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THE FATAL ATTRACTION OF PAY-FOR-DELAY

BY ROBIN C. FELDMAN* & PRIANKA MISRA**

Pay-for-delay settlements, a strategic tactic in which brand-name drug manufacturers induce generic companies to agree to stay off the market by sharing portions of their monopoly profits, once constituted bread-and-butter anticompetitive behavior in the pharmaceutical industry.¹ Commentators often referred to these tactics as “reverse payment” settlements due to the inverted direction of compensation.² Specifically, in an ordinary settlement, the defendant ends the lawsuit by agreeing to pay some amount to the plaintiff in exchange for the plaintiff’s agreement to drop the lawsuit. Here, the *plaintiff*, who is the patent holder and the brand-name drug manufacturer, pays an amount to the *defendant*, who is the alleged infringer. In return, the generic company agrees to stay off the market for a period of time.

These settlements take place in the context of the Hatch-Waxman system for accelerated approval of generic drugs. With Hatch-Waxman, a company hoping to launch a generic drug must certify that all patents listed by the brand company as related to the drug (1) have not been filed, (2) have expired already, (3) will have expired by the time the generic enters, or (4) are invalid or that the generic will not infringe—a certification that operates as an artificial act of infringement and opens the door for the brand-name company to sue.³

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1. See ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 24 (2017) (describing the pay-for-delay settlement tactic as “commonplace” in the pre-*Actavis* era).

2. See *id.* at 24.

3. 21 U.S.C. § 355(j)(2)(A)(vii)(I–IV) (2017).

Pay-for-delay agreements emerged following the 1984 implementation of the Hatch-Waxman Act, more formally known as the Drug Price Competition and Patent Term Restoration Act.⁴ Therefore, these agreements coincided with the proliferation of generic drugs on the market.⁵ In *FTC v. Actavis*, the Supreme Court opened the door to challenging pay-for-delay settlements, following decades of these agreements.⁶ The Court ruled in *Actavis* that pay-for-delay could constitute illegal, anti-competitive actions, opening the door to a probing analysis of these settlements. This decision ended any perceived antitrust immunity for these agreements, enabling their condemnation under the antitrust laws. Many observers believed the decision signaled much more intense scrutiny of such settlements, which would serve as a warning for those engaged in the practice.⁷

The Supreme Court decision in *Actavis* followed years of studies and commentary from academics and policy-makers raising concerns about the negative economic implications of settlements that have the effect of paying one's generic competitor to stay off the market.⁸ Lower courts have since weighed in with their own antitrust analysis of the scope of the *Actavis* decision, with most federal courts holding that antitrust scrutiny should

4. 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.).

5. See FELDMAN & FRONDORF, *supra* note 1, at 35; see also Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, U. ILL. L. REV. 1, 11–13 (2018); Daryl Lim, *Biologics As The New Antitrust Frontier: Reflections, Riposte, and Recommendations*, U. ILL. L. REV. ONLINE 209, 212 (2018) (noting that Hatch Waxman “spurred a flood of generics” to 88 percent of all prescriptions, up from 19 percent the year the Act was passed); Ann M. Thayer, *30 Years of Generics*, 92 CHEMICAL & ENGINEERING NEWS (Sept. 29, 2014), <https://cen.acs.org/articles/92/i39/30-Years-Generics.html>.

6. See FELDMAN & FRONDORF, *supra* note 1, at 24; see also Daniel Hougendobler, *The End of “Pay-for-Delay”? By Opening Collusive Pharmaceutical Settlements to Antitrust Scrutiny, FTC v. Actavis Promises to Make Medicines More Affordable*, GEORGETOWN LAW O’NEILL INSTITUTE BLOG (June 21, 2013), <http://oneill.law.georgetown.edu/the-end-of-pay-for-delay-by-opening-collusive-pharmaceutical-settlements-to-antitrust-scrutiny-ftc-v-actavis-promises-to-make-medicines-more-affordable/>; Lauren Krickl & Matthew Avery, *Roberts Was Wrong: Increased Antitrust Scrutiny After FTC v. Actavis Has Increased Generic Competition*, 19 VA. J. L. & TECH. 509 (2015).

7. Aaron S. Kesselheim & Nathan Shiu, *FTC v. Actavis: The Supreme Court Issues a Reversal on Reverse Payments*, HEALTH AFFAIRS (June 21, 2013), <https://www.healthaffairs.org/doi/10.1377/hblog20130621.032326/full/> (noting that the post-*Actavis* landscape “holds the promise of preventing settlements involving reverse payments that simply exist to prop up weak or invalid patents”); Peter Levitas, *Post-Actavis, Pay-for-Delay Debate is Far from Over*, LAW 360 (December 18, 2013), https://files.arnoldporter.com/post%20actavis%20pay%20for%20delay%20debate%20is%20far%20from%20over_law360.pdf; see also FELDMAN & FRONDORF, *supra* note 1 at 46 (citing cases that indicate there was “no doubt that the guidance in *Actavis* [was] being used to scrutinize these settlements heavily”).

8. See FELDMAN & FRONDORF, *supra* note 1, at 24; see generally C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649–52 (2009) [hereinafter “Hemphill, *An Aggregate Approach*”]; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579–80 (2006) [hereinafter “Hemphill, *Paying for Delay*”].

attach to pay-for-delay agreements employing non-monetary payment, as well as to cash payments.⁹

Even before *Actavis*, the rising chorus of complaints prompted Congress in 2003 to require that the text of settlement agreements in litigation between branded and generic companies regarding the manufacture, marketing, or sale of generic drugs must be filed with the Federal Trade Commission (“FTC”) and the Assistant Attorney General at the Antitrust Division of the Department of Justice.¹⁰ Given this provision the FTC now monitors certain pay-for-delay agreements and tracks the trajectory of these agreements on the whole.¹¹

One could easily conclude that the battle has been won, and some policy-makers seem to be leaning in that direction. For example, comments from the FTC paint an optimistic picture.¹² During a workshop hosted by the FTC in late 2017, FTC Chairman Maureen Ohlhausen described pay-for-delay as one of the most problematic issues involving prescription pharmaceuticals, but she noted a few days later that the agency may have “finally started to turn the corner on the issue.”¹³ Similarly, FTC reports have concluded that an increasing number of settlements are being completed without reverse payments at all.¹⁴ For example, the FTC Report on the year

9. See *In re* Loestrin Antitrust Litig., 814 F.3d 538, 550 (1st Cir. 2016).

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

11. See FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAYOFFS COST CONSUMERS BILLIONS 7 (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>.

12. Maureen Ohlhausen, Acting Chairman, U.S. Fed. Trade Comm’n, 2017 ABA Fall Forum: The First Wealth is Health: Protecting Competition in Healthcare Markets (Nov. 16, 2017) at 3 https://www.ftc.gov/system/files/documents/public_statements/1275573/mko_fall_forum_2017.pdf (stating that the FTC may have begun to “turn the corner” on pay-for-delay problems; see also Michael Carrier, *FTC v. Actavis: Where We Stand After 5 Years*, IP WATCHDOG (June 18, 2018), <http://www.ipwatchdog.com/2018/06/18/ftc-v-actavis-stand-5-years/id=98536/> (in which Carrier states that the number of pay for delay settlements has declined since Actavis from 40 to 14 over the 2012–2015 period). But see Towe & Albert, *infra* note 15; Lisa Schencker, *Pay-for-Delay Deals Protected Branded Drugs are Falling*, MODERN HEALTHCARE (Jan. 14, 2016), <https://www.modernhealthcare.com/article/20160114/NEWS/160119926> (quoting FTC Director Debbie Fensterstein saying “it is too soon to know if these are lasting trends,” and expert Lisl Dunlop saying “The focus on pay-for-delay has forced the drug companies to be more creative.”).

13. Svetlana Gans, Chief of Staff, U.S. Fed. Trade Comm’n, Intro and Keynote Remarks at the FTC’s Prescription Drug Workshop, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics, Segment 1: Intro and Keynote Remarks (Nov. 8, 2017); Melissa Lipman, *FTC’s Ohlhausen Sees Light at End of Pay-for-Delay Tunnel*, LAW 360 (Nov. 16, 2017), <https://www.law360.com/articles/986119/ftc-s-ohlhausen-sees-light-at-end-of-pay-for-delay-tunnel> (quoting Chairman Ohlhausen at the American Bar Association Fall Forum on Nov. 16, 2017).

14. See FED. TRADE COMM’N, OVERVIEW OF AGREEMENTS FILED IN FY 2015: A REPORT BY THE BUREAU OF COMPETITION 1 (2017) [hereinafter “FTC SUMMARY 2015”] (noting the continuing decline in the number of “potential” pay-for-delay settlements despite an increasing number of total settlements,

2014 concluded that although more settlements were filed than in any previous years, pharmaceutical companies managed to settle without “any compensation” to the generic company 80 percent of the time.¹⁵

Moreover, the FTC also has reported extremely low numbers of a variant of the pay-for-delay settlement known as a no-authorized generic settlement, which has the effect of ensuring that generics other than the one settling will be deterred from entering the market.¹⁶ The FTC reported only four of these agreements in 2013 and five in 2014, compared to a record high of nineteen no-authorized generic commitments in 2012.¹⁷

Nevertheless, the FTC Commissioner’s suggestion that brand-name drug companies may be “starting to get the message that fending off legitimate patent challenges by paying generics to delay entry will not be tolerated” may be overly optimistic. This article looks closely at the FTC’s evolving terminology, as well as each of the FTC’s reports, and we conclude that there is cause for continued concern. In particular, the number of settlements between brand-name and generic companies increased by roughly 50 percent between 2010 and 2015. Most important, much of the Agency’s cheery rhetoric about these agreements relies on an inability to categorize most of them. Specifically, the majority of the settlements between branded and generic drugs from 2009 to 2015 fall into a nebulous “X” category of agreements in the FTC summary reports—a category that could easily include deals with anticompetitive effects. In fact, across time, the FTC has moved at least one type of agreement from the nebulous X category into a category of concern. Moreover, anecdotal evidence demonstrates that the complexity of these deals can mask troubling

and explaining the lowest ratio of potential pay-for-delay settlements relative to total final settlements since FY 2004).

15. Jamie Towey & Brad Albert, *Is FTC v. Actavis Causing Pharma Companies to Change Their Behavior?*, FED. TRADE COMM’N BLOG (Jan. 13, 2016), <https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharma-companies-change-their>.

16. These agreements are also known as no-AG commitments. Brand-name companies can make generic, unbranded versions of their own drugs to compete against a first generic competitor. The brand-name company can launch its generic at a lower price, and the product would not be subject to generic approval processes since the brand-name company already has FDA approval. Authorized generics, therefore, create a way for a brand-name company to keep to a portion of profits that would otherwise go to the first-to-file generic competitor. A no-AG commitment is a brand-name company’s promise *not* to launch such a product. For a more detailed discussion of no-AG commitments, see FELDMAN & FRONDORF, *supra* note 1, at 60–64.

17. FED. TRADE COMM’N, OVERVIEW OF AGREEMENTS FILED IN FY 2012: A REPORT BY THE BUREAU OF COMPETITION 2 (2013) [hereinafter “FTC SUMMARY 2012”] (reporting nineteen no-AG commitments); FED. TRADE COMM’N, OVERVIEW OF AGREEMENTS FILED IN FY 2013: A REPORT BY THE BUREAU OF COMPETITION 1 (2014) [hereinafter “FTC SUMMARY 2013”] (reporting four no-AG commitments); FED. TRADE COMM’N, OVERVIEW OF AGREEMENTS FILED IN FY 2014: A REPORT BY THE BUREAU OF COMPETITION 1 (2016) [hereinafter “FTC SUMMARY 2014”] (reporting five no-AG commitments).

anticompetitive effects. Given the rise of these highly convoluted deals that defy ready classification, it would be foolhardy to conclude that the entire X category contains only squeaky-clean deals between players who just happen to be competitors.

