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The Price Tag of "Pay-for-Delay"

Robin C. Feldman

UC Hastings College of the Law, feldmanr@uchastings.edu

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THE PRICE TAG OF “PAY-FOR-DELAY”

Robin Feldman*

In a landmark decision nearly a decade ago, the U.S. Supreme Court opened the door for antitrust suits against brand and generic pharmaceutical companies who engage in collusive settlements to delay the time for the generic to come to market. With these “pay-for-delay” agreements, brand-name companies offer prospective generics some form of compensation in exchange for the generic’s promise not to enter the market until an agreed-upon date. Laying the groundwork for the lawsuit that would eventually lead to the Actavis decision, the Federal Trade Commission (“FTC”) published a study estimating that pay-for-delay agreements cost American consumers \$3.5 billion annually, a figure that has been cited repeatedly by scholars and policymakers alike.

To understand the state of pay-for-delay agreements, this Article presents an in-depth examination of the burden that pay-for-delay imposes, both on society at large and on individual patients, and explores the modern legal landscape that has emerged since the Supreme Court’s historic pronouncement. Part I describes pay-for-delay agreements, exploring the literature on the potential harm of such agreements among pharmaceutical competitors. Part II presents a new analysis demonstrating that the cost of pay-for-delay to American consumers is far greater than anyone has recognized, and well beyond the \$3.5 billion figure cited by the FTC in 2010. We applied six different methodologies to provide as fair and broad a view as possible. The range of methodologies show that at a minimum, the cost of pay-for-delay settlements on the U.S. population between 2006 and 2017 is \$6.2

* Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, Director, Center for Innovation (C4i), University of California Hastings Law. Research for this piece was funded in part by a generous grant from the Laura and John Arnold Foundation. I wish to express my thanks to Ramy Alsaffar, Chief Data Scientist at C4i, for his work in conducting the empirical analysis. I am grateful to Matthew Avery for helpful comments and to Christopher Kim, Brittany Ng, Oriana Tang, Nathan Brown, Joseph Clateman and Nicholas Massoni for research assistance. I am particularly indebted to Gideon Schor for leading the research team.

billion per year—almost double that of the FTC’s estimate. The methodology with the largest result suggests that the cost could be as high as \$37.1 billion per year—ten times higher. Part III argues that courts are allowing this costly problem to flourish unchecked. This part reviews pay-for-delay decisions since Actavis, arguing that the courts have failed to properly analyze such cases from the perspective of all three notions inherent in the words “pay,” “for,” and “delay.” Finally, Part IV offers a path forward through the doctrinal haze.

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I. INTRODUCTION

The skyrocketing price of prescription medication continues to plague the pharmaceutical industry. For example, an analysis of one million Medicare patients between 2010 and 2017 found that the average price of brand-name drugs increased by 313 percent even after accounting for rebates.¹ Although complex biologics

¹ Robin Feldman, *The Devil in the Tiers*, J.L. & BIOSCI. 1, 19 (2021). The RAND Corporation found in 2021 that the price of brand-name prescription drugs in the U.S. is 256 percent of the prices

contribute heavily to the nation’s overall spending on medicine, consumers have experienced substantial price increases for many ordinary, non-biologic drugs.² One in four Americans have difficulty affording their medications, and three in ten say costs have prevented them from taking their medications as prescribed.³ With rising out-of-pocket costs and patients dangerously rationing medication, these prices are causing real pain for American patients. Diabetic patients, for example, paid nearly \$6,000 per year out-of-pocket for insulin in 2016, compared to less than \$3,000 in 2012.⁴ As difficult as these burdens are for any patient, the burden of high prices lands particularly hard on lower-income groups, threatening access to life-saving treatments and creating further gaps in equity across society.

Basic economic principles suggest that the presence of generic drugs in the market should drive down prices for the drug. With this in mind, Congress approved the Hatch-Waxman Act in the early 1980s, creating a pathway for generic drugs to rapidly enter as soon as a drug’s patent protection expires.⁵ Since that time, the nation has pinned its hopes for lower drug prices on the disciplining effects generic drugs can bring as they enter the market and drive prices down to competitive levels. However, something is seriously amiss. Although generics continue to enter

in thirty-two OECD countries combined, ranging from 170 percent of prices in Mexico to 779 percent of prices in Turkey (ANDREW W. MULCAHY ET AL., RAND CORP., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES 26 (2021), https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf).

² See Feldman, *Devil*, *supra* note 1 at n. 4 (citing to Cal. Office of Statewide Health Planning and Development, Prescription Drug Wholesale Acquisition Cost (WAC) Increases (2019) (detailing wholesale price increases of more than 16% for hundreds of drugs between 2017 and Q2 of 2019 and including common, non-biologic drugs for depression, high cholesterol, and reflux.)

³ *Id.* at 2–3, citing KAISER FAMILY FOUNDATION, PUBLIC OPINION ON PRESCRIPTION DRUGS AND THEIR PRICES Fig. 5 (2020), <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>.

⁴ JEAN FUGLESTEN BINIEK & WILLIAM JOHNSON, HEALTH CARE COST INST., SPENDING ON INDIVIDUALS WITH TYPE 1 DIABETES AND THE ROLE OF RAPIDLY INCREASING INSULIN PRICES 2 (2019), https://healthcostinstitute.org/images/easyblog_articles/267/HCCI-Insulin-Use-and-Spending-Trends-Brief-01.22.19.pdf.

⁵ ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 19–23 (2017). One should note that the Hatch-Waxman Act system governs only what are known as small-molecule or chemical drugs. In 2010, Congress passed the Biosimilars Act, or Biologics Price Competition and Innovation Act (“BPCIA”) to govern rapid entry of lower-priced versions of biologic drugs. 42 U.S.C. § 262 (2019). Biologics, in contrast to small-molecule drugs, are produced from living cells and may be composed of tens of thousands of atoms; as a result, biologic molecules, unlike their small-molecule peers, cannot be visualized in a two-dimensional sketch or chemically replicated to the same degree. See Robin Feldman, *The Cancer Curse: Regulatory Failure by Success*, 21 COLUM. SCI & TECH. L. REV. 1, 20 (2020) (differentiating biologics from small-molecule drugs). The process for enacting biosimilars regulations took many years, and the FDA did not approve the first biosimilar until 2015. See Diane S. Aschenbrenner, *First Biosimilar Drug Approved*, 115 AM. J. NURS. SCI. 24 (2015). Litigation under the biosimilar system has only recently begun, providing little time for information to emerge on pay-for-delay agreements between brand and biosimilar companies. As a result, this article focuses on available information on brand and generic drugs governed by the Hatch-Waxman system for chemical drugs.

the market in record numbers,⁶ drug prices, out-of-pocket costs, and real spending on drugs continue to soar unabated.

The pharmaceutical industry is a complex and convoluted market, with significant distortions and inefficiencies.⁷ Among these problems, generic companies cannot effectively discipline prices when they collude with their brand competitors.

In a landmark decision nearly a decade ago, the Supreme Court in *Actavis* opened the door for antitrust suits against brand and generic pharmaceutical companies who engage in collusive agreements to delay the time for the generic to come to market.⁸ With these “pay-for-delay” agreements, brand-name companies offer prospective generic competitors something of value in exchange for the generic’s promise not to enter the market until an agreed-upon date. Specifically, the *Actavis* case held that although pay-for-delay agreements are not presumptively illegal, they can be contested under antitrust principles. Laying the groundwork for the lawsuit that would eventually lead to the *Actavis* decision, the Federal Trade Commission (“FTC”) published a study estimating that pay-for-delay agreements cost American consumers \$3.5 billion annually, a figure that has been cited repeatedly by scholars and policymakers alike.⁹ Similar concerns led Congress, in 2003, to require that brand and generic manufacturers file with the FTC and the DOJ the text of any settlement agreement such companies enter into in litigation regarding manufacture, marketing, or sale of generic.¹⁰

To understand the state of pay-for-delay agreements, this article leverages a range of methodologies to present an in-depth examination of the burden that pay-for-delay imposes, both on individual patients and society at large. The findings are

⁶ See Evan Hoffman, *Competitive Dynamics of the Generic Drug Manufacturing Industry*, 52 BUS.ECON. 68, 68 (2017) (noting the growth in the generic market from 55% of all prescribed drugs in 2005 to 88.7% in 2015); Marc-Andre Gagnon & Karena Volesky, *Merger Mania: Mergers and Acquisitions in the Generic Drug Sector, 1995-2016*, 13 GLOB. & HEALTH 62, 62 (2017) (following implementation of the Hatch-Waxman system, the total market share of all generic drugs increased to 43% in 1995, 72% in 2008, and 89% in 2016).

⁷ See generally FELDMAN & FRONDORF, *supra* note 5, at 13–19.

⁸ *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) (holding that reverse payment, or pay-for-delay settlements, are open to antitrust scrutiny, although they are not presumptively illegal).

⁹ FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> [hereinafter FTC, PAY-FOR-DELAY].

¹⁰ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003). For discussion of the content of these reports, see Robin Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 251–52 (2019) [hereinafter Feldman & Misra, *Fatal Attraction*], citing Jamie Towey & Brad Albert, *Is FTC v. Actavis Causing Pharma Companies to Change Their Behavior?*, FED. TRADE COMM’N BLOG: COMPETITION MATTERS (Jan. 13, 2016), <https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharma-companies-change-their>; see also Laura Karas, Gerald F. Anderson & Robin Feldman, *Pharmaceutical “Pay-for-Delay” Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959, 964 (2020).

alarming, and they demonstrate that the \$3.5 billion figure vastly understates the landscape. Highlights of these findings include:

- **Pay-for-delay settlements cost the U.S. population at least \$6.2 billion annually:** Calculations ranged from \$6.2 billion to as high as \$37.1 billion per year in total costs based on list prices, as the postponement of generic options required the continued usage of expensive brands.
- **Pay-for-delay settlements saddled American patients with more than \$600 million in annual out-of-pocket costs:** Patients each year collectively paid between \$619 million and \$2.9 billion more out-of-pocket as a result of pay-for-delay.
- **Pay-for-delay settlements cost the Medicare Part D program at least \$2.3 billion annually:** The government paid between \$2.3 and \$13.5 billion more each year to fund Part D because of pay-for-delay.

Moreover, although the Supreme Court’s landmark decision in *Actavis* opened the door for antitrust litigation, courts have failed to utilize the pathway provided. This Article explores the modern legal landscape that has instead emerged since the Supreme Court’s historic pronouncement.

The Article proceeds as follows. Part I describes pay-for-delay agreements, exploring the literature on the potential harm of such agreements among pharmaceutical competitors. Part II presents a new analysis demonstrating that the cost of pay-for-delay to American consumers is far greater than anyone has recognized, and well beyond the \$3.5 billion figure cited by the FTC in 2010. We applied six different methodologies to provide as fair and broad a view as possible. The range of methodologies show that at a minimum, the cost of pay-for-delay settlements on the U.S. population between 2006 and 2017 is \$6.2 billion per year—almost double that of the FTC’s estimate. The methodology with the largest result suggests that the cost could be as high as \$37 billion per year—ten times higher than the FTC’s estimate. Part III argues that courts are allowing this costly problem to flourish unchecked. This part reviews pay-for-delay decisions since *Actavis*, arguing that the courts have failed to properly analyze such cases from the perspective of all three notions inherent in the words “pay,” “for,” and “delay.” Finally, Part IV offers a path forward through the doctrinal haze.

When competitors shake hands and agree that the lower-priced drug should stay off the market, it is bad for consumers. This article demonstrates the magnitude of that suffering.

II. THE LANDSCAPE OF “PAY-FOR-DELAY”

In pay-for-delay agreements, brand-name pharmaceutical companies settle litigation with generic companies by paying the generic to stay off the market for a given amount of time, allowing the brand to enjoy its monopoly for a longer

period.¹¹ Such agreements leverage the mutual interests of pharmaceutical companies against the interests of consumers. From an economic perspective, the brand-name company is sharing a portion of its monopoly rents with the generic company, in exchange for the generic remaining off the market.¹² Although initially structured as straight cash payments, pay-for-delay settlements have taken on increasingly convoluted forms since their genesis in the aftermath of the 1984 Hatch-Waxman Act. Regardless of the form of the agreement, these deals continue to saddle consumers with additional years' worth of brand-name monopoly prices.¹³

A. The Hatch-Waxman System

To understand the origins of pay-for-delay, one must understand the market landscape of drug development. Researching and developing a single successful drug is a long, costly, and risky endeavor. Although sources differ on the cost of developing a drug, and not all drugs require the same level of investment and risk, some estimates suggest that the cost, including failed drug candidates, can rise as high as \$2.6 billion.¹⁴ The prospect of a period of patent monopoly creates an incentive for drug companies to engage in this research. During this initial period of market exclusivity, the pharmaceutical company holds a monopoly over the

¹¹ See generally C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1153 (2006) [hereinafter Hemphill, *Paying for Delay*]; C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009) [hereinafter Hemphill, *Aggregate Approach*]; Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009); Steve D. Shadowen, Keith B. Leffler, & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1 (2009); Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1 (2013); Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008).

¹² See *id.*

¹³ See generally FELDMAN & FRONDORF, *supra* note 5.

¹⁴ The DiMasi (Tufts) estimate has been challenged on multiple fronts. Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the pharmaceutical industry: new estimates of R&D costs*, 47 J HEALTH ECON., 20, 30 (2016); see also Aaron E. Carroll, *\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES (Nov. 18, 2014), www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html (suggesting that the disparity in the findings stems from methodological mistakes in the Tufts study and noting that the Tufts Center is funded by pharmaceutical companies); Tufts Ctr. for the Study of Drug Dev., *Financial Disclosure*, <https://csdd.tufts.edu/financial-disclosure/> (last visited Jan. 22, 2021). Several other studies propose more modest figures. See, e.g. Steve Morgan et al., *The Cost of Drug Development: A Systematic Review*, 100 HEALTH POL. 4 (2011), www.ncbi.nlm.nih.gov/pubmed/21256615 (analyzing 13 different studies to estimate that drug development costs range from \$161 million to \$1.8 billion); Olivier J. Wouters, Martin McKee, Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844, 844 (2020) (finding that drug development estimates range from \$300 million to \$2.6 billion).

drug’s sales, enabling it to charge high prices and enjoy maximum profits that can amount to billions of dollars.¹⁵

Under this incentive structure, consumers bear the costs associated with the monopolist’s high prices until a bioequivalent generic enters the marketplace, generating the requisite competition to drive prices down. A 2019 U.S. Food and Drug Administration (“FDA”) report found that drugs with a single generic competitor experience a 39 percent reduction in average manufacturer prices. The same report concluded that four generic competitors reduce the price by around 80 percent, and six or more competitors produce a reduction of over 95 percent.¹⁶ In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act—better known as the Hatch-Waxman Act—in order to facilitate rapid entry of generic drugs.¹⁷ Previously, brand-name pharmaceutical companies saw their monopolies extend beyond the twenty-year drug patent term because generic companies were not permitted to file for FDA approval until the brand-name drug’s patent term ended.¹⁸ In addition to the extra period of delay, generic companies were disincentivized from entering the market by the fact that the FDA required them to run their own clinical trials. The brand-name company could recoup those costs during the period of patent monopoly, but the generic would receive no such benefit. The high cost of such trials, coupled with the low profitability of generic drugs, discouraged companies from attempting to compete with brand-name pharmaceuticals.¹⁹

To combat these market conditions, the Hatch-Waxman Act introduced two innovations in the generic entry process. First, a generic company is permitted to rely on the brand-name company’s clinical trial results to prove safety and efficacy when it files for approval with the FDA. Rather than repeating those trials, the generic files what is known as an Abbreviated New Drug Application (“ANDA”) with the FDA in which the generic merely needs to prove that its version of the drug is bioequivalent.²⁰ Second, the generic company is allowed to file for approval of its drug before patent protection on the brand-name drug has expired. In particular, the generic may challenge one or more of the patents covering the brand-name drug by filing what is known as a Paragraph IV certification as part of its abbreviated new drug application to the FDA. Such a certification alleges that the

¹⁵ FELDMAN & FRONDORF, *supra* note 5, at 7; *cf.* Einer Elhauge, *Defining Better Monopolization Standards*, 56 STAN. L. REV. 253, 272 (2003) (noting that the establishment of a monopoly creates inefficiencies in the market as the monopolist is permitted to charge well above its costs).

¹⁶ RYAN CONRAD & RANDALL LUTTER, U.S. FOOD & DRUG ADMIN., *GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES 2–3* (2019), <https://www.fda.gov/media/133509/download>.

¹⁷ Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

¹⁸ *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863–64 (Fed. Cir. 1984); FELDMAN & FRONDORF, *supra* note 5, at 28.

¹⁹ *See* Elizabeth S. Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 585–90 (2003).

