

5-2020

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Pharmaceutical “Pay-for-Delay” Reexamined: A Dwindling Practice or a Persistent Problem?

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The Supreme Court ruled in FTC v. Actavis that a delay in generic entry may be anticompetitive when part of a patent settlement includes a large and otherwise unjustified value transfer to the generic company, termed a reverse payment patent settlement, or “pay-for-delay.” Following Actavis, drug companies have limited the size of reverse payments and have fashioned settlement terms that include more discreet categories of compensation to generic companies. In light of the fact that such settlements retain the potential for anticompetitive effects, the apparent size of the reverse payment may no longer be a useful gauge of the legality of pay-for-delay deals. In this Article, we argue that convoluted settlements in the post-Actavis landscape that camouflage value transfers from brand-name to generic companies necessitate a shift in the focus of antitrust scrutiny to the existence of any restriction on generic entry, together with a category of patent less likely to survive a challenge. We conclude with a discussion of pay-for-delay bills in the 116th Congress and propose several reforms to deter pay-for-delay behavior.

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INTRODUCTION

Reverse payment patent settlements (commonly referred to as “pay-for-delay”) have been used to settle patent litigation between brand-name drug companies and generic manufacturers through a transfer of value from the brand to the generic company, in return for an agreed-upon delay in entry of the generic drug to market.¹ The value transfer may include direct monetary payments or indirect forms of compensation, such as an assurance that the brand company will not enter the market with its own “authorized generic” to compete with the generic first-filer.² In its 2010 report, the Federal Trade Commission (FTC) estimated that pay-for-delay agreements would cost consumers \$35 billion over the next ten years.³ Members of the FTC testified before Congress expressing concern for the “permissive legal treatment” being accorded to pay-for-delay settlements in U.S. courts, and they urged a legislative solution that would end the sharing of monopoly profits between brand and generic companies, with the aim of accelerating access to lower-priced generic drugs.⁴ Unfortunately, nearly ten years later, no such legislation has become law. There is renewed Congressional interest in pay-for-delay, and several bills addressing the matter are being debated in Congress in 2019.⁵

In May 2019, the FTC reported a significant reduction in those pay-for-delay agreements most likely to be anticompetitive based on its most recently released data.⁶ In this Article, we examine the legal standard applied to pay-for-delay settlements in the United States. We argue that pay-for-delay settlements may not be on the decline, as the FTC has claimed, but rather they have evolved to include other categories of value transfer less likely to attract antitrust scrutiny. We conclude with a discussion of pay-for-delay bills under consideration in Congress and offer several policy proposals at the nexus of patent law and antitrust that strike at the heart of the pay-for-delay problem.

1. See, e.g., WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL32377, THE HATCH-WAXMAN ACT: LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS 13 (2004); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1556–1557 (2006).

2. Federal Trade Commission Brief as Amicus Curiae at 7–9, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 (D. N.J. Sept. 13, 2013).

3. FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010).

4. *How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs: Prepared Statement of the Fed. Trade Comm’n Before the Subcomm. on Commerce, Trade, & Consumer Prot. Comm. on Energy & Commerce*, 111th Cong. 4, 7 (2009) (statement of Thomas Rosch, Comm’r, Fed. Trade Comm’n).

5. See *infra* Table 1.

6. Press Release, Fed. Trade Comm’n, FTC Staff Issues FY 2016 Report on Branded Drug Firms’ Patent Settlements with Generic Competitors (May 23, 2019), <https://www.ftc.gov/news-events/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent>.

I. THE LEGAL APPROACH TO PAY-FOR-DELAY SETTLEMENTS

In 2013, the Supreme Court addressed pay-for-delay agreements head-on in *FTC v. Actavis*.⁷ In the case at issue, a brand drug company, Solvay Pharmaceuticals, settled patent infringement litigation in 2006 with several generic drug companies, including Actavis, which sought to market a generic version of Solvay's brand drug AndroGel.⁸ In the settlement, Solvay paid tens of millions of dollars to the generic drug companies in return for a delay in marketing the generic product.⁹ Actavis, in particular, agreed to postpone bringing its generic to market until 2015, nine years after the settlement but prior to the expiration of Solvay's patent.¹⁰ This is a fairly common example of a pay-for-delay settlement.