Other indicators suggest that reports of the demise of pay-for-delay may be premature.¹⁸ Recent settlements individually and collectively have had great impact and have involved the world's top-selling drugs. In addition, FTC pay-for-delay reports to date cover only agreements related to small-molecule drugs, and not to biologics. Given the rapidly burgeoning spend on biologics, the relatively unexamined biologic and biosimilar terrain provides ample new real estate for the pay-for-delay creature to inhabit. In short, like the iconic character in the movie, *Fatal Attraction*,¹⁹ these agreements may still be alive and well, despite any apparent death throes.

This article teases out the current state of pay-for-delay. Part I provides introductory information on the traditional approval pathway for small molecule drugs, the history of pay-for-delay settlements in the pharmaceutical space, and a discussion of the implications of the landmark *FTC v. Actavis* Supreme Court case. Part II explores indicators suggesting that pay-for-delay has not been conquered or even tamed, but simply has found better ways to camouflage itself. In light of this, Part III makes a few limited recommendations for addressing the current state of pay-for-delay agreements.

PART I: INTRODUCTION

Background: The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act, more commonly known as the Hatch-Waxman Act, covers generic entry of drugs into the market.²⁰ The Act, which was passed in 1984, created a pathway for generic drugs to quickly enter and compete with branded drugs, either drugs whose patents have expired or those that have invalid patent protections.²¹

18. On June 2, 1897, Mark Twain was quoted by The New York Times to have said: "the report of my death was an exaggeration." See *On This Day: June 2*, N. Y. TIMES ARCHIVE (June 2, 2008) <https://learning.blogs.nytimes.com/on-this-day/june-2/>.

19. *FATAL ATTRACTION* (Jaffe/Lansing Productions 1987) (fictional movie in which, after the protagonist appears to have vanquished an insane attacker, the attacker rises from the waters of a bathtub, wielding a knife).

20. 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.).

21. See FELDMAN & FRONDORF, *supra* note 1, at 21 & 33; see also Jennifer E. Sturiale, *Hatch-Waxman Patent Litigation and Inter Partes Review: A New Sort of Competition*, 69 ALABAMA L. REV. 59, 63 (2017).

Of greatest importance, the pathway allows the generic to avoid the burden of conducting its own clinical trials. With Hatch-Waxman's abbreviated new drug application ("ANDA") process²², the generic is able to rely on a brand-name drug's existing trials to prove the generic drug's safety and efficacy. If the brand-name drug claims patent protection, the generic applicant must file what is known as a Paragraph IV certification—alleging that the patent(s) listed with the drug in the Orange Book are invalid or would not be infringed by the generic drug—in order to enter the market before the patents expire.²³ The generic company's application under the Act is considered an artificial act of infringement and, as a result, the brand-name company is allowed to sue the generic applicant, even though it has not produced or marketed the allegedly infringing drug or done anything "wrong" per se, thus beginning to turn the wheels of patent infringement litigation against the generic.²⁴ While the expense and risk of litigation is a deterrent to the generic companies, they do not face liability for damages from sales of the product, if the patent is found valid given that they have not actually engaged in any sales.²⁵ Furthermore, the first generic company to file a Paragraph IV certification (also known as the "first-filer") and gain FDA approval for its product is given 180 days of exclusive competition rights along with the brand-name drug.²⁶ This exclusivity period provides an opportunity for the first-filer(s)—and no other subsequent filers—to compete with the branded drug unfettered by other generics.²⁷

Reverse Payment Settlements

Hatch-Waxman's provisions created an environment to encourage the rapid introduction of generic drugs after the expiration of legitimate periods of exclusivity for the brand drug.²⁸ While brand-name companies face up to billions of dollars in development costs for their drugs, they enjoy patent

22. 21 U.S.C. § 355(j) (2012) (allowing for abbreviated new drug applications); 21 U.S.C. §§ 355(j)(2)(A)(i)–(v) (stating that an abbreviated new drug application should contain information to show that several qualities of the generic—including conditions of use, active ingredients, labeling information, and more—have already been approved under another drug).

23. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

24. 21 U.S.C. § 355(j)(5)(B)(iii).

25. See FELDMAN & FRONDORF, *supra* note 1, at 22.

26. 21 U.S.C. § 355(j)(5)(B)(iv). For a discussion of exceptions and stipulations, see FELDMAN & FRONDORF, *supra* note 1, at 39–40.

27. 21 U.S.C. § 355(j)(5)(D)(iii)(II).

28. See FELDMAN & FRONDORF, *supra* note 1, at 21 (citing Wendy H. Schacht & John R. Thomas, CONG. RES. SERV., REPORT R41114, THE HATCH- WAXMAN ACT: A QUARTER CENTURY LATER, at Summary (2011), https://www.everycrsreport.com/files/20120313_R41114_c3d450e3002442e4553739527f3ce5f42e6de67b.pdf; ROBIN FELDMAN, RETHINKING PATENT LAW 159 (Harvard University Press 2012).

protections and FDA-granted exclusivities that allow them usually 20 or more years of marketing exclusivities to recoup their investments. Meanwhile generics were being encouraged to enter the market early with the prospect of exclusive competition rights, all without having to bear those same development costs. Two possible outcomes emerge from the generic's Paragraph IV challenge. If the generic loses, the brand can keep collecting monopoly profits on its blockbuster drug, provided the drug's patents remain unchallenged by other companies.²⁹ However, if the generic wins and the branded drug patents are invalidated, duopoly between the generic drug and the branded drug will begin immediately, potentially costing the brand manufacturer billions of dollars if this happens significantly before the branded drug's patent expires.³⁰ With stakes this high, paying the competition to stay away was a tempting solution.

Pay-for-delay settlements were thus the hazardous byproducts of this situation: a brand-name company drops its patent infringement suit with the generic company (usually the product of Paragraph IV certification), agreeing to make a cash payment to the generic company if the generic stays out of the picture until a specific market entry date.³¹ In other words, if BrandCo can preserve its monopoly over Brand Drug X for several years by paying Generic Inc. \$150 million—dropping the patent infringement lawsuit, and agreeing together on a launch date for the generic drug—why not pursue that?³²

It is important to understand that both the brand-name and generic manufacturer's interests are aligned in this scenario.³³ Besides the obvious ways in which a brand-name company would benefit from this arrangement, pay-for-delay also presents advantages for the generic. A first-filer generic company is able to lock in its 180-day market exclusivity alongside the branded drug, and generally does not have to forfeit this period so long as the settlement does not assign blame to either party or reach a decision on patent validity.³⁴ The icing on the cake is that the generic company usually does not care about its drug's market entry date, so long as its sales are

29. See FELDMAN & FRONDORF, *supra* note 1, at 21 (citing Wendy H. Schacht & John R. Thomas, CONG. RES. SERV., REPORT R41114, THE HATCH- WAXMAN ACT: A QUARTER CENTURY LATER, at Summary (2011), https://www.everycrsreport.com/files/20120313_R41114_c3d450e3002442e4553739527f3ce5f42e6de67b.pdf; ROBIN FELDMAN, RETHINKING PATENT LAW 159 (Harvard University Press 2012).

30. See FELDMAN & FRONDORF, *supra* note 1, at 37.

31. See *id.* at 34–35.

32. See *id.* at 35.

33. See Hemphill, *Paying for Delay*, *supra* note 8, at 1580–81.

34. See Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1, 11 (2013).

unlikely to drop before the branded drug's patent expires and it secures the whole six months of marketing exclusivity alongside the branded drug.³⁵ Moreover, even if the first-filer generic were to withdraw its Paragraph IV certification or lose its infringement case, no other subsequent generic filer can receive the 180-day exclusivity.³⁶ From the first-filer generic company's perspective, it has 180-day exclusivity in its pocket and a cash payment dangling in front of it.³⁷ The delayed entry does not seem so bad.

Yet even if generic and branded drug manufacturers do not feel negative effects, consumers do. Scholars and commentators have documented potential harms from pay-for-delay, and federal antitrust authorities have kept a watchful eye on the practice as well. Economic modeling studies have shown that settlements involving cash payments from patent holders to patent infringers result in lower consumer welfare compared to lawsuits that are litigated to completion.³⁸ Professor Scott Hemphill notes, "privately optimal agreements that impose large negative effects upon nonparties frequently raise antitrust concerns," and that nonparties in pay-for-delay cases are average consumers.³⁹ Whereas settlements without payment reflect the perceived strength of a branded drug's patent, those involving payment induce generic firms to accept later entry dates, transferring wealth from consumers to drug manufacturers in the form of continued high prices of pharmaceuticals.⁴⁰ Meanwhile, brand-name companies share a slice of this transfer with the generic company, benefiting both parties (the brand and the generic manufacturers) at the expense of nonparties (consumers).⁴¹ Hemphill's study of 21 drug settlements involving monetary payment revealed that a one-year delay in generic entry represented a transfer of \$12 billion from consumers to producers, by a conservative estimate.⁴² The average pre-patent-expiration delay for these drugs was 4.1 years, weighted by drug sales.⁴³ In a 2010 report, the FTC estimated that pay-for-delay

35. See Hemphill, *Paying for Delay*, *supra* note 8, at 1590–91.

36. 21 U.S.C. § 355(j)(5)(D)(iii)(II).

37. *Id.*

38. See Hemphill, *Paying for Delay*, *supra* note 8, at 1572.

39. *Id.*

40. See FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAYOFFS COST CONSUMERS BILLIONS 1, 2 & 9 (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> (noting that settlements without payment reflect the strength of the patent, and that pay-for-delay causes consumers to miss out on generics that cost 90 percent less than brand-name drugs).

41. Hemphill, *An Aggregate Approach*, *supra* note 8, at 635–36.

42. *Id.*

43. *Id.* at 650.

settlements cost consumers \$3.5 billion annually.⁴⁴ Another FTC study found that in lawsuits filed with a first generic applicant, the generic prevailed in 73 percent of court decisions, while the brand-name company won in only 27 percent of cases.⁴⁵ So perhaps, if generic drug companies had not settled for delayed entry, they could have won their patent infringement suits and given consumers access to affordable treatments much more quickly. Commentators argue that pay-for-delay's negative effects on consumers constitute violations of antitrust law—specifically a restraint on trade in violation of Section 1 of the Sherman Act—and should be viewed as a form of illegal monopolization.⁴⁶

Supreme Court Decision: FTC v. Actavis

In 2013, the Supreme Court dealt a major blow to traditional pay-for-delay settlements in *FTC v. Actavis*. The case involved drug manufacturers Solvay (an AbbVie predecessor) and Actavis. When Actavis challenged a patent protecting AndroGel (a topical testosterone treatment) set to expire in 2021 and submitted an application for approval of a generic version of the treatment, the brand company sued for patent infringement.⁴⁷ The parties settled the litigation in 2006—after the FDA had approved Actavis' application for generic entry.⁴⁸ The end result of the settlement was that the Actavis generic version of the drug would not be available until 2015.⁴⁹

The 2015 entry date for the generic was still 65 months before AndroGel's original 2020 patent expiration. However, had the company's patent been found invalid, unenforceable, or not infringed, the generic would have entered the market eight to nine years earlier, as early as 2006 or 2007.⁵⁰ In exchange for keeping its generic drug locked away and off the market,

44. See FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAYOFFS 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>.

45. See FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION 16–17 (2002), <https://perma.cc/MF3N-MDMZ>.

46. See Hemphill, *Paying for Delay*, *supra* note 8, at 1596; see also 15 U.S.C. § 2 (2004) (prohibiting monopolization); Hemphill, *An Aggregate Approach*, *supra* note 8, at 636.

47. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013).

