
2017

AIA Proceedings: A Prescription for Accelerating the Availability of Generic Drugs

Nora Xu

Follow this and additional works at: <https://scholarlycommons.law.emory.edu/elj>

Recommended Citation

Nora Xu, *AIA Proceedings: A Prescription for Accelerating the Availability of Generic Drugs*, 66 Emory L. Rev. 1007 (2017).

Available at: <https://scholarlycommons.law.emory.edu/elj/vol66/iss4/6>

This Comment is brought to you for free and open access by Emory Law Scholarly Commons. It has been accepted for inclusion in Emory Law Journal by an authorized editor of Emory Law Scholarly Commons. For more information, please contact law-scholarly-commons@emory.edu.

AIA PROCEEDINGS: A PRESCRIPTION FOR ACCELERATING THE AVAILABILITY OF GENERIC DRUGS

ABSTRACT

The Hatch-Waxman Act of 1984 increases patient access to lower-cost generic drugs by incentivizing generic manufacturers to challenge the patents covering successful drug products. The Hatch-Waxman framework creates an automatic stay that blocks the Food and Drug Administration (FDA) from approving a new generic drug for thirty months. The purpose of the thirty-month stay is to provide time for any patent infringement claims to be litigated before the new generic drug is permitted onto the market. The stay may be terminated before the end of the thirty-month period if the generic manufacturer prevails in invalidating the patents blocking generic market entry.

More recently, the America Invents Act (AIA) of 2011 created new administrative proceedings at the U.S. Patent and Trademark Office (USPTO) that replace certain aspects of district court patent litigation. Generic manufacturers are using these administrative proceedings to challenge the validity of drug patents in hopes of expediting the FDA's approval of their new generic drugs. This practice raises some unanticipated questions. Should the USPTO invalidate the relevant drug patents before the related district court litigation is finalized, a question arises as to the effect of that USPTO decision on the thirty-month stay of FDA approval. It is unclear whether the FDA should immediately approve the generic drug for market entry or whether the thirty-month stay should continue after the USPTO's decision of unpatentability.

This Comment examines the relevant statutory provisions of the Hatch-Waxman Act and AIA and explores the scenarios that give rise to uncertainty about the thirty-month stay. It argues that the thirty-month stay should terminate when the Federal Circuit affirms the USPTO's unpatentability determination and issues the formal mandate. Because neither the FDA nor courts are likely to construe the relevant statutory provisions to this effect, this Comment proposes an amendment to incorporate AIA proceedings into the Hatch-Watchman framework.

INTRODUCTION	1009
I. THE HATCH-WAXMAN ACT	1011
A. <i>The Regulatory Approval Process for Generic Drugs and Extensions of Exclusivity for Pioneer Drugs</i>	1011
B. <i>Patent Litigation Scheme Under the Hatch-Waxman Act</i>	1015
1. <i>Paragraph IV Certification and the Thirty-Month Stay of FDA Approval</i>	1015
2. <i>Incentives to Challenge the Patents Blocking Generic Market Entry</i>	1018
II. CHALLENGING ORANGE BOOK-LISTED PATENTS VIA IPR AND PGR REVIEW	1020
A. <i>Inter Partes Review and Post-Grant Review</i>	1021
B. <i>Advantages of PTAB Litigation over District Court Litigation</i>	1023
III. PTAB DECISION AND FEDERAL CIRCUIT APPEAL CAN PREDATE THE END OF THE THIRTY-MONTH PERIOD	1026
A. <i>Prospective ANDA Filers Can Bring Pre-Suit Patent Challenges at the PTAB</i>	1027
B. <i>By Bringing a Pre-Suit IPR or PGR Challenge, the ANDA Filer Can Obtain a PTAB Decision and Federal Circuit Appeal Before the End of the Thirty-Month Period</i>	1028
IV. NEITHER A PTAB DECISION OF UNPATENTABILITY NOR THE FEDERAL CIRCUIT'S AFFIRMANCE OF THAT DECISION ARE SUFFICIENT TO TERMINATE THE THIRTY-MONTH STAY OF FDA APPROVAL	1032
A. <i>Statutory Text of the Hatch-Waxman Act and AIA Does Not Permit a PTAB Decision Affirmed by the Federal Circuit to Terminate the Thirty-Month Stay</i>	1032
B. <i>Congressional Intent Indicates that PTAB Decisions Cannot Terminate the Thirty-Month Stay</i>	1035
V. ANDA APPROVAL UPON PREVAILING AT THE PTAB AND FEDERAL CIRCUIT	1037
A. <i>Pathways for Terminating the Thirty-Month Stay</i>	1038
1. <i>Stay-Terminating Triggers Expressly Recognized by Statute</i>	1038
2. <i>Extra-Statutory Triggers that Prematurely Terminate the Thirty-Month Stay</i>	1040
B. <i>Statutory Amendment to Integrate IPRs and PGRs into the Thirty-Month Stay Provisions</i>	1044
CONCLUSION	1048

INTRODUCTION

The legal framework governing the generic drug industry involves a delicate balance between two opposing policy interests.¹ First, it seeks to increase the availability of generic drugs.² This benefits society by reducing the financial strain caused by illness, promoting patient adherence to medication regimes, and reducing government spending on medical care.³ On the other hand, the legal framework incentivizes the development of new, pioneer drugs.⁴ Pioneer drug developers spend significant upfront expenses on developing and winning administrative approval—around \$2.87 billion and twelve years for each new drug—and need a period of marketing exclusivity to recoup the expenses.⁵ In 1984, Congress attempted to balance these opposing policy interests in the Hatch-Waxman Act.⁶

¹ Generic drugs are copies of pioneer drugs that “enter the market at a lower price” once the patents covering the pioneer drugs expire. Joanna Shepherd, *Disrupting the Balance: The Conflict Between Hatch-Waxman and Inter Partes Review*, N.Y.U. J. INTELL. PROP. & ENT. L. 14, 22 (2016). A “generic” could be either a generic version of a small-molecule drug or a generic version of a biologic medicine. Small-molecule drugs “are created by purely chemical processes and have relatively simple structures”; they “comprise the majority of commonly used drugs.” Ryan Timmis, Comment, *The Biologics Price Competition and Innovation Act: Potential Problems in the Biologic-Drug Regulatory Scheme*, 13 NW. J. TECH. & INTELL. PROP. 215, 217 (2015). Biologic medicines are manufactured from living cells through biological processes and have a more complex structure than small-molecule drugs. JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 772–73 (2d ed. 2010). This Comment exclusively addresses generic small-molecule drugs, which are regulated through a different pathway than generic biologic medicines. *Id.* at 26 (discussing the Biologics Price Competition and Innovation Act (2010)).

² See, e.g., *Actavis Elizabeth LLC v. U.S. Food & Drug Admin.*, 625 F.3d 760, 765 (D.C. Cir. 2010); *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1368 (Fed. Cir. 2010) (Clevenger, J., concurring), *rev'd*, 566 U.S. 399 (2012).

³ Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?*, 15 YALE J. HEALTH POL'Y L. & ETHICS 293, 315–17 (2015) (explaining that high drug costs contribute to medication non-adherence among patients with limited income).

⁴ See, e.g., *Actavis*, 625 F.3d at 761; *Novo Nordisk*, 601 F.3d at 136. The pioneer drug is the new drug on the market. See *Novo Nordisk*, 601 F.3d at 1360.

⁵ Brian T. Apel, 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*, 114 MICH. L. REV. 107, 108 (2015); Jennifer E. Sturiale, *The Hatch-Waxman Act, Post-Grant Review, and the PTAB: A New Sort of Competition* 15 (Sept. 14, 2016) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2824764 (on file with the author) (“[T]he total capitalized research and development costs per approved drug, including the cost of failed drugs and post-approval research and development spending, is about \$2.87 billion in 2013 dollars.”). The cost of new drug development is deeply contested, and one study has estimated the cost at as low as \$130 million to \$195 million adjusted for the risk of failure. U.N. Secretary-General’s High-Level Panel on Access to Medicines, *Promoting Innovation and Access to Health Technologies*, at 35 (Sept. 14, 2016), <http://www.unsgaccessmeds.org/final-report/>.

⁶ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355(j) (2012)); see, e.g., *Novo Nordisk*, 601 F.3d at 1360; *Actavis*, 625 F.3d at 765 (“The Hatch-Waxman Amendments ‘struck a balance between expediting generic drug

The Hatch-Waxman Act creates a complex patent litigation scheme that allows generic manufacturers to win earlier market entry by showing that the patents blocking generic entry are invalid or not infringed.⁷ Faster market entry creates competition in the drug market, which ultimately will reduce prices for patients.⁸ The patent litigation scheme provides a stay of thirty months to allow the pioneer drug developer to assert its patent rights before generic market entry.⁹ This stay is important because its end marks the earliest date that a proposed generic drug can be approved by the Food and Drug Administration (FDA) and become available to the American public, with some exceptions.¹⁰ Generic sponsors strive to prevail early in the patent litigation to lift the stay before the end of the thirty-month period.¹¹ Until recently, these patent disputes were litigated in the only available forum: Article III courts.

With the America Invents Act (AIA) in 2011, Congress introduced new administrative proceedings at the U.S. Patent and Trademark Office (USPTO) that effectively replace certain aspects of district court litigation.¹² Generic sponsors have been using the AIA proceedings to attack the drug patents blocking generic entry in hopes of expediting FDA approval and market entry.¹³ This practice raises unanswered questions about the Hatch-Waxman statutory scheme.

applications and protecting the interests of the original drug manufacturers.” (quoting *Abbott Labs v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990)).

⁷ 21 U.S.C. § 355(j)(2)(A)(vii) (2012). Patent validity is “determined on a claim-by-claim basis”; however, the “Hatch-Waxman Act speaks in terms of a ‘patent’ being found invalid, not a ‘patent claim.’” Sturiale, *supra* note 5, at 7 n.28. For simplicity’s sake, this Comment will speak in terms of “patent,” rather than “claim,” validity.

⁸ See Sturiale, *supra* note 5, at 38.

⁹ 21 U.S.C. § 355(j)(5)(B)(iii); *Mylan Pharm., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 201 (D.D.C. 2012).

¹⁰ See 21 U.S.C. § 355(j)(2)(A)(vii), (j)(5)(B)(iii); *Mylan*, 856 F. Supp. 2d at 201.

¹¹ See 21 U.S.C. § 355(c)(3)(C)(i), (j)(5)(B)(iii)(I).

¹² Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified at 35 U.S.C. §§ 1–375). In pursuit of the AIA’s goal to “limit unnecessary and counterproductive litigation costs,” the USPTO sought “to create a timely, cost-effective alternative to [district court] litigation” in crafting the *inter partes* review regulations. Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 48,680 (Aug. 14, 2012) (codified at 37 C.F.R. § 42); see also *Universal Elecs., Inc. v. Universal Remote Control, Inc.*, 943 F. Supp. 2d 1028, 1029 (C.D. Cal. 2013) (“The Leahy-Smith America Invents Act . . . intended to improve the former *inter partes* reexamination proceeding with a new *inter partes* review proceeding.”).

¹³ Arlene Chow & Ernest Yakob, *Novel AIA Adversarial Procedures for Challenging Validity of Pharmaceutical Patents*, 21 WESTLAW J. INTEL. PROP., Feb. 4, 2015, at 3, 5; see also 35 U.S.C. §§ 311(b), 321(b) (2012) (“A petitioner in a post-grant review may request to cancel as unpatentable 1 or more claims of a patent . . .”).

This Comment addresses a question the AIA did not answer: Can the USPTO's finding of unpatentability in an AIA proceeding terminate the stay of FDA approval before the end of the thirty-month period? The courts and agencies have yet to address this question.¹⁴

This Comment, proceeding in five parts, proposes that the thirty-month stay should terminate when the U.S. Court of Appeals for the Federal Circuit affirms the USPTO's unpatentability determination. This proposal furthers the policy goals of the Hatch-Waxman Act and AIA, increases patient access to generic drugs, and protects the innovator's patent rights. Parts I and II examine the relevant provisions of the Hatch-Waxman Act and the AIA. Part III establishes that a Patent Trial and Appeal Board (PTAB) decision affirmed on appeal can occur before the end of the thirty-month period. In those circumstances, however, the relevant statutory provisions do not permit termination of the thirty-month stay, as shown in Part IV. Part V proposes an amendment to incorporate the AIA proceedings into the Hatch-Waxman Act's thirty-month stay framework.

I. THE HATCH-WAXMAN ACT

The Hatch-Waxman Act governs the FDA's approval of generic drugs and sets out a complex procedural scheme for challenging the patents blocking generic market entry. Section A describes the FDA's approval process for generic drugs. Section B examines the procedural scheme for resolving the underlying patent disputes.

A. *The Regulatory Approval Process for Generic Drugs and Extensions of Exclusivity for Pioneer Drugs*

Before 1984, 65% of drugs with expired patents lacked a generic alternative.¹⁵ As a result of this void, pioneer drug developers could charge

¹⁴ See, e.g., Sturiale, *supra* note 5, at 42–43.

¹⁵ THOMAS, *supra* note 1, at 10–12 (stating that before the Hatch-Waxman Act, a patentee could preserve its market exclusivity beyond the patent term because a generic manufacturer could not commence seeking FDA approval until the appropriate patents had expired); 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) (stating that before the Hatch-Waxman Act, approximately 150 brand-name drugs lacked a generic alternative); Jonathan M. Lave, *Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?*, 64 U. PITT. L. REV. 201, 202 (2002) (discussing that nearly 100% of the top-selling drugs with expired patents have generic versions available today, versus only 35% in 1983).

high prices beyond the drug's patent term.¹⁶ Congress responded to this need for generic competition by enacting the Hatch-Waxman Act of 1984, which spawned a transformation in the American pharmaceutical industry.¹⁷ Between 1984 and 2015, the market share of generic drugs has increased from merely 19% of drugs dispensed to 89%.¹⁸ The Hatch-Waxman Act is designed to balance two competing policy interests—expanding the availability of generic drugs while encouraging the innovation of pioneer drugs.¹⁹

The Hatch-Waxman Act reduces the barriers to generic market entry by creating the Abbreviated New Drug Application (ANDA).²⁰ Prior to the ANDA, generic sponsors were required to submit their own clinical data to the FDA, forcing them to duplicate the clinical investigations already performed by pioneer-drug developers.²¹ For pioneer drugs, these clinical investigations are required to prove that they are “sufficiently safe and effective” to be marketed to the public.²² But for generic drugs, clinical investigations are needlessly costly and time-consuming because generic drugs are chemically identical to approved drugs that have already undergone years of clinical investigations.²³ These investigations account for over 90% of pioneer research and development spending and years of study, in part because they include human test subjects.²⁴ The ANDA allows the generic sponsor to shortcut the burden of conducting its own clinical investigations, enabling it to bring “drugs to market at a small fraction of the cost of” new pioneer drugs.²⁵ The ANDA

¹⁶ Apel, *supra* note 5, at 111.

¹⁷ Shepherd, *supra* note 1, at 17–18.

¹⁸ *Id.* (“The generic industry exploded after the [Hatch-Waxman Act]” and “was assisted by drug substitution laws in every state that allow, or sometimes require, pharmacists to automatically substitute a generic equivalent drug when a patient presents a prescription for a brand drug”).

¹⁹ See, e.g., Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008); Biotechnology Indus. Org. v. District of Columbia, 505 F.3d 1343, 1347 (Fed. Cir. 2007).