The Eleventh Circuit affirmed the dismissal of the FTC's complaint and ruled that if the anticompetitive effects of a settlement fell within "the scope of the exclusionary potential of the patent" (meaning in most cases that generic entry was permitted prior to expiration of the patent in question), the settlement would not trigger antitrust scrutiny.¹¹ Reversing the Eleventh Circuit decision, the Supreme Court held that such settlements could not be immunized from antitrust laws simply because the settlements did not extend beyond the original term or earnings potential of the patent.¹² In the majority opinion, Justice Breyer noted the unusual nature of a reverse payment from the brand to the generic company.¹³ Highlighting legal precedent, Justice Breyer underscored the need to consider both patent and antitrust policies in determining the power conferred by a patent and, therefore, in evaluating the legality of patent settlements.¹⁴

The Supreme Court declined to label a pay-for-delay settlement presumptively illegal.¹⁵ Instead, it held that a settlement in which the reverse payment is "large and unjustified" can "bring with it the risk of significant anticompetitive effects" and should be subject to a "rule-of-reason" legal analysis, an approach to antitrust cases that requires a finding of market power, followed by a weighing of procompetitive rationales and anticompetitive effects.¹⁶ According to Justice Breyer, the proper analysis permits consideration of "legitimate justifications" for the terms of the patent settlement.¹⁷ The Court did, however, open the door to a more streamlined version of the rule-of-reason test, noting that trial courts could "structure" the rule-of-reason test to fit varying

7. 570 U.S. 136, 140–41 (2013).

8. *Id.* at 144–45.

9. *Id.* at 145.

10. *Id.*

11. Fed. Trade Comm'n v. Watson Pharm., Inc., 677 F.3d 1298, 1312, 1315 (11th Cir. 2012).

12. *Actavis*, 570 U.S. at 148–49.

13. *Id.* at 147.

14. *Id.* at 148–49.

15. *Id.* at 158–59.

16. *Id.* at 158.

17. *Id.* at 156.

circumstances.¹⁸ The Supreme Court remanded *Actavis* to the lower court, and the last of the drug companies settled in February 2019, accepting a stipulated injunction not to engage in similar reverse payment agreements.¹⁹

While the Court's decision amounted to an important rejection of the Eleventh Circuit's test (which has been called the "scope of the patent" test), and the FTC hailed the decision as a victory for antitrust enforcement, *Actavis* did not categorically prohibit pay-for-delay deals and arguably did not go far enough to address drug companies' dedication to circumventing the rules in their favor. The rule of reason promises a careful assessment but runs the risk that its nuanced approach will amount to leniency. It has attracted criticism for its burdensome complexity and for lacking sufficient focus and discipline to be a highly operative tool of antitrust enforcement.²⁰ As legal scholar Herbert Hovenkamp noted in discussing the limitations of the rule of reason, "unfocused explorations of restraints generally turn up something that appears beneficial; and as long as plaintiffs have the burden of proof, complexity favors defendants."²¹ In the context of pay-for-delay, the courts' attempts at a balanced evaluation may become self-defeating if drug companies veil anticompetitive settlements with procompetitive "window dressing" in order to avoid an antitrust violation.

Factors that Justice Breyer articulated as suggestive of anticompetitive effect (payments large in size and scope relative to litigation costs and independent of services for which a payment might be compensation)²² provide guideposts to detect a potentially unlawful agreement but fall short of clear-cut bright-line rules. Nonetheless, since the Court's decision in *Actavis*, the FTC has brought suit and enforcement action against several pharmaceutical companies, including Impax,²³ Teva,²⁴ and Endo,²⁵ for unlawful pay-for-delay settlements.

18. *Id.* at 159–60; see also Robin Feldman, *Ending Patent Exceptionalism & Structuring the Rule of Reason: The Supreme Court Opens the Door for Both*, 15 MINN. J.L. SCI. & TECH. 61, 74 (2014).

19. Press Release, Fed. Trade Comm'n, Last Remaining Defendant Settles FTC Suit that Led to Landmark Supreme Court Ruling on Drug Company "Reverse Payments" (Feb. 28, 2019), <https://www.ftc.gov/news-events/press-releases/2019/02/last-remaining-defendant-settles-ftc-suit-led-landmark-supreme>.

20. Robin Cooper Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079, 2107–08 (1999).

21. HERBERT HOVENKAMP, *THE ANTITRUST ENTERPRISE: PRINCIPLE AND EXECUTION* 8 (2005).

22. *Actavis*, 570 U.S. at 159.

23. Press Release, Fed. Trade Comm'n, FTC Concludes that Impax Entered into Illegal Pay-for-Delay Agreement (Mar. 29, 2019), <https://www.ftc.gov/news-events/press-releases/2019/03/ftc-concludes-impax-entered-illegal-pay-delay-agreement>.

