

IV. *Actavis, Wellbutrin XL, and the Rule of Reason in Reverse Payment Settlements*

A. Introduction

This article focuses on the “rule of reason” antitrust doctrine and how courts have recently applied it to reverse payment settlements between pharmaceutical companies in patent infringement cases. The article is broken down into four sections. Section B discusses the historical roots of the rule of reason and Section C analyzes the Supreme Court’s recent holding in *FTC v. Actavis*. Section D then discusses how lower courts have applied the *Actavis* holding, focusing in particular on the Third Circuit’s holding in *Wellbutrin XL*, and the piece concludes with Section E.

B. Historical Roots of the Rule of Reason

The rule of reason is a judicial doctrine of antitrust law which requires a plaintiff to show that a defendant had market power and engaged in anticompetitive behavior.¹ The origins of the rule of reason reside in former President and Supreme Court Justice William Taft’s opinion in the 1888 case *United States v. Addyston Pipe & Steel Co.*² The basis for the rule of reason is to distinguish between restraints that were mostly or entirely intended to restrain trade, and those that are ancillary to a procompetitive main purpose.³ In *Standard Oil Co. v. New Jersey*, a case decided during Taft’s presidency, the Court first used the phrase “rule of reason” in its rejection of the government’s argument that the Sherman Act should embrace every contract in restraint of trade.⁴ Rather, the Court held that a lack of specific definition for restraint of trade in the statute indicated the boundaries should

¹ Herbert Hovenkamp, *The Rule of Reason*, 70 FLA. L. REV. 81, 83 (2018) (explaining that “[c]ourts evaluate most antitrust claims under a “rule of reason,” which requires the plaintiff to plead and prove that defendants with market power have engaged in anticompetitive conduct”).

² *United States v. Addyston Pipe & Steel Co.* 85 F. 271 (6th Cir. 1888) (describing the basis of the rule of reason).

³ *Id.* at 282 (holding that conventional restraints of trade cannot be enforced unless they are “merely ancillary to the main purpose of a lawful contract”).

⁴ *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 60–61 (1911) (stating that the criteria for determining whether a violation of the Sherman Act has been committed is the “rule of reason”).

be “determined by the light of reason.”⁵ The next significant ruling came in *Board of Trade of City of Chicago v. United States* when the Court, headed by Justice Brandeis, ruled that the true test of legality is whether the restraint on trade promotes competition or restricts competition.⁶ According to Justice Brandeis, the test should consider “the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable.”⁷ Between the decision in *Board of Chicago* in 1918 and the 1970s, the rule of reason was largely vacated by per se rules.⁸ However, through a number of cases in the 1970s and 1980s the Court signaled its intent to bring back the rule of reason and restrict the reach of per se rules, stating the principal tendency of the rule of reason is whether the restraint would have an anticompetitive effect on markets and consumers.⁹

C. FTC v. Actavis

A recent landmark rule of reason case came in 2013 when the Supreme Court decided *FTC v. Actavis*, a pharmaceutical case dealing with “reverse payment” settlements that resolve patent infringement litigation.¹⁰ Reverse payments occur when a drug patentee pays a generic drug manufacturer to stay out of the relevant drug market, thus allowing the patent holder to avoid competition.¹¹

⁵ *Id.* at 64.

⁶ *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 238 (1918) (holding the “true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition”).

⁷ *Id.*

⁸ Thomas C. Arthur, *A Workable Rule of Reason: A Less Ambitious Antitrust Role for the Federal Courts*, 68 ANTITRUST L.J. 337, 337 (2000) (observing that until “the late 1970s, the rule of reason had been almost completely replaced by a comprehensive network of per se rules”).

⁹ *Id.*

¹⁰ *See generally* Fed. Trade Comm’n v. Actavis, Inc., 570 U.S. 136 (2013) (“Reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust law.”).

¹¹ *See id.* at 141 (stating that “most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation.” These payments are considered reverse payments because the plaintiff (patentee) is paying the defendant (infringer), rather than typical settlement offers which flow from the infringer to the patentee.).