²⁰ 21 U.S.C. § 355(j)(2)(A)(iv).

relevant patent listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations document ("Orange Book") is invalid, unenforceable, or would not be infringed by the entry of the generic drug.²¹

Under the Act, a Paragraph IV certification constitutes an artificial act of infringement, which allows the parties to begin the process of working through any patent disputes prior to expiration of the patent. Once a Paragraph IV certification is filed, the brand-name company has a period of time to respond by suing the generic, which allows the parties to litigate whether the patents are both valid and validly applied to the drug at issue. A patent infringement suit brought after a Paragraph IV certification triggers a 30-month stay on the abbreviated new drug application, during which time the patent litigation occurs.²²

Litigation resulting from a Paragraph IV certification produces one of two results. If the generic company loses its challenge, the brand-name drug continues to enjoy its monopoly, barring additional challenges. If the generic company wins, it may begin to compete with the brand-name drug as soon as it secures FDA approval.²³ Although the generic must bear the expense and risk of litigation for filing a Paragraph IV certification, bringing the litigation before entry ensures that the generic does not face liability for damages from actual sales of the drug should a court uphold the brand-name company's patent assertion.²⁴ The certification thus enables the generic to contest the brand-name company's patents in a relatively low-risk manner.²⁵

The Paragraph IV pathway reflects the concern that not all patents are valid or validly applied to the particular drug against which they are asserted. As an additional incentive for generic companies to challenge improper patents, Hatch-Waxman gives the first generic company that successfully files a Paragraph IV certification an extra bonus. Specifically, the company receives a 180-day exclusivity period in which no other generic may enter the market. During this period, only the brand-name drug and the first applicants.²⁶ The six-month period

²¹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

²² 21 U.S.C. § 355(c) (3)(C).

²³ Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 255.

²⁴ Launching without the protection of the Hatch-Waxman system is known as launching at-risk, and generics do choose this route in certain circumstances. For example, when Hatch-Waxman's 30-month stay of approval expires but litigation is still pending, some generics choose to launch, even though the litigation has not been resolved. *See, e.g., In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 673 (D. Mass. 2020) ("[l]aunching at-risk means launching a generic product with the risk of losing a patent infringement case brought by the brand company").

²⁵ *Id.*; *see also* FELDMAN & FRONDORF, *supra* note 5, at 37.

²⁶ If more than one generic files on the same day, both can enter the market during the 180-day exclusivity period. In that case, there is a rush to get to market first to trigger the 180-day period before other first-filers are ready to enter. In addition, a brand company wishing to hold off competition would have to sue all of them and arrange settlements with all of them. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAs ARE SUBMITTED ON THE SAME DAY (2003), <https://www.fda.gov/files/drugs/published/180-Day-Exclusivity-When-Multiple-ANDAs-Are-Submitted-on-the-Same-Day.pdf>, 5; *See also* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) ("[a]s used in this subsection, the term "first applicant" means an applicant

can net hundreds of millions of dollars for generic companies and comprise a significant proportion of a generic company’s overall return on the drug, especially given that competition from additional generics will quickly drive the price further down.²⁷

Hatch-Waxman has done well in its objective of facilitating generic entry. By 2006, the median time between FDA approval of a brand-name drug and its first Paragraph IV challenge across all categories of drugs was just four years, which reflects the earliest time that a generic may file a Paragraph IV challenge. In other words, Hatch-Waxman guaranteed brand-name drugs a period of at least four years of exclusivities regardless of whether any valid patents exist.

Generics also have seen success in their contests over patent applicability: For example, a 2002 FTC report found that generics won their Paragraph IV challenges 73 percent of the time when they pursued the litigation to conclusion.²⁸ Together, the increased incentives of the Hatch-Waxman Act put pressure on the bottom line for brand-name drug companies, with each year of lost monopoly representing billions in profits.²⁹ Given that merely a few more months of monopoly power can bring hundreds of millions of dollars in sales without competition, these conditions

that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.”). Two separate prospective generics could submit a substantial paragraph IV certification on the same day, and both be considered first filers.

²⁷ See Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 178 (2008), (citing Leila Abboud, *Drug Makers Use New Tactic To Ding Generic-Drug Firms*, WALL ST. J. (Jan. 27, 2004), <https://www.wsj.com/articles/SB107515784029812090>) (“One provision set up a big carrot to encourage the generics companies to challenge weak patents in court: The first generics company to file and win a suit against a branded-drug maker would get the exclusive right to sell its generic version for six months. The payoff for a generics company is substantial: In 2002, when Barr successfully challenged the patent protection on Eli Lilly & Co.’s big antidepressant Prozac, Barr got revenue of about \$368 million from the new drug, or 31% of its total for the year.”).

²⁸ FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 13* (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf [hereinafter *FTC, GENERIC DRUG ENTRY*]. See also *infra* text accompanying notes 188–191 (describing additional academic studies on the topic).

One could argue that parties with weak claims tend to settle. Although well beyond the scope of this article, the issue of whether Hatch-Waxman parties settle weak claims is interesting and complex. In general, parties settle when they believe the costs and risks of litigation—including the strength of their case—do not weigh in favor of continuing to trial. For a generic, the preservation of the 180-day exclusivity period with a settlement, when it might be lost if the case is lost, provides an incentive to settle a weak case. Nevertheless, settling with a transfer of value from the patentholder to the accused infringer, when an ordinary case settlement would flow from the accused infringer to the patent-holder, suggests a decision that is not solely based on the merits of the case.

One should also note that Hatch-Waxman litigation ends in settlement far less frequently than patent cases on the whole. See *Hatch-Waxman ANDA Litigation Report 2017*, LEX MACHINA (2017) at iii (documenting that Hatch-Waxman cases end in settlement 56.5% of the time while other patent litigation ends in settlement 77.8% of the time).

²⁹ See, e.g., Duff Wilson, *Drug Firms Face Billions in Losses in ’11 as Patents End*, N.Y. TIMES (Mar. 6, 2011), <https://www.nytimes.com/2011/03/07/business/07drug.html>.

create a strong incentive for brand-name manufacturers to delay generic entry for as long as possible.³⁰

B. The Anatomy of a Pay-for-Delay Deal

In response to the increased pressure of generic entry and Paragraph IV challenges, pay-for-delay settlements emerged as a valuable strategy. With pay-for-delay settlements, brand-name companies can extend their monopoly by taking advantage of shared interests with generic companies. Under a basic pay-for-delay agreement, the brand-name company and the generic settle the patent infringement suit that the brand company had filed against the generic in response to the generic filing for FDA approval using a Paragraph IV certification. As part of the settlement, the brand-name company provides something of value to the generic in exchange for the generic's promise to stay out of the market until a specific entry date. While the brand-name company preserves its monopoly, the generic company enjoys benefits as well. The generic company receives an immediate financial benefit without fully pursuing the lawsuit. In fact, it is possible that the generic company might even have filed a Paragraph IV certification in hopes of receiving a payout, rather than taking the case to a final judgment.³¹ Most important, although the generic agrees to stay out of the market for a period of time, it retains the most valuable benefit of the Hatch-Waxman scheme. Specifically, the generic maintains its 180-day first-filer marketing exclusivity period when it does finally enter the market. In other words, the generic company shares some of the brand-name company's monopoly rent and still keeps other generics out for 180 days at the end of the delay period.³²

While both generic and brand-name pharmaceutical companies benefit from pay-for-delay, consumers bear the costs. The generic company's hold on the first-filer exclusivity period creates a bottleneck that bars other generics from entering in its place.³³ The brand-name company's prolonged period of monopoly control enables it to maintain prices at high levels or even raise them, restricting patients from accessing life-saving drugs.³⁴ In light of these consequences, commentators have argued that pay-for-delay settlements constitute violations of antitrust law. In a seminal article on the economics of pay-for-delay, Professor C. Scott Hemphill suggested that pay-for-delay schemes infringe on Section 1 of the Sherman Act and

³⁰ FELDMAN & FRONDORF, *supra* note 5, at 92.

³¹ See Hemphill, *Paying for Delay*, *supra* note 11, at 1581.

³² *Id.* at 1578–80. See generally Robin Feldman, *Ending Patent Exceptionalism & Structuring the Rule of Reason: The Supreme Court Opens the Door for Both*, 15 MINN. J.L. SCI. & TECH. 61 (2014) [hereinafter Feldman, *Patent Exceptionalism*]; Hemphill, *Aggregate Approach*, *supra* note 11, at 34 (“[a]lthough framed as an antitrust case by plaintiffs, the Federal Circuit has embraced the view that settlement is essentially a patent issue, governed by patent law—indeed, arguably governed by Federal Circuit law—and that patent law trumps antitrust doctrine within the nominal scope of the patent.”).

³³ See FTC, *GENERIC DRUG ENTRY*, *supra* note 28, at 57, 62–63.

³⁴ See Emily Miller, *Big Pharma's Block on Competition: A Bad Prescription for U.S. Drug Prices*, DRUGWATCH (Sept. 14, 2017), <https://www.drugwatch.com/featured/big-pharmas-competition-block/> (last updated Feb. 25, 2021); FTC, *PAY-FOR-DELAY*, *supra* note 9, at 2.

that the agreements should be considered a form of illegal monopolization.³⁵ Indeed, Hemphill asserted in 2009 that the relationship between pay-for-delay and antitrust law is “the most important unresolved issue in US antitrust policy, measured by economic importance and high-level judicial attention.”³⁶

C. Actavis Opens the Door

The Supreme Court appeared to make progress on this issue in 2013 when it ruled in *FTC v. Actavis, Inc.* that pay-for-delay settlements, although not presumptively illegal, can be contested under antitrust principles. The decision came down against the backdrop of a legal landscape in which many of the Justices were wary of supporting expansive antitrust enforcement measures. This general reticence, following the rise of the Chicago School of Economics approach to markets, took hold in the 1960s;³⁷ *Actavis* represented a significant step towards enabling future action against pay-for-delay. In spite of widespread optimism, however, *Actavis* has not produced the change many hoped it would deliver.³⁸

FTC v. Actavis, Inc. revolved around Solvay Pharmaceuticals’ brand-name topical testosterone drug AndroGel. Solvay filed a New Drug Application for AndroGel in 1999 and received FDA approval in 2000. The company obtained a patent in 2003 that was set to expire in 2021.³⁹ In 2003, Actavis, Inc., filed an Abbreviated New Drug Application for a generic version of AndroGel. Paddock Laboratories, joined by Par Pharmaceutical, followed suit.⁴⁰

In accordance with Hatch-Waxman, Solvay initiated Paragraph IV litigation against the generic companies Actavis and Paddock.⁴¹ Although the FDA approved Actavis’s generic thirty months later—meaning the generic would have been permitted to enter the market as early as 2006 if Solvay’s patent were found invalid, unenforceable, or not infringed—all parties settled in 2006.⁴² Actavis agreed to not enter the market with its generic until August 31, 2015, sixty-five months before Solvay’s patent expired, and to promote brand-name AndroGel to urologists.

³⁵ See Hemphill, *Paying for Delay*, *supra* note 11, at 1596; Hemphill, *Aggregate Approach*, *supra* note 11, at 636; see also 15 U.S.C. § 2 (2004); Michael A. Carrier, *Payment after Actavis*, 100 IOWA L.R. 7 (2013); Feldman & Misra, *Fatal Attraction*, *supra* note 10.

³⁶ Hemphill, *Aggregate Approach*, *supra* note 11, at 631.

³⁷ See Herbert J. Hovenkamp & Fiona Scott Morton, *Framing the Chicago School of Antitrust Analysis*, 168 U. PA. L. REV. 1843 (2020); Thomas A. Piraino, Jr., *Reconciling the Harvard and Chicago Schools: A New Antitrust Approach for the 21st Century*, 82 IND. L.J. 345, 350–353 (2007) (describing the “Chicago School” approach to antitrust analysis and its permeation of the judicial system, led by judges like Richard Posner and Robert Bork); cf. Robin Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079, 2084–2086 (1999) (describing the Chicago school of antitrust and its emphasis on price theory as falling short in evaluating leverage cases).

³⁸ See generally Feldman & Misra, *Fatal Attraction*, *supra* note 10.

³⁹ *FTC v. Actavis, Inc.*, 570 U.S. 136, 145 (2013); Second Amended Complaint for Injunctive and Other Equitable Relief at 15–16, *FTC v. Actavis*, 570 U.S. 136 (2013) (No. 12-416).

⁴⁰ *Actavis*, 570 U.S. at 144.

⁴¹ Par shared patent litigation costs with Paddock in exchange for a cut of the profits but did not file an application of its own. See *id.*

⁴² *Id.*; see also Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 257.

Paddock and Par made similar promises. In return, Solvay agreed to pay Paddock \$12 million, Par \$60 million, and Actavis between \$19 and 30 million a year for nine years, ostensibly for other services the generics promised Solvay.⁴³

Although all parties stated that these payments were intended to compensate for services the generic companies would perform for Solvay, the FTC contended that the services had little value. Arguing that the “true point of the payments was to compensate the generics for agreeing not to compete against AndroGel until 2015,” the FTC filed a lawsuit against Solvay, Actavis, Paddock, and Par on January 29, 2009, alleging that the companies violated Section 5 of the FTC Act prohibiting unfair or deceptive practices.⁴⁴ The district court dismissed the complaint and the Court of Appeals for the Eleventh Circuit affirmed. Specifically, the Court of Appeals found that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”⁴⁵ In other words, the court acknowledged that although payments not to enter the market are typically considered antitrust violations, Solvay’s status as a patent holder distinguished its settlements over AndroGel because patent holders have a “lawful right to exclude others from the market” until the patent expires.⁴⁶ Given that the settlement allowed Actavis to begin selling its generic before Solvay’s patent would expire in 2021, it could not constitute a violation.⁴⁷

The Supreme Court reversed. In a 5–3 decision written by Justice Stephen Breyer, the Supreme Court found that the FTC’s case should not have been dismissed and that pay-for-delay settlements are open to antitrust scrutiny.⁴⁸ The court did not go so far as to declare all reverse payment schemes per se unlawful. Rather, the Justices decided that a rule of reason test should be used to determine whether such settlements violate antitrust law.⁴⁹ This decision dealt a blow to pay-for-delay settlements even as it incentivized pharmaceutical companies to enter into ever more complicated agreements to circumvent legal challenges. On one hand, the ruling pushed back against the reluctance of modern courts to frame any behaviors related to the patent rights in antitrust terms for fear of having to test the validity of the patents. However, the Supreme Court stressed in *Actavis* that it is not necessary to determine whether a patent is valid in order to assess whether a settlement has anticompetitive effects. Rather, the size of a reverse payment could serve as a “surrogate for the patent’s weakness” and as a “strong indicator” of the brand’s market power (that is, its ability to manipulate the price of an item in the market and/or erect barriers against competition).⁵⁰ The Supreme Court’s assertion

⁴³ *Actavis*, 570 U.S. at 145.

⁴⁴ *Id.*

⁴⁵ *Id.* at 145–46 (quoting *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012), *rev’d and remanded sub nom.* *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013)).

⁴⁶ *Id.* at 146 (quoting *Watson Pharms., Inc.*, 677 F.3d at 1307).

⁴⁷ *Id.*; see also Feldman, *Patent Exceptionalism*, *supra* note 32.

⁴⁸ *Actavis*, 570 U.S. at 147.

⁴⁹ *Id.* at 159.

⁵⁰ *Id.* at 158.

that pay-for-delay settlements can constitute antitrust violations therefore cracked open the door to future allegations.

On the other hand, the rule of reason test places such a high burden on the plaintiff that its invocation has usually signaled defeat.⁵¹ Although the rule of reason test is the normal standard for evaluating behavior under the Sherman Antitrust Act, it is frequently described as complex and burdensome.⁵² It is a meandering test that cannot even be described in a simple sentence. The formulation arises from the 1918 *Board of Trade of City of Chicago v. U.S.* case:

The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its conditions before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.⁵³

Application of the rule of reason test in practice is no less nebulous than its formulation, despite the fact that courts add numbers to each of the various steps. The Supreme Court itself has described the rule of reason test as requiring an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries.⁵⁴ In short, the test is notoriously convoluted, making cases that turn on the rule of reason test expensive to litigate and difficult to win.⁵⁵

In what could be read as a subtle acknowledgement of the difficulty for plaintiffs trying to establish a case under the rule of reason, the majority in *Actavis*

⁵¹ See Feldman, *Defensive Leveraging*, *supra* note 37, at 2107–08

(citing *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 34 (1984) (O'Connor, J., concurring) (comparing rule of reason to the peculiar form of *per se* rule applied in tying cases and describing both as requiring extensive and time-consuming economic analysis)); *Continental TV, Inc., v. GTE Sylvania*, 433 U.S. 36, 50 (1977) (describing rule of reason trials as complex and burdensome on litigants and the judicial system); *United States v. Trenton Potteries Co.*, 273 U.S. 392 (1927) (refusing to apply the rule of reason because of the practical difficulties of the minute inquiry into economic organization required); see also Robert Pitofsky, *Antitrust in the Next 100 Years*, 75 CALIF. L. REV. 817, 830 (1987).

⁵² See *Continental TV, Inc.*, 433 U.S. at 50 n.16; see also Herbert Hovenkamp, *The Rule of Reason*, 70 FLA. L. REV. 81, 87–92 (2018) (describing how the rule of reason is important for deciding antitrust cases due to the sparse language of the Sherman Act).