24. Press Release, Fed. Trade Comm'n, FTC Enters Global Settlement to Resolve Reverse-Payment Charges Against Teva (Feb. 19, 2019), <https://www.ftc.gov/news-events/press-releases/2019/02/ftc-enters-global-settlement-resolve-reverse-payment-charges>.

25. Press Release, Fed. Trade Comm'n, Endo Pharmaceuticals Inc. Agrees to Abandon Anticompetitive Pay-for-Delay Agreements to Settle FTC Charges; FTC Refiles Suits Against Generic Defendants (Jan. 23, 2017), <https://www.ftc.gov/news-events/press-releases/2017/01/endo-pharmaceuticals-inc-agrees-abandon-anticompetitive-pay-delay>.

II. THE EVOLUTION OF PAY-FOR-DELAY AGREEMENTS SINCE *ACTAVIS*

One regulatory response to pay-for-delay has been mandatory reporting of pharmaceutical patent settlements between brand and generic companies in the Hatch-Waxman regulatory system to the FTC and Department of Justice (DOJ) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“Medicare Modernization Act”).²⁶ Similarly, the Patient Right to Know Drug Prices Act, signed into law in 2018, expanded mandatory reporting to those settlement agreements between makers of biologics and biosimilars licensed under the Biologics Price Competition and Innovation Act.²⁷

The Medicare Modernization Act enables the FTC to track pay-for-delay settlements over time, and the FTC makes publicly available summary data on the settlement agreements. At first glance, the FTC’s reported data present a picture of successful deterrence since *Actavis*: the number of potential pay-for-delay settlements decreased from a high of forty in fiscal year (FY) 2012 to twenty-one in FY 2014 and fourteen in FY 2015, though the number increased to thirty in FY 2016, the most recent year for which the FTC has released data.²⁸

Former FTC Chairman Maureen Ohlhausen commented in 2017 that brand 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 by either the enforcement agencies or the courts.”²⁹ Such a view, however, may be overly optimistic. The total number of settlements between brand and generic companies has continued to increase, with 232 settlement agreements in the latest year reported, which is an increase from 170 settlement agreements in the preceding year.³⁰ Pharmaceutical manufacturers are profit-making entities. If there were no value to be gained, why would brand and generic companies continue to engage in these settlements with increasing frequency?³¹

Moreover, the suggestion that pay-for-delay deals may be declining rests on an inability to categorize most of the agreements. Since 2010, the majority of the agreements between brand and generics fall into a nebulous category that

26. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111–18, 117 Stat. 2066, 2461–64 (2003).

27. FED. TRADE COMM’N, MEDICARE PRESCRIPTION DRUG AND IMPROVEMENT ACT REQUIRES DRUG COMPANIES TO FILE CERTAIN AGREEMENTS WITH THE FEDERAL TRADE COMMISSION AND U.S. DEPARTMENT OF JUSTICE (2019).

28. FED. TRADE COMM’N, BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2016 (2019) [hereinafter FTC FY 2016 REPORT]; see also *infra* Figure 1.

29. Maureen K. Ohlhausen, Acting Chairman, Fed. Trade Comm’n, Remarks at the 2017 ABA Fall Forum: The First Wealth is Health: Protecting Competition in Healthcare Markets 4 (Nov. 16, 2017), https://www.ftc.gov/system/files/documents/public_statements/1275573/mko_fall_forum_2017.pdf.

30. FTC FY 2016 REPORT, *supra* note 28, at 4; FED. TRADE COMM’N, BUREAU OF COMPETITION, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2015 (2017).

31. See Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHL-KENT J. INTELL. PROP. 249, 261 (2019).

one scholar has called "Category X," in which the generic agrees to delay entry but the FTC does not see a flow of value from the brand to the generic.³² The number of Category X agreements increased in 2016 to 151, rising from 126 the year before and a mere 75 the year the Supreme Court decided *Actavis*.³³ Once again, this begs the question: why would generics enter into these agreements in increasing numbers if they stand to receive no benefit?