48. See Press Release, FTC Sues Drug Companies for Unlawfully Conspiring to Delay the Sale of Generic AndroGel Until 2015, FED. TRADE COMM'N (Feb. 2, 2009), <https://www.ftc.gov/news-events/press-releases/2009/02/ftc-sues-drug-companies-unlawfully-conspiring-delay-sale-generic>; see also Edward Wyatt, *Justices to Look at Deals by Generic and Branded Drug Makers*, N.Y. TIMES (Mar. 24, 2013), <https://www.nytimes.com/2013/03/25/business/generic-brand-name-drug-case-goes-to-supreme-court.html>.

49. See Wyatt, *supra* note 48.

50. *Id.*

Actavis was paid between \$19 and \$30 million annually for each year of delay, totaling hundreds of millions of dollars.⁵¹

The lower courts had dismissed the FTC's complaint, ruling that the agreement was immune to antitrust scrutiny because the parties had not delayed entry beyond the expiration of the last patent.⁵² In particular, the Eleventh Circuit had rejected the FTC's suggestion that in an antitrust pay-for-delay case, antitrust immunity should be breached when a court finds that the patent holder is unlikely to prevail. In response to the suggestion, the circuit court noted, "it is simply not true that an infringement claim that is 'likely' to fail actually will fail."⁵³

The Supreme Court, however, reversed. Justice Breyer writing for the majority, ruled that the FTC's allegations should not have been dismissed and that pay-for-delay settlements are open to antitrust scrutiny.⁵⁴

The fact that this litigation could go forward was a major victory for the FTC. Modern courts had been extremely reluctant to allow antitrust allegations to go forward against patent holders for behavior relating to the enforcement of patent rights.⁵⁵ The Supreme Court's delineation of the test to be applied in evaluating the power of a patent in an antitrust context, however, marked an end to those courts that accorded patents per se enforceability without any real inquiry. Allegations under federal antitrust law generally are tested under the Rule of Reason, a notoriously convoluted test that is expensive to litigate and difficult to win.⁵⁶ Although the *Actavis* Supreme Court opinion denied the FTC's request that reverse payment agreements should be illegal per se and opted instead for a Rule of Reason analysis, the opinion also said this standard was not "to require the courts to insist . . . that the Commission need litigate the patent's validity, empirically

51. *Id.*

52. *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298, 1311 (11th Cir. 2012), *rev'd and remanded sub nom. F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013); *In re AndroGel Antitrust Litig.*, 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

53. *Watson Pharms., Inc.*, 677 F.3d at 1312.

54. *Actavis Inc.*, 133 S. Ct. at 2237.

55. *See id.* (citing *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902); *United States v. Gen. Elec. Co.*, 272 U.S. 476, 485 (1926)).

56. For a discussion of the rule of reason and criticism of it, *see* Robin Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079, 2107–08 (1999) (citing *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 34 (1984) (O'Connor, J., concurring) (comparing the Rule of Reason to the odd form of *per se* rule applied in trying cases and describing both as requiring extensive and time-consuming economic analysis)); *see also* *Cont'l T.V., Inc. v. GTE Sylvania*, 433 U.S. 36, 50 n.16 (1977) (describing Rule of Reason as complex and burdensome on litigants and the judicial system); *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (noting that Rule of Reason analysis requires complicated and prolonged economic investigation into the entire history of an industry and related industries); Robert Pitofsky, *Antitrust in the Next 100 Years*, 75 CALIF. L. REV. 817, 830 n.42 (1987) (explaining that the court refused to apply Rule of Reason given the practical difficulties of the minute inquiry required into economic organization)).

demonstrate the virtues or vices of the patent system, present every possible supporting fact, or refute every possible pro-defense theory.”⁵⁷ The opinion states instead that the size of a reverse payment from a branded company to a generic manufacturer is a “strong indicator” of the brand company’s market power—the power to charge anticompetitive prices.⁵⁸ As indicated above, the Court held that one may be able to assess anticompetitive effects and justifications of a payment without necessarily assessing the validity of the patent, indicating that the scale of an unexplained payment to generic defendants could function as a “surrogate for the patent’s weakness.”⁵⁹

Applying the *Actavis* decision, various courts and commentators have fleshed out an approach for testing pay-for-delay settlements under the Rule of Reason. Many courts have followed traditional antitrust burden-shifting analysis. One such approach delineates what plaintiffs must establish to prove a pay-for-delay arrangement: first, that the plaintiff must prove that the alleged infringer (the generic company) has agreed to abstain from using the patented innovation, and second, that there is an unexplained payment flowing from the patent holder (the brand-name company) to the alleged patent infringer (the generic company). Evaluating whether there is an unexplained payment requires three steps—(1) assessing the value of any compensation flowing from the patentee to the alleged infringer (these can take on non-cash forms, appearing, for example, no-AG agreements);⁶⁰ (2) subtracting from a projected value of litigation costs that the patent holder avoided by pursuing a settlement; and finally (3) subtracting from the value of any goods, services, or other benefits that the alleged infringer transferred

57. *Actavis, Inc.*, 133 S. Ct. at 2237.

58. *Id.* at 2236.

59. *Id.* at 2236–38. Subsequent rulings have used *Actavis*’ rationale when examining the question of patent validity in potential pay-for-delay settlements. *See* *Time Ins. Co. v. AstraZeneca AB*, 52 F. Supp. 3d 705, 709 (E.D. Pa. 2014) (ruling that plaintiffs could assert and prove anticompetitive conduct without litigating the validity of AstraZeneca’s patents during the time of agreements, and could rely on characteristics of the settlements themselves); *but see* *F.T.C. v. Cephalon, Inc.*, 36 F. Supp. 3d 527, 532–37 (E.D. Pa. 2014) (A brand firm found to have engaged in inequitable conduct could not introduce evidence regarding patent validity, enforceability, or infringement.) (“I do not read [*Actavis*]’ language as precluding consideration of the patent, but rather, as offering an alternative to full blown exploration of the patent’s validity within an antitrust trial [ruling].”).

60. Whether or not non-cash deals and no-AG agreements fit within *Actavis*’ definition of payment has been an important source of attention. However, two post-*Actavis* appellate court rulings, and several decisions from lower courts, have answered this question in the affirmative. *See* *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015) (ruling that the *Actavis* holding is not limited to cash reverse payments and that a no-AG agreement is subject to antitrust scrutiny under the Rule of Reason); *see also* *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co.* (*In re* *Loestrin 24 FE Antitrust Litig.*), 814 F.3d 538, 550 (1st Cir. 2016) (vacating and remanding a district court’s decision that non-cash payments did not fall under the scope of *Actavis*, on the grounds that it would “give drug manufacturers carte blanche to negotiate anticompetitive settlements so long as they involve non-cash reverse payments”); *In re* *Impax Laboratories, Inc.*, No. 9373, slip op. at 102 (F.T.C. May 18, 2018) (“[I]t is settled that *Actavis* applies to non-cash payments.”).

to the patent holder (also called “linked transactions”).⁶¹ Any positive net resulting payment—specifically, a payment that is in excess of a payment for the avoided costs of litigation or for another good or service that the generic company provided—is an unexplained payment and can be interpreted as an illegal pay-for-delay deal.⁶² Assessing these values can be an intricate, complex process. Scholars have noted that the onus of parts (1) and (2) above—that is to say, the burden of valuing the payments net of avoided litigation costs and proving that such payments are large—fall on the plaintiffs in a pay-for-delay case. In other words, the burden falls on those who want to challenge the agreement. Furthermore, it is no surprise that defendants are incentivized to muddy the settlement with services or features that make it difficult to construe both the direction and magnitude of payments.⁶³ As a result, the documentation of the settlement is often thoroughly cloaked in claims of joint privilege, leaving challengers no real contemporaneous evidence. This makes it incredibly important not to turn a blind eye to the intricate, convoluted patent settlements that could simply serve as disguises for pay-for-delay tactics.

PART II: THE DEMISE OF PAY-FOR-DELAY IS PREMATURELY REPORTED

FTC Summary Reports

Agreements between generic and brand-name companies filed with the FTC are a testament to the obfuscation mentioned above. The Congressional requirement to file generic-brand agreements with the FTC gives the FTC an opportunity to identify and challenge troubling settlements or patterns of settlements between drug makers.⁶⁴ The FTC’s resources are limited, however, and the reports also provide an important source of information for state antitrust enforcers, plaintiff attorneys, and others who could examine or follow up on the information. Unfortunately, the FTC has experienced delays in publishing overviews of the settlements in recent years, releasing the information for 2014 in January 2016.⁶⁵ Similarly, numbers for

61. See Aaron Edlin et al., *Activating Actavis*, 28 ANTITRUST 16, 18 (2013).

62. *Id.*

63. *Id.*

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

65. Press Release, Fed. Trade Comm’n, FTC Report on Drug Patent Settlements Shows Potential Pay-for-Delay Deals Decreased Substantially in the First Year Since Supreme Court’s Actavis Decision, (Jan. 13, 2016), <https://www.ftc.gov/news-events/press-releases/2016/01/ftc-report-drug-patent-settlements-shows-potential-pay-delay>.

agreements executed in calendar year 2015 were not produced until November 2017.⁶⁶ Moreover, examining the Agency's reports from 2009 to 2015, the language used to describe settlements filed under the Act has changed in subtle ways, particularly in the past four to five years. These adjustments in nomenclature reveal much about the changing nature of reverse payment settlements, particularly the difficulty of understanding the anticompetitive effects. Details of the changing nomenclature also reveal that the picture may not be as rosy as one might wish.

By the Numbers

As described above, FTC reports and commentary suggest that the agency may have “finally started to turn the corner on the issue.”⁶⁷ In a recent FTC blog, for example, the FTC concluded that although more settlements between brand-name companies and generics occurred than in any previous year, pharmaceutical companies managed to settle without “any compensation” to the generic company 80 percent of the time.⁶⁸

We will parse the settlement categories in great detail below. Before turning to that, however, we do want to pause to note the overall rise in the number of total settlements across time. That number has risen from just 14 in 2004, to 113 in 2010, and finally to 170 in 2015.⁶⁹ These are rational, profit-making companies—both the generics and the brand-name companies. Why generics enter into these settlements in increasing numbers if they are receiving no benefit? Why would more and more companies file these suits across time, if they lead nowhere? It is possible that an innocent explanation exists, but the numbers alone suggest that something is happening, even if government actors are unable to unravel it.

66. See *FTC Staff Issues FY 2015 Report on Branded Drug Firms' Patent Settlements with Generic Competitors*, FED. TRADE COMM'N (Nov. 1, 2017), <https://www.ftc.gov/news-events/press-releases/2017/11/ftc-staff-issues-fy-2015-report-branded-drug-firms-patent>. The FTC's fiscal year runs from October 1 to September 30. For example, the FTC report on brand-generic settlements for its fiscal year 2015 refers to agreements filed from October 1, 2014, to September 30, 2015. All references to FTC summary report years are referencing FTC fiscal years. The FTC's reports for 2016 and 2017 are yet to become publicly available, which may speak to the fact that the agreements are becoming increasingly difficult to decipher and document.

67. Svetlana Gans, Chief of Staff, U.S. Fed. Trade Comm'n, Intro and Keynote Remarks at the FTC's Prescription Drug Workshop, Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics, Segment 1: Intro and Keynote Remarks (Nov. 8, 2017); Melissa Lipman, *FTC's Ohlhausen Sees Light at End of Pay-for-Delay Tunnel*, LAW 360 (Nov. 16, 2017), <https://www.law360.com/articles/986119/ftc-s-ohlhausen-sees-light-at-end-of-pay-for-delay-tunnel> (quoting Chairman Ohlhausen at the American Bar Association Fall Forum on Nov. 16, 2017).

68. Jamie Towey & Brad Albert, *Is FTC v. Actavis Causing Pharma Companies to Change Their Behavior?*, FED. TRADE COMM'N BLOG (Jan. 13, 2016), <https://www.ftc.gov/news-events/blogs/competition-matters/2016/01/ftc-v-actavis-causing-pharma-companies-change-their>.