Typically, a drug manufacturer will file a New Drug Application to gain U.S. Food and Drug Administration (FDA) approval to manufacture a new drug, an often long and costly undertaking.¹² Once approved, under the Hatch-Waxman Act,¹³ generic drug manufacturers can submit an “Abbreviated New Drug Application” (ANDA) with the FDA which states that their generic drug has the same ingredients as the patented drug, thus making the approval process considerably cheaper and faster.¹⁴ This practice is seen as pro-competitive as the generic drug manufacturers can “piggyback” off the innovation of the patent-holder and consequently manufacture affordable drugs for consumers.¹⁵ To gain approval for an ANDA under the Hatch-Waxman Act, the generic manufacturer must assure the FDA that they will not infringe upon the patent holder’s patent.¹⁶ Importantly, the Hatch-Waxman Act incentivizes generic manufacturers to be the first to file an ANDA by awarding a 180 day exclusivity period where no other generic manufacturer can compete.¹⁷ This period of exclusivity can be worth “several hundred million dollars.”¹⁸ If a generic manufacturer files an ANDA under the theory that a patent is invalid or their generic drug will not infringe upon the patent, litigation typically ensues, with the FDA withholding approval of the ANDA for thirty months.¹⁹ Once the thirty-month period ends and the FDA grants approval, the brand-name manufacturer and generic manufacturer may

¹² *Id.* at 142.

¹³ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2006)) (describing the procedure for filing an Abbreviated New Drug Application).

¹⁴ *Actavis, Inc.*, 570 U.S. at 142 (ruling that the Hatch-Waxman Act allows a generic to file an Abbreviated New Drug Application specifying that the generic has the “same active ingredients as” and is “biologically equivalent to” the already-approved brand-name drug (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012))).

¹⁵ *Actavis, Inc.*, 570 U.S. at 142.

¹⁶ *Id.* at 143 (finding a generic must “assure the FDA” that the generic “will not infringe” the brand-name’s patents (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012))).

¹⁷ *Actavis, Inc.*, 570 U.S. at 143 (holding that the first applicant “will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug)”).

¹⁸ *Id.* at 144 (citing C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

¹⁹ *Id.* at 143.

agree upon a reverse payment settlement, with the brand-name paying the generic to stay out of the market for a specified period of time rather than litigate the patent's validity.²⁰ Between 2005 and 2012, appellate courts upheld these settlements, justifying their deference for five reasons: (i) the significance of settlements, (ii) the relationship between innovation and settlements, (iii) patents are assumed to be valid, (iv) the breadth of the patent, and (v) the "natural" status of reverse payments under the Hatch Waxman Act.²¹ Multiple circuits upheld settlement payments using this "scope of the patent test," ultimately reasoning that a payment within the patent term could not adversely affect competition because the patent holder may prevent competition due to the patent.²²

The Supreme Court rejected the "scope of the patent test" in the 2013 case of *Federal Trade Commission v. Actavis*.²³ The case involved Solvay Pharmaceuticals, a company that had a New Drug Application approved by the FDA in 2000 for a drug called AndroGel.²⁴ In 2003, Solvay received a patent for AndroGel, a fact they disclosed to the FDA under Hatch-Waxman requirements.²⁵ A number of generic manufacturers, including Actavis, filed ANDAs with the FDA, claiming that Solvay's patent was invalid and their generic drugs did not infringe upon it.²⁶ Solvay sued Actavis and the other generic manufacturers, claiming patent infringement.²⁷ The FDA ultimately allowed Actavis to produce the generic drug, prior to the

²⁰ Hemphill, *supra* note 18, at 1557.

²¹ Schering-Plough Corp. v. Fed. Trade Comm'n, 402 F.3d 1056, 1058 (11th Cir. 2005) (stating that "reverse payments are a natural by-product of the Hatch-Waxman process"); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 60–66 (2009) (listing five reasons why courts were deferential to reverse payments between the years of 2005 and 2012).