²⁰ See 21 U.S.C. § 355(j) (2012); Caraco, 527 F.3d at 1282; Ranbaxy Labs., Ltd. v. Leavitt, 459 F. Supp. 2d 1, 2 (D.D.C.), *aff'd*, 469 F.3d 120 (D.C. Cir. 2006).

²¹ THOMAS, *supra* note 1, at 14–15; Shepherd, *supra* note 1, at 23. While many generic manufacturers had to perform clinical investigations, some could rely on published scientific literature demonstrating the safety and efficacy of the brand-name drug. However, this kind of literature was not available for all drugs. *Id.* The clinical investigation data were oftentimes protected as trade secrets. Henry G. Grabowski et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFF. 2157, 2157 (2011).

²² THOMAS, *supra* note 1, at 7. Clinical investigations occur over several stages, involving the testing of the new drug in hundreds or thousands of patients. *Id.* at 7–8.

²³ FTC v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013); THOMAS, *supra* note 1, at 14.

²⁴ Shepherd, *supra* note 1, at 24; Sturiale, *supra* note 5, at 6; see also Grabowski et al., *supra* note 21, at 2157.

²⁵ 21 U.S.C. § 355(j)(2)(A)(iv); Teva Pharm., USA, Inc. v. Leavitt, 548 F.3d 103, 104 (D.C. Cir. 2008); 21 C.F.R. §§ 314.94(a)(7), 314.127(a)(6)(i) (2017); Shepherd, *supra* note 1, at 19, 23 (a generic manufacturer

filer may rely on the clinical investigations originally conducted by the pioneer if it demonstrates that the proposed generic is “bioequivalent” to the approved pioneer drug,²⁶ meaning that it has similar chemical interactions in the human body.²⁷ The FDA may then approve the proposed generic drug for marketing, provided all other requirements are met.²⁸

While beneficial to consumers, generic competition can harm the incentives for pioneer drug development by decreasing the lifetime sales of pioneer drugs.²⁹ The cost of pioneer drug development is over \$2 billion.³⁰ To recoup these expenses and finance future drug development, drug pioneers rely on the exclusive marketing rights granted by the FDA and the U.S. patent system.³¹

The Hatch-Waxman Act actively incentivizes pioneer drug development by extending the pioneer’s market exclusivity period.³² The extensions compensate the pioneer for the time spent seeking FDA approval and for allowing the ANDA filer to piggyback off its clinical investigations.³³ There are two types of extensions.

spends only a few million dollars to bring a generic drug to market; “[w]ith these significantly lower costs, generic companies can afford to charge a lower price for their drugs and still earn impressive profits”).

²⁶ See *supra* note 25.

²⁷ See *Actavis*, 133 S. Ct. at 2228; Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & L. 275, 277–78 (1996). Bioequivalency requires that “the rate and extent of absorption” of the proposed generic drug cannot “show a significant difference” from that of the approved drug. 21 U.S.C. § 355(j)(8)(B)(i).

²⁸ 21 U.S.C. § 355(j)(2)(A)(i)–(v) (requiring the ANDA to demonstrate that the proposed generic is the same as the previously approved pioneer drug with respect to active ingredient, indication, dosage form, route of administration, strength, and labeling); 355(j)(4) (requiring the FDA to approve an ANDA unless it finds, among other things, that the ANDA has not provided sufficient evidence of the necessary requirements).

²⁹ See *Apel*, *supra* note 5, at 108; *Shepherd*, *supra* note 1, at 20.

³⁰ See *supra* note 5 and accompanying text.

³¹ See, e.g., H.R. REP. NO. 98-857, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648 (discussing that the House Committee on Energy and Commerce Report explained that patents are designed to incentivize innovative activities by enabling innovators to obtain greater profits than could have been obtained if direct competition existed); 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>.

³² See 130 CONG. REC. 24,427 (1984) (statement of Rep. Henry Waxman) (“[A]s a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product.”); THOMAS, *supra* note 1, at 18–19.

³³ See *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1346 (Fed. Cir. 2007) (“[T]he Drug Price Competition and Patent Term Restoration Act of 1984 . . . add[s] stimulus for research on new drugs . . . through an extension of patent life to help recover the costs of obtaining FDA approval.” (quoting 130 CONG. REC. 15,846 (statement of Senator Hatch)); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996); THOMAS, *supra* note 1, at 18–19.

The first restores the patent term for the time lost in clinical investigations and FDA review of the new drug application (NDA).³⁴ Through patent term restoration, the drug pioneer's marketing exclusivity period is extended by one-half the time spent conducting clinical investigations, plus the entire period spent by the FDA in reviewing the NDA.³⁵ The extension for patent term restoration is capped at five years.³⁶

As for the second type, the Hatch-Waxman Act creates marketing exclusivities that are independent of patent protection.³⁷ They extend the drug pioneer's monopoly by five years for new chemical entities and by three years for new clinical investigations.³⁸ The five-year marketing exclusivity is available for drugs containing a new chemical entity (NCE), which is an active ingredient never previously approved by the FDA.³⁹ During the five years, the FDA is precluded from approving an ANDA for a proposed generic containing the same NCE.⁴⁰ The Act also prevents the FDA from accepting such ANDAs in the first instance, which has the practical effect of blocking generic market entry for five years plus the length of the FDA's review of the ANDA.⁴¹ If, for example, the FDA needs two years to review the ANDA, the effect of NCE exclusivity is to grant seven years of protection from generic competition.⁴² As for the three-year marketing exclusivity, it is awarded if the pioneer's NDA contains new clinical investigations to support changes such as a new dosage form or indication.⁴³ Its purpose is to encourage drug developers to improve FDA-approved drugs.⁴⁴ Unlike NCE exclusivity, the three-year exclusivity does not prevent the FDA from accepting an ANDA with respect to that drug.⁴⁵ Therefore the FDA is permitted to issue tentative approvals that become effective at the end of the three-year period.⁴⁶

³⁴ 35 U.S.C. § 156 (2012).

³⁵ *Id.*; THOMAS, *supra* note 1, at 18.

³⁶ 35 U.S.C. § 156(g)(6)(A).

³⁷ THOMAS, *supra* note 1, at 18.

³⁸ 21 U.S.C. § 355(j)(5)(F)(ii) (2012).

³⁹ *See* 21 C.F.R. § 314.108(a) (2017).

⁴⁰ 21 U.S.C. § 355(j)(5)(F)(ii); THOMAS, *supra* note 1, at 433.

⁴¹ THOMAS, *supra* note 1, at 433.

⁴² *Id.*

⁴³ *Id.* at 435.

⁴⁴ *See id.*

⁴⁵ *Id.* at 436. This difference between the two marketing exclusivities renders the NCE exclusivity of more value than the three-year exclusivity. *Id.*

⁴⁶ *Id.* (explaining that the FDA is permitted to do so at the close of its ANDA review if the three-year exclusivity bars ANDA approval).

B. Patent Litigation Scheme Under the Hatch-Waxman Act

Even after the marketing exclusivities run their course, a generic drug may still be blocked from market entry by the drug pioneer's patents. For instance, the NCE exclusivity for the insomnia drug, Lunesta, ended in December 2009, but the patents covering Lunesta expired in February 2014.⁴⁷ An ANDA filer must challenge the active patents blocking FDA approval to gain earlier market entry.⁴⁸ The Hatch-Waxman Act sets out a complex procedural scheme for resolving the patent disputes between generic manufacturers and drug pioneers.⁴⁹

1. Paragraph IV Certification and the Thirty-Month Stay of FDA Approval

The Hatch-Waxman Act requires the ANDA to list the patents “to which a claim of patent infringement could reasonably be asserted” against the proposed generic.⁵⁰ These patents are published in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.”⁵¹ The Orange Book consists of U.S. patents having claims covering the approved active ingredients, formulations, and methods of use.⁵² The ANDA filer must certify as to the relevant Orange-Book listed patents.⁵³

⁴⁷ Benjamin Burck, *First to File and Beyond: Paragraph IV Business Strategies*, THOMSON REUTERS INTELL. PROP. & SCI. GENERICS & API INTELLIGENCE, <http://thomsonreuters.com/content/dam/openweb/documents/pdf/pharma-life-sciences/misc/burck-paragraph-iv-webinar.pdf> (last visited Feb. 12, 2017). Another example involves Daiichi's hypertension drug Benicar (olmesartan medoxomil), which gained FDA approval on April 25, 2002. BENICAR, <http://benicar.com/> (last visited Sept. 2016); *Product Details No. N021286*, FDA, http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021286 (last visited Feb. 19, 2017); *Patent and Exclusivity No. N021286*, FDA, http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Appl_type=N&Appl_No=021286&Product_No=001 (last visited Oct. 29, 2016). There are two patents listed in the Orange Book for Benicar—U.S. Patent Nos. 5,616,599 (the ‘599 patent) and 6,878,703 (the ‘703 patent). The ‘599 patent covers the olmesartan active compound and expires on October 25, 2016. The ‘703 patent covers methods of treatment and would have expired on November 19, 2021. *Supra Patent and Exclusivity No. N021286*.

⁴⁸ Sturiale, *supra* note 5, at 9; Erik Hovenkamp & Jorge Lemus, Pay for Go-Away: Reverse Payment Settlements and Holdup Under PTAB 3 (Nov. 3, 2016) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2814532.

⁴⁹ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228–29 (2013).

⁵⁰ 21 U.S.C. § 355(b)(1) (2012).

⁵¹ See *Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA (36th ed. 2016), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>. The Hatch-Waxman Act requires drug pioneers to list pertinent patents it believes would be infringed by a proposed generic, in addition to the expiration dates of those patents. See 21 U.S.C. §§ 355(b)(1), (c)(2); THOMAS, *supra* note 1, at 15–16. The FDA is required to publish this patent information in the Orange Book. See 21 U.S.C. § 355(c)(2).

⁵² 21 C.F.R. § 314.53(b) (2017).

⁵³ See 21 U.S.C. § 355(j)(2)(A); *Dey Pharma, LP v. Sunovion Pharm. Inc.*, 677 F.3d 1158, 1159 (Fed. Cir. 2012).

The first two kinds of certifications, Paragraphs I and II certifications, are for drugs without patent protection and permit immediate approval of the ANDA, while the Paragraph III certification permits approval only after the relevant Orange Book-listed patents have expired.⁵⁴

The fourth kind, the Paragraph IV certification, challenges the drug patents blocking generic market entry and sets off the Hatch-Waxman patent litigation scheme.⁵⁵ The Paragraph IV certification states that the drug pioneer's patents are invalid, unenforceable, or will not be infringed by the proposed generic.⁵⁶ The ANDA filer must provide notice to the drug pioneer "of the factual and legal basis" of its patent challenge.⁵⁷ The filing of the Paragraph IV certification is a technical act of patent infringement⁵⁸ and gives the pioneer an immediate right to sue by creating the case or controversy to support subject-matter jurisdiction.⁵⁹ If successful, the pioneer will prevent generic market entry until after its patents expire.⁶⁰

Upon receiving notice of the Paragraph IV certification, the pioneer has a forty-five day window to sue on the relevant patents.⁶¹ If the pioneer fails to sue within the forty-five days, the FDA is permitted to immediately approve

⁵⁴ 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(III); 21 C.F.R. § 314.94(a)(12).

⁵⁵ See *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012) ("Filing a paragraph IV certification means provoking litigation."); see also 21 U.S.C. § 355(j)(2)(B), (j)(5)(B)(iii), (j)(5)(C); 35 U.S.C. § 271(e)(2) (2012).

⁵⁶ 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12).

⁵⁷ 21 U.S.C. § 355(j)(2)(B)(iii)(II); see also *id.* § 355(b)(3)(B) (requiring that the filer of an ANDA containing a Paragraph IV certification provide the patent owner with notice of such action within twenty days of filing the ANDA); 21 C.F.R. § 314.95(c)(6) ("The applicant shall include . . . (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed. (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.").

⁵⁸ 35 U.S.C. § 271(e)(2). The charge of infringement under § 271(e)(2) is technical in nature because "[a]t this stage the generic manufacturer has done nothing more than request FDA approval to market a drug." THOMAS, *supra* note 1, at 16–17.

⁵⁹ See *Caraco*, 566 U.S. at 407, 412; *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Before the ANDA filer makes a Paragraph IV certification, the Hatch-Waxman Act provides it with a safe harbor from patent infringement liability while it develops the generic version of the approved drug. 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."); *Allergan, Inc. v. Actavis, Inc.*, No. 2:14-CV-188, 2014 WL 7336692, at *1 (E.D. Tex. Dec. 23, 2014).

⁶⁰ 35 U.S.C. § 271(e)(4); THOMAS, *supra* note 1, at 17.

⁶¹ 21 U.S.C. § 355(j)(5)(C)(i); see also *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (stating that the pioneer has the option of suing on all, some, or none of the patents included in the Paragraph IV Certification).

the ANDA even though the pioneer drug is covered by patent protection.⁶² The ANDA filer may obtain patent certainty before entering the market by seeking a declaratory judgment for invalidity or noninfringement under the Hatch-Waxman amendments in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.⁶³ If the drug pioneer sues within the forty-five day window, the FDA is stayed from approving the proposed generic for thirty months,⁶⁴ preventing generic market entry and competition for that time.⁶⁵ The thirty-month stay is effectively the equivalent to an automatic preliminary injunction and provides the drug pioneer with the opportunity to assert its patent rights before generic market entry.⁶⁶ If the ANDA litigation lasts for longer, the FDA will approve the ANDA at the thirty-month mark even if litigation is ongoing.⁶⁷

The thirty-month stay “is likely to keep the generic drug off the market for a lengthy period” of time.⁶⁸ However, it can be terminated early if the ANDA filer prevails in court before the expiry of the thirty-months.⁶⁹ The Hatch-Waxman provisions contemplate that the ANDA filer can prevail in two ways.

⁶² See 21 U.S.C. § 355 (j)(5)(B)(iii); see, e.g., *Eli Lilly*, 557 F.3d at 1348; *Janssen*, 540 F.3d at 1356; *Mylan Pharm., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 201 (D.D.C. 2012).

⁶³ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, § 1102(a), 117 Stat. 2066, 2457–60 (2003) (codified at 21 U.S.C. § 355(j) (2012)); 21 U.S.C. § 355(j)(5)(C)(i)(II) (“[A] declaratory judgment that the [listed] patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . .”). Congress extended federal court jurisdiction over these declaratory judgment actions “to the extent consistent with the Constitution.” *Janssen*, 540 F.3d at 1357 (quoting 35 U.S.C. § 271(e)(5) (2012)). “Therefore, federal courts have jurisdiction over these declaratory judgment actions to the extent that they present an Article III case or controversy.” *Id.*

⁶⁴ *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1245 (Fed. Cir. 2000) (stating that the FDA must suspend approval of the ANDA until “the date that is thirty months from the date the owner of the listed drug’s patent received notice of the filing of a Paragraph IV certification” (citing 21 U.S.C. § 355(j)(5)(B)(iii)(I)–(III))). While the thirty-month stay blocks final approval, the FDA may still grant “tentative approval” to an ANDA that meets all scientific and procedural standards. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); *Mylan*, 856 F. Supp. 2d at 201 n.3. But a generic drug that has been “tentatively approved” may not be legally marketed until the FDA issues a final approval letter. See 21 C.F.R. §§ 314.105(d), 314.107(b)(3)(v) (2017).

⁶⁵ See 21 U.S.C. § 355(j)(5)(B)(iii); *Mylan*, 856 F. Supp. 2d at 201.

⁶⁶ See, e.g., *Mylan*, 856 F. Supp. 2d at 201; *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 578 (D.N.J. 2001); THOMAS, *supra* note 1, at 17.

