



NOTE

Antitrust and Authorized Generics: A New Predation Analysis

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Abstract. Much attention in the antitrust world has been focused on efforts by brand drug manufacturers to delay or deter generic entry into the pharmaceutical markets following these brand drugs' loss of patent exclusivity. Scholars have recounted and criticized recent exclusionary techniques by brand drug manufacturers, including pay-for-delay (or reverse-payment settlement) agreements, noncash pay-for-delay agreements, and product hopping. These efforts, while successful in stymieing generic entry into the prescription drug market, have largely been struck down by courts as anticompetitive in a series of recent decisions. In light of these decisions, a key, but underanalyzed, concern now is that in order to keep generics out of the market, or at least delay their entry, brand manufacturers will turn to a new tactic: predatory pricing using authorized generics. While some scholarly attention was paid to authorized generics in the early 2000s, almost none has been given since the Supreme Court held unlawful brand drug manufacturers' other main exclusionary tactics, despite the fact that the time is now ripe for the launch of authorized generics. Given that courts have already permitted a brand manufacturer's launch of an authorized generic during a first-filer generic's exclusivity period, brand manufacturers could deter generic entry by launching an authorized generic upon the start of the first filer's exclusivity period but pricing the authorized generic below the generic's costs, thereby preventing the generic from recouping its substantial entry costs. Eventually, if generics see a pattern of brands launching authorized generics during the first filer's period of exclusivity, generics may be deterred from entering the market at all before patent expiration, thereby depriving consumers of price competition in the pharmaceutical market, resulting in higher drug prices overall.

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The problem, however, is that if brand manufacturers are in fact pricing their authorized generics below the generic manufacturers' costs in order to deter generic entry, it is unduly difficult to hold the brand manufacturers accountable under the Supreme Court's current predatory pricing doctrine. Its test, as enunciated in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, only imposes liability if a predator prices below some measure of its own costs and if there is a reasonable probability that the predator will recoup its initial investment in low prices. This Note provides a new analysis that better accounts for the unique regulatory structure and patent protection of the prescription drug market. It argues that a test based on limit pricing, or pricing below the entrant's costs, would more effectively address this exclusionary conduct that harms consumers.

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Introduction

Brand drug prices continue to rise at high rates and to increasingly high levels. In 2018, prices for 267 commonly used brand-name drugs rose by 5.8%—over twice the rate of inflation.¹ While the rate at which prices increased over the past several years peaked at a whopping 15.9% in 2014,² the still-lofty rate of rising drug prices means that Americans will pay more for their healthcare—through their own insurance plans or ultimately, as government spending on healthcare increases, through higher taxes.³ Examples of exorbitantly priced brand-name prescription drugs have dominated headlines recently—Humira, an immunosuppressant, costs \$3,000 per month,⁴ while Zytiga, which treats prostate cancer, costs \$10,000 per month.⁵ Even common drugs such as insulin can now cost over \$300 for a single vial (triple what the price was in 2002).⁶

Patients lose when drug prices are high, especially as “cost-containment strategies” by insurance companies have shifted a greater share of prescription drug costs to patients themselves.⁷ In a recent poll, 29% of adults reported that cost prevented them from taking their medicine as prescribed at some point in the past year, and 8% reported that their condition worsened because of this.⁸

The main reason that prescription drugs cost so much is that “branded products [are] protected by market exclusivity provisions granted by the U.S. Patent and Trademark Office and the Food and Drug Administration (FDA).”⁹ While generic manufacturers have come under criticism as well for price

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1. AARP Pub. Policy Inst., *Brand Name Drug Prices Increase More Than Twice as Fast as Inflation in 2018*, at 1 (2019), <https://perma.cc/NLG5-D5SK>. The AARP report notes that 2018 had the “slowest average annual price increase for widely used brand name prescription drugs since at least 2006.” *Id.* (emphasis added). But, as the report makes clear, “in the absence of meaningful legislative change,” it is “difficult to determine whether the trend will continue.” *See id.*
 2. *Id.* at 2.
 3. *Id.* at 1.
 4. Siena Ruggeri, *Exorbitant Drug Pricing: A Moral Issue*, NETWORK LOBBY FOR CATH. SOC. JUST. (Mar. 5, 2019), <https://perma.cc/E8AH-RYEE>.
 5. Ezekiel J. Emanuel, *Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up*, ATLANTIC (Mar. 23, 2019), <https://perma.cc/F7KF-VA3D>.
 6. See Audrey Farley, Perspective, *Drug Prices Are Killing Diabetics. “Walmart Insulin” Isn’t the Solution.*, WASH. POST (Feb. 19, 2019, 3:00 AM PST), <https://perma.cc/A3T5-ANGF>.
 7. Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 864 (2016).
 8. Ashley Kirzinger et al., *KFF Health Tracking Poll—February 2019: Prescription Drugs*, KFF: POLLING (Mar. 1, 2019), <https://perma.cc/WB4R-JVC3>.
 9. See Kesselheim et al., *supra* note 7, at 860.

spikes in certain generic drugs,¹⁰ generics are nonetheless critical to providing a low-cost drug option for consumers. Yet efforts by brand drug manufacturers to delay or deter generic entry can have a severely negative impact on consumer welfare in the form of higher drug prices.¹¹

Competition between brand and generic drugs in the pharmaceutical industry has long been a topic of discussion for antitrust commentators. The unique nature of the regulatory environment and the patent protection afforded to most brand drug manufacturers makes the pharmaceutical market ripe for antitrust concerns. And indeed, antitrust violations have materialized across the industry as brand drug manufacturers seek to maintain their market exclusivity by delaying or deterring generic entry even after their patents have expired or have been invalidated.¹²

Recently, brand manufacturers have engaged in a more insidious form of exclusionary conduct: launching authorized, or branded, generics to compete with potential generic entrants. There is nothing inherently problematic under the antitrust laws with a brand drug manufacturer launching another product line—after all, antitrust laws *encourage* competition to lower prices for consumers, and an authorized generic may be just another competitor.¹³ An antitrust problem, however, begins to emerge when authorized generics are launched as a means to deter generics from entering the market before patent expiration. If authorized generics are priced in such a way as to effectively deter generics, this may be a form of predation meant to exclude generics from the market in order to maintain the brand manufacturer's patent-induced monopoly. This monopolistic conduct harms consumers because it eliminates generic competitors with lower-priced drug options from the market, leaving consumers with a supracompetitively priced brand drug and an authorized generic that may be only temporarily available at a low price. And harm to consumer welfare is the exact problem the antitrust laws are meant to remedy.

10. See, e.g., Stephen Barlas, *Generic Prices Take Flight: The FDA Is Struggling to Ground Them*, 39 PHARMACY & THERAPEUTICS 833, 843-45 (2014).

11. See FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 4 (2011), <https://perma.cc/4A4M-6NZZ> (considering whether and by how much authorized generics may “delay generic entry, diminish generic competition, and reduce consumer benefits from lower-priced generic products”); see also Letter from Rep. Henry A. Waxman to Deborah Majoras, Chairman, FTC (Sept. 13, 2005), reprinted in FTC, *supra*, at B-2 (“If the rise in authorized generics causes generic drug manufacturers to stop challenging patents for certain products, generic competition will be significantly delayed, and consumers, businesses, and governments will unnecessarily pay monopoly drug prices for much longer periods.”).

12. See, e.g., *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 649 (2d Cir. 2015) (discussing findings that the manufacturer of prescription drug Namenda appeared to have engaged in anticompetitive conduct, thereby violating the antitrust laws, in order “to impede generic competition and to avoid the patent cliff”).

13. See *infra* Part II.D.

As other efforts by brand drug manufacturers to maintain their patent-protected monopolies over drug markets have faced increasing scrutiny by the courts,¹⁴ brand drug manufacturers may now rely more heavily on launching authorized generics in an effort to thwart generic entry and extend the length of their patent and market exclusivity, making this tactic a pressing problem for the antitrust laws.

This Note argues that current antitrust doctrine is ill equipped to account for such practices and advocates for a new predation test using limit pricing, rather than below-cost pricing, as a mechanism for determining whether the launch of an authorized generic during a generic's exclusivity period is anticompetitive.

Part I provides an overview of the various competitors in the pharmaceutical market and the federal regulatory framework that governs the market, particularly the Hatch-Waxman Act. Part II describes competition within the Hatch-Waxman regulatory framework. Part III explains how the launch of authorized generics may be a form of price predation if certain conditions are met, but argues that the Supreme Court's current predatory pricing doctrine is ill equipped to impose liability on this type of exclusionary action. Finally, Part IV puts forth a theory of limit pricing and argues that a limit-pricing test is better suited than the Court's current below-cost test to account for predation by authorized generics.

I. Regulation and Competition in the Pharmaceutical Market

This Part introduces the main cast of characters competing in the pharmaceutical market and the unique regulatory framework in which they act.

A. Primary Actors

As a preliminary matter, significant competition in the pharmaceutical market occurs between brand drugs and generic drugs.¹⁵ Brand drugs are those which are protected by patents. These patents enable brand manufacturers to

14. See *FTC v. Actavis, Inc.*, 570 U.S. 136, 141, 158 (2013) (holding that pay-for-delay agreements may constitute antitrust violations); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549 (1st Cir. 2016) (holding that noncash pay-for-delay agreements are governed by *Actavis*); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (same); see also *Schneiderman*, 787 F.3d at 654 (holding that product hopping, a practice whereby brand drug manufacturers reformulate their drugs and thereby extend patent exclusivity in order to delay generic entry, violates the Sherman Act).

15. See Richard G. Frank & Raymond S. Hartman, *The Nature of Pharmaceutical Competition: Implications for Antitrust Analysis*, 22 INT'L J. ECON. BUS. 301, 304 (2015).

exclude other competitors during the patent term, thereby allowing them to maintain a legal monopoly over the market for the patent-protected drug.¹⁶ A generic drug is one “created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.”¹⁷ Generics may differ in their inactive ingredients, colors, or flavors, since trademark laws prohibit generic drugs from looking identical to brand drugs.¹⁸ The advantage of generic drugs is that they are priced much lower than brand drugs because, at least under the current legal framework, the generic manufacturers need not conduct the same costly clinical trials on generic drugs or spend “huge sums [on] advertising, marketing, and lobbying.”¹⁹ Authorized generics add another element to this competitive framework, discussed further in Part II below.

The nature of this competition between the brands and generics in the pharmaceutical market is due in large part to this market’s unique regulatory structure, which determines which drugs may enter, when they may enter, and how long they may stay.

B. The Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act (FDCA)²⁰ governs the manufacturing and marketing of all pharmaceuticals in the United States. The FDCA requires that any pharmaceutical company wishing to market a *new* drug first submit a New Drug Application (NDA).²¹ The application must set forth “full reports of investigations” showing whether the drug is safe and

16. See Allan N. Littman, *Monopoly, Competition and Other Factors in Determining Patent Infringement Damages*, 38 IDEA 1, 6 (1997) (noting that “patents are legal monopolies the value of which depends on the marketplace” (capitalization altered)).

17. *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN., <https://perma.cc/4PJL-FUSM> (last updated June 1, 2018).

18. Melissa Stoppler, *Generic Drugs, Are They as Good as Brand Names?*, MEDICINENET, <https://perma.cc/2SV6-RHU7> (archived Jan. 16, 2020). While brand drugs and generic drugs are, in the vast majority of cases, interchangeable products (and the FDA treats them as such, see *Generic Drug Facts*, U.S. FOOD & DRUG ADMIN., <https://perma.cc/XMN2-8Z5N> (last updated June 1, 2018)), the minor differences between brands and generics may affect certain people such that they cannot substitute the products, see, e.g., Beth Levine, *The Truth About Generic vs. Brand-Name Medications*, HUFFPOST (Feb. 22, 2015, 9:11 AM ET), <https://perma.cc/JPV4-5PLS>. For the purposes of this Note’s analysis, however, I treat the drugs as equivalent and perfectly substitutable as that is nearly always the case.

19. ASS’N FOR ACCESSIBLE MEDS., *GENERIC DRUG ACCESS & SAVINGS IN THE U.S.* 24 (2017), <https://perma.cc/4C3Q-X3NX>.

20. 21 U.S.C. §§ 301-399i (2018).

21. *Id.* § 355(a).

effective and “a full list of the articles used as components of such drug.”²² The FDA must approve the NDA before the new drug may be marketed.²³

Even before the FDCA underwent significant changes in 1984,²⁴ the FDA permitted the marketing of generic copies without requiring generic manufacturers to submit an NDA, at least for drugs whose brand-name equivalents were approved and had been in use “to a material extent or for a material time.”²⁵ In a 1970 rulemaking, the FDA established the Abbreviated New Drug Application (ANDA) for generic manufacturers wishing to enter the market,²⁶ whereby the generic manufacturers needed only to confirm that the generic drug had the same therapeutic effect and active ingredient as the brand drug.²⁷

However, there were still significant limitations on the ability of generic manufacturers to take advantage of the abbreviated approval process. Critically, “the FDA’s initial ANDA process applied only to generic forms of drugs approved by the FDA prior to 1962.”²⁸ For any drug approved after 1962, the FDA kept confidential the reports attached to the brand drug’s NDA.²⁹ Section 301(j) of the original FDCA “prohibited the public disclosure or use of any method or process obtained by FDA . . . where such information was entitled to protection as a trade secret.”³⁰ This prevented generic manufacturers from leveraging the brand manufacturer’s existing information and research in order to bring a drug to market without having to incur the same, often highly expensive, start-up costs. As a result, before the Hatch-Waxman Act amended the FDCA, generics did not have a large presence in the pharmaceutical market.³¹

C. The Hatch-Waxman Act

While the FDCA has been amended several times, the most influential changes came in 1984. Concerned about rising drug prices, Congress enacted

22. *Id.* § 355(b).

23. *Id.* § 355(a).

24. See *infra* Part I.C (describing the 1984 Hatch-Waxman Act’s amendments to the FDCA).

25. See Ellen J. Flannery & Peter Barton Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 272 (1985).

26. See 21 C.F.R. §§ 314.92-.99 (2019); see also Approval of Certain New-Drug Applications and Supplements, 35 Fed. Reg. 6574, 6574-75 (Apr. 24, 1970).

27. Flannery & Hutt, *supra* note 25, at 274.

28. See Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 587, 589 (2003).

29. *Id.* at 589-90.

