversight.

Next, one would argue that 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 are titled "Relation to *other proceedings* and actions,"[182] suggesting that IPRs and PGRs are "proceedings" and not "actions." The same sections frequently use the words "proceeding" and "matter" in referencing the IPR or PGR, while referring separately to "civil actions."[183] Nowhere in the IPR or PGR statutes is there any reference to the Hatch-Waxman Act, the MMA, or any other related statute that would suggest using an IPR or PGR to trigger 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, one would argue, suggests that Congress did not intend for 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 provisions. Section 12 of the AIA, while not relating to IPRs or PGRs, specifically references litigation pursuant to the Hatch-Waxman Act.[184] Thus, one could argue that the AIA-enacting Congress legislated with full awareness of the Hatch-Waxman Act and was capable of amending the forfeiture provisions to include the new USPTO proceedings, but chose not to. Furthermore, because IPRs and PGRs contain some differences from declaratory judgment actions,[185] one could argue Congress wanted it to be easier to invalidate patents generally but not easier to trigger forfeiture of exclusivity for pharmaceutical patents. Although this was more likely an oversight by Congress in a complex area of law, a court or FDA would be unlikely to adopt an inclusive interpretation in light of the powerful textual arguments available.

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[180] *Id.* §§ 311–319 (2000).
[181] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (2006).
[182] (emphasis added).
[183] 35 U.S.C. §§ 315, 325 (2012).
[184] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 12(a), 125 Stat. 284, 326 (2011) (codified at 35 U.S.C. § 257(c)(2)(A)) ("Paragraph (1) shall not apply to . . . a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II))."); H.R. REP. No. 112-98, pt. 1, at 78 (2011).
[185] *See supra* Section III.A.

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

A later filing generic's strongest arguments for an inclusive construction flow from the strong 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.[186] This estoppel attaches to any future USPTO proceeding, ITC action, or declaratory judgment action,[187] and an IPR or PGR final decision is appealable only directly to the Court of Appeals for the Federal Circuit.[188] 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.[189] In effect, the AIA directly replaced certain types of declaratory judgment actions with IPRs and PGRs to reduce the amount of patent litigation.[190] Without strong estoppel attaching to IPRs and PGRs, litigation in district court might not be reduced.

Interpreting forfeiture provision to *exclude* IPRs and PGRs could lead an unusual result—i.e., an IPR or PGR final decision of invalidity affirmed on appeal could actually *prevent* the challenger from triggering a forfeiture event.[191] If neither the Board's final decision nor the Court of Appeals' 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.[192] But, as described above, the challenger is estopped from bringing the action and may not even have a justiciable case or controversy given the Court of Appeals' previous decision.[193]

An argument for a broad statutory construction would not be unprecedented in this context but would likely be unsuccessful. In *Sullivan v. Hudson*,[194] 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

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186 35 U.S.C. §§ 315(e), 325(e) (2012).
187 *Id.*
188 *Id.* §§ 319, 329.
189 *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).
190 *See supra* Section I.B.
191 *See* Sabharwal & Varughese, *supra* note 171.
192 *See id.*
193 *Id.*
194 490 U.S. 877 (1989).

results Congress sought to promote."[195] An IPR or PGR by a later-filing generic 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.[196] 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."[197] The strong estoppel that attaches to IPRs and PGRs means that an invalidity ruling from an IPR or PGR 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*, however, will likely fail because neither an IPR nor PGR is a "necessary" condition for resolving the patent dispute; it is simply a sufficient one. A patent challenger can choose whether to file for declaratory judgment or a USPTO proceeding. Both lead to a resolution of the dispute, but neither one is necessary for resolving the dispute.

A later-filing generic who prevails in IPR or PGR could petition FDA to determine whether or not the Board's decision falls within the language of the forfeiture provision. If FDA adopts an interpretation that excludes IPRs and PGRs from the statutory language, the challenger would face an uphill battle if a reviewing court affords FDA *Chevron* deference for its interpretation.[198] This result is unlikely; FDA has a track record of strict interpretations of the Hatch-Waxman Act.[199] For example, FDA interpreted a different part of the failure to market provision[200] to effectively allow a pioneer to "pull the rug" out from under the first-filer by removing the patent from FDA's official list of patents that protect approved drugs

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195 *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).