⁶⁷ 21 U.S.C. § 355(j)(5)(B)(iii); see also Hovenkamp, *supra* note 48, at 11. If the generic manufacturer enters the market before the ANDA litigation concludes, it risks “being held liable for treble damages for willful infringement if the court later” rules in favor of the pioneer drug developer. Sturiale, *supra* note 5, at 10.

⁶⁸ *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 408 (2012).

⁶⁹ See 21 U.S.C. § 355(j)(5)(B)(iii)(I); Hovenkamp, *supra* note 48, at 11. On the other hand, if the ANDA filer loses in court before the end of the thirty-months, FDA approval will “be made effective on the date the court determines that the patent will expire or otherwise orders.” 21 C.F.R. § 314.107(b)(3)(iii).

First, if a district court rules that the relevant patents are invalid, unenforceable, or not infringed, the FDA will approve the ANDA on “the date on which the court enters judgment reflecting the decision.”⁷⁰ An appeal will not reinstate the stay.⁷¹ Alternatively, the stay will be lifted if on appeal, the Federal Circuit finds the relevant patents invalid or not infringed, even if the ANDA filer loses in district court.⁷² As a side note, the stay may also end or be extended if a court finds that either party improperly delays the litigation,⁷³ among others.⁷⁴

2. *Incentives to Challenge the Patents Blocking Generic Market Entry*

The Paragraph IV certification process “actively incentivizes” ANDA filers “to challenge the validity of brand patents before they expire.”⁷⁵ Congress was concerned that invalid patents were blocking generic competition and created incentives for ANDA filers to weed out invalid drug patents.⁷⁶ Congress was also cognizant of the high barriers to generic market entry; ANDA litigation can cost up to \$5 million through trial and the ANDA filer additionally risks incurring liability for patent infringement.⁷⁷

⁷⁰ 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa); *see also* 21 U.S.C. § 355(c)(3)(C)(i) (“[I]f before the expiration of [the thirty-month] period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the [FDA] approval shall be made effective on the date on—which the court enters judgment reflecting that decision”); 21 C.F.R. § 314.107(b)(3)(ii).

⁷¹ *Sanofi-Aventis v. FDA*, 725 F. Supp. 2d 92, 100 (D.D.C. 2010) (stating Congress intended “that the entry of judgment by the district court be the event that triggers the termination of the thirty-month stay notwithstanding any subsequent appeal or ruling by the appellate court”).

⁷² 21 U.S.C. §§ 355(c)(3)(C)(ii)(I)(aa), (j)(5)(B)(iii)(II)(aa) (“[I]f before expiration of [the thirty-month] period *the district court* decides that the patent has been infringed—if the judgment of *the district court* is appealed, the approval shall be made effective on the date on which *the court of appeals* decides that the patent is invalid or not infringed” (emphasis added)). The thirty-month stay also ends if a court of appeals endorses a settlement agreement stating that the patent is invalid or not infringed before issuing an opinion. *Sanofi-Aventis*, 725 F. Supp. 2d at 99.

⁷³ 21 U.S.C. § 355(j)(5)(B)(iii); *see also* *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009); 21 C.F.R. § 314.107(b)(3)(i)(A).

⁷⁴ *See infra* Section V.A.

⁷⁵ *Shepherd*, *supra* note 1, at 23–24; 149 CONG. REC. S16104 (daily ed. Dec. 9, 2003) (statement of Sen. Hatch) (the Act gives “an incentive for vigorous patent challenges”).

⁷⁶ *See* FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4–5 (2002) (interpreting the Hatch-Waxman Act).

⁷⁷ AM. INTELL. PROP. LAW ASS’N, 2015 REPORT OF THE ECONOMIC SURVEY 37–38 (2015), <http://files.ctctcdn.com/e79ee274201/b6ced6c3-d1ee-4ee7-9873-352dbe08d8fd.pdf> (for a controversy greater than \$25 million, median litigation costs for ANDA litigation are \$3 million through the end of discovery and \$5 million through trial).

One incentive permits the FDA to accept the Paragraph IV ANDA one year early—beginning on the fourth, rather than fifth, year of NCE exclusivity.⁷⁸ The ANDA filer may then start the patent litigation suit during the fourth year of NCE exclusivity, and possibly gain earlier market entry.⁷⁹ ANDA submission during year four may increase the risk of lengthening the stay of FDA approval.⁸⁰ Nevertheless, Paragraph IV ANDA filers tend to submit their ANDAs on the first date possible, the fourth anniversary of the FDA’s approval of the NDA.⁸¹

The Hatch-Waxman Act also incentivizes Paragraph IV patent challenges by creating a lucrative reward, the 180-day exclusivity, for the first generic to submit a Paragraph IV ANDA (first filer).⁸² During the 180-day period, all other generic competitors are blocked from the market,⁸³ creating a duopoly and allowing the first filer to shadow the pioneer’s high price.⁸⁴ The exclusivity period is so valuable for the first filer that the Generic Pharmaceutical Association estimates that the “vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.”⁸⁵ Afterwards, other generic manufacturers will enter the market and rapidly drive down prices and the first filer’s profits.⁸⁶

⁷⁸ 21 U.S.C. § 355(j)(5)(F)(ii); *see also* 21 C.F.R. §§ 314.101(e)(2)(ii), 314.108(b)(2) (2017).

⁷⁹ *See* 35 U.S.C. § 271(e)(2) (2012); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012) (the filing of the Paragraph IV certification creates the case or controversy to confer jurisdiction on federal courts); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

⁸⁰ 21 U.S.C. § 355(j)(5)(F)(ii) (allowing the thirty-month stay to be “extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval”); *see also* 21 C.F.R. § 314.107(b)(3)(i)(B) (ANDA “approval may be made effective at the expiration of the 7 1/2 years from the date of approval of the application for the patented drug product”); THOMAS, *supra* note 1, at 17–18.

⁸¹ *See, e.g.*, Burck, *supra* note 47, at 24.

⁸² 21 U.S.C. § 355(j)(5)(B)(iv) (establishing exclusivity period); *see, e.g.*, *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008). The first filer is awarded the 180-day exclusivity regardless of whether or not the NDA holder brings suit. Sturiale, *supra* note 5, at 13–14.

⁸³ 21 U.S.C. § 355(j)(5)(B)(iv); *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) (during the 180-day period, “no other generic can compete with the brand-name drug”). The FDA enforces the first filer’s market exclusivity by delaying approval of subsequent ANDAs until the 180-day period has expired. 21 U.S.C. § 355(j)(5)(B)(iv); *Janssen*, 540 F.3d at 1356; 21 C.F.R. § 314.107(c)(1).

⁸⁴ Grabowski et al., *supra* note 21 (“[d]uring the 180-day exclusivity period,” the first filer “provides only limited price discounts compared to the” pioneer drug “and thus earns substantial revenues and profits”); Shepherd, *supra* note 1, at 24; Sturiale, *supra* note 5, at 11.

⁸⁵ *Actavis*, 133 S. Ct. at 2229. The 180-day exclusivity is possibly “worth several hundred million dollars.” *Id.* (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)). The exclusivity reward is so valuable that it has given rise to “reverse payment” settlements (also known as pay-for-delay settlements), in which the pioneer pays the generic to delay entering the market. The pioneer is then able to charge higher prices than if the first filer had prevailed in the litigation. In 2003, Congress attempted to remedy this problem with several amendments to the Hatch-Waxman Act in the MMA. *See generally* C. Scott Hemphill, *Paying for Delay: Pharmaceutical*

The 180-day exclusivity will be awarded to multiple ANDA filers if they submit substantially complete ANDAs on the same day.⁸⁷ Most 180-day exclusivities are now shared, as an unintended consequence of the MMA of 2003.⁸⁸ The impact of shared exclusivity has been to substantially decrease the first filers' profits and to change the economics of Hatch-Waxman litigation.⁸⁹ ANDA filers can no longer afford to spend millions in legal fees to challenge Orange Book-listed patents and are seeking to cut litigation costs.⁹⁰ Since 2012, new administrative proceedings have provided ANDA filers with an additional, cost-effective avenue for challenging the Orange Book-listed patents blocking generic entry.

II. CHALLENGING ORANGE BOOK-LISTED PATENTS VIA IPR AND PGR REVIEW

The America Invents Act (AIA) of 2011 introduced new post-grant patent proceedings that are becoming an integral part of Hatch-Waxman litigations.⁹¹ The purpose of these proceedings is to encourage "meritorious patentability challenges" to "further improve patent quality."⁹² Section A of this Part describes the new post-grant proceedings, which include inter partes review (IPR), post-grant review (PGR), and covered business review (CBM) and are adjudicated by the Patent Trials and Appeal Board (PTAB), an arm of the USPTO.⁹³ The PTAB is a cost-effective alternative to the district courts for adjudicating patent validity, but unlike the district courts, it does not decide

Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1579 (2006) (describing the 180-day exclusivity as a "bounty" that "provides a substantial inducement to challenge drug patents").

⁸⁶ Grabowski et al., *supra* note 21. Even after other generic manufacturers enter the market, the first filer may still "benefit from a 'first mover' advantage, meaning that even when price is matched, the first generic manufacturer may be likely to capture a higher share of the market." *Id.*

⁸⁷ 21 U.S.C. § 355(j)(B)(iv)(II)(bb) (defining a "first applicant" as any applicant that submits a "substantially complete" application "on the first day on which a [nother] substantially complete application" was submitted); THOMAS, *supra* note 1, at 19, 25.

⁸⁸ Scott A. McKeown, *Generic Pharma Leverages PTAB*, PATS. POST-GRANT (Mar. 20, 2014), <http://www.patentspostgrant.com/generic-pharma-eyes-ptab>.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ Pub. L. No. 112-29, 125 Stat. 284 (2011).

⁹² *Coalition for Affordable Drugs VI, LLC v. Celgene Corp.*, No. IPR2015-01092, at 4 (P.T.A.B. Sept. 25, 2015); *see also* *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1326-27 (Fed. Cir. 2016) (Newman, J., dissenting) ("The America Invents Act responds to concerns that the time and cost and uncertainty of resolving patent validity challenges are a disincentive to development and commercialization of new science and technology."); 157 Cong. Rec. S952 at S.23 (daily ed. Feb. 28, 2011) (statement of Sen. Grassley) (stating that IPRs will "provide faster, less costly alternatives to civil litigation").

⁹³ 35 U.S.C. §§ 311-319, 321-329 (2012).

questions of infringement.⁹⁴ Section B of this Part highlights the advantages of the PTAB for patent challengers.

A. *Inter Partes Review and Post-Grant Review*

Of the three types of AIA proceedings, IPRs are most relevant to Hatch-Waxman litigations. As of March 2016, one study identified 228 IPR petitions filed on Orange Book-listed patents and just a handful of PGR and CBM petitions, with 152 of the IPR petitions filed by generic manufacturers.⁹⁵ That is a significant increase from past years; in 2015, only 151 IPR petitions were filed on Orange Book-listed patents while 49 were filed in 2014.⁹⁶ The increase can partly be explained by the explosion of Paragraph IV challenges in recent years; 467 Paragraph IV challenges were filed over proposed generics in 2015, compared to a yearly average of 269 between 2009 and 2013.⁹⁷

IPR proceedings are an attractive option for ANDA filers with strong prior art and weak noninfringement positions. IPRs are instituted on the basis of anticipation or obviousness challenges using patents or printed publications and are only available beginning nine months after patent issuance.⁹⁸ An IPR petitioner who files with weak prior art will risk losing at the PTAB, which may bolster the patent owner's validity arguments in district court.⁹⁹ If the ANDA filer possesses strong noninfringement positions, it may also avoid IPR proceedings; the PTAB may broadly construe the claims, which could weaken the ANDA filer's noninfringement arguments in the district court litigation.

In comparison, PGR proceedings can be used to challenge patentability on more expansive grounds than anticipation or obviousness in light of printed

⁹⁴ See 35 U.S.C. §§ 311–319, 321–329. Only a federal court may address questions of infringement; a federal court could “conclude that the patent claims are not infringed” if it “has devised an alternative, noninfringing means of achieving bioequivalence.” Sturiale, *supra* note 5, at 5 n.19, 10 n.51.

⁹⁵ Kevin E. Noonan, *PTAB Statistics from Spring BIO IPCC Meeting*, PAT. DOCS (Apr. 17, 2016), <http://www.patentdocs.org/2016/04/ptab-statistics-from-spring-bio-ipcc-meeting.html>; see also Grant Shackelford, *Challenging Orange Book-Listed Patents in AIA Reviews*, IIPRD 2015 Symposium, slides 5 & 8 (2015), <http://www.patentofficetrial.com/wp-content/uploads/2015/10/orangebook2.pdf>.

⁹⁶ Ryan Davis, *The Firms That Handle the Most ANDA Patent Cases*, LAW360 (Apr. 26, 2016, 10:37 PM), <https://www.law360.com/articles/787767/the-firms-that-handle-the-most-anda-patent-cases>.

⁹⁷ *Id.*; Shepherd, *supra* note 1, at 24.

⁹⁸ 35 U.S.C. §§ 311(b), 311(c)(1). The PTAB will institute an IPR if “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” *Id.* § 314(a).

⁹⁹ A Practical Guide to Inter Partes Review, WILMERHALE (2013), http://www.wilmerhale.com/uploadedfiles/wilmerhale_shared_content/wilmerhale_files/events/wilmerhale-webinar-ipr1-20jun13.pdf.

prior art.¹⁰⁰ They are available for patents only during the nine months after issuance and with an effective filing date on or after March 16, 2013.¹⁰¹ The USPTO has yet to issue many patent applications after this filing date, so there have been few PGR filings to date.¹⁰² As more PGR-eligible patents issue, PGR proceedings may become more common in Hatch-Waxman litigations.

But IPRs will remain the most relevant for two main reasons. Petitioners are hesitant to use PGRs due to their broad estoppel effects which bar the petitioner from later raising any claim it “raised or reasonably could have raised during that” PGR.¹⁰³ Because a PGR petitioner “can challenge validity on practically any ground,” unlike in IPR where the grounds may only be based on anticipation and obviousness, the estoppel that attaches to PGR is much broader.¹⁰⁴ The other reason is that generic manufacturers may not be monitoring pioneer drug patents closely enough to bring challenges in time for the nine-month window.

CMB review is not particularly relevant to pharmaceutical patent litigation because it is only available for patents directed to “financial product[s] or service[s].”¹⁰⁵ The CBM petitioner must additionally have been sued for infringement.¹⁰⁶ So far, the PTAB has denied most, if not all, CBM petitions filed on Orange Book-listed patents on the basis that they do not qualify for CBM treatment.¹⁰⁷

¹⁰⁰ 35 U.S.C. § 321(b) (2012); 37 C.F.R. § 42.204 (2017) (listing “statutory grounds permitted under 35 U.S.C. § 282(b)(2) or (3)”). A petitioner can request PGR on any grounds of 35 U.S.C. § 101 (patentable subject matter), § 102 (prior use, sales, public availability, and printed publications), § 103 (obviousness), § 112 (written description, enablement, indefiniteness, but not best mode), and § 251 (new matter in reissue patents). 35 U.S.C. § 321(b).

¹⁰¹ 35 U.S.C. § 321(c). The PTAB will institute a PGR if the petitioner has demonstrated that “it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” *Id.* § 324(a) (2012).

¹⁰² Paul R. Gugliuzza, *(In)valid Patents*, 92 NOTRE DAME L. REV. 271, 283 (2016); Shepherd, *supra* note 1, at 32.

¹⁰³ 35 U.S.C. § 325(e) (2012); Gugliuzza, *supra* note 102, at 283.