30. Flannery & Hutt, *supra* note 25, at 272.

31. Weiswasser & Danzis, *supra* note 28, at 590.

the Drug Price Competition and Patent Term Restoration Act of 1984,³² otherwise known as the Hatch-Waxman Act, which governs the approval of brand and generic drugs today. The Act emerged as a balance between the competing interests of making lower-cost generic drugs more available while still incentivizing brand manufacturers to innovate and to develop new drugs. In so doing, the Act enables brand manufacturers to “enforce and protect their patent rights prior to generic entry,” while also facilitating generic entry by “substantially relaxing the testing requirements imposed on generic manufacturers” and allowing them to take advantage of the safety and effectiveness data already submitted by the brand manufacturers as part of their NDAs.³³ The Act made several key changes to the FDCA in order to effectuate these goals.

First, the Hatch-Waxman Act adopted “bioequivalence” as the new standard for approval of a generic ANDA. For a generic to be bioequivalent, it must use the same active ingredient; be absorbed by the body at approximately the same rate and to the same extent; and contain the same conditions of use, route of administration, dosage form, strength, and labeling as the brand drug.³⁴ If the generic manufacturer can prove as much, the Act allows it to use the safety and efficacy studies already submitted by the brand drug manufacturer as part of its original NDA³⁵—avoiding the costly submission of replicated scientific studies and data and better facilitating entry of generics into the pharmaceutical market.

Second, the Act created an “experimental use exception” that “insulates ANDA-related clinical research from patent-infringement liability.”³⁶ This exception enables generic drug manufacturers to begin bioequivalence testing before the expiration of the patent on the relevant brand drug.³⁷

Third, the Act incentivizes generic manufacturers to enter the market by granting the first ANDA filer a 180-day exclusivity period, during which only that generic and the brand drug can be marketed.³⁸ This 180-day exclusivity period is immensely profitable for the first-filer generic because it effectively

32. Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code) (enacting the Hatch-Waxman Act in its original form); *see also* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 117 Stat. 2066, 2448-61 (codified as amended at 21 U.S.C. §§ 355(j), 355a; and 35 U.S.C. § 271(e) (2018)) (amending the Hatch-Waxman provisions).

33. Weiswasser & Danzis, *supra* note 28, at 590.

34. 21 U.S.C. § 355(j)(2)(A), 355(j)(8)(B).

35. *See id.* § 355(j)(2)(A)(iv), (vi).

36. Thomas Chen, Note, *Authorized Generics: A Prescription for Hatch-Waxman Reform*, 93 VA. L. REV. 459, 464 (2007).

37. *Id.*; *see also* 35 U.S.C. § 271(e)(1).

38. 21 U.S.C. § 355(j)(5)(B)(iv)(I), (II)(aa)-(bb).

grants a temporary monopoly over the generic market, a prospect that induces generics to enter the market to reap a higher profit.³⁹

At the same time, the Act protects the brand manufacturers by restoring part of the patent term that elapses while the brand manufacturer awaits FDA approval of its NDA. The extension period is capped at five years, for a total effective patent term of no more than fourteen years.⁴⁰ The purpose of the patent term restoration is to enable brand manufacturers to recoup the costs expended during the lengthy NDA approval process while also compensating the brand manufacturers for the generic drug industry's use of the proprietary reports and studies that they generate as part of their NDA applications.⁴¹

Additionally, the Act created a new mechanism for the resolution of patent disputes. The Act requires the generic manufacturer to certify that it has met one of the following criteria with respect to each patent listed in the Orange Book⁴²:

- *Paragraph I*: “[P]atent information has not been filed” by the brand manufacturer.⁴³
- *Paragraph II*: The patent has expired.⁴⁴
- *Paragraph III*: The generic manufacturer indicates “the date on which the patent will expire.”⁴⁵
- *Paragraph IV*: The “patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted.”⁴⁶

39. See, e.g., FTC, *supra* note 11, at i (“During that period, because of the absence of competition, both the generic drug price and the first-filer’s revenues are significantly higher than they would be when there are additional generic competitors. Congress created this exclusivity as an incentive for generic companies to enter as soon as possible by challenging invalid patents or patents that are not infringed.”).

40. See 35 U.S.C. § 156(a)(4), (c), (g).

41. See JOHN R. THOMAS, CONG. RESEARCH SERV., R44643, THE HATCH-WAXMAN ACT: A PRIMER 5 (2016), <https://perma.cc/CYT2-YLN9> (“[O]bservers have frequently noted that [the Act] presents a fundamental trade-off: In exchange for permitting manufacturers of generic drugs to gain FDA marketing approval by relying on safety and efficacy data from the brand-name firm’s NDA, the brand-name firms receive a period of regulatory exclusivity and patent term extension.”).

42. The “Orange Book,” or the *Approved Drug Products with Therapeutic Equivalence Evaluations*, is the compilation of all approved pharmaceuticals and associated patent information. *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, U.S. FOOD & DRUG ADMIN., <https://perma.cc/S2N5-4HL8> (last updated Oct. 18, 2019).

43. 21 U.S.C. § 355(j)(2)(A)(vii).

44. *Id.*

45. *Id.*

46. *Id.*

If an applicant makes a certification under Paragraph I or II, so long as the other regulatory requirements are met, “approval may be made effective immediately.”⁴⁷ An ANDA bearing a certification under Paragraph III, however, may not be approved “until the [brand] drug’s listed patent expires.”⁴⁸

If an ANDA makes a Paragraph IV certification attesting to noninfringement or patent invalidity on the part of the brand drug, the generic manufacturer must notify the brand manufacturer that holds the patents at issue.⁴⁹ The brand manufacturer may then file a patent infringement suit within forty-five days of receiving the required notice from the generic manufacturer that submitted the Paragraph IV ANDA; this filing triggers an automatic thirty-month stay on FDA approval of the ANDA unless a court decision that the patent is invalid or not infringed is made earlier.⁵⁰ Then, so long as the generic has not been held to infringe the brand drug’s patent, the FDA allows the generic drug to be marketed and must grant the first filer of the ANDA the 180-day exclusivity period.⁵¹

Along with the Hatch-Waxman Act, states have further facilitated generic accessibility through substitution laws and regulations.⁵² These substitution rules often provide, with certain exceptions, that a pharmacist may fill a prescription by substituting a generic drug in for a brand drug if a generic drug is available.⁵³ “Currently, all States have some form of generic substitution law.”⁵⁴

The Hatch-Waxman Act has significantly increased “both the speed and success of generic entry.”⁵⁵ According to an FTC report, “[i]n 2009, 74 percent of all U.S. prescriptions . . . were filled by generics, up from 43 percent in 1996

47. *Id.* § 355(j)(5)(B)(i).

48. THOMAS, *supra* note 41, at 7; *see also* 21 U.S.C. § 355(j)(5)(B)(ii).

49. *Id.* § 355(j)(2)(B).

50. *Id.* § 355(j)(5)(B)(iii).

51. *Id.* § 355(j)(5)(B)(iii)-(iv).

52. For example, California authorizes a pharmacist to substitute a generic for a brand drug (or biological product) if certain conditions are met, such as the generic having the same active ingredients and dosage and the prescriber not having indicated that substitution is not permissible. *See* CAL. BUS. & PROF. CODE §§ 4073, 4073.5(a) (West 2019). Georgia similarly authorizes a pharmacist to substitute a “pharmaceutically equivalent” generic drug or “an interchangeable biological product” for “the express purpose of making available to the consumer the lowest retail priced” equivalent drug or interchangeable biological product in stock. GA. CODE ANN. § 26-4-81 (2019).

53. *See* Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, NAT’L CONF. ST. LEGISLATURES (May 3, 2019), <https://perma.cc/Z7C4-3PQ9>.

54. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 628 (2011) (Sotomayor, J., dissenting).

55. Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of “Authorized Generics,”* 62 FOOD & DRUG L.J. 739, 742 (2007).

and only 19 percent in 1984.⁵⁶ As of 2016, “[g]enerics account for 89% of prescriptions dispensed” in the United States, but “only 26% of total drug costs.”⁵⁷ The Generic Pharmaceutical Association credits much of the success of generic marketing efforts to the 180-day exclusivity period promised by the Act, stating that “[t]he vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.”⁵⁸ This exclusivity period is so important to generic drug manufacturers because once the exclusivity period expires and other generics may enter the market, the resulting price competition will “drive[] prices to the competitive level,” which can be “as little as 20% of the pre-generic-entry prices,” thus “making immediate entry by multiple firms unpromising” for the profit-seeking generic.⁵⁹

D. Authorized Generics and Hatch-Waxman

While not explicitly addressed by the Hatch-Waxman Act, authorized generics have come to play a major role in the pharmaceutical market by taking advantage of the regulatory framework established by the Act. Authorized generics are “pharmaceutical products that are approved as brand-name drugs but marketed as generic drugs.”⁶⁰ Authorized generics may be launched by the brand drug manufacturer itself (or an authorized third-party distributor) via the brand drug’s NDA, rather than by a separate manufacturer via an ANDA.⁶¹

Authorized generics first achieved popularity and profitability in the early 2000s as a result of greater generic adoption by pharmacists in general,⁶² but they have continued to grow in prominence more recently.⁶³ The price of an authorized generic is usually lower than that of the corresponding brand-name drug, making it competitive with other generics on the market.⁶⁴ The FTC

56. FTC, *supra* note 11, at 3.

57. ASS’N FOR ACCESSIBLE MEDS., *supra* note 19, at 16.

58. FTC, *supra* note 11, at 4 (alteration in original) (quoting Generic Pharm. Ass’n, Comment Letter on Authorized Generic Drug Study: FTC Project No. P062105, at 2 (2006), <https://perma.cc/CV8M-58FX>).

59. See Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 OHIO ST. L.J. 467, 491 (2015).

60. FTC, *supra* note 11, at i.

61. See JOHN R. THOMAS, CONG. RESEARCH SERV., RL33605, AUTHORIZED GENERIC PHARMACEUTICALS: EFFECTS ON INNOVATION 6 (2013), <https://perma.cc/PT2V-9C6Z>.

62. See *id.*

63. See Carol Forster, *The Value of Authorized Generics*, U.S. NEWS & WORLD REP. (May 19, 2016, 6:00 AM), <https://perma.cc/9XND-KYUQ> (“[A]uthorized generics have steadily increased in popularity. By 2014, more than one-third of brand drugs had a matching authorized generic.”).

64. See THOMAS, *supra* note 61, at 1.

found that authorized generics were present in 61% of first-filer exclusivity periods from 2003 to 2008.⁶⁵ And this percentage likely would have been higher but for agreements between brand manufacturers and generic manufacturers not to launch an authorized generic during the first-filer generic's exclusivity period in exchange for delayed first-filer entry.⁶⁶

Because the FDA maintains that a brand manufacturer need not file an ANDA or an NDA in order to market its drug as an authorized generic,⁶⁷ it is relatively easy for brand manufacturers to launch authorized generics since they do not have to pay any of the startup costs associated with a new drug such as clinical trials and regulatory reports.⁶⁸ And because the Hatch-Waxman Act's 180-day exclusivity period does not cover drugs that do not require *some* form of application, authorized generics may enter the market during the first filer's exclusivity period.⁶⁹

Courts have agreed with the FDA. In *Teva Pharmaceutical Industries Ltd. v. Crawford*, the D.C. Circuit held that the Hatch-Waxman Act "clearly does not prohibit" authorized generics from being sold during the 180-day exclusivity period.⁷⁰ Further, in *Mylan Pharmaceuticals, Inc. v. U.S. FDA*, the Fourth Circuit held that the Hatch-Waxman Act did not prohibit a brand drug manufacturer from marketing an authorized generic through a third-party manufacturer during the first-filer generic's exclusivity period.⁷¹ As a result, brand drug manufacturers have continued to launch authorized generics at the beginning of or during the first-filer exclusivity period.

65. FTC, *supra* note 11, at 26. The prevalence of authorized generics during exclusivity periods may suggest that, in some cases, brand manufacturers found it profitable to launch authorized generics in order to compete with generics even without using them as a means of predation, but rather to preserve some of their market share that would have otherwise been lost to generic manufacturers. What this 61% does not capture, however, is how frequently the authorized generics were in fact used as a form of predation to deter generic entry. *See infra* Part IV.C.

66. *See* FTC, *supra* note 11, at 26-27.

67. *See* THOMAS, *supra* note 61, at 10-11.

68. *See generally* Thomas J. Moore et al., *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, 178 JAMA INTERNAL MED. 1451, 1454 (2018) (finding that the median cost of clinical trials for new drugs from 2015 to 2016 was \$19 million).

69. FTC, *supra* note 11, at 4; THOMAS, *supra* note 61, at 10-11.

70. 410 F.3d 51, 55 (D.C. Cir. 2005).

71. *See* 454 F.3d 270, 276 (4th Cir. 2006).

II. Competition Within the Hatch-Waxman Act's Regulatory Framework

This Part describes how the Hatch-Waxman Act both impedes and facilitates competition among these various actors in the pharmaceutical market, as well as the potential antitrust concerns posed by authorized generics.

A. Price Competition

The Hatch-Waxman Act, insofar as the competition regarding the generic first filer's exclusivity period is concerned, created three distinct periods of competition within the pharmaceutical market: pre-exclusivity, exclusivity, and post-exclusivity. In the pre-exclusivity period—during the patent term and before first-filer generic entry—a brand manufacturer can price its brand drug at whatever price the market will sustain because patent protection grants the brand drug a legal monopoly.⁷² And this monopoly period can last for years: “[T]he median length of [post-patent-approval] market exclusivity is 12.5 years for widely used drugs . . . and 14.5 years for highly innovative, first-in-class drugs”⁷³

Any competing brand drugs have different molecules as their active ingredients and compete primarily on quality and clinical profile rather than on price. For example, Bystolic is a brand drug that treats hypertension with the patented nebivolol molecule as its active ingredient,⁷⁴ meaning that during the patent term, no other drug can compete directly by producing a drug with the nebivolol molecule as its active ingredient. However, there are numerous other drugs, with *different* molecules as their active ingredients, that also treat hypertension.⁷⁵ Bystolic may have tried to market itself as a better or more appropriate hypertension drug than others in order to acquire customers. But, for those patients who needed or wanted Bystolic in particular, its manufacturer had a monopoly over the market for the nebivolol molecule, forcing consumers to buy brand-name Bystolic and pay whatever monopoly price Bystolic's seller charged. Thus, in practice, “competition between 2 or more

72. Indeed, this market exclusivity is the “most important factor that allows brand manufacturers to set high drug prices for brand-name drugs.” Kesselheim et al., *supra* note 7, at 861.