⁵³ *Board of Trade v. U.S.*, 246 U.S. 231, 238 (1918).

⁵⁴ See *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958).

⁵⁵ PHILLIP E. AREEDA, *ANTITRUST LAW* § 1502, 371–72 (1986), *reprinted in* FELDMAN & FRONDORF, *supra* note 5, at 45.

noted that the lower courts could “structure” the rule of reason in pay-for-delay cases. The dissent, which would have made pay-for-delay presumptively anticompetitive, referred to the “unruliness” of the rule of reason.⁵⁶

D. After Actavis

Given these measures to facilitate antitrust action, has *Actavis* indeed ushered in the end of pay-for-delay? Some seem to think so.⁵⁷ In a 2017 speech, then-acting FTC Chair Maureen K. Ohlhausen remarked that “perhaps firms are starting to get the message that fending off legitimate patent challenges by paying generics to delay entry will not be tolerated by either the enforcement agencies or the courts.”⁵⁸ But the reality has not been so rosy. Although the FTC reported a decline in anticompetitive pay-for-delay agreements between 2013 and 2016, its optimism stems largely from its inability to categorize most settlements between brand-name and generic companies.⁵⁹ Not only did the total number of settlements more than double over the same seven-year period; the number of settlements in which a generic delayed entry but the FTC could not find evidence of payment on the face of the agreement increased as well—a grouping that one scholarly work dubbed the unclassifiable “category X.”⁶⁰

The FTC reports provide other troubling indicators of potentially anticompetitive behaviors. For example, across the fourteen years in which the FTC has reported settlements between brand and generic drug companies, there have been more than 1,500 settlements. The vast majority of those involve an agreement by the generic to stay out of the market for a period of time. In the most recent report year, 2017, 80 percent of the settlements contained some form of acceleration clause,⁶¹ a type of agreement that scholars have described as anticompetitive.⁶² Acceleration clauses permit the generic company to enter before the agreed-upon date if an authorized generic is released by the brand-name manufacturer or another generic enters the market. In so doing, however, acceleration clauses make it less likely that any other generic will try to enter. If they do, their entry would trigger

⁵⁶ *FTC v. Actavis, Inc.*, 570 U.S. 136, 160 (2013).

⁵⁷ See, e.g., Lauren Krickl & Matthew Avery, *Roberts Was Wrong: Increased Scrutiny After FTC v. Actavis Has Accelerated Generic Competition*, 19 VA. J.L. & TECH. 510, 547 (2015).

⁵⁸ MAUREEN K. OHLHAUSEN, ACTING CHAIRMAN, FED. TRADE COMM’N, 2017 ABA FALL FORUM: THE FIRST WEALTH IS HEALTH: PROTECTING COMPETITION IN HEALTHCARE MARKETS 3 (Nov. 16, 2017), https://www.ftc.gov/system/files/documents/public_statements/1275573/mko_fall_forum_2017.pdf.

⁵⁹ Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 260–65;

⁶⁰ *Id.* at 261, 264.

⁶¹ FED. TRADE COMM’N, OVERVIEW OF AGREEMENTS FILED IN FY 2017 4 (2020), https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/mma_report_fy2017.pdf [hereinafter *FTC, FY 2017 REPORT*].

⁶² See Carrier, *supra* note 35 (describing acceleration clauses as a form of poison pill); Karas et al., *supra* note 10 (explaining that acceleration clauses give brand companies extra “bang for the buck”).

immediate competition from the generic that settled. Thus, acceleration clauses allow a brand-name company to get “additional bang for the buck,” settling with one generic company while discouraging others from entering.⁶³ In a similarly troubling vein, 90 percent of settlements involved the generic company receiving rights to patents not subject to any litigation by the parties.⁶⁴ The transfer of rights such as these, particularly given that they were not at issue in the Paragraph IV litigation, could easily signal a transfer of value or provide market sharing. In short, rather than heralding an end to pay-for-delay, these statistics suggest that pharmaceutical companies have moved away from straight cash payments in the wake of *Actavis* and towards more complex transactions.⁶⁵

This process may be due in part to the way that lower courts have chosen to apply *Actavis*. Following the *Actavis* language, courts generally require plaintiffs to prove both that the generic company has agreed not to use the patented innovation (the drug) and that the generic company is receiving an unexplained payment from the brand-name company.⁶⁶ To prove the existence of an unexplained payment, one must subtract from the amount in compensation the generic receives from the brand-name company a) the amount the brand-name company saves in litigation costs by pursuing a settlement and b) the amount the generic transfers to the brand-name company in goods, services, or other benefits (called “linked transactions”).⁶⁷ A positive net payment is considered an unexplained payment that can be interpreted as a pay-for-delay deal.⁶⁸

Given that one must calculate exact value amounts in order to prove the existence of an unexplained payment, companies are incentivized to enter into settlements that obscure the amount transferred and the direction of the transfer. Instead of offering cash, for example, brand-name companies may overpay generic companies for marketing services the generic companies are not actually equipped to tender.⁶⁹ Solvay’s agreement that Actavis would market AndroGel to urologists in exchange for nine years of payment is one example of this type of agreement. They may allow generic companies to make or sell other drugs from the brand-name company’s portfolio.⁷⁰ Or they may promise generic companies they will not introduce an authorized generic—a generic released by the brand-name company alongside its branded drug—to compete with the non-branded generic during the generic company’s promised 180-day exclusivity period.⁷¹ Because of these obfuscations, lower courts have struggled to understand and measure the nature of

⁶³ Karas et al., *supra* note 10.

⁶⁴ FTC, FY 2017 REPORT, *supra* note 61, at 3–4.

⁶⁵ See generally Feldman & Misra, *Fatal Attraction*, *supra* note 10; Karas et al., *supra* note 10.

⁶⁶ See Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16, 18 (2013).

⁶⁷ *Id.*

⁶⁸ *Id.*; see also Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 260.

⁶⁹ See Hemphill, *Aggregate Approach*, *supra* note 11, at 663–65.

⁷⁰ See *K-Dur*, 686 F.3d at 205–06; Hemphill, *Aggregate Approach*, *supra* note 11, at 666.

⁷¹ FELDMAN & FRONDORF, *supra* note 5, at 59–64.

pay-for-delay settlements, thereby limiting the change *Actavis* was primed to deliver.

III. PRICING PAY-FOR-DELAY

In its 2010 study, the FTC found that agreements with compensation from the brand to the generic in exchange for delaying entry, on average, prohibited generic entry for nearly 17 months longer than agreements without such payments.⁷² In addition, the FTC estimated that pay-for-delay deals would cost American consumers \$3.5 billion per year over the next 10 years.⁷³ This \$3.5 billion figure has been widely cited by academics⁷⁴ and political actors on both sides of the aisle.⁷⁵ While the figure has drawn important attention to a process through which drugmakers “game” the system, the problem of pay-for-delay may be much greater than previously imagined.

There are two reasons for our speculation that the FTC’s cost figure drastically underestimates the true cost of these settlements. First, the FTC study and its findings are more than a decade old and thus fail to account for newer forms of pay-for-delay settlements growing out of the *Actavis* decision.⁷⁶ Even before the *Actavis* ruling, pay-for-delay agreements had been evolving with increasing complexity. This evolution had already produced convoluted agreements that substituted cash for unrelated services and features, making it more difficult to identify the exchange of value between brand and generic and therefore more challenging for plaintiffs to establish the basic elements of the antitrust case.⁷⁷ Second, the FTC’s methodology uses broad estimates of some of the key statistical figures it employs. These include: consumer savings resulting from generic competition; the likelihood that a settlement that delays entry in return for compensation is reached; the length of entry delay from such settlements; and the combined sales volume of drugs for which settlements are likely. We believe it is possible to achieve a greater level of granularity and precision by examining specific settlements and specific drugs.

The empirical approach pursued in this Article addresses both of these limitations of the FTC report. The Article utilizes two primary datasets: one

⁷² FTC, PAY-FOR-DELAY, *supra* note 9, at 2.

⁷³ *Id.*

⁷⁴ See, e.g., Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 257 (2019); Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 500, 512 (2016); Daryl Lim, *Patent Misuse and Antitrust: Rebirth or False Dawn?*, 20 MICH. TELECOMM. & TECH. L. REV. 299, 338 (2014).

⁷⁵ See, e.g., Press Release, U.S. Senator Chuck Grassley (R-Iowa), Grassley, Klobuchar Urge Federal Trade Commission To Examine Whether “Pay For Delay” Tactics Are Keeping Cheaper Biosimilar Medicines Off The Market (Jun. 22, 2018), <https://www.grassley.senate.gov/news/news-releases/grassley-klobuchar-urge-federal-trade-commission-examine-whether-pay-delay>; Press Release, Gov. Gavin Newsom (Calif.), Governor Gavin Newsom Signs Legislation Banning “Pay for Delay” to Fight Runaway Prescription Drug Costs (Oct. 7, 2019), <https://www.gov.ca.gov/2019/10/07/governor-gavin-newsom-signs-legislation-banning-pay-for-delay-to-fight-runaway-prescription-drug-costs/>.

⁷⁶ See generally FELDMAN & FRONDORF, *supra* note 5.

⁷⁷ See generally Feldman & Misra, *Fatal Attraction*, *supra* note 10.

containing prescription drug claims from one million Medicare Part D beneficiaries between 2006 and 2018,⁷⁸ and another consisting of twelve pay-for-delay settlements that occurred between 2006 and 2017. For each of the settlements analyzed, the analysis first determined the period of delay. The analysis then used the post-delay generic-to-brand price ratio to determine what patients would have paid for generics during the delay interval. This revealed the cost incurred by consumers as a result of the improper extension of the brand’s monopoly. The resulting cost figures were averaged to derive an average cost per settlement. This was extrapolated to the entire Medicare Part D program and U.S. population, and then to the number of unique brand drugs with pay-for-delay settlements during the observed time period.

The remainder of this section details the process we developed to analyze the cost of pay-for-delay, beginning with the parameters used to select the appropriate settlement agreements. Based on the following methodologies, the actual cost of pay-for-delay to consumers far surpasses what the FTC report would suggest—by up to ten-fold annually.

A. Data Collection

The analysis required compiling a dataset of existing pay-for-delay settlement agreements. The process began by defining a pay-for-delay settlement to be any agreement that contained either explicit or potential compensation from a brand manufacturer to a generic manufacturer, and a restriction on the generic manufacturer’s ability to market its product in competition with the branded product. Cash payments were obviously included in this definition, but so were less “tangible” exchanges of value such as no-authorized-generic clauses and acceleration clauses.⁷⁹ The settlement identification and collection process faced

⁷⁸ Each claim referenced a single prescription drug event—that is, a single dispensing of a drug at a pharmacy—and contained information on the drug purchased, the amount paid by the patient, and the price paid for the drug at the point of sale. Our methodology required that our Medicare Part D claims data extend past the pay-for-delay dataset. In order to accurately assess the cost amount of a pay-for-delay deal, we needed both the sales volume of the brand during the delay period in addition to the sales volume of the generic and brand both following the delay. Because our Part D claims dataset extended only through 2018, we limited our pay-for-delay dataset to include drugs whose generic entry was delayed until 2017 at the latest (including 2018 pay-for-delay cases, in other words, would have required 2019 claims data).

⁷⁹ Treatment of acceleration clauses in federal courts has been varied. In *Actos*, the court rejected the indirect purchaser plaintiffs’ argument that the acceleration clauses in the settlement at hand were anticompetitive, reasoning that if no other generic entered the market before the settlement entry date, the effect of the clauses would be neutral, and if another generic manufacturer did enter before the settlement entry date the effect would be “indisputably procompetitive.” In re *Actos* End Payor Antitrust Litig., No. 13-CV-9244 (RA), 2015 U.S. Dist. LEXIS 127748, at *46-47 (S.D.N.Y. Sep. 22, 2015). The court in *Loestrin*, however, found that acceleration clauses could plausibly be alleged as one component of an unlawful reverse payment. The court explained that “absent the acceleration clause, generics would have entered earlier and that the clause deterred later filers, providing Watson with substantial value” in the form of its forfeited exclusivity. In re *Loestrin* 24 FE Antitrust Litig., 433 F. Supp.3d 274, 321 (D.R.I. 2019). Because courts have gone in different directions on this issue, we chose to exclude, from our dataset, cases like *Actos* in which a court ruled that an acceleration provision did not constitute pay-for-delay and chose to include cases in

two significant challenges: the lack of a centralized pay-for-delay database⁸⁰ and the lack of a widely accepted definition for a pay-for-delay deal.⁸¹ Given the lack of a centralized repository of pay-for-delay deals, the analysis required searching for settlements from a wide array of sources including company press releases, legal news services,⁸² public health non-profit reports,⁸³ academic papers,⁸⁴ and high-profile litigation involving regulatory agencies.⁸⁵ This foray generated an initial list of pay-for-delay cases from which to research the details of the settlements and the related drugs. To do this, we relied on two primary sources: A searchable FDA database of FDA-approved drugs⁸⁶ and court filings of patent and antitrust litigation. The FDA database provided information on a drug's active ingredient, marketing status, date of filing, and approval dates. Court filings were used to confirm those details and provided additional details relevant to the settlement as listed factually by the parties, such as information on active and expired patents, regulatory exclusivities, the start and end of the 30-month stay period, and the date the settling generic was allowed to enter the market. These documents were also useful in assessing the anticompetitive nature of the settlement and tracking the alleged exchange of value between brand and generic.

The settlement identification and collection process yielded a list of 40 distinct brand drugs associated with pay-for-delay settlements. The fact that the Medicare Part D claims dataset providing the basis for the empirical analysis ranged from 2006 to 2018 required narrowing the settlement selections to those made during this time range⁸⁷ and encompassing drugs covered by Medicare Part D. Applying

which a court did not explicitly rule against a claim that an acceleration clause constituted a reverse payment.

⁸⁰ The FTC's yearly pay-for-delay reports aggregate data and do not release information on the specific companies and drugs that engage in pay-for-delay settlements. *See, e.g.*, FTC, FY 2017 REPORT, *supra* note 61.

⁸¹ *See generally* FELDMAN & FRONDORF, *supra* note 5; Feldman & Misra, *Fatal Attraction*, *supra* note 10.

⁸² Legal news services such as Law360 report on the developments of major pay-for-delay litigation in both federal and state courts.

⁸³ *See e.g.*, CMTY CATALYST & U.S. PIRG, TOP TWENTY PAY-FOR-DELAY DRUGS: HOW DRUG INDUSTRY PAYOFFS DELAY GENERICS, INFLATE PRICES, AND HURT CONSUMERS (2013), <https://www.communitycatalyst.org/doc-store/publications/top-20-pay-for-delay-drugs.pdf>.

⁸⁴ *See e.g.*, Hemphill, *Aggregate Approach*, *supra* note 11; Keith M. Drake, Martha A. Starr & Thomas McGuire, *Do "Reverse Payment" Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay?* (Nat'l Bureau of Econ. Rsch., Working Paper No. 20292, 2015).

⁸⁵ *See e.g.*, Federal Trade Comm'n, Press Release, FTC Again Charges Endo and Impax with Illegally Preventing Competition in U.S. Market for Oxymorphone ER (Jan. 25, 2021), <https://www.ftc.gov/news-events/press-releases/2021/01/ftc-again-charges-endo-impax-illegally-preventing-competition-us>.

⁸⁶ *Drugs@FDA: FDA-Approved Drugs*, FDA, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm> (last visited May 5, 2021).

⁸⁷ Although our Part D sample data starts in 2006, two of the selected drugs (Effexor XR and Provigil) have 30-month stays ending in 2005. The decision to include these reflected our need to build as thorough of a dataset as possible. The ramification of this decision is that the delay interval

these constraints narrowed the initial list of 40 drugs to a final dataset of 12, presented in Table 1.

Table 1. Selected 12 drugs associated with pay-for-delay settlements⁸⁸

Name	NDA ⁸⁹ Number	30-Month Stay End	Average ANDA Method ⁹⁰	Latest Date of Primary Patent or Regulator y Exclusivity ⁹¹	Allowed Generic Entry Following Pay-For- Delay Settlements ⁹²
Aggrenox	20884	2009-11-30	2010-11-30	2017-01-18	2015-07-01
Asacol HD	21830	2014-05-08	2013-07-30	2013-07-30	2016-08-01

is reduced, producing a slight underestimation of the cost. Consequently, our findings are conservative.

⁸⁸ Although Lipitor was included in our original set of drugs, we removed it from our dataset upon further investigation after deeming the cost of the Lipitor pay-for-delay deal to be an outlier. Removing Lipitor lowers our estimated cost of pay-for-delay deals on society, making the empirical findings more conservative.

⁸⁹ NDA is a New Drug Application, submitted to the FDA for all new therapeutic products. Listed in this column are the application numbers associated with each drug’s NDA.