²² Michael A. Carrier, *The Rule of Reason in the Post Actavis World*, 18 COLUM. BUS. L. REV. 25, 36 (2018) (stating that courts "upheld settlements by applying a test that found that they fell within the scope of the patent"). A payment within the patent term is a settlement agreement which allows entry by the generic before the date of patent expiration.

²³ *Actavis, Inc.*, 570 U.S. at 159.

²⁴ *Id.* at 144.

²⁵ *Id.* ("Solvay obtained a relevant patent and disclosed that fact to the FDA, as Hatch-Waxman requires.").

²⁶ *Id.*

²⁷ *Id.* at 145.

conclusion of the patent infringement litigation.²⁸ However, rather than bring the drug to market, Solvay and Actavis agreed upon a reverse payment settlement in 2006, with Solvay paying Actavis millions of dollars to delay their entry into the market until August 31, 2015—sixty-five months before the expiration of Solvay’s patent.²⁹ The Federal Trade Commission (FTC) subsequently brought suit, alleging a violation of section 5 of the Federal Trade Commission Act.³⁰ Specifically, the FTC alleged that respondents illegally agreed “to share in Solvay’s monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.”³¹ The Supreme Court ultimately ruled that the FTC could bring a claim under the rule of reason for these reverse payment settlements, citing five reasons.³² First, the Court noted that these payments have the “potential for genuine adverse effects on competition.”³³ Second, the anticompetitive consequences will in some circumstances be unjustifiable.³⁴ However the Court did note two justifications for reverse payment settlements: (i) litigation costs saved through settlements,³⁵ and (ii) compensation for services the generic manufacturer has promised to perform.³⁶ Third, when a reverse payment has the potential to bring about unjustified anticompetitive harm, the patentee probably has the power to bring about such harm.³⁷ Fourth, a large and unjustified payment is a surrogate for a patent’s weakness, making it unnecessary to actually determine the

²⁸ *Id.*

²⁹ *See id.*

³⁰ *Id.* (stating that the FTC decided to challenge the legality of these settlements under the Federal Trade Commission Act).

³¹ *Id.* at 145.

³² While the Court acknowledged the value of patent litigation settlements, it went on to state that “five sets of considerations lead us to conclude that the FTC should have been given the opportunity to prove its antitrust claim.” *Id.* at 154.

³³ *Id.* (citing *Fed. Trade Comm’n v. Indiana. Fed’n of Dentists*, 476 U.S. 447, 460–61(1986)).

³⁴ *Actavis, Inc.*, 570 U.S. at 156.

³⁵ *Id.* (“The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement.”).

³⁶ *Id.*

³⁷ *Id.* at 157 (declaring that a firm that lacks market power would not make a large payment to keep others out of a competitive market).

validity of the patent.³⁸ Lastly, parties can settle their patent litigation cases in ways other than involving large and unjustified payments, such as non-monetary agreements that allow a generic to enter the market prior to the patent's expiration.³⁹ Importantly, the Court did not apply a quick look test as advocated for by the FTC, concluding the FTC must make its case similar to other rule of reason cases.⁴⁰ The Supreme Court went on to note that the reasonableness of a reverse payment is dependent on "its size, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."⁴¹ In sum, large and unjustified payments should be subject to rule of reason analysis.⁴² While large and unjustified payments trigger rule of reason analysis, the concluding remarks of the majority opinion noted that they intended to assign the structuring of the current rule of reason antitrust litigation to the lower courts.⁴³

The dissent, authored by Chief Justice Roberts, argued that a "patent carves out an exception to the applicability of antitrust laws," and the only inquiry should have been whether the settlement agreement gave Solvay monopoly power beyond what the patent provided.⁴⁴ The dissent strongly advocated for the scope of the patent test, claiming the majority ignored precedent regarding reverse payment settlements.⁴⁵ Chief Justice Roberts concluded the dissent by arguing that the majority opinion in *Actavis* will weaken protections

³⁸ *Id.* (responding to the Eleventh Circuit's concern that requiring the litigation of an underlying patent in every reverse payment settlement would make antitrust scrutiny unworkable).