69. See FTC SUMMARY 2015, *supra* note 14, at 4 (showing total number of final settlements progressing from 14 in 2004 to 170 in 2015).

The Ever-Changing Categories

The FTC's terminology shifted several times in the years between 2009 and 2015. The terminology shifts, and the agency's explanations, demonstrate both an effort to carefully capture camouflaged value transfers and a recognition that such efforts may be falling short. The following section explains each of the shifts. A summary of the categories in each year and the total number of settlements within each category can be found at Appendix A.

The FTC's report in 2009 organized the settlements in a form similar to a branching tree.⁷⁰ The report identified a total of 68 brand-generic final settlement agreements, and the initial branching separated these into agreements containing a restriction on generic entry and agreements with no restriction on generic entry.⁷¹ Only 11 of the 68 final agreements contained no restriction on generic entry, meaning that 83 percent of the 2009 final agreements had a restriction on entry.⁷²

The category of those with restrictions on entry then branched further into those involving some payment to the generic and those involving no payment to the generic.⁷³ The branch of agreements containing payment to the generic branched further into four categories: agreements in which the generic received cash, agreements in which the generic benefitted in the form of some other side deal, agreements in which the brand-name company agreed to refrain from launching an authorized generics, and agreements in which the generic benefitted from both a side deal and from the brand-name company's promise not to launch an authorized generic.⁷⁴

In describing the branch separating 1) agreements with restrictions on entry involving payment to the generic from 2) agreements with restrictions on entry involving no payment to the generic, the 2009 report noted that the term "payments" includes only *explicit* promises by the brand-name company to provide compensation to the generic.⁷⁵ The report acknowledges, however, that "some agreements without explicit compensation may nonetheless provide incentives that could lead to increased profits for one of the parties."⁷⁶ In other words, the agency suspected that additional transfers of benefit, along with their potential

70. FED. TRADE COMM'N, SUMMARY OF AGREEMENTS FILED IN FY 2009: A REPORT BY THE BUREAU OF COMPETITION 2, 3 & 8 (2011) [hereinafter "FTC SUMMARY 2009"].

71. *Id.* at 2.

72. *Id.* at 3.

73. *Id.*

74. *See* FTC SUMMARY 2009, *supra* note 70, at 3–4.

75. *Id.* at 1 n.2.

76. *Id.*

anticompetitive effects, were not being captured. In short, in 2009, some 38 agreements included a restriction on generic entry but no explicit compensation.⁷⁷

From 2010-2012, the FTC's nomenclature changes completely. Rather than the complex branching of 2009, agreements are separated into those that have restrictions on entry and those that have no restriction on entry. Within the category of those that have restriction on entry, the FTC identifies a subcategory of those that constitute "potential pay-for-delay" because they have compensation.⁷⁸ At the end of the day, one can identify three categories in the 2010-2012 reports: 1) no restrictions on entry; 2) restrictions on entry and with compensation that constitutes potential pay-for-delay; and 3) restrictions on entry without explicit compensation.

In the 2013-2015 reports, the FTC creates a new category. In addition to settlements that have restrictions on entry with compensation that constitutes *potential* pay-for-delay, the FTC also has a category for settlements containing restrictions on entry and compensation that constitutes *possible* compensation. The agency explained that with the agreements in the possible compensation category, it was "not immediately obvious" whether the generic patent challenger received compensation through the agreement's provisions. These settlements reside in what may be the darkest corner of the pay-for-delay universe, where determining whether or not the generic has been compensated "requires inquiry into specific marketplace circumstances"—an inquiry that, according to the FTC, is beyond the scope of its summary report.⁷⁹

With the new category, the FTC appears to be attempting to broaden the notion of agreements that could possibly raise concerns about pay-for-delay and its anticompetitive effects. In short, one can identify four categories in the 2013-2015 reports: 1) no restrictions on entry; 2) restrictions on entry and with compensation that constitutes potential pay-for-delay; 3) restrictions on entry and with compensation that constitutes possible pay-for-delay; and 3) restrictions on entry without compensation that constitutes potential or possible pay-for-delay.

77. *Id.* at 5.

78. FED. TRADE COMM'N, SUMMARY OF AGREEMENTS FILED IN FY 2010: A REPORT BY THE BUREAU OF COMPETITION 2 (2011) [hereinafter "FTC SUMMARY 2010"]. This grouping silently abandoned the 2009 notion that agreements (or at least some of the agreements) with compensation should be described as *explicit* compensation. From 2010 onward, the term "explicit" only remains as a negative reference, in that the reports refer to settlements that restrict entry but "contain *no* explicit compensation" (emphasis added). The affirmative references are described as *potential* or *possible* pay-for-delay.

79. FTC SUMMARY 2013, *supra* note 17, at 2.

The Mysterious Category X

In each of the years, one can tease out a category that lies in the interstices of what is specifically called out by the FTC. We refer to this group of settlements as the “X” category. The X category is a mysterious group of agreements that has the “delay” part of pay-for-delay, without an obvious “pay” part, at least not that the FTC can easily determine.

The FTC does not identify what we call category X, nor does the agency name it. Nevertheless, one can see the group each year tucked into the categories that *are* named in the report.

The definition of this X category changes across time, but the concept remains consistent. Each report year has a group of agreements in which the generic agrees to delay entry and for which the FTC is at a loss to find a flow of value. In 2010-2012, this group consisted of agreements that restrict entry but contain no explicit compensation.⁸⁰ In 2013-2015, this group consists of agreements that restrict generic entry but contain no explicit or possible compensation.⁸¹

The size of this X category is striking. Although there were only 66 X category agreements in 2010 that number had risen to 126 by 2015. The number is particularly striking in relation to brand-generic settlements on the whole. X category settlements have consistently constituted the majority of *all* brand-generic final agreements for each of the years from 2009 onward.⁸²

The trend line is worth noting, as well. The X category accounted for close to 56 percent of all settlements in 2009 and 51 percent of settlements in 2013. After the 2013 *Actavis* decision, the number of X category settlements rises to 69 percent in 2014, and 74 percent in 2015.⁸³ In other words, in the most recent report year, nearly three-quarters of the agreements fall into this mysterious X category, in which generic entry is delayed but the FTC cannot identify compensation to the generic.

Of course, it is always possible that generic companies are simply giving up most of the time, agreeing to delay entry without receiving anything in return. As noted above, however, these are rational, profit-

80. FTC SUMMARY 2009, *supra* note 70, at 5; FTC SUMMARY 2010, *supra* note 78, at 1; FED. TRADE COMM’N, SUMMARY OF AGREEMENTS FILED IN FY 2011: A REPORT BY THE BUREAU OF COMPETITION 1 (2012) [hereinafter “FTC SUMMARY 2011”]; FTC SUMMARY 2012, *supra* note 17, at 1.

81. FTC SUMMARY 2013, *supra* note 17, at 2; FTC SUMMARY 2014, *supra* note 17, at 2; FTC SUMMARY 2015, *supra* note 14, at 2.

82. For a table of the different categories of settlements (including X category settlements) and number of total brand-generic settlements from years 2010-2015, *see* Table 1 in Appendix A.

83. *See* FTC SUMMARY 2009, *supra* note 70, at 3 (showing 38 out of 68 total settlements in the X category); FTC SUMMARY 2013, *supra* note 17, at 2 (showing 75 out of 145 X category settlements); FTC SUMMARY 2014, *supra* note 17, at 2 (showing 111 out of 160 “X” category agreements); FTC SUMMARY 2015, *supra* note 14, at 2 (showing 126 out of 170 “X” category agreements).

making companies. Why would generics enter into these settlements in increasing numbers if they are receiving no benefit? Is it possible that the agreements contain provisions that amount to reverse payments, but on their face, are too complicated or obscure to clearly designate as possible or potential pay-for-delay? The restricted generic entry present in these settlements leaves plenty of room for suspicion about that something is afoot. In particular, the jump in X category agreements after the *Actavis* decision could suggest that with the threat of increased antitrust scrutiny, brand-name and generic companies have simply become more adept at camouflaging the agreements.⁸⁴

We still know so little about these X category agreements, including the value of the generic sales restricted or the value of branded drugs involved in these agreements. Something is driving these numbers, and one should be loath to declare victory, absent a clear vision of the cost and benefit flows embedded within. In short, what we cannot see may, indeed, be hurting us.

The Saga of Declining Royalty Structure Agreements:

When an X Category Type Is Reclassified

The saga of declining royalty structure agreements demonstrates that things in the X category are not always entirely innocent. Consider declining royalty structure provisions. With a declining royalty structure provision, the generic is obligated to pay royalties to the brand-name company, but that obligation is decreased or eliminated if the brand launches an authorized generic into the market.⁸⁵ If the brand, on the other hand, chooses to launch its own authorized generic product, the generic company no longer owes royalties, or at least pays reduced royalties.⁸⁶

In 2010, the FTC's discussion of declining royalty structures acknowledged that they "may achieve the same effect as an explicit agreement by the brand not to compete with an authorized generic and, thus, could be characterized as potentially involving pay-for-delay."⁸⁷ Nevertheless, the three royalty agreements were included in the 2010 X category, rather than designated as potential pay-for-delay.⁸⁸

84. See Lisa Schencker, *supra* note 12; see also Ryan Davis, *High Court Pay-for-Delay Ruling to Revamp Drug Patent Deals*, LAW 360 (June 17, 2013), <https://www.law360.com/articles/450736/high-court-pay-for-delay-ruling-to-revamp-drug-patent-deals> (noting that post-*Actavis*, drug companies would feel the need to look more closely at how they structure deals with generic companies in order to avoid the overt appearance of payment for delayed generic entry).

85. FTC SUMMARY 2010, *supra* note 78, at 1.

86. *Id.*

87. *Id.* at 1.

88. *Id.*

In 2013, however, declining royalty agreements moved up in the world of FTC categories. The FTC cited declining royalties as an “example” of the type of agreement in the newly minted category of “possible” compensation.⁸⁹ The point is simply that unknown information may not be harmless. Just as the FTC has come to understand the implications of declining royalty provisions, so may there be other complex provisions whose implications are difficult to discern on their face.

Don't Forget Biologics

Although biologic drugs are not included in the FTC's summary reports, the developing market for biologics has created uncharted and potentially lucrative territory for pay-for-delay. Biologics are derived and manufactured from natural sources such as living microorganisms, plant cells, or animal cells. Biologics are a rapidly growing segment of the pharmaceutical market. Spending on biologics grew 13 percent in 2016 and grew more than 10 percent annually for the preceding five years, corresponding to an upsurge in biologic remedies for autoimmune disorders and cancer.⁹⁰ Biologics and biosimilars often fall within a subset of medicines referred to as “specialty drugs”, which generally cost more than traditional drugs and may be used to treat less common diseases.⁹¹

Although biologics represented less than one percent of prescriptions in the country, they accounted for 28 percent of prescription drug spending in 2015.⁹² Biologics also accounted for 40 percent of prescription drug spending and 70 percent of prescription drug spending growth over the 2010 to 2015 period.⁹³

Copies of small molecule drugs are called generics. The system for rapid entry of generics is governed by the Hatch-Waxman Act. In contrast, copies of biologic drugs are called “biosimilars” or “interchangeables” and the system for their entry is governed by the Biologic Price Competition and

89. FTC SUMMARY 2013, *supra* note 17, at 2. In 2010, the FTC described declining royalty structures as “provisions that may provide implicit compensation to the generic in order to agree to a restriction on entry.” FTC SUMMARY 2010, *supra* note 78, at 1.

90. See IQVIA INSTITUTE, MEDICINES USE AND SPENDING IN THE U.S.: A REVIEW OF 2016 AND OUTLOOK TO 2021, 11 (2017), https://structurecms-staging-psyclone.netdna-ssl.com/client_assets/dwonk/media/attachments/590c6aa0/6970/2d2d/4182/0000/590c6aa069702d2d41820000.pdf?1493985952.