¹⁰⁴ Gugliuzza, *supra* note 102, at 283; 35 U.S.C. §§ 311(b), 321(b).

¹⁰⁵ 37 C.F.R. § 42.301(a) (defining a covered business method patent as “a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions”). The Federal Circuit has instructed that “the definition of ‘covered business method patent’ is not limited to products and services of only the financial industry, or to patents owned by or directly affecting the activities of financial institutions such as banks and brokerage houses.” *Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1325 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2510 (2016).

¹⁰⁶ 37 C.F.R. § 42.302(a).

¹⁰⁷ *Roxane Labs. v. Jazz Pharm., Inc.*, No. CBM2014-00161 (P.T.A.B. Feb. 9, 2015); *Par Pharm., Inc. v. Jazz Pharm., Inc.*, No. CBM2014-00149 (P.T.A.B. Jan. 13, 2015). Note that it may be possible for “Risk Evaluation and Mitigation Strategies (REMS)” type patents, which are listed in the Orange Book, to be eligible

B. Advantages of PTAB Litigation over District Court Litigation

The AIA establishes some “powerful incentive[s] to challenge patent validity in the PTAB.”¹⁰⁸ Generic manufacturers are using the IPR proceedings to challenge Orange Book-listed patents blocking ANDA approval and generic market entry.¹⁰⁹

Litigation before the PTAB litigation is faster and less expensive than in district court.¹¹⁰ By statute, the PTAB must resolve IPRs and PGRs within twelve to eighteen months from institution compared to the twenty-five to thirty-two months typically required in district courts.¹¹¹ Litigation at the PTAB is generally less expensive due to the reduced timeframe and the limited nature of discovery.¹¹² An IPR proceeding will cost up to \$350,000 while the total ANDA litigation can cost up to \$5 million.¹¹³ Some ANDA filers are

for CBM review. These patents cover the REMS protocols mandated by the FDA for high-risk drugs. The PTAB has so far denied institution for CBM review of Orange Book-listed REMS patents but has never stated that REMS-type patents are ineligible for CBM review. Adam C. Krol & Muna Abu-Shaar, *Safety, Innovation, or Access? REMS Creates Another Battlefield Between Branded & Generic Pharmaceuticals*, THE AIPLA ANTITRUST NEWS, Apr. 2015, at 5, 12–13, http://www.aipla.org/committees/committee_pages/antitrust-law/Committee%20Documents/Antitrust%20News/2015/AIPLA%20Antitrust%20News%20April%202015.pdf; Andrew Williams, *PTAB Update—No Institution of CBM Patent Review for Jazz’s Orange Book Listed Patents*, PAT. DOCS (Jan. 15, 2015), <http://www.patentdocs.org/2015/01/ptab-update-no-institution-of-cbm-patent-review-for-jazzs-orange-book-listed-patents-.html>.

¹⁰⁸ *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 840 (Fed. Cir. 2015).

¹⁰⁹ See *supra* note 95 and accompanying text. The PTAB will institute an IPR if it determines that there is a “reasonable likelihood that the petitioner would prevail with respect to at least 1” challenged patent claim. 35 U.S.C. § 314(a) (2012). For PGRs, the petitioner must show that it is “more likely than not” that at least one challenged claim is unpatentable. *Id.* § 324(a).

¹¹⁰ See, e.g., *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1326–27 (Fed. Cir. 2016) (Newman, J., dissenting) (stating that IPRs will “provide faster, less costly, alternatives to civil litigation” (quoting 157 Cong. Rec. S952 at S.23 (daily ed. Feb. 28, 2011) (statement of Sen. Grassley))).

¹¹¹ See 35 U.S.C. § 326(a)(11)–(c) (2012) (requiring the PTAB to issue a final written decision within twelve months of institution); 37 C.F.R. § 42.200(c) (2017) (providing a maximum extension of six months “for good cause”); Howard W. Levine et al., *Inter Partes Review in Generic Drug Litigation—Why the USPTO Should Exercise Its Discretion to Deny IPR Petitions in Appropriate Hatch-Waxman Act Disputes*, FINNEGAN (Mar. 7, 2014), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=ef284b32-7634-4bc3-b718-7d387a8bc57f>; see also Shepherd, *supra* note 1, at 19.

¹¹² Compare 35 U.S.C. § 316(a)(5) (2012) (limiting IPR discovery to evidence “necessary in the interest of justice”), and 35 U.S.C. § 326(a)(5) (limiting PGR discovery to “evidence directly related to factual assertions advanced by either party in the proceeding”), with FED. R. CIV. P. 26(b) (defining the scope of discoverable material in federal courts).

¹¹³ AM. INTELL. PROP. LAW ASS’N, *supra* note 77, at 37–38; see also McKeown, *supra* note 88 (stating that IPR costs can “be between 10% and 20% of that of district court litigation”).

particularly cost conscious, such as first filers who are forced to share the 180-day exclusivity and subsequent ANDA filers.¹¹⁴

In addition to cost and speed, the PTAB uses legal standards that are favorable to patent challengers. As a result, invalidity arguments may fare better at the PTAB than in district courts; there have been instances where the PTAB invalidated claims previously upheld as not invalid by a district court over many of the same prior art references.¹¹⁵ One significant difference is the lower burden of proof applied by the PTAB to establish unpatentability. A patent challenger must prove invalidity by clear and convincing evidence in district court, but must only establish it by “a preponderance of the evidence” before the PTAB.¹¹⁶ The PTAB also gives a broader claim construction to challenged claims, making invalidation easier by opening them up to a larger universe of prior art. The PTAB gives claims their “broadest reasonable interpretation,” which is broader than the *Phillips* “ordinary and customary meaning” standard employed by federal courts.¹¹⁷ In addition to broader claim construction, the PTAB does not apply the presumption of validity.¹¹⁸ Federal courts presume that issued patents are valid.¹¹⁹ In view of that presumption, federal judges and juries are hesitant to invalidate claims issued by the USPTO, especially when the particular prior art references were already

¹¹⁴ See McKeown, *supra* note 88; Christopher R. Noyes, *When Inter Partes Review Meets Hatch-Waxman Patents*, LAW360 (Sept. 9, 2014, 7:58 AM), https://www.wilmerhale.com/uploadedFiles/Shared_Content/Editorial/Publications/Documents/Law360-when-inter-partes-review-meets-hatch-waxman-patents-9Sep14.pdf.

¹¹⁵ *E.g.*, *Noven Pharm., Inc. v. Novartis AG*, IPR2014-00550, at 3, 7 (P.T.A.B. Sept. 28, 2015) (finding claims 7 and 16 of the ‘031 patent obvious over the combined teachings of Enz and Sasaki); *Novartis Pharms. Inc. v. Noven Pharms. Inc.*, 125 F. Supp. 3d 474, 479, 487 (D. Del. Aug. 31, 2015) (finding claims 7 and 16 of the ‘031 patent not invalid as obvious over the asserted prior art references, which included Enz and Sasaki).

¹¹⁶ 35 U.S.C. §§ 282(a), 316(e) (2012).

¹¹⁷ 37 C.F.R. § 42.100(b) (2017) (defining “broadest reasonable construction”). *Compare Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–18 (Fed. Cir. 2005) (en banc) (using “ordinary and customary meaning” standard), *with Facebook, Inc. v. Pragmatius AV, LLC*, 582 Fed. App’x 864, 869 (Fed. Cir. 2014) (“The broadest reasonable interpretation of a claim term may be the same as or broader than the construction of a term under the *Phillips* standard. But it cannot be narrower.”). In at least one case, a difference in the claim construction standard resulted in different dispositions. *See, e.g.*, *Patent Owner Allergan Sales, LLC’s Preliminary Response at 2–3, Ferrum Ferro Capital, LLC v. Allergan Sales, LLC*, No. IPR2015-00858 (Mar. 9, 2015) (The Federal Circuit majority found claim 4 of the ‘149 Patent not invalid. However, when interpreted under the broadest reasonable interpretation standard applicable in IPR proceedings, claim 4 would have been invalid for obviousness.).

¹¹⁸ *See, e.g., In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008); *cf. Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 605 (Fed. Cir.), *on reh’g*, 771 F.2d 480 (Fed. Cir. 1985) (explaining that litigation presumption of patent validity does not apply in reexamination proceedings, as purpose of such proceedings is “the remedy of administrative error”).

¹¹⁹ *See* 35 U.S.C. § 282(a).

considered during patent examination.¹²⁰ The PTAB is more willing to accept such prior art as grounds for unpatentability.¹²¹

Generic manufacturers also prefer the PTAB because of the character of the decisionmaker.¹²² Oftentimes the generic must base its invalidity positions on highly technical obviousness arguments. IPRs and PGRs take place before a panel of Administrative Patent Judges (APJs) who possess the relevant scientific knowledge, oftentimes in the technical area of the dispute.¹²³ By comparison, district court judges and juries generally possess limited knowledge of the technology and patent laws.¹²⁴ APJs are more likely to understand and appreciate the obviousness arguments due to their scientific expertise.¹²⁵ In part because of these differences, challengers have succeeded in invalidating patents on the basis of obviousness at a higher rate at the PTAB than in the district courts.¹²⁶

¹²⁰ See, e.g., *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1329 (Fed. Cir. 2004) (holding that a patent is presumed valid, in part because of the expertise of patent examiners and the presumption that they have done their jobs properly).

¹²¹ See *Merck & Cie v. Gnosis S.P.A.*, 808 F.3d 829, 840 (Fed. Cir. 2015) (holding that for PTAB proceedings, the AIA eliminates “any deference to the prior examination and grant of the patent”).

¹²² THE PRACTITIONER’S GUIDE TO TRIALS BEFORE THE PATENT TRIAL AND APPEAL BOARD 21–22 (Erika Harmon Arner & Joseph E. Palys eds., 2014). “On the other hand, if the patent challenger has a great story to tell and the technology is relatively straightforward, [district court litigation] may be preferred.” Jason E. Stach & Jeffrey A. Freeman, *District Court or the PTO: Choosing Where to Litigate Patent Invalidity*, FINNEGAN (Mar./Apr. 2014), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=e7ad4528-cec4-4889-a23d-d17bca527ca2>. The PTAB limits the ability of the patent owner to tell an invention story. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012) (“The [PTAB] does not envision that live testimony is necessary at oral argument. However, parties may file a motion for live testimony in appropriate situations.”).

¹²³ See 35 U.S.C. § 6 (2012) (defining APJs as “persons of competent legal knowledge and scientific ability”); Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 1974 n.66 (2013) (“Each APJ has a law degree, is admitted to practice law in at least one state bar, and holds at least a bachelor’s degree in science or engineering.” (citing JAMES MOORE ET AL., A VIEW BEHIND [sic] THE CURTAIN: THE BPAI DECISION MAKING PROCESS 2 (2010), http://usptols.org/uploads/A_View_Behind_the_Curtain__6_-UPDATE100408.pdf)).

¹²⁴ THE PRACTITIONER’S GUIDE TO TRIALS BEFORE THE PATENT TRIAL AND APPEAL BOARD, *supra* note 122, at 21–22. There are some exceptions; for example, the District of Delaware hears numerous Hatch-Waxman cases. See Davis, *supra* note 96 (“ANDA litigation is overwhelmingly concentrated in the District of Delaware.”).

¹²⁵ Bernard Knight, *New Ways to Invalidate Pharmaceutical Patents—Brands and Generics Need to Change Their Intellectual Property Business Models*, PHARM. L. & INDUS. REP. 347 (2014).

¹²⁶ For PTAB proceedings, data through 2015 shows that 49.6% of the claims initially challenged were found unpatentable for obviousness under 35 U.S.C. § 103. Fitzpatrick, Cella, Harper & Scinto, *2016 Findings on USPTO Contested Proceedings*, 2 POST-GRANT HQ REPORTER 1, 10 (2016), http://www.postgrantHQ.com/wp-content/uploads/2014/10/PostgrantHQ_Reporter.pdf. By comparison, the district courts invalidated claims under § 103 at a rate of 27.8%. John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1784, 1787 fig.4 (2014). The percentages for

So far, the most common PTAB challenges against Orange Book-listed patents are IPRs challenging the validity of ancillary patents. These types of patents cover the ancillary aspects of a drug, such as the drug's chemical variants, formulations, methods of administration, and combinations, rather than the active ingredient.¹²⁷ Pioneer-drug developers apply for ancillary patents and list them in the Orange Book to extend the duration of patent protection and market exclusivity; some scholars refer to this strategy as "evergreening."¹²⁸ General manufacturers are more likely to challenge ancillary patents, because the patents covering the active ingredient are difficult to invalidate.¹²⁹ By challenging ancillary patents through IPR, generic manufacturers are counteracting evergreening and benefiting consumers,¹³⁰ but this new litigation strategy raises some unanticipated questions.

III. PTAB DECISION AND FEDERAL CIRCUIT APPEAL CAN PREDATE THE END OF THE THIRTY-MONTH PERIOD

ANDA filers have been using IPRs as part of their Hatch-Waxman litigation strategy,¹³¹ raising an important question concerning the thirty-month stay of FDA approval. If the PTAB invalidates the patents blocking generic entry before expiry of the thirty months, it is unclear whether the stay should end or continue afterwards.¹³² That question arises when the PTAB decision

successful 35 U.S.C. § 102 (anticipation) challenges were 37.5% at the PTAB and 31.1% in district courts. *Id.*; Fitzpatrick, Cella, Harper & Scinto, NewYorkBio Conference May 5, 2015, Large Molecules, Small Proceedings: The Intersection of Biologics and IPRs, slide 12 (2015), http://www.fitzpatrickcella.com/wp-content/uploads/BioNewYork%20Presentation_05_04_15.pptx.

¹²⁷ See Erica J. Pascal, *Are IPRs Impacting the Pharmaceutical Industry?*, DLA PIPER (2015), <https://www.dlapiper.com/en/us/insights/publications/2015/06/ipt-news-q2-2015/are-iprs-impacting-the-pharmaceutical-industry/>; cf. 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, 1799 (2011) (discussing "evergreening," where pioneer drug companies' file patents on follow-on developments rather than new active ingredients).

¹²⁸ C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 615, 642 (2011).

¹²⁹ Pascal, *supra* note 127.

¹³⁰ See *Inside Views: Q&A with Erich Spangenberg on Patents and Drug Prices*, INTELL. PROP. WATCH (Mar. 6, 2016), <http://www.ip-watch.org/2016/06/03/qa-with-erich-spangenberg-on-patents-and-drug-prices/#comments>.

¹³¹ Stephanie E. O'Byrne, *IPRs and ANDA Litigation: All a Matter of Timing*, 62 FED. LAW., Jan./Feb. 2015, at 54; see, e.g., *Eli Lilly & Co. v. Accord Healthcare Inc.*, No. 1:14-cv-00389-SEB-TAB, 2015 WL 8675158, at *1 (S.D. Ind. Dec. 11, 2015) (granting defendant's motion to stay district court litigation pending completion of IPR of patents at issue in this case). Outside of the Hatch-Waxman context, accused infringers commonly seek IPRs. See, e.g., *Endo Pharm., Inc. v. Depomed, Inc.*, No. IPR2014-00652, at 3-4 (P.T.A.B. Sept. 16, 2015) (discussing seven related co-pending federal district court cases).

¹³² See Sturiale, *supra* note 5, at 42-43.

and Federal Circuit appeal predate the end of the thirty-month period. The ANDA filer can obtain the PTAB and Federal Circuit's decisions before the thirty-months' end if it initiates the IPR or PGR before submitting the Paragraph IV ANDA, as demonstrated in section B of this Part. Section A explains that ANDA filers are able to bring these types of pre-suit patent challenges because the PTAB has no standing requirement to file an IPR or PGR petition.