⁹⁰ We developed the average ANDA method because, for three drugs—Aggrenox, Glumetza and Namenda—the allowed generic entry date precedes the latest date of primary patent or regulatory exclusivity protection. Nevertheless, generic versions of each of the three drugs were delayed by pay-for-delay settlements. *See* text accompanying notes 125–129 for a description of the patent settlements that delayed generic entry for each of the three drugs. In order to measure the cost of delayed generic versions of these three drugs, we adjusted our methodology to calculate the beginning of the generic delay period using the first ANDA filing for that drug, plus a standard length of time averaged from the other drugs in our dataset—a method we term the “Average ANDA Method.” Specifically, for these three drugs we used a date equal to 46 months after the first ANDA for each drug was filed—46 months being the average length of time between the first ANDA filing and the latest patent or exclusivity expiration date for the other nine drugs in the dataset. The “Average ANDA Method” pertains only to Aggrenox, Glumetza and Namenda, and only these three drugs, therefore, have a “Average ANDA Method” date that differs from its Latest Date of Primary Patent or Regulatory Exclusivity date. For the other nine drugs, the date in the “Average ANDA Method” column mirrors the date in the “Latest Date of Primary Patent or Regulatory Exclusivity” to indicate that the Average ANDA Method was not applied to these drugs.

⁹⁴ The Latest Date of Primary Patent or Regulatory Exclusivity reflects the later of: The expiration date of the primary patent (i.e., composition patent) protecting the drug and the expiration of any FDA-granted exclusivities protecting the drug.

⁹² This is the date following a pay-for-delay settlement at which a generic could launch its product. Quite frequently, this date coincides with the actual date at which the generic launches its new product; however, the two dates do not necessarily have to be the same. For example, the allowed generic entry date for the drug Namenda following pay-for-delay agreements was July 11, 2015. However, the first generic Namenda launched its product three days later than this on July 14, 2015. In this scenario, we elected to use the earlier date to more conservatively represent the impact of pay-for-delay on generic entry.

Effexor XR	20699	2005-09-24	2008-06-13	2008-06-13	2010-07-01
Glumetza	21748	2012-05-06	2013-05-27	2016-09-19	2016-02-01
Intuniv	22037	2012-10-05	2012-09-02	2012-09-02	2014-12-01
Lidoderm	20612	2012-07-15	2012-05-02	2012-05-02	2013-09-15
Namenda	21487	2010-04-01	2011-08-01	2015-10-11	2015-07-11
Nuvigil	21875	2012-06-02	2010-06-15	2010-06-15	2016-06-01
Opana ER	21610	2010-07-25	2009-06-22	2009-06-22	2013-01-01
Provigil	20717	2005-09-28	2007-07-23	2007-07-23	2012-04-06
Seroquel XR	22047	2011-04-01	2013-06-02	2013-06-02	2016-11-01
Zetia ⁹³	21445	2009-09-22	2011-12-05	2011-12-05	2016-12-12

Using Asacol HD as an example, the table can be read as follows. The 30-month stay on Asacol HD, which initiated automatically after a paragraph IV certification was filed,⁹⁴ ended on May 8, 2014. The drug's last regulatory exclusivity or primary patent expired on July 30, 2013, but pay-for-delay settlements prevented Asacol HD generics from entering until August 1, 2016. Because the expiration of primary patents and regulatory exclusivities preceded the allowed generic entry, we did not need to employ the average ANDA method for Asacol HD.⁹⁵ The delay of nearly three years (2013-2016) is used to calculate the cost to Asacol HD consumers caused by the pay-for-delay settlement.

⁹³ A reissued patent, U.S. Patent No. RE37,721 ('721 patent), with methods of use and composition claims (i.e., a primary patent) for ezetimibe, Zetia's active ingredient, was set to expire in 2017. However, a district court was poised to strike down the portions of the '721 patent, including the ezetimibe claims, when Merck, the Zetia manufacturer, settled with first-filer Glenmark. *See In re Zetia (Ezetimibe) Antitrust Litig.*, No. CV 2:18-MD-2836, 2019 WL 1397228, at *7 (E.D. Va. Feb. 6, 2019), *report and recommendation adopted as modified*, 400 F. Supp. 3d 418 (E.D. Va. 2019) ("[o]n April 19, 2010, the district court granted Glenmark's motion for summary judgment on improper reissue. . . . The functional result of this partial ruling would have been invalidation of claims 10-13 in the '721 patent, which claimed ezetimibe expressly and had been added in reissue."). Consequently, we considered the latest expiration of regulatory exclusivities for Zetia. Zetia's New Chemical Entity exclusivity expired in 2008, but we more conservatively elected to include the New Patient Population exclusivity that expired three years later, on December 5, 2011—even though a generic entrant is able to circumvent a New Patient Population exclusivity by excluding the treatment of that population from its label. *See RINKU PATEL, U.S. FOOD & DRUG ADMIN., EXCLUSIVITY—WHICH ONE IS FOR ME?* 15–16 (2019); Bryan Walsh, *Skinny Labeling: A Pathway for Timely Generic Drug Competition*, COMMONWEALTH FUND (Oct. 19, 2021), <https://www.commonwealthfund.org/blog/2021/skinny-labeling-pathway-timely-generic-drug-competition> (explaining skinny labeling).

⁹⁴ *See* 21 U.S.C. § 355(c) (3)(C) (outlining the procedure of paragraph IV certifications and the 30-month stay).

⁹⁵ *See supra* note 90 (explaining the average ANDA method and its applicability).

To better characterize the collected data, the next section describes the settlements that delayed generic versions of two drugs in our dataset—Provigil and Intuniv—before outlining the methodologies used to enumerate the cumulative cost of pay-for-delay.

B. Case Studies

We have included a sample of two cases: Provigil, a narcolepsy drug manufactured by Cephalon, and Intuniv, an ADHD treatment manufactured by Shire Pharmaceuticals. These are intended to provide examples of the types of agreements and issues involved in pay-for-delay settlements.

1. Provigil

In December 1998, the FDA approved Cephalon’s new drug application for Provigil, a blockbuster drug used to treat narcolepsy and other sleep disorders.⁹⁶ Cephalon’s patent for a specific formulation of modafinil, the active pharmaceutical ingredient in Provigil, was originally set to expire on October 6, 2014. Cephalon ultimately obtained an additional six months of exclusivity for testing the drug in pediatric patients, extending its protection to April 6, 2015.⁹⁷

Teva, Ranbaxy, Mylan, and Barr each filed Paragraph IV abbreviated new drug applications on December 24, 2002, allowing them to share the 180-day exclusivity as first-filers.⁹⁸ Following the Hatch-Waxman dance, the brand company, Cephalon, initiated a patent infringement suit action against the generic manufacturers shortly thereafter. During litigation, the generic manufacturers alleged that Cephalon had made material misrepresentations and omissions to the U.S. Patent & Trademark Office (“USPTO”) in obtaining its patent.⁹⁹ With motions for summary judgment pending, the parties settled the action between December 2005 and February 2006.

Cephalon entered into separate settlement agreements with each generic manufacturer, the terms of which were extensive and unique to each.¹⁰⁰ However, each of the agreements included a provision in which Cephalon granted the generic manufacturer a license to market generic modafinil on April 6, 2012, three years before the brand-name company’s patent protection for Provigil was set to expire.¹⁰¹ The agreements also included an acceleration clause, providing that the

⁹⁶ *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 406-07 (E.D. Pa. 2015).

⁹⁷ *Id.* at 407.

⁹⁸ *Id.* The value of the 180-day exclusivity period awarded to the first ANDA filer, during which time no other generic company may market its product, means that it is not uncommon for multiple generic companies to file an ANDA as soon as a brand company’s 4-year new chemical entity exclusivity period is set to expire. In fact, the FDA has issued guidance clarifying that multiple ANDAs can be awarded the first-filer exclusivity period if, as is the case here, they are submitted on the same day. *See* U.S. FOOD & DRUG ADMIN, *supra* note 26.

⁹⁹ *King Drug Co. of Florence*, 88 F. Supp. 3d at 407.

¹⁰⁰ *See id.* at 407–410 (detailing each of the settlements).

¹⁰¹ *Id.* at 407.

generic manufacturers could enter the market on an earlier date if certain conditions occurred. Most notably, each of the agreements provided that Cephalon would pay the generic manufacturers, or their associates, a total of approximately \$300 million.¹⁰²

The FTC filed a complaint against Cephalon in 2008, alleging that it had engaged in anticompetitive conduct by making cash payments to its generic competitors to abandon their patent challenges and refrain from marketing their generic drug products for six years. Following the Supreme Court's 2013 ruling in *Actavis*, and on the eve of trial, the FTC and Teva (which had acquired Cephalon in 2012) reached a settlement. Under the terms of the settlement, Teva would make \$1.2 billion available to compensate purchasers who had overpaid as a result of Cephalon's unlawful conduct.¹⁰³ The colossal penalty undoubtedly forced branded drug manufacturers to take notice. In short, Cephalon's pay-for-delay deals served as a cautionary tale for brand manufacturers seeking to extend their market reign by doling out cash payments to generic competitors.

2. Intuniv

Although *Actavis* effectively prohibited cash payments in pay-for-delay deals, pharmaceutical firms have employed more inventive means of transferring value in order to entice generics to delay entry. Some of these techniques were on display as Shire settled with potential generic entrants competing with its ADHD treatment, Intuniv. Readers should note that although pharmaceutical company Actavis was involved in the case involving the drug Intuniv, this is not the same as the Supreme Court's *Actavis* decision, which involved the testosterone drug AndroGel.

In September 2009, the FDA approved Shire's new drug application for Intuniv. Supporting Shire's monopoly, however, were only three "secondary" patents—as opposed to patents on the chemical formulation. Such secondary patents are more likely to be invalidated in Paragraph IV litigation, when the litigation is taken to conclusion.¹⁰⁴ Within months, Actavis, followed by TWi, Anchen and several others, filed abbreviated new drug applications with Paragraph IV certifications, alleging that each of Shire's three Intuniv patents were invalid or not infringed by the generics. Subsequently, Shire sued each abbreviated new drug application filer,

¹⁰² *Id.*

¹⁰³ See Fed. Trade Comm'n v. Cephalon, Inc., No. 2:08-CV-2141, 2015 WL 4931442, at *4 (E.D. Pa. June 17, 2015) (ordering Cephalon to pay \$1.2 billion and outlining a disbursement of the settlement funds).

¹⁰⁴ Picone v. Shire PLC, No. 16-CV-12396-ADB, 2017 U.S. Dist. LEXIS 178150, at *8 (D. Mass. Oct. 20, 2017). One patent covered Intuniv's "method of use," whereas the other two protected the sustained release coating. These, and other secondary patents, are invalidated more than two-thirds of the time. See C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013) (showing that 89% of patents in settled litigation disputes are secondary patents, which courts usually (68% of the time) find invalid or not infringed), reprinted in Carrier, *supra* note 35, at 46–47.

triggering the 30-month stay of FDA approval for any Intuniv generic competitor.¹⁰⁵

Two crucial settlement agreements enabled Shire to insulate its Intuniv monopoly from generic competition for more than two additional years beyond the stay period. First, in September 2012, Shire settled its patent litigation with TWi and Anchen, announcing that Shire granted permission to TWi and Anchen to produce an authorized generic to compete with Actavis—the first to file a generic application—during their 180-day exclusivity period.¹⁰⁶ According to the agreement, TWi and Anchen would pay Shire a royalty for any authorized generic sales, with the right to launch its own generic in 2016 (or earlier, if Shire so chose).¹⁰⁷ Besides neutralizing potential generic competitors, the settlements with TWi and Anchen provided Shire with significant leverage over Actavis, the first generic filer. The terms of these settlements implied that unless Actavis agreed to settle its patent litigation with Shire, Shire would ensure that an authorized generic joined Actavis’ generic on the market during its 180-day exclusivity period, crippling Actavis’ potential profits.¹⁰⁸

Consequently, although Actavis was well-positioned to prevail in its patent infringement suit, Actavis and Shire settled before a court decision in April 2013.¹⁰⁹ The settlement allegedly contained a Shire promise to not launch or license an authorized generic during Actavis’ first-filer period (also dubbed a “no-authorized-generics” clause).¹¹⁰ In return, Actavis delayed its generic entry until December 2014 and agreed to pay Shire 25% of gross profits on future generic Intuniv sales.¹¹¹ Despite the distraction posed by Actavis’ “unreasonably low” royalty payments back to Shire,¹¹² the principal transfer of value in this agreement was Shire’s no-authorized-generics clause. The guarantee of a competition-free exclusivity period compensated Actavis for delaying the launch of its generic for an additional 20

¹⁰⁵ *Picone*, U.S. Dist. LEXIS 178150 at *7.

¹⁰⁶ *Id.* at *8–9.

¹⁰⁷ *Id.* at *9.

¹⁰⁸ See FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACTS 28 (2011) [hereinafter FTC, AG REPORT] (finding that authorized generic competition can cost a generic first-filer up to 45% of its revenue during the exclusivity period); see also C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch–Waxman Act*, 77 ANTITRUST L.J. 947, 953 (2011) (noting that, in many cases, the exclusivity period provides the majority of revenue earned in a generic drug’s lifetime).

¹⁰⁹ *Picone*, U.S. Dist. LEXIS 178150 at *10.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* Other courts have failed to appreciate how partial royalty payments from the generic to the brand can function as transfers of value from the brand to the generic—in other words, a reverse payment. See, e.g., *Actos*, 2015 U.S. Dist. LEXIS 127748 at *17 (finding that a 75% royalty paid by a generic company to a brand for a license should not trigger pay-for-delay scrutiny under *Actavis*, despite the fact that the 25% the generic kept did constitute a payment for delaying entry).

months.¹¹³ Shire, thus, successfully issued payment to keep Intuniv generics longer off the market—not cash, but value, nonetheless.

Indirect purchasers of Intuniv sued Shire and Actavis, alleging violations of federal and state antitrust laws, and the defendants moved to dismiss the operative class action complaint. As to the pay-for-delay claims, the plaintiffs argued that the no-authorized-generics clause¹¹⁴ and the low royalty rates negotiated with TWi, Anchen, and Actavis represented unlawful reverse payments under *Actavis*. The court agreed, finding that a no-authorized-generics agreement may constitute an illegal reverse payment within the meaning of *Actavis*. Given that finding, the court declined to address whether a below-market royalty rate alone might constitute an impermissible reverse payment. The court nevertheless acknowledged that it did not interpret *Actavis* to “completely insulate” a below-market royalty rate when paired with a plausibly alleged no-authorized-generics clause.¹¹⁵ The court found that the plaintiffs had adequately alleged an unlawful reverse payment settlement agreement and denied the motion to dismiss those claims.¹¹⁶ Thus, the case illustrates the expanding set of forms brand companies employ to entice generics’ delay.

The stories of Provigil and Intuniv are but a sampling of the lengths to which branded drug manufacturers will go to protect their golden geese, adapting quickly to dodge the potentially devastating effects that *Actavis*, if properly applied, could pose for them.

Having presented in greater depth some of the settlements that produce generic delay, the Article turns now to the various methodologies we leveraged to evaluate what such agreements cost consumers.

C. Methodology

There is no simple, agreed-upon method of measuring the components of a pay-for-delay settlement or its impact. In developing a methodological approach, we sought to be as fair and inclusive as possible. Thus, we decided to go to the extraordinary lengths of developing six distinct ways of calculating the cost of pay-for-delay deals.

The first step in this calculation was to determine the start and end dates of the delay period to establish how long generic entrance was delayed. We chose two

¹¹³ *Picone*, U.S. Dist. LEXIS 178150 at *11. Actavis’ ANDA was approved in October 2012, immediately following the expiration of the 30-month stay. Ultimately, 26 months passed between this date and the December 2014 launch of Actavis’ generic. Additionally, the no-AG clause preserved higher prices for another 180 days, until full generic competition commenced in July 2015.

¹¹⁴ It should be noted that although the plaintiffs in *Picone* alleged that Shire’s settlement with Actavis included a Shire promise to not launch its AG during Actavis’ 180-day exclusivity period, the manufacturer defendants contend that the settlement agreement did not contain such a term. Plaintiffs allege that there was nevertheless a “tacit no-AG agreement.” *Id.* at *29.

¹¹⁵ *Id.* at *35-36.

¹¹⁶ *Id.* at *41. Litigation of this action is ongoing.

distinct dates as the start of delay. The first relates to the 30-month period in which the FDA stays any approval of an abbreviated new drug application to allow the Paragraph IV litigation to proceed. The second relates to the expiration date of key protections attached to the brand-name drug. For these two groups, the length of delay was further measured in three distinct ways—individually for each settlement, averaged for the settlements in our dataset, and assumed to be 17 months—for a total of six approaches. The two approaches to determining the start date of the delay period will each be described below.

