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Antitrust Law: Pharmaceutical “Pay for Delay” Reexamined

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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; the brand pays the generic company for an agreed-upon delay in entry of the generic drug to market.[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 urged Congress to end the sharing of monopoly profits between brand and generic companies and accelerate access to lower-priced generic drugs.[4] Unfortunately, nearly ten years later, no such legislation has become law.

In May 2019, the FTC reported, based on its most recently released data, a significant reduction in the pay-for-delay agreements most likely to be anticompetitive.[5] This Chapter examines the legal standard applied to pay-for-delay settlements in the United States. It argues that pay-for-delay settlements may

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[1] Excerpted and adapted from Laura Karas, Gerald Anderson & Robin Feldman, *Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959 (2020).

[2] *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, 1556–57 (2006).

[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] Press Release, Fed. Trade Comm'n, *FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors* (May 23, 2019).

not be on the decline, as the FTC claimed, but rather that they have evolved to favor categories of value transfer less likely to attract antitrust scrutiny. It concludes with a discussion of pay-for-delay bills under consideration in Congress and offers several policy proposals at the nexus of patent law and antitrust that strike at the heart of the pay-for-delay problem.

The Legal Approach to Pay-for-Delay Settlements

In 2013, the Supreme Court addressed pay-for-delay agreements head-on in *FTC v. Actavis*.[6] There, 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.[7] 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.[8] 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.[9] This is a fairly common example of a pay- for-delay settlement.

Reversing the Eleventh Circuit's dismissal of the complaint,[10] 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.[11] In the majority opinion, 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.[12]

The Supreme Court declined to label a pay-for-delay settlement presumptively illegal.[13] Instead, it held that a

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[6] 570 U.S. 136, 140–41 (2013).
[7] *Id.* at 144–45.
[8] *Id.* at 145.
[9] *Id.*
[10] Fed. Trade Comm'n v. Watson Pharm., Inc., 677 F.3d 1298, 1312, 1315 (11th Cir. 2012).
[11] *Actavis*, 570 U.S. at 148–49.
[12] *Id.*
[13] *Id.* at 158–59.

settlement in which the reverse payment appears "large and unjustified" should be subject to a "rule-of-reason" legal analysis,[14] which permits consideration of "legitimate justifications."[15] 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 circumstances.[16]

While the Court's decision amounted to an important rejection of the Eleventh Circuit's "scope of the patent" test, *Actavis* did not categorically prohibit pay-for-delay deals and arguably did not go far enough to address drug companies' dedication to circumventing the antitrust rules in their favor. The rule of reason promises a careful assessment but runs the risk that its nuanced approach will amount to leniency.[17] 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.[18]

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)[19] provide guideposts to detect a potentially unlawful agreement but fall short of bright-line rules. Nevertheless, since the Court's decision in *Actavis*, the FTC has brought suit and enforcement actions against several pharmaceutical companies, including Impax, Teva, and Endo, for unlawful pay-for-delay settlements.[20]

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[14] *Id.* at 158.
[15] *Id.* at 156.
[16] *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).
[17] Robin Cooper Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079, 2107–08 (1999).
[18] *See* HERBERT HOVENKAMP, THE ANTITRUST ENTERPRISE: PRINCIPLE AND EXECUTION 8 (2005).
[19] *Actavis*, 570 U.S. at 159.
[20] Press Release, Fed. Trade Comm'n, *FTC Concludes that Impax Entered into Illegal Pay-for-Delay Agreement* (Mar. 29, 2019); Press Release, Fed. Trade Comm'n, *FTC Enters Global Settlement to Resolve Reverse-Payment Charges Against Teva* (Feb. 19, 2019); Press Release,

The Evolution of Pay-for-Delay Agreements since Actavis

One regulatory response to pay-for-delay agreements has been to mandate, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act")[21] reporting to the FTC and Department of Justice of pharmaceutical-patent settlements between brand and generic companies in the Hatch-Waxman regulatory system. Similarly, the Patient Right to Know Drug Prices Act, signed into law in 2018, expanded mandatory reporting to settlement agreements between makers of biologics and biosimilars licensed under the Biologics Price Competition and Innovation Act.[22]

The Medicare Modernization Act enables the FTC to track pay-for-delay settlements over time. 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 fourteen in FY 2015.[23] Yet the number of all settlements has continued to increase, with 232 settlement agreements in 2016, up from 170 in 2015.[24] The suggestion that pay-for-delay deals may

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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).

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

[22] 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).

[23] 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].