A. Prospective ANDA Filers Can Bring Pre-Suit Patent Challenges at the PTAB

A party need not have Article III standing to participate in an IPR or PGR.¹³³ The lack of standing requirements permits generally anyone besides the patent owner to petition for institution of an IPR or PGR proceeding.¹³⁴ The petitioner does not need to have been charged with infringement or even establish an interest in practicing the technology covered by the patent.¹³⁵ The party may petition for review so long as it does so within one year if previously served with an infringement complaint¹³⁶ and it did not previously seek a declaratory judgment of non-infringement or invalidity on the same patent.¹³⁷

Therefore a generic manufacturer does not need to wait until the drug developer sues to challenge patent validity before the PTAB.¹³⁸ The generic

¹³³ *E.g.*, *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1261 (Fed. Cir. 2014), *cert. denied*, 135 S. Ct. 1401 (2015) (“Article III standing is not necessarily a requirement to appear before an administrative agency.”). *Compare* 37 C.F.R. § 42.101 (2017) (defining who can petition for inter partes review), *and id.* § 42.201 (2017) (defining who can petition for a post-grant review), *with* U.S. CONST. art. 3, § 2 (defining the case or controversy requirement), *and* *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61, 573–74 (1992).

¹³⁴ 37 C.F.R. §§ 42.101 (defining who can petition for inter partes review), 42.201 (2017) (defining who can petition for a post-grant review); *see, e.g.*, *Allergan, Inc. v. Ferrum Ferro Capital, LLC*, No. 8:15-cv-00992 (C.D. Cal. June 19, 2015); *Coalition for Affordable Drugs II LLC v. NPS Pharm., Inc.*, No. IPR2015-00990 (P.T.A.B. June 3, 2015); *Initiative for Responsibility in Drug Pricing LLC v. Wyeth LLC*, No. IPR2014-01259 (P.T.A.B. Feb. 13, 2015).

¹³⁵ *See* O’Byrne, *supra* note 131, at 56; *supra* note 134 and accompanying text.

¹³⁶ 35 U.S.C. § 315(b) (2012) (mandating that an ANDA defendant must file for IPR within twelve months of receiving the infringement complaint).

¹³⁷ 35 U.S.C. § 315(a)(1) (“[I]nter partes review may not be instituted if before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent.”); 37 C.F.R. § 42.201 (prohibiting post-grant review from being instituted “[b]efore the date on which the petition for review is filed, the petitioner or real party-in-interest filed a civil action challenging the validity of a claim of the patent”). These bars serve to conserve judicial resources by forcing the patent challenger to choose one forum for resolving the validity issues.

¹³⁸ American Conference Inst., Paragraph IV Disputes Master Symposium 10, <http://www.lockelord.com/newsandevents/events/2015/09/~~/media/7B03704225DE44BC927F92AC555C104A.ashx> (last visited Mar. 2,

manufacturer can challenge patent validity before filing its Paragraph IV ANDA with the FDA. During that time, a declaratory judgment action for invalidity in district court would be impossible.¹³⁹ The generic manufacturer may even bring the patent challenge *before* the fourth year of NCE exclusivity.¹⁴⁰ That allows the generic manufacturer to circumvent the NCE exclusivity provisions, which prohibit challenges against Orange-book listed patents in district court before the fourth year of NCE exclusivity.¹⁴¹

The generic manufacturer may prevail in invalidating any patents blocking generic entry by the fifth year of NCE exclusivity, which is the earliest permissible date of generic market entry irrespective of patent protection.¹⁴² That allows the generic manufacturer to launch its product on the earliest possible date.¹⁴³ It may even have an appeal from the PTAB decision by that date, allowing it to launch without risk of patent infringement liability.¹⁴⁴

B. By Bringing a Pre-Suit IPR or PGR Challenge, the ANDA Filer Can Obtain a PTAB Decision and Federal Circuit Appeal Before the End of the Thirty-Month Period

To obtain the PTAB and Federal Circuit's decisions before the expiry of the thirty months, the generic manufacturer should bring a pre-ANDA suit challenge at the PTAB to the relevant Orange Book-listed patents.¹⁴⁵ The Federal Circuit appeal can be completed before the thirty months' end if the generic manufacturer brings the challenge before the fourth year of NCE exclusivity, given the relevant timeframes. IPRs and PGRs are completed in eighteen to twenty-four months from start to finish.¹⁴⁶ If the PTAB finds the

2017) (discussing how IPR and PGR "petitions may be filed in advance of traditional Paragraph IV litigation").

¹³⁹ See *supra* note 133 and accompanying text.

¹⁴⁰ McKeown, *supra* note 88.

¹⁴¹ 21 U.S.C. § 355(j)(5)(F)(ii) (2012).

¹⁴² *Id.*; McKeown, *supra* note 88.

¹⁴³ See *supra* notes 78–79 and 140–42 and accompanying text.

¹⁴⁴ McKeown, *supra* note 88. To seek judicial review of the PTAB's decision in the Federal Circuit, the generic manufacturer must meet the constitutional requirements for standing. See *Consumer Watchdog v. WARF*, 753 F.3d 1258, 1261 (Fed. Cir. 2014).

¹⁴⁵ Assuming the patent owner files an infringement suit within the forty-five-day timeframe and initiates the Paragraph IV process.

¹⁴⁶ After the petitioner files an IPR or PGR petition, the patent owner has three months to file a preliminary response, see 37 C.F.R. § 42.207(b) (2017), and the Director has three months from the time the patent owner files a preliminary response to determine whether to institute a PGR, see 35 U.S.C. § 324(c)(1) (2012). Once instituted, the PTAB must issue a final decision within one year, but "may, for good cause

claims unpatentable, the patent owner would appeal that decision to the Federal Circuit.¹⁴⁷ The Federal Circuit appeal should take about eighteen months.¹⁴⁸ During or after the Federal Circuit appeal, the generic manufacturer would submit its Paragraph IV ANDA to the FDA on the fourth year of NCE exclusivity.

Some generic manufactures have already embraced this strategy of preemptively bringing patent challenges at the PTAB in advance of traditional Paragraph IV litigation.¹⁴⁹ This strategy was employed by Paragraph IV ANDA filers, Apotex Inc. and Mylan Inc., against Novartis's \$2.5 billion multiple sclerosis drug, Gilenya.¹⁵⁰ Gilenya was initially approved by the FDA in 2010¹⁵¹ and is covered by four Orange Book-listed patents—the earliest expiring in 2019 and the latest in 2027.¹⁵² Apotex and Mylan petitioned for IPR of the second-latest expiring patent, U.S. Patent No. 8,324,283 (the '283 patent), before submitting ANDAs with the FDA.¹⁵³ Apotex filed its IPR petition in December 2014¹⁵⁴ before submitting a Paragraph IV ANDA with

shown, extend the 1-year period by not more than 6 months.” 35 U.S.C. § 316(a)(11) (2012); *see also* 37 C.F.R. § 42.200(c).

¹⁴⁷ *See* 37 C.F.R. § 90.2 (2017).

¹⁴⁸ After the PTAB's final written decision, the patent owner may seek rehearing within thirty days, 37 C.F.R. § 42.71(d)(2), or appeal to the Federal Circuit within sixty-three days from either the PTAB's final written decision or decision on rehearing, 37 C.F.R. § 90.3(a)(3). After the patent owner files a notice of appeal, the USPTO has forty days to transmit the record to the Federal Circuit. 35 U.S.C. § 143 (2012); FED. CIR. R. 17(b)(1). The Federal Circuit's median time to disposition for appeals from the USPTO is ten months. U.S. COURT OF APPEALS FOR THE FED. CIRCUIT, MEDIAN TIME TO DISPOSITION IN CASES TERMINATED AFTER HEARING OR SUBMISSION [hereinafter MEDIAN TIME TO DISPOSITION], <http://www.cafc.uscourts.gov/sites/default/files/the-court/statistics/mediandisptimemerits.table.sy05-14.pdf> (last visited Jan. 8, 2016).

¹⁴⁹ *See* O'Byrne, *supra* note 131, at 56–57 (for example, Apotex filed pre-suit patent challenges at the PTAB against Wyeth and Alcon's Orange Book-listed patents).

¹⁵⁰ Joe C. Mathew, *Torrent Wins Patent Battle Against Novartis' \$2.5 Billion Drug Gilenya in US*, BUS. TODAY INDIA (Nov. 17, 2015, 8:49 PM), <http://www.businesstoday.in/sectors/pharma/torrent-wins-patent-battle-against-novartis-usd-2.5-billion-drug-gilenya-in-us/story/224308.html> (“With \$2.5 billion annual sales in 2014, Gilenya is the highest revenue generating drug for Novartis worldwide.”).

¹⁵¹ *Orange Book: Product Details for Gilenya (Fingolimod)*, FDA, http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=022527 (last visited Feb. 13, 2017) (listing an approval date of Sept. 21, 2010).

¹⁵² *Orange Book: Patent and Exclusivity for Gilenya (Fingolimod)*, FDA, http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=022527&Appl_type=N (last visited Feb. 13, 2017).

¹⁵³ *Id.* (expiring on Mar 29, 2026); *Torrent Pharm. Ltd. v. Novartis AG*, No. IPR2014-00784 (P.T.A.B. Sept. 24, 2015).

¹⁵⁴ *Petition for Inter Partes Review, Apotex, Ltd. v. Novartis AG*, No. IPR2015-00518 (P.T.A.B. Dec. 31, 2014).

the FDA in mid-2015; Novartis subsequently brought suit in October 2015.¹⁵⁵ Mylan joined an instituted IPR as a real party-in-interest in early 2015; that instituted IPR had been initiated by Torrent Pharmaceuticals in a May 27, 2014, petition.¹⁵⁶ Mylan submitted a Paragraph IV ANDA with the FDA in early 2016 and Novartis brought suit in district court on April 22, 2016.¹⁵⁷

The Gilenya cases illustrate that an ANDA filer can obtain a PTAB decision, and Federal Circuit affirmance of that decision, well before the end of the thirty-month period if it brings the IPR challenge early enough. The thirty-month stay will expire in March 2018 in Novartis's district court suit against Apotex and in October 2018 in the suit against Mylan.¹⁵⁸ The PTAB issued a final written decision for the '283 patent on September 24, 2015, finding all the claims unpatentable.¹⁵⁹ Novartis appealed the PTAB's decision to the Federal Circuit, and the Federal Circuit's disposition of the case is expected soon.¹⁶⁰

In the cases above, the invalidation of the '283 patent will not result in earlier generic market entry because Gilenya is covered by a later-expiring patent that is blocking generic market entry.¹⁶¹ Generic manufacturers will achieve earlier market entry only by proving invalidity or noninfringement as to the *latest* expiring patent, which in Gilenya's case expires one year and three months after the '283 patent.¹⁶²

While the Gilenya case did not result in invalidation of the latest-expiring patent, the next case does. It involves Novartis's drug Exelon for treatment of

¹⁵⁵ Complaint, *Novartis AG v. Apotex Inc.*, No. 0:15-cv-62273-BB (S.D. Fla. Oct. 28, 2015); Complaint, *Novartis AG v. Apotex Inc.*, No. 1:15-cv-00975-LPS, 6 (D. Del. Oct. 26, 2015). Apotex's notice of ANDA filing to Novartis was dated September 14, 2015. *Id.*

¹⁵⁶ *Apotex, Ltd. v. Novartis AG*, No. IPR2015-00518 (P.T.A.B. Feb. 17, 2015) (instituting inter partes review and granting motion for joinder); Petition for *Inter Partes* Review, *Torrent Pharm. Ltd. v. Novartis AG & Mitsubishi Pharma Corp.*, No. IPR2014-00784 (P.T.A.B. May 27, 2014).

¹⁵⁷ Complaint, *Novartis AG v. Mylan Pharm. Inc.*, No. 1:16-cv-00289-UNA (D. Del. Apr. 22, 2016). Mylan's notice of ANDA filing to Novartis was dated April 6, 2016. *Id.*

¹⁵⁸ The thirty-month stay begins on the date that the NDA holder receives notice of the Paragraph IV certification. 21 C.F.R. § 314.107(b)(3) (2017). Apotex's notice of ANDA filing to Novartis was dated September 14, 2015, Complaint at 6, *Novartis v. Apotex Inc.*, No. 0:15-cv-62273-BB, and Mylan's notice was dated April 6, 2016, Complaint at 6, *Novartis v. Mylan Pharm. Inc.*, No. 1:16-cv-00289-UNA.

¹⁵⁹ *Torrent Pharm., Ltd. v. Novartis AG*, No. IPR2014-00784, at 2–3 (P.T.A.B. Sept. 24, 2015).

¹⁶⁰ Notice of Docketing, *Novartis AG v. Torrent Pharm.*, No. 16-01352 (Fed. Cir. Dec. 21, 2015); *see also* MEDIAN TIME TO DISPOSITION, *supra* note 148 (stating that the Federal Circuit's median time to disposition of cases from the Patent Office is ten months).

¹⁶¹ *Orange Book: Patent and Exclusivity for Gilenya (Fingolimod)*, *supra* note 152.

¹⁶² *Id.*

Alzheimer's and Parkinson's disease and illustrates that an IPR filed *after* ANDA submission will likely not result in a PTAB final decision that predates the end of the thirty-month period.

There, Noven Pharmaceuticals submitted a Paragraph IV ANDA to the FDA in early 2013, seeking approval for a generic version of Novartis's Exelon.¹⁶³ Novartis filed suit on April 3, 2013, after receiving Noven's Paragraph IV notice letter.¹⁶⁴ Noven petitioned for IPR of the two Orange Book-listed patents blocking approval of generic Exelon on April 2, 2014, immediately before the one-year bar for IPR review.¹⁶⁵ The PTAB instituted review for both patents and issued final written decisions on September 28, 2015, finding all the challenged claims unpatentable.¹⁶⁶ The thirty-month stay for the district court case ended in August 2015,¹⁶⁷ before the PTAB reached its decision.

Noven is not alone in waiting until the deadline for the one-year bar to petition for IPR. Many ANDA filers wait until the deadline even though earlier filing results in earlier resolution.¹⁶⁸ By waiting, the ANDA filer can vet the best prior art for the IPR during discovery in the district court case.¹⁶⁹ The ANDA filer can also use the district court case to test out the patent owner's best validity arguments in response to the asserted prior art.¹⁷⁰

Had Noven brought its IPR challenges before submitting its Paragraph IV ANDA, it could have obtained the PTAB's determinations of unpatentability well before the end of the thirty-month period. That fact pattern would have

¹⁶³ Press Release, Noven, Noven Confirms Filing of Abbreviated New Drug Application for Generic Version of Exelon (Rivastigmine Transdermal System) (Apr. 3, 2013), <http://www.noven.com/PR040313.php>.

¹⁶⁴ Complaint at 1, *Novartis Pharm. Corp. v. Noven Pharm., Inc.*, No. 1:13-cv-00527-UNA (D. Del. Apr. 3, 2013).

¹⁶⁵ Petition for *Inter Partes* Review, *Noven Pharm., Inc., v. Novartis AG*, No. IPR2014-00550 (P.T.A.B. Apr. 2, 2014); Petition for *Inter Partes* Review, *Noven Pharm., Inc., v. Novartis AG*, No. IPR2014-00549 (P.T.A.B. Apr. 2, 2014); *Orange Book: Patent and Exclusivity for Rivastigmine (Exelon) Film, Extended Release*, FDA, http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=005&Appl_No=022083&Appl_type=N (last visited Sept. 23, 2016) (stating that U.S. Patent Nos. 6,316,023 and 6,335,031 both expire on Jan. 8, 2019).