73. *Id.*

74. See Allergan, Inc., *Drug Label Information: Bystolic—Nebivolol Hydrochloride Tablet*, DAILYMED (updated Jan. 9, 2019), <https://perma.cc/X39Q-XG9V>.

75. See Jim Morelli, *High Blood Pressure (Hypertension) Medications*, RXLIST, <https://perma.cc/6CDZ-3W8V> (archived Jan. 17, 2020) (describing various categories of hypertension drugs with different active ingredients).

brand-name manufacturers selling drugs in the same class does not usually result in substantial price reductions.”⁷⁶

The end of patent protection and the entry of the first-filer generic drug transforms the market from a legal monopoly to a duopoly of sorts during the exclusivity period. The brand manufacturer still has a legal monopoly over its precise formulation of the drug, but the first-filer generic manufacturer can produce a product with the same active ingredient; absorbed by the body at the same rate and to the same extent; and with the same conditions of use, route of administration, dosage form, strength, and labeling.⁷⁷ Importantly, the first filer is afforded a legal monopoly over the generic market during the 180-day exclusivity period. And because the first filer has a monopoly over the generic version of the drug, the FTC found that, in the absence of authorized generic competition, the generic drug is priced, on average, at 86% of the brand price before generic entry.⁷⁸ Thus, consumers may choose between the high-priced brand drug and the modestly lower-priced generic drug.

The exclusivity period granted to the first filer is a critical incentive for the generic manufacturer to challenge the brand drug manufacturer’s patents through a Paragraph IV certification because it enables the generic manufacturer to recoup its expenses, including research and development and litigation. This recoupment occurs through the generic’s higher price (compared to its eventual post-exclusivity price) *and* the greater market share promised by exclusivity.

After the first-filer generic’s exclusivity period ends and other generics enter the market, competition increases. There is typically a significant decrease in generic drug prices, with the added competition “driving prices down to as little as 20% of pre-generic-entry prices.”⁷⁹ As a result, the brand drug loses on average 90% of its market share within the first year of generic entry.⁸⁰ This drop in prices is great for consumer welfare—according to one study, savings attributable to generic competition totaled \$253 billion in 2016 alone.⁸¹ Scott Hemphill and Mark Lemley illustrate the dramatic fall in drug prices after the entry of multiple generics with the case of simvastatin, a drug

76. Kesselheim et al., *supra* note 7, at 861.

77. *See supra* text accompanying note 34.

78. FTC, *supra* note 11, at ii-iii. With authorized generic competition, the first-filer generic drug is priced on average at 82% of the brand drug’s pre-generic-entry price. *Id.*

79. Hovenkamp, *supra* note 59, at 491; *see also* Zain, *supra* note 55, at 754 (“[S]tudies using different data sets have found that the average price of generics decrease[s] as more generics enter a market.”).

80. FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), <https://perma.cc/UCH6-7ZWK>.

81. ASS’N FOR ACCESSIBLE MEDS., *supra* note 19, at 39.

treating high cholesterol sold in brand form as Zocor.⁸² In that case, around six months after the first generic entered the market, the brand drug sold for around \$150 for a one-month supply while the generic sold for as low as \$7 for the same quantity.⁸³ However, “after the first few entrants, the marginal effect of each new entrant on generic prices and shares tends to be negligible”; specifically, the generic price stops significantly decreasing after four or five entrants.⁸⁴

As the price of the generic drug declines, the price of the brand drug either increases or stays the same because of the brand manufacturer’s ability to price discriminate—that is, to target those customers for whom the demand for the precise brand formulation is inelastic and charge them a higher cost. But because of the rapid loss in market share, the brand drug is unable to profit to the same extent it did before generic entry.

B. Brand Manufacturers’ Response to Generic Competition

Because generic entry can eviscerate a brand manufacturer’s market share—sometimes capturing “as much as 80-90 percent [of drug sales] in a matter of weeks”—the vigorous price competition resulting from the increased entry of generics has negatively affected the profits of brand manufacturers.⁸⁵ As a result, brand manufacturers have engaged in various efforts—the subject of much discussion and controversy among regulators and academics alike—to protect their profits.⁸⁶

82. See C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 952 (2011).

83. *Id.*

84. Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers’ Welfare*, 26 HEALTH AFF. 790, 792 (2007); see also *id.* at 795 (“Any changes in the long-run number of generics are unlikely to affect generic price and share for the many drugs with more than four or five generic entrants . . .”).

85. See Zain, *supra* note 55, at 739; see also Frank & Hartman, *supra* note 15, at 304 (“Rapid market penetration by generic drugs leads to substantial loss of market share by the branded manufacturer and a dramatic decrease in generic and market prices.”).

86. See, e.g., FTC, *supra* note 80, at 1-2 (“Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time.”); Frank & Hartman, *supra* note 15, at 309 (“The recent and continued trend toward greater generic price discounts and increased generic penetration rates has had a fundamental impact upon the pricing strategies of innovator drug manufacturers.”); Kesselheim et al., *supra* note 7, at 861 (“For pharmaceutical manufacturers, ‘product life-cycle management’ involves preventing generic competition and maintaining high prices by extending a drug’s market exclusivity.”).

A popular practice in recent years has been “pay-for-delay” agreements.⁸⁷ Pay-for-delay, or reverse-payment settlement, agreements occur when a brand manufacturer agrees to pay a potential generic entrant challenging its patents to stay out of the market for a specified period of time, often a duration shorter than the patent term but longer than the generic manufacturer would have waited if it had prevailed in litigation.⁸⁸ These agreements occur within the context of the Hatch-Waxman framework: A generic manufacturer submits an ANDA with a Paragraph IV certification, attesting that its generic product does not infringe any of the brand manufacturer’s patents or that the patents are invalid. The brand manufacturer then challenges the generic manufacturer’s declaration and files a patent infringement suit against the generic manufacturer, triggering the thirty-month stay. “Given the costs and potential uncertainty of patent litigation,” the parties often settle their litigation by allowing the generic to enter at some point before patent expiration but later than when the generic would have entered had it prevailed in the patent litigation.⁸⁹ These agreements are also called reverse-payment settlement agreements because the patent *holder* is paying the patent *infringer* to stay out of the market, so the payment is “moving in the opposite direction than what would be ordinarily expected in patent litigation.”⁹⁰ And these payments do not just affect the first-filer generic: Because of the Hatch-Waxman framework, “[b]y paying the generic to delay entering the market, the brand can prevent entry by not only that generic, but also all other generics” since no other generic may challenge the patent after the first filer.⁹¹ These agreements raise antitrust concerns because they enable brand manufacturers to maintain monopoly power over the market for their drug for longer than they ordinarily would if a generic filed a Paragraph IV certification. The FTC has estimated that these settlements cost consumers, taxpayers, and insurance companies approximately \$3.5 billion per year.⁹²

87. See “Pay-for-Delay” Settlements: Antitrust Violation or Proper Exercise of Pharmaceutical Patent Rights?, A.B.A. (Jan. 31, 2011), <https://perma.cc/8S5U-EYKY> (“In recent years, there has been a surge of agreements between pharmaceutical patent holders and generic drug manufacturers in which the market entry of competing generic drugs is delayed by agreement, effectively extending the patent holder’s market exclusivity and profit.”); see also Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 24 (2004) (“Exit or non-entry payment cases are a novelty in antitrust. They became popular after the Hatch-Waxman Act took effect because of the unique effect that the statute has had on generic entry.”).

88. See FTC, *supra* note 80, at 1-3.

89. *Id.* at 3.

90. See Gregory H. Jones et al., *Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 1398, 1398-99 (2016).

91. See Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 15 (2014).

92. See FTC, *supra* note 80, at 8.

In *FTC v. Actavis, Inc.*, the Supreme Court held that such pay-for-delay settlements “can sometimes violate the antitrust laws” because they have the “potential for genuine adverse effects on competition.”⁹³ The Court was concerned that, as opposed to a typical settlement, the “payment may . . . provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.”⁹⁴ The Court thus held that these agreements are subject to the rule of reason analysis to determine if they violate section 1 of the Sherman Act.⁹⁵

While the *Actavis* decision clearly subjected pay-for-delay agreements in the form of cash settlements to heightened scrutiny, its effect on noncash exclusionary payments was less clear.⁹⁶ As a result, instead of paying generic manufacturers to stay out of the market, brand manufacturers have continued to engage in a variety of exclusionary practices, such as paying generic manufacturers “for IP licenses, for supplying raw materials or finished products, and for helping to promote products.”⁹⁷ Additionally, brand manufacturers have begun to include no-authorized-generic provisions in these settlement agreements, whereby the brand promises to refrain from launching an authorized generic, forgoing significant profits during the first-filer generic’s exclusivity period, in exchange for delayed generic entry.⁹⁸ Some courts of appeals have held these noncash pay-for-delay agreements to be subject to antitrust scrutiny under the *Actavis* decision,⁹⁹ but not all courts have weighed in on the issue.

93. 570 U.S. 136, 141, 153 (2013) (quoting *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 460 (1986)). The decision also held that pay-for-delay agreements must be subjected to the rule of reason analysis, rather than making them per se unlawful. *See id.* at 159. In the rule of reason analysis, the anticompetitive effects of an agreement are weighed against its procompetitive justifications to determine if the agreement is an unreasonable restraint of trade. *See* 1 WILLIAM C. HOLMES, *INTELLECTUAL PROPERTY AND ANTITRUST LAW* § 5:7 (West 2019).

94. *Actavis*, 570 U.S. at 154.

95. *Id.* at 141, 158–60. Section 1 of the Sherman Act governs horizontal agreements between competitors and prohibits “[e]very contract, combination . . . [,] or conspiracy, in restraint of trade.” *See* 15 U.S.C. § 1 (2018).

96. *See Carrier*, *supra* note 91, at 34–35 (comparing cash and noncash pay-for-delay settlements).

97. *See* Michael A. Carrier, *Eight Reasons Why “No-Authorized-Generic” Promises Constitute Payment*, 67 RUTGERS U. L. REV. 697, 700 (2015).

98. *See id.* at 701.

99. *See In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549, 552 (1st Cir. 2016) (holding that noncash reverse payments fall within the scope of *Actavis*); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (holding that a “no-[authorized-generic] agreement falls under *Actavis*’s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the

footnote continued on next page

The FTC has made combating these agreements “one of [its] top priorities.”¹⁰⁰ The reason for such ardent enforcement against pay-for-delay agreements is that they have deleterious effects on consumer welfare, which antitrust laws are designed to prevent.¹⁰¹ For example, one study analyzing twenty pay-for-delay settlements involving monetary payment found that these settlements represented a \$12 billion transfer of wealth from consumers to producers after only one year of delay.¹⁰²

Given that courts and antitrust enforcers have imposed increased scrutiny on both cash and noncash pay-for-delay agreements, there is reason to believe that brand manufacturers will instead turn to authorized generics in order to protect their profits from generic competition, especially as no-authorized-generic provisions have become common terms in noncash pay-for-delay agreements. And, in fact, there was a spike in authorized generic launches in 2014, the year after *Actavis* was decided.¹⁰³ While the number of explicit no-authorized-generic provisions in settlement agreements seems to have decreased in recent years, brand manufacturers have continued to include, in their patent settlements, agreements regarding authorized generics that may have the same effect as explicit no-authorized-generic provisions.¹⁰⁴ For example, in the FTC’s most recent report on drug-patent settlement agreements, the FTC noted that the “most common form of possible compensation” in final settlements without explicit compensation is a promise by the brand manufacturer to refrain from using a third party to distribute an authorized generic, which “could have the same effect as an explicit no-[authorized-generic] commitment.”¹⁰⁵ Additionally, the FTC remarked that “[a]nother

alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition”).

100. See Prepared Statement of Markus H. Meier, Acting Dir., Bureau of Competition, FTC, to the House of Representatives Comm. on the Judiciary, Subcomm. on Regulatory Reform, Commercial & Antitrust Law 1, 14 (July 27, 2017), <https://perma.cc/33FH-XERB>.

101. See *id.* at 14.

102. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 650 (2009).

103. According to the FDA’s list of authorized generic launches, there were only 80 launches in 2013, but 156 launches in 2014. See FDA, FDA Listing of Authorized Generics as of December 19, 2019 (2019), <https://perma.cc/C4P8-V3HQ>. This is consistent with the argument that brand manufacturers have begun to rely upon authorized generics as a substitute anticompetitive strategy. It is important to note that, at least for some of these launches, exogenous factors (such as date of patent expiration) could also have affected the timing of the launch. See *infra* note 253.

104. See FTC, Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2016, at 1-2, 4 tbl. (2019), <https://perma.cc/FK5R-6Z4D>.

105. *Id.* at 1-2.

common form of possible compensation” is a “declining royalty structure, in which the generic’s obligation to pay royalties is reduced or eliminated if the brand launches an authorized generic product.”¹⁰⁶ This type of agreement, too, may “achieve the same effect as an explicit no-[authorized-generic] commitment.”¹⁰⁷

C. The Effects of Authorized Generics

When a brand manufacturer launches an authorized generic at the beginning of the first-filer generic’s exclusivity period, price competition begins much sooner. After the launch, the first-filer generic no longer reaps the benefits of a high drug price during exclusivity, but must now compete with an authorized generic on price in order to acquire customers, thereby driving down the price.¹⁰⁸ On average, the presence of an authorized generic decreases the generic price by 7% to 14%.¹⁰⁹ Additionally, the presence of an authorized generic reduces revenues to the first-filer generic by as much as 40% to 52% during the exclusivity period, and by 53% to 62% during the thirty months following exclusivity.¹¹⁰ This represents a significant decrease in profits for the first-filer generic. Importantly, FTC economists found that the presence of an additional competitor lowers generic drug prices by a greater *incremental* amount during the exclusivity period than outside of it, meaning that authorized generics have an outsized effect on the price of the first-filer generic.¹¹¹

A key element in assessing the effects of authorized generics on competition is the interaction between market size—defined as the total revenues generated by a drug—and competition. The literature demonstrates that because market size is a key determinant of the number of entrants, the level of competition varies depending on the size of the drug market. FTC economists studied a large sample of drugs, including those with and without exclusivity periods, and found that drugs in the highest deciles of sales—large drug markets—“clearly face more competitors than lower sales decile drugs.”¹¹² Another study found that there were, on average, 5.8 generic manufacturers present in large markets (outside of the exclusivity period), compared to only 2.7 in smaller

106. *Id.* at 2.