Mindful of the Supreme Court decision in *Actavis*, drug companies have crafted settlements that comply with the guidance provided by the Court but that may still amount to anticompetitive behavior. Most settlements involving explicit compensation from the brand to the generic manufacturer and constraints on the ability of the generic to market its product have limited reverse payments of cash to \$7 million or less, a rough maximum target the FTC has set for reasonable litigation costs.³⁴ Fourteen settlements contained a form of "possible compensation" along with a restriction on generic entry; nine of the fourteen settlements contained a provision that the brand company would not distribute an authorized generic via a third party, which the FTC admits "could have the same effect" as an agreement by the brand company not to sell its own authorized generic.³⁵ Three of the fourteen settlements contained a potentially anticompetitive "declining royalty structure" that involves a reduction in royalty payments to the brand company if it launches an authorized generic to compete with the first generic entrant.³⁶ An agreement not to compete with a generic paired with delayed generic entry has a similar impact on competition as direct compensation in return for delayed generic entry. If the thirty settlements with a pay-for-delay structure and the fourteen settlements containing "possible compensation" are combined,³⁷ the total number of potentially problematic pay-for-delay agreements in FY 2016 exceeds that of the peak year 2012.

Other exotic variants exist, including acceleration clauses, in which the generic has the right to move up the date of entry based on other events, such as the release of an authorized generic or another generic company entering the market.³⁸ Acceleration clauses can have the effect of discouraging other generic companies to enter, leading one academic to describe them as having a "poison pill" effect.³⁹ Specifically, potential generics know that when they get to market,

32. *Id.* at 264–65.

33. FTC FY 2016 REPORT, *supra* note 28, at 2; Feldman & Misra, *supra* note 31, at 282.

34. Press Conference, Fed. Trade Comm'n, FTC Press Conference on Pay for Delay Case (May 28, 2015), https://www.ftc.gov/system/files/documents/videos/pay-delay-case-press-conference/ftc_press_conference_on_pay_for_delay_case_5-28-15_-_transcript.pdf.

35. See FTC FY 2016 REPORT, *supra* note 28, at 1–2.

36. *Id.* at 2.

37. *Id.* at 1 (explaining that three of the thirty settlements containing a restriction on generic entry and a form of explicit compensation also contained a form of "possible compensation," and so are counted in both figures).

38. Lizbeth Hasse, *When IP Settlements Create Antitrust Headaches*, NAT'L L.J. (Mar. 21, 2016), <https://www.jamsadr.com/files/uploads/documents/articles/hasse-nlj-ip-settlements-2016-03-21.pdf>.

39. Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 37–38 (2014).

they will face immediate entry from the settling generic.⁴⁰ Acceleration clauses represent yet another way that a brand company can get additional “bang for the buck”—settling with one generic while discouraging others from entering.

In the most recent year of FTC reports, 76% of the settlements between brand-name and generic companies contained some form of acceleration clause, with “the brand manufacturer licensing a third party with an earlier entry date” listed among the most common triggers.⁴¹ The actual number cannot be determined, however, because the FTC did not quantify how many of the acceleration clauses included this trigger event. In addition, the FTC’s language suggests that the clause would relate only to authorized generics that involve a third party, not an authorized generic made by the company itself. In hints of other anticompetitive aspects to the deals, the FTC reported that more than 90% of all settlements between brands and generics involved the generic receiving rights to patents not subject to any litigation between the two companies.⁴² Additional rights such as these can be the vehicles for transferring value or sharing markets.

Hence, there is good reason to believe that anticompetitive pay-for-delay agreements continue to be reached in the United States post-*Actavis*. A reduction in explicit payments to figures below \$7 million can likely be attributed to Justice Breyer’s emphasis on the size of the reverse payment in *Actavis*.⁴³ However, payments below litigation costs can still present anticompetitive harm. A small reverse payment should not immunize anticompetitive behavior any more than does allowing generic entry prior to expiration of the patent in question. The “scope of the patent” test has effectively been replaced by a “size of the payment” test, permitting brand companies with more complex deals but modest explicit payments to stay under the radar. Moreover, modern deals now provide potential vehicles for transferring value other than cash in a convoluted manner.

In the view of the authors, less attention should be paid to the form or even the size of the value transfer, and the primary focus of antitrust scrutiny should be any restriction on generic entry together with a category of patent less likely to survive a challenge. The strength of the category of patent in question must necessarily be part of a proper pay-for-delay evaluation by the courts or the FTC because, following *Actavis*, the size of the reverse payment can no longer be presumed a reliable indicator of patent strength or weakness. Nor can reporting requirements alone provide a complete safeguard. Given the complexity of modern pay-for-delay deals, the actual transfer of value can be deeply camouflaged, hidden among the folds of layers of interactions between the

40. *Id.* at 28–29.