[24] FTC FY 2016 REPORT, *supra* note 23, 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).

be declining rests on an inability to categorize the agreements. Since 2010, most agreements between brand and generics fall into a nebulous category that I have 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.[25] 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*.[26]

Why would generics enter into these agreements in increasing numbers if they stand to receive no benefit?[27] The answer is that, mindful of the Supreme Court decision in *Actavis*, drug companies have crafted settlements that comply with the Court's guidance but that may still amount to anticompetitive behavior. 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.[28] Three of the fourteen contained a potentially anticompetitive "declining royalty structure" that involves a reduction in royalty payments to the brand company if it launches an authorized generic.[29] An agreement not to compete with a generic paired with delayed generic entry has a similar impact on competition as direct compensation for delayed generic entry. If the thirty settlements with a pay-for-delay structure and the fourteen settlements containing "possible compensation" are combined,[30] the total number of potentially problematic agreements in FY 2016 exceeds that of the peak year 2012.

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[25] Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 24–65 (2019).

[26] FTC FY 2016 REPORT, *supra* note 23, at 2; Feldman & Misra, *supra* note 25, at 282.

[27] *See* Feldman & Misra, *supra* note 25.

[28] *See* FTC FY 2016 Report, *supra* note 23, at 1–2.

[29] *Id.* at 2.

[30] *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).

Other exotic variants exist, including acceleration clauses, in which the generic can move up the date of entry based on events such as the release of an authorized generic or the entry of another generic.[31] Acceleration clauses can discourage other generic companies from entering[32] because they know that when they get to market, they will face immediate competition from the settling generic.[33] In the most recent year of FTC reports, 2016, 76% of settlements between brand-name and generic companies contained some form of acceleration clause.[34] In hints of other anticompetitive aspects, 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.[35] Additional rights such as these can be the vehicles for transferring value or for 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*.[36] However, 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.

Evidence shows that settlements involving delayed generic entry now resolve patent-challenge proceedings before the recently created Patent Trial and Appeal Board,[37] which may allow some of

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[31] Lizbeth Hasse, *When IP Settlements Create Antitrust Headaches*, NAT'L L.J. (Mar. 21, 2016).

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

[33] *Id.* at 28–29.

[34] *See* FTC FY 2016 REPORT, *supra* note 23, at 3.

[35] *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.").

[36] *See* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 158 (2013).

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

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).[38] It is essential for the FTC and the courts to correctly label settlements as unlawful pay-for-delay agreements when appropriate, regardless of the venue in which the agreement is reached and despite the strategic construction of settlements with less overtly anticompetitive terms.

Policy Recommendations

Several substantive changes to the antitrust approach to pay-for-delay settlements can help ameliorate the problem. 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, pay-for-delay is only a problem if the patent is invalid or aimed at the wrong product, since the generic could enter the market immediately upon that determination. Pay-for-delay agreements tend to settle litigation over a "secondary patent," which covers some feature of a drug other than the active pharmaceutical ingredient.[39] Evidence shows that secondary patents form part of a deliberate strategy to prolong a drug's effective period of patent protection.[40] Though few patent cases reach a final decision on validity,[41] secondary

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[38] Jamie Towey & Brad Albert, *Then, Now, and Down the Road: Trends in Pharmaceutical Patent Settlements After* FTC v. Actavis, FTC BLOG (May 28, 2019, 12:23 PM).

[39] Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE, Dec. 2012, at 1.

[40] María José Abud, Bronwyn Hall & Christian Helmers, *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 39, at 2.

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

drug patents are frequently found invalid when challenged.[42] Thus, secondary patents may over-reward a pharmaceutical drug's actual innovative contribution with unwarranted extensions of patent protection. The category of the patent in question in a pay-for-delay agreement is thus highly germane to an 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 emphasizes an agreement's aim to restrict competition rather than downstream effects on the marketplace.[43] Although intent can be difficult to establish under U.S. law, 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.

Finally, regulatory disincentives may be a more effective deterrent of pay- for-delay deals than monetary penalties. For example, the FTC and FDA could jointly prohibit a generic company that is found to have participated in a pay-for-delay deal 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.[44] Regulatory disincentives can counterbalance the

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[42] *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); Jessica Hodgson, *AstraZeneca Suffers U.S. Patent Blow*, WALL ST. J. (Apr. 2, 2013, 4:37 AM).

[43] Eur. Comm'n, Decision of 9 July 2014, at 240–41 C(2014); Treaty on the Functioning of the European Union Art. 101(1), Oct. 26, 2012, 2012 O.J. (C 326) 88.

[44] 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,

"carrots" in the Hatch-Waxman Act, thereby rewarding innovation and hastening competition.

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 consumers 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 consumers. 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 agree 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.

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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). The first paragraph IV ANDA applicant to challenge a patent is eligible for 180 days of exclusive rights to market the generic drug upon FDA approval. *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 & HUM. SERVS., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY: QUESTIONS AND ANSWERS 10 (2017).

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