107. *Id.*

108. See Berndt et al., *supra* note 84, at 792.

109. FTC, *supra* note 11, at ii.

110. *Id.* at iii.

111. Luke M. Olson & Brett W. Wendling, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period* 29 (FTC, Working Paper No. 317, 2013), <https://perma.cc/Q29K-5CC9>.

112. *Id.* at 16.

markets.¹¹³ The study further found that “the incumbent in smaller drug markets lowers price in response to an increase in potential competition, and this price reduction is an effective entry deterrent.”¹¹⁴ This makes sense because as the number of entrants increases over time, the average price of a drug declines;¹¹⁵ thus, the sales from a drug must be large enough to make entry profitable even when there are additional competitors driving down the unit price.

This trend holds true for Paragraph IV challenges to brand drugs, which, again, are the method of market entry for generic drugs before patent expiration. Paragraph IV challenges were found to “involve a disproportionate number of the highest revenue brand drugs.”¹¹⁶ For example, the top 40% of drugs by revenue with Paragraph IV decisions had annual retail sales “greater than the average cost of brand drug development up to the point [of] FDA marketing approval”—around \$970.83 million (in 2007 dollars).¹¹⁷ In contrast, there were far fewer Paragraph IV challenges for smaller drug markets. For example, one study found that, based on a ranking of drugs in terms of retail sales, only 19.4% of Paragraph IV decisions concerned drugs that were ranked greater than 200th in terms of revenues.¹¹⁸ By contrast, 33.9% were ranked in the top twenty-five drugs by revenue.¹¹⁹ Thus, more generics are incentivized to enter drug markets with larger sales than those with relatively smaller sales lest the smaller markets become unprofitable—not only because the price would be driven down, but also because there would be a larger number of players with which to split sales. Insofar as authorized generics are concerned, studies “indicate that the marketing of an authorized generic prior to patent expiration will likely only have a direct impact on drug prices in smaller

113. See Steven Tenn & Brett W. Wendling, *Entry Threats and Pricing in the Generic Drug Industry*, 96 REV. ECON. & STAT. 214, 216 (2014).

114. *Id.* at 227.

115. See Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation*, 18 INT’L J. ECON. BUS. 177, 186 & fig.3 (2011). One study found that drug prices decline to approximately 55% of the brand price when only two generics are present, 33% with five generics, and 13% with fifteen generics. See Kesselheim et al., *supra* note 7, at 861.

116. Laura E. Panattoni, *The Effect of Paragraph IV Decisions and Generic Entry Before Patent Expiration on Brand Pharmaceutical Firms*, 30 J. HEALTH ECON. 126, 127, 144 (2011) (constructing a novel dataset of seventy-two Paragraph IV decisions and finding that such decisions “included a non-trivial portion of all brand drugs that face generic entry, a disproportionate number of high revenue drugs, and cases where the period of exclusivity at issue was a large portion of the average length of patent protection”).

117. *Id.* at 127.

118. *Id.* at 138.

119. *Id.*

markets; whereas in larger markets it may (at most) only delay entry.”¹²⁰ In larger markets, the revenues are such that the market can sustain a greater number of competitors without meaningful impact on price. But in smaller markets, where competitors are vying for a share of a smaller revenue pool, “studies seem to indicate that an authorized generic would result in higher prices, and possibly the elimination of all entry.”¹²¹

D. Potential Antitrust Concerns with Authorized Generics

Given that authorized generics can enter the market during the first-filer generic’s exclusivity period, they have been the subject of controversy among scholars and drug manufacturers alike. Generic drug manufacturers argue that the introduction of authorized generics during the exclusivity period is anticompetitive because it undermines generic drug manufacturers’ incentives under the Hatch-Waxman Act to enter the market before patent expiration.¹²² This is because, they argue, the higher exclusivity pricing is needed to recoup the costs of the Paragraph IV challenge and ensuing patent litigation.¹²³ The costs of a Paragraph IV challenge include research and development in formulating the generic version of the drug as well as the litigation expenses of defending against the likely patent infringement suit initiated by the brand drug manufacturer.¹²⁴ Though there is a wide range of cost estimates for a Paragraph IV challenge, in 2011, the FTC found that the mean cost of a challenge was \$5 million.¹²⁵

Moreover, generic manufacturers rely on this exclusivity period to make “60% to 80% of their potential profit.”¹²⁶ If they cannot hope to recoup their costs, so the argument goes, generics will not enter the market during the patent term, thereby depriving consumers of a lower-priced drug option.¹²⁷ At the same time, it can also be argued that there are significant procompetitive benefits of authorized generics launched during the exclusivity period, namely

120. Zain, *supra* note 55, at 756.

121. *Id.* at 756-57.

122. *See* FTC, *supra* note 11, at ii.

123. *See id.*

124. *See* Hemphill & Lemley, *supra* note 82, at 951-52.

125. *See* FTC, *supra* note 11, at 111. Litigation has been found to increase the cost of a Paragraph IV challenge to at least \$10 million. Hemphill & Lemley, *supra* note 82, at 952.

126. Carrier, *supra* note 97, at 710 (quoting Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective: From Ticlid® to Pravachol®, Apotex Has Difficulty Telling Who’s on First*, 25 BIOTECHNOLOGY L. REP. 525, 525-26 (2006)); *see also id.* (indicating that generic pharmaceuticals make the “vast majority of potential profits” during the exclusivity period (quoting *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013))).

127. *See* FTC, *supra* note 11, at 4.

that they create competition among generics sooner, thereby driving down the price of generic drugs for consumers during the exclusivity period by as much as 14%.¹²⁸

Nothing would stop a brand manufacturer from lowering the price of its own brand drug to compete with the generics.¹²⁹ But the concern unique to authorized generics is that a brand manufacturer can leverage its patent-induced monopoly over a brand drug to deter generic competitors by introducing a nominally differentiated product, in the form of an authorized generic, into the market for generic drugs. The authorized generic can then avail itself of state generic substitution laws, giving it an advantage in competing with the generics that the brand drug lacks. Moreover, brand drug manufacturers launch authorized generics only when facing the threat of generic competition, lest they cannibalize their own market, indicating that this is an anticompetitive tactic aimed at deterring or delaying generic competition.

These concerns accompanying the launch of an authorized generic sit at the intersection of antitrust and intellectual property (IP) law. On the one hand, the purpose of antitrust law is to increase consumer welfare by facilitating robust competition that results in lower prices, better products, and a healthy supply chain. On the other hand, IP law permits and encourages the exclusion of competitors in order to protect and promote innovation. The strategic use of IP to create a less competitive environment does not itself violate the antitrust laws, but antitrust concerns *are* implicated in the IP context when “one firm possesses [IP-based] market power and uses it in exclusionary ways.”¹³⁰ More specifically, “the lawful holder of IP giving substantial power in a market might exploit that IP in a manner that expands or protects the power by injuring competitors in a manner not efficiency justified.”¹³¹ This would amount to a manipulation of the IP laws that violates the antitrust laws.

III. Authorized Generics as Price Predation

Brand manufacturers that leverage their IP rights in an exclusionary manner have already faced antitrust liability for certain exclusionary tactics—namely, cash and noncash pay-for-delay agreements.¹³² This Note focuses on

128. *See id.* at 33.

129. Unless, of course, the price of the brand drug was so low as to constitute predatory pricing, but this would be an irrational strategy for the brand. And there appears to be no evidence that brand manufacturers are lowering the prices of their *branded* drugs at all, let alone to predatory levels.

130. *See* LAWRENCE A. SULLIVAN ET AL., *THE LAW OF ANTITRUST: AN INTEGRATED HANDBOOK* § 12.6 (3d ed. 2016).

131. *Id.* § 12.8.

132. *See supra* Part II.B.

another theory of antitrust liability for authorized generics: price predation. Specifically, brand manufacturers should face antitrust liability if they launch an authorized generic during the first filer's exclusivity period, price it at a predatory level, and thus deter generic manufacturers from entering during the patent term—thereby enabling the brand manufacturers to maintain (unjustifiably) their monopoly for a longer period of time. Liability for this price predation will be more likely to attach in smaller markets in which the profits to be made by a drug are sufficiently low so as to deter entry by generics when an authorized generic is present and priced below the first filer's costs.

Delaying or deterring generic entry harms consumer welfare by lengthening the time during which consumers can buy only the higher-priced drug option. Targeting behavior that is harmful to consumer welfare is the very purpose of the antitrust laws. The problem, however, is that the Court's current predatory pricing doctrine is insufficient to hold liable predatory actors with monopoly power in certain markets that lack fluid entry and exit. The remaining Parts of this Note will discuss the theory of predation, the current predation doctrine as espoused by the Supreme Court in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*,¹³³ and how a limit-pricing test would provide a better alternative to the *Brooke Group* analysis for penalizing anticompetitive behavior, especially in the unique regulatory environment in which authorized generics exist.

A. The Theory of Predatory Pricing

Broadly speaking, predatory pricing “occurs when a firm with market power [sets] prices below a competitive level for the purpose of, or with the effect of, deterring or eliminating price competition from current or future rivals.”¹³⁴ It has been described as a “tactic used by highly capitalized firms to bankrupt rivals and destroy competition.”¹³⁵ The basic theory of predatory pricing is that it is a two-step process whereby a firm strategizes to earn monopoly profits.¹³⁶ First, a firm sacrifices short-term profits by engaging in “abnormally low pric[ing] in order to drive rivals from the market,” as the rival cannot match such low prices.¹³⁷ But “[t]hese low prices do not reflect competition on the merits,” as “they will only be available temporarily.”¹³⁸

133. 509 U.S. 209 (1993).

134. SULLIVAN ET AL., *supra* note 130, § 4.1.

135. Lina M. Khan, Note, *Amazon's Antitrust Paradox*, 126 YALE L.J. 710, 722 (2017).

136. See Aaron S. Edlin, Essay, *Stopping Above-Cost Predatory Pricing*, 111 YALE L.J. 941, 952 (2002).

137. See *id.*

138. *Id.*

Then, once its rivals have been driven out, the predatory firm will raise its prices to a supracompetitive level in order to recoup its investment in charging the initial abnormally low prices and eventually earn an outsized profit.¹³⁹ For predatory pricing to be rational, the recoupment gains must be greater than the losses from the initial, predatorily low pricing.¹⁴⁰ Importantly, an incumbent may derive more benefits from a predatory pricing strategy than merely defeating the direct competitor at issue: For example, the predatory regime may send a warning signal to other potential entrants of what they will face upon entry.¹⁴¹ In this sense, the “predatory behavior can deter future competition *before* it occurs.”¹⁴²

The basic theory of predation using authorized generics is as follows. The brand drug manufacturer, *BM*, has a patent on drug *B*. During the term of the patent, or at least until a generic manufacturer enters, *BM* can charge a supracompetitive monopoly price because the patent prevents any rivals from entering the market until an ANDA has been filed and approved. The first-filer generic manufacturer, *GM*, submits an ANDA to enter the market with a generic drug, *G*, that is bioequivalent to *B*, and makes a Paragraph IV certification attesting either that its drug would not infringe *BM*’s patent or that the patent is invalid. As a result, *BM* commences patent litigation against *GM*, triggering the thirty-month stay. Let us assume that the parties do not settle and the thirty-month stay ends without a court decision either way. The FDA then approves the entry of the generic drug into the market, and *GM* enjoys the 180-day exclusivity period promised by the Hatch-Waxman Act as an incentive for being the first to file and challenge *BM*’s patents.¹⁴³ This 180-day exclusivity period enables *GM* to recoup the costs of the Paragraph IV challenge to *B* because *G* has no other generic competitors, meaning that *GM* can charge a price high enough to make a profit but still lower than the price of *B*, thereby drawing customers away from *BM*.

Now assume that *BM* introduces an authorized generic, *AG*, into the market at the beginning of *G*’s exclusivity period. If *AG* is priced lower than *G*, then *GM* will be forced to lower its prices in order to compete with *AG*. If *AG* is priced below *G*’s marginal costs such that *GM* is unable to recover its costs of entry and production, then *GM* will be unable to sustain this low price and will be forced to operate at a loss—especially once the exclusivity period ends and

139. *See id.*

140. *See* PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 723a (CCH 2019).

141. *See id.* ¶ 726d5.

142. *Id.*

143. *See supra* Part I.C.

other generics enter the market, driving down the price even further. *GM* will eventually be forced to raise its price, exit the market completely, or both.

But the real problem here is not driving *GM* out of this particular market; rather, it is the deterrence of future Paragraph IV challenges and resultant generic entry. Assuming brand drug manufacturers engage in a pattern of launching authorized generics, which many have already been shown to do,¹⁴⁴ they will gain a reputation for being predatory, and generic manufacturers as a whole will be deterred *ex ante* from challenging the brand drug's patents given concerns over inability to recoup their initial investment.¹⁴⁵ This will enable a brand drug manufacturer to charge a monopoly price throughout the entire term of the patent as generic manufacturers would be unable to recoup the costs of patent litigation via the exclusivity period. This deterrence of generic entrants is the crux of the problem.

On its face, this conduct poses anticompetitive concerns: A monopolist brand manufacturer takes advantage of a regulatory framework in order to exclude rivals—the very rivals that the regulations were meant to protect. Because “the anticipation of an authorized generic entrant reduces the expected profitability during the exclusivity period,” patent challenges by prospective generic manufacturers may thereby be deterred.¹⁴⁶ Yet “[i]f some of those forgone challenges had been successful, then independent generic entry might be delayed in the absence of the challenge, harming consumers.”¹⁴⁷

The problem, as the following Subpart will explain, is that the current legal framework for predatory pricing is insufficient to penalize brand drug manufacturers that launch authorized generics in order to deter generic entry before patent expiration.

B. The Current Framework: The *Brooke Group* Test

Antitrust law has been concerned with predatory pricing ever since the Supreme Court's decision to break up Standard Oil in 1911.¹⁴⁸ Predatory pricing implicates section 2 of the Sherman Act, which prohibits monopolization and attempted monopolization when a firm “has deliberately followed a course

144. “[B]eginning in 2003 there was a substantial increase in the number of [authorized generic] launches for drugs that were subject to a Paragraph IV certification, and by 2007-2008 most [authorized generics] were versions of drugs for which there had been a Paragraph IV certification.” FTC, *supra* note 11, at 31.

145. *See id.* at 38 (“[I]n the long-run, the expectation of an [authorized generic] may deter ANDA-generic firms from challenging questionable patents using a Paragraph IV certification.”).