41. See FTC FY 2016 REPORT, *supra* note 28, at 3.

42. *Id.* at 2 (“215 of the 232 final settlements involve the generic manufacturer receiving rights to patents that were not the subject of any litigation between the brand manufacturer and that generic manufacturer.”).

43. See Fed. Trade Comm’n v. *Actavis, Inc.*, 570 U.S. 136, 158 (2013).

brand-name and generic company. Regulatory agencies examining the deal paperwork on its face are unlikely to stay ahead of the game.

Evidence shows that settlements involving delayed generic entry now resolve patent challenge proceedings before the recently created Patent Trial and Appeal Board,⁴⁴ which may allow some of these settlements to escape detection (though the FTC has declared that settlements before the Patent Trial and Appeal Board fall under the purview of the Medicare Modernization Act's reporting mandate).⁴⁵ It is essential for the FTC and the courts to correctly label pay-for-delay as unlawful when appropriate, regardless of the venue in which the agreement is reached and despite the strategic construction of settlements with less overtly anticompetitive terms.

III. PAY-FOR-DELAY LEGISLATION IN THE 116TH CONGRESS

Several pay-for-delay bills have been introduced in the 116th Congress.⁴⁶ In May 2019, the U.S. House of Representatives passed a health care bill that included provisions to prohibit pay-for-delay settlements.⁴⁷ The bill would create a rebuttable presumption of illegality for any reverse payment patent settlement involving a transfer of value to a generic or biosimilar company in return for its agreement to "limit or forego" efforts to develop, manufacture, market or sell the drug in question.⁴⁸ The Preserve Access to Affordable Generics and Biosimilars Act,⁴⁹ and its companion bill in the Senate,⁵⁰ also create a presumption of anticompetitive effects in pay-for-delay deals and shift the burden of proof from the FTC to the settling parties to demonstrate that either the value transfer constitutes compensation for goods and services, or the procompetitive benefits of the settlement outweigh the anticompetitive effects. Both of the aforementioned bills permit payment to the generic (or biosimilar) company for reasonable litigation expenses up to \$7.5 million.⁵¹ The Competitive DRUGS Act of 2019 would additionally impose a tax on parties to pay-for-delay deals and claw back research and development tax benefits.⁵²

The U.S. trade group for generic drug companies, the Association for Accessible Medicines (AAM), has taken a position in opposition to the pay-for-

44. Erik Hovenkamp & Jorge Lemus, *Delayed Entry Settlements at the Patent Office*, 54 INT'L REV. L. & ECON. 30, 30 (2018).

45. Jamie Towey & Brad Albert, *Then, Now, and Down the Road: Trends in Pharmaceutical Patent Settlements After FTC v. Actavis* (May 28, 2019, 12:23 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent>.

46. See *infra* Table 1.

47. Strengthening Health Care and Lowering Prescription Drug Costs Act, H.R. 987, 116th Cong. § 111 (2019).

48. *Id.*

49. Preserve Access to Affordable Generics and Biosimilars Act, H.R. 2375, 116th Cong. (2019).

50. Preserve Access to Affordable Generics and Biosimilars Act, S. 64, 116th Cong. (2019).

51. H.R. 2375 § 27(c)(2)(A); S. 64 § 27(c)(2).

52. Competitive DRUGS Act of 2019, H.R. 1344, 116th Cong. §§ 2, 3 (2019).

delay bills in Congress and instead urges codification of the *Actavis* decision.⁵³ Why would a lobbying group for generic drug companies oppose bills that would enable generic drugs to come to market sooner? AAM argues that the FTC already screens settlements for pay-for-delay activity, and that most settlements do not delay generic competition,⁵⁴ both of which are true. But *Actavis* did not categorically prohibit pay-for-delay deals, as the AAM claims; rather, the decision established that such deals *may* have anticompetitive effects but left it to the lower courts to hash out the rule-of-reason analysis.⁵⁵ The bills in Congress, on the other hand, take a tougher stance by labeling the agreements as unlawful unless proven otherwise, shifting the burden to drug companies to disprove antitrust concerns.⁵⁶ In addition to the FTC's recently reported data on pay-for-delay, AAM's position should make policymakers and regulators question whether generic companies still stand to gain from pay-for-delay settlements in their post-*Actavis* form.

IV. POLICY RECOMMENDATIONS

We propose several substantive changes to the antitrust approach to pay-for-delay settlements.