1. 30-Month Stay as the Start of the Delay

When a brand-name manufacturer challenges a generic’s Paragraph IV certification by suing the generic, the Hatch-Waxman Act dictates that the FDA will automatically impose a 30-month stay on the generic’s approval so that the parties can resolve their patent dispute.¹¹⁷ Only after the expiration of this 30-month period can the FDA confirm a generic’s final approval, and only then can a generic enter the market.¹¹⁸ Thus, the analysis assumes that any improper extension of a brand’s monopoly procured by the settlement should be measured as having started after the expiration of the stay period, given that this period represents a period of delay specified by the Hatch-Waxman litigation. Of course, the brand-name company could have simply declined to initiate the patent lawsuit and allowed the generic to enter. Nevertheless, under the Hatch-Waxman Act, the brand-name company is entitled to the 30-month stay of approval, which provided a natural point beyond which any delay should be deemed to result through the actions of the improper pay-for-delay settlement. The study also determined a delay end date, which was the date the generic was allowed to come to market.

2. Protection Cliff as the Start of the Delay

As an alternative perspective, the study also analyzed the data using a start related to expiration of patent protection, rather than from the end of the 30-month stay. There are two categories of patents: primary patents covering a drug’s active ingredient and secondary patents covering different dosage forms, formulations, and production methods associated with a drug. Primary patents offer the strongest protection on a drug while secondary patents are likely to be weaker and typically form the basis of patent litigation.¹¹⁹ New drug application holders meeting certain

¹¹⁷ 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii); *see* Ben Venue Labs., Inc. v. Novartis Pharm. Corp., 146 F. Supp. 2d 572, 579 (D.N.J. 2001) (“the purpose of the 30-month stay is...to create an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market.” (citing 130 Cong. Rec. 24,416 (1984); 130 Cong. Rec. 23,764 (1984))).

¹¹⁸ 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii). There are instances in which litigation may be pending after the 30-month stay has expired. If litigation is pending, generics can choose to enter the market “at-risk.” By choosing this date to mark the start of the delay period, we assumed that if litigation had been pending, the generic would have launched at risk.

¹¹⁹ *See* KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 8–10 (2020).

statutory requirements also are eligible for exclusivities that insulate their drug products from generic competition.¹²⁰ To determine the latest date of a drug's protection, we chose the later of: the expiration of regulatory exclusivities granted by the FDA¹²¹ (e.g., New Chemical Entity Exclusivity, Orphan Drug Exclusivity) and the expiration date of primary patents.

Three drugs in our analysis—Aggrenox, Glumetza, Namenda—required adjustments to this methodology, however, as described below. For each of these three drugs, generics postponed by pay-for-delay settlements were nevertheless allowed to enter before the date of latest primary patent or exclusivity expiration. The patent litigation for Aggrenox, for example, unlike most other drugs in our dataset, involved primary rather than secondary patents.¹²² In other words, instead of waiting for a court to determine whether a drug's primary patent was invalid or not infringed, the Aggrenox manufacturer instead paid the generic ANDA filers to stay off the market.¹²³ Aggrenox, thus, belongs in our dataset of drugs on account of its pay-for-delay settlement, but measuring the cost of its delay to society using the “latest date of protection” method required adjusting our methodology, as described below.

For Glumetza and Namenda, on the other hand, only secondary patents protected against generic entry at the time of patent settlement,¹²⁴ but significant

¹²⁰ 21 C.F.R. 314.50-316.34 (2021). See Robin Feldman, *Regulatory Property: The New IP*, 40 COLUM. J.L. & ARTS 53, 103 (2016) (listing roughly a dozen non-patent exclusivities).

¹²¹ Our analysis excluded any regulatory exclusivities, gathered from Drugs@FDA, that were granted *after* the brand company signed its first settlement. See U.S. FDA, DRUGS@FDA, *supra* note 86. To ensure the most conservative approach, we chose to include regulatory exclusivities granted for new indications and new patient populations, even though a generic drug may still enter the market if the only protections on a brand drug are exclusivities for new indications or patient populations. Specifically, the generic drug may exclude, or “carve out,” the protected indication or patient population from its drug label. This tactic, known as “skinny labeling,” can speed generic entry by several years in some cases. See Patel, *supra* note 93 at 15-16; Walsh, *supra* note 93. Consequent to our conservative approach—which accounts for the latest primary patent or exclusivity even if the latest exclusivity could be “carved out”—the latest date of primary patent or regulatory exclusivity in our analysis for two drugs, Provigil and Seroquel, is more than a year after the date of patent and exclusivity expiration referenced in their respective litigation. See *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F.Supp.3d 402, 419 (E.D. Pa. 2015) (“[i]n February 2005, a Cephalon consultant wrote that Provigil faces the certain prospect of generic competition by June 2006.”) (quotations omitted); *In re Seroquel XR (Extended Release Quetiapine Fumarate) Litig.*, No. 19-cv-8296 (CM), 2020 U.S. Dist. LEXIS 145615, at *8-9 (S.D.N.Y. Aug. 12, 2020) (“[e]ach EPP indirectly purchased, paid and/or reimbursed for some or all of the purchase price for one or more Seroquel XR and its AB-rated generic equivalent in class state(s) during the class period — from *September 29, 2011* until the anticompetitive effects of Defendants' challenged conduct cease.”) (emphasis added).

¹²² *In re Aggrenox Antitrust Litig.*, 94 F.Supp.3d 224, 236 (D.Conn 2015).

¹²³ *Id.*

¹²⁴ Because the active ingredients of Glumetza (metformin hydrochloride) & Namenda (memantine hydrochloride) had been discovered many years prior to the drugs' respective approvals, only secondary, and not primary patents, remained as protection. See *In re Glumetza Antitrust Litig.*, No. C 19-05822 WHA, 2021 WL 1817092, at *1 (N.D. Cal. May 6, 2021); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F.Supp.3d 152, 185 (S.D.N.Y. 2018). Namenda also held a pediatric exclusivity attached to its secondary patent '703, which did not exclude the ANDAs

time had elapsed between the latest expiration of any primary patents and regulatory exclusivities and the first generic ANDA filing for each drug, meaning that to begin with the latest primary patent or exclusivity expiration for each of these drugs would overstate the amount of time generic versions of Glumetza or Namenda were kept off the market as a result of pay-for-delay settlements.

For Aggrenox, Glumetza and Namenda we opted for a more conservative approach that derived the beginning of the generic delay from the first ANDA filing for that drug, plus a standard length of delay averaged from the other drugs in our dataset. Specifically, rather than the latest date of primary patent or exclusivity expiration as the start of the delay period, for these three drugs we used a date 46 months after the first ANDA for each drug was filed—equal to the average length of time between the first ANDA filing and the latest patent or exclusivity expiration date for the other nine drugs in the dataset. That is, for Aggrenox, Glumetza, Namenda, our “latest date of protection” method applies the average duration between ANDA filing and latest expiration date to approximate the effect of pay-for-delay settlements on the entry of generics for those three drugs.

Thus, with these three exceptions, the “protection cliff as start of delay” methodology considers the delay of generic entry to begin with the expiration of these primary patents and exclusivities. The expiration dates of secondary patents—including patents protecting dosage forms, formulations and methods of use—were not considered in determining the latest protection date of a drug because secondary patents on brand drugs are usually found invalid or not infringed by courts.¹²⁵ Nevertheless, to account for the fact that secondary brand patents are sometimes upheld in court as valid or infringed by a prospective generic, we counted only 73% of all costs incurred during the delays calculated from the latest date of primary patent or exclusivity protection. The 73% figure reflects the FTC’s finding that “generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute.”¹²⁶ As with the 30-month stay analysis, this methodology used the earliest date a generic was allowed to come to market as the end of the delay period.

With the delay start and end dates established, the study then calculated the cost incurred by purchasers due to these settlements. There were two primary measures of cost: 1) a drug’s list price less rebate information,¹²⁷ a figure borne by all purchasers including taxpayers, private insurers, the government, and beneficiaries;

that filed with a paragraph IV certification alleging the secondary patent was invalid or not infringed. See *Namenda*, 331 F.Supp.3d. at 191.

¹²⁵ FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* vi (2002) (“generic applicants have prevailed in 73 percent of the cases in which a court has resolved the patent dispute.”) [hereinafter *FTC PATENT STUDY*]; Hemphill & Sampat, *supra* note 104 (“[o]f the 48% of cases litigated to completion (not settlement), the branded firm...usually loses asserting secondary patents (32% wins).”).

¹²⁶ *FTC PATENT STUDY*, *supra* note 125, at vi.

¹²⁷ The list price of brand drugs was rebated with rebate percentages derived from figures found in annual Medicare Trustees Reports.

and 2) patient out-of-pocket costs borne specifically by the patient.¹²⁸ For each measure, the study calculated the generic-to-brand price ratio after delay had ended (when generic competitors had entered the market) and used this ratio to derive what the generic cost would have been during the delay period (when the brand was the only drug on the market). This figure, along with the sales volume derived from the claims dataset, was used to calculate how much more purchasers paid due to the illegitimate extension of monopoly gained through the settlement.¹²⁹ This calculation was performed for each of the twelve settlements and averaged to derive an average cost for each month during the delay interval.

The study then extrapolated this monthly average to derive the cost of all pay-for-delay settlements between 2006 and 2017¹³⁰ for both the Medicare Part D program and the U.S. population. The study performed two extrapolations: one to the population targeted and the second to all brand drugs with pay-for-delay deals to encompass the total cost. This was because the calculations were based on sample claims data of 1 million Medicare Part D beneficiaries and a dataset of twelve brand drugs with pay-for-delay deals. The study first extrapolated the monthly cost to the average Part D and U.S. populations¹³¹ between 2006–2017. Then, the study applied the result to the total number of brand-name drugs with pay-for-delay deals during this period. Given that the claims dataset was

¹²⁸ While out-of-pocket costs may refer to any amount paid by the patient regardless of insurance status, out-of-pocket costs in this paper refer solely to patient co-pays and co-insurance. Co-pay and co-insurance data came from the initial and gap coverage phases only. These two coverage phases best represent what covered beneficiaries pay to fill their prescription drugs. Coverage phases unique to Medicare Part D enrollees, such as the catastrophic coverage, were ignored so as to ensure that the extrapolation to the U.S. population was reasonable.

¹²⁹ We calculated the ratio percentage of what patients paid for the generic to what patients paid for the corresponding brand, during the post-delay period. For example, if the average amount that patients paid for the brand was \$40 and the average amount that patients paid for the generic competitor was \$10, the ratio percentage is 25%. This percentage was then used in conjunction with what patients paid for the brand during the delay period to derive what patients would have paid for the generic had generic competitors entered the market. The average ratio percentage across the 12 settlements was 49% with a minimum ratio of 17%. In other words, if a patient paid \$100 out-of-pocket for a brand drug, the average out-of-pocket cost for a generic was \$49, and it could be as low as \$17. On average, generic drugs would have saved purchasers more than 50% of the rebated brand price during the delay interval if generics had entered the market. It is also worth noting that in a few cases, the generic drug was placed on a higher tier than its brand counterpart during the post-delay period. Prior literature has documented this irrational placement of drugs. *See* Feldman, *Devil, supra* note 1. When encountering this anomalous scenario, the brand and generic co-pays and co-insurance was reversed. For example, if the amount patients paid for the generic was \$40 and the amount patients paid for the brand was \$10, the ratio percentage was inverted from 400% to 25%.

¹³⁰ One could argue that the relevant study period should encompass only settlements after the *Actavis* decision in 2013. However, the article considers the cost of pay-for-delay in general to society. More important, the article examines whether the FTC's 2010 estimate was accurate by using more granular methodology. *See supra* text accompanying notes 76–78. Thus, the period of time considered by the FTC is relevant, at least for the years in which the author had access to the data necessary for applying the more granular methodology.

¹³¹ The average Medicare Part D population between 2006-2017 is 31 million; the average US population between 2006-2017 is 312 million.

representative of the entire Part D population, performing this scaling is reasonable and statistically sound.

The study chose to examine the twelve drugs because the companies that produce these twelve drugs indisputably engaged in pay-for-delay settlements. There were other cases identified for which pay-for-delay might have occurred—and there may have been other pay-for-delay deals during the study period that have never been identified—but the study limited the analysis to those with greater certainty. With a small sample, there is always a concern regarding whether the result will be less accurate than a large sample investigation. When it is impossible to obtain the necessary sample size—as is the case with pay-for-delay agreements given that the secrecy surrounding much of the information—one can mitigate the concern by using multiple models and averaging. Thus, the study employed six different analytic models.

To extend this figure to measure the cost of all pay-for-delay settlements, the study needed to multiply it by the number of unique pay-for-delay settlements made during the twelve-year window. Obtaining this figure required accessing annually published FTC reports on agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, pharmaceutical companies are required to file certain agreements with the FTC and the Department of Justice (“DOJ”) within ten days of their execution.¹³² These reports contain limited information on the number of settlements made during the fiscal year and the nature of these settlements. The study totaled the number of settlements between 2006 and 2017 identified in the FTC’s reports as “settlements with restriction on generic entry and compensation,” which generated 276 settlements. Given that this count could have included settlements made between a single branded drug and multiple generic competitors, the study inferred that each brand drug makes agreements with approximately two generic competitors¹³³ and thus halved the 276 figure to arrive at a total of 138 distinct branded drugs with pay-for-delay settlements.¹³⁴ The study multiplied the average cost figure by this

¹³² Section 1112 of Subtitle B (“Federal Trade Commission Review”) of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. § 355 note), as amended, requires that brand-name drug manufacturers, generic drug applicants, and biosimilar biological product applicants file certain agreements with the Federal Trade Commission and the Department of Justice (the Agencies) within 10 business days of execution of the agreement. *Pharmaceutical Agreement Filings*, FEDERAL TRADE COMM’N, <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care/pharmaceutical-agreement-filings> (last visited Apr. 2, 2021).

¹³³ The FTC, FY 2016 Report reported 232 deals related to 103 brand drugs. *See* FED. TRADE COMM’N, OVERVIEW OF AGREEMENTS FILED IN FY 2016: A REPORT BY THE BUREAU OF COMPETITION 1 (2019) [hereinafter FTC, FY 2016 REPORT]. The FTC, FY 2017 Report reported 226 deals related to 114 drugs. *See* FTC, FY 2017 REPORT, *supra* note 61, at 1. These were the only reports that reported both the number of deals and the number of brand drugs.

¹³⁴ We further winnowed the 138 figure when extrapolating cost for the Medicare Part D population. This is because there are some drugs that are not covered by Medicare Part D. Weighting this figure led to 116 total settlements with distinct brand drugs for the Medicare Part D extrapolation.

number to derive the total cost of all pay-for-delay settlements made during the years 2006 and 2017 on the Medicare Part D program.

Next, the extrapolation to the U.S. population mirrored the extrapolation to the Medicare Part D program. The study multiplied the average cost figure by the 138 settlements to encompass all pay-for-delay settlements made between 2006 and 2017 and multiplied the resulting figure by the average U.S. population between 2006 and 2017.¹³⁵ There was, however, one significant modification. The claims data used to derive the average cost figure stemmed from Medicare Part D beneficiaries, the vast majority of whom qualify for Medicare by being 65 and older.¹³⁶ Given that drug consumption amongst elderly patients is significantly higher than that of the average American citizen, the study down-weighted the initial average cost figure to reflect this difference in drug utilization.¹³⁷ The study also ensured that the figures were conservative by calculating a weighted rebate average (across private insurers, Medicare, and Medicaid) for the year 2016 and confirming that this weighted rebate average was significantly lower than the Medicare Part D rebate figures that had been applied.¹³⁸

In addition to the method outlined above, calculating the cost figure such that the delay period of each settlement was taken individually, the study also utilized two other calculation methods. For one approach, the study calculated the average length of delay and applied that average to each settlement. For the final approach, the study assumed that the length of delay for each settlement was 17 months, adopting the average length of delay figure found by the FTC in its 2010 study.¹³⁹

D. Results

The results are summarized below:

¹³⁵ *Id.*

¹³⁶ The percentage of the one million patients in our Medicare Part D claims dataset over the age of 65 is 64.3%.

¹³⁷ Because drug consumption among Medicare Part D enrollees is significantly higher than that of the average American citizen, we weighted down our base cost figure by 21.8% which represents the percentage of the U.S. population that used three or more prescription drugs in the past 30 days between 2013 and 2016. NAT'L CEN. FOR HEALTH STATS., HEALTH, UNITED STATES, 2018 tbl. 38 (2019).

¹³⁸ We calculated the average Medicare Part D rebate to be 27%. Using figures from an Altarum paper (*see* CHARLES ROEHRIG, ALTARUM, THE IMPACT OF PRESCRIPTION DRUG REBATES ON HEALTH PLANS AND CONSUMERS (2018), https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf), we derived a weighted average rebate that considered all rebates among private insurers, Medicare, Medicaid, and noncovered patients (21%). Our findings are conservative because the rebates we applied on brand drug prices are larger than the weighted rebates average and thus the drug price post-rebate is lower. Drug spending was also consistent between 2006 and 2018 so we assumed that the rebates would have remained similar as well.

¹³⁹ FTC, PAY-FOR-DELAY, *supra* note 9.