¹⁶⁶ *Noven Pharm., Inc., v. Novartis AG*, No. IPR2014-00550, at 3 (P.T.A.B. Sept. 28, 2015); *Noven Pharm., Inc., v. Novartis AG*, No. IPR2014-00549, at 3 (P.T.A.B. Sept. 28, 2015).

¹⁶⁷ The thirty-month stay begins on the date that the NDA holder receives notice of the Paragraph IV certification. 21 C.F.R. § 314.107(b)(3) (2016). Noven provided its Paragraph IV certification notice letter to Novartis on February 18, 2013. Press Release, *supra* note 163.

¹⁶⁸ O'Byrne, *supra* note 131, at 56–57.

¹⁶⁹ *Id.* at 57.

¹⁷⁰ *See id.*

raised questions about the effect of the PTAB's determination of unpatentability on the thirty-month stay of FDA approval.

IV. NEITHER A PTAB DECISION OF UNPATENTABILITY NOR THE FEDERAL CIRCUIT'S AFFIRMANCE OF THAT DECISION ARE SUFFICIENT TO TERMINATE THE THIRTY-MONTH STAY OF FDA APPROVAL

Should the Federal Circuit affirm the PTAB's decision of unpatentability before the end of the thirty-month stay, the question arises as to whether the stay should end before the expiry of the thirty months. Given the text of the Hatch-Waxman Act and AIA, those circumstances alone cannot prematurely terminate the thirty-month stay, as shown in section A of this Part. An examination of the legislative history produces the same conclusion, as demonstrated in section B.

A. *Statutory Text of the Hatch-Waxman Act and AIA Does Not Permit a PTAB Decision Affirmed by the Federal Circuit to Terminate the Thirty-Month Stay*

Starting with an analysis of the plain text,¹⁷¹ the language of the Hatch-Waxman and AIA statutes clearly does not tie termination of the thirty-month stay to a PTAB decision of unpatentability, even after that decision has been affirmed by the Federal Circuit. Neither statute indicates that such events can trigger termination of the thirty-month stay. In light of the clear statutory text, the courts and FDA should "resist reading . . . elements into a statute that do not appear on its face."¹⁷²

The thirty-month stay provisions in the Hatch-Waxman Act have plain meaning¹⁷³ and do not provide that a PTAB decision, even when affirmed by the Federal Circuit, can terminate the thirty-month stay. The statutory language explicitly lays out the specific circumstances in which termination can

¹⁷¹ S. Cal. Edison Co. v. Fed. Energy Regulatory Comm'n, 195 F.3d 17, 23 (D.C. Cir. 1999) ("[T]he starting point, and the most traditional tool of statutory construction, is to read the text itself.")

¹⁷² Bates v. United States, 522 U.S. 23, 29 (1997); see also United States v. Goldenberg, 168 U.S. 95, 103 (1897) ("No mere omission . . . which it may seem wise to have specifically provided for, justif[ies] any judicial addition to the language of the statute."); Nat'l Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Serv., 416 F. Supp. 2d 92, 100 (D.D.C. 2006) (stating that a court will not read into a section what is not stated therein nor ignore its plain language).

¹⁷³ Sanofi-Aventis v. FDA, 725 F. Supp. 2d 92, 100 (D.D.C. 2010).

occur.¹⁷⁴ It provides that where an ANDA otherwise meets the standards for approval, it shall “be made effective upon the expiration of the thirty-month period . . . *except*” in a series of specific circumstances that do not include a PTAB decision of unpatentability.¹⁷⁵ Courts have cautioned that “[w]here [Congress] has acted to except certain categories from the operation of a particular law, it is to be presumed that [Congress] in its exceptions intended to go only as far as it did, and that additional exceptions are not warranted.”¹⁷⁶ Courts have adhered to this principle in strictly construing the thirty-month stay provisions of the Hatch-Waxman Act.¹⁷⁷

The Hatch-Waxman Act expressly states that the stay-terminating event must originate from a district court action. The thirty-month stay ends if a “*district court* decides that the patent is invalid or not infringed.”¹⁷⁸ The stay will be lifted upon the entry of judgment by the district court, regardless of any subsequent appeal.¹⁷⁹ The stay can also end if the ANDA filer loses in the district court but wins on appeal.¹⁸⁰ If “the *district court* decides that the patent

¹⁷⁴ *Endo Pharm. Inc. v. Mylan Techs. Inc.*, No. 11-220-GMS, 2013 WL 936452, at *5 (D. Del. Mar. 11, 2013) (explaining that the statutory language explicitly provides that termination of the thirty-month stay will occur only in certain prescribed ways).

¹⁷⁵ *See* 35 U.S.C. § 355(c)(3)(C) (2012) (emphasis added).

¹⁷⁶ *See, e.g.,* *Sierra Club v. EPA*, 719 F.2d 436, 453 (D.C. Cir. 1983) (quoting *Colo. Public Interest Research Grp., Inc. v. Train*, 507 F.2d 743, 747 (10th Cir. 1974)).

¹⁷⁷ Courts have strictly construed the thirty-month stay provision for the reason that the “statutory language explicitly provides the prescribed ways in which termination can occur.” *Endo Pharm. Inc.*, 2013 WL 936452, at *5 (declining to find that a dismissal order ends the thirty-month stay); *see also* *Merck & Co. v. Apotex, Inc.*, 488 F. Supp. 2d 418, 427–28, 430 (D. Del. 2007), *aff’d in part, vacated in part*, 287 F. App’x 884 (Fed. Cir. 2008) (declining to opine whether a dismissal for lack of subject matter jurisdiction would lift the thirty-month stay, but stating that “the court cannot remedy every harm or prejudice a party endures” from actions that are “expressly sanctioned by the Hatch-Waxman” Act); *Sanofi-Aventis*, 725 F. Supp. 2d at 100 (holding that the plain language of the Hatch-Waxman Act dictates that the thirty-month stay terminates upon the entry of judgment by a district court that a patent is invalid or not infringed, regardless of any subsequent appeal).

¹⁷⁸ 21 U.S.C. §§ 355(c)(3)(C)(i)(I), (j)(5)(B)(iii)(I)(aa) (emphasis added); *see also* 21 C.F.R. § 314.107(b)(3)(B)(ii) (2017). A “substantive determination that there is no cause of action for patent infringement or invalidity” is a decision directed at the merits. 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa).

¹⁷⁹ 21 U.S.C. §§ 355(c)(3)(C)(i)(I), (j)(5)(B)(iii)(I)(aa). The thirty-month stay terminates upon the entry of judgment by a district court that a patent is invalid or not infringed, regardless of any subsequent appeal. *Sanofi-Aventis*, 725 F. Supp. 2d at 100. The *Sanofi* court stated that “the court” in this provision plainly refers only to a district court and the “date on which the court enters judgment” refers to a “specific, unambiguous event described in Federal Rule of Civil Procedure 58.” *Id.* at 98; *see also* 21 U.S.C. §§ 355(c)(3)(C)(i)(I), (j)(5)(B)(iii)(I)(aa); FED. R. CIV. P. 58.

¹⁸⁰ 21 U.S.C. §§ 355(c)(3)(C)(ii), (j)(5)(B)(iii)(II) (“[I]f before expiration of [the thirty-month] period the *district court* decides that the patent has been infringed—if the judgment of the *district court* is appealed, the approval shall be made effective on—the date on which the *court of appeals* decides that the patent is invalid or not infringed.” (emphasis added)); KENNETH L. DORSNEY, ANDA LITIGATION: STRATEGIES AND TACTICS FOR PHARMACEUTICAL PATENT LITIGATORS 63 (2012).

has been infringed” and “the judgment of the *district court* is appealed,” then the thirty-month stay will be lifted when the “court of appeals decides that the patent is invalid or not infringed.”¹⁸¹

A PTAB decision, even if affirmed by the Federal Circuit, does not fall within the specific circumstances set out in these provisions because the PTAB is not a district court. Under a plain reading of the statute, invalidation by the PTAB does not enable the FDA to lift the thirty-month stay and immediately approve the ANDA.¹⁸²

Similarly, the plain text of the AIA does not support an interpretation that an IPR or PGR can terminate the thirty-month stay. The statutory language is silent as to this issue and does not give any indication that patent resolution at the PTAB can terminate the thirty-month stay.¹⁸³

When viewed in context of all the provisions in the AIA, the omission is glaring. Two other provisions, though not directly related to IPRs or PGRs, specifically reference litigation pursuant to the Hatch-Waxman Act; AIA § 12 refers to the Paragraph IV notice letter, and AIA § 19 governs the consolidation of overlapping Hatch-Waxman claims against different ANDA filers.¹⁸⁴ The *Russello* canon of construction provides that, “where Congress includes particular language in one section . . . but omits it in another section of the same Act, it is generally presumed that Congress act[ed] intentionally . . . in the disparate inclusion or exclusion.”¹⁸⁵ The omission

¹⁸¹ 21 U.S.C. § 355(j)(5)(B)(iii)(II).

¹⁸² See Sturiale, *supra* note 5, at 5, 42–43.

¹⁸³ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

¹⁸⁴ 35 U.S.C. § 257(c)(2)(A) (2012) (“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 . . .”). Section 505(j)(2)(B)(iv)(II) provides that an ANDA “applicant that makes a [Paragraph IV] certification . . . shall include in the application a statement that the applicant will give notice as required . . .” 21 U.S.C. § 355(j)(2)(B)(i); 35 U.S.C. § 299(a) (2012) (showing that new joinder rules do not apply to “an action or trial in which an act of infringement under section 271(e)(2) has been pled”); see also 35 U.S.C. § 271(e)(2) (2012) (“It shall be an act of infringement to submit—an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent.”).

¹⁸⁵ *Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)). The Supreme Court has applied the *Russello* canon of construction to infer congressional intent when one section of an Act lacks specific language contained in a different section of the same Act. See, e.g., *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452–53 (2002); *United States v. Gonzales*, 520 U.S. 1, 5 (1997); *Fedorenko v. United States*, 449 U.S. 490, 512 (1981). The Federal Circuit and D.C. Circuit regularly apply the *Russello* canon of construction. See, e.g., *Texas v. EPA*, 726 F.3d 180, 188 (D.C. Cir. 2013); *Burden v. Shinseki*, 727 F.3d 1161, 1171 (Fed. Cir. 2013); *Sioux Honey Ass’n v. Hartford Fire Ins.*, 672 F.3d 1041, 1052 (Fed. Cir. 2012) (concluding that “Congress’s use of the term ‘jurisdiction’ in [28 U.S.C.] §§ 1581–1584 but not in § 1585 suggests that it did not intend for . . . the concept of supplemental

could suggest that Congress intended the thirty-month stay to continue after the PTAB decision of unpatentability and the Federal Circuit affirmance of that decision.

B. Congressional Intent Indicates that PTAB Decisions Cannot Terminate the Thirty-Month Stay

If the statutory language is clear as to the scope of the thirty-month stay provisions, the courts and FDA ordinarily “will not inquire further.”¹⁸⁶ An inquiry into Congressional intent is necessary only to determine whether there is “a clearly expressed legislative intent to the contrary.”¹⁸⁷ Here, the backdrop against which Congress legislated indicates an intent to exclude PTAB proceedings from the types of events that can terminate the thirty-month stay.

When Congress enacted the Hatch-Waxman Act in 1984, a party could challenge patent validity at the USPTO in a type of post-grant proceeding: the *ex parte* reexamination.¹⁸⁸ An *ex parte* reexamination could be finalized before the end of the thirty-month stay if initiated well before the Hatch-Waxman litigation. Yet Congress did not mention the *ex parte* reexamination in the Hatch-Waxman statute in 1984.¹⁸⁹ In the House Report on the Hatch-Waxman Act, the Committee on Commerce stated its intent to tie early termination of the thirty-month stay to a district court decision.¹⁹⁰

jurisdiction” to apply to § 1585); *Ford v. Mabus*, 629 F.3d 198, 206 (D.C. Cir. 2010) (“[I]t is through the ‘dint of . . . phrasing’ that Congress speaks, and where it uses different language in different provisions of the same statute, we must give effect to those differences.”). However, the Supreme Court has indicated that the *Russello* canon must be considered in light of “the design of the statute” as a whole and “its object and policy,” *Negusie v. Holder*, 555 U.S. 511, 519 (2009) (quoting *Dada v. Mukasey*, 554 U.S. 1, 16 (2008)), and has cautioned against the use of the *Russello* canon where there are an increasing number of differences between the provisions being compared, *see City of Columbus v. Ours Garage and Wrecker Serv.*, 536 U.S. 424, 435–36 (2002).

¹⁸⁶ *Lin Qi–Zhuo v. Meissner*, 70 F.3d 136, 140 (D.C. Cir. 1995) (holding that if the plain language of the statute is clear, the court need not inquire further into its meaning, at least in the absence of “a clearly expressed legislative intent to the contrary” (quoting *Reves v. Ernst & Young*, 507 U.S. 170, 177 (1993))).

¹⁸⁷ *Id.*

¹⁸⁸ 35 U.S.C. §§ 301–307 (2012). *Ex parte* reexamination historical statistics show seventy-eight filed in 1981, 187 filed in 1982, and 186 filed in 1983. USPTO, *EX PARTE* REEXAMINATION FILING DATA—SEPTEMBER 30, 2014 (Sept. 30, 2014), http://www.uspto.gov/sites/default/files/documents/ex_parte_historical_stats_roll_up_EOY2014.pdf [hereinafter USPTO *EX PARTE* REEXAMINATION FILING DATA].

¹⁸⁹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

¹⁹⁰ The House Report on the Hatch-Waxman Act states that the “Committee recognizes that some ANDA’s will be submitted and ready for approval before the patent on the listed drug has expired.” H.R. REP. NO. 98-857, pt. 1, at 27 (1984). “[A]pproval of the ANDA may not be made effective until [the end of the stay] unless a *district court* has decided a case for patent infringement earlier.” *Id.* (emphasis added).

In 2003, when Congress amended the Hatch-Waxman Act, another type of post-grant proceeding was available to patent challengers: the inter partes reexamination.¹⁹¹ An inter partes reexamination could have been finalized before the end of the thirty-month period if initiated early. In 2003 alone, the USPTO received 392 requests for ex parte reexamination and twenty-one requests for inter partes reexamination.¹⁹² Yet Congress did not provide for either type of proceeding in the Hatch-Waxman amendments of 2003.¹⁹³ To the contrary, Congress amended the statutory language to clarify that the stay can end only after a district court action. The amendment specified that the court that “decides that such patent is invalid or not infringed” must be a district court.¹⁹⁴

The legislative history indicates the thirty-month stay provisions were a “hard-won compromise” that should be construed narrowly.¹⁹⁵ The existence of the regulatory stay and its length were the result of hard-won compromises between members of Congress, the pioneer drug developers, and the generic drug industry. The stay was added “to accommodate the competing concerns” of the brand-name and generic industries, according to the House Report.¹⁹⁶ And even though the addition of the stay was against the generic manufacturers’ interests, they “were willing to live with [the statutory stay] because of other provisions in the bill.”¹⁹⁷ Members of Congress engaged in heated debate over the length of the stay.¹⁹⁸ The length was revised numerous

¹⁹¹ 35 U.S.C. §§ 311–319 (2012) (effective Nov. 1999).