First, the key criterion in determining an unlawful agreement should be the existence of a restriction on generic entry—not the size or presence of a value transfer—considered in light of the strength of the category of patent in question. Arguably, the legitimacy of a pay-for-delay settlement is predicated on the strength of the underlying patent; in other words, pay-for-delay is only a problem insofar as the patent to which the deal relates is invalid or aimed at the wrong product, since the generic could enter the market immediately upon that determination. Much is at stake in these deals; several years of lost patent protection could translate into several billions of dollars of lost savings for the brand company.⁵⁷ Pay-for-delay agreements tend to settle litigation over a “secondary patent,” which is a patent on some feature of a drug other than the active pharmaceutical ingredient, such as a production process, a method of treatment, a salt or crystalline form, a new delivery mechanism, a new formulation, or even an ancillary aspect of a drug, such as the pill's coating.⁵⁸ Evidence shows that secondary patents form part of a deliberate strategy to

53. See Christina Girardi, *Check the Facts on “Pay-for-Delay” Legislation*, ASS'N FOR ACCESSIBLE MEDS. (Mar. 28, 2019), https://accessiblemeds.org/sites/default/files/2019-03/AAM-Patent-Settlement-Fact-Sheet_0.pdf.

54. *Id.*

55. Fed. Trade Comm'n v. *Actavis, Inc.*, 570 U.S. 136, 158–60 (2013).

56. See *infra* Table 1.

57. See Glynn S. Lunney Jr., *FTC v. Actavis: The Patent-Antitrust Intersection Revisited*, 93 N.C. L. REV. 375, 406–07 (2015).

58. Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, PLOS ONE, Dec. 2012, at 1.

prolong a drug's effective period of patent protection.⁵⁹ Though few patent cases reach a final decision on validity,⁶⁰ secondary drug patents are frequently found invalid when challenged.⁶¹ Thus, secondary patents may over-reward a pharmaceutical drug's actual innovative contribution with unwarranted extensions of effective patent protection, and both the brand and generic companies may have a good sense of the likelihood that a disputed secondary patent will survive a court challenge. For this reason, the category of the patent in question in a pay-for-delay agreement is highly germane to a meaningful examination of the potential illegality of the deal.

Next, the United States should move closer to a presumptive standard in evaluating pay-for-delay settlements in order to achieve more efficient and effective antitrust enforcement. The pay-for-delay bills introduced in Congress will help achieve that goal, as would adopting a standard similar to that of the European Union that places emphasis on an agreement's aim to restrict competition rather than downstream effects on the marketplace.⁶² Although intent can be difficult to establish under U.S. law—particularly if plaintiffs must find smoking-gun evidence of subjective intent—those difficulties can be overcome by designing standards that use objective criteria as a means of inferring a company's likely intent. The category of patent and the failure to sue on the core chemical or biological patent could be part of those objective criteria. The reluctance to call pay-for-delay presumptively illegal in the United States reflects a desire to preserve the freedom to settle and to avoid clogging the courts with costly and protracted patent litigation. However, the current approach to pay-for-delay favors industry over patients, and unless the approach is changed, drug prices will remain supra-competitive for periods longer than the Hatch-Waxman regulatory regime intended. In addition, deterring the litigation in the first place would reduce the burden on the courts, as well as the burden on society.

Finally, regulatory disincentives may be a more effective deterrent of pay-for-delay deals than monetary penalties. For example, the FTC and FDA could

59. María José Abud et al., *An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile*, PLOS ONE, Apr. 2015, at 1, 3–4; Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, 31 HEALTH AFF. 2286, 2286–87 (2012); C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 615 (2011); Kapczynski et al., *supra* note 58, at 2.

60. See Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 88 (2013).

61. See, e.g., *In re Janssen Biotech, Inc.*, 880 F.3d 1315, 1325 (Fed. Cir. 2018); Jeppe Brinck-Jensen & Kamilla Kelm Demant, *Quetiapine Patent Invalidated—Danish Court Follows Suit*, LEXOLOGY (Sept. 7, 2016), <https://www.lexology.com/library/detail.aspx?g=dff84c34-9985-4a05-b038-2b86558e74a6>; Jessica Hodgson, *AstraZeneca Suffers U.S. Patent Blow*, WALL ST. J. (Apr. 2, 2013, 4:37 AM), <https://www.wsj.com/articles/SB10001424127887323296504578397852484365558>.