³⁹ *Id.* at 158.

⁴⁰ A quick look approach is utilized when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." The Court ruled that reverse payment settlements in this context do not meet this criterion. *Id.* at 159.

⁴¹ *Id.*

⁴² *Id.* at 158.

⁴³ *Id.* at 160 (stating the Supreme Court would "leave to the lower courts the structuring of the present rule-of-reason antitrust litigation").

⁴⁴ *Id.*

⁴⁵ *Id.* at 162 (advocating for a scope-of-patent test, stating that "under our precedent, this is a fairly straight-forward case").

provided by patents and frustrate the longstanding public policy of favoring settlements.⁴⁶

While the majority in *Actavis* answered the question as to the proper legal standard for reverse payments, the lack of guidance in applying the rule of reason has raised a number of questions for lower courts to answer.

D. Rule of Reason Post-Actavis

Certain questions initially left unresolved under the rule of reason *Actavis* standard have already been answered. First, lower courts have extended the ruling in *Actavis* regarding reverse payment settlements to non-cash payments.⁴⁷ Second, the Third Circuit has clarified the appropriate pleading standard required for an antitrust plaintiff to defeat a motion to dismiss in reverse payment situations.⁴⁸ The Third Circuit held that, for pleading purposes, a plaintiff does not need to exactly quantify how “large” a reverse payment is, and only needs to plead facts that make it plausible that the reverse payment is “large.”⁴⁹ The Third Circuit also ruled that when pleading a reverse payment to be “unjustified,” a plaintiff only needs to plausibly allege the absence of a justification, rather than rebut all possible justifications.⁵⁰ Lower courts have also attempted to answer the question as to what constitutes a “large” payment, with the majority of decisions holding that a comparison to saved litigation costs by the brand name

⁴⁶ *Id.* at 176–77 (claiming the majority departs from the longstanding approach and “weakens the protections afforded to innovators by patents, frustrates the public policy in favor of settling, and likely undermines the very policy it seeks to promote by forcing generics who step into the litigation ring to do so without the prospect of cash settlements”).

⁴⁷ *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co.* (*In re* Loestrin 24 Fe Antitrust Litig.), 814 F.3d 538 549 (1st Cir. 2016) (holding that the district court erred in ruling that “non-monetary reverse payments do not fall under *Actavis*’s scope”).

⁴⁸ *In re* Lipitor Antitrust Litig., 868 F.3d 231, 253 (3rd Cir. 2017) (setting out the pleading requirements for plaintiffs alleging a large and unjustified payment from a brand-name manufacturer to a generic manufacturer to stay out of the relevant market).

⁴⁹ *Id.*

⁵⁰ *Id.* at 257 (holding that “plaintiffs sufficiently alleged the absence of a convincing justification for the reverse payment and were not required to plead more than that”).

manufacturer is an inadequate inquiry by itself.⁵¹ As for the question of what constitutes an “unjustified” payment, lower courts have made clear that the analysis is an “open-ended inquiry that may be assessed separately . . . and battled over in the burden-shifting framework.”⁵²

However, no post-*Actavis* ruling has been as important and controversial as the Third Circuit’s 2017 decision in *Wellbutrin XL*, where the court implemented an additional causation requirement.⁵³ In *Wellbutrin XL*, the Third Circuit addressed the issue of antitrust standing for private plaintiffs, an issue the Supreme Court left unanswered in *Actavis*.⁵⁴ The facts in *Wellbutrin XL* resembled those in *Actavis*. GSK, a drug manufacturer, developed a drug named Wellbutrin XL to treat depression after receiving an exclusive license from Biovail.⁵⁵ Following approval from the FDA in 2002, a number of generic manufacturers filed ANDA’s to market generic versions of Wellbutrin XL.⁵⁶ Biovail and GSK sued the generic manufacturers, claiming patent infringement.⁵⁷ The brand-name and generic manufacturers ultimately agreed upon a reverse payment, with the brand-name manufacturer paying the generic manufacturer tens of millions of dollars to delay their entry into the market for nine years.⁵⁸ Following