¹⁹² USPTO *EX PARTE* REEXAMINATION FILING DATA, *supra* note 188; USPTO, *INTER PARTES* REEXAMINATION FILING DATA—SEPTEMBER 30, 2014 (Sept. 30, 2014), http://www.uspto.gov/sites/default/files/documents/inter_parte_historical_stats_roll_up_EOY2014.pdf.

¹⁹³ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003); Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, 113 Stat. 1501 (1999) (codified as 35 U.S.C. §§ 311–319 (2012)).

¹⁹⁴ 21 U.S.C. §§ 355(c)(3)(C)(i), (j)(5)(B)(iii)(I) (2012) (emphasis added). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended the Hatch-Waxman Act to specify that the thirty-month stay will be terminated by a decision of invalidity or noninfringement by a district court or by a court of appeals after appeal from a district court case. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2450, 2454 (2003) (codified as 21 U.S.C. §§ 355(c)(3)(C)(i), (j)(5)(B)(iii)(I)). As originally enacted, the Hatch-Waxman Act provided that the thirty-month stay terminates if “*the court* decides that such patent is invalid or not infringed.” Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, 1589, 1595 (1984) (emphasis added).

¹⁹⁵ *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 557 F.3d 1346, 1354 n.3 (Fed. Cir. 2009) (Prost, J., dissenting).

¹⁹⁶ See H.R. REP. NO. 98-857 pt. 2, at 9–10 (1984).

¹⁹⁷ *Id.*

¹⁹⁸ *Eli Lilly*, 557 F.3d at 1354 n.3; 130 CONG. REC. H24426–31 (Sept. 6, 1984).

times during the legislative process, from eighteen months in the House's version of the Act to thirty months in the Senate's.¹⁹⁹ Given this legislative history, courts should properly read the thirty-month stay provisions to cover only the "narrow circumstances described in the statute."²⁰⁰ Otherwise, the compromise that created the thirty-month stay provisions will "cease[] to have meaning."²⁰¹

Further, Congress has carefully balanced the incentives for pharmaceutical innovation with increasing patient access to generic drugs.²⁰² That balance is "quintessentially a matter for legislative judgment."²⁰³ Because Congress has already articulated its legislative judgment, the courts "must attend closely to [those] terms."²⁰⁴

When Congress enacted the AIA in 2011,²⁰⁵ Hatch-Waxman litigations were common and had been around since the 1980s.²⁰⁶ Congress presumably legislated with the awareness that the new IPR and PGR proceedings would be used with respect to Orange Book-listed patents. It was within Congress's purview to integrate the thirty-month stay into the statutory framework for IPRs and PGRs, but Congress did not. The omission might alternatively have been an oversight by Congress in a complex area of law. Nonetheless, the courts and FDA should narrowly construe the thirty-month stay provisions given the powerful textual arguments available.²⁰⁷

V. ANDA APPROVAL UPON PREVAILING AT THE PTAB AND FEDERAL CIRCUIT

Section A of this Part examines how the thirty-month stay may be terminated after an ANDA filer prevails at the PTAB and Federal Circuit. These pathways for terminating the stay involve unnecessary delays in ANDA approval and require the ANDA filer to navigate through complex maneuvers. The result is to delay generic market entry and patient access to lower-priced

¹⁹⁹ H.R. 3605, 98th Cong. § 101 (1984); S. 2926, 98th Cong. § 101 (1984).

²⁰⁰ *Eli Lilly*, 557 F.3d at 1354 n.3.

²⁰¹ *Id.*

²⁰² *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005); Shepherd, *supra* note 1, at 22.

²⁰³ *Teva Pharm. Indus.*, 410 F.3d at 54.

²⁰⁴ *Id.*

²⁰⁵ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

²⁰⁶ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

²⁰⁷ *Apel*, *supra* note 5, at 129.

generic drugs. To mitigate this problem, section B of this Part proposes a statutory amendment to integrate IPRs and PGRs into the Hatch-Waxman framework.

A. Pathways for Terminating the Thirty-Month Stay

The Hatch-Waxman Act delineates specific circumstances that can end the thirty-month stay, and the FDA permits certain extra-statutory triggers to automatically terminate the stay. Currently, resolution of patent validity at the PTAB and Federal Circuit does not automatically terminate the thirty-month stay.

1. Stay-Terminating Triggers Expressly Recognized by Statute

The Hatch-Waxman Act expressly delineates triggers that can terminate the stay of FDA approval before the end of the thirty-month period. The thirty-month stay terminates if, in a district court proceeding, the ANDA filer establishes “that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity).”²⁰⁸ If the ANDA filer loses in the district court, the thirty-month stay can still end if on appeal, the “court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity).”²⁰⁹

Under these statutory provisions, an ANDA filer who prevails at the PTAB and the Federal Circuit before the end of the thirty-month period has two pathways for effecting termination of the stay. The ANDA filer may have a district court take judicial notice of the PTAB and Federal Circuit’s decisions of invalidity.²¹⁰ The second way is to obtain a settlement order or consent decree from a federal court certifying that the patents-at-issue are invalid, unenforceable, or not infringed.²¹¹

The first way of effecting termination requires a decision from the PTAB, affirmed by the Federal Circuit, that the relevant Orange Book-listed patents are unpatentable. Assuming the ANDA filer is engaged in parallel litigation before a district court, once the ANDA filer succeeds at the PTAB and Federal

²⁰⁸ 21 U.S.C. §§ 355(c)(3)(C)(i), (j)(5)(B)(iii)(I) (2012); *see also* 21 C.F.R. § 314.107(b)(3)(ii) (2017).

²⁰⁹ 21 U.S.C. §§ 355(j)(5)(B)(iii)(II); *see also* 21 C.F.R. § 314.107(b)(3)(iii).

²¹⁰ Sturiale, *supra* note 5, at 26.

²¹¹ 21 C.F.R. § 314.107(b)(3).

Circuit, it will ask the district court to take judicial notice of the Federal Circuit's decision. The district court is bound to the PTAB's decision so long as the case in the district court has not been finally decided.²¹² Upon affirmance of the PTAB's decision, the USPTO will cancel the relevant claims, which has the effect of extinguishing the patent owner's patent rights.²¹³ Therefore, the district court should enter judgment that the asserted claims are invalid,²¹⁴ which under the statute is a decision by "the district court . . . that the patent is invalid" and that terminates the thirty-month stay.²¹⁵

The ANDA filer must navigate through a series of complex maneuvers because the stay does not automatically terminate upon patent resolution at the PTAB and Federal Circuit.²¹⁶ Requiring the ANDA filer "to navigate these maneuvers is terribly inefficient" and "only delays [market] entry by generic drug manufacturers."²¹⁷

The stay could also end prematurely if the parties to a district court proceeding enter a settlement order certifying that the patent claims are invalid or not infringed,²¹⁸ which is a "substantive determination that there is no cause of action for patent infringement or invalidity."²¹⁹ The patent owner might agree to such a settlement order if there is a separate appeal that will decide the validity of the asserted claims. Those circumstances occurred in Cubist Pharmaceuticals' ANDA suits for infringement of patents covering its antibiotic product. Cubist sued two separate ANDA filers Mylan and Hospira for infringement of the same patent claims. The *Hospira* appeal reached the Federal Circuit before resolution between Cubist and Mylan in district court.

²¹² Jonathan Tamimi, *Breaking Bad Patents: The Formula for Quick, Inexpensive Resolution of Patent Validity*, 29 BERKELEY TECH. L.J. 587, 613 (2014); see *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1339–40 (Fed. Cir. 2013) ("[C]ancellation of claims during reexamination would be binding in concurrent infringement litigation.").

²¹³ 35 U.S.C. § 328(b) (2012); Gugliuzza, *supra* note 102, at 312; see also *ePlus, Inc. v. Lawson Software, Inc.*, 760 F.3d 1350, 1356–57 (Fed. Cir. 2014) (discussing the USPTO's decision of unpatentability, its cancellation of the relevant claim, and the removal of the rights previously conferred by that claim), *amended by* 789 F.3d 1349 (Fed. Cir. 2015).

²¹⁴ Gugliuzza, *supra* note 102, at 312; Sturiale, *supra* note 5, at 42; see also FED. R. EVID. 201(b)(2) ("The court may judicially notice a fact that is not subject to reasonable dispute because it can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.").

²¹⁵ 21 U.S.C. §§ 355(c)(3)(C)(i), (j)(5)(B)(iii)(I) (2012).

²¹⁶ Sturiale, *supra* note 5, at 42–43; see *supra* notes 212–16.

²¹⁷ Sturiale, *supra* note 5, at 43.

²¹⁸ Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. 6802, 6863 (Feb. 6, 2015); Hovenkamp, *supra* note 48, at 11.

²¹⁹ 21 U.S.C. § 355(j)(5)(B)(iii); see Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. at 6863.

Therefore, Cubist and Mylan stipulated in the district court proceeding that the asserted claims are invalid in light of the Federal Circuit's decision in the *Hospira* appeal.²²⁰ The Federal Circuit ultimately invalidated Cubists' asserted claims in the *Hospira* appeal and the *Mylan* district court entered a consent judgment certifying that the claims are invalid.²²¹

2. *Extra-Statutory Triggers that Prematurely Terminate the Thirty-Month Stay*

A number of events that are not delineated in the Hatch-Waxman provisions can trigger termination of the thirty-month stay.²²² The fact that the FDA allows for extra-statutory triggers suggests that it might agree to dissolve the thirty-month stay for an ANDA filer who prevails at the PTAB and Federal Circuit. The FDA's view on this issue is not known because it has not yet been presented with it. However, if the FDA were to dissolve the thirty-month stay under these circumstances, it would be acting outside its authority.

The FDA will prematurely terminate the thirty-month stay in three types of extra-statutory scenarios,²²³ the latter two of which are arguably outside the FDA's authority. Under the first scenario, the FDA will terminate the stay if the patent owner agrees to ANDA approval. In some settlements, the patent owner might grant a license to the ANDA filer and agree to ANDA approval.²²⁴ Because the FDA will "permit termination of the 30-month stay . . . without a court order," the FDA's practice is not authorized by the Hatch-Waxman provisions, which expressly require a court's determination of infringement or invalidity.²²⁵ Nevertheless, the FDA possesses the authority to terminate the thirty-month stay under these circumstances. The patent owner is "granted a statutory benefit or right" in the thirty-month stay and may "waive

²²⁰ *Cubist Pharm. LLC v. Mylan Labs. Ltd.*, Case 1:13-cv-01679-GMS, slip op. at 1 (Fed. Cir. May 24, 2016); see also Hovenkamp, *supra* note 48, at 21.

²²¹ *Cubist Pharm. LLC v. Mylan Labs. Ltd.*, Case 1:13-cv-01679-GMS (D. Del. Feb. 2, 2016).

²²² See Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69,580, 69,582 (Oct. 6, 2016) (codified at 21 C.F.R. pt. 314, 320) ("addressing other scenarios in which a 30-month stay may be terminated").

²²³ See *id.* ("[W]ritten consent to approval by the patent owner or exclusive patent licensee, a court order terminating the stay, or a court order of dismissal without a finding of infringement.")

²²⁴ See also Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,626–27 ("Written consent to approval by patent owner . . . if the patent owner . . . agreed in writing that the . . . ANDA may be approved, the 30-month stay . . . would be terminated and the approval may be granted on or after the date of the consent."); Hovenkamp, *supra* note 48, at 11.

²²⁵ Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. 6802, 6864 (Feb. 6, 2015); see also 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

that benefit or right.”²²⁶ Once the patent owner consents to ANDA approval, there is no longer infringement under the patent statute and no longer a basis for the infringement action.²²⁷

Under the other two extra-statutory triggers, the FDA will terminate the thirty-month stay if a court order requires termination or if a court dismisses the ANDA suit without a finding of invalidity or noninfringement.²²⁸ These extra-statutory triggers are arguably outside the authority of the courts and FDA to carry out.

The courts lack the statutory authority to terminate the thirty-month stay unless “either party . . . [has] failed to reasonably cooperate in expediting the action.”²²⁹ The Hatch-Waxman statute recognizes that only in those circumstances may a district court shorten the thirty-month stay. By circumventing the language of the statute, a court would be exceeding its authority.²³⁰ The Federal Circuit has narrowly construed the thirty-month stay provisions to permit termination only when expressly authorized by statute.²³¹ It has narrowly construed the failure to “reasonably cooperate in expediting the action” provision to exclude scenarios such as improper conduct before the FDA or delaying resolution of the overall patent dispute.²³² A counterargument might stress the federal courts’ inherent authority “to manage their own affairs,” which presumably could extend to the thirty-month stay.²³³ That

²²⁶ Kirkland & Ellis LLP, Comment on the Food and Drug Administration (FDA) Proposed Rule: Abbreviated New Drug Applications and 505(b)(2) Applications (July 7, 2015), <https://www.regulations.gov/document?D=FDA-2011-N-0830-0010>; *see also* Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,626–27 (“[T]his provision . . . permits the party that receives the benefit of the statutory 30-month stay to waive that benefit.”).

²²⁷ 35 U.S.C. § 271(a) (2012) (the manufacture or sale of a patented article “without authority” is an infringement); *Lexmark Int’l, Inc. v. Impression Prods., Inc.*, 816 F.3d 721, 733 (Fed. Cir. 2016) (“[I]nfringement . . . mean[s] what § 271 came to say—committing the identified acts without authority (synonymously, without consent or permission) . . .”).

²²⁸ Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,627.

²²⁹ 21 U.S.C. § 355(j)(5)(B)(iii); *Sturiale, supra* note 5, at 36.

²³⁰ *Sturiale, supra* note 5, at 36.

²³¹ *See, e.g., Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (“We find no such authority in the statute . . . Thus, the district court exceeded its authority in shortening the thirty-month stay.”)

²³² *Id.* at 1376.

²³³ *See, e.g., Dietz v. Bouldin*, 136 S. Ct. 1885, 1891 (2016) (“[T]his Court has long recognized that a district court possesses inherent powers that are ‘governed not by rule or statute but by the control necessarily vested in courts to manage their own affairs so as to achieve the orderly and expeditious disposition of cases.’”); *Purdue Pharma L.P. v. Mallinckrodt Inc.*, No. 06 Civ. 13095, 2007 WL 1437742, at *2–4 (S.D.N.Y. May 15, 2007) (describing that the drug developer “move[d] this Court . . . to invoke its inherent powers to issue a thirty-month stay” and “ask[ed] that its motion be granted pursuant to the Court’s ‘inherent authority’ over the thirty-month stay provision”).

argument fails to appreciate that the thirty-month stay is imposed by statute, rather than by the courts.²³⁴ Therefore the courts likely have no inherent authority over the thirty-month stay.²³⁵

The third extra-statutory trigger occurs once a district court dismisses the ANDA suit for lack of subject matter jurisdiction; the FDA will then terminate the thirty-month stay even though the statutory prerequisite for a finding of noninfringement or invalidity is lacking.²³⁶ The FDA acknowledges that “this issue was not addressed by Congress”; the Hatch-Waxman statute permit termination of the stay after a district court enters an “order of dismissal without a finding of infringement.”²³⁷ But according to the FDA, termination is justified “because it avoid[s] unwarranted delays in approval of . . . [an] ANDA while protecting innovator intellectual property rights.”²³⁸

The FDA’s extra-statutory practices suggest that it might agree to dissolve the stay before the end of the thirty-month period for an ANDA filer who prevails at the PTAB. The ANDA filer would petition the FDA to dissolve the stay after obtaining a determination from the PTAB that the relevant Orange Book-listed patents are unpatentable. The FDA might dissolve the stay after the Federal Circuit affirms the PTAB and issues a formal mandate. The formal mandate officially closes the case under the Federal Circuit’s jurisdiction and allows time for the patent owner to exhaust its right to be reheard by that court.²³⁹ Permitting those circumstances to terminate the thirty-month stay would further the FDA’s express policy goals of preventing delays in generic drug approval and allowing the patent owner to assert its rights before generic entry.²⁴⁰

²³⁴ See Sturiale, *supra* note 5, at 36.