196 35 U.S.C. § 315(e) (2012).

197 149 CONG. REC. S15885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) (discussing the intended purpose of the failure to market provision).

198 Chevron, U.S.A., Inc. v. Natural Res. Def. Counsel, 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 reasonable one. *Id.* at 842–43.

199 *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 8–9 [hereinafter Dorzolamide Letter] (Oct. 28, 2008), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CenterforDrugEvaluationandResearch/ucm119602.pdf; Granisetron Letter, *supra* note 125, at 5–6.

200 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

and trigger forfeiture of the first-filer's 180-day exclusivity.[201] The D.C. Circuit Court of Appeals overturned FDA's interpretation, determining that removing a patent from FDA's official list only triggers forfeiture if done by court order, rather than by the voluntary act of the pioneer.[202] FDA has also strictly interpreted one of the MMA's other forfeiture provisions: the failure to obtain tentative approval provision.[203] Under this provision, the exclusivity is forfeited if the first-filer "fails to obtain tentative approval . . . within [thirty] 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."[204] This provision was designed to prevent generics from quickly filing poor ANDAs in order to obtain the exclusivity when final approval might come several years later.[205] Initially, FDA construed the second half of the provision (excusing a delay stemming from a change in review requirements) in a rather "draconian" fashion.[206] Applying an *expressio unius est exclusio alterius* argument, FDA stated that

> [t]his 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.[207]

FDA's hard-line stance has been dubbed "our failure is your failure."[208] Although FDA has been lenient in some circumstances,[209] FDA remains committed to this position.[210]

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[201] *Teva*, 595 F.3d at 1305. 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.

[202] *Id.* at 1317.

[203] 21 U.S.C. § 355(j)(5)(D)(i)(IV) (2012).

[204] *Id.* This 30-month period was extended by § 1133 of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, 128 Stat. 993, 1122 (2012), to 40 months for some applications and 36 months for others in order to allow the FDA to process a backlog of ANDAs. *US FDA Extends Timeline for Generic Drug Approval*, BIOSPECTRUM (Oct. 29, 2012), http://www.biospectrumasia.com/biospectrum/news/121139/us-fda-extends-timeline-generic-drug-approval.

[205] Upadhye, *supra* note 85, at 1326.

[206] Kurt R. Krast, *OGD Management Review Results in Forfeiture of Generic ACTONEL 180-Day Exclusivity Eligibility*, FDA L. BLOG (Sept. 1, 2014), 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.

[207] Dorzolamide Letter, *supra* note 199, at 9 (emphasis added).

[208] Krast, *supra* note 206.

[209] *E.g.*, Letter from Janet Woodcock, Dir., Ctr. For Drug Evaluation and Research, to Stephen Auten, Vice President, Sandoz, Inc. 9 (Sept. 20, 2011), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2010-P-0632-0017 (determining exclusivity not forfeited when first-filer chose to change drug's formulation from a sealed glass ampule to a stoppered glass vial); Letter from

Lastly, pharmaceuticals are a highly-regulated industry, and courts usually defer to Congress and agencies in these instances.[211] Congress has spoken frequently and recently in matters related to pharmaceutical approval and patent disputes: the Hatch-Waxman Act in 1984, the America Protects Inventors Act in 1999,[212] the MMA in 2003, and the AIA in 2012. Thus, an amendment to the statute by Congress is likely to be the only workable solution.[213]

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

Because neither a court nor FDA is likely to construe the failure to market provision to include IPRs and PGRs, statutory change would be required to bring IPRs and PGRs within the failure to market provision. Additionally, amending the failure to market provision would remove uncertainty in a field where so much is at stake and 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)(VII) 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.[214]

Gary Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, to Marcy Macdonald, Dir., Regulatory Affairs, Sandoz, Inc. 2–3 (Mar. 31, 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/040445s000ltr.pdf (determining exclusivity not forfeited when drug's labeling requirement remained under review); *see* Letter from Gary Buehler, Dir., Office of Generic Drugs, Ctr. for Drug Evaluation and Research, to Nicholas Tantillo, Senior Dir., Regulatory Affairs, Barr Laboratories, Inc. 2 (July 30, 2009), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/078104s000ltr.pdf (declining to determine if a first-filer forfeited exclusivity until another applicant becomes eligible for approval).