62. Eur. Comm'n, Decision of 9 July 2014, 240–41 C(2014), http://ec.europa.eu/competition/antitrust/cases/dec_docs/39612/39612_12448_6.pdf (explaining that “for the purpose of the application of Article 101 of the [sic] Treaty, there is no need to take into account the actual effects of an agreement which has as its object the prevention, restriction or distortion of competition within the internal market. Consequently, it is not necessary to show actual anti-competitive effects where the anti-competitive object of the conduct in question is proved.”); Treaty on the Functioning of the European Union Art. 101(1), Oct. 26, 2012, 2012 O.J. (C 326) 88.

jointly prohibit a generic company that is found to have participated in pay-for-delay from eligibility for the 180-day exclusivity period for any Abbreviated New Drug Application (ANDA) that it files in the ensuing five years. Without exclusive marketing rights as the first generic to file an ANDA, the generic company stands to lose the bulk of its profits on any generic drug launched in that five-year period. By enticing generic companies with profitable settlements, brand companies have co-opted the paragraph IV challenge, initially intended to enable generic companies to challenge weak or invalid patents.⁶³ As a penalty for participation in pay-for-delay deals, the generic company could be prohibited from filing a paragraph IV certification on any ANDA for a certain number of years, effectively making the company ineligible for the 180-day exclusivity period and shutting them out of pay-for-delay settlements—at least those arising from patent litigation. Regulatory disincentives can counterbalance the “carrots” in the Hatch-Waxman Act, thereby rewarding innovation and hastening competition when the time is ripe.

CONCLUSION

Settlement agreements to end patent disputes are common and not in and of themselves indicative or suggestive of antitrust infringement. Often, settlements are a favored alternative to continuing costly litigation. However, pay-for-delay settlements come at a steep cost to patients by delaying the entry of less expensive generic alternatives to brand drugs. The ability to wield competition laws effectively against these settlements is of major importance to regulators, policymakers, and patients. Shifting the focus of antitrust scrutiny to restrictions on generic entry vis-à-vis the strength of the category of underlying patent, and creating disincentives for generic companies to acquiesce to pay-for-delay deals, will help grease the wheels of the Hatch-Waxman Act and accelerate the path to affordable drug prices for U.S. patients.

63. A generic company seeking FDA approval to market a generic drug before the brand drug's patents have expired must file a “paragraph IV certification” with the FDA, asserting that the brand drug's patents listed within the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the Orange Book) are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug product for which the application is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2018). A paragraph IV certification is considered an artificial act of infringement by the ANDA applicant that often prompts the patent owner to initiate a patent infringement action against the ANDA applicant. *See id.* The first paragraph IV ANDA applicant to challenge a patent is eligible for 180 days of exclusive rights to market the generic drug product upon FDA approval, termed the 180-day exclusivity period. *Id.* Currently, this statutory incentive is retained even when the patent owner does not initiate suit against the ANDA applicant, or when the patent infringement suit is subsequently settled. FOOD & DRUG ADMIN., U.S. DEP'T HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY: QUESTIONS AND ANSWERS 10 (2017).