²³⁵ See *id.*

²³⁶ Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,627 (“[A] Federal district court’s entry of an order of dismissal . . . of patent infringement . . . will terminate the 30-month stay period . . .”); see, e.g., *Merck & Co. v. Apotex, Inc.*, 287 F. App’x 884, 887 (Fed. Cir. 2008) (explaining how FDA dissolved the thirty-month stay once the district court dismissed the case for lack of Article III jurisdiction).

²³⁷ Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,627; see also Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. at 6864 (“[T]he statute does not address whether a 30-month stay may be terminated and . . . [an] ANDA approved if the court enters an order of dismissal without a finding of patent infringement . . .”).

²³⁸ Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,627.

²³⁹ See FED. R. APP. P. 41.

²⁴⁰ The FDA’s policies are “intended to avoid unnecessary delays in approval of generic drugs” and allow the patent owner to assert its rights before generic entry. Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. at 6805. The FDA “recognizes that a party may request rehearing by the appellate

The ANDA filer might argue that an appeal from the PTAB should be no different from an appeal from the district court. For appeals from district court decisions, the FDA will approve the ANDA once the Federal Circuit issues a mandate “entering judgment that the patent is invalid, unenforceable, or not infringed”; the FDA should follow this same practice for PTAB appeals.²⁴¹ Further, the Federal Circuit affirmance of an invalidity judgment is functionally the same regardless of whether the judgment was made by the district court or PTAB because both result in extinguishing the relevant patent rights.²⁴²

Though the FDA has good policy reasons for adopting extra-statutory exceptions to the thirty-month stay provisions, it is outside the FDA’s authority to do so. Agencies have no freestanding authority “to ‘correct’ the text [of a statute] so that it better serves the statute’s purposes . . . [or because] its preferred approach would be a better policy.”²⁴³ Congress expressly set forth the bases for dissolving the thirty-month stay in the Hatch-Waxman Act, and later in the 2003 Amendments to the Hatch-Waxman Act.²⁴⁴ The Hatch-Waxman provisions impose the thirty-month stay unless specific, express exceptions are met.²⁴⁵ Those express exceptions preclude the FDA from adopting new, extra-statutory exceptions.²⁴⁶

Regardless of the FDA’s ultimate decision on this issue, any party who challenges it in court will likely lose. The pharmaceutical industry is a highly

panel or rehearing en banc. . . . [I]t would be premature to terminate the thirty-month stay . . . while a decision regarding patent noninfringement, invalidity, or unenforceability was being reheard.” *Id.* at 6863–64.

²⁴¹ 21 C.F.R. § 314.107(b)(3)(iii)(A) (2017) (“If before the expiration of the 30-month period . . . the district court decides that the patent has been infringed, and if the judgment of the district court is appealed, the . . . ANDA may be approved on . . . [t]he date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid, unenforceable, or not infringed . . .”).

²⁴² 35 U.S.C. §§ 318(b), 328(b) (2012) (showing that the USPTO cancels claims after the time for appeal has passed or after the Federal Circuit affirms the PTAB’s decision); *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971) (once a court invalidates a patent, future defendants may rely on the previous judgment of invalidity under the doctrine of issue preclusion); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994), *as corrected on reh’g* (Sept. 14, 1994).

²⁴³ *Engine Mfrs. Ass’n v. EPA*, 88 F.3d 1075, 1089 (D.C. Cir. 1996).

²⁴⁴ *See supra* notes 174–81, 191–94 and accompanying text; Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,580.

²⁴⁵ *See supra* notes 174–77 and accompanying text.

²⁴⁶ The doctrine of *expressio unius est exclusio alterius* precludes the courts and FDA from creating extra-statutory exceptions. *See, e.g.*, *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2238 (2014) (“By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend the FDCA to preclude requirements arising from other sources.”).

regulated industry, and the courts usually defer to the FDA in such contexts.²⁴⁷ A party who challenges the FDA's decision would face a formidable obstacle if the reviewing court affords the FDA *Chevron* deference.²⁴⁸ Under the *Chevron* analysis, Congress has not directly spoken to the precise question of whether a PTAB decision can terminate the thirty-month stay.²⁴⁹ The party would face the challenge of proving that the FDA's decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."²⁵⁰

As illustrated in the preceding section, the pathways for terminating the thirty-month stay involve unnecessary delays. The drug developer's patent rights are extinguished once the ANDA filer prevails at the PTAB and the Federal Circuit.²⁵¹ Yet, the Hatch-Waxman statute does not permit automatic termination of the thirty-month stay in those circumstances.²⁵² This Comment therefore proposes an amendment to the Hatch-Waxman statute.

B. Statutory Amendment to Integrate IPRs and PGRs into the Thirty-Month Stay Provisions

Congress last amended the Hatch-Waxman Act in 2003.²⁵³ In the last four or so years, the AIA has dramatically changed the patent landscape, more so than since the Patent Act of 1952.²⁵⁴ Using IPRs in ANDA litigation has raised unanticipated questions and created significant uncertainty in pharmaceutical

²⁴⁷ *Apel*, *supra* note 5, at 132; *see also* *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–44 (1984).

²⁴⁸ *Chevron*, 467 U.S. at 842–43 (“When a court reviews an agency’s construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. . . . [I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute.”).

²⁴⁹ *See* 35 U.S.C. § 355(j)(B)(iii)(I); *see also* *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1279 (D.C. Cir. 2004) (applying *Chevron*, rather than *Skidmore*, deference to the FDA’s application of the Hatch-Waxman provisions).

²⁵⁰ *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 117 (D.D.C.), *aff’d*, 389 F.3d 1272 (D.C. Cir. 2004).

²⁵¹ *See supra* note 213 and accompanying text.

²⁵² *See supra* notes 212–17 and accompanying text.

²⁵³ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, § 1102(a), 117 Stat. 2066, 2457–60 (2003) (codified at 21 U.S.C. § 355 (2012)).

²⁵⁴ *See* Wayne C. Jaeschke, Zhun Lu & Paul Crawford, *Comparison of Chinese and U.S. Patent Reform Legislation: Which, If Either, Got It Right?*, 11 J. MARSHALL REV. INTELL. PROP. L. 567, 573 (2012).

patent rights.²⁵⁵ Congress should amend the Hatch-Waxman Act to clarify the interplay between IPRs and ANDA litigation, especially as the number of IPR challenges to Orange Book-listed patents continues to increase.²⁵⁶ Specifically, Congress should tie termination of the thirty-month stay to patent resolution at the PTAB and Federal Circuit. This amendment would to improve administrative efficiency and patient access to generic drugs.

Given that IPRs and PGRs will become an integral part of ANDA litigation,²⁵⁷ Congress should revisit Hatch-Waxman to integrate IPRs and PGRs into the statutory framework and resolve questions raised by the use of IPRs in ANDA litigation.²⁵⁸ Congress may use this opportunity to assess whether there is a proper balance between stimulating drug innovation and encouraging generic entry.²⁵⁹ Some commentators argue that amending the statutory scheme is unnecessary due to lack of evidence of systematic failure and uncertainty about the effects of IPRs on pharmaceutical innovation.²⁶⁰ Yet, the number of IPRs on Orange Book-listed patents continues to increase, even if not yet occurring in large numbers.²⁶¹ In 2015, there were twice as many IPR petitions filed on Orange Book-listed patents compared to 2014, and the number likely increased again in 2016.²⁶²

Further, Congress needs to provide clarity to the regulated entities, the agencies and the courts. For the regulated entities, greater certainty encourages business investments, reduces unnecessary litigation, and facilitates

²⁵⁵ See, e.g., Shepherd, *supra* note 1, at 17.

²⁵⁶ *Id.* at 25–26.

²⁵⁷ See, e.g., American Conference Inst., Paragraph IV Disputes: Expert Insights on Hatch-Waxman Litigation Strategies for Brand Names and Generics 5, http://www2.americanconference.com/content/download-content/pdf/marketing/688L15_12pager_E.pdf?sp (last visited Mar. 2, 2017).

²⁵⁸ Shepherd, *supra* note 1, at 25–26; Abbreviated New Drug Applications and 505(b)(2) Applications, 80 Fed. Reg. at 6805 (“[The FDA regulations] preserve the balance struck in the Drug Price Competition and Patent Term Restoration Act of 1984.” (citation omitted)); see also Apel, *supra* note 5, at 110 (noting that the AIA does not address this question: “Can a party that prevails in [an IPR or PGR] trigger the failure to market provision in the Hatch-Waxman Act, thereby unparking the first filer’s exclusivity?”); Sturiale, *supra* note 5, at 40 (noting that currently only the first filer is awarded the 180-day exclusivity, even if a subsequent filer invalidates the patent blocking generic entry at the PTAB).

²⁵⁹ Some commentators have raised concerns that IPRs disrupt the balance that the Hatch-Waxman Act sought to strike between medical innovation and patient access. See, e.g., Shepherd, *supra* note 1, at 26; Letter from Arti K. Rai & Jacob S. Sherkow to U.S. Senate Committee on the Judiciary (June 18, 2015).

²⁶⁰ See, e.g., Letter, *supra* note 259; Noonan, *supra* note 95.

²⁶¹ Shepherd, *supra* note 1, at 25–26.

²⁶² *Id.* Note that the statistics for the number of IPR petitions filed on Orange Book-listed patents in 2016 are unavailable at the time of this writing.

compliance.²⁶³ Legal certainty also improves administrative efficiency and facilitates enforcement by the agencies and courts.²⁶⁴

In amending the statute, Congress should tie termination of the thirty-month stay to patent resolution at the PTAB and Federal Circuit. The statutory amendment should streamline IPRs and PGRs into ANDA litigation by requiring stay dissolution once the Federal Circuit affirms the PTAB and issues a formal mandate.

This proposed amendment is a modest change, but it is a good step toward improving access to lower-cost generic drugs.²⁶⁵ This improvement furthers the goals of the Hatch-Waxman Act by ensuring that invalid patents do not impede generic market entry.²⁶⁶ It reduces unnecessary delays in FDA approval of otherwise approvable ANDAs,²⁶⁷ which in turn, accelerates generic market entry, creates competition in the drug market, reduces prices, and increases access to drugs.²⁶⁸

This proposal also ensures fairness to the patent owner and comports with the Hatch-Waxman Act's goal of preserving the pioneer's patent incentives.²⁶⁹ By tying stay dissolution to the appellate mandate, the proposed amendment preserves the drug developer's right to request rehearing at the Federal Circuit.²⁷⁰ The statutory purpose of the thirty-month stay is to provide the drug developer with adequate time to assert its patent rights against accused infringers.²⁷¹ But once the Federal Circuit affirms the PTAB and issues the mandate, the USPTO is required to cancel the relevant claims, which has the

²⁶³ Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,580 (“[The FDA] intend[s] to reduce unnecessary litigation . . . and provide business certainty to both brand name and generic drug manufacturers.”).

²⁶⁴ *Id.*

²⁶⁵ *Cf. Apel, supra* note 5, at 134; Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,580 (The 2003 amendments to the Hatch-Waxman Act addressed a key concern that “anticompetitive strategies . . . may delay access to generic drugs by . . . [l]imiting the availability of 30-month stays of . . . ANDAs that are otherwise ready to be approved . . .”).

²⁶⁶ *See supra* Letter, *supra* note 259, at 3; *supra* note 76 and accompanying text.

²⁶⁷ *See, e.g., Sturiale, supra* note 5, at 42–43.

²⁶⁸ *See id.* at 38.

²⁶⁹ *See supra* notes 4–6, 31 and accompanying text.

²⁷⁰ *See* FED. R. APP. P. 40.

²⁷¹ *See, e.g., Mylan Pharm., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 201 (D.D.C. 2012); Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,582 (“[T]he statutory purpose of the stay . . . [is] to allow time for patent infringement claims to be litigated prior to approval of the potentially infringing product[.]”).

effect of extinguishing the drug developer's patent rights.²⁷² There is no reason for the thirty-month stay to continue after the appellate mandate.

Further, this proposal advances the AIA's goal of promoting the PTAB as a forum for challenging patent validity. Congress intended for the PTAB to serve as a more efficient and correct surrogate for district court litigation of patent validity.²⁷³ A goal of the AIA was to remove patent challenges from the district courts and place them before the PTAB.²⁷⁴ If IPRs and PGRs are streamlined into ANDA litigation, ANDA filers will pursue more patent challenges at the PTAB.²⁷⁵

The proposal outlined in this Comment does not implicate concerns about harming pharmaceutical research and development innovation. Some commenters have expressed concern that IPRs "may dislodge the balanced statutory framework underlying the [Hatch-Waxman] Act."²⁷⁶ They argue that expanding the generic industry will reduce drug developers' ability to develop new drugs, which will reduce the quality of healthcare in the future.²⁷⁷ The proposed amendment might slightly shift the present balance in favor of generic manufacturers, but only as a consequence of counteracting the effects of evergreening which has priced many patients out of drugs.²⁷⁸ Further, the amendment only affects patent claims that have already been invalidated by the PTAB and Federal Circuit. Once invalidated, the patent claims no longer provide a valid basis for blocking generic market entry.²⁷⁹ Removing this unnecessary roadblock will open up the market to generic drugs.

²⁷² See *supra* note 213 and accompanying text.

²⁷³ See, e.g., *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1283–84 (Fed. Cir. 2015) (Newman, J., dissenting) (quoting H.R. REP. NO. 112-98, pt. 1, at 48, 68 (2011)) (noting that the PTAB "provid[es] quick and cost effective alternatives to litigation"); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1297, 1305 (Fed. Cir. 2015) (Newman, J., dissenting) (noting that the purpose of the PTAB was to "achieve rapid, efficient, and correct resolution of issues of patent validity that heretofore required trial in the district courts").

²⁷⁴ See *supra* note 273 and accompanying text.

²⁷⁵ See, e.g., Sturiale, *supra* note 5, at 43.

²⁷⁶ Kameshwari Sridhar, *Inter Partes Review—A New Frontier for Hatch-Waxman Generics vs Innovators Pharma Patent Battles* 16 (Jan. 26, 2015) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=255568116; see also Shepherd, *supra* note 1, at 26.

²⁷⁷ Shepherd, *supra* note 1, at 7–8.

²⁷⁸ See *supra* notes 127–30 and accompanying text.

²⁷⁹ See *supra* notes 213–15 and accompanying text.

CONCLUSION

AIA proceedings provide new opportunities to accelerate the FDA's approval of generics, and in turn, increase patient access to generic drugs. This Comment proposes a modest change to the Hatch-Waxman statutory framework to allow generic marketing approval once the patents blocking generic market entry have been invalidated in an IPR or PGR. This amendment will ensure that invalid patents do not impede patient access to generic drugs. It also accommodates the competing policy interests of incentivizing new drug innovation and increasing generic availability. If adopted, this proposal has the potential to accelerate generic market entry, which will create competition, reduce prices and increase patient access to lower-cost generic drugs.

NORA XU*

* J.D. Candidate, Class of 2017, Emory University School of Law; B.S. Chemical Engineering, 2011, Rice University. I wish to thank Professors Timothy Holbrook and Jacob Sherkow for their invaluable guidance; Nathan North, Ariel Winawer, and the *Emory Law Journal* editors and staff for their help in preparing this paper for publication; and my parents, Jin Xu and Chaoying Ma, for their endless love and support.