Table 2. Cost of Pay-for-Delay Settlements from 2006–2017 on the Medicare Part D Program Based on List Price

Approach	Total Cost	Cost per Year
30-Month Stay with Individual Delay Length	\$162.0 billion	\$13.5 billion
Protection Cliff with Individual Delay Length	\$74.7 billion	\$6.2 billion
30-Month Stay with Average Delay Length	\$125.9 billion	\$10.5 billion
Protection Cliff with Average Delay Length	\$69.1 billion	\$5.8 billion
30-Month Stay with 17 Months of Delay	\$42.3 billion	\$3.5 billion
Protection Cliff with 17 Months of Delay	\$27.2 billion	\$2.3 billion

Table 3. Cost of Pay-for-Delay Settlements from 2006–2017 on the Medicare Part D Program Based on Out-of-Pocket Costs (Copays and Coinsurance)

Approach	Total Cost	Cost per Year
30-Month Stay with Individual Delay Length	\$18.3 billion	\$1.5 billion
Protection Cliff with Individual Delay Length	\$9.4 billion	\$782.0 million
30-Month Stay with Average Delay Length	\$14.7 billion	\$1.2 billion

Protection Cliff with Average Delay Length	\$9.2 billion	\$770.1 million
30-Month Stay with 17 Months of Delay	\$4.9 billion	\$411.2 million
Protection Cliff with 17 Months of Delay	\$3.6 billion	\$303.3 million

Table 4. Cost of Pay-for-Delay Settlements from 2006–2017 on the U.S. Population Based on List Price

Approach	Total Cost	Cost Per Year
30-Month Stay with Individual Delay Length	\$445.8 billion	\$37.1 billion
Protection Cliff with Individual Delay Length	\$205.7 billion	\$17.1 billion
30-Month Stay with Average Delay Length	\$346.6 billion	\$28.9 billion
Protection Cliff with Average Delay Length	\$190.1 billion	\$15.8 billion
30-Month Stay with 17 Months of Delay	\$116.3 billion	\$9.7 billion
Protection Cliff with 17 Months of Delay	\$74.9 billion	\$6.2 billion

Table 5. Cost of Pay-for-Delay Settlements from 2006–2017 on the U.S. Population Based on Out-of-Pocket Costs (Copays and Coinsurance)

Approach	Total Cost	Cost Per Year
30-Month Stay with Individual Delay Length	\$35.2 billion	\$2.9 billion
Protection Cliff with Individual Delay Length	\$21.9 billion	\$1.8 billion
30-Month Stay with Average Delay Length	\$26.4 billion	\$2.2 billion
Protection Cliff with Average Delay Length	\$18.8 billion	\$1.6 billion
30-Month Stay with 17 Months of Delay	\$8.8 billion	\$734.2 million
Protection Cliff with 17 Months of Delay	\$7.4 billion	\$619.3 million

The results show that between 2006 and 2017, the cost of pay-for-delay settlements on the Medicare Part D program ranged from \$2.3 billion per year to \$13.5 billion per year based on list price, and ranged from \$303 million per year to \$1.5 billion per year based on patient out-of-pocket costs. During the same time period, the cost of pay-for-delay settlements on the U.S. population ranged from \$6.2 billion to \$37.1 billion per year based on list price, and \$619 million per year to \$2.9 billion per year based on patient out-of-pocket costs.

By contrast, the FTC's estimate of the cost of these settlements was \$3.5 billion per year. If one compares the FTC's figure to the study's estimate of the annual cost of pay-for-delay settlements, it is clear that the consequences of these deals on purchasers are drastically underestimated in the older FTC report. The lower end

of the range the study calculated for the cost of these deals on the U.S. population, based on list price, \$6.2 billion, is nearly twice that of the \$3.5 billion calculated by the FTC. To put this number into perspective, \$6.2 billion is roughly 2% of the average U.S. annual spending on drugs,¹⁴⁰ and the average of this cost range, \$19.2 billion, is roughly 7% of the average U.S. annual spending on drugs.¹⁴¹

IV. INTERPRETING “PAY,” “FOR,” AND “DELAY”

Our empirical results highlight the fact that pay-for-delay is a far more costly problem than previously recognized by organizations such as the FTC. The Supreme Court opened the door to challenge these settlements in *Actavis*, but in applying the decision, lower courts, competition agencies, and relevant parties have struggled with each of the three aspects of the phrase: “pay,” “for,” and “delay.” Despite the opinion’s stated expectation that lower courts would be able to provide structure to the rule of reason in a pay-for-delay inquiry,¹⁴² that structure has not materialized in a meaningful manner. The problem arises in part from the nature of the rule of reason inquiry and in part from the forms of deals that have emerged. Definitions of “pay” and “for” are often limited in that they only recognize exchanges of money as evidence of anticompetitive pay-for-delay deals. This ignores other potentially significant dealings between generic and brand-name companies, such as the transfer of patent rights, or no-authorized-generics clauses. Definitions of “delay” also often fall short in assuming that a settled patent is valid and properly applied, rather than considering the possibility that the patent assertion would have failed if pursued to completion, allowing immediate entry for the generic. *What Constitutes “Pay”*

One might imagine that the definition of “pay” would be simple. Nevertheless, some courts have struggled with the question of what might constitute an exchange of value and whether payment can extend beyond cash. Beyond the question of what types of value are included in the notion of pay, the inquiry itself has created obstacles for parties and competition authorities to actually measure value in a way that is satisfactory under a rule of reason analysis.

In particular, some parties have asserted that cash is king. From this perspective, the only exchange of value that matters would be dollars exchanging hands. Thus, in the immediate wake of *Actavis*, some courts initially failed to recognize noncash forms of compensation—such as no-authorized-generic clauses—as unexplained payments from brands to generics.¹⁴³ Although higher courts eventually issued

¹⁴⁰ *Prescription drug expenditure in the United States from 1960 to 2020*, STATISTA, <https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/> (last visited Apr. 2, 2021).

¹⁴¹ *Id.*

¹⁴² *Actavis*, 570 U.S. at 159–160 (explaining that trial courts would be able to appropriately “structure” the antitrust litigation).

¹⁴³ *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180 (D.R.I. 2014), *vacated and remanded*, 814 F.3d 538 (1st Cir. 2016); *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560 (D.N.J. 2014), *vacated and remanded sub nom. King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015). The payment in the settlement litigated in

rectifying decisions in *Lamictal*¹⁴⁴ and *Loestrin*,¹⁴⁵ both of which expanded the *Actavis* precedent to include methods of payments other than cash, damage was already done. Permitting certain forms of pay-for-delay—even temporarily—serves to incentivize similarly designed anticompetitive deals, at great cost to patients and society.¹⁴⁶ Protracted court battles also strain regulatory bandwidth, particularly when every instance of anticompetitive conduct must be demonstrated to the courts.

In the sophisticated world of modern commerce, however, there are many ways to provide value beyond simply cash. For example, one of the most valuable assets for an entering generic is the 180-day period in which the first filing generic can enter the market free of competition from other generics. Generic companies may earn a substantial portion of their profit during this period of time.¹⁴⁷ Brand-name companies, however, found a way to turn that period of time into an asset that can substitute for a cash payment.

The scheme springs from the fact that although a generic must obtain FDA approval to enter the market, the brand-name company already has such an approval

Actavis was a cash transfer from the brand to the generic; subsequent pay-for-delay settlements have featured payment forms that are less easily enumerated, such as no-authorized generic agreements. In this case, the brand company—in lieu of a cash payment—agrees to not launch an authorized generic during the first-filing generic company's 180-day exclusivity period, thereby boosting the generic company's revenues.

¹⁴⁴ After the district judge invalidated the main claim in the brand drug's patent, the parties entered a settlement which included allowing the generic to enter the market significantly early for one, but not another, version of the drug and in which the brand agreed not to release its own authorized generic versions during the generic's first-filer 180-day period of exclusivity. Although the plaintiff's complaint was ultimately dismissed, the court acknowledged in this case that settlements other than cash payments can violate antitrust principles. See FELDMAN & FRONDORF, *supra* note 5 at 523–524; see also *King Drug Co.*, 791 F.3d at 403–406.

¹⁴⁵ As part of the settlement agreement in which the generic agreed to delay entering the market for an oral contraceptive, the brand-name company allowed the generic to sell a different oral contraceptive and an anti-inflammatory drug. The brand also agreed not to sell or license another generic company to sell an authorized generic during the first-filing generic's 180-day exclusivity period. The plaintiff's complaints were dismissed, but the courts nonetheless acknowledged that reverse payment settlements may be based on transfers of value other than straight cash. See *Loestrin*, 814 F.3d at 549–550.

¹⁴⁶ Evidence since *Actavis* suggests that pharmaceutical companies hew closely to guidelines implied by court decisions. According to the FTC 2017 report, only three of twenty agreements with explicit compensation exceeded the \$7M allowed by *Actavis* for litigation fees; moreover, following a spate of court cases finding that a no-AG promise amounted to anticompetitive payment, 2017 saw no settlement agreements that included a no-AG clause. See Betsy Lordan, *FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors*, FTC (Dec. 3, 2020), <https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent>.

¹⁴⁷ See 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 BIOTECH. L. REP. 525, 525–26 (2006); see generally C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch–Waxman Act*, 77 ANTITRUST L.J. 947, 953 (2011) (stating that “[f]or many drugs, the exclusivity period offers the majority of the profits available to the generic firm,” and that once other generics enter, “the falloff in sales can be extreme”), reprinted in Carrier, *supra* note 35, at 40.

in its pocket. Thus, the brand-name company may market its own generic version of a drug—called an authorized generic or a branded generic—without the need for a lengthy approval process.¹⁴⁸ Although the Hatch-Waxman Act does not explicitly provide for authorized generics, courts have affirmed that nothing prevents the innovator company from marketing an authorized generic version of its drug.¹⁴⁹

The launch of an authorized generic has significant consequences for a first-filing generic. According to the FTC, competing with an authorized generic can cost a generic first-filer up to 45% of its revenue during the exclusivity period.¹⁵⁰ The ability to remove that threat becomes an asset that the brand-name company can hand to the generic company in exchange for an agreement to stay off the market. A brand-name company can promise not to introduce an authorized generic, particularly during the valuable 180-day period. The deal is a little like old movies portraying protectionist rackets, in which the neighborhood shakedown artist says, “Nice front window you have there. Be a real shame if it got smashed in.” Here, a brand-name company can say the equivalent of, “Nice 180-day exclusivity period. Be a real shame if you lost half of it. Tell you what, just stay off the market for a while, and it is all yours.”

As courts and competition authorities have become suspicious of these “no-authorized-generic” agreements, companies have developed more complex variations of these kinds of arrangements. Rather than explicitly promising not to compete by producing an authorized generic, a brand-name company can promise not to license any *third parties* to make authorized generics, while reserving the right to make an authorized generic itself. If the brand manufacturer has a limited track record of launching authorized generics, this agreement can have the same effect as the no-authorized-generic clause.¹⁵¹

In other complicated variants, brand-name companies may give the generic who agrees to stay off the market a license to make an authorized generic version of

¹⁴⁸ See generally John M. Rebman, *Dr. Strange Drug, Or: How I Learned to Stop Worrying and Love Authorized Generics*, 12 DEPAUL J. HEALTH CARE L. 159 (2009). Although authorized generics may be launched at any time, the FTC found in 2011 that they were increasingly appearing during the 180-day exclusivity period. See FTC, AG REPORT, *supra* note 108, at 28. Although a brand can release an authorized generic at any time following the approval of its NDA, the company would have no incentive to offer one while their more expensive product is the only one on the market. Additionally, the exclusivity period would be the most favorable time to launch because there are the least generic competitors .

¹⁴⁹ See *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005) (holding that Hatch-Waxman does not prohibit an NDA holder from marketing a “brand-generic” version of its drug during the exclusivity period); *Mylan Pharm., Inc. v. U.S. Food & Drug Admin.*, 454 F.3d 270, 276 (4th Cir. 2006) (holding that the FDA has no legal basis for outlawing authorized generics).

¹⁵⁰ *Teva*, 410 F.3d at 58.

¹⁵¹ See Jamie Towey & Brad Albert, *Then, now, and down the road: Trends in pharmaceutical patent settlements after FTC v. Actavis*, FTC (May 28, 2019), <https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent> (“an agreement in which the brand company commits not to license any third party to sell an AG product for a period of time (a no-third-party-AG commitment) . . . could nonetheless replicate the adverse effect of a no-AG commitment, particularly if the brand company has little or no experience selling generic products in the United States”).

their branded drug, with the generic paying a royalty to the brand.¹⁵² When the royalty payment is less than the market value of the benefit that the generic receives, that excess value may be camouflaging a “reverse” flow of payments in exchange for the generic’s agreement to stay off the market.¹⁵³ The transfer of value may be worth it for the brand, if the patents at issue are weak and at risk of being invalidated at trial. Patent invalidation would open the door to having all generics enter the market after the 180-exclusivity period for the first generic filer. By allowing the first-generic filer to make an authorized version, the brand protects its patents and limits the damage to having a single competitor in the field for an extended period of time.

In another variation of the authorized generic scenario, the brand and generic may agree that the royalty payment the generic will pay for permission to launch an authorized generic will decline if the brand-name company launches a competing authorized generic.¹⁵⁴ By creating a disincentive for the brand to launch a competing authorized generic, declining royalty agreements operate much like a garden variety agreement by the brand not to launch an authorized generic.

Courts and competition authorities now generally recognize that no-authorized-generic agreements can constitute a form of payment for the purposes of pay-for-delay, although it took some time to reach that point.¹⁵⁵ Nevertheless, the law has not fully addressed the anticompetitive potential of the complex variations. These variants are difficult to tease out, let alone establish with the degree of proof that the rule of reason test requires, making obfuscation a successful strategy. For example, the most-recent FTC reports showed 226 agreements between brand and generic companies that year,¹⁵⁶ a significant increase from the 170 settlements two years prior.¹⁵⁷ Ninety percent of those agreements included a transfer of patent rights that were not at issue in the lawsuit. Many of these could easily constitute a transfer of value.¹⁵⁸

¹⁵² See, e.g., *Actos*, 2015 WL 5610752, at *17; the generic benefits from keeping some portion of the royalties (i.e. the percentage not returned to the brand licensor), but regulators may not construe the arrangement as a reverse payment because the only explicit payment flows from the generic back to the brand in the form of a percentage of royalties. The generic, of course, also benefits from reduced competition during the 180-day exclusivity period (i.e. exclusively marketing an authorized generic is equivalent to marketing a generic during an exclusivity period where the authorized generic does not launch). Finally, this arrangement allows brand companies to entice non-first-filing generics with an otherwise unattainable exclusivity period.

¹⁵³ This arrangement differs from the declining royalty structure by granting the generic company license specifically to the *authorized* generic.

¹⁵⁴ See FTC, AG REPORT, *supra* note 108 at 149. These are known as “declining royalty structures.”

¹⁵⁵ See *supra* text accompanying notes 143–145 (describing rulings in *Loestrin* and *Lamictal*); see also *infra* note 166 (describing the evolving perspective the FTC has taken toward declining royalty structures in the past decade).

¹⁵⁶ FTC, FY 2017 REPORT, *supra* note 61, at 1.

¹⁵⁷ Fed. Trade Comm’n, Overview of Agreements Filed in FY 2015: A Report by the Bureau of Competition 1 (2017) [hereinafter FTC, FY 2015 REPORT].

¹⁵⁸ See FTC, FY 2017 REPORT, *supra* note 61.

Challenging even a simple no-authorized-generic agreement is no easy task. For example, although the judicial definition of payment now includes “no-authorized-generic” agreements,¹⁵⁹ private plaintiffs or the government bears the burden of evaluating a no-authorized-generic agreement in terms of the equivalent cash value.¹⁶⁰ The requirement follows the logic that in order to demonstrate the unreasonably large nature of a payment, as the *Actavis* decision specified, plaintiffs generally are required to translate that agreement into a specific, quantifiable value to the court’s satisfaction. Thus, a plaintiff who wishes to challenge even a simple no-authorized-generic agreement as anticompetitive must be prepared to engage in an expensive and lengthy court battle, with no consistent approach to valuation.¹⁶¹ Consider the *Effexor* case. The district court in *Effexor* rejected the plaintiffs’

¹⁵⁹ See, e.g., *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014) (“I agree with the bulk of the recent decisions holding that courts need not restrict the definition of “payments” under *Actavis* to cash. See, e.g., *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp.2d 367, 382 (D.Mass.2013) (rejecting a motion to dismiss because a no-authorized-generic term could be a payment for the delay because a broader definition of payment “serves the purpose of aligning the law with modern-day realities.”); see also *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014) (“reverse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments” when considering a no-authorized-generic agreement); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) (“[w]e do not believe *Actavis*’s holding can be limited to reverse payments of cash. For the following reasons, we think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason.”).

¹⁶⁰ See Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 259–260 (explaining how the often-onerous burden of proving anticompetitive harm under rule of reason rests on the plaintiffs); see also Feldman, *Defensive Leveraging*, *supra* note 37 (describing the difficulty of successfully pleading a rule of reason case).