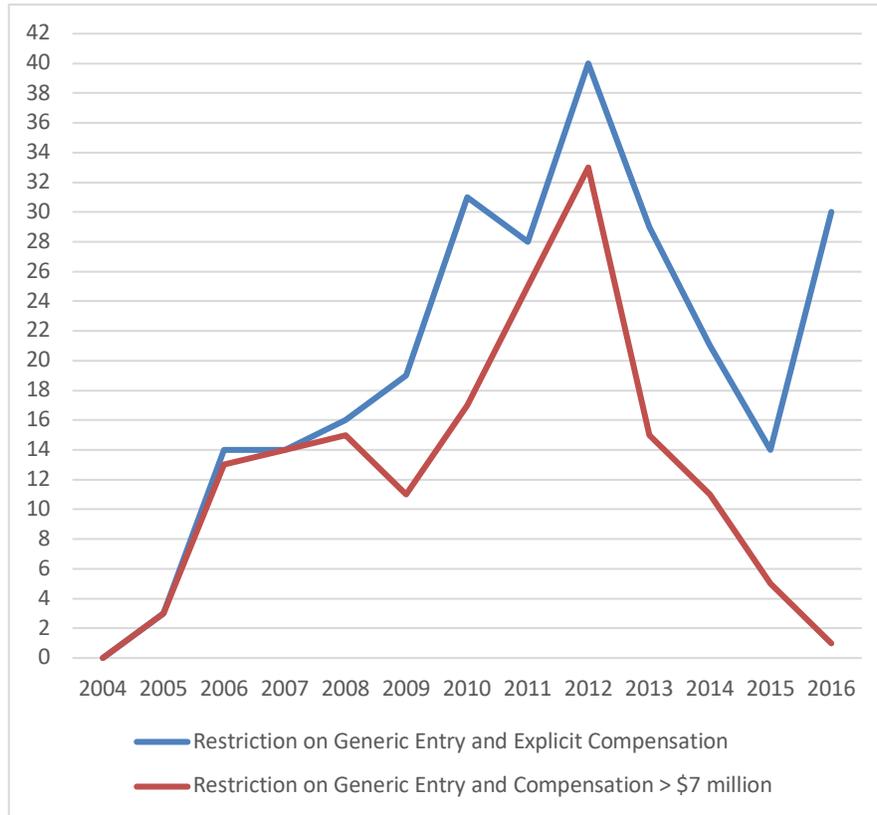
TABLE 1: PAY-FOR-DELAY BILLS INTRODUCED IN THE 116TH CONGRESS

Bill No.	Title	Sponsor	Summary of Provisions	Latest Action
H.R. 1499	Protecting Consumer Access to Generic Drugs Act of 2019	Rep. Bobby Rush [D-IL]	It shall be unlawful for a New Drug Application (NDA) or Biologics License Application (BLA) holder and a subsequent filer to enter into an agreement settling a patent infringement claim if the agreement involves a transfer of value directly or indirectly from the NDA or BLA holder to the subsequent filer, and the filer agrees to limit or forgo research, development, manufacturing, marketing, or sales of the product in question for any period of time. Such an agreement will not be unlawful if a party to the agreement demonstrates by clear and convincing evidence that the value transfer is compensation solely for goods and services provided by the filer.	Passed as part of H.R. 987 (05/16/2019)
H.R. 987	Strengthening Health Care and Lowering Prescription Drug Costs Act	Rep. Lisa Blunt Rochester [D-DE-At Large]	Contains the provisions on pay-for-delay of H.R. 1499.	Passed in the House by recorded vote: 234–183 (05/16/2019); Received in the Senate and referred to the Committee on Health, Education, Labor and Pensions (05/20/2019)

H.R. 2700	Lowering Prescription Drug Costs and Extending Community Health Centers and Other Public Health Priorities Act	Rep. Michael C. Burgess [R-TX]	Contains the provisions on pay-for-delay of H.R. 1499.	Referred to the House Subcommittee on Antitrust, Commercial, and Administrative Law (06/26/2019)
H.R. 2375; S. 64	Preserve Access to Affordable Generics and Biosimilars Act	Rep. Jerrold Nadler [D-NY]; Sen. Amy Klobuchar [D-MN]	Any agreement between an ANDA filer or abbreviated Biologics License Application (aBLA) filer in which that party receives anything of value and agrees to limit or forgo research, development, manufacturing, marketing or sales of their product for any period of time will be presumed anticompetitive and in violation of the Federal Trade Commission Act, unless, by clear and convincing evidence, the value is demonstrated to be compensation solely for goods and services provided by the ANDA/aBLA filer, or the procompetitive benefits of the agreement outweigh the anticompetitive effects. An agreement for entry of the ANDA or biosimilar product prior to the expiration of the relevant patent or statutory exclusivity period will not be taken as a presumption that the agreement is procompetitive.	Ordered to be reported by voice vote in the House (04/30/2019); Referred to the Senate Committee on the Judiciary (01/09/2019)
H.R. 1344	Competitive Deals	Rep. Lloyd Doggett	The FTC may initiate enforcement proceedings for	Referred to the Subcommittee

	<p>Resulting in Unleashed Generics and Savings Act of 2019 (or Competitive DRUGS Act of 2019)</p>	<p>[D-TX]</p>	<p>pay-for-delay settlements (provisions of H.R.2375/S.64). Contains a provision to claw back R&D tax benefits for manufacturers engaging in pay-for-delay. Imposes a tax equal to 50% of the amount paid under the pay-for-delay agreement and denial of a tax deduction for payments made as part of pay-for-delay deals.</p>	<p>on Antitrust, Commercial, and Administrative Law (03/25/2019)</p>
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FIGURE 1: PAY-FOR-DELAY SETTLEMENTS IN THE UNITED STATES, 2004–2016, BASED ON THE MOST RECENT PUBLICLY REPORTED DATA FROM THE FEDERAL TRADE COMMISSION⁶⁴



64. For the data displayed in Figure 1, see FTC FY 2016 REPORT, *supra* note 28.