⁵¹ See Lisa Jose Fales et al. *Cover Story, Welcome to the Wild, Wild West: Actavis Five Years Later*, 32 ANTITRUST ABA 18, 18 (2018) (stating that “the majority of decisions that analyze ‘large’ hold that saved litigation costs are not dispositive and must be accompanied by additional considerations”). See also *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (holding “[a] ‘large’ payment is anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer.”); *In re K-Dur Antitrust Litig.*, No. 01-cv-1652-SRC, 2016 WL 755623, at *12 (D.N.J. Feb. 25, 2016) (holding a payment was large when it “exceeded the estimated cost of litigation and the costs of other services and products”).

⁵² Fales et al., *supra* note 51, at 19.

⁵³ See generally *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017) (requiring a showing of causation from a private plaintiff in order to establish antitrust standing).

⁵⁴ The *Actavis* Court did not address the issue of antitrust standing for a private party due to the FTC not being a private party. See generally *Fed. Trade Comm’n v. Actavis, Inc.*, 570 U.S. 136 (2013).

⁵⁵ *Wellbutrin XL*, 868 F.3d at 145.

⁵⁶ *Id.*

⁵⁷ *Id.* (stating that “Biovail filed patent infringement suits against all four generic companies”).

⁵⁸ *Id.* at 160.

the settlement agreement, two putative classes (direct purchasers and indirect purchasers) brought suit against Biovail and GSK, alleging they “conspired to prevent generic versions of Wellbutrin XL from entering the market.”⁵⁹ Petitioners alleged that the “instrumentalities” of a conspiracy ultimately resembled sham lawsuits, sham FDA petitions, and an unlawful reverse payment settlement.⁶⁰

The Third Circuit in *Wellbutrin XL* analyzed the settlement agreements under a two-part analysis.⁶¹ In the first part, the court ruled that the agreements were not immune from antitrust scrutiny and that the rule of reason test applied, finding that the reverse payment was “large and unjustified.”⁶² This resembled a direct application of the legal standard proffered in *Actavis*, where the Court decided that large and unjustified payments should be subject to rule of reason analysis.⁶³ However, the Third Circuit court applied a second step analysis, determining that the Plaintiffs did not have proper antitrust standing.⁶⁴ The Third Circuit went on to state that in order to establish antitrust standing, the Plaintiffs must show that they (i) experienced an injury which antitrust law aims to prevent; and (ii) this injury directly flows from the defendant’s actions.⁶⁵ In this case, the Plaintiffs had to show that the harm they experienced (increased drug prices) was caused by the settlement payments.⁶⁶ After analyzing both a license-based scenario and a litigation-based scenario in which a generic drug could have entered the market in lieu of the existing patent, the Third Circuit ruled that the Plaintiffs failed to show that either situation would have

⁵⁹ *Id.* at 146.

⁶⁰ *Id.* (“[T]he instrumentalities of the alleged conspiracy were . . . sham lawsuits, a sham FDA petition, and an unlawful reverse payment settlement.”).

⁶¹ *Id.* at 160–66 (implementing a two-step analysis considering both antitrust scrutiny and antitrust standing).

⁶² *Id.* at 162.

⁶³ *Actavis*, 570 U.S. at 158 (concluding that large and unjustified payments carry the risk of anticompetitive effects).

⁶⁴ *Wellbutrin XL*, 868 F.3d at 169 (affirming the District Court’s grant of summary judgement because Plaintiff’s “do not have antitrust standing”).

⁶⁵ *Id.* at 164 (citing *Ethypharm S.A. France v. Abbott Laboratories*, 707 F.3d 223, 233 (3d Cir. 2013)).