91. See MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 427 n.37 (2017).

92. Ameet Sarpatwari et al., *Progress and Hurdles for Follow-On Biologics*, 372 N. ENG. J. MED. 2380, 2380 (2015).

93. Michelle Hoffman, *Biosimilars: The Cure for Sky-High Prices or a Stake in the Heart of Innovation?*, STAT NEWS (Feb. 8, 2018), <https://www.statnews.com/2018/02/08/biosimilars-biologics-drug-prices-innovation/>.

Innovation Act of 2009 (“Biosimilars Act”), which is part of the Affordable Care Act.⁹⁴ Former President Obama signed the Biosimilar Act into law in 2010.⁹⁵ Under the Act, biosimilars are copies of the original biologic that are deemed “highly similar” in safety, purity, and potency and that bear “no clinically meaningful differences” to the original product.⁹⁶ Although biosimilars have been approved in Europe for more than a decade, the FDA only approved the first U.S. biosimilar in 2015 and had only approved four until 2017, when the number of approved biosimilars more than doubled.⁹⁷

Biosimilars present an especially compelling alternative given the upward trajectory of biologic drugs, which have seen spending grow over 10 percent annually for the past five years and 16 percent in 2016.⁹⁸ U.S. Biosimilars have been estimated to result in cost savings of \$25 billion from 2009 to 2019, which included \$5.9 billion in savings for the U.S. government.⁹⁹ Another analysis estimates that biosimilars could reduce spending on biologic drugs by up to \$54 billion over the next eight years.¹⁰⁰

As noted above, unlike the regulatory approval by new drug application for traditional small-molecule drugs, the Biosimilars Act created an abbreviated approval pathway for biosimilars (§ 351(k)) that is analogous to the Hatch-Waxman pathway for generic drugs.¹⁰¹ The complex framework

94. Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. § 7001 (2010).

95. *Id.*; FOOD & DRUG ADMIN., *Implementation of the Biologics Price Competition and Innovation Act of 2009*, <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/ucm215089.htm> (last visited Aug. 8, 2018). The first biosimilar to be approved in the U.S. was a drug called Zarxio in 2015, made by Sandoz (a division of Novartis). See FOOD & DRUG ADMIN. CTR. FOR DRUG EVALUATION & RESEARCH, *Approval Package for Application Number 125553Orig1s000*, (Mar. 6, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125553Orig1s000Approv.pdf; FDA Approves First Biosimilar Zarxio from Sandoz, SANDOZ (Mar. 6, 2015), <https://www.sandoz.com/news/media-releases/fda-approves-first-biosimilar-zarxiotm-filgrastim-sndz-sandoz>; Sabrina Tavernise & Andrew Pollack, *FDA Approves Zarxio, Its First Biosimilar Drug*, N.Y. TIMES (Mar. 6, 2015) <https://www.nytimes.com/2015/03/07/health/fda-approves-zarxio-first-biosimilar-drug.html>.

96. 42 U.S.C. § 262(i)(2) (2017); FOOD & DRUG ADMIN CTR. FOR DRUG EVALUATION & RESEARCH, *ADVANCING HEALTH THROUGH INNOVATION: 2017 NEW DRUG THERAPY APPROVALS 21* (2017) (listing five biosimilar drugs under “additional approvals”).

97. See *Update 2: Novartis Wins Approval for First U.S. Biosimilar Drug*, REUTERS (Mar. 6, 2015), <https://in.reuters.com/article/health-biosimilars-novartis/update-2-novartis-wins-approval-for-first-u-s-biosimilar-drug-idINL5N0W82UZ20150306>; Jacob F. Siegel & Irena Royzman, *U.S. Biosimilar Approvals Soar in 2017*, BIOLOGICS BLOG (Dec. 18, 2017), <https://www.biologicsblog.com/us-biosimilar-approvals-soar-in-2017>; see also Norman R. Augustine et al., *Making Medicines Affordable: A National Imperative*, NAT’L ACADEMIES OF SCI., ENG’G, AND MED. 82 (2017),

98. See IQVIA INSTITUTE, *supra* note 90, at 11.

99. See Augustine et al., *supra* note 97, at 82 (citing CONGRESSIONAL BUDGET OFFICE, CONGRESSIONAL BUDGET OFFICE COST ESTIMATE: BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2007 (2008)).

100. See Hoffman, *supra* note 93 (citing Andrew W. Mulcahy et al., *Biosimilar Cost Savings in the United States*, RAND CORP. 1, 10 & 16 (2017)).

101. See *id.* (citing 42 U.S.C.S. § 262 (LEXIS through PL 115-277, approved Nov. 3, 2018)).

of the Biologics Act, however, is different from that of the Hatch-Waxman Act. Key differences between the approval pathways for small-molecule/generic drugs and biologic/biosimilar drugs include the following:

- **Interchangeability:** A biosimilar designation does not necessarily imply that the drug is interchangeable with the reference drug. The Biosimilars Act requirements for interchangeability are more stringent than for biosimilarity, so not all biosimilars can be swapped out for reference biologic drugs at the pharmacy.¹⁰² Hatch-Waxman, on the other hand, ensures that all approved generic products are interchangeable with the reference product.
- **Patent linkage:** Under the Hatch-Waxman pathway, challenging a brand-name drug's patent through Paragraph IV certification will trigger a 30-month stay on FDA approval. For biosimilars, there are no patent linkages—the processes for resolving patent disputes are entirely independent of FDA approval.¹⁰³
- **Development costs:** Biologics are often costlier to develop than small-molecule drugs.¹⁰⁴ Recent estimates suggest the average cost of developing a small-molecule drug is \$800 million, compared to a \$2 billion average for biologic

102. 42 U.S.C. § 262(k)(4)(A)(i–ii)(LEXIS through PL 115-277, approved Nov. 3, 2018); *see also* FOOD & DRUG ADMIN., SCIENTIFIC CONSIDERATIONS IN DEMONSTRATING BIOSIMILARITY TO A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY (2015), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf>; FOOD & DRUG ADMIN., DEMONSTRATING INTERCHANGEABILITY WITH A REFERENCE PRODUCT: GUIDANCE FOR INDUSTRY (2017), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537135.pdf>; *see also* Fiona Scott Morton & Lysle T. Boller, *Enabling Competition in the Pharmaceutical Markets*, HUTCHINS CTR. ON FISCAL & MONETARY POL'Y AT BROOKINGS 9 (2017).

103. Video Interview with Scott Lassman, *The BPCIA Versus Hatch-Waxman Litigation*, THE CTR FOR BIOSIMILARS (Mar. 7, 2018).

104. Denis Kent et al., *Disruption and Maturity: The Next Phase of Biologics*, QUINTILESIMS 17 (2018) (“Development costs are higher [for biologics] than for small molecules due to greater clinical trial requirements, requirement for larger and more sophisticated manufacturing facilities, promotional activity, and drawn out expensive patent litigation lawsuits.”); *see also* Lim, *supra* note 5, at 210 (referencing a traditional rheumatoid arthritis treatment that costs \$300 annually, while its biologic analog costs \$200,000); Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 471–72 (2013) (stating that making a “sufficiently uniform product” is a complicated and costly process, and that the steep learning curve can give larger pharmaceutical companies with more manufacturing experience a cost advantage in the production of biologic and biosimilar drugs); Eric Palmer, *Conquering the Complexities of Biologics to Get to Biosimilars*, FIERCEPHARMA (Mar. 26, 2013), <https://www.fiercepharma.com/regulatory/conquering-complexities-of-biologics-to-get-to-biosimilars> (explaining that the increased molecular complexity of biologics necessitates a higher level of precision than with small-molecule drugs and expertise across many disciplines, bringing manufacturing costs up).

products.¹⁰⁵ Accordingly, one may predict that the significant price drops that accompany market entry of multiple generic small-molecule drugs, will not precisely mirror the effect of multiple biosimilar drugs' market entry.¹⁰⁶

- **Exclusivity periods:** The Biosimilars Act affords reference biologic drugs a 12-year data exclusivity period, during which time any approval of a biosimilar application referencing that product cannot be effective.¹⁰⁷ The Biosimilars Act also allows the first product that is found to be *interchangeable* with the reference product to have one full year of exclusivity. The first-to-file biosimilar is not afforded this same exclusivity, nor does it receive the 180-day exclusivity that first-filers of small-molecule generic drugs are given in the Hatch-Waxman pathway.¹⁰⁸

Many factors suggest that the road to biosimilar success is not an easy one. Differences between the two approval pathways have led some to predict that competition between biologic and biosimilar drugs will follow the strategic game-playing observed between small-molecule branded and generic drugs. The antitrust implication of that prediction is that pay-for-

105. See Lim, *supra* note 5, at 210. There are a few reasons for this. The lower cost for generic small molecule drugs compared to biosimilars is partly thanks to the Hatch-Waxman Act, which allows generics to prove bioequivalence to the branded drug in lieu of conducting expensive, time-consuming clinical trials. Biologic drugs are also made of complex molecules that are “hundreds of times the size” of traditional drugs, which makes them costly and difficult to replicate. See *Going Large*, THE ECONOMIST (Dec. 30, 2014) <https://www.economist.com/business/2014/12/30/going-large>; Carrier & Minniti III, *supra* note 5, at 3; Kirke M. Hasson & Maria Salgado, *Biosimilars Enter the Courts: How Will Patent Infringements Settlements Be Tested for Validity Under Antitrust Laws?*, THE ANTITRUST SOURCE 1 (2016) (citing Henry G. Grabowski, *Regulatory and Cost Barriers Are Likely to Limit Biosimilar Development and Expected Savings in the Near Future*, 33 HEALTH AFF. 1048, 1050 (2014)).

106. See Richard Mortimer et al., *Will “Biosimilar” Medications Reduce the Cost of Biologic Drugs?*, SCIENTIFIC AMERICAN BLOG (Mar. 9, 2017), <https://blogs.scientificamerican.com/guest-blog/will-biosimilar-medications-reduce-the-cost-of-biologic-drugs/> (describing reasons that economic effects and penetration rates of biosimilars may be diminished compared to those of generic small-molecule drugs, including costly and lengthy phase III trials that are part of the approval process and biosimilar manufacturers' interest in sales and manufacturing in the absence of automatic substitution, rather than price discounts).

107. FDA, *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, FOOD & DRUG ADMIN., <https://www.fda.gov/downloads/drugs/guidances/ucm444661.pdf> (last visited Oct. 16, 2018); see also FDA, GUIDANCE FOR INDUSTRY: REFERENCE PRODUCT EXCLUSIVITY FOR BIOLOGICAL PRODUCTS FILED UNDER SECTION 351(A) OF THE PHS ACT (2014). Notably, Hatch-Waxman also affords reference drugs various other forms of non-patent exclusivities (such as a five-year new chemical entity marketing exclusivity, a three-year new clinical studies exclusivity, and a seven-year orphan drug exclusivity). Overall, there are 13 different forms of non-patent exclusivities for new drugs. See FELDMAN & FRONDORF, *supra* note 1, at 33.

108. See Carrier & Minniti III, *supra* note 5, at 15–16.

delay settlements may be less likely in the biologic arena.¹⁰⁹ Scholars argue that navigating the issue of interchangeability and the exorbitant costs of product development may dissuade drug companies from even attempting to jump over these hurdles to enter the market and launch their own biosimilars.¹¹⁰ Some even claim that the race in the biologics space resembles brand-to-brand competition more than anything else.¹¹¹ An additional issue cited is physician reluctance to substitute a reference drug with another that has not been deemed completely interchangeable with the original, or hesitance to prescribe an alternative that they feel may not have identical effects or efficacy rates.¹¹²

Apart from this, some scholars interpret differences in the two approval pathways as disincentives to biosimilar market entry in the first place or believe that reverse payment settlements in the biologic space would not have as much impact as in the traditional branded drug setting.¹¹³ Specific reasons cited include relatively modest economic effects of biosimilar entry on biologic sales, extensive advantages for reference biologics, and the increased use of *inter partes review* (“IPR”) proceedings.¹¹⁴ After all, how much market share can a biosimilar drug snatch away from a reference drug when it has to wait 12 years to enter the market, spend hundreds of millions of dollars on clinical trials, and compete with all other biosimilars for consumers without any guarantee that it can be substituted at the pharmacy or that a doctor will prescribe it?