¹⁶¹ Compare *United Food*, 74 F. Supp. 3d at 1071 (“Plaintiffs estimate the value of the no-authorized-generic agreement by calculating the difference between Watson’s projected revenues with the agreement and Watson’s projected revenues had it competed with Endo/Teikoku’s authorized generic from the start. Plaintiffs rely on a study conducted by the FDA to allege that it “is common in the pharmaceutical industry” for the first generic drug entering the market without competition to capture 80% of the brand-name’s market share, and set the price at 90% of the brand-name’s. (citing *Generic Competition and Drug Prices*, FDA (Dec. 13, 2019), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>). In contrast, a generic drug entering the market with an authorized generic competitor will only take 40% of the market, and the resulting competition will drive the price down to 52% of the brand-name’s. Applying these percentages to Endo’s publicly available sales information, Watson’s projected revenues for the seven and one half month period would be \$278,437,500 with the agreement, but only \$107,250,000 without the agreement.) with *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 260 (3d Cir. 2017) (“Effexor plaintiffs note that the Effexor XR market is a multi-billion dollar market annually, and, with the no-AG agreement, “Teva would (a) garner all of the sales of generic Effexor XR during Teva’s generic exclusivity period ... and (b) charge higher prices than it would have been able to charge if it was competing with Wyeth’s authorized generic.” Effexor plaintiffs further cite several aggregate studies noting that, historically, authorized-generic versions of a drug bring down the price of the generic drug, with one study observing that the entry “of an authorized generic causes generic prices to be 16% lower than when there is no authorized generic.” Those allegations plausibly allege a large reverse payment, with Wyeth’s no-AG agreement “allow[ing] Teva to maintain a supra-competitive generic price as the only generic manufacturer on the market, and to earn substantially higher profits than it otherwise would have earned.”)

valuation of a no-authorized-generic agreement. This valuation was based on an estimation of what an authorized generic cost the generic manufacturer of a different drug with nearly identical sales.¹⁶² Plaintiffs were able to obtain a reversal on appeal,¹⁶³ but obtaining the appellate decision took three years beyond the time that had already passed for the trial court ruling. The more a settlement deal twists and turns, the harder it is to tease out the value transfer and pin down a specific dollar equivalent.

In theory, the FTC reports required by the 2003 Medicare Modernization Act¹⁶⁴ could shed light on newer forms of anticompetitive agreements between brands and generics. The agency is limited in its resources, however. Reports are frequently beset by delays, offer only annualized statistics, and may fail to adequately appreciate the nuanced, rapidly evolving techniques used by drug companies—some of which may not be obvious on the face of the agreement.¹⁶⁵

For example, the FTC only released its annual report covering the year 2017 in December 2020. Annual reports for the 2018 and later years have yet to appear. Moreover, although the 2017 report includes declining royalty structures¹⁶⁶ and agreements not to license authorized generics to third parties (as opposed to a brand's agreements not to launch an authorized generic itself)¹⁶⁷ as examples of “possible compensation” arrangements, the FTC declines to assess the anticompetitive quality of these arrangements as “beyond the scope of [the] report.”¹⁶⁸

¹⁶² *In re Effexor XR Antitrust Litig.*, No. CIV.A. 11-5479 PGS, 2014 WL 4988410, at *21 (D.N.J. Oct. 6, 2014), *rev'd and remanded sub nom. Lipitor*, 868 F.3d 231 (“The value of the no-authorized generic agreement in the Complaint appears to be based on a comparison between the \$2.39 billion in reported sales of Effexor in 2009 (the year before generic competition) and the \$2.31 billion in reported sales of a similarly situated drug, Paxil. The first-filer generic manufacturer of that drug, Apotex Corp., allegedly informed the FDA that the presence of an authorized generic for Paxil cost the company approximately \$400 million in sales during its 180-day exclusivity period...while this comparison is useful for purposes of showing that a no-authorized generic agreement has value, it does not specifically value the monetary amount of the no-authorized generic agreement in the instant case”).

¹⁶³ *Lipitor*, 868 F.3d at 260 (finding that the size of the Effexor market, coupled with studies showing that an authorized generic reduces prices, qualified the no-authorized-generic clause as a large payment).

¹⁶⁴ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§1111-18, 117 Stat. 2066, 2461-64 (2003), *reprinted in* Karas et al., *supra* note 10, at 964 (2020).

¹⁶⁵ See *id.* at 260-265.

¹⁶⁶ See FTC, FY 2017 Report, *supra* note 61, at 2 (recognizing that the declining royalty structure may achieve the same effect as an explicit no-AG clause); see also Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 265-66 (noting that FTC reports have become increasingly cognizant of the declining royalty structure as an anticompetitive tool, re-categorizing them from a form of unknown payment in 2010 to a form of possible compensation in 2013).

¹⁶⁷ FTC, FY 2017 Report, *supra* note 61, at 2; for certain brand companies that do not usually manufacture authorized generics, an agreement to not license AGs to third parties can function as a no-AG clause.

¹⁶⁸ *Id.* at 2.

Although the 2017 report finds zero cases of the no-authorized-generic agreements so prevalent a decade earlier,¹⁶⁹ it would be naïve to assume that the end of simple no-authorized-generic clauses marks the end of authorized generics in pay-for-delay. Rather, anecdotal evidence¹⁷⁰ suggests that the character of brand-generic patent settlements is simply changing in response to the spate of court rulings finding that no-authorized-generic clauses constitute payment under *Actavis*.¹⁷¹

A. What Constitutes “For”

Similar to the notion of what constitutes “pay,” courts and agencies have struggled over whether a transfer of value in an agreement constitutes a payment for staying off the market or simply a payment for legitimate value provided by the generic.

Side deals come in many shapes and sizes including: 1) arrangements to promote other drugs in the firms’ portfolios;¹⁷² 2) licensing deals that allow the brand or generic to manufacture the other party’s drug;¹⁷³ 3) agreements authorizing the generic to manufacture and/or sell a brand’s “authorized generic” without filing for generic approval; 4) research and development collaboration on future projects; and 5) deals to supply the brand company with raw materials for manufacturing.¹⁷⁴ Such side deals are rarely found outside the settlement context. According to one academic in the field, “many—such as an arrangement by which a brand relies on a generic for its marketing expertise—believe common sense.”¹⁷⁵

The valuation of agreements featuring noncash provisions is further complicated by the fact that the details of these settlements are shrouded in

¹⁶⁹ See Lordan, *supra* note 146 (noting that “for the first time since [fiscal year] 2004, no agreement contains a no-AG commitment”); see also FTC, AG Report, *supra* note 108, at vi (finding that 39 of 157 patent settlements filed between 2004-2010 contained an agreement not to compete with an authorized generic).

¹⁷⁰ See, e.g., In re Intuniv Antitrust Litig., 496 F. Supp. 3d 639, 651 (D. Mass. 2020) (settlement agreement including both a declining royalty structure and an agreement by the brand-name company not to launch its AG via a third party.)

¹⁷¹ See, e.g., FTC, FY 2017 Report, *supra* note 61, at 2 (listing forms of “possible compensation” including declining royalty structures); for further evidence of how the composition of reverse payment settlements has been shaped by the courts, see also *id.* at 1 (“in 17 of the 20 final settlements that contained explicit compensation to the generic company and a restriction on selling a generic product for a period of time, the only explicit compensation was \$7 million or less in litigation fees. In *Actavis*, the Court noted that avoided litigation expenses might constitute a justified payment”).

¹⁷² See, e.g., *Actavis*, 570 U.S. at 136 (noting that the settlement included an agreement to promote AndroGel to physicians).

¹⁷³ See, e.g., FELDMAN & FRONDORF, *supra* note 5, at 50 (describing a Schering-Upsher settlement that delayed the entry of K-Dur in 1997).

¹⁷⁴ See Hemphill, *Aggregate Approach*, *supra* note 11, at 663-666, reprinted in FELDMAN & FRONDORF, *supra* note 5, at 51.

¹⁷⁵ Carrier, *supra* note 35, at 9.

secrecy.¹⁷⁶ The lack of transparency makes it difficult to identify and quantify the value of noncash settlements. Even if the presence of side deals is suspected, plaintiffs will rarely, if ever, have access to the terms of those agreements. Several district courts have dismissed pay-for-delay litigation for failing to plausibly allege a large and unjustified payment.¹⁷⁷ For example, the district court in *Actos* dismissed the indirect purchasers' claims that Takeda engaged in anticompetitive conduct by entering into settlement agreements with generic manufacturers.¹⁷⁸ While the court shared the majority view that *Actavis* was not limited to settlements dealing with pure cash, it also held that to find an unlawful reverse payment involving noncash settlement terms, the court "must be able to estimate the value of the term, at least to the extent of determining whether it is "large" and "unjustified."¹⁷⁹ Given that the plaintiffs could not explain the basis for their assertions nor offer any method of calculating the value of the licensing side deal, there was no factual basis for the court to reasonably estimate the value of the settlement terms and evaluate the settlement's alleged anticompetitive effect.

The legality of settlements featuring side deals continues to be challenged. While the view in the majority of courts is that side deals are not immune to antitrust scrutiny, plaintiffs still bear the burden of pleading information sufficient to estimate the value of these agreements. To describe the task of determining whether these terms are "large" and "unjustified" as difficult is an understatement.

It is interesting to note that although the FTC's reports on pay-for-delay settlements for fiscal years 2015¹⁸⁰ and 2016¹⁸¹ reported no side deals, the most recent report for fiscal year 2017 listed three settlements with side deals.¹⁸² These side deals included an agreement in which the brand manufacturer assigned the generic manufacturer five patents unrelated to the litigated product at no cost, another in which the generic sold intellectual property related to the litigated product to the brand manufacturer, and a third in which the brand manufacturer acquired the generic manufacturer's potentially competing product that was the subject of the patent litigation.¹⁸³ These indicators suggest there is reason for concern that side deals can be used to hide payments for delay and that courts and agencies would be unable to ferret out any anticompetitive conduct.

¹⁷⁶ See FELDMAN & FRONDORF, *supra* note 5, at 66.

¹⁷⁷ *Effexor*, 2014 WL 4988410 at *22; *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 546 (D.N.J. 2014), *rev'd and remanded*, 868 F.3d 231 (3d Cir. 2017); see also Robin A. van der Meulen & Rudi Julius, *Cash or No Cash—That is No Longer the Question*, ANTITRUST HEALTH CARE CHRONICLE (Apr. 22, 2016), <https://www.labaton.com/blog/cash-or-no-cash-that-is-no-longer-the-question>.

¹⁷⁸ See *Actos*, 2015 WL 5610752 at *29.

¹⁷⁹ *Id.* at *13.

¹⁸⁰ FTC, FY 2015 Report, *supra* note 157.

¹⁸¹ FTC, FY 2016 Report, *supra* note 133.

¹⁸² See FTC, FY 2017 Report, *supra* note 61, at 1–2.

¹⁸³ *Id.* at 1–2.

B. What Constitutes “Delay”

Creating a full sweep, courts have also struggled with the question of what constitutes delay. The uncertainty centers on whether an agreement in which the generic enters before the patents expire should be considered delay. Supporters of pay-for-delay settlements routinely argue that such settlements can be procompetitive because they facilitate early entry of a generic before a branded drug’s patents have expired.¹⁸⁴ In such instances, consumers would benefit from lower prices sooner than if the Paragraph IV challenge had never taken place. In *Actavis*, the Supreme Court recognized this procompetitive potential, commenting that early entry settlements, or settlements permitting the patent challenger to enter the market before the patent expires, could “bring about competition . . . to the consumer’s benefit.”¹⁸⁵

That argument, however, assumes the patent is valid and infringed.¹⁸⁶ Various studies suggest that assumption is unwarranted. For example, a 2002 FTC report found that considering all the Hatch-Waxman patent infringement cases between generic and brand manufacturers between 1992 and 2000, generic applicants prevailed in 73 percent of cases.¹⁸⁷ Similarly, an academic analysis of Federal Circuit decisions between 2002 and 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim found that generic challengers had a 70 percent success rate.¹⁸⁸ In a more recent analysis, a study of patent lawsuits filed in a federal district court between 2008 and 2009 found that accused infringers won 74 percent of the definitive merits rulings while patentees won only 26 percent of the time.¹⁸⁹ In fact, the FDA has gone so far as to provide a registry of disputed

¹⁸⁴ See, e.g., Pay-for-Delay Deals: Limiting Competition and Costing Customers: Hearing Before the Subcomm. on Antitrust, Comp. Pol. and Consumer Rights of the S. Comm. on the Judiciary, 113th Cong. 80-82 (2013) (prepared statement of Diane E. Biari, on behalf of PhRMA).

¹⁸⁵ *Actavis*, 570 U.S. at 154.

¹⁸⁶ See Karas et al., *supra* note 10, at 968-969; Laura Karas, *When ‘Pay-For-Delay’ Becomes ‘Delay-Without-Pay’: Humira Antitrust Claims*, BILL OF HEALTH (Feb. 1, 2021), <https://blog.petrieflom.law.harvard.edu/2021/02/01/pay-for-delay-humira-antitrust/>.

¹⁸⁷ FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 16 (2002). Generic litigation success can generate substantial savings for society. See *Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government Are Paying Too Much for Prescription Drugs: Hearing Before the Subcomm. on Cts. & Comp. Policy of the H. Comm. on the Judiciary*, 111th Cong. 13 (2009) (prepared statement of Federal Trade Comm’n) (estimating that generic competition following successful challenges involving a mere four major brand drugs saved purchasers more than \$9 billion).

¹⁸⁸ Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 20 (2006); see also John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-06 (1998) (study of all patent validity litigation from 1989-1996 found 46 percent of all patents litigated to judgment held invalid).

¹⁸⁹ John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1787 (2014). In contrast, an industry analyst’s report found a success rate for generics of only 48% at trial and a success rate of 76% when trial and settlements are included. See *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 215 n. 11 (3rd Cir. 2012) (citing Adam Greene & D.D. Steadman, *RBC Capital Mkts., Pharmaceuticals: Analyzing Litigation Success Rates*, 212 PHARMACEUTICALS, 4 (2010),

patent information in order to address inaccurate or extraneous patent listings on new drugs.¹⁹⁰ As the author has previously written, “one can never assume that just because a company holds a patent that the patent is either valid or validly applied to the drug at issue.”¹⁹¹

A patent that is invalid or not infringed would have no power to stop entry. Thus, if the generic had pursued the litigation to conclusion, the result could easily have moved the patent barrier out of the way, allowing the generic to enter right away. As a result, it would be nonsensical to say that there is no delay if the parties agreed to stay out of the market until the expiration date of a non-infringed patent. Nevertheless, some courts have failed to contemplate that possibility in analyzing agreements.

Consider *In re Humira*.¹⁹² Plaintiffs alleged that AbbVie’s settlement agreements with biosimilar manufacturers, in which the biologic company granted licenses for biosimilars to market the Humira biosimilar in Europe in 2018 while delaying entry into the U.S. market until 2023, constituted an unlawful pay-for-delay scheme.¹⁹³ Patients with arthritis saw the out-of-pocket cost of Humira rise to \$1,552 per month in 2019, up from \$874 in 2014.¹⁹⁴ In dismissing the lawsuit, the district court found that the settlements were permissible because they allowed AbbVie’s rivals to enter the U.S. market before the patents on Humira (the latest of which expires in 2039) expired.¹⁹⁵ The court failed to recognize, however, that the settlements eliminated the possibility that the biosimilars might have entered the U.S. market earlier than the stipulated date if they had pursued the litigation to conclusion and prevailed. As with many cases, the patents might not have been valid or validly applied. The point is simply that if the generic had won the case, the generic drug could have entered the market immediately—before the date that the patents were set to expire.

V. PAVING A PATH FORWARD

As noted at the outset, when competitors shake hands and agree that the lower-priced drug should stay off the market, it is bad for consumers. The benefit to

<https://amlawdaily.typepad.com/pharmareport.pdf> as submitted in evidence by the pharmaceutical industry and noting that even the industry figures show that a substantial fraction of Hatch–Waxman patent challenges succeed on the merits). For a discussion of the strength or weakness of the cases settled as opposed to those fully litigated, *see supra* note 28.

¹⁹⁰ U.S. FOOD & DRUG ADMIN., ORANGE BOOK PATENT LISTING DISPUTE LIST, <https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-patent-listing-dispute-list> (last visited May 4, 2021); *see also* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 OXFORD J.L. & BIOSCI. 590, 603 (2018) (contextualizing the Orange Book Patent Listing Dispute List).

¹⁹¹ FELDMAN & FRONDORF, *supra* note 5, at 42.

¹⁹² *In re Humira* (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811 (N.D. Ill. 2020).

¹⁹³ *Id.* at 836.

¹⁹⁴ Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices*, Consum. Rep. (Nov. 26, 2019), <https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/>.

¹⁹⁵ *Id.* at 827.

pharmaceutical companies is so great, however, that it will require significant effort by competition authorities to curb the practice.