146. Berndt et al., *supra* note 84, at 792.

147. *Id.*

148. *See Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 42-43 (1911).

of market conduct through which it has obtained or maintained power to control price or exclude competition.”¹⁴⁹ Here, predatory pricing enables a firm to do both by utilizing its incumbency and cost advantages to squeeze out rivals by pricing at abnormally low levels. Predatory pricing may also implicate the Robinson-Patman Act, which “condemns certain forms of price discrimination,” such as when a firm cross-subsidizes its predatory pricing in one market by its actions in another market.¹⁵⁰

The challenge for courts in predatory pricing cases has been to distinguish between low prices that are part of meritorious competition and low prices that are not. In a series of harsh decisions for would-be predators, such as *Utah Pie Co. v. Continental Baking Co.*,¹⁵¹ the Supreme Court’s early antitrust case law “reinforced the illegitimacy of predatory pricing.”¹⁵² But the Court, influenced by Robert Bork and the Chicago School, subsequently changed course and formulated a new test for predatory pricing in *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*,¹⁵³ premised on the notion not only that competitors would be reluctant to attempt a predatory pricing regime but also that they would rarely be successful in doing so.¹⁵⁴

The central claim in *Brooke Group* was made by generic cigarette manufacturer Liggett, which alleged that its competitor Brown & Williamson, which had previously only operated in the brand-name cigarette market, “cut prices on generic cigarettes below cost and offered discriminatory volume rebates to wholesalers to force Liggett to raise its own generic cigarette prices and introduce oligopoly pricing” into the generic cigarette market.¹⁵⁵ When Brown & Williamson entered the generic market, it undercut Liggett’s generic prices for wholesale distribution, which instigated a “price war” in the form of rebates between the two manufacturers, during which Brown & Williamson

149. See SULLIVAN ET AL., *supra* note 130, § 3.1(a); see also *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). See generally 15 U.S.C. §§ 1-7 (2018).

150. See Christopher R. Leslie, *Predatory Pricing and Recoupment*, 113 COLUM. L. REV. 1695, 1698 (2013); see also 15 U.S.C. § 13(a) (“It shall be unlawful for any person engaged in commerce . . . to discriminate in price between different purchasers of commodities of like grade and quality . . . where the effect of such discrimination may be substantially to lessen competition . . .”).

151. 386 U.S. 685, 703 (1967).

152. See Khan, *supra* note 135, at 725.

153. See 509 U.S. 209, 222-24 (1993).

154. See Khan, *supra* note 135, at 726, 729-30 (“[T]he Court adopted the Chicago School’s narrow conception of what constitutes this harm (higher prices) and how this harm comes about—namely, through the alleged predator raising prices on the previously discounted good.”).

155. See *Brooke Grp.*, 509 U.S. at 212.

“maintained a real advantage over Liggett’s prices.”¹⁵⁶ After the price war, Brown & Williamson was selling its generic cigarettes “at a loss.”¹⁵⁷

Liggett thus “alleged that Brown & Williamson’s volume rebates to wholesalers amounted to price discrimination that had a reasonable possibility of injuring competition,” because they were “integral to a scheme of predatory pricing.”¹⁵⁸ To effectuate this scheme, Liggett argued, “Brown & Williamson reduced its net prices for generic cigarettes below average variable costs” with the “inten[t] to pressure [Liggett] to raise its list prices on generic cigarettes, so that the percentage price difference between generic and branded cigarettes would narrow.”¹⁵⁹ According to Liggett, it would have been impossible to further “reduce its wholesale rebates without losing substantial market share to Brown & Williamson,” so it was forced to raise its retail prices.¹⁶⁰ This “resulting reduction in the list price gap” would thus “restrain the growth of the [generic] segment and preserve Brown & Williamson’s supracompetitive profits on its *branded* cigarettes.”¹⁶¹ Thus, the crux of Liggett’s claim was that Brown & Williamson would be able to recoup its losses on the generic cigarettes by raising prices on its branded cigarettes.

In analyzing Liggett’s claims, the Court made clear that under either the Robinson-Patman Act or section 2 of the Sherman Act, a successful predatory price claim must allege that “[a] business rival has priced its products in an unfair manner with an object to eliminate or retard competition and thereby gain and exercise control over prices in the relevant market.”¹⁶² Specifically, the Court required a plaintiff prove two key elements.

First, a plaintiff must demonstrate that the predator reduced its prices to a level “*below* an appropriate measure of its [own] costs.”¹⁶³ The Court rejected arguments that an antitrust claim could rest on prices being above cost but “below general market levels or the costs of a firm’s competitors,” reasoning that “the exclusionary effect of prices above a relevant measure of cost either reflects the lower cost structure of the alleged predator, and so represents competition on the merits, or is beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price cutting.”¹⁶⁴

156. *See id.* at 215-16.

157. *Id.* at 216.

158. *Id.* at 216-17.

159. *Id.* at 217.

160. *Id.*

161. *Id.* (emphasis added).

162. *Id.* at 222.

163. *Id.* (emphasis added).

164. *See id.* at 223.

Second, a plaintiff must demonstrate that the competitor had “a reasonable prospect,” for claims brought under the Robinson-Patman Act, or a “dangerous probability,” for claims brought under section 2 of the Sherman Act, “of recouping its investment in below-cost prices.”¹⁶⁵ For the Court, “[r]ecoupment is the ultimate object of an unlawful predatory pricing scheme; it is the means by which a predator profits from predation” because “[w]ithout it, predatory pricing produces lower aggregate prices in the market, and consumer welfare is enhanced.”¹⁶⁶ Thus, “unsuccessful predation is in general a boon to consumers.”¹⁶⁷ The Court emphasized the fact that “below-cost pricing may impose painful losses on its target is of no moment to the antitrust laws if competition is not injured: It is axiomatic that the antitrust laws were passed for ‘the protection of *competition*, not *competitors*.”¹⁶⁸ To that end, the plaintiff must show that ultimately “there is a likelihood that the predatory scheme alleged would cause a rise in prices above a competitive level that would be sufficient to compensate for the amounts expended on the predation, including the time value of the money invested in it.”¹⁶⁹ In essence, the predator must be able to “obtain enough market power to set higher than competitive prices, and then must sustain those prices long enough to earn in excess profits what they earlier gave up in below-cost prices.”¹⁷⁰

Recognizing that it would be difficult for plaintiffs to meet this test, the Court explained that its rationale for imposing such rigid obstacles to liability for predation was its concern for false positives, which could chill legitimately competitive price cuts that would benefit consumers.¹⁷¹

Applying its newly formulated test to the facts at hand, the Court found that Liggett failed to meet the second requirement for showing predatory pricing. While the Court found that Brown & Williamson’s prices on its generic cigarettes were indeed below its costs, it held that Liggett had failed to satisfy the recoupment prong.¹⁷² Specifically, Liggett was unable to show that

165. *Id.* at 224.

166. *Id.*

167. *Id.*

168. *Id.* (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)).

169. *Id.* at 225; see also C. Scott Hemphill & Philip J. Weiser, *Beyond Brooke Group: Bringing Reality to the Law of Predatory Pricing*, 127 *YALE L.J.* 2048, 2052 (2018) (“As the Court saw it, a price cut—at least as long as the price remains above cost—is unambiguously desirable because it increases output, thereby raising total and consumer welfare.”).

170. *Brooke Grp.*, 509 U.S. at 225-26 (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 590-91 (1986)).

171. See *id.* at 226-27 (“It would be ironic indeed if the standards for predatory pricing liability were so low that antitrust suits themselves became a tool for keeping prices high.”).

172. See *id.* at 231.

“Brown & Williamson had a reasonable prospect of recovering its losses from below-cost pricing through slowing the growth of generics.”¹⁷³ It is important to note that much of this analysis turned on facts particular to this case—specifically that the key means of recoupment would be through oligopolistic, supracompetitive price coordination among rival branded cigarette firms, which the Court reasoned Brown & Williamson would be unlikely to achieve and sustain.¹⁷⁴

The *Brooke Group* test reflects the Court’s narrow view of predatory pricing whereby liability attaches only if a predatory firm prices below some measure of its own costs with a reasonable probability that any losses it incurs will be recouped—this is referred to as a “negative-profit” standard.¹⁷⁵ The result of this narrower view is that far fewer predatory pricing claims are brought,¹⁷⁶ and almost none have been successful,¹⁷⁷ demonstrating how difficult such claims are for plaintiffs to prove—despite the antitrust concerns posed by such pricing.¹⁷⁸

The Court’s test in *Brooke Group* has been the subject of heavy criticism and may ultimately be more harmful to consumers than a stricter test that penalizes more predatory conduct but eliminates temporary, predatorily low prices for consumers.¹⁷⁹ Much of the criticism has focused on the below-cost pricing prong of the *Brooke Group* test. Many worry that this requirement will “ignore strategies that are legitimately anticompetitive but that can be accomplished at fully profitable prices,” meaning that predators who can avoid pricing below their own costs while still driving out competition will escape liability.¹⁸⁰ This is particularly worrisome because in “cases of monopolization

173. *Id.*

174. *See id.* at 227-28; *see also* Hemphill & Weiser, *supra* note 169, at 2050 (“The Court’s unusually detailed review of particular case facts in *Brooke Group* provides a further reason to confine *Brooke Group*’s dicta that predation is implausible.”).

175. *See* Steven C. Salop, *Exclusionary Conduct, Effect on Consumers, and the Flawed Profit-Sacrifice Standard*, 73 ANTITRUST L.J. 311, 326 (2006). The Court failed to define which measure of costs should be used (and the correct cost measure remains disputed), but many lower courts and commentators use average variable costs. *See, e.g.*, SULLIVAN ET AL., *supra* note 130, §§ 4.3(a), 4.4; Phillip Areeda & Donald F. Turner, *Predatory Pricing and Related Practices Under Section 2 of the Sherman Act*, 88 HARV. L. REV. 697, 704 (1975).

176. *See* Hemphill & Weiser, *supra* note 169, at 2049 (“Over the past twenty-five years, antitrust claims alleging a predatory price cut have fallen into disuse.”).

177. *See id.* at 2062 & n.65 (noting that as of November 2017, “no predatory pricing case . . . has been litigated to a final judgment for plaintiffs”).

178. *See, e.g.*, Kenneth L. Glazer, *Predatory Pricing and Beyond: Life After Brooke Group*, 62 ANTITRUST L.J. 605, 606 (1994) (“[P]redatory pricing will be virtually a dead letter in federal antitrust cases.”).

179. *See, e.g.*, Hemphill & Weiser, *supra* note 169, at 2053.

180. *See* AREEDA & HOVENKAMP, *supra* note 140, ¶ 736a.

or attempted monopolization, such ‘above-cost predation’ may be more plausible and prevalent than below-cost predation,”¹⁸¹ yet would not face liability under *Brooke Group*. The Court’s reluctance to penalize predatory price cuts that still remain above a predator’s costs reflects its fear of false positives.¹⁸² But this reluctance leads to false negatives—failing to penalize true exclusionary conduct—that have a detrimental effect on consumer welfare. Quite problematically, “the long-run welfare costs of exclusion from predatory price cutting could be much greater than the short-run benefits of lower prices.”¹⁸³

Moreover, the Court in *Brooke Group* seemed to think that even if a predator were to price below its costs, recoupment of those costs would be unlikely to occur. Yet scholars have levied criticism against the recoupment prong as well. Christopher Leslie argues that as a fundamental matter, successful recoupment is unnecessary for predation to harm consumer welfare. He argues that this is because it is the predatorily low pricing that comes in the first phase of a predatory pricing strategy, not the recoupment that comes later, that actually drives out rivals, leaving a monopoly for the predator in the second phase.¹⁸⁴

Others have criticized the recoupment prong for failing to take into account explicitly the reputational benefits that often accompany predation, arguing that “[m]easuring recoupment solely by reference to [a single] product ignores any benefits that result because the defendant’s reputation for predatory responses carries to all . . . of its products.”¹⁸⁵ Specifically, the predator’s reputation for aggressive pricing may deter or drive out rivals in other markets in which it competes, even without the predator actually having to engage in the low-cost pricing. Many courts and scholars, however, have interpreted the recoupment prong to include recoupment in other markets by reputational effects.¹⁸⁶ Relatedly, many criticize the *Brooke Group* test for also failing to

181. Edlin, *supra* note 136, at 942.

182. Hemphill & Weiser, *supra* note 169, at 2052 (“The Court’s approach accepts some false negatives—anticompetitive above-cost price cuts—in order to avoid the chilling effect of false positives.”).

183. Hemphill & Weiser, *supra* note 169, at 2053. Another criticism of the Court’s greater concern about false positives over false negatives targets its assumption that false negatives are rare. *See id.* (observing that the Court offered “this famous dictum . . . without adequate empirical support”).

184. *See* Leslie, *supra* note 150, at 1741-42 (“The sad irony of the repeated judicial misapplication of the recoupment requirement in the predatory pricing cases is the fact that this element is unnecessary and inappropriate. Whether a monopolist recoups the money it has spent to acquire monopoly power does not determine whether its anticompetitive conduct has harmed consumer welfare.”).

185. AREEDA & HOVENKAMP, *supra* note 140, ¶ 727g.

186. *See, e.g.,* Hemphill & Weiser, *supra* note 169, at 2050 (“[A] plaintiff is free, even under *Brooke Group*, to show that the defendant successfully recouped by acquiring a

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account for explicitly the deterrence effect of aggressive price cuts on potential new entrants against which the cuts were not directed.¹⁸⁷ This failure, in turn, incentivizes predatory behavior because the predator, if successful in excluding one rival, will more likely be successful in excluding other rivals without even having to engage in the predatory scheme again.

Despite these criticisms, the *Brooke Group* test has persisted. Yet it is particularly inappropriate for scrutinizing conduct in markets in which there is an incumbent monopolist who can employ predatory above-cost pricing and entry barriers, making recoupment all the more likely. The airline industry has been cited as one such market.¹⁸⁸ The predatory use of authorized generics in the pharmaceutical market is another example that underscores fundamental flaws of the *Brooke Group* test that allow certain predators to escape liability while damaging consumer welfare in the long-term. The remainder of this Note will use the example of authorized generics to highlight the problems with the *Brooke Group* test and demonstrate how using a limit-pricing test would better capture the antitrust concerns posed by authorized generics. Given the recent epidemic of rising drug prices, it is critical that predation analysis effectively penalize conduct that directly harms consumers.