Nevertheless, there is reason to believe that pay-for-delay settlements may still make an appearance in biologic drugs in a manner that raises competition concerns. First, although biosimilars will encounter hurdles to market entry, other factors point to the likelihood that biosimilars will soon

109. *See generally id.* at 4, 21–24.

110. Jared S. Hopkins, *What’s Harder Than Making Copycat Biotech Drugs? Selling Them*, BLOOMBERG (Aug. 15, 2017), <https://www.bloomberg.com/news/articles/2017-08-15/what-s-harder-than-making-copycat-biotech-drugs-selling-them> (citing doctor and patient loyalty to innovative drugs that work well, insurance payors caution in adopting new alternatives, and lack of interchangeability).

111. Erin Mershon, *As the Drug Industry Eyes the Burgeoning Biosimilar Market, its United Front is Starting to Crack*, STAT NEWS (June 25, 2018), <https://www.statnews.com/2018/06/25/biosimilars-drug-industry-washington/> (quoting Kurt Karst describing competition between biologics and biosimilars a “brand to brand paradigm”).

112. Andrew W. Mulcahy et al., *Biosimilar Cost Savings in the United States*, RAND CORP. 13 (2017) (citing Elaine Nguyen et al., *Impact of Non-Medical Switching on Clinical and Economic Outcomes, Resource Utilization and Medication-Taking Behavior: A Systematic Literature Review*, 32 CURRENT MED. RESEARCH & OPINION (2016)); Hoffman, *supra* note 93 (claiming that U.S. physicians place a high value on certainty of drugs and would “balk” at the use of biosimilars in “critical no-fail areas”).

113. *See* Hasson & Salgado, *supra* note 105, at 5; *see also* Carrier & Minniti III, *supra* note 5, at 1–2, 19 & 21–24.

114. *See* Carrier & Minniti III, *supra* note 5, at 21–22 (citing 35 U.S.C. § 311 (2012)).

jump into the ring alongside the original biologic drugs. The U.S. biologic and biosimilar landscape faces what some call a “patent cliff 2.0,” in which patent losses for blockbuster drugs put pressure on large pharmaceutical companies to somehow retain exclusivity or major portions of their market share.¹¹⁵ A recent estimate suggested that 45 percent of the sales at risk looking forward from 2017 is for biologics.¹¹⁶ Other estimates say that the U.S. holds the majority of biosimilar potential across the world almost 60 percent of global biologic sales came from the U.S.¹¹⁷ Given that biologics are extremely lucrative, makers of reference biologics have strong incentives to try to retain portions of their monopoly rents.

Further, commentators have predicted that over time, the costs of developing a biosimilar will go down as a result of technological advances.¹¹⁸ Others have noted that while well-established biologic manufacturers have economies of scale working in their favor, biosimilar manufacturers may be able to use their newer technologies or innovative methods to bring down manufacturing, thereby decreasing prices for their products.¹¹⁹ Thus, although biologics and biosimilars do not have as high of a price differential as branded and generic small-molecule drugs, the differential is predicted to widen as the cost of making copycat versions of reference drugs decreases and interchangeable biologics replace biosimilars as a predominant alternative.¹²⁰ Importantly, interchangeable status connotes a full-year exclusivity period alongside the reference biologic, as mentioned above. If more biosimilar drugs become interchangeable with reference biologics, reference companies may be threatened by the prospect of direct substitution and may be incentivized to settle patent infringement litigation, pay off biosimilar companies, and delay the biosimilar’s launch.¹²¹ In short, several factors have the potential to promote the widespread use of biosimilars: shrinking price differentials due to lower development costs;

115. See Eric Sagonowsky, *Big Pharma Faces \$26.5B in Losses this Year as Next Big Patent Cliff Looms, Analyst Says*, FIERCEPHARMA (Apr. 21, 2017), <https://www.fiercepharma.com/pharma/big-pharma-faces-26-5b-patent-loss-threats-year-analyst-says>; see also Kent et al., *supra* note 104, at 16 (noting that an estimated 6 out of 20 biologics have lost exclusivity in the U.S. and that this was projected to increase to 15 out of 20 by the year 2020).

116. See Sagonowsky, *supra* note 115.

117. See Kent et al., *supra* note 104, at 21.

118. See Lim, *supra* note 5, at 215–16.

119. Blackstone & Fuhr, *supra* note 104, at 473.

120. James Forsyth & Cameron McClearn, *Five Barriers that Could Keep Biosimilar Manufacturers from Cracking the U.S. Market*, DELOITTE BLOG (June 22, 2018), <http://blogs.deloitte.com/centerforhealthsolutions/five-barriers-that-could-keep-biosimilar-manufacturers-from-cracking-the-us-market/> (noting that while a generic drug might cost 70 percent lower than the brand, biosimilars cannot offer the same price difference compared to the originator); see also Lim, *supra* note 5, at 215–16.

121. See Lim, *supra* note 5, at 216.

easier pathways to achieving “interchangeable” status from the FDA; health plans or buyer institutions mandating use; and increased prescriber or patient education leading to greater acceptance are just a few.¹²² If any or several of these factors gain traction, the possibility of paying a biosimilar to stay off the market will become increasingly tempting for biologic manufacturers.

Apart from the increased uptake of biosimilars, other factors lend credence to the possibility of pay-for-delay. Until now, settlements under the Biosimilars Act did not have to be reported to the FTC, a striking contrast to the reporting requirements for settlements under the Hatch-Waxman Act for rapid entry of generic drugs. This left room for highly opaque settlements that could contain strategic anticompetitive behavior.¹²³

In October of 2018, President Trump signed into law an amendment that would require certain settlements under the Biosimilars Act to be reported. The Amendment, however, only requires certain types of settlements to be reported, leaving plenty of room for settling without incurring a reporting requirement. Under the Biosimilars Act, after the biosimilar company files for approval, the brand company has 60 days to provide a list of patents it believes will be infringed, and the biosimilar applicant has another 60 days to respond. Only certain of those responses would trigger a settlement reporting obligation. In other words, if the parties choose to settle, or enter into complex side agreements before the 120-day clock runs down, there will be no reporting obligation.¹²⁴ Once again, this leaves room for opaque settlements and strategic behavior in the biologic space. For example, commentators have suggested that one of the Humira settlements would not have triggered reporting requirements under the 2018 Amendments.¹²⁵

Finally, creating a biologic is a much more complicated process than creating a small molecule drug.¹²⁶ Therefore, there are more steps to patent, creating opportunities for large walls of patents. The sheer breadth of the

122. See *id.*; Mulcahy et al., *supra* note 112; Fiona Scott Morton et al., *The Impact of the Entry of Biosimilars: Evidence from Europe* (Harvard Bus. Sch., Working Paper No. 16-141, 2016), <https://doi.org/10.1007/s11151-018-9630-3>; Kent et al., *supra* note 104, at 21 (stating that PBMs have been outspoken in saying they want to use biosimilars).

123. Lim, *supra* note 5, at 216 (citing Darren S. Tucker & Gregory F. Wells, *Emerging Competition Issues Involving Follow-On Biologics*, 29 ANTITRUST MAGAZINE 100 (2014)).

124. See Limin Zheng, *How Will Trump's New FTC/DOJ Reporting Requirements Impact Biosimilars?*, BIOSIMILAR DEVELOPMENT (Nov. 13, 2018), https://www.gcalaw.com/wp-content/uploads/2018/11/article_how-will-trump-s-new.pdf (describing the “patent dance” under the Biosimilars Act, what is known as Paragraph 3(B)(ii)(I) statements, and the fact that only certain settlements must be reported following the 2018 amendments).

125. See *id.* See also text accompanying *infra* notes 148-153 (describing the Humira settlements in general).

126. See Kent et al., *supra* note 104, at 18 (describing complexity in the structure of biologic drugs).

patent walls, along with the complexity created by the number of patents involved, invites the type of elaborate settlements that can mask transfers of value and result in pay-for-delay.

The challenges to biosimilars and the disincentives in the Biologics Act are real. Under the current system, biosimilars and interchangeables may never provide the same price benefit as generics and therefore may never pose the same threat. Nevertheless, the dollars at stake in the biologics market create incentives to develop strategic behavior to limit or delay competition. The examples outlined in the section below suggest that pay-for-delay is, indeed, making its way into the biologics market.

A Sampling of Recent Pay-for-Delay Agreements: No Wonder These are Difficult to Detect and Interpret

The modern era of pay-for-delay agreements bears little resemblance to its earlier predecessors. The agreements may be more cleverly disguised, and they often incorporate complex side-deals that are difficult for courts and antitrust authorities to unravel. To understand the challenge of identifying these modern behaviors, this section describes a selection of the modern agreements, along with their strange, counter-intuitive elements.

Under one common side-deal arrangement, the brand-name company overpays the generic for certain services or rights it has transferred to the brand. These services are woven into the patent infringement settlement. Consider the case involving the drug K-Dur, in which the generic company provided the brand with an unrelated product license.¹²⁷ Why would a generic company give licensing rights for an unrelated product to a brand company—especially when these kinds of services are rarely found outside the context of settlement? As one scholar has noted, the answer may be that the branded company could overstate the value of the generic's contribution and therefore overpay the generic, asserting that the payment was cash consideration for the generic's contribution, rather than for delay (which was also part of the settlement).¹²⁸ Drugs including Naprelan, Provigil, and Adderall XR all involved similar product or patent licensing provisions, demonstrating the growing popularity of such arrangements in pay-for-delay.¹²⁹

Recent patent settlements involving the drug Cialis also illustrate how resolutions between parties involved in patent litigation have evolved to

127. See Hemphill, *An Aggregate Approach*, *supra* note 8, at 664–65.

128. See *id.* at 663.

129. See *id.* at 664 n.140.

disguise potentially anticompetitive effects in complex, hard-to-detect ways. The basic Cialis patent was slated to expire in November 2017. Lilly, the drug's manufacturer, asserted a patent that was set to expire in 2020, and ultimately reached a patent settlement with several competing companies (including Aurobindo, Teva Pharmaceutical, Alembic, Watson, Sun Pharmaceutical, and Synthron) who had contested it. The settlement extended the drug's basic patent lifespan by almost a year, requiring generic contenders to wait at least until September 2018 to launch their versions of Cialis.¹³⁰ The agreement was not insignificant for Lilly. As the company's second best-selling product, Cialis has generated more than \$17 billion in sales throughout its 14 years of patent protection (from 2003 to 2017). In particular, the drug garnered just under \$1.47 billion in U.S. sales in 2016 and \$1.36 billion in 2017.¹³¹

That agreement, however, was only one piece of a complex web of agreements among rivals in which Cialis played a role. Two years before its 2017 settlement with the generic companies, Lilly granted its rival Sanofi an exclusive license to sell a new generic version of over-the-counter Cialis in 2015.¹³² Why would such an agreement between rivals over a new version of a blockbuster drug be formed? What might be the incentives? The agreement has the potential to create a few effects of great interest to the company and of great concern for competition. First, the agreement could position Lilly for a product hop—a strategy in which a brand-name company makes “new” versions of a drug to shift consumers away from the generic product and prevent it from gaining a foothold in the market.¹³³

For example, generics gain a foothold in the market when doctors prescribe a particular drug and the pharmacist fills the prescription with the cheaper, generic version. Pharmacists can only substitute, however, if the drug is precisely the same—including dosage, delivery system, everything. If the generic is a 20 mg formulation, and the doctor writes a prescription for the patient to take 40 mgs, the pharmacist cannot automatically substitute a generic and just instruct the patient to take two pills a day. Thus, companies

130. Eric Sagonowsky, *Lilly Fends Off Cialis Generics with New Patent Settlement*, FIERCEPHARMA (July 13, 2017), <https://www.fiercepharma.com/pharma/lilly-fends-off-cialis-generics-for-another-9-months-new-patent-settlement>.