⁶⁶ *Id.* at 164–65 (explaining that “[i]n order to establish antitrust injury here, the Appellants must show that the harm they say they experienced—increased drug prices for Wellbutrin XL (and its generic equivalents)—was caused by the settlement they are complaining about”).

been possible.⁶⁷ Thus, the Plaintiffs failed to show their injuries were caused by the settlement, and therefore did not have antitrust standing.⁶⁸

The Third Circuit also noted they were persuaded by an amicus brief filed by a number of economists which argued that risk aversion makes it difficult to use the amount of settlement as a proxy for likelihood of success in litigation.⁶⁹ The Third Circuit claimed that this risk aversion theory is an effective rebuttal to the Plaintiffs' claim that size of reverse payments should be deemed a surrogate for the weakness of the patent.⁷⁰ This argument was featured in the dissent in *Actavis*, with Chief Justice Roberts also arguing that risk averse patent holders may be willing to pay large sums to settle disputes that they are likely to win.⁷¹ Risk aversion was an idea rebuffed by the majority in *Actavis*.⁷²

Commentators have been split on whether the holding in *Wellbutrin XL* can be squared with the holding in *Actavis*.⁷³ After the appellants in *Wellbutrin XL* sought a rehearing, a group of fifty-eight professors submitted an amicus brief arguing that the Third Circuit did not follow the guidance of the *Actavis* holding by failing to infer an anticompetitive effect from a large, unexplained reverse payment.⁷⁴

⁶⁷ *Id.* at 169 (holding that “both of the scenarios advanced by the Appellants fail to show that Anchen would have been able to launch its 150 mg version of Wellbutrin XL without running afoul of the Andrx patent”).

⁶⁸ *Id.* (affirming summary judgement due to Plaintiff’s failing to establish antitrust standing).

⁶⁹ *Id.* at 168.

⁷⁰ *Id.* at 168–69 (claiming that risk aversion theory “serves as an effective rebuttal to the Appellants’ claim that the size of the reverse payment is a ‘surrogate’ for the weakness of the 708 patent”).

⁷¹ *Actavis*, 570 U.S. at 172 (arguing that even if the risk of losing is low, after years of litigation the company “grows increasingly risk averse, tired of litigation, and concerned about the company’s image, so it pays the competitor a ‘large’ payment”).

⁷² *Id.* at 157 (declining to accept that a small risk of losing a patent infringement case justifies a large reverse payment).

⁷³ See generally Carrier, *supra* note 22 (arguing that the *Wellbutrin* Court ignored the Supreme Court’s holding in *Actavis*); Margaret O’Grady & Peter Spaeth, Principles of Antitrust Causation are Alive and Well[butrin]: Why the Third Circuit Got it Right, BLOOMBERG LAW (2018).

⁷⁴ Brief for 58 Law, Economics, and Business Professors as Amici Curiae Supporting Appellants at 4, *In re Wellbutrin XL Antitrust Litig.* 868 F.3d 132 (2017) (No. 15-2875) (hereinafter Brief for 58 Professors).

The brief went on to contend that the holding in *Wellbutrin XL* was inconsistent with relevant policy, arguing that the Hatch-Waxman Act was intended to promote generic competition.⁷⁵ Professor Michael Carrier, one of the signees on the amicus brief, has gone on to argue that the Third Circuit ignored the *Actavis* holding by considering “multiple plausible ways” to interpret the settlements, rather than using a large unexplained reverse payment to suggest an objective between patentee and challenger to maintain supracompetitive prices.⁷⁶ Those who disagree with the *Wellbutrin XL* holding believe the Third Circuit went beyond the legal test set out in *Actavis* by carving out an exception for “complex and multifaceted settlements,” and by ignoring the *Actavis* ruling which treated large and unexplained payment as a surrogate for a patents weakness.⁷⁷