C. Authorized Generics as a Price-Predation Strategy

In an effort to maintain monopolistic power, some brand drug manufacturers use authorized generics as a form of price predation in order to deter other generics from entering the market before patent expiration. The problem with authorized generics is that, “in the long-run, the expectation of an [authorized generic] may deter ANDA-generic firms from challenging questionable patents using a Paragraph IV certification.”¹⁸⁹ As one treatise put it, “[a]rguably, the development of authorized generics is intended by pharmaceutical patent owners as a form of predation, making patent challenges by generics uneconomic by squeezing out the profits associated with a successful patent challenge.”¹⁹⁰ And some documents by brand manufacturers

reputation for predation in other markets.”); Leslie, *supra* note 150, at 1720-21 (noting that “[c]ourts apparently do not appreciate the prospect of recoupment in another market” but “recoupment can happen in markets for complements, substitutes, and replacement goods”).

187. See, e.g., Hemphill & Weiser, *supra* note 169, at 2053.

188. See Edlin, *supra* note 136, at 980-87.

189. FTC, *supra* note 11, at 38.

190. HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 16.02[A] (CCH 2019); see also FTC, *supra* note 11, at 57-59 (noting that an “ANDA-generic product usually takes a larger share of the market when it does not face an [authorized generic] competitor,”
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themselves reflect such an intention. One internal document by a brand drug manufacturer cited in an FTC report states that “[f]inancially speaking,” launching an authorized generic is “not a particularly attractive proposition,” but “strategically we may want to send a message” that the brand manufacturer “will launch authorized generics” and thus “hopefully reduce future [generic] competition for subsequent . . . products coming off patent.”¹⁹¹

In the unique regulatory framework set up by the Hatch-Waxman Act, as opposed to in markets closer to perfect competition, predatory pricing may be far more successful because of the barriers to entry and the patent protection afforded to brand drug manufacturers.¹⁹²

First, the first-filer generic will be forced to bear significant costs resulting from the Paragraph IV challenge but without the benefit of charging a higher price during the exclusivity period.¹⁹³ These costs are far greater than those of a generic wishing to enter *after* patent exclusivity because they include not only the research and development costs to create the generic version of the brand drug but also the litigation expenses involved in defending against the likely patent infringement suit initiated by the brand manufacturer that triggers the thirty-month stay.¹⁹⁴ Thus, the first filer requires the opportunity to recoup its expenses in the form of higher drug profits, which are most easily obtained during the 180-day exclusivity period.

Second, it is very inexpensive for a brand manufacturer to launch an authorized generic. The brand manufacturer need only incur the minimal marginal costs of manufacturing additional units of a drug for which it has already built and scaled the production mechanism. This enables the brand manufacturer to cheaply produce a new drug and then price it at a low rate without having to incur a profit sacrifice.

Again, the FTC found that the presence of an authorized generic during the exclusivity period “reduces the first-filer generic’s revenues by 40 to 52 percent.”¹⁹⁵ As a result, the generic manufacturer may be forced to exit the market because it cannot compete with the low prices of the authorized generic. And, seeing this predatory conduct by the brand manufacturer, other

but “introducing an [authorized generic] has a large and negative effect on ANDA revenues”).

191. FTC, *supra* note 11, at 71-72 (third alteration in original) (quoting an internal company document).

192. Cf. Janusz A. Ordover & Robert D. Willig, *An Economic Definition of Predation: Pricing and Product Innovation*, 91 YALE L.J. 8, 13 (1981) (“In markets in which structural factors permit successful predation, a firm may rationally attempt to induce the exit of a rival in order to gain additional monopoly profits.”).

193. See *supra* notes 122-26 and accompanying text.

194. See *supra* text accompanying notes 49-51.

195. FTC, *supra* note 11, at iii.

generic manufacturers would be deterred from entering the market altogether during the patent term because the threat of an authorized generic would make their entry unprofitable.¹⁹⁶ Thus, brand drug manufacturers would be able to avoid Paragraph IV challenges to their patents and the resultant exclusivity period, enabling them to charge monopoly prices for much longer, giving them a windfall and harming consumers. That is the very type of conduct the Hatch-Waxman Act meant to eliminate by making it *easier*, not harder, for generics to enter the market so that consumers could pay lower prices for drugs.

Importantly, this conduct would most likely occur in smaller drug markets and would likely be unsuccessful if attempted in larger markets given the economics of these respective markets: “Studies indicate that the marketing of an authorized generic prior to patent expiration will likely only have a direct impact on drug prices in smaller markets; whereas in larger markets, it may (at most) only delay entry.”¹⁹⁷ This suggests that for larger markets, “to the extent that [an] authorized generic deters or delays entry, it will be insufficient to permit a branded drug company to increase generic prices” in the long run.¹⁹⁸ This is because larger markets are profitable enough to sustain a number of competitors. In larger markets, the benefits in the form of broad sales past the exclusivity period would outweigh the first-filer generic’s costs of litigation and of being forced to price-match the authorized generic during exclusivity. In smaller markets, however, sales would not be large enough for the first-filer generic to recoup the cost of being forced to compete with the authorized generic during exclusivity, thereby deterring entry.¹⁹⁹ Moreover, there are often multiple first-filer generics in certain large markets precisely because there are greater profits to be reaped. Thus, if generics in these markets are not deterred from filing an ANDA and Paragraph IV certification—even knowing that they may have to split the exclusivity period with another first-filer generic—an authorized generic would be unlikely to deter their entry, in contrast to smaller markets where the authorized generic would have a greater effect.²⁰⁰

196. See *supra* notes 144-47 and accompanying text.

197. Zain, *supra* note 55, at 756.

198. *Id.*

199. See FTC, *supra* note 11, at 117-18, 118 fig.6-6 (modeling the decision whether a generic files a Paragraph IV challenge in a smaller drug market and showing that generic manufacturers are more likely to break even in larger markets).

200. See David Reiffen & Michael R. Ward, “*Branded Generics as a Strategy to Limit Cannibalization of Pharmaceutical Markets*,” 28 *MANAGERIAL & DECISION ECON.* 251, 263 (2007) (“[O]ur estimates suggest that the price changes resulting from branded generic entry are largest in relatively small markets.”).

Empirical data are consistent with this hypothesis. In 2011, the FTC issued a report on the short-term and long-term effects of authorized generics.²⁰¹ In so doing, it analyzed information from “more than 100 brand-name and generic manufacturers [along] with price and sales data acquired from commercial sources and information gleaned from FDA databases to assess [authorized generics’] competitive effects.”²⁰² The report found that any “disincentive effects” stemming from the introduction of an authorized generic during the exclusivity period “would likely be experienced in small markets or in situations where the generic had little chance of winning the patent suit anyway.”²⁰³ Specifically, the report found that the generic manufacturer’s lost revenue when facing an authorized generic would be “most likely to affect decisions to challenge patents on products with small sales.”²⁰⁴ For example, the FTC, using its break-even analysis with higher estimates of generic manufacturers’ entry costs, found that the presence of an authorized generic in the market for drugs with sales below \$27.3 million was likely to deter a Paragraph IV challenge, and that using lower cost estimates, an authorized generic would have the same effect in a market below \$15 million.²⁰⁵ Another study analyzing drug pricing and entry data found that “[i]t is likely that entry deterrence is more costly in large markets due to their greater profitability. Consequently, an entry-detering pricing strategy may not be profit maximizing in these markets.”²⁰⁶ But this same study found that “the

201. In 2009, the FTC issued an interim report that “focused on the short-term effects of [authorized generics] during the 180-day exclusivity period.” FTC, *supra* note 11, at ii. The 2011 final report “refine[d]” the FTC’s short-term analysis and “expand[ed]” the analysis to consider long-term effects.” *Id.*

202. *Id.*

203. *Id.* at iii. The FTC report demonstrates that “[i]f a challenger anticipates a 50 percent chance of success, an expectation of [authorized generic] competition could tilt the balance against bringing a patent challenge in markets with brand sales between \$12 million and \$27 million, a range that accounts for 13 percent of drugs.” *Id.*

204. *Id.* The FTC also noted that brand manufacturers would be less likely to launch authorized generics in small markets anyway. *See id.* However, such an assumption may not hold true if the brand manufacturers recognize that engaging in a successful predation strategy can deter entry across other product lines by gaining a predatory reputation. Further, at the time the report was authored, brand manufacturers were frequently engaged in other methods to delay generic entry, including making settlements with generic manufacturers whereby they agreed not to launch an authorized generic in exchange for the generic manufacturer delaying its entry into the market. *See supra* notes 87-92 and accompanying text. As a result, brand manufacturers may not have been as focused on launching authorized generics in all drug markets.

205. FTC, *supra* note 11, at 115.

206. Tenn & Wendling, *supra* note 113, at 221. This study also found that

[f]or small drug markets, where it is easier to deter entry due to lower expected profits, we find that price falls in response to an increase in competition. Few manufacturers enter these

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incumbent in smaller drug markets lowers price in response to an increase in potential competition, and this price reduction is an effective entry deterrent.”²⁰⁷ Thus, it would seem that authorized generics launched in smaller drug markets could effectively deter generic entry.

D. The Failure of Current Predation Doctrine

The problem, however, is that under the current predatory pricing doctrine, it would be very difficult for plaintiffs to challenge the launch and aggressively low pricing of authorized generics because they would likely not meet the below-cost prong of *Brooke Group*,²⁰⁸ allowing brand drug manufacturers to charge supracompetitive prices unscathed.

It would be nearly impossible for the authorized generics to meet this requirement because “the economics of patents rarely lend themselves to pricing that is truly below marginal cost.”²⁰⁹ Rather, a brand manufacturer would take advantage of the structural barriers to entry imposed by the patent and the regulatory regime, and price the authorized generic below some measure of the *true* generic’s costs, instead of the authorized generic’s costs, so that it could still maximize profits in the short term while simultaneously driving out a rival in the long term. It makes little to no economic sense for a patent holder to price below its *own* (lower) costs since it gains no incremental competitive benefit from doing so and is thus cutting into its own profits, when it could achieve the same effect by merely pricing below the generic

markets following expiration of the Hatch-Waxman exclusivity period, indicating this price reduction is an effective deterrent. In contrast, in larger drug markets where entry deterrence is less likely to be successful, the incumbent maintains a high price until forced to respond to actual competition.

Id. at 214.

207. *Id.* at 227; see also Reiffen & Ward, *supra* note 200, at 263 (finding that branded generic entry is most influential in small drug markets).

208. See HOVENKAMP ET AL., *supra* note 190, § 16.02[A] (“[A] pure predatory pricing claim may be even harder to prove in the authorized generic context. Even where a predatory pricing claim involves patented goods rather than licenses themselves, the economics of patents rarely lend themselves to pricing that is truly below marginal cost.”); see also Edlin, *supra* note 136, at 955 (“[I]n a market where a monopoly has cost or other advantages over entrants, the *Brooke Group* rule could lead to adverse welfare consequences. At worst, it could allow a monopoly to charge high prices perpetually, never facing an entrant.”); Bryan A. Liang, *The Anticompetitive Nature of Brand-Name Firm Introduction of Generics Before Patent Expiration*, 41 ANTITRUST BULL. 599, 619 (1996) (finding that, “in the [authorized] generics case, in a monopoly market maximum profit is gained at monopoly prices; rational firms will only price below this level . . . in expectation of future returns as a result of a reduction of future competition,” where the monopoly price is above the monopolist’s cost).

209. HOVENKAMP ET AL., *supra* note 190, § 16.02[A].

manufacturer's costs. As a result, plaintiffs would virtually never be able to meet the pricing-below-cost prong of the test.

As for the second prong of the test, monopolist brand manufacturers would have a far easier time recouping their investment than did the oligopolistic competitors in *Brooke Group*.²¹⁰ To play this out more clearly, the major concern with authorized generics is that the predatory pricing in one market would be cross-subsidized by supracompetitive prices charged in another market in which generics were deterred from entering because of the predatory reputation gained by the launch of authorized generics in the first market by a brand that has multiple differentiated drug products.²¹¹ For example, if *B* successfully launched an authorized generic in market M_1 and priced it below cost such that the first-filer generic suffered a great loss, and *B* thereby gained a predatory reputation, then *B*'s reputation for predatory pricing would have an *in terrorem* effect on competitors contemplating entering market M_2 , in which *B* also had a brand drug. Thus, *B* would recoup its costs from market M_1 by charging supracompetitive prices in market M_2 .²¹² Given that the major pharmaceutical companies simultaneously have products in a large number of markets, it is entirely conceivable, even likely, that they would gain such predatory reputations.

The particular regulatory structure of the pharmaceutical industry lends itself more easily than the oligopolistic situation in *Brooke Group* to recoupment success for two reasons. First, because a brand drug is patent protected, the patent serves as a barrier to entry, meaning that any other drug manufacturer, generic or otherwise, wishing to enter the market must engage in patent litigation to do so. Litigation has a high cost (often raising the price of Paragraph IV certification to at least \$10 million²¹³) that generic manufacturers would be unwilling to bear unless they could recoup it through the exclusivity period, which the presence of the authorized generic would prevent. Thus, generic entry would be delayed until after the patent term expires, since generic manufacturers would be deterred from attempting to invalidate the

210. Insofar as the recoupment prong of the *Brooke Group* test is read to include recoupment in other markets via reputational effects, the use of authorized generics satisfies this prong. If a court (arguably erroneously) read the prong to exclude such reputational benefits, then I would advocate for a modification to the test that accounts for the reputational benefits of predation.

211. *Cf.* AREEDA & HOVENKAMP, *supra* note 140, ¶ 723c (“[W]e presume that losses incurred through predation could be regained in at least some markets with high barriers to entry.”). And again, pharmaceutical markets have high barriers to entry. *See supra* note 192 and accompanying text.

212. In this sense, the situation somewhat parallels that in *Brooke Group*, where Brown & Williamson would have recouped its costs from predatory pricing in the market for generic cigarettes by charging a higher price in the market for brand cigarettes.

213. Hemphill & Lemley, *supra* note 82, at 952.

patent via a Paragraph IV certification, giving the brand manufacturer ample time to recoup its initial investment. This stands in stark contrast to *Brooke Group*, in which the Court assumed that entry by other competitors would be easy once the predator raised its prices because the oligopoly pricing in that case was difficult to police.²¹⁴ It is important to note that “[p]rofitable recoupment does not require that all entry be deterred indefinitely, it requires entry only sufficiently [deterred] to make the predation investment profitable.”²¹⁵ Thus, even though other generics may enter after the patent has expired, once they can avoid the costs associated with making a Paragraph IV certification, the fact that entry will be deterred in the interim would, in most cases, be enough to facilitate successful recoupment.