131. Eli Lilly, Annual Report (Form 10-K) 17 (Feb. 21, 2017); Eli Lilly, Annual Report (Form 10-K) 17 (Feb. 20, 2018).

132. *Sanofi and Lilly Announce Licensing Agreement for Cialis (tadalafil) OTC*, ELI LILLY (May 28, 2014), <https://investor.lilly.com/news-releases/news-release-details/sanofi-and-lilly-announce-licensing-agreement-cialisr-tadalafil>.

133. See FELDMAN & FRONDORF, *supra* note 1, at 66–67 (citing HERBERT HOVENKAMP ET AL., *IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW* § 12.5 (1st ed. 2002) (discussing and naming the phenomenon “product hopping”)).

can make it more difficult for generics to enter the market by making slight shifts in the drug's formulation, dosage or delivery system.

With a product hop, the brand-name drug may put out a "new, improved version" of the drug, marketing the new version heavily to doctors so that pharmacists cannot automatically substitute the generic. In a similar vein, a company facing generic competition could choose to move its drug to over-the-counter. With an over-the-counter drug, there is no prescription written, and there will be no automatic substitution for the generic, which must go back and gain approval for over-the-counter. Even when both drugs are on the shelves, patients may end up choosing the brand-name drug, particularly if it is being marketed as "new, and improved." In this manner, the brand-name company can hold onto more of its market share as the generic comes to market.

Second, when generic rivals come to market, a brand-name company can hold onto some of its market share by introducing its own generic version, or authorizing someone else to provide a generic version. Such "authorized generics" do not need separate FDA approval because the brand-name company already has FDA approval to make the drug or license others to make it. By giving another company authorization to make a generic version of its drug, and an over-the-counter version at that, the brand-name maker of Cialis might be able to discourage generics from entering the market. At the very least, the brand-name company has better leverage in any pay-for-delay negotiations with generics, and it may be able to better retain some of its market share when those generics eventually enter.

In this case, however, Lilly has given a rival brand-name drug company—Sanofi—the exclusive license on the "new" version of the product. When rivals enter an agreement such as this, the situation may be more nuanced. Although one cannot know the effects of the agreement without knowing the undisclosed details, such an agreement could operate in a number of troubling ways. In particular, the two brand-name companies could have decided to work together in holding off generics, sharing the resulting spoils. Lilly could be telling Sanofi the following: You do the over-the-counter version.¹³⁴ If we choose to launch our own authorized generic prescription version, you will still have room in the over-the-counter market. Together, we can dominate both the over-the-counter market and the prescription market. This has the advantages of a product hop to over-the-

134. See Peter Loftus, *Lilly Strikes Licensing Deal with Sanofi for Over-the-Counter Cialis*, WALL ST. JOURNAL (May 28, 2014), <https://www.wsj.com/articles/lilly-strikes-licensing-deal-with-sanofi-for-over-the-counter-cialis-1401244689?ns=prod/accounts-wsj> (quoting the head of Lilly's biomedicines unit, who said that Lilly chose to strike a deal with Sanofi to market OTC Cialis in an effort to focus on patented prescription drugs, as well as for Sanofi's global OTC business and its track record of switching prescription drugs to OTC).

counter in a way that preserves a flow of return for the brand company from both the over-the-counter version and the prescription version. Such bifurcation of the market may be particularly useful in the erectile-dysfunction market, given that certain strengths of the drug may be most appropriate for over-the-counter use.¹³⁵

Later generic entrants could be discouraged from entry. Not only would they have to face the brand company making its own authorized generic, they would also have to face an over-the-counter threat. The lingering disincentive of such an agreement puts Lilly in a better position in negotiating settlement agreements with the generics waiting in the wings.

From another perspective, perhaps FDA approval for over-the-counter Cialis will be difficult to obtain. In that case, Sanofi could choose to wait on the sidelines. The mere existence of the agreement sends an implicit message to later generics: They should be wary of entering the generic Cialis market because at any time, Lilly and Sanofi could cut the legs out from under the generic prescription market by introducing an over-the-counter formulation.

Anticompetitive red flags might be particularly appropriate in this case. The year after the two rivals, Lilly and Sanofi, formed the Cialis agreement, they also entered into a separate agreement in which Lilly agreed to refrain from competing with Sanofi's blockbuster insulin drug Lantus in the U.S. for fifteen months, although it was allowed to enter worldwide.¹³⁶ Thus, among the twisted byways of these multiple agreements, one could imagine that Sanofi may receive value from the fact that Lilly stays out of the highly lucrative U.S. insulin market, and Lilly may receive value from the fact that Sanofi helps with the Cialis generics problem. One has to wonder whether the worldwide market on an erectile dysfunction drug (if not also the insulin market) is being quietly carved up by large players, just when it should be going off patent. While there is no definitive proof that the Cialis deal is a form of collusion among giants, it should certainly give pause to those attempting to understand the current state of affairs in the universe of reverse payments. When giants dance, the ground shakes.

Along with wearing greater camouflage, modern settlements between brand-name and generic companies seem to have great potential economic

135. See Carissa Andrew, *Drug Competition, The Patent Game, and Generic Cialis*, CANADIAN PHARMACY WORLD (Mar. 6, 2017), <https://www.canadianpharmacyworld.com/blog/drug-competition-the-patent-game-and-generic-cialis> (citing an expert in the prescription to over-the-counter switch arena that, "Cialis has a number of dosages, and presumably it would be the lower dose that would be switched").

136. See Press Release, Sanofi-Aventis U.S. LLC, Sanofi Reaches Patent Settlement on Lantus SoloSTAR (Sept. 28, 2015) <http://www.news.sanofi.us/2015-09-28-Sanofi-Reaches-Patent-Settlement-on-Lantus-SoloSTAR>.

impact, shielding remarkably high sales quantities and revenues. For example, pharmaceutical manufacturer Endo's fourth-quarter-company presentation boasts several settlements shielding sales of \$1.2 billion, \$850 million, \$500 million, \$400 million, and \$50 million respectively, per drug. The settlements have confidential terms, but according to the presentation, several others delayed first-to-file generic drug launches until 2020.¹³⁷

The magnitude of these settlements is reflected in the recent history of the drug, Humira. Humira (or adalimumab) is a biologic drug used to treat rheumatoid arthritis and other inflammatory conditions.¹³⁸ It is the world's top-selling brand-name medication.¹³⁹ In 2016, Humira had sales of \$10.4 billion in the U.S. and \$16 billion across the globe. The drug accounted for 63 percent—nearly two-thirds—of its manufacturer AbbVie's \$25.6 billion revenue.¹⁴⁰ In 2017, Humira reached more than \$18 billion in global sales, and AbbVie projects that the number will approach \$21 billion in 2020.¹⁴¹ The medication has been around for more than 15 years, and its initial date of FDA approval in the U.S. dates back to 2002.¹⁴² Humira's main composition patent was set to expire in 2016.¹⁴³

The price of Humira has risen substantially in recent years. Over a three-week period from December 2017 to January 2018, AbbVie raised the list price of the drug 9.7 percent. The increase is estimated to be the costliest spike among the leading pharmaceutical companies for that time frame,

137. ENDO INT'L PLC, Q4 2017 EARNINGS REPORT 9 (Feb. 27, 2018), <http://investor.endo.com/static-files/555658e6-8d3d-4b87-925d-a3d8b2ddd1e1>.

138. See IQVIA INSTITUTE, *supra* note 90, at 34; see also Danny Hakim, *Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.*, N.Y. TIMES (Jan. 6, 2018), <https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html>.

139. IQVIA INSTITUTE, MEDICINES USE AND SPENDING IN THE U.S.: A REVIEW OF 2017 AND OUTLOOK TO 2022, 42 (2018); see also Tamara Mathias, *AbbVie, Samsung, Bioepis in Deal: Humira Biosimilar US Release in 2023*, REUTERS (Apr. 5, 2018), <https://www.reuters.com/article/us-abbvie-biogen/abbvie-samsung-bioepis-in-deal-humira-biosimilar-u-s-release-in-2023-idUSKCN1HC1SP>.

140. See Hakim, *supra* note 138; Lisa Schencker, *AbbVie Protects Blockbuster Drug Humira for 5 Years Through Settlement*, CHICAGO TRIBUNE (Sept. 28, 2017), <http://www.chicagotribune.com/business/ct-biz-abbvie-settles-over-humira-092917-story.html>; Press Release, *AbbVie Reports Full-Year and Fourth-Quarter 2016 Financial Results*, ABBVIE (Jan. 27, 2017), <https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2016-financial-results.htm> (reporting full-year global sales of Humira of \$16.078 billion).

141. Tamara Mathias & Anuron Kumar Mitra, *AbbVie Says Humira Sales Will Balloon to \$21 Billion in 2020, Shares Rise*, REUTERS (Oct. 27, 2017), <https://www.reuters.com/article/us-abbvie-results/abbvie-says-humira-sales-will-balloon-to-21-billion-in-2020-shares-rise-idUSKBN1CW1JK>; Press Release, *AbbVie Reports Third Quarter 2017 Financial Results*, ABBVIE (Oct. 27, 2017), <https://news.abbvie.com/news/abbvie-reports-third-quarter-2017-financial-results.htm>.

142. *FDA Approved Drug Products*, FOOD & DRUG ADMIN. (Dec. 31, 2002), <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=125057> (approving Adalimumab (HUMIRA)); Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG (Sept. 7, 2017), <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug>.

143. Koons, *supra* note 142.

adding approximately \$1.2 billion in costs to the U.S. healthcare system.¹⁴⁴ Over the course of the past five years, Humira's price has more than doubled.¹⁴⁵

It is no surprise that recently, competitor manufacturers have swarmed to the scene like bees to honey—a drug this lucrative with an expiring patent on its main ingredient was ripe for the taking.¹⁴⁶ AbbVie, however, has created a wall of more than 100 patents as a defense against competitors drugs entering the market, going as far as to openly share its aggressive strategy in a company presentation.¹⁴⁷

Despite these preparations, Amgen (the biosimilar company) attempted to enter the market with its version of Humira called Amjevita. Amjevita gained FDA approval in September 2016 but was hit with a patent infringement suit from AbbVie (the biologic company). In *AbbVie Inc. v. Amgen Inc.*, the reference biologic company claimed that the copycat version had infringed upon 61 of Humira's patents, ten of which it decided to litigate.¹⁴⁸ The case ultimately resulted in a settlement agreement that dismissed all pending litigation on the U.S. patents, with AbbVie, the reference drug maker, prohibiting competition in the U.S.¹⁴⁹ The agreement requires the biosimilar company to wait until January 31, 2023, to sell a generic version of Humira in the U.S., despite the fact that the drug's main composition patent was set to expire in 2016.¹⁵⁰ While the financial terms of the settlement are confidential and there is no public language connoting an explicit pay-for-delay agreement, the reference biologic's fortress of patents creates an environment for pay-for-delay. Specifically, the reference company has ample opportunity to pursue patent infringement litigation and

144. Eric Sagonowsky, *Pfizer, Novartis and More Post Price Hikes on Dozens of Drugs, But AbbVie's is Worth the Most*, FIERCEPHARMA (Jan. 4, 2018), <https://www.fiercepharma.com/pharma/drug-price-hikes-a-few-bad-actors-or-widespread-pharma>.

145. *Id.*

146. Koons, *supra* note 142.

147. *Id.*; RICHARD GONZALEZ, *ABBVIE LONG TERM STRATEGY* 14–16 (Oct. 30, 2015), <https://investors.abbvie.com/static-files/af79eef2-5901-4b62-9354-982d2d95404e>.