There is an old saying that insanity is doing the same thing over and over again while expecting a different result. After watching plaintiffs and competition authorities struggle to satisfy the rule of reason in order to establish a pay-for-delay case, it is clear that continuing down the same path is unlikely to be fruitful. Other paths, however, could be pursued. Three policy and regulatory changes could pose a challenge to anticompetitive pay-for-delay deals. First, both parties of a settlement between pharmaceutical manufacturers could be asked to demonstrate that such a settlement is procompetitive. Second, the rules surrounding the 180-day period of first-filer market exclusivity for generics could be amended as to discourage delaying the activation of this period of exclusivity. Last, firms could be required to publicize financial data surrounding pay-for-delay deals.

A. Structuring Presumption into the Rule of Reason

As described above,¹⁹⁶ the intricate requirements of the rule of reason, not to mention the burden it places on parties and the courts,¹⁹⁷ make the rule of reason particularly ill-suited for examining the increasing number of agreements between brand and generic competitors. As a result, some scholars have argued that the rule of reason should be shelved entirely in pay-for-delay cases.

Pinning hopes for pay-for-delay reform on an outright ban may not prove politically tenable, however, and other commentators have proposed intriguing alternatives. One scholar has suggested that Hatch-Waxman agreements between brands and generics are problematic if the generic obtains a benefit it could not obtain by winning the lawsuit.¹⁹⁸ In that case, the agreement presumably does not reflect the strength of the brand's patent, but some other value changing hands.¹⁹⁹ Other prospective solutions seek to improve upon the fines used currently to

¹⁹⁶ See *supra* text accompanying notes 51–56 (discussing challenges posed by the rule of reason).

¹⁹⁷ See, e.g., *Cont'l T.V., Inc. v. GTE Sylvania*, 433 U.S. 36, 50 n.16 (1977) (describing rule of reason trials as complex and burdensome on litigants and the judicial system); *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (noting that the rule of reason analysis requires an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries); *United States v. Topco Assocs.*, 405 U.S. 596, 609-10 (1958) ("[I]nability to weigh, in any meaningful sense, destruction of competition in one sector of the economy against promotion of competition in another sector is one important reason we have formulated per se rules."); see also Feldman, *Defensive Leveraging*, *supra* note 37, at 2107-08 (describing the rule of reason); Pitofsky, *supra* note 51 (citing *United States v. Trenton Potteries Co.*, 273 U.S. 392, 397 (1927) (Court refused to apply the rule of reason because of the practical difficulties of the minute inquiry into economic organization required)); *NCAA v. Alston*, 141 U.S. 2141, 2160–61 (2021) (noting that 90% of plaintiffs since 1977 have failed to advance their rule of reason case past the initial step of showing a substantial anticompetitive effect); cf. *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 34 (1984) (O'Connor, J., concurring) (comparing rule of reason to the peculiar form of per se rule applied in tying cases and describing both as requiring extensive and time-consuming economic analysis).

¹⁹⁸ See Carrier, *supra* note 35, at 7.

¹⁹⁹ *Id.*

disincentivize pay-for-delay conduct. As this article's analysis demonstrates, however, even companies fined by the FTC for pay-for-delay may profit handsomely from the practice.²⁰⁰ Considering the failure of fines to sufficiently discourage pay-for-delay, some scholars have advanced alternative punishments for cited drug companies. For instance, a first-filing generic company that agreed to postpone production in exchange for a no-authorized-generic clause could be stripped of its 180-day exclusivity period.²⁰¹ Other approaches might provide that brand companies forfeit the chance to earn additional non-patent regulatory exclusivities²⁰² for a drug whose monopoly period they paid competitors to extend. This way, instead of simply reducing the profits of offending drug-makers, the repercussions of pay-for-delay redound as social benefit.

Despite potential remedy-related reforms, however, the most important change needed pertains to evaluating the anticompetitive nature of the agreement itself. The landmark decision in *Actavis* expressed optimism that courts would be able to manage the analysis in a more structured manner. That reality has not materialized. To resolve the problem, one should return to the basic notion that agreements between competitors are strongly disfavored under antitrust law. As the leading treatise on antitrust law explains, agreements between competitors "are antitrust's most 'suspect' classification, which as a class provoke harder looks than any other arrangement."²⁰³ In fact, horizontal agreements between competitors are so frowned upon that some are examined not with the convoluted rule of reason but rather by a simple per se test.²⁰⁴

Given that agreements between competitors are disfavored, the test for agreements between brands and generics in the context of Hatch-Waxman litigation should begin with a presumption that the agreement is anticompetitive. This

²⁰⁰ Cf. Table 4 (finding that the U.S. paid at least \$6.2 billion more for prescription drugs annually due to pay-for-delay); FELDMAN & FRONDORF, *supra* note 74, at 515-516 (calculating based on statement by company executive that even after deducting for fines and settlements totaling \$1.2 billion, the company still earned an additional \$2.3 billion in revenue as a result of the pay-for-delay agreement on the drug Provigil).

²⁰¹ See Karas et al., *supra* note 10, at 969-970.

²⁰² For a description of roughly a dozen non-patent exclusivities available through the FDA, see Feldman, *Regulatory Property: The New IP*, *supra* note 120. Such regulatory exclusivities include orphan drug designation, which provides seven years of protection and may be added onto other protections. Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (prior to 1984 amendment).

²⁰³ See 11 PHILIP AREEDA & HERBERT HOVENKAMP, *ANTITRUST LAW*, § 1902 at 232 (3d ed. 2006) (explaining why horizontal agreements provoke stricter scrutiny than any other acts, including unilateral acts, horizontal mergers, or vertical agreements); cf. Feldman, *Patent Exceptionalism*, *supra* note 32, at 61-62 (arguing that courts should avoid treating agreements related to patents differently from any other agreements, and that patent exceptionalism in the context of Hatch-Waxman litigation is allowing patent holders to exercise inappropriate levels of power).

²⁰⁴ See, e.g., *United States v. Trenton Potteries Co.*, 273 U.S. 392, 397 (1927) (certain classes of behavior, such as price-fixing agreements between competitors, should be treated as a per se violation of antitrust law); cf. FED. TRADE COMM'N, *GUIDE TO ANTITRUST LAWS*, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers> (last visited Nov. 26, 2021) (explaining that "[t]he greatest antitrust concern arises with proposed mergers between direct competitors.").

approach respects the essential design of the Hatch-Waxman system to ensure rapid entry of generic drugs, in part, by providing an incentive for generic drug companies to challenge patents that are invalid or invalidly applied.²⁰⁵ Only when the public interest is clearly served should the presumption be overcome.

A presumption offers a variety of advantages to the judiciary and regulatory systems. It would ease the burdens on regulators such as the FTC, which tend to lack the resources needed to scrutinize and, if necessary, litigate each of the dozens of brand-generic settlements that occur annually.²⁰⁶ In addition, by shifting the burden to the companies themselves, a presumption avoids rewarding those who concoct increasingly elaborate schemes. The company would have to establish how a complex scheme works and why it is procompetitive.

There are many ways a presumption could be designed and implemented. For example, the state of California passed a rebuttable presumption in pay-for-delay cases,²⁰⁷ and other states are contemplating their own versions.²⁰⁸ At the federal level, the House in 2019 passed pay-for-delay legislation containing a presumption. The bill did not reach the Senate floor.²⁰⁹ House and Senate members jointly introduced a pay-for-delay bill, currently pending in both Houses of Congress, that adopts a rebuttable presumption.²¹⁰ In a similar vein, the “quick look” approach, recommended by the FTC in *Actavis* and rejected by the Supreme Court in *Actavis*, was also a form of presumption.²¹¹ Perhaps the quick look deserves another glance.

The details of any individual approach may vary. Regardless of the form, however, the key is the establishment of a presumption that shifts the burden of convincing courts and competition agencies of the value of such agreements into the hands of those who hold the information. Doing so would discourage the continued creation of complex, anticompetitive vehicles.

One could argue that presuming anticompetitiveness in the event of a settlement between brand and generic companies would disincentivize the ability of parties to enter into good faith settlements to avoid the costs of litigation.²¹² Litigating parties are generally encouraged to settle their differences, sparing the legal system the

²⁰⁵ See *supra* text accompanying notes 17–27 (describing the Hatch Waxman system for rapid entry of generic drugs, Paragraph IV certifications, and the 180-day exclusivity for first-filing generics that successfully challenge patents.)

²⁰⁶ See Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 260–261 (noting that, although all brand-generic agreements under the Hatch-Waxman Act must be filed with the FTC, the agency’s delays in publishing pay-for-delay reports, and the reports’ relative lack of specificity, suggests limited resources to address the problem of pay-for-delay).

²⁰⁷ See A.B. 824, 2018-2019 Reg Sess. (Ca. 2019), which creates a rebuttable presumption of pay-for-delay in settlements between brand and generic companies.

²⁰⁸ See S.B. 764, 81st Leg. Assemb., Reg. Sess. (Or. 2021).

²⁰⁹ Protecting Consumer Access to Generic Drugs Act of 2019, H.R. 1499, 116th Cong. (2019).

²¹⁰ Preserve Access to Affordable Generics and Biosimilars Act, S. 64, 117th Cong. (2021-2022);

²¹¹ *FTC v. Actavis, Inc.*, 570 U.S. 136, 138–40 (2013).

²¹² See Reply Brief for Plaintiff-Appellant at 22–23, *Assoc. for Affordable Meds. v. Xavier Becerra*, No. 2:19-cv-02281-TLN-DB (9th Cir. Mar. 19, 2020), 2020 WL 1496262.

time and expense of a trial. A presumption, however, can be rebutted by appropriate evidence within the purview of the companies. It is far less drastic a test than certain other types of agreements between competitors—which are illegal per se under antitrust law—such as horizontal price-fixing, bid-rigging, and market-allocation schemes.²¹³

B. A Rolling Exclusivity Period

Although the threat of an antitrust action could provide a disincentive for the parties to enter into pay-for-delay settlements, the law could remove some of the current incentives for entering into the settlements. Specifically, Hatch-Waxman could be amended so that if a generic settles with the brand, the generic loses its 180-day exclusivity period and the period rolls to the next-filing generic.²¹⁴ With such a system, at some point, it would become economically infeasible for the brand to settle with every potential generic. If the patent really is weak, someone will want the valuable 180-day exclusivity period and will be willing to see the patent challenge through, which is what the Hatch-Waxman legislation intended. In addition, a rolling period removes any incentive that might exist for a generic to file a “strike suit,” hoping for a quick settlement value even if the brand’s patent is valid.

The necessary legal change would be relatively simple. In 2003, Congress amended the Hatch-Waxman Act to provide that the first-filing generic loses its 180-day exclusivity under certain circumstances if the generic delays or fails to come to market.²¹⁵ Specifically, the generic forfeits its 180-day exclusivity if it fails to come to market within a short period of time after a court enters a final judgement in the generic’s favor.²¹⁶ Pay-for-delay settlements avoid the hammer of forfeiture because they are settlements, rather than final judgements of invalidity or noninfringement, and may be worded to avoid a finding of invalidity or noninfringement.

To properly provide for a rolling exclusivity, the relevant Hatch-Waxman section could be amended to provide forfeiture if the generic does not come to market within a short period of time after settling the litigation with the brand, rather than the current forfeiture requirement, which only applies if a court enters a final judgement. In addition, the Act currently provides that if all first-filers forfeit their exclusivity periods, no applicant qualifies for the 180-day exclusivity.²¹⁷

²¹³ See, e.g., U.S. DEP’T OF JUST., PRICE FIXING, BID RIGGING AND MARKET ALLOCATION SCHEMES: WHAT THEY ARE AND WHAT TO LOOK FOR (2005), <https://www.justice.gov/atr/file/810261/download#:~:text=Price%20fixing%2C%20bid%20rigging%2C%20and%20other%20forms%20of%20collusion%20are,United%20States%20Department%20of%20Justice>

²¹⁴ See Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 194 (2008) (suggesting a rolling exclusivity period among generic filers).

²¹⁵ See 21 U.S.C. section 355(j)(5)(D).

²¹⁶ 21 U.S.C. section 355(j)(5)(D)(i)(I)(bb)(AA) and (BB).

²¹⁷ 21 U.S.C. section 355(j)(5)(D)(iii)(II).

Thus, the section would need to be further amended to allow the exclusivity to keep rolling. These changes would help ensure that the settlement value does not reflect more than the costs and risks of litigation. In addition, a Hatch-Waxman amendment would avoid complicating the general concepts within antitrust law by trying to fit them into the Hatch-Waxman context.

The downsides to such a system would include lessening the incentive to settle, which can save judicial resources, as well as time and cost for both parties. It would also make entry more expensive for first-filing generics, which can now receive benefit from brands in addition to the benefit of a 180-day exclusivity. That benefit to generics, however, is provided by consumers who pay in the form of higher prices during any period of delay. It is not a benefit anticipated by the Hatch-Waxman Act, and it runs counter to the foundations of the legislation.

C. *Sunlight is the Best Disinfectant*²¹⁸

As is so often true in pharmaceutical markets, meaningful, detailed data about reverse payment settlements are unavailable, protected by claims of trade secrecy or otherwise kept hidden by the pharmaceutical parties.²¹⁹ The opacity of information with regard to pay-for-delay inhibits comprehensive analyses of anticompetitive misconduct, thereby hamstringing effective policy design. At least one avenue for the meaningful disclosure of settlement information already exists: the 2003 Medicare Modernization Act requires that every brand-generic settlement be reported to the FTC.²²⁰ Although the FTC does publish annual reports tabulating the total number of such settlements, this information is often delayed several years, and offers little granularity beyond rough categories of deals.²²¹ But without data specific to individual agreements or drug products, these reports are limited in their utility to outside investigators, researchers and policymakers.

More robust transparency mandates, whether achieved through regulatory or legislative action, could mark a major step in combating pay-for-delay practices, even in the absence of further policy changes. Greater information availability would enable outside investigators, such as state attorney general offices, antitrust enforcers and civil attorneys, to bring anticompetitive misconduct to account.²²² Granting access to a larger force of investigators in this way may help alleviate the

²¹⁸ LOUIS BRANDEIS, *What Publicity Can Do, in OTHER PEOPLE’S MONEY* (1914).

²¹⁹ See generally Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 21 YALE J. L. TECH. 61 (2020) (discussing how trade secrets are used to suppress drug pricing transparency across the pharmaceutical supply chain).

²²⁰ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003).

²²¹ See, e.g., FTC, FY 2017 Report, *supra* note 61, at 6 (showing the general categories into which settlements are split; as a reference for the degree of FTC publication delays, the 2017 report was published in 2020); see also Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 265–266 (discussing the ambiguity of various FTC report categories).

²²² Cf. Feldman & Misra, *Fatal Attraction*, *supra* note 10, at 259 (noting that the FTC reports inform external efforts to address pay-for-delay).

FTC's regulatory burden, and the increased threat of litigation could prove an effective deterrent to prospective pay-for-delay schemes.

Transparent and accessible data regarding brand-generic settlements will also facilitate more complete research into the problem. The above findings pull from a small basket of publicly disclosed pay-for-delay settlements that required many research hours to gather. A policy to make brand-generic settlement data accessible would produce a more precise and fuller portrait of how the practice impacts the drug industry and consumers. Furthermore, a substantiated body of evidence demonstrating pay-for-delay's economic and social harm may encourage a shift to an analysis such as the quick look presumption recommended by the FTC in *Actavis*,²²³ helping to codify a more unified response in the courts. Greater public awareness of pay-for-delay may also galvanize support for other policy measures, such as the proposals discussed above. Considering drug companies' creativity and nimbleness when faced with profit-lowering obstacles, it may prove wise to have many arrows in the quiver.

VI. CONCLUSION

The Hatch-Waxman Act was designed to bring generic drugs to the market as quickly as possible, ensuring rapid entry of generics as soon as the patent on the medication expired. To reach that goal, Congress included a powerful incentive for generic companies, providing a valuable 180-day period of exclusivity to generics who successfully challenge patents that are invalid or invalidly applied to a particular drug. This essential provision reflects a recognition of the problem of improper use of the patent system, as well as an understanding of the need to give generic companies an incentive to enter the fray and do battle with the big guns. That provision—so essential for ensuring the public interest—has been hijacked. Instead of facilitating the end of improper patent use, brand and generic companies now pen agreements to share monopoly rents and delay the moment that the public can access affordable medications. The law must become as nimble and creative as these complex schemes.

As one former FDA commissioner has been cited as explaining, “the greatest creativity at pharmaceutical companies should be in the lab, not in the legal department.”²²⁴ To discourage the ever-more-complex, anticompetitive legal settlements that have appeared, antitrust law related to settlements of Hatch-Waxman litigation should be revised. Agreements between brand and generic companies to settle such litigation should be subject to a presumption that such an agreement between competitors is anticompetitive. Regardless of the details, exceptions, safe harbors, etc. that may develop, the basic inquiry must place the

²²³ See *supra* text accompanying notes 205–213 (proposing a quick-look presumption for pay-for-delay settlements).

²²⁴ See Feldman, *May Your Drug Price*, *supra* note 190, at 617 (citing Dr. Donald Kennedy, Comm'r, U.S. Food & Drug Admin., Keynote Address at the UC Hastings Conference: Faces of Forensics (Mar. 2008)).

burden on the settling competitors to demonstrate why their desire to end the litigation encouraged by the Hatch-Waxman system is good for competition.