Second, once the generic manufacturers are disincentivized from entering the market before the patent term’s expiration, brand drug manufacturers that still launch an authorized generic can benefit from a “first-mover advantage.”²¹⁶ This advantage enables them to keep customers even after other generics enter the market once the patent has expired.²¹⁷ Authorized generics can “target[] the irrational brand loyalties of patients and physicians” who may be reluctant to use an *unauthorized* generic, but who would feel comfortable using a generic launched by the brand manufacturer, believing it to be the same product as the actual brand drug.²¹⁸ In so doing, authorized generics can “lock in consumers and thereby create substantial switching costs that deter later entrants.”²¹⁹ These switching costs “can deter subsequent entry by forcing later entrants to invest extra resources to attract customers away from the first-mover firm.”²²⁰

Third, any other drug manufacturer wishing to enter the market with a substitute drug (that is, a drug with a different active ingredient) would be unable to take advantage of the Hatch-Waxman framework and would instead have to file an NDA, which is a lengthy and expensive process.²²¹ This means that, in many cases, the patent holder would maintain a monopoly while the

214. See *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 238-40 (1993).

215. AREEDA & HOVENKAMP, *supra* note 140, ¶ 729a.

216. See Chen, *supra* note 36, at 480.

217. See *id.*

218. See *id.*

219. *Id.*

220. *Id.*; accord Robert E. Hall, *Potential Competition, Limit Pricing, and Price Elevation from Exclusionary Conduct*, in 1 ISSUES IN COMPETITION LAW AND POLICY 433, 437 (ABA Section of Antitrust Law ed., 2008) (“Getting as many users as possible to adopt a product means that the rival entering in the future has to persuade people to incur switching costs as well as pay the price of the new product.”).

221. See *supra* Part I.B.

potential rival attempted to enter the market. Either way, the ability of authorized generics to deter generic entry into the market would enable the brand to maintain supracompetitive prices in order to recoup its initial investment in lowering the price of the authorized generic.

Additionally, the Court's concern in *Brooke Group* regarding the recoupment prong was that it would be difficult to implement and sustain supracompetitive pricing because that would require coordination among multiple actors.²²² Here, however, recoupment would be more easily obtained because only a single actor—the brand manufacturer—would be imposing the supracompetitive pricing, thereby eliminating the coordination problems at issue in *Brooke Group*.²²³

Thus, we are left with a situation in which a challenge to predatory pricing would most likely fail the *Brooke Group* test because the brand manufacturers are not engaging in below-cost pricing, even though their pricing is still entry deterrent, and even though the recoupment prong is easily proven. This, in turn, incentivizes brand drug manufacturers to pursue predatory pricing strategies more aggressively. After all, “[w]hat might maximize consumer welfare in the short run does not necessarily do so in the long run.”²²⁴ To limit losses to consumer welfare from authorized generics' predatory pricing schemes, we need a different line of attack.

IV. Limit Pricing: A Better Measure of Predation for Authorized Generics

Some scholars have argued that the *Brooke Group* test's requirements for a predatory pricing claim of below-cost pricing and reasonable probability of recoupment “may be sufficient to make out a predatory pricing case, but they should not be necessary.”²²⁵ This means that there are other ways in which firms can engage in predatory pricing that ultimately harms consumer welfare. But, as demonstrated above, authorized generics will likely fail the below-cost element of the *Brooke Group* test given the patent context and regulatory framework of the pharmaceutical industry. Nonetheless, this framework enables the brand drug manufacturer to achieve the same goal (ensuring supracompetitive pricing by driving out rivals) without pricing

222. See *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227-28 (1993).

223. See Hemphill & Weiser, *supra* note 169, at 2065 (“One source of flexibility arises where a monopoly, rather than oligopoly, is concerned. If recoupment is undertaken by a monopoly protected by high barriers to entry, we are far from the oligopoly considered in *Brooke Group*.”).

224. AREEDA & HOVENKAMP, *supra* note 140, ¶ 723d2.

225. Edlin, *supra* note 136, at 943; see also *supra* Part III.B.

below its *own* costs. Rather, a brand manufacturer need only employ limit pricing, or pricing below the cost necessary for a *generic* manufacturer to recoup its initial investment in the Paragraph IV certification and the resulting patent litigation. Thus, one solution to policing the predatory launch of authorized generics is through a limit-pricing test that penalizes authorized generics when they are priced below the first-filer generic's entry costs.

A. Theory

Limit pricing describes the setting of a price “at a level just below that which a prospective entrant to the market would need to charge in order to sustain a successful entry.”²²⁶ Limit pricing occurs when an incumbent firm prices “below the short-run profit-maximizing price but above the competitive level” in order to deter or prevent would-be entrants.²²⁷ The limit price is “intended by the monopolist to impair the opportunities of rivals, and, if successful, it does prevent competition from arising.”²²⁸ While a monopolist without the fear of entrants can charge whatever price will maximize its immediate profit, monopolists facing potential entry threats are constrained in how they may price if they want to maintain at least some of their monopoly profits. For example, say a brand manufacturer's profit-maximizing price for an authorized generic is \$10 per unit, but this is high enough that it would encourage entry by other generics. If the brand manufacturer's costs for producing the drug were only \$7 per unit, but the generic entrant's costs were \$9 per unit, then the brand manufacturer could price the authorized generic at \$8 in order to deter generic entry and sustain its monopoly because the generic manufacturer, if it matches the \$8 price, would not be able to make a profit since its higher costs exceed the price charged.²²⁹ So long as the long-term profits from pricing at the lower price exceed those from pricing at the higher price, even while a brand manufacturer accepts an entrant and the resulting market share dilution, the brand manufacturer would rationally choose the lower price.²³⁰

226. Leslie, *supra* note 150, at 1716 (quoting *Phototron Corp. v. Eastman Kodak Co.*, 842 F.2d 95, 101 (5th Cir. 1988)).

227. *Glossary of Statistical Terms: Limit Pricing*, OECD, <https://perma.cc/D3QC-J8CL> (last updated Mar. 16, 2002).

228. AREEDA & HOVENKAMP, *supra* note 140, ¶ 736b1(A).

229. *Cf. id.* (providing a numerical example of how, while the limit price is the long-term profit-maximizing price, it is below the short-term profit-maximizing price).

230. *See* Hall, *supra* note 220, at 441 (“[T]he present value calculated from the incumbent's profits from a limit-pricing strategy applied over the remainder of the product life should exceed the present value of the incumbent's revenue from the duopoly. If not, limit pricing is not profitable and would not have been undertaken.”).

The pharmaceutical market is an ideal market for brand manufacturers to engage in limit pricing because “the classical limit-pricing strategy is directed at potential entrants whose costs are higher than those of the incumbent,”²³¹ making limit pricing a better test of predation. Limit pricing would trigger liability when a brand drug manufacturer prices its authorized generic below a reasonable measure of the generic manufacturer’s costs to enter the market,²³² which would include the fixed costs of Paragraph IV certification, resultant patent litigation, and manufacturing. Using limit pricing, rather than below-cost pricing, as a measure of predation would more effectively penalize the type of conduct we want to deter as harmful to consumers, while still serving as an effective screen for those cases in which low costs truly represent competition on the merits. That is because predators who employ limit pricing would *raise* their prices once entry had been deterred, making the price cuts only temporary. Additionally, limit pricing offers courts a practicable and objective way to distinguish between legitimate and illegitimate pricing strategies by comparing the price charged per unit to the fixed costs of entry plus the marginal cost of each additional unit sold. Of course, expert economic analysis would be needed, as it is in nearly all antitrust cases, in order to determine the limit price and the brand manufacturer’s likelihood of recoupment in other markets. However, once that information was provided to the courts, they would have an objective metric of judging when an incumbent brand manufacturer was pricing below the generic manufacturer’s costs in a real attempt to deter generic entry in its other markets.²³³

There are several ways in which a monopolist can leverage its dominant position to introduce limit pricing to deter potential rivals.²³⁴ Incumbent

231. See AREEDA & HOVENKAMP, *supra* note 140, ¶ 736b1(A).

232. I do not propose a specific measure of the generic manufacturer’s costs in this Note, but whatever measure is used must include the fixed costs necessary for market entry.

233. Aaron Edlin, in a similar attempt to revise the *Brooke Group* test in order to better penalize above-cost predatory pricing, offers a “dynamic” standard for adjudicating predation” cases. Edlin, *supra* note 136, at 945. Specifically, Edlin argues:

In markets where an incumbent monopoly enjoys significant advantages over potential entrants, but another firm enters and provides buyers with a substantial discount, the monopoly should be prevented from responding with substantial price cuts or significant product enhancements until the entrant has had a reasonable time to recover its entry costs and become viable, or until the entrant’s share grows enough so that the monopoly loses its dominance.

Id. While this approach certainly has merit and would curb above-cost predatory pricing in the pharmaceutical market, it is much better suited for a legislative solution, *see infra* Part IV.C, given that it does far more than merely tweak the measure of cost used in *Brooke Group*, and instead advocates for an entirely new paradigm under which to evaluate predatory pricing.

234. As part of Edlin’s proposal for a new category of predation, whereby “[m]onopolization under Sherman Act section 2 [would] include[] price reductions or quality improvements by an incumbent monopoly in response to a substantial entry before the entrant has

footnote continued on next page

monopolists that have a “significant cost or noncost advantage over entrants”²³⁵ can utilize these advantages to deter competitors from entering the market. Importantly, and distinct from predatory pricing as contemplated in the classic case such as *Brooke Group*, predation in this model does not require the predator to give up all of its monopoly profits in the short-term. Because “the predator’s cost is below the entrant’s at the margin, [if] the goods are homogeneous” and “competition is over prices” rather than quality, then “the incumbent’s short-run [profit-]maximizing response” is to deter competitors from entering the market altogether.²³⁶

For the limit-pricing theory to hold, then, it must be the case that the monopolist incumbent has cost or noncost advantages over the rival such that it can price below the rival’s costs but above its own. Incumbent monopolists typically have several cost advantages. First, the monopolist has the sunk cost of its initial expenditure that has already been recovered from the sales of the monopoly-priced product and that, unlike the potential entrant, it need not incur again.²³⁷ If barriers to entry are high, then the one-time costs of entry matter even more because, while the monopolist was able to recoup its investment in entry by charging monopoly profits when it had the market to itself (before the entry of the first-filer generic), any potential entrants will necessarily lack the possibility of recoupment through supracompetitive pricing as they will still face the incumbent brand (and likely its authorized generic) as competitors. Second, the monopolist will frequently have lower variable costs than the entrant.²³⁸ This will continue to be the case so long as the marginal costs of the monopolist do not increase significantly, which would threaten to destroy any of its cost advantages.²³⁹

had a reasonable time to recover its entry costs and become viable,” he discusses at length how monopolists can use the inherent advantages in their dominant position to drive out competitors. See Edlin, *supra* note 136, at 966-70.

235. *Id.* at 944.

236. See *id.* at 958.

237. *Id.* at 959; see also Ordovery & Willig, *supra* note 192, at 11-12 (“These [entry] hurdles exist whenever the prospective entrant is cost-disadvantaged relative to the incumbent solely because the incumbent is already functioning as a going concern, and the entrant has not yet committed the requisite resources. In general, entry hurdles arise when investments are not fully reversible. The need to incur the irreversible portion of the investment, and thereby to put that amount at risk, confronts the prospective entrant with a cost disadvantage relative to the incumbent whose resources are already committed. Thus, an incumbent may have an incentive to induce the exit of an entrant, who would then face an entry hurdle afresh.” (footnotes omitted)).

238. Edlin, *supra* note 136, at 959.

239. *Id.*

Additionally, there are several noncost advantages an incumbent monopolist may have over the potential entrant, such as brand loyalty and network effects.²⁴⁰ The upshot of this is that “incumbents with cost advantages may find predation rational and even short-run maximizing, even in a full information setting.”²⁴¹

Another key factor that makes this scenario different from that in *Brooke Group* is that once a monopolist has gained a reputation for predatory pricing, potential rivals will be deterred *ex ante* from entering the market because the incumbent monopolist is signaling to the potential entrant that entry would be futile.²⁴² At that point, an incumbent monopolist may not need to engage in limit pricing at all, since these rivals will be deterred from entering the market altogether, knowing that the monopolist may at any point again engage in such limit pricing to deter entry.

B. Application

The patent and regulatory framework of the pharmaceutical market puts the brand manufacturer, as the incumbent monopolist, in an excellent position to launch authorized generics using a strategy of limit pricing to deter potential generic rivals *ex ante*.

As described above, at least two factors must be present for limit pricing to be a successful predation strategy: (1) an incumbent monopolist and (2) cost or noncost advantages of the monopolist over the potential entrants.

First, brand drug manufacturers are incumbent monopolists by virtue of their patents, which give them a legal monopoly over a particular drug market until the patent expires or a first-filer generic launches a successful Paragraph IV challenge triggering the exclusivity period.

Second, brand manufacturers have significant cost advantages over potential generic entrants. The brand manufacturer has already expended the sunk cost of obtaining the patent and conducting the clinical trials and research necessary for NDA approval by the FDA. Thus, the marginal cost of creating and marketing an authorized generic is substantially lower for the brand manufacturer because it need only increase the quantity of its current output. Because authorized generics can take advantage of state generic substitution laws,²⁴³ the brand manufacturers need not invest in marketing

240. *Id.*

241. *Id.* at 958.

242. See Hemphill & Weiser, *supra* note 169, at 2067; see also Greg LeBlanc, *Signalling Strength: Limit Pricing and Predatory Pricing*, 23 RAND J. ECON. 493, 494 (1992) (noting that this *ex ante* deterrence stands in contrast to the predatory pricing model in which a firm, perceiving a low risk of entry by competitors, will wait until a rival enters the market before engaging in the predatory price-cutting).

243. See *supra* notes 52-54 and accompanying text.

and product placement as they would for a brand drug. Here, the brand manufacturer has greater financial staying power because it already has one successful product—the brand drug—on the market that will continue to attract a customer base. While the generic manufacturers need not incur the same initial costs of conducting research and clinical trials (after all, avoiding these costs is the entire point of the ANDA), they must still invest in the research and testing necessary to prove bioequivalence, along with the infrastructure and supplies necessary to create and scale a new drug product.

Additionally, there are significant barriers to entry for first-filer generics that do not exist for the brand drug because the litigation costs associated with a first filer's Paragraph IV certification erect a significant entry hurdle for the first-filer generic.²⁴⁴ What is more, while the first-filer generic cannot sell its product during the thirty-month stay triggered by the patent litigation, the brand manufacturer will continue reaping a profit.

The brand drug manufacturer also possesses significant noncost advantages over the potential generic entrants. These noncost advantages include brand loyalty, mistrust of generic drugs by consumers, and in certain instances high switching costs, whereby once a consumer begins taking a brand drug, it is difficult to incentivize that same consumer to switch to the generic version of the drug.²⁴⁵ Additionally, studies “suggest that to the extent that a generic market has first mover advantages, an authorized generic would be particularly well positioned to obtain those advantages.”²⁴⁶

With these requisite factors met, exploring two hypothetical scenarios demonstrates when a brand manufacturer would face liability under a limit-pricing test for launching an authorized generic and when it would not.

In the unlawful scenario, assume that brand manufacturer *BM* is a major pharmaceutical company with numerous patent-protected drugs spread across various markets. *BM* is facing generic competition in the market for its brand drug *B₁*—a first-filer generic has already made a Paragraph IV certification and is about to enjoy its exclusivity period. *BM* launches an authorized generic, *AG₁*, for *B₁* at the start of the first filer's exclusivity period and prices it below the first filer's costs. The first filer is unable to recoup its entry and other costs given the steep price competition with *AG₁* and suffers significant losses.

244. See *supra* note 123 and accompanying text.

245. See generally Kathleen Iacocca et al., *Why Brand Drugs Priced Higher Than Generic Equivalents*, 9 INT'L J. PHARMACEUTICAL & HEALTHCARE MARKETING 3, 16-17 (2015) (finding that brand loyalty, personal preferences, and price insensitivity lead brand manufacturers to maintain the high price of their drugs even after generics have entered the market).

246. Zain, *supra* note 55, at 757. But see FTC, *supra* note 11, at 12 (noting that “many brand-name companies . . . contract with ANDA-generic companies to market their [authorized generics]”).

Seeing this behavior in the market for B_1 , another generic manufacturer wishing to challenge the patents for BM 's B_2 , a smaller market, changes course and decides to wait until the patent for B_2 expires, knowing that it would not be able to recoup the entry costs of a Paragraph IV certification if BM were to launch an authorized generic in the market for B_2 . Because BM , a monopolist brand manufacturer, launched an authorized generic priced below its competitor's costs and deterred generic entry in B_2 , BM 's launch of AG_1 would satisfy the limit-pricing test. Assuming BM recouped its investment in launching AG_1 by the deterrence in the market for B_2 , this conduct would also satisfy the recoupment prong, and thus BM should be liable under section 2 of the Sherman Act for predatory pricing.²⁴⁷

Now, assume the same facts except that BM 's other drugs were all in large markets in which a generic's entry costs constituted only a small portion of its total profits. Even seeing the launch of AG_1 , the authorized generic in the market for B_1 , generic manufacturers are not deterred from filing Paragraph IV certifications in the *other* drug markets because they know that even if BM launches an authorized generic priced below their costs in these markets, the resultant profit they would make even after exclusivity would still be enough to recoup their investment. Thus, because there is no entry deterrence, this would fail the predation test, and BM would not be held liable under the antitrust laws.

C. Potential Limitations

While a limit-pricing theory of liability would lend itself more readily to penalizing predatory pricing via authorized generics, such liability would be premised on brand manufacturers actually engaging in this strategy. In 2011, the FTC analyzed short-term and long-term competitive effects of authorized generics and concluded that, while authorized generics reduced the first-filer generic's revenues during the exclusivity period, the presence of an authorized generic during this period "has not affected the generic's incentives in a way that has measurably reduced the number of patent challenges by generic firms."²⁴⁸ But the FTC clarified that "[a]ny disincentive effects would likely be experienced in small markets or in situations where the generic had little chance of winning the patent suit anyway."²⁴⁹

The FTC's analysis, however, is not fatal to a limit-pricing theory of liability for several reasons. First, the FTC failed to analyze whether the authorized generics were being priced *below* the first filer's entry costs. If not,

247. See 15 U.S.C. § 2 (2018).

248. FTC, *supra* note 11, at iii.

249. *Id.*

then the fact that the generic manufacturers were not deterred from entering the market makes sense because they would still presumably be generating enough revenue, even though forced to split these revenues with an authorized generic, to recoup their investment. And if the brand manufacturers began to engage in a limit-pricing strategy and generics were deterred, then liability under this theory would attach.

Second, the FTC report considered data only from 2001 to 2008.²⁵⁰ During this time period, which was before the *Actavis* decision scrutinizing pay-for-delay agreements, drug manufacturers were busy entering into these pay-for-delay agreements to deter generic entry, including ones in which brand manufacturers promised not to launch an authorized generic in exchange for later generic entry. These agreements were brand manufacturers' dominant exclusionary strategies before *Actavis*, indicating that they were likely less concerned with engaging in predatory efforts with regard to authorized generics. In this same report, the FTC found that from 2003 to 2008, authorized generics were present in 61% of first-filer exclusivity periods, and indicated that this percentage might have been higher but for agreements between brand and generic manufacturers not to launch an authorized generic in exchange for delayed generic entry.²⁵¹

An analysis of the launches of authorized generics from an official FDA database demonstrates that there were 156 authorized generics launched in 2014 alone, one year *after* the *Actavis* decision came out—up from only 82 launched in 2012, and 80 launched in 2013.²⁵² While not conclusive, this analysis indicates that brand manufacturers may have been switching tactics upon learning that their main strategy of delaying generic entry was subject to increased scrutiny.²⁵³

Now that cash—and, in several circuits, noncash—pay-for-delay agreements are subject to increased scrutiny by the courts, there is reason to believe that brand manufacturers will engage in other exclusionary strategies, including predatory pricing via authorized generics.²⁵⁴ And if so, a limit-pricing theory should be utilized to determine price predation claims.

250. *Id.* at 7.

251. *Id.* at 6, 32.

252. *See* FDA, *supra* note 103.

253. Other exogenous factors, such as patent expiration, may also have contributed to the uptick in launches of authorized generics in 2014. *See, e.g., Big Pharma's Patent Cliff: Tallying Up the Fallout from Patent Expirations*, BLOOMBERG (Nov. 14, 2013, 8:27 PM PST), <https://perma.cc/JH6L-HQQ5>; Dan Carroll, *The Biggest Victims of the Patent Cliff in 2014*, MOTLEY FOOL (Dec. 15, 2013, 2:28 PM), <https://perma.cc/ZH68-LCS2>.

254. For example, a 2015 survey by Cutting Edge Information, a research firm, found that 42% of brand-name drug companies “have used [authorized generics] as a competitive tactic.” Doug Bartholomew, *In Defense of the Anti-Generic: Authorized Generics Are the Controversial Hero of Post-Patent Profitability*, PHARMA MANUFACTURING (May 4, 2017), *footnote continued on next page*

Beyond the question whether brand manufacturers are engaging in limit pricing in practice, there are several theoretical considerations raised by a limit-pricing theory of predation.

One argument that critics of a new theory of predation may make is that pricing below a generic manufacturer's costs is nothing more than competition on the merits via robust competition on pricing. However, *United States v. Grinnell Corp.*—the seminal case defining the test for monopolization—defines a monopoly that violates section 2 of the Sherman Act as “willful acquisition or maintenance of . . . [monopoly] power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”²⁵⁵ And brand manufacturers are not launching authorized generics *sua sponte* to provide a low-cost option for consumers; rather, they are launching authorized generics *in response* to generic entry. The FTC found that the launch of authorized generics “simultaneously with or shortly after ANDA-generic entry” is consistent with “strategies based on retaining revenues and with strategies premised on deterring patent challenges.”²⁵⁶ Moreover, we must take these actions in the context of the other exclusionary strategies aimed at driving out generic manufacturers in which brand manufacturers have recently engaged, such as cost and noncost pay-for-delay agreements and product hopping. And when considered in that light, it seems much clearer that launching authorized generics is a tactic to drive out rivals rather than to engage in robust price competition. After all, “a firm that preserves its monopoly by charging low prices only when its rivals make the mistake of entering the market, and only until they exit, denies consumers the benefits from competition on the merits,”²⁵⁷ and the firm should be held liable for that conduct.²⁵⁸

<https://perma.cc/Y83X-7W5W>; see also Silvia Appelt, *Authorized Generic Entry Prior to Patent Expiry: Reassessing Incentives for Independent Generic Entry*, 97 REV. ECON. & STAT. 654, 659 (2015) (“Industry experts assert that generic firms must expect authorized generic entry in large drug markets in particular.”).

255. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

256. FTC, *supra* note 11, at 72. Moreover, the FTC analyzed documents from brand drug manufacturers and found that the brand manufacturers clearly understood that the launch of authorized generics during the 180-day exclusivity period could “reduce the revenues of generic rivals and could deter future generic entry.” *Id.* at iv. While this Note does not advocate for adding an “intent” prong to the predatory pricing test, this analysis demonstrates that the brand manufacturers were in fact engaging in strategic conduct.

257. Edlin, *supra* note 136, at 966.

258. Additionally, under a limit-pricing theory, the brand manufacturer is still pricing below its short-term profit-maximizing price, meaning that it is leaving money on the table. Such a strategy is rational (and we assume firms are rational actors) only if there is a reasonable probability that the firm will recoup this lost profit in some other way. And here, that way is by deterring generics from entering before the end of exclusivity in the brand manufacturer's *other* drug markets, enabling the brand to continue charging monopoly prices, and making a monopoly profit, for longer in those markets.

Relatedly, an incumbent monopolist may try to justify its actions by making a “meeting competition” defense.²⁵⁹ However, meeting the price of the competitor may still be anticompetitive if its effect is to drive rivals out of the market or deter their entry in the long term, thereby harming consumers when the predator raises the price.²⁶⁰ This could occur, for example, if more consumers stay with the authorized generic because of switching costs, or if the generic manufacturer is unable to sustain charging such a low price because it is losing part of the market to the monopolist so its output is lower. In this case, “the ability to match prices may be the source of the anticompetitive problem.”²⁶¹

Finally, some may argue that a legislative solution prohibiting authorized generic entry during the exclusivity period would be better tailored to solve this anticompetitive problem than a judicial test created by courts. While that may be true, until it happens, courts have a duty under the Sherman Act to police anticompetitive conduct as it occurs and thus should modify their predation analysis to capture the anticompetitive concerns posed by authorized generics. After all, “[a]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.”²⁶² And the pharmaceutical market is no different.

Conclusion

There is good reason for courts to be skeptical of price predation claims since they are often very difficult to evaluate successfully. But *Brooke Group’s* concern for false positives has the perverse effect of insulating certain predatory pricing schemes that do not meet its specific criteria but that nonetheless harm consumer welfare in the long term. Specifically, *Brooke Group* shields monopolists in markets with cost advantages and high barriers to entry

259. Often used as an express defense against unlawful price discrimination under the Robinson-Patman Act, *see generally* Note, *Meeting Competition Under the Robinson-Patman Act*, 90 HARV. L. REV. 1476 (1977), the meeting competition defense provides that it is not unlawful for a seller to lower its price “in good faith to meet an equally low price of a competitor,” 15 U.S.C. § 13(b) (2018). The seller has the burden of proof to “demonstrate that a ‘reasonable and prudent’ person would have believed that the granting of the lower price to the allegedly favored customer or customers ‘would in fact meet the equally low price of a competitor,’ and that he acted in ‘good faith’ on this belief.” WILLIAM C. HOLMES & MELISSA H. MANGIARACINA, ANTITRUST LAW HANDBOOK: 2018-2019 EDITION § 4:4, at 658-59 (2018) (quoting *Falls City Indus., Inc. v. Vanco Beverage, Inc.*, 460 U.S. 428, 438, 451 (1983)).

260. *See* Edlin, *supra* note 136, at 971-72.

261. *Id.* at 972.

262. *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411-12 (2004) (quoting *Town of Concord v. Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990)) (refusing, based on antitrust principles, to create a new exception for the telecommunications industry to the rule that businesses have “no duty to aid competitors”).

from liability if they decide to price their products below their rivals' costs in order to deter entry. This Note argues that in these situations, a new test for predatory pricing—limit pricing—is better suited to penalize this very conduct that is detrimental to consumer welfare.

The pharmaceutical market exemplifies these concerns about predatory pricing under the current test, as brand manufacturers can launch authorized generics in order to deter generic entry. While these brands would escape liability under the *Brooke Group* test because they would rarely price the authorized generics below some measure of their own costs, a limit-pricing test would hold brands accountable when they price their authorized generics below a generic entrant's costs in order to deter generic entry.

If courts continue to analyze predation solely under the *Brooke Group* test, drug manufacturers will be free to charge high prices without the constraint of competition, which will have obvious detrimental effects on consumer welfare.²⁶³ “[I]t makes little sense for the law to focus exclusively on the failures of incumbents to short-run-maximize, or, indeed, on extreme failures that involve losing money and pricing below appropriate measures of cost, as required by *Brooke Group*.”²⁶⁴ Moreover, “a rule that favors granting a powerful firm maximum pricing freedom, such as would be the probable result under the below-cost and recoupment-screening tests in *Brooke Group*, may bring a few short-term welfare benefits that are more than offset by welfare losses from long-term higher prices.”²⁶⁵ In the specific context of the pharmaceutical market, when brand manufacturers engage in tactics that successfully deter generic competition, consumers lack “the opportunity to choose the generic alternative until the (potentially invalid or not-infringed) patent of the brand had expired,”²⁶⁶ which could take years. When these tactics come within the purview of the antitrust laws, courts should analyze them in a way that better maximizes consumer welfare.²⁶⁷

Brand drug manufacturers that engage in exclusionary tactics designed to delay and deter generic entry violate the spirit of both antitrust law, which protects consumer welfare, and intellectual property law, which protects only valid innovation for a specified period of time. While more empirical research is needed to determine the extent of this problem as it currently stands, this Note lays out the theoretical foundation for how best to penalize this exclusionary conduct.

263. See Edlin, *supra* note 136, at 955.

264. *Id.* at 958-59.

265. SULLIVAN ET AL., *supra* note 130, at 158 (footnote omitted).

266. FTC, *supra* note 11, at 38.

267. See Kesselheim et al., *supra* note 7, at 864-65 (summarizing alternatives).