148. Complaint at 3–4, *AbbVie, Inc. v. Amgen, Inc.*, No. 16-00666 (D. Del. Sept. 28, 2017); Peter Loftus, *AbbVie, Amgen Reach Settlement in Humira Patent Dispute*, WALL ST. JOURNAL (Sept. 28, 2017), <https://www.wsj.com/articles/abbvie-amgen-reach-settlement-in-humira-patent-dispute-1506635070>; *Prescription Drug Pricing: A Public Policy Analysis*, EXPRESS SCRIPTS 1, 3–4 (2018).

149. See Loftus, *supra* note 140; *Prescription Drug Pricing: A Public Policy Analysis*, *supra* note 148; *Amgen and AbbVie Agree to Settlement*, AMGEN (Sept. 28, 2017), <https://www.amgen.com/media/news-releases/2017/09/amgen-and-abbvie-agree-to-settlement-allowing-commercialization-of-amgevita/> (using the phrase “country by country”).

150. *Amgen and AbbVie Agree to Settlement*, AMGEN (Sept. 28, 2017), <https://www.amgen.com/media/news-releases/2017/09/amgen-and-abbvie-agree-to-settlement-allowing-commercialization-of-amgevita/>; Peter Loftus, *AbbVie, Amgen Reach Settlement in Humira Patent Dispute*, WALL ST. JOURNAL (Sept. 28, 2017), <https://www.wsj.com/articles/abbvie-amgen-reach-settlement-in-humira-patent-dispute-1506635070>.

to shield its monopoly in exchange for sharing its rents with the competitors in the form of reverse payments through some form of value exchange. In fact, the reference drug company stated in its complaint that “if and when Amgen provides its 180-day Notice of Commercial Marketing, AbbVie will assert the remainder of the patents.”¹⁵¹ In other words, the company can reach into its arsenal again when competition looms in 2023.

Furthermore, the prospect of a reverse payment settlement involving any other competitor that stands in the way is alive and well. This could be a tempting prospect for smaller companies eager to get a slice of the pie in exchange for delaying a launch.¹⁵² For example, in April 2018, AbbVie announced a second agreement blocking a Humira competitor, saying it signed a deal with Samsung Bioepis to delay the latter’s launch of biosimilar Imraldi until June 30, 2023.¹⁵³ In the same month, a patient advocacy group called on the FTC to investigate the deal, claiming AbbVie was using illegal anticompetitive settlements to prevent cheaper alternatives from coming to market.¹⁵⁴

Despite the FTC’s commitment to challenge reverse payment agreements, it has challenged only a handful in the last decade. The last one the FTC chose to file was an administrative complaint in January 2017 regarding a questionable deal between drug manufacturers Impax and Endo involving the drug Opana.¹⁵⁵ In the complaint, the FTC alleged that the companies had formed an illegal agreement over the drug Opana ER, a brand-name opioid for pain management made by the company Endo. Commissioners stated that the agreement, formed in June 2010, consisted of two different forms of payment to Impax: one was in the form of a no-AG commitment, in which Endo promised not to launch an authorized generic version of its own brand-name product during the Impax generic’s first 180 days on the market, *or* otherwise to pay Impax a cash value reflecting the expected profits from that first period of exclusivity. The second form of payment in the agreement, the FTC asserted, was that Endo paid Impax \$40 million for what was called an “independent development and co-promotion deal,” which “made no business or economic sense for Endo” except in that

151. See Complaint at 4, *AbbVie, Inc. v. Amgen, Inc.*, No. 16-00666 (D. Del. Sept. 28, 2017).

152. Ed Silverman, *AbbVie and Amgen Lock Horns in the Latest Squabble Over Biosimilars*, STAT NEWS (Aug. 8, 2016), <https://www.statnews.com/pharmalot/2016/08/08/abbvie-amgen-biosimilars-patent/>.

153. Mathias, *supra* note 139.

154. *Patient Group Calls for Investigation Into AbbVie’s Abusive Pay-for-Delay Deals*, PATIENTS FOR AFFORDABLE DRUGS (Apr. 19, 2018), <https://www.patientsforaffordabledrugs.org/2018/04/19/patient-group-calls-for-inestigation-into-abbvies-abusive-pay-for-delay-deals/>.

155. See *In re Impax Laboratories, Inc.*, No. 9373, slip. op. at 6 (F.T.C. May 18, 2018).

it convinced Impax to keep its product off the market for more than two years. The FTC alleged that these agreements together constituted \$112 million in reverse payments.¹⁵⁶

An administrative law judge issued an initial decision dismissing the case in May 2018 on the grounds that the magnitude and extent of anticompetitive behavior was somewhat theoretical in that the FTC's argument was based on an inference that Impax would have entered the market before January 2013. The judge ruled that such a launch would have been "at risk," as pending patent litigation between the two companies had not yet been resolved, and that Impax would not have completed an "at risk" launch as it is small company with an "infrequent" history of such launches that would not consider risking the first-filer exclusivity.¹⁵⁷ Based on this, the judge valued the agreement to be worth between only \$33 million and \$43 million. The judge ruled further that the deal's pro-competitive benefits outweighed its anticompetitive aspects, specifically citing a broad licensing agreement (covering the patent at issue and all of Endo's future patents that could potentially affect the Impax drug) contained in the settlement.¹⁵⁸ The FTC has filed a Notice of Appeal on the initial decision and the outcome of the appeal will have important repercussions for future interpretations of deals between brand-name and generic companies.¹⁵⁹

These cases, involving the drugs Cialis, Humira, and Opana ER, demonstrate the complexities that have formed around deals between generics and brand-name companies. Payment flows from plaintiffs to defendants are no longer simply in cash, but take many other forms that ultimately serve the same purpose: blocking generic competition. Simplicity is hardly to be found in the midst of gag clauses, confidential terms, and concealed compensation, making it all the more difficult to track down and curtail this problematic behavior. In the process, consumers are left waiting for life-saving remedies at affordable prices.

156. See Complaint at 2, *In re Impax Laboratories, Inc.*, No. 9373 (F.T.C. May 18, 2018).

157. See *In re Impax Laboratories, Inc.*, slip. op. at 62–63. It is important to note, however, that a no-AG agreement can constitute a form of payment. See FELDMAN & FRONDORF, *supra* note 1, at 61–63.

158. *In re Impax Laboratories, Inc.*, slip. op. at 6–7, 62–67 (explaining reasons for why they would not pursue an at-risk launch); *Id.* at 75 (discussing broad licensing agreement); *Id.* at 114–15 (estimating \$33 million and \$43 million agreement worth). For additional commentary on the decision, see Matthew Perlman, *Impax Case Offers Clues on Pay-for-Delay Under Actavis*, LAW 360 (May 23, 2018), <https://www.law360.com/articles/1046578/impax-dismissal-offers-clues-on-pay-for-delay-under-actavis>.

159. Complaint Counsel's Notice of Appeal, *In re Impax Laboratories, Inc.*, No. 9373 (F.T.C. May 18, 2018); see also *Administrative Law Judge Dismisses FTC Antitrust Complaint Against Generic Pharmaceutical Company Impax Laboratories, Inc.*, FED. TRADE COMM'N (May 24, 2018), <https://www.ftc.gov/news-events/press-releases/2018/05/administrative-law-judge-dismisses-ftc-antitrust-complaint>.

CONCLUSION

Pay-for-delay is not yet over. Rather, it has changed its appearance. This is evidenced by 1) the high numbers of settlements in the mysterious and continually evolving “X” category; 2) the increasing complexity of settlements; and 3) agreements appearing in extraordinarily lucrative drugs in the biologic space. In short, the practice has not ceased, but rather has morphed into something harder to detect yet possibly having more impact than ever. Given these troubling indicators, the evolving landscape of pay-for-delay deserves attention. We offer the following brief thoughts on possible approaches.

As an initial matter, both state and federal regulators need more information in order to understand the nature and impact of the agreements. Mandating disclosure of the names of the companies, the drugs involved in the agreements, and additional details could go a long way towards providing greater transparency, if not greater deterrence. In addition, under the current system, the burden is on federal regulators to ferret out which agreements are problematic and bring actions against the parties. Perhaps one might shift some of this burden by requiring some form of certification in which companies reporting brand-generic agreements must certify under penalty of perjury to issues such as: 1) that there are no unwritten related agreements and 2) any ancillary business agreements were conceived and negotiated prior to settlement talks (along with producing evidence to support the certification). Finally, in competition contexts, one tends to think of penalties as monetary damages. Given the enormous sums involved in blockbuster drugs, the risk of incurring such damages may simply be a cost of doing business. Other types of penalties, however, may have more of a deterrent effect. These could include, limiting a drug company’s ability to file for new drug approvals at the FDA if they have engaged in inappropriate pay-for-delay settlements or limiting the right of lawyers to appear before certain state or federal agencies. Most important, competition authorities at both the state and federal level should engage in extensive investigation of settlements between brand and generic companies. The potential for collusion when competitors shake hands in this way is simply too great.

Key wins such as the FTC’s success in *Actavis* have paved the way for recognizing anticompetitive agreements and for increasing scrutiny of pay-for-delay agreements. These wins are precisely the reason companies have been forced to find newer, more covert ways to incorporate reverse payments into settlements. In challenging settlements over the past decade, the FTC has fought long and hard. Considerably more challenges, however, lie ahead.

APPENDIX A

	2010	2011	2012	2013 [†]	2014	2015
“Potential pay-for-delay”	31	28	40	29	21	14
“Possible compensation” (2013-2015 only)*				10	8	10
“X” category**	66	100	81	75	111	126
“No restrictions on entry”	16	28	19	31	20	20
Total	113	156	140	145	160	170

Numbers from the FTC’s 2009 report are purposely omitted from this table, as the 2009 settlement categories are significantly different than those of the 2010-2015 reports. The 2009 report categorizes a total of 68 final brand-generic agreements as either posing “restriction on generic entry” (57) or “no restriction on generic entry” (11). Of those that involved a restriction, the 2009 report describes these agreements as involving “no payment to the generic”(38), or involving “payment to the generic” (19).¹⁶⁰

*Definition of “possible compensation”: Possible compensation settlements contain a restriction on generic entry, in which “it is not clear from the face of each settlement agreement whether certain provisions act as compensation to the generic patent challenger.” Furthermore, the 2013-2015 reports note, “Analysis of whether there is compensation requires inquiry into specific marketplace circumstances, which lies beyond the scope of this summary report.”¹⁶¹

**Definition of “X” category from 2010 to 2012: Settlements that “restrict the generic manufacturer’s ability to market its product, but contain no explicit compensation.”¹⁶² Definition of “X” category from 2013 to 2015:

160. FTC SUMMARY 2009, *supra* note 70, at 3.

161. FTC SUMMARY 2013, *supra* note 17, at 3; FTC SUMMARY 2014, *supra* note 17, at 1; FTC SUMMARY 2015, *supra* note 14, at 2.

162. FTC SUMMARY 2010, *supra* note 78, at 1; FTC SUMMARY 2011, *supra* note 80, at 1; FTC SUMMARY 2012, *supra* note 17, at 1.

Settlements that “restrict the generic manufacturer’s ability to market its product but contain no explicit or possible compensation.”¹⁶³

† The Supreme Court decided *FTC v. Actavis, Inc.* in June 2013. However, the FTC’s 2013 report notes, “Because this decision came nearly three quarters of the way through FY 2013, there are not yet enough post-*Actavis* settlements to draw meaningful conclusions from the data.”¹⁶⁴

163. FTC SUMMARY 2013, *supra* note 17, at 2; FTC SUMMARY 2014, *supra* note 17, at 2; FTC SUMMARY 2015, *supra* note 14, at 2.

164. FTC SUMMARY 2013, *supra* note 17, at 1