[210] Mem. from Robert L. West, Deputy Dir., Office of Generic Drugs (HFD-600) (June 10, 2014), http://www.fdalawblog.net/ACTONEL%20-%20180-Day%20Exclusivity%20Forfeiture%20FDA%20Letter%20Decision.pdf.

[211] *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143–45 (2000); Chevron, U.S.A., Inc. v. Natural Res. Def. Counsel, Inc., 467 U.S. 837, 842–44 (1984).

[212] Pub. L. 106-113-App'x I, §§ 4001–4808, 113 Stat. 1501A-521 (1999).

[213] *See Brown & Williamson*, 529 U.S. at 155–56.

[214] Although this Note proposes legislative change, a court or agency decision that adopts an inclusive interpretation would effectuate the same result.

First, this amendment would provide greater procedural certainty for later-filers who wish to "unpark" a first-filer's exclusivity. Utilizing an IPR or PGR avoids both the uncertainty in standing for pursuing a declaratory judgment action and the uncertainty of how to go about proving a rule of reason antitrust violation. More to the point, this amendment would confirm for later-filers 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 price making business executives and investors particularly anxious.[215]

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 when it created the failure to market provision.[216] For some generics, it 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 generic competition after the first-filer's exclusivity elapses.[217]

Third, this amendment would also 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.[218] 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-filers will pursue the new USPTO administrative 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 FTC (and potentially private parties) greater leverage in fighting pay-for-delay settlements.[219] Another option would be to reduce the ability of the pioneer to market their own "authorized generic" which competes with the first-filer during the 180-day exclusivity period, depriving the first filer of their full reward.[220] Yet another option would be to tie the 180-day exclusivity to the first generic to prevail in court,

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215 *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).
216 149 CONG. REC. S15885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy).
217 *See supra* notes 58–68 and accompanying text.
218 *See* H.R. REP. No. 112-98, pt. 1, at 39–40 (2011).
219 Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 RUTGERS L.J. 83, 94–96 (2009).
220 *Id.* at 97–99.

rather than the first that submits their ANDA to FDA.[221] These options, however, propose a similar kind of overhaul the MMA-enacting Congress rejected.[222] Additionally significant reform risks unintended consequences; exclusivity parking was an unintended consequence of the Hatch-Waxman Act.

This proposed amendment is by no means a complete fix to the exclusivity parking problem. As mentioned, IPRs and PGRs can be settled,[223] meaning that later-filing generics could use IPRs as leverage to extract their own settlement from the pioneer company. While settlements that do not unpark the first-filer's exclusivity fail to lead to timely full generic competition, the prospect 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 place.

Furthermore, this proposed amendment would also allow a *first*-filer to defeat a pioneer patent potentially more quickly and more cheaply. If it were easier to defeat a pioneer patent, Congress may have to reduce the length of the exclusivity for first-filers who 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. Thus, Congress should proceed cautiously with even moderate reform. This amendment, being specific and narrow, can be done now.

CONCLUSION

Patents provide a great incentive for pioneer drug developers to search for treatments for a plethora of medical conditions and help offset the substantial cost of ensuring new drugs are both safe and effective for consumers. 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 affordability. 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

[221] *Id.* at 99–103.
[222] *See supra* notes 84–85 and accompanying text.
[223] *See supra* note 82 and accompanying text.

effectuate greater generic competition,[224] this is the mechanism Congress has chosen and reaffirmed.[225]

Congressional efforts to close the loopholes that allowed exclusivity parking have proven marginal at best. Antitrust plaintiffs face a multi-year uphill battle to prevail in a rule of reason case 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 action.

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

[224] *See* Upadhye, *supra* note 85, 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").
[225] *See supra* notes 84–85 and accompanying text.