However, other commentators have argued that the holding in *Wellbutrin XL* can be read within the threshold of the legal test set out in *Actavis* by making private plaintiffs show that more likely than not a generic version would have entered the market absent the reverse payment.⁷⁸ In applying a two-step analysis, the Third Circuit separated antitrust liability and antitrust injury, finding that antitrust liability was present in *Wellbutrin XL* but antitrust injury was not.⁷⁹ This provides an important distinction between the plaintiffs in *Actavis* and in *Wellbutrin XL*; in *Actavis*, the plaintiffs were the FTC, a governmental agency, while the plaintiffs in *Wellbutrin XL* were private parties.⁸⁰ Section 5 of the FTC Act—upon which liability in *Actavis* was based—requires only a showing of “deceptive or unfair practices” that are “likely to cause substantial injury to consumers.”⁸¹ Thus, the FTC need not show a specific injury because they enforce substantive antitrust laws directly.⁸² However, when a private party brings a claim under the Clayton Act, they must show an injury-in-fact resulting from

⁷⁵ *Id.* at 5 (stating that “[o]ne central objective of the Hatch-Waxman Act, Congress’s comprehensive legislation balancing competition and innovation in the pharmaceutical industry, was to promote generic competition”).

⁷⁶ Carrier, *supra* note 22, at 40.

⁷⁷ Brief for 58 Law, Economics, and Business Professors, *supra* note 74 at 2.

⁷⁸ O’Grady & Spaeth, *supra* note 73 (arguing that “*Wellbutrin* does not represent a departure from *Actavis*, and should be viewed as a needed affirmation of the core principles of antitrust standing and causation”).

⁷⁹ *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 161–70 (3d Cir. 2017).

⁸⁰ O’Grady & Spaeth, *supra* note 73.

⁸¹ 15 U.S.C. § 45 (2012).

⁸² *California v. Am. Stores Co.*, 495 U.S. 271, 295–96 (1990).

the anti-competitive conduct by the defendant.⁸³ Furthermore, the FTC backed this private plaintiff-government distinction in an amicus brief filed in *Wellbutrin XL*, stating that because the FTC (along with the Department of Justice) enforces the substantive antitrust laws directly, they do not need to show a specific injury.⁸⁴ This view can be understood as a narrow understanding of the holding in *Actavis*. Since *Actavis* involved a governmental agency, it did not consider antitrust standing, thus never reaching the second step of the analysis.⁸⁵ However, since *Wellbutrin XL* involved a private plaintiff, a causal showing of damages was required by the Third Circuit.⁸⁶

E. Conclusion

Six years after the Supreme Court applied the rule of reason analysis to reverse payment settlements in *Actavis*, unanswered questions remain. Lower courts have ruled that the holding in *Actavis* extends to non-cash payments, and have taken steps to identify what constitutes a “large” and “unjustified” payment. However, no decision has been as important as the Third Circuit’s holding in *Wellbutrin XL*, which added a second prong to the *Actavis* rule by imposing a causation element for private plaintiffs. It is yet to be determined to what extent the Supreme Court would require a showing of causation for private plaintiffs, as the Supreme Court has not heard a reverse payment settlement case since *Actavis*. While the Court in *Actavis* left the structuring of the rule of reason analysis to lower courts, it is possible another Supreme Court decision is required to answer remaining questions.

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⁸³ *Wellbutrin XL*, 868 F.3d at 165 (citing *Zenith Radio Corp. v. Hazeltine Res., Inc.*, 395 U.S. 100, 114 (1969)) (explaining that a plaintiff, under the Clayton Act, “must prove that it has suffered at least ‘some damage flowing from the unlawful conspiracy’”).

⁸⁴ Brief for the Fed. Trade Comm’n as Amicus Curiae at 20, *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017).

⁸⁵ O’Grady & Spaeth, *supra* note 73.

⁸⁶ *Wellbutrin XL*, 868 F.3d at 165 (stating that in order for there to be antitrust injury, “the Appellants must show that the harm they say they experienced . . . was caused by the settlement they are complaining about”).

⁸⁷ Student, Boston University School of Law (J